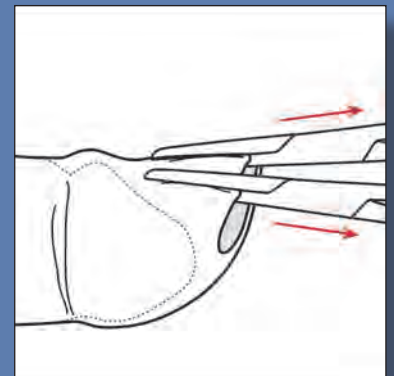
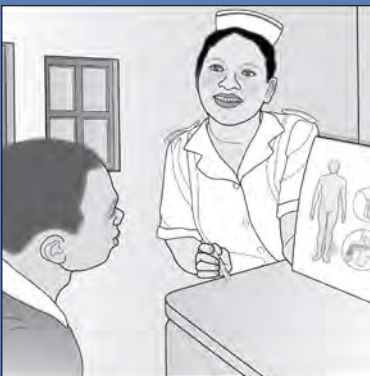


MALE CIRCUMCISION FOR HIV PREVENTION

CLINICAL MANUAL

MANUAL FOR MALE CIRCUMCISION UNDER LOCAL ANAESTHESIA AND HIV PREVENTION SERVICES FOR ADOLESCENT BOYS AND MEN

APRIL 2018



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CIRCUMCISION UNDER
LOCAL ANAESTHESIA
AND HIV PREVENTION
SERVICES FOR ADOLESCENT
BOYS AND MEN**

APRIL 2018



**World Health
Organization**



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CONTENTS

Abbreviations	6
Preface	7
Acknowledgements	8
Financial support	8
Summary of new and updated content	9
Chapter 1. Overview of male circumcision as an HIV prevention strategy	1-1
Chapter 2. An opportunity for expanded services for adolescent boys and men	2-1
Chapter 3. Facilities, supplies and infrastructure for male circumcision programmes	3-1
Chapter 4. Recordkeeping, reporting and quality assurance	4-1
Chapter 5. Infection prevention and control	5-1
Chapter 6. Educating and counselling clients, and obtaining informed consent	6-1
Chapter 7. Preprocedure screening of clients and preparations for the circumcision procedure	7-1
Chapter 8. Basic surgical skills required for safe circumcision	8-1
Chapter 9. Circumcision methods for adolescent boys and men	9-1
Chapter 10. Postoperative care and management of adverse events during and after circumcision	10-1
<i>Adverse event action guide for voluntary medical male circumcision by surgery or device, 2nd edition</i>	10-26

ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
CDC	US Centers for Disease Control and Prevention
COSECSA	College of Surgeons of East, Central and Southern Africa
HIV	human immunodeficiency virus
IMEESC	Integrated management for emergency and essential surgical care
<i>Manual</i>	<i>Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men</i>
PEPFAR	US President's Emergency Plan for AIDS Relief
PSI	Population Services International
SSI	surgical site infection
UNAIDS	United Nations Programme on HIV/AIDS
US	United States
VMMC	voluntary medical male circumcision
WHO	World Health Organization

PREFACE

Male circumcision has been performed on adolescent boys and men for many years, primarily for religious and cultural reasons, such as a rite of passage to mark the transition to adulthood. In 2007, due to consistent and compelling scientific evidence that men who are circumcised have a 60% reduced risk of acquiring HIV transmitted through heterosexual contact, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended male circumcision as an additional option for HIV prevention. Countries with generalized HIV epidemics were considered priority for implementing this additional HIV prevention option. Other recommendations issued in 2007 stated the following:

- Male circumcision should be delivered as part of a minimum package that includes: information about risks and benefits, counselling on safer sexual practices, access to HIV testing services and condoms and management of sexually transmitted infections.
- Male circumcision is provided with full adherence to medical ethics and human rights principles, including informed consent and confidentiality.
- Supervision systems for quality assurance should be established along with referral systems to manage complications.

Male circumcision has also been shown to provide additional benefits, such as reducing the transmission of some sexually transmitted infections, for example—the human papillomavirus.

To support implementation of safe, quality medical male circumcision services, WHO partnered with Jhpiego and other stakeholders to draft the 2009 *Manual for male circumcision under local anaesthesia*, which has been widely available online since its publication. At the time it was written, experience in performing male circumcision services in countries with a generalized HIV epidemic predominantly came from research settings, and the provision of circumcision services was not standardized. Complication rates following traditional male circumcision were reportedly high, but the true incidence of complications was unknown.

Between the issuance of the 2007 WHO and UNAIDS recommendation on male circumcision for HIV prevention and 2016, more than 14 million adolescent boys and men, in 14 countries in East and Southern Africa, have been circumcised through public health programmes that offer male circumcision services. The new 2018 edition—*Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men (Manual)*—takes into account lessons learnt from providing male circumcision services to millions of adolescent boys and men, as well as relevant new recommendations on various aspects of care. Although adverse events or complications from male circumcision have been rare, particular attention has been taken to amend every section of the 2018 *Manual* in light of reported events so that risk may be reduced even further. New surgical male circumcision methods that have been reviewed for efficacy and safety, including the use of devices prequalified by WHO, are also addressed in the *Manual*, although the reader is referred to the device-specific manufacturer's instructions for use for details. Lastly, this version reflects the need for more person-centred services, so greater emphasis is placed on adolescents compared to the first edition because adolescents represent a large number of the individuals seeking male circumcision.

This *Manual* is primarily intended for nonsurgical, qualified providers and for trainers who are involved in the provision of male circumcision services for HIV prevention and other health benefits in East and Southern Africa. In this *Manual*, the description of techniques was written targeting the skills of this midlevel provider. A secondary audience for use of this *Manual* may be providers, globally, who undertake medical male circumcision procedures on males with normal anatomy and without contraindications—that is, primarily for reasons other than HIV prevention.

A major objective of this *Manual* is to support male circumcision clinics and providers in providing high-quality services and reducing the risk of adverse events to as low a level as possible. The *Manual* has a special emphasis on preventing the rare but serious life-threatening adverse events related to bleeding, infection (including tetanus) and anaesthesia.

The *Manual* is one of many documents and guidelines to assist countries implement programmes for safe male circumcision services within their HIV and sexual and reproductive health programmes. Most documents are available on the Clearinghouse on Male Circumcision for HIV prevention's website (www.malecircumcision.org) and the WHO's website (<http://www.who.int/hiv/en/>).

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The following people from Jhpiego and WHO contributed to the preparation and production of this version of the *Manual*:

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SUMMARY OF NEW AND UPDATED CONTENT

TOPIC	NEW OR UPDATED CONTENT
Title	The title changed to <i>Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men</i> .
Population focus	<p>Clinical and surgical procedures described in the <i>Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men (Manual)</i> are only for adolescent boys and men; information on infant and child circumcision is not in this <i>Manual</i>, but a reference to it is provided.</p> <p>This <i>Manual</i> places a greater emphasis on adolescent boys because they represent the large number of males seeking circumcision. Chapter 2 provides new content on addressing adolescents and providing male friendly services.</p>
Better definition of the various roles in the circumcision clinic	The second edition includes clearer definition of the roles of the various providers in the circumcision team. These include education, counselling, screening, surgery and surgical assisting, postprocedure and follow-up care and recognition of other needs that may require referral to other services.
Patient safety	As in the first edition, client safety remains paramount. In this second edition, there is improved description of roles and responsibilities to clarify and reinforce safety and accountability.
Education and counselling (Chapters 1, 2 and 6)	The <i>Manual</i> expands the list of messages to convey at each point of service (see Table 6.1 in Chapter 6) and provides expanded information on the package of additional services.
Items needed for emergencies (Chapter 3)	Chapter 3 now includes a list of items needed in case of an emergency during a conventional or device-based surgical circumcision procedure.
Infection prevention and control (Chapters 5, 7 and 9)	<p>Contents in Chapters 5 and 7 were extensively revised to align with the World Health Organization's (WHO's) current infection prevention and control recommendations (including hand hygiene and surgical hand preparation). Revisions include more details that emphasize correct hand hygiene practices and an updated surgical hand rubbing technique (see Fig. 7.8 in Chapter 7). Also in Chapter 7, Fig. 7.9 details how to put on surgical gloves, and Fig. 7.10 details how to take off surgical gloves. Related hand hygiene content align with each other.</p> <p>The <i>Manual</i> recommends that the skin in the client's genital area be prepared a minimum of three times before the procedure (see Section 9.3.1 in Chapter 9).</p> <p>The <i>Manual</i> discusses safety-engineered syringes in line with WHO's recommendations, which shift to the use of such injury-protection supplies, and offers considerations for safety-engineered devices that permit aspiration, as required for injection of anaesthesia.</p> <p>Chapter 5 provides more detail on preventing contamination in medicine vials through 'double dipping' (see Fig. 5.2).</p> <p>The <i>Manual</i> provides extensive information on decontamination and waste management, which are aligned with updated guidance from WHO.</p> <p>Chapter 5 provides updated post-exposure prophylaxis information to reflect current recommendations (see Box A5.1.1).</p>

TOPIC	NEW OR UPDATED CONTENT
Preprocedure screening (Chapters 6 and 7)	<p>This <i>Manual</i> discusses screening for tetanus-toxoid containing vaccination and bleeding disorders and offers advice on hypertensive or diabetic clients. This <i>Manual</i> also provides guidance on screening for substance use and mental health problems.</p> <p>Chapter 7 has more photographs of genital abnormalities to assist providers in recognition of such conditions (see Annex 7.2). It also offers an adaptation of WHO's surgical checklist for use in conventional or device-based male circumcision (see Annex 7.3).</p>
HIV testing and prevention	<p>The <i>Manual</i> aligns testing and partner notification recommendations, and consideration of pre-exposure prophylaxis for those at substantial risk for HIV with other WHO guidance.</p>
Conventional and device-based surgical circumcision	<p>The <i>Manual</i> considers device-based circumcision to be a surgical procedure. Device-based methods are described generally. Specific instructions should be obtained from the manufacturer's instructions for use.</p>
Diathermy (Chapter 8)	<p>Chapter 8 includes improved description of diathermy with new illustrations.</p>
Local anaesthesia dose tables (Chapter 9)	<p>Chapter 9 provides dosing information for the combination of lidocaine/lignocaine and bupivacaine.</p>
Surgical techniques	<p>The surgical techniques are presented in a step-by-step manner with illustrations. In light of experience, some steps have been modified from the first edition. The <i>Manual</i> continues to place emphasis on basic surgical skills, avoiding common errors and managing errors if they occur.</p>
Forceps-guided method (Chapter 9)	<p>Chapter 9 clarifies the placement of forceps in the forceps-guided method.</p> <p>Forceps-guided method should not be used in clients below 15 years of age due to the clients' immature physical development.</p> <p>For the forceps-guided method, an option to trim the inner cuff is shown in Fig. 9.13 (see Chapter 9).</p>
Dorsal slit (Chapter 9)	<p>Technique has been modified on where to place the artery forceps to better display where the dorsal slit cut should be made (see Section 9.6.2 in Chapter 9).</p>
Adverse events (Chapter 10)	<p>Some adverse events were detected during the implementation of voluntary medical male circumcision programs, and these events were not included in the previous edition (for example, tetanus). Therefore, this <i>Manual</i> adds information to enable earlier recognition of and response to possible adverse events associated with circumcision. This information is based on evidence gained from the performance of millions of male circumcisions through various HIV prevention programmes.</p> <p>The <i>Adverse events guide for voluntary medical male circumcision by surgery or device</i>—prepared by the Population Services International/College of Surgeons of East, Central and Southern Africa/US Centers for Disease Control and Prevention—is presented in its entirety as Annex 10.3 (see Chapter 10) to enhance ease of access to this information. The <i>Manual's</i> text on adverse events aligns with the <i>Adverse events guide for voluntary medical male circumcision by surgery or device</i>.</p>

CHAPTER 1

OVERVIEW OF MALE CIRCUMCISION AS AN HIV PREVENTION STRATEGY



This chapter provides information on the following:

- need to prioritize safety when providing male circumcision
- various terms used for male circumcision, from clinical and programmatic perspectives, and how the procedure is performed
- biomedical basis for male circumcision for reducing the risk of HIV infection
- World Health Organization's minimum package of services to be provided in male circumcision for HIV prevention programmes and optional expanded service packages
- importance of informed consent (and assent for minors) to ensure that clients are opting to undergo the procedure voluntarily
- importance of ensuring confidentiality and privacy, and providing kind, respectful care to all clients seeking male circumcision
- benefits and risks of male circumcision, including benefits to female partners
- typical client flow through male circumcision services

1.1. INTRODUCTION

More than 14 million adolescent and adult males in east and southern Africa have undergone male circumcision (removal of the penis foreskin) for HIV prevention in the past decade. Since 2007, the World Health Organization has recommended male circumcision as part of a comprehensive public health prevention effort to end the region's HIV epidemic. Although much of the information and guidance provided in this (*Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men (Manual)*) is based on experience in limited-resource settings in African countries, the *Manual* is intended to support safe male circumcision anywhere in the world, wherever providers are doing circumcisions on adolescent and adult males for health promotion and partial protection against HIV (see Box 1.1). The many young men who are electing to undergo the procedure are helping to protect their own health and well-being and the well-being of their partners. In this elective surgical procedure, every effort must be taken to mitigate the risk of adverse events. The provider who performs the procedure, along with his or her team, is responsible for providing the safest care possible.

Box 1.1. Intent of *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men (Manual)*

This *Manual* is intended to support safe conventional or device-based surgical circumcision anywhere in the world where providers are doing circumcisions on adolescent and adult males for health promotion and partial protection against HIV.

1.1.1. What male circumcision is and how it is performed

Male circumcision is the permanent and complete removal of the foreskin (or prepuce), the fold of skin that covers the head (or glans) of the penis. Male circumcision can be performed by several conventional or device-based surgical methods (see Box 1.2). It can be performed for medical reasons or as part of traditional and religious practices (called traditional foreskin cutting in this *Manual*). Male circumcision can be performed for therapeutic reasons, such as to correct a pathological condition (for example, phimosis). It can also be performed for elective purposes, such as improved hygiene, prevention of HIV or other sexually transmitted infections, and aesthetic preferences. In this *Manual*, male circumcision refers to elective (versus therapeutic) circumcision of males performed by trained health care providers, unless otherwise noted.

This *Manual* is primarily concerned with male circumcision for adolescents—at least 10 years old—and adults performed under local anaesthesia. The 10-year age cut-off is based on evidence of safety and the client's capacity to assent and cooperate (1). Male circumcision may also be performed during early infancy, that is, under two months of age. For more information on medical circumcision of male infants, refer to the *Manual for early infant male circumcision under local anaesthesia* (2) and its accompanying learning package.

Although traditional foreskin cutting is not the subject of this *Manual*, some information on the practice is relevant here. Traditional foreskin cutting has been widely performed for religious and cultural reasons, often within two weeks of birth or at the beginning of adolescence, as a rite of passage into adulthood. Whether performed for religious or cultural reasons, traditional foreskin cutting is often associated with higher rates of complications than circumcision that is performed within the formal health care sector and has sometimes even led to death (3, 4). For additional information on this practice, as well as considerations for male circumcision programmes in countries where traditional foreskin cutting is practiced, refer to the World Health Organization's 2010 consultation with traditional circumcision providers (5).

Box 1.2. Important note about device-based surgical methods

In 2013, the World Health Organization stated that the male circumcision devices it prequalifies are efficacious, safe and acceptable as additional methods of male circumcision for HIV prevention among healthy men. A list of devices that have been prequalified by the World Health Organization is available on its website. Although some information and guidance related to these devices are provided in this *Manual*, no information is given for applying or removing the devices. Providers who perform circumcisions using device-based surgical methods should be appropriately trained and competent in the use of the specific device (and consult manufacturer's instructions for use). See the Bibliography section for additional information.

1.1.2. Male circumcision and HIV infection

A randomized controlled trial is the gold standard for scientific studies, and three such trials conclusively determined that male circumcision reduces female-to-male HIV transmission by about 60% (6–8). Long-term follow-up demonstrates that the protective effect continues beyond five years (9–11). Responding to this evidence, in March 2007, the World Health Organization and UNAIDS issued recommendations on male circumcision and HIV prevention: male circumcision programmes would have the greatest population-level impact in countries with a primarily heterosexually driven epidemic, high prevalence of HIV, low prevalence of male circumcision and large populations at risk for HIV. There is insufficient evidence to suggest that circumcision reduces HIV infection among men who have sex with men (12, 13). More recently, reduced incidence of HIV has been shown in community-level studies of HIV prevalence in areas where rates of male circumcision have increased through male circumcision programmes (9, 14).

1.1.3. Biological explanations for the protective effect of male circumcision

The mechanisms through which male circumcision reduces the risk of HIV transmission have been widely studied (15), resulting in the following findings:

The primary target cells through which HIV enters the body are immune system target cells with CD4 receptors, including Langerhans cells. These cells are present in high density in the epithelium of the inner foreskin and are close to the surface (16–22).

In an in vitro study, HIV uptake by cells from the mucosal surface of the foreskin was seven times more efficient than uptake by cells from tissue of the female cervix (23).

The highly vascularized foreskin mucosa and the mucosa at the frenulum are prone to tearing and bleeding during intercourse. These microinjuries allow easy entry of HIV into the bloodstream (22).

A factor that further facilitates transmission of the virus is the presence of an ulcerative sexually transmitted infection—such as herpes simplex, chancroid or syphilis—which tends to be more common in uncircumcised men (22, 24, 25, 28–30).

Research on the microbial environment of the foreskin has demonstrated a high concentration of anaerobic bacteria causing inflammation, which may recruit immune system target cells to the surface of the foreskin (26, 27, 31).

1.2. WORLD HEALTH ORGANIZATION'S MINIMUM PACKAGE OF SERVICES AND RECOMMENDATIONS FOR MALE CIRCUMCISION PROGRAMMES

In 2007, the World Health Organization and Joint United Nations Programme on HIV/AIDS (32) recommended male circumcision as a strategy that provides partial protection against HIV infection and that it is an important part of a comprehensive HIV prevention package. Recently, viral suppression with early initiation of antiretroviral treatment has been identified as another key prevention strategy. Based on the evidence of partial protection provided by circumcision, the World Health Organization now recommends the following, along with services directly related to the circumcision procedure, as essential components in the minimum male circumcision package:

- HIV testing services
- active or supported referral of clients who test positive for HIV to HIV care and treatment programmes
- screening for sexually transmitted infections and provision of or referral for treatment
- promotion and provision of condoms
- promotion of safer sex practices (see Box 1.3)

Box 1.3. Safer sex practices

Safer sex practices include delaying the age of first intercourse, abstinence from penetrative sex, reduction in the number of sexual partners, having only one sexual partner at a time, and correct and consistent use of male or female condoms.

1.2.1. HIV testing and referral of HIV-positive clients

Over the past 30 years, global availability and uptake of HIV testing services has increased sharply. Despite the growing number of people receiving HIV testing every year, half of all people with HIV remain unaware of their status (33). HIV testing coverage continues to be low in most endemic settings, and late diagnosis and linkage to prevention, care and treatment services persist (34).

Male circumcision services provide an excellent opportunity for adult males to learn their HIV status and to identify undiagnosed HIV. Because of the low rate of HIV infection in young clients, HIV testing does not need to be routinely offered to adolescents under 15 years of age unless requested or clinically indicated. Priorities are linking HIV-positive clients to HIV care and treatment, and providing male circumcision services to HIV-negative high-risk men, such as those treated for sexually transmitted infections. Effectively scaling up HIV testing services to diagnose 90% of all people with HIV by 2020 has been highlighted as the first of three global targets set by the United Nations, as part of the strategy of the Joint United Nations Programme on HIV/AIDS: Fast-Track: Ending the AIDS Epidemic by 2030 (35, 36).

The World Health Organization and UNAIDS promote the routine offering of HIV testing services at health facilities; this includes clinics offering male circumcision services, particularly in settings with high HIV prevalence and incidence (37). Furthermore, HIV testing with linkages to prevention, treatment and care should be offered to all adolescents living in areas with a generalized epidemic. However, this service should remain voluntary, and clients should have the option to refuse the offer of an HIV test without affecting their access to male circumcision or other care and services offered at the male circumcision site. Male circumcision clients who are not ready to test for HIV can be offered the test again during postprocedure visits and informed about self-testing (37).

The remaining elements of the minimum services package (screening for sexually transmitted infections, provision of condoms and promotion of safer sex practices) are all covered in detail in subsequent chapters of this *Manual*.

1.3. MAKING SAFETY A PRIORITY

The foundation of good health care is providers who have training and resources to perform services according to global safety standards. Use of the World Health Organization's *Surgical safety checklist and implementation manual* (see the Bibliography section and Chapter 7, Section 7.6.2), which has been adapted for the male circumcision procedure, supports many of the safe practices discussed below.

1.3.1. Standard precautions for infection prevention

Infection prevention and control are vital to protecting both clients and clinic staff. This includes hand hygiene; use of personal protective equipment; safe handling of needles, syringes and sharp instruments; and appropriate measures for cleaning and proper waste disposal. A major concern is the potential transmission of bloodborne pathogens, such as hepatitis B and C virus, and HIV, to clients or health care providers. This risk is greatly reduced by implementing standard precautions.

1.3.2. Client eligibility and deferral or referral as appropriate

Providers must perform appropriate screening to ensure eligibility for male circumcision. Some conditions, such as acute febrile illness or infection, must be treated before a client can safely undergo the procedure. Other contraindications to the procedure at the clinic level include known or suspected bleeding disorder, hypospadias and pathological phimosis; clients with such conditions should be referred as appropriate.

1.3.3. Tetanus mitigation (based on national policy)

Tetanus is a deadly disease that is preventable through proper vaccination and wound care. Clinics should ensure that clients are offered tetanus toxoid-containing vaccination according to the client's need and in line with national policy and male circumcision method.

1.3.4. Safe anaesthesia

Local anaesthesia is recommended for male circumcision services and is simpler, safer and less expensive than general anaesthesia (see Chapter 9, Section 9.4).

1.3.5. Haemostasis

Providers can help prevent life-threatening bleeding by carefully screening clients to identify bleeding disorders. All providers must be competent to use surgical techniques to stop bleeding (see Chapter 8, Section 8.4.1). If bleeding cannot be stopped using surgical techniques, then all providers must be competent to control blood loss by applying pressure.

1.3.6. Emergency plan

Although the risk of adverse events in male circumcision is low, the team should be able to identify conditions that require emergency care, and have a plan that outlines roles and responsibilities of all team members in an emergency, outlines each step in the emergency response, and identifies emergency referral facilities.

1.3.7. Postprocedure instructions and follow-up

Key postprocedure messages relate to the following:

- proper hygiene practices
- proper wound care and warnings against the use of home remedies on the wound
- the need for abstinence during the wound-healing period (or wearing a condom if abstinence is not possible)
- the importance of returning for follow-up care as recommended and

- description of symptoms that indicate a need to return to the clinic or a need to seek medical attention immediately

1.4. CONFIDENTIALITY AND PRIVACY

Confidentiality means that health care providers and other staff protect and do not share a client's personal information—it is an individual's right to decide when and with whom to share information about his health. All client information should be kept confidential, and client records should be safely secured. Privacy is about making sure that anyone who is not accompanying or directly interacting with the client neither hears (audio privacy) nor sees (visual privacy) the client during discussion of personal health matters, physical examination and surgical procedure.

1.4.1. Informed consent and assent

Informed consent and assent are critical components of male circumcision service delivery. The client—or in the case of a minor, the client and his parent(s)/guardian(s)—must be given understandable, complete, accurate information about the risks, benefits and limitations of the procedure. All clients—or parent(s)/guardian(s) in the case of a minor—need to sign a consent form to document the consent process before the procedure. Consent or assent is also needed for HIV testing.

1.5. EXPANDED OPTIONAL SERVICES

For many adolescent boys and men, accessing male circumcision services is their first encounter with health services since early childhood. Male circumcision programmes may supplement the minimum package, defined by the World Health Organization, with services that include tuberculosis screening, HIV treatment eligibility determination, antiretroviral therapy initiation, oral pre-exposure prophylaxis for HIV prevention, HIV testing services for couples or for sexual partners of clients, and screening for noncommunicable diseases or problems (for example, substance use or mental health problems). Hence, policy-makers and decision-makers are encouraged to consider these and other options as they apply to local needs and individual clients. Opportunities for providing additional services must be balanced with resources available. In addition, clear mechanisms of linkage and referral are essential to facilitate male circumcision clients' access to these additional services. When considering the offer of expanded services, great care has to be taken when other information is offered in the context of the circumcision procedure.

1.6. BENEFITS, RISKS AND LIMITATIONS OF MALE CIRCUMCISION

The decision of an adult or adolescent male to be circumcised, or of parent(s)/guardian(s) to have their son circumcised, can be based on various factors. These factors include cultural, religious and personal preference, and evidence-based information on the benefits, risks and limitations of the procedure, which are given to the client through education and counselling by a trained male circumcision service provider, as described in Chapter 6.

1.6.1. Benefits for males

Male circumcision offers a range of benefits related to general health and disease prevention, or for personal preferences (see Box 1.4). Potential health benefits of male circumcision are the following:

- reduced risk of female-to-male transmission of HIV
- reduced risk of some sexually transmitted infections, including, syphilis, herpes, chancroid and ulcers (29, 30, 38–40)
- reduced risk of human papillomavirus and resultant lower risk of penile cancer (41–43)
- possible increased ease of keeping the penis clean or having better hygiene
- reduced inflammation of the glans (balanitis) and the foreskin (posthitis)
- reduced risk for formation of foreskin scar tissue, which may lead to phimosis (inability to retract the foreskin) and paraphimosis (swelling of the retracted foreskin, resulting in the inability to return the foreskin to its normal position)

1.6.2. Benefits to female partners

As men accrue the benefits of reduced HIV and sexually transmitted infections, their female partners experience secondary health benefits, including reduced risk of contracting the following:

- HIV—as more men are circumcised, fewer men will become infected with HIV, thereby decreasing the chance that a woman will encounter an HIV-positive sexual partner; thus over time, female HIV incidence will decline (44)
- human papillomavirus and, therefore, of developing cervical cancer (42, 45)
- herpes simplex virus, syphilis, trichomonas vaginalis and bacterial vaginosis and, therefore, of developing related consequences to pregnancy outcomes, including preterm labour (25, 46, 47)

Box 1.4. Limitations—what male circumcision can and cannot do

When discussing the benefits of male circumcision, it is important to help clients to also understand the limitations of the procedure.

- Although male circumcision *reduces* the client's risk of becoming infected with HIV, that risk is *not* eliminated. Male circumcision provides partial (not 100%) protection against female-to-male HIV transmission. After male circumcision, clients must practice additional risk-reduction strategies to further reduce the risk of acquiring HIV; such strategies include correct and consistent condom use, fewer sexual partners, and avoidance of concurrent sexual partnerships.
- There is insufficient evidence to determine whether circumcision reduces HIV infection among men who have sex with men (12, 13). Also, circumcision does not provide any direct protection against HIV transmission from HIV-positive men to their female partners.
- Male circumcision is **not a cure** for erectile dysfunction, sexual performance problems, infertility and other conditions that some clients may believe the procedure will address. It is important for the provider to assess the client's beliefs about the benefits of male circumcision.

1.6.3. Risks of male circumcision

As with all medical procedures, male circumcision poses a level of risk to clients, albeit that risk is low. The vast majority of clients of male circumcision programmes do not experience any adverse events; however, when such events occur, they are usually mild and quickly resolved. In cases where moderate or severe adverse events have occurred, accurate identification and treatment have limited the severity of outcomes. One study followed the outcome of male circumcision in more than 1 million men across six African countries; the study occurred from 2010 to 2012 and found the combined risk of moderate and severe adverse events to be less than 1% (48). In rare instances, complications progressed, resulting in permanent deformity or disability. Death following male circumcision is extremely rare; causes include tetanus, bleeding disorders and local anaesthetic toxicity.

When adverse events do happen, they typically occur within the first week after the procedure, although this is not always the case. More information on risks of male circumcision is in Chapter 6 and the management of adverse events is in Chapter 10.

1.6.4. Risk compensation

Risk compensation is the practice of increasing sexual risk behaviour because of a false sense of security. This is a concern with any partially protective intervention against HIV, including male circumcision. Three studies have compared men's sexual risk behaviours before and after circumcision; they found that behaviour did not significantly change after circumcision (49–52). Additional studies have indicated that there are higher-risk behaviours among circumcised men than among their uncircumcised counterparts (53–55). It may be, however, that men choosing circumcision engage in higher-risk behaviours before becoming circumcised and simply continue those behaviours after circumcision (this is not

risk compensation). A good way to help clients avoid engaging in risk compensation behaviour is to ensure that they understand that male circumcision provides only partial (versus full) protection against HIV (53–55).

1.6.5. Sexual function and satisfaction after male circumcision

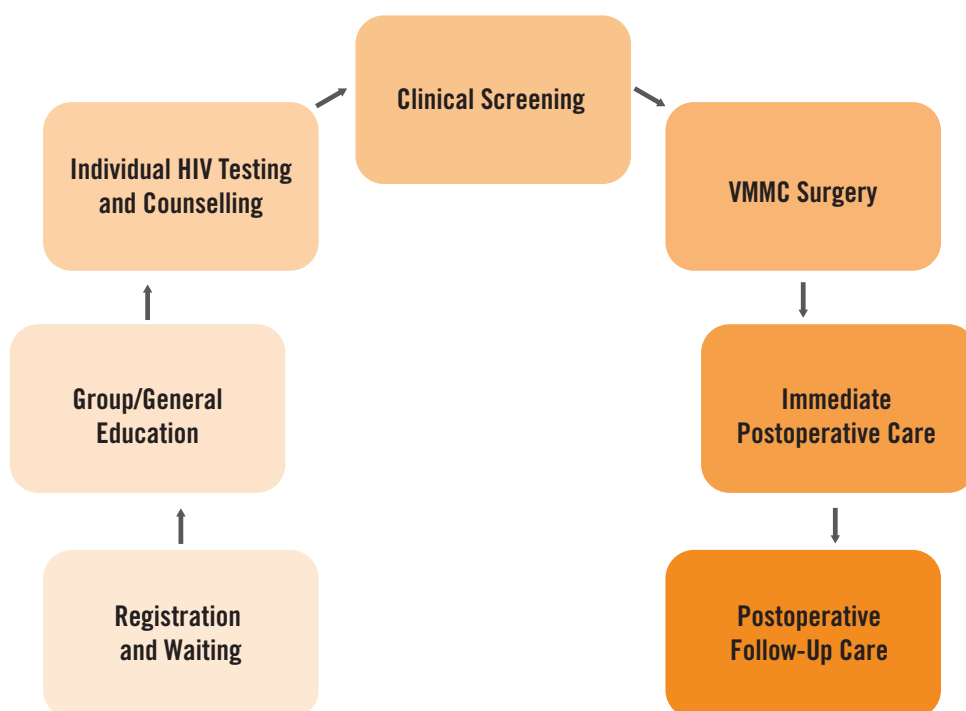
A systematic review (56) of studies on the effect of male circumcision on sexual sensation, function or satisfaction did not demonstrate any significant changes. The only consistent finding was a slight prolongation in the time to ejaculation (about 30 seconds longer). A study of female sexual partners of men who had been circumcised during the partnership found that most women either had no preference or preferred circumcision for their partners; only 3% preferred their partners to be uncircumcised. Women reported preferring circumcision because of improved hygiene and longer duration of coitus (57, 58).

1.7. TYPICAL CLIENT FLOW THROUGH MALE CIRCUMCISION SERVICES

Based on resources available, onsite capacity and other factors, male circumcision teams should decide how to provide critical services for safe circumcision at appropriate stages in the male circumcision process. Steps in client flow are shown in Fig. 1.1 and listed below:

- registration and waiting
- group education about male circumcision, HIV risk reduction and other aspects of reproductive and sexual health, including the circumcision procedure—by itself and as part of a comprehensive HIV prevention strategy
- individual counselling, including the offer of HIV testing services
- screening to determine client eligibility, followed by informed consent or assent, as appropriate
- the circumcision procedure
- immediate postprocedure care, including wound care instructions and follow-up at 48–72 hours, seven days and six weeks

Fig. 1.1. Education and counselling integrated with other male circumcision services



Source: Adapted from (59)

1.8. KEY MESSAGES

- Male circumcision is permanent removal of the foreskin, either through the use of conventional or device-based surgical methods.
- Male circumcision is a one-time procedure that reduces the risk of female-to-male HIV transmission by about 60%.
- Male circumcision provides partial protection and should be offered as part of a minimum package of services as defined by the World Health Organization. Such package should include the following:
 - HIV testing services
 - active or supported referral of clients who test positive for HIV to HIV care and treatment programmes
 - screening for sexually transmitted infections and provision of or referral for treatment
 - promotion and provision of condoms
 - promotion of safer sex practices
- Informed consent (and assent, for minors) is a critical component of male circumcision service delivery to ensure that the procedure is being accepted voluntarily.
- Assurance of confidentiality and privacy is an important aspect of quality health services and supports the effectiveness of education and counselling.
- In addition to partially preventing HIV, male circumcision provides other health benefits for men and women.
- The rate of reported adverse events following the 14 million male circumcisions that have been performed in Africa has been low.
- Client safety is a priority.

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CHAPTER 2

AN OPPORTUNITY FOR EXPANDED SERVICES FOR ADOLESCENT BOYS AND MEN



This chapter provides information on the following:

- health interventions that should be linked to male circumcision services, including those specific to adolescent boys
- the importance of pathways and protocols for referring male circumcision clients to additional services they need or seek, and how to ensure that the referral is successful
- how male circumcision programmes can increase adolescent boys' and men's engagement in health services as well as increase their understanding of factors affecting their health
- how to overcome barriers to reach adolescent boys and men, and how to design person-centred, male-friendly services
- how a male circumcision service provides education, HIV testing and linkages to relevant services for HIV prevention and care
- the importance of diagnosing and treating sexually transmitted infections—and other high-risk conditions—among adolescent boys and men prior to male circumcision, and the need for active follow-up to ensure that they return for male circumcision services
- the importance of recognizing clients whose main problem or concern is sexual dysfunction, infertility or another condition that circumcision may not address, and linking clients to appropriate services
- the importance of addressing issues around masculinity and gender-equitable norms

2.1. INTRODUCTION

For many adolescent boys and men, accessing male circumcision services may be their first encounter with health services since early childhood. This contact presents a valuable opportunity to address other aspects of adolescent boys' and men's health, including sexual and reproductive health; prevention and treatment of HIV and other sexually transmitted infections; other communicable diseases; or noncommunicable diseases. Male circumcision is positioned well to provide a platform for linking adolescent boys and men with a range of health services. Linkages may be in both directions—male circumcision sites may refer clients to other services, and other service providers may refer clients to male circumcision sites.

Many adolescents (aged 10–19 years) may lack adequate knowledge and skills about their general physical, mental, sexual and reproductive health. Therefore, adolescents may be supported to make critical health-related decisions, laying the foundation for them to develop proactive care-seeking behaviours.

2.1.1. Timing of client education or counselling on other sexual or general health issues

Although male circumcision services may provide an excellent opportunity for adolescent boys and men to access additional services, great care has to be taken in determining the most appropriate time to give clients information that is not directly related to circumcision (see Box 2.1).

- On the day of the circumcision but before the procedure, the client—and his parent(s)/guardian(s) if he is a minor—should only receive information directly pertinent to the operation.
- If it becomes apparent that the client has not come for circumcision but for other concerns or problems, such as infertility or sexual dysfunction, the provider should address these issues with the client, as it may not be appropriate to proceed with circumcision, or at the very least make sure the client understands what benefits circumcision will and will not provide. Likewise, if a condition that makes the client ineligible for circumcision is found during screening, such as a sexually transmitted infection or an unmanaged chronic illness, then the circumcision should be deferred and a referral should be made.

- After the procedure, the focus should be on ensuring that the client receives and understands information about wound care, when to return for follow-up and what activities he can and cannot perform during the period of wound healing. At the time of the first follow-up visit, if wound healing is going well, then a good opportunity exists to inform the client about other available relevant services and condom use, and to reoffer HIV testing to those who initially declined.
- During further follow-up visits, and only after wound healing has been assessed and found to be normal, additional information should be given about contraception, sexual or other health issues, and related services. If there are problems with wound healing or other adverse events, then the information and care given should focus on dealing with the adverse event; until there is resolution of the adverse event, only information directly relevant to its management should be given.

Box 2.1. Giving too much information

An overload of information may diminish the client's understanding or recall of important instructions pertinent to the male circumcision procedure itself, including wound-care instructions, abstinence during the period of wound healing and need to return for follow-up visits.

2.1.2. Barriers to accessing male health services

There are a number of barriers to the uptake of health services by adolescent boys and men, including the following:

- **potentially unfriendly attitudes** of health care providers towards men and, particularly, adolescent boys who are sexually active
- **gender norms** among adolescent boys and men, which contribute to the following:
 - **beliefs about masculinity**, such as risk taking, which undermine healthy choices
 - **men's reluctance** to ask for help or seek medical care
 - **embarrassment and feelings of alienation** when using health facilities that are perceived as servicing women and children
- **gender biases in the health system**, as evidenced by the following:
 - more health services designed primarily to meet the needs of women and children than adolescent boys and men
 - inconvenient hours of operation at the clinic (that is, hours when men may be at work or adolescent boys may be in school)
 - lack of separate waiting and service areas for men, lack of trained male staff, lack of male-friendly or adolescent-friendly clinics
 - inadequate training or experience of health care providers in addressing adolescent boys' and men's sexual and reproductive health issues
 - lack of information on adolescent boys' and men's needs and concerns, which could inform the design of appropriate programmes and services (for example, health services may not seem relevant to the men they are meant to target)

Adolescent boys may face additional barriers:

- many adolescents may not have accurate information about their health, which may have a significant impact on their current and future well-being
- adolescents may have limited resources (for example, money and transport), reducing their access to health services
- younger adolescents require consent from parent(s)/guardian(s)—ideally, in person—for certain services, including HIV testing and male circumcision

Being aware of the barriers to accessing services will help male circumcision clinics better reach, understand and serve their clients. Additional information about addressing gender-related barriers is in Annex 2.1.

2.1.3. Developmentally appropriate care: a key challenge for male circumcision service providers

In addition to addressing the barriers described above, clinics need to find ways to accommodate the wide range of clients that services target. Prospective clients include adolescent boys, young men and adults. Prospective clients are in very different stages of life, with different needs, concerns, risks and lifestyles. For example, married adult men have very different health needs than prepubescent boys. Even within a given stage, there may be significant differences between any two clients. One 14-year-old client may appear to be a physically developed man and be sexually active with one or more partners, whereas another client of the same age may look more like a child and not yet have engaged in sexual activity.

These differences in clients influence every aspect of care: how to reach a client, how to build a trusting relationship with him, how to educate and counsel him about male circumcision and other aspects of his sexual and reproductive health, and what method(s) of circumcision is the safest choice for him.

2.1.3.1. Adolescent boys need special consideration

Male circumcision services generally target the entire age range of males; however, adolescent boys require specific attention (1). As a male circumcision client, an adolescent is more likely than an adult to require age-appropriate and more user-friendly (simplified) education and counselling on the procedure and its benefits, risks and limitations as an HIV prevention method. Adolescents may be particularly vulnerable to myths and misconceptions about circumcision and may not fully understand their risk or consequences of acquiring HIV and other sexually transmitted infections. They may also require special support from male circumcision providers and others in accessing any additional services. Parent(s)/guardian(s) of minors are required to provide consent for surgery and need to be encouraged to be involved throughout the male circumcision process (see Box 2.2).

When developing interventions that could contribute to the health of adolescent boys, it is important to consider the differences in age groups within adolescence. The developmental changes that take place during adolescence have implications for physical development and intellectual capacities; relationships; and parental, peer and social influences. To understand characteristics and changes taking place, the adolescent period may be considered in three age bands (see Table 2.1). However, the period is more often divided into two age groups to make it easier to develop and monitor adolescent sexual and reproductive health interventions (see Tables 2.2 and 2.3). These tables summarize how these two groups may differ in terms of specific attitudes and behaviours that have particular relevance to male circumcision services. In tailoring interventions, take into account the life phase of adolescent boys.

Box 2.2. Involving parent(s)/guardian(s)

In most instances, the decision for male circumcision of an adolescent boy starts with the parent(s)/guardian(s). Parent(s)/guardian(s) may be involved through information campaigns or may be targeted in demand creation. Once there is a decision for male circumcision, consent from parent(s)/guardian(s) is required for adolescent boys if they are under the national legal age at which they can make their own decisions about undergoing the procedure or testing for HIV. Health care providers will need to involve parent(s)/guardian(s) in discussions about male circumcision services. Even if consent is provided by the parent(s)/guardian(s), the adolescent client also needs to assent to the procedure before it can be performed. All clients have the right to refuse the procedure at any point in the process and for any reason.

To obtain consent from parent(s)/guardian(s), it is important to inform them about what will be done (removal of the foreskin), how this will be done (surgery or device) and what will happen if a device cannot be used if the male is ineligible. Information must be given about how long the procedure will take, the degree of discomfort one can normally expect and the follow-up requirements for wound care. Information should include the benefits and risks of circumcision and, where appropriate, HIV testing. It is particularly important to give adolescent boys clear information about the need to avoid masturbation or sexual activity until the wound has healed. This may need to be done when the adolescent is alone, by using language that is appropriate. The same information should be given to parent(s)/guardian(s). It is important to provide opportunities for parent(s)/guardian(s) to ask questions. Their involvement aids in obtaining an accurate medical history, assures better understanding of postoperative wound care and helps achieve better outcomes.

The presence of parent(s)/guardian(s) can pose challenges in the context of ensuring the client's privacy and confidentiality of information related to the client's sexual and reproductive health. Often, adolescents are too embarrassed to speak freely in the presence of parent(s)/guardian(s). The provider should make every effort to accommodate the adolescent's need for privacy and an age-appropriate level of autonomy (evolving capacities).

Table 2.1. Changes characteristic of early, middle and late adolescence (2)

	EARLY 10–12 YEARS (2)	MIDDLE 13–15 YEARS	LATE 16–19 YEARS
Growth	<ul style="list-style-type: none"> • Secondary sexual characteristics appear • Testicular growth • Growth spurt • Growth accelerates and reaches a peak 	<ul style="list-style-type: none"> • Secondary sexual characteristics advanced • Growth slows down, about 95% of adult stature attained 	<ul style="list-style-type: none"> • Physically mature • Growth spurt usually ends
Cognition	<ul style="list-style-type: none"> • Concrete thinking • Existential orientation • Long-range implications of actions not perceived 	<ul style="list-style-type: none"> • Thinking is more abstract • Capable of long-range thinking • Reverts to concrete thinking when stressed 	<ul style="list-style-type: none"> • Established abstract thinking • Future-oriented • Perceives long-range options
Psychosocial	<ul style="list-style-type: none"> • Preoccupied with rapid physical growth and body image 	<ul style="list-style-type: none"> • Re-establishes body image • Preoccupied with fantasy and idealism • Sense of invincibility 	<ul style="list-style-type: none"> • Intellectual and functional identity established
Family	<ul style="list-style-type: none"> • Defining boundaries of independence and dependence 	<ul style="list-style-type: none"> • Conflicts over control 	<ul style="list-style-type: none"> • Transposition of child-parent(s)/guardian(s) relationship to adult-adult relationships
Peer group	<ul style="list-style-type: none"> • Seeks affiliation to counter instability 	<ul style="list-style-type: none"> • Needs identification to affirm self-image • Peer group defines behavioural code 	<ul style="list-style-type: none"> • Peer group recedes in favour of individual friendship
Sexuality	<ul style="list-style-type: none"> • First ejaculation • Self-exploration and evaluation 	<ul style="list-style-type: none"> • Preoccupied with romance • Ability to attract opposite sex 	<ul style="list-style-type: none"> • Plans for future

Table 2.2. Examples of different attitudes and behaviours in younger versus older adolescents (2)

	YOUNGER ADOLESCENCE (10–14 YEARS)	OLDER ADOLESCENCE (15–19 YEARS)
Attitudes about future and HIV risk	A younger adolescent is likely to be a concrete thinker, focused on what he sees and knows in the present. He may give little thought to the consequences of his actions and how they could affect his future .	An older adolescent can think more abstractly; he is likely to think a lot about his future . Also, greater life experience has taught him that his actions directly affect the future, sometimes permanently .
Appeal of male circumcision	The idea that circumcision may make good hygiene easier to achieve may be of more importance to younger adolescents than the fact that it provides partial protection against HIV, which indirectly helps protect their female partners.	The older adolescent may be part of a committed couple and concerned about how a potentially positive HIV status will affect the relationship. Or, he may have several partners and fear the stigma of sharing a positive status with many others. In comparison to younger adolescent boys, he is likely to be more concerned about his HIV risk but also more interested in reducing his risk .
Importance of peer group's opinion and fitting in	A younger adolescent is likely to be concerned about fitting in with his friends and may be strongly influenced by them. What the client's peer group says and does may be more important to him than what adults or his parent(s)/guardian(s) say and do. The client is likely to adopt his peer group's opinion about circumcision.	An older adolescent may be less influenced by his peer group . He may seek the opinion of a few trusted friends but is likely to make his own decisions based on information he sees as relevant to his health.
Perspectives on adults	A younger adolescent may also be uncomfortable talking about sexual or reproductive health issues around adults—such as their parent(s)/guardian(s)—or with adults (such as health care providers).	Because they see themselves as more grown up, older adolescents are likely to be less shy in talking about adult concerns with health care providers.

Table 2.3. Overview of stages of adolescent development with implications for intervention design (3)

	EARLY 10–12 YEARS (2)	MIDDLE 13–15 YEARS
Worries	Will my friends make fun of me? Am I normal? What is happening to my body?	Do I have to have sex? Will my friends think that I am a man? Will they think that I am gay?
Where to reach me	School, adolescent/youth programmes and community support groups, including churches	School, youth programmes, community support groups, workplace, military and sports
Relationships	Usually still nervous with partners Sexual experimentation without penetration in most cases Masturbation	First sexual relationship with penetration usually occurs
Services	Mostly information services for other needs, such as healthy behaviours	Information, condoms and testing for sexually transmitted infections, including HIV

Additional resources for caring for adolescents are listed at the end of the chapter in the Bibliography section.

2.1.3.2. Men also need special consideration

Men may not be comfortable discussing sexual and reproductive health issues in the presence of adolescents, especially young adolescents (this is discussed further in Chapter 6). When delivering basic information about male circumcision and related services, the recommended practice is to provide separate group education sessions for adolescent boys and men. An adult client may also be more likely than an adolescent one to be in a stable, long-term relationship, and problems or issues affecting him may also be relevant to a partner or to his entire family. The client may be working to provide a livelihood for several people, which may affect how he feels about getting tested for HIV and possibly receiving a positive diagnosis. If accompanied by a partner at the clinic, some men may be uncomfortable responding to questions about their sexual behaviours, especially if truthful answers may cause problems in their relationships. Male circumcision providers should offer an opportunity for each client to discuss potentially sensitive matters privately. They should also encourage appropriate involvement of partners, such as when there are findings or issues that might impact a partner's health or well-being.

2.1.4. Person-centred care

Experience has shown that a person-centred approach to providing health services can greatly increase the impact of a single client contact. Some key concepts in person-centred care are listed below:

- People are the focus.
 - Care should be organized around the health needs and desires of an individual rather than around diseases or conditions targeted by services.
 - Services are designed with the target population in mind and should be acceptable, relevant and accessible to those who need them.
- The goal is to enable people to feel empowered.
 - They are given the education and support to make decisions and participate in their own care.
 - They are encouraged to ask questions.
 - They are informed of their right to consent/assent to or decline services.
- Each person is cared for in a whole-person way.
 - Services are delivered to provide each individual with a continuum of these and other services: health promotion, disease prevention, diagnosis, treatment and disease management. Throughout the person's life, services are provided at different levels of care and at different sites within the health system, and according to the person's needs.
 - Individuals are encouraged to seek and access other services. These service linkages are supported with information and active referral where possible.

2.2. EXPANDED PACKAGE OF SERVICES

Based on experience and recent innovations, one or more of the following expanded health care services could be considered for male circumcision clients:

- information on additional HIV testing options, such as self-testing
- assisted partner notification services for those who are HIV positive (4)
- diagnostic testing for sexually transmitted infections other than HIV; depending on local prevalence, consider adding onsite rapid syphilis testing

- promotion of more detailed information on reproductive health and family planning, safer sex practices and HIV risk reduction:
 - provide both male and **female condoms** (currently, most male circumcision programmes provide only male condoms) as well as information about their correct use
 - consider referral for pre-exposure prophylaxis **as relevant to those at substantial risk for HIV**
- improved **referral of clients with conditions** that are identified through male circumcision screening or the circumcision procedure (for example, hypospadias, pathological phimosis, or history suggestive of a potential bleeding disorder)

2.2.1. Additional services

Male circumcision programmes and providers are also encouraged to consider integrating other services with the male circumcision package—if applicable to individual clients or especially relevant in a particular setting—and to ensure that clients are successfully linked to these services. Based on their experience, programmes should consider assessment, care, treatment, management and referral of the following:

- infectious diseases prevalent locally, such as tuberculosis or malaria
- noncommunicable diseases that are prevalent locally, such as diabetes or hypertension
- other individual problems identified through the course of male circumcision services:
 - alcohol or substance use (including use of harm reduction services, such as needle and syringe programmes)
 - mental health issues
 - sexual dysfunction and infertility

Male circumcision sites are also encouraged to introduce or link clients to gender or masculinity education, including the following:

- examining gender norms, and the positive and negative impact the norms may have on the health of men and adolescent boys
- promoting respect for women's and girls' sexual and reproductive health needs and rights, as well as male involvement in female sexual and reproductive health care
- establishing or reinforcing the importance of preventing gender-based violence

Annex 2.3 has additional guidance for defining and planning the male circumcision package of services to be delivered in a given clinic and for developing a referral map.

2.2.2. Other reasons men may visit the circumcision clinic

Providers need to assess a client's reasons for coming to the clinic. In some cases, a client may visit because of an infertile partnership or, in other cases, because of sexual problems, such as premature ejaculation, erectile dysfunction or, very rarely, congenital erectile deformity. For reasons related to sexual or fertility issues, health care providers should make the appropriate referral.

2.3. STRATEGIES FOR REACHING ADOLESCENT BOYS AND MEN WITH MALE CIRCUMCISION AND OTHER HEALTH SERVICES (3)

Various strategies have been used to extend sexual and reproductive health services to adolescent boys and men, and to involve them in the health care of women and children. Male circumcision clinics and providers should consider these strategies, in forms appropriate to the local culture, to attract adolescent boys and men to male circumcision and other health services.

2.3.1. Reaching and attracting clients

Male circumcision clinics should work to address the barriers that adolescent boys and men face in accessing services, and they should do this in ways that are appropriate to the local cultural context. For example, clinics can do the following:

- Have **convenient clinic operating hours**. Services should be offered when adolescent boys and men are likely to have time available—for example, outside of typical workday or school hours.
- Maintain a **friendly, welcoming and supportive** environment. Both health care providers and support staff should do the following:
 - Be kind and respectful towards clients.
 - Examine their attitudes towards men, including sexually active young men.
 - Encourage and empower clients to take an active role in their health care, ask questions and access other services they need.
- **Protect, respect and fulfil a client's rights** to information about their health and health care options, privacy (audio and visual, as appropriate) and confidentiality. Clients have a right to experience nondiscriminatory and nonjudgemental attitudes and practices in the health care setting. Standards and values of the male circumcision staff and services may be presented and shared in a client-friendly manner; for example, through posters on the waiting room walls (see Box 2.3).

Box 2.3. Examples of messages to clients, suitable for posting in health facilities

- Safety is our top priority.
- Circumcision does not fully protect you from HIV or other sexually transmitted infections. Make sure you understand what circumcision can and cannot do for you.
- If you have any questions or concerns, please let us know.

- **Establish and maintain quality services.** The male circumcision clinic should have the following:
 - staff and providers trained to provide effective health services for adolescent boys and men
 - staff and providers who can ensure safety of both clients and themselves
 - equipment, medicines, supplies and technology needed to ensure safe and effective service provision
 - service delivery protocols available to all male circumcision providers (for example, documented in a checklist or other job aid, and in a facility procedural guide)
- **Design services specifically for male clients, and ensure that services are age appropriate for adolescent boys and men.** Such services may include the following:
 - male friendly and not appear as places that only provide care for women and children (for example, through male-only hours, waiting room and entrance)
 - male-oriented information, with separate age-appropriate education and counselling on sexuality, physiological development, family planning, sexually transmitted infections and HIV, genital health and hygiene, interpersonal communication and behaviours that affect a person's quality of health, including sexual and reproductive
 - providing print materials to clients on the availability of expanded services
 - having male service providers available locally if culturally relevant to clients
 - offering care services that specifically address male health concerns—for example, identifying medical indications for male circumcision or offering diagnosis and treatment of sexual dysfunction; sexually transmitted infections/ HIV; or cancer of the prostate, testis and penis

- **Raise awareness among adolescent boys and men, as well as the community in general, about the services being offered.**
 - Efforts may be made to reach men with information through the workplace, the military and men’s groups, as well as through schools and youth groups. Some services can also be provided in these settings, where appropriate.
 - Special outreach campaigns may be launched to target young men with information on health issues relevant to them and on related services.
 - Educational campaigns through the media and special initiatives may be situated in predominantly male contexts (for example, outreach through schools, places of employment, or football matches or other popular sporting events).
 - Information about services can be integrated with existing male-focused initiatives, such as community-based distribution and social marketing of condoms.
 - Services for men can be advertised through well-established, clinic-based services so that community members already accessing health care can learn about these services and spread information about them to others in the community.
 - Peer educators (see Box 2.4), including satisfied clients, can be used to spread knowledge about male circumcision.
 - All male circumcision clients as well as their partners—if clients are minors, then their parent(s)/guardian(s)—should be encouraged to speak to others in the community about male circumcision and refer others to male circumcision services. Well-respected community advocates can have a significant impact on individuals using health services.

Box 2.4. Role of peers

There is evidence that, especially for adolescent boys, peers and friends are by far the most influential factor in helping them decide whether to get circumcised. Adolescents also have unique channels for accessing information, including through peers (both boys and girls) and increasingly through interactive or social media. For all age groups, male circumcision programmes should identify circumcised adolescent boys and men from the community who are satisfied with their circumcision and are willing and able to advocate for the male circumcision programme. The active support of respected, trusted male circumcision advocates can be very persuasive in convincing men to access male circumcision services. Conversely, information spread by clients who receive bad care or treatment can be a powerful deterrent.

2.3.2. Linking male circumcision clients to additional health services (5)

Male circumcision services need to prioritize provision of safe services, good follow-up care for clients, prompt recognition and proper management of adverse events, and reaching highest-risk men or adolescent boys with services (such as those diagnosed with sexually transmitted infections or HIV-negative males whose partners are HIV positive). Once these prioritized services are well established, clinics should move to the provision of additional health services. Ideally, all related services that a male circumcision client may need would be organized within the same facility or setting; however, when additional services are indicated, the client will often need to be referred to another health service provider or facility. Sometimes, these services may be required before the circumcision can be performed (for example, treatment of a sexually transmitted infection, specialist opinion regarding an anatomical abnormality or dose of tetanus toxoid-containing vaccination), or the client may need to be referred to a higher level of care for the circumcision (for example, if he has a bleeding disorder). In other cases, the services may not be directly related to the circumcision (or to whether, when or where it can be performed), but they are recommended by the provider or requested by the client based on information gathered through counselling or screening (for example, help for substance use disorders, mental health or treatment of infertility). Rarely, a complication may arise during or after the circumcision procedure that requires emergency care. Timely, effective management of adverse events is the right of every male circumcision client; it is also critical to maintain demand for male circumcision services. Some of the nonemergency conditions commonly seen in male circumcision

clients are in Table A2.3.2 in Annex 2.3. Management of life-threatening complications and adverse events is discussed in Chapter 10.

In order for male circumcision services to be as safe and effective as possible—as well as to have the greatest impact on the overall health and well-being of male circumcision clients and the community—reliable mechanisms of referral to relevant services must be established. Doing so may require the involvement of another facility (see Box 2.5). Staff in male circumcision programmes should work in partnership with specialists, the district hospital, higher levels of care and other health services, as well as other relevant entities (for example, youth centres, schools and universities, major employers, community members and livelihood programmes) to raise awareness about male circumcision services, discover and respond to potential gaps in service for male circumcision clients, and effectively use male circumcision services as an entry point for other health interventions. Tips and tools for planning male circumcision services, including mechanisms for referral, are in Annex 2.3.

Box 2.5. The basics of the referral process

A referral is when a health care provider at one level of the health system—with insufficient resources (in terms of drugs, equipment or skills) to manage a particular clinical condition or provide a certain service—seeks the assistance of a more appropriate facility. This appropriate facility may be at the same or a higher level than the referring facility but is able to assist in or take over the management of the client's condition or respond to the client's needs.

Key reasons for deciding to refer either an emergency or a routine case include seeking:

- expert opinion regarding the client
- additional or different services for the client
- admission and expert management of the client or
- access to diagnostic and therapeutic tools.

In the context of this *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men*, referral indicates the process—initiated by the male circumcision clinic—of linking clients to facilities or providers offering additional services (see Annex 2.2 for a sample referral form) (6).

In collaboration with relevant health care providers and facility staff, specific referral protocols should be established before a site begins providing male circumcision services. This groundwork will enable the clinics providing male circumcision services to create an inventory of other or related health services and interventions available within the community and through nearby providers and facilities (such as gender and masculinity education), develop a referral map, and document referral options and protocols. Male circumcision programmes should also establish a system for monitoring the efficacy of referrals and the return of clients after referral. Referral protocols should also be reviewed and updated on a regular basis.

As part of providing quality care, male circumcision clinic staff and providers, and the referral facility staff and providers, should be trained on the clinic's referral protocols and know how to facilitate linkages for individual clients. Adolescents, especially, may face difficulties in navigating referral pathways in health systems that are often fragmented, thereby making linkages and referrals for such clients important. Strategies that male circumcision providers and teams can use to help support clients in accessing additional services, some of which are especially appropriate and important for adolescent clients, include the following:

- giving complete contact information to the client for referral services, support groups or other services
- making appointments for other services that are needed directly with or for the client during the male circumcision visit
- accompanying the client to the other needed or recommended services

- helping the client make a list of people who are close to him and who can assist him in adhering to guidance or instructions provided and in accessing other services as needed
- connecting the client with a postdiagnosis HIV support group, as appropriate

Other supporting measures include the following:

- using cellphones or SMS technology and call centres to disseminate key health information
- establishing buddy systems, in which clients in similar situations provide mutual support to one another, and linking these systems with relevant health services
- ensuring that peer support and community-based outreach approaches are supported, integrated and linked with relevant services

KEY MESSAGES

- Other information and health services (for example, sexual and reproductive health education and services) are important for adolescent boys and men, as well as their partners. Male circumcision provides an important potential entry point for accessing expanded health services.
- Multiple approaches and strategies are needed to reach and attract different subpopulations of males to health services.
- Male circumcision clients identified as HIV positive must be actively referred for care and treatment, and screened for tuberculosis.
- Services, communication and counselling need to be adapted to the specific needs of adolescent clients (10–19 years old); the services need to be age appropriate and include different messaging for younger (10–14 years old) and older adolescents (15–19 years old).

ANNEX 2.1. ADDRESSING MALE NORMS AND MASCULINITY

Many of the barriers in accessing male health services stem from beliefs, widely held in many societies, about what it means to be a man (for example, men do not need help, men are strong and invulnerable, men are superior to women). Thus, in the past decade, an increasing number of HIV prevention and reproductive or sexual health promotion interventions targeting men and boys have incorporated a gender perspective. This means that the interventions take into account what is deemed appropriate for males or expected of them in a given society, as well as the economic and social context in which boys and men live.

Gender-transformative approaches—such as group discussions, education and counselling—are designed to bring attention to the powerful influence that patriarchy, social structures and gender norms have on individual men's choices and behaviours. The activities help adolescent boys and men:

- distinguish between the positive and harmful gender norms to which they adhere;
- assess how gender norms affect their lives, including their health; and
- challenge unhealthy or harmful norms by considering alternative beliefs and practices.

Multiple encounters with providers are needed to change attitudes and behaviours dictated by gender norms, especially among men (see Box A.2.1.1).

Box A2.1.1. Enlisting men in improving health outcomes

As husbands, boyfriends, fathers, brothers and friends, men can influence health outcomes by (7) doing the following:

- using condoms consistently and correctly to prevent the spread of sexually transmitted infections, and supporting and encouraging regular condom use
- using contraception, or supporting its use by partners, so women are better able to control the number and timing of their pregnancies
- refraining from all forms of violence against women and girls, including coercive sex
- accessing other nonhealth, social and gender education and counselling services that promote gender-sensitive behaviours among males:
 - supporting women to receive safe, effective care during pregnancy, childbirth and the postpartum period
 - ending harmful traditional or sociocultural practices that expose women to increased risk of HIV and other psychosocial and health problems

Adolescence may be a good time to address issues around gender and masculinity. In the context of male circumcision, many of the activities that surround the traditional practice focus on learning to become a man. Similarly, through male circumcision services, adolescent boys can be linked to other relevant community services that address social norms, masculinity and gender values, thereby supporting a healthy transition to adulthood. These programmes may also address issues such as the use of tobacco, alcohol and other psychoactive substances; risk taking and peer pressure; attitudes towards caring and parenting; and interpersonal violence, including gender-based violence and its negative consequences for adolescent girls and young women, families and communities.

Key messaging around positive gender roles and the uptake of male circumcision and other reproductive and sexual health services for adolescents equate healthy reproductive and sexual health choices and practices with being a desirable boyfriend; working towards a desired future; and transitioning into a becoming a strong responsible adult, one who is a good partner and a productive member of society.

For adolescent boys, these messages include that **male circumcision and other reproductive and sexual health services do the following:**

- Support them in **becoming a desirable boyfriend** by potentially reducing their partners' overall risk of HIV/sexually transmitted infections and demonstrating self-value: *"My health is worth protecting, and my partner's is too."*

Male circumcision may also make it easier to maintain good hygiene, which can be attractive to partners.

- Can help them **grow into the men they want to be**, as well as **protect and achieve the future they desire**.

The analogy of going to school to be ready for a good job can be helpful—in the same way, healthy choices and practices now can help prepare adolescent boys for good health, healthy relationships and a productive future: *"My future is worth protecting; I can have a better future if I am healthy."*

- Are a good first step towards **taking responsibility for one's health**, providing a foundation for making healthy, grown-up, sexual, reproductive and general health choices—potentially for the rest of their lives.

These choices will also help to protect the health of their present partners and future partners and families: *"Strong men take responsibility for their health and actively support others in protecting their health as well."*

For parent(s)/guardian(s), messages should specifically target the health benefits of circumcision and should help to position parent(s)/guardian(s) to discuss male circumcision in an informed way with their sons (and daughters). Mothers may deserve special consideration given their general influence and involvement in their children's health.

ANNEX 2.2. SAMPLE REFERRAL FORM

NAME OF FACILITY	REFERRAL FORM			ORIGINAL/COPY
Referred by:	Name:		Position:	
Initiating facility name and address:			Date of referral:	
Telephone arrangements made:	Yes	No	Facility tel. no.	Fax no.
Referred to facility name and address:				
Client name:				
Identity number:		Age:	Sex: M <input type="checkbox"/> F <input type="checkbox"/>	
Client address:				
Mobile phone no.:				
Clinical history:				
Findings:				
Treatment given:				
Reason for referral:				
Documents accompanying referral:				
Print name, sign and date:	Name:	Signature:	Date:	
Note to receiving facility: On completion of client management, please fill in and detach the referral back slip below and send with patient or send by fax or mail.				

ANNEX 2.3. TIPS FOR PLANNING MALE CIRCUMCISION SERVICES AND DEVELOPING A SERVICE SUPPORT REFERENCE GUIDE

In establishing the male circumcision services to be offered in a particular clinic, the male circumcision team and clinic manager or supervisor should consider the World Health Organization's minimum male circumcision package and optional expanded packages in terms of the following:

- onsite capacity (that is, skills, training and experience) to provide a service
- availability of resources (that is, supplies and equipment) needed for a service
- national policies on relevant and related issues (for example, on tetanus toxoid-containing vaccination and legal age of consent for the procedure)
- local needs (for example, high prevalence of tuberculosis or diabetes)
- accessibility of referral facilities (district hospital or other higher level of care), specialists and other related services (for example, HIV care and treatment)

Based on these considerations, the male circumcision team should design the package of services they will offer (aside from education and counselling, screening, provision of the procedure and follow-up), specifying the protocol for each. Briefly, protocols describe who will do what, where and when. The male circumcision team should also develop a services support reference guide or compilation that includes these protocols and other clinic procedures (documented); a referral map describing where clients will be referred for specific additional services; and the guidelines and other resources required to provide their male circumcision package safely, effectively and consistently.

In this clinic:

1. What circumcision methods are offered?

- Conventional surgical methods:
 - Dorsal slit _____
 - Forceps-guided _____
 - Sleeve resection _____
- Device-based surgical methods (for example, one collar clamp device or elastic collar compression device):
 - If so, please specify type and brand name: _____
 - If so, please specify type and brand name: _____

2. What is the male circumcision package of services offered? For services that are essential components of male circumcision services (**bolded** in Table A2.3.1) and those recommended by the World Health Organization as part of the minimum male circumcision package (*italicized* in Table A2.3.1), clinics should determine their capacity to provide the service. If they can provide the service, they should define their service delivery protocol (who will be accountable, what they will do, and where and when they will do it). If they cannot provide the services, they should identify accessible facilities and programmes that provide the service, and establish protocols for referral (see Table A2.3.1).

3. What are the conditions and needs for which clients will be referred? Where will clients be referred? What will be the protocol in each case? A tool such as the one below (see Table A2.3.1) can assist clinics in creating a referral map (see Table A2.3.2).

Table A2.3.1. Clinic male circumcision package planning tool (with example entries)^a

A tool such as this can help the male circumcision team to define the package of male circumcision services it will provide and how they will provide them. This process can also support the development of an onsite male circumcision resources guide and a referral map (see Table A2.3.2).

		PROTOCOL What should be done, when, where and by whom (at the clinic)	KEY RESOURCES Tools, checklists, guidelines available to support carrying out the task according to standards	NOTES Tasks to be completed before task can be performed according to standards
Essential service delivery components for male circumcision services				
Registration and intake	✓	Team member X will do this in the blue room during male circumcision special hours or days; they will start the client record and collect identification from adolescents. They will also collect the tetanus toxoid-containing vaccination record.	<ul style="list-style-type: none"> Male circumcision client record 	<ul style="list-style-type: none"> Determine best hours or days for male circumcision clinic. Confirm legal age to consent for circumcision and HIV testing.
Group education				
Counselling		Team member X, Y or Z counsels clients in the exam room before screening.	<ul style="list-style-type: none"> Male circumcision client record Male circumcision counselling checklist Referral form 	<ul style="list-style-type: none"> Determine where to refer clients concerned about sexual dysfunction, infertility, etc.
Screening: history		Team member X, Y or Z performs the history in the exam room after counselling.	<ul style="list-style-type: none"> Male circumcision client record Referral form Sexually transmitted infection diagnosis and management guidelines 	<ul style="list-style-type: none"> Determine conditions to be referred and the referral provider/facility—and the protocol for each.
Screening: physical and genital examination		Team member A or B performs the physical and genital examination in the exam room after counselling.	<ul style="list-style-type: none"> Male circumcision client record Referral form Sexually transmitted infection diagnosis and management guidelines 	<ul style="list-style-type: none"> Determine conditions to be referred and the referral provider/facility—and protocol for each.
Informed consent/assent				
Preparation of procedure room, client, equipment and supplies				
Surgical checklist				
Performance of procedure				
Postprocedure monitoring				
Postprocedure counselling				
Releasing client				
Processing room and used equipment/supplies				
Follow-up care				
Recordkeeping				
Monitoring				
Offer of HIV testing services (except for adolescents under 15 years old, unless otherwise indicated)		Team member X, Y or Z will offer and perform testing as part of the counselling session.	<ul style="list-style-type: none"> Male circumcision client record Referral form HIV testing and counselling guidelines 	<ul style="list-style-type: none"> Determine where to refer clients who test HIV positive for additional counselling and for initiation of treatment.

		PROTOCOL What should be done, when, where and by whom (at the clinic)	KEY RESOURCES Tools, checklists, guidelines available to support carrying out the task according to standards	NOTES Tasks to be completed before task can be performed according to standards
		<i>Active and supported referral of clients who need additional services, including referral of those who test positive for HIV, to HIV care and treatment programmes</i>		
		<i>Screening and treatment for sexually transmitted infections (ensure that men who are treated for sexually transmitted infections are actively followed, so they are able to receive male circumcision services after treatment)</i>		
		<i>Provision of male and/or female condoms, along with promotion of their correct and consistent use, and education on reproductive health and family planning</i>		
		<i>Promotion of safer sex practices and provision of HIV risk-reduction counselling</i>		
		<i>Tetanus toxoid-containing vaccination (per individual need and national policy)</i>		
Additional services to be addressed based on national policy or local needs				
		Tuberculosis screening		
		Blood sugar testing		
		[Other?] gender-normative education		

^a Components essential to male circumcision services are **bolded**; those recommended by the World Health Organization as part of the minimum male circumcision package are italicized; other services the male circumcision team may want included, based on national policy and local need, should also be part of the planning process.

Table A2.3.2. Example male circumcision clinic referral map planning tool^a

CONDITION	REFERRAL TYPE	REFERRAL FACILITY OR PROVIDER	PROTOCOL		
			ANY SPECIAL INSTRUCTIONS?	FOLLOW UP WITH REFERRAL FACILITY?	FOLLOW UP WITH CLIENT?
Substance use		<i>For each, specify:</i> <ul style="list-style-type: none"> • Name of facility/provider • Address • Contact information • Point person to contact 			
HIV care and treatment					
Infertility			<i>Mondays only</i>	<i>Follow up in three weeks to learn the outcome of referral.</i>	<i>Contact clinic after client has accessed referral services to determine whether they still want circumcision.</i>
Sexual dysfunction					
Anatomic abnormality (hypospadias, pathological phimosis)					
Gender normative education					
[Others] Adolescent-centred services					

^a Explanation of column headings:

Referral type: Specify what type of referral this is, for example: emergency; recommended but optional (client can proceed with circumcision and access as desired); or required (for example, before proceeding with the circumcision, the client must access services).

Referral facility or provider: Local facility or provider that clinic is linked with, or plans to link with, in order to fill this service gap.

Any special instructions? Anything different from clinic's standard referral protocol.

Follow up with referral facility? Protocol for follow-up with facility or provider after referral; this is especially important if referral delayed circumcision or condition was a contraindication to circumcision at the clinic.

Follow up with client? Protocol for follow-up with client after referral; this is especially important if referral delayed circumcision or condition was a contraindication to circumcision at the clinic.

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CHAPTER 3

FACILITIES, SUPPLIES AND INFRASTRUCTURE FOR MALE CIRCUMCISION PROGRAMMES



This chapter provides information on the following:

- facility considerations for male circumcision programmes
- procedure room recommendations
- suggested client flow for male circumcision procedures and related services
- equipment and supplies required for male circumcision

3.1. INTRODUCTION*

A male circumcision site's facilities, supplies, equipment and other necessary resources should be prepared and ready for the provision of male circumcision services **before** staff are trained to provide these services. Training is most effective when the learnt skills are put to use immediately after the training is complete. Offering male circumcision services before the site is fully prepared or before training is completed can lead to bottlenecks in the flow of male circumcision services, imbalances in the supply and demand of services, and, most significantly, a reduction in the quality of services—all of which can lower demand for this protective procedure that can have significant beneficial impact on entire populations. Well-prepared male circumcision sites and staff are able to provide safe, quality male circumcision services.

3.2. DIFFERENT TYPES OF FACILITIES

From a programmatic perspective, there are three different types of male circumcision that can be combined in some form to serve the community most effectively within the constraints and requirements of a particular male circumcision programme.

- **Fixed sites** are located in permanent structures and are appropriate in areas where the population is dense, and there is likely to be a continuing demand for services. These sites may be dedicated sites or integrated into other health care facilities.
- A **mobile site** is often a temporary structure that may expand the reach of fixed sites or provide services that supplement those offered at fixed sites. Such sites may operate on a long-term basis or be used for outreach during periods of high demand; for example, during male circumcision campaigns.
- **Outreach sites** are often established in existing structures that are modified to make male circumcision services available to harder-to-reach clients, such as those in rural areas. They can also help raise awareness and generate demand in such populations, and provide temporary short-term support during campaigns.*

Although male circumcision sites may vary in significant ways, all male circumcision sites should have sufficient space and other necessary resources to provide confidential counselling, perform safe circumcision and manage emergencies. For more information on determining the most appropriate site options in the context of creating demand or addressing other local needs, see *PEPFAR's best practices for voluntary medical male circumcision site operations (1)*.

3.3. CLINIC DESIGN TO SUPPORT GOOD CLIENT FLOW

Client flow refers to the number and pattern of clients moving through a facility as they receive services. Well-coordinated client flow is critical to avoid congestion and confusion as clients move from one component of male circumcision services to the next (such as from screening to the undergoing the procedure). It also supports staff in providing services in a consistent and organized manner that contributes to improved health outcomes for clients. Client flow is important for all components of the minimum package of male circumcision services and for expanded services. Good client flow may help to conserve time and other resources for staff and clients, thereby enabling the provision of a broader range of health-enhancing services.

*Adapted from (1)

Some characteristics of service delivery design and function, which support good client flow in male circumcision or general health sites, are the following:

- Clients have easy access to separate entry and exit points, ideally at opposite ends of the clinic.
- Waiting areas and periods of waiting between different service components are used rather than wasted—these may be opportunities to educate clients, reinforce key health messages or provide other services.
- Closely related services are combined if doing so does not compromise the client's rights to privacy and confidentiality, as well as safe quality services (for example, counselling and screening are often combined).
- The risk of client contact with biohazardous material is reduced to as low a level as possible.
- A recovery area is available and is close to the exit, allowing clients to rest while being monitored until the provider deems it safe for them to leave.
- The exit point is situated close to a place where the client can easily be given, in private, the following:
 - postprocedure counselling, a brochure on postprocedure self-care instructions and a list of warning signs that indicate a need to seek emergency care
 - specific information about the upcoming follow-up appointment
 - analgesics provided for the client to take home

3.4. THE PROCEDURE ROOM

Ideally, the procedure room used in male circumcision services should be used only for circumcisions, but the room may, if necessary, be used for other surgical procedures. A dedicated male circumcision procedure room helps staff achieve a high level of quality and consistency in service delivery and cleanliness (see Box 3.1), and maintain the appropriate equipment and supply setup for circumcision. The procedure room itself must have the following characteristics:

- Be **well ventilated** (for example, with a window, air conditioner or vent).
- Be **adequately furnished** (as described below).
- Be **free of clutter** (containing nothing that is not required for performing the procedure—for example, storage boxes).
- Have surfaces that are easy to clean and disinfect.
- Allow for **visual and audio privacy**.
- Have a **floor made** of seamless nonporous material. Concrete, wooden and tile floors may be acceptable provided they are properly sealed, but this requires regular maintenance or resealing; packed dirt floors should be avoided.

The procedure room should be equipped with a **narrow operating table or examination couch** that is high enough to allow the provider doing the circumcision to perform the procedure without stooping or bending. There should be sufficient space around the bed for client flow and infection prevention measures, and for resuscitation if needed. A small set of steps (or foot-step stool) can be provided to enable the client to climb up onto the table with ease. Blocks can be placed under the table legs at the foot end of the table to create a head-down position when needed. The room should also contain an **instrument trolley or table**, upon which the instrument set can be unpacked.

Box 3.1. Cleaning the procedure room

Between procedures, the instrument trolley and the operating tabletop should be disinfected. Any spillage on the floor should first be contained with an absorbent material, then mopped with clean water and detergent, and, finally, disinfected.

At the end of the operating day, all flat surfaces in the procedure room should be thoroughly cleaned and disinfected, including the floor. A liquid disinfectant should be used; the liquid should be diluted as recommended by the manufacturer. There should be a periodic (weekly or monthly) thorough clean when ceilings and walls are also cleaned; how often this is done will depend on intensity of the room's use and also whether the room is used only for circumcision or for other types of surgery. Standard precautions for infection prevention are covered in more detail in Chapter 5.

The **lighting** in the procedure room should be arranged so that the client's penis is well illuminated and the provider doing the procedure can easily see what he/she is doing. Ideally, the clinic should be equipped with an operating theatre minor procedures lamp or head lamps. Alternatively, fluorescent lighting over the operating table can provide adequate illumination. As part of the permanent setup for circumcision procedures, **emergency medications and equipment** for managing adverse events, such as anaphylaxis, should be available in or near the procedure room (see Chapter 9, Section 9.2). These medications and equipment should be kept in a clearly labelled location that is cool and away from direct sunlight.

3.5. EQUIPMENT AND SUPPLIES

This section describes the equipment and supplies needed for routine male circumcision services and those needed for the management of adverse events. It is important to ensure that there are adequate amounts and quantities of all of these items at all times. Checking items needed for standard services should be a routine part of the male circumcision team's daily preprocedure preparation. Checking emergency medications and supplies should also be done on a regular basis (either at the start of each day or at the start of each week) to ensure that they are stocked and that none of the medications are approaching or beyond the expiry date; this inventory and expiry check should be logged. This routine must be part of the male circumcision site's process for ordering, stocking and monitoring inventory. For more information, see the World Health Organization's *Surgical care at the district hospital* (see the Bibliography section).

3.5.1. Items needed for standard services

Box 3.2 lists equipment and instruments required for routine adolescent and adult male circumcision using any of the conventional or device-based surgical methods described in this *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men*. At the start of the day, the provider doing the procedure should make sure that there is an adequate supply of these standard items and that they are easily accessible. Between procedures, there should be a check and replenishment of the supply as needed.

In addition to the supplies needed for the procedure, male circumcision clinics will also need to ensure that there is an adequate supply of condoms, information materials and any other items they plan to distribute to clients.

Box 3.2. Standard equipment and supplies needed for a single conventional or device-based surgical male circumcision procedure

- O drape (80 cm x 80 cm, with ~ 5 cm hole)
- 1% or 2% lidocaine/lignocaine
- Artery forceps, also known as mosquito forceps (three straight, five curved)
- Large artery forceps (straight cross clamp)
- Curved dissection scissors
- Dissecting forceps (finely toothed), also known as tweezers
- Gallipot for antiseptic solution (for example, povidone iodine)
- Gentian violet (no more than 5 mL) or sterile marker pen
- Gloves, masks, caps and aprons
- Injection needles (21-gauge, 23-gauge, 25-gauge or 27-gauge)
- Instrument tray wrapped with sterile drape
- Needle holder
- Gauze impregnated with petroleum jelly (5 cm x 5 cm or 5 cm x 10 cm) and sticking plaster or paper tape
- Plain gauze swabs (10 x 10 cm; 10 for the procedure, five for the dressing)
- Povidone iodine (50 mL 7.5–10% aqueous-based solution)^a
- Scalpel knife handle and blades
- Stitch scissors
- Suture material (chromic catgut or polyglactin 910 [Vicryl Rapide™] 3-0 and 4-0) with 3/8 circle reverse-cutting needle^b
- Syringe, 10 or 20 mL
 - Ideally, if programmatically feasible, stock syringes with these safety features: reuse prevention and sharps injury prevention. The models selected should allow repeated aspiration to permit correct injection technique, and providers may also prefer models with detachable needles, which allow use of different gauges for anaesthetic withdrawal and injection.[†] If reuse prevention syringes are not available, single-use syringes and needles without reuse prevention features are a second choice. If these are also unavailable, use equipment suitable for steam sterilization. Also see the World Health Organization's *Guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings* (see Bibliography for citation).

^a It is important to have available alternative solutions for skin disinfection, such as chlorhexidine, for patients allergic to povidone iodine.

^b Extra suture materials and needles should be available for every procedure.

[†] Based on a Zambia pilot, by Jhpiego, that assessed reuse prevention syringes to ensure their usability and appropriateness in male circumcision

3.5.2. Items needed for emergencies

The male circumcision team should be trained and prepared to respond to an emergency if it occurs. As part of this preparation, the male circumcision site should establish standard operating procedures for emergency response and ensure that the emergency equipment and supplies listed in Box 3.3 are available and ready for use at any time.[‡] At the start of the day, the provider doing the procedure should make sure that these items are easily accessible.

Box 3.3. List of emergency equipment and supplies (2)

- Adhesive tape (strapping)
- Alcohol swabs
- Best practice guidelines for emergency care^a
- Blood pressure measuring equipment, including adult and paediatric cuffs
- Stethoscope
- Gauze
- Gloves (examination)
- Intravenous cannulas and infusion sets
- Oropharyngeal airway (adult and paediatric sizes)
- Resuscitator bag valve and mask (adult and paediatric)
- Normal saline solution for intravenous infusion: 0.9% sodium chloride (NaCl)
- Syringes with needles (disposable)
 - Ideally, if programmatically feasible, stock syringes with these safety features: **reuse prevention** and sharps injury prevention. The models selected should allow repeated aspiration to permit correct injection technique, and providers may also prefer models with detachable needles, which allow use of different gauges for anaesthetic withdrawal and injection.[§] If reuse prevention syringes are not available, single-use syringes and needles without reuse prevention features are a second choice. If these are also unavailable, use equipment suitable for steam sterilization. Also see the World Health Organization's *Guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings* (see Bibliography for citation).
- Tourniquet

Make sure that there is an inventory list of emergency equipment and supplies to cross-reference against items in stock. Additional items per national guidance should be included also.

^a Refer to guidelines on this webpage: <http://www.who.int/surgery/publications/en/>

[‡] Adapted from (2)

[§] Based on a Zambia pilot, by Jhpiego, that assessed reuse prevention syringes to ensure their usability and appropriateness in male circumcision

3.5.3. Maintenance and care of instruments

A critical aspect of maintaining surgical instruments for use is to process them appropriately for infection prevention, as described in Chapter 5. It is also important to make sure that instruments are fit for safe use. In addition to the normal checks made during cleaning at regular intervals, the clinic should evaluate all surgical instruments for signs of wear (see Box 3.4).

Box 3.4. Checklist for assessing instruments for signs of wear

For haemostatic artery forceps:

- Do the points (or teeth) meet accurately?
- Are the points worn?
- If serrated, are the ridges worn?
- Does the ratchet lock securely, or is it worn?

For surgical dissection scissors:

- Is the cutting edge of the blade sharp?
- Do the blades meet securely?
- Is the screw loose?

For needle holders:

- Do the points (or teeth) meet accurately?
- Are the points worn?

For dissection forceps (tweezers):

- Do the points (or teeth) meet accurately? (Crossed points are a common problem with old instruments.)
- If serrated, are the ridges worn?

- **Where reusable surgical instruments are used**, providers should be aware that these wear out with use and with repeated disinfection and sterilization. Failure to maintain instruments in good working condition can lead to operative difficulties and complications. For example, haemostatic artery forceps with bent blades will not properly occlude a bleeding vessel, while blunt dissection scissors can result in a ragged wound. **In a clinic where both reusable and disposable instruments are available**, care must be taken to prevent mixing the two types because disposable instruments may not have the durability to withstand repeated autoclaving for proper sterilization, which can lead to increased risk of infection.

KEY MESSAGES

- A male circumcision site's facilities, supplies, equipment and other necessary resources should be prepared and ready for the provision of male circumcision services **before** staff are trained to provide these services.
- Three different types of male circumcision sites—fixed (either standalone or situated within a larger facility, such as a district hospital), mobile and outreach—can be combined to serve the community most effectively within the constraints and requirements of a particular male circumcision programme.
- Ideally, the procedure room should be dedicated to circumcision only. This helps staff achieve a high level of quality and consistency in service delivery and cleanliness, and maintain appropriate equipment and supply setup for circumcision.
- Well-coordinated client flow from one component of male circumcision services to the next is critical to avoid congestion and confusion; it also contributes to quality of care, and can save time and resources.
- A routine part of the male circumcision team's daily and preprocedure preparations— and of the male circumcision site's process for ordering, stocking and monitoring inventory—is to ensure that equipment and supplies needed for male circumcision services and adverse events are available, ready for use and in good working order.

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CHAPTER 4

RECORDKEEPING, REPORTING AND QUALITY ASSURANCE



This chapter provides information on the following:

- the importance of record keeping for quality client care and for monitoring and evaluation
- standards and indicators for male circumcision programmes and services
- reporting severe adverse events using guidance from the College of Surgeons of East, Central and Southern Africa
- characteristics of good clinical data
- key data included in recordkeeping
- tools used for recordkeeping and data collection
- analysis and use of indicator data for decision-making at the site level
- the use of quality improvement tools

4.1. INTRODUCTION

There is an old saying: “If it is not written down, it did not happen.” Similarly, if what is written down is **not reviewed or shared**, even the best records are of limited value. Recordkeeping and reporting are essential components of any quality assurance or quality improvement effort. These processes help ensure that adolescent boys and men who seek male circumcision services receive safe, quality care and, as a result, have better health and overall well-being.

Recordkeeping is a key responsibility of health care providers in health facilities; it is also necessary for accurate reporting and is critical to any quality assurance effort. In the context of male circumcision services, **quality** can be defined as the degree to which care given to patients by providers and clinic adheres to standards. Standards outline key elements and expected level of performance that define quality. Male circumcision-specific standards in Box 4.1 are for use at the facility level to guide the setup, assessment and improvement of male circumcision services.

Along with health services provided at male circumcision clinics, the recordkeeping, reporting and quality assurance activities performed at these sites have been critical to the success of male circumcision programmes (see Box 4.2). The information yielded through these efforts has also informed new guidance for male circumcision providers, thus contributing to quality assurance on a global level and to a potentially significant decrease in the incidence of adverse events.

Male circumcision services that continually improve their safety and quality should attract increasing numbers of adolescent boys and men, leading to fewer people becoming infected with HIV and improved health outcomes for populations hardest hit by HIV.

Box 4.1. World Health Organization's male circumcision standards

Standard 1	An effective management system is established to oversee the provision of male circumcision services.
Standard 2	A minimum package of male circumcision services is provided.
Standard 3	The facility has necessary medicines, supplies, equipment and environment for providing male circumcision services that are safe and of good quality.
Standard 4	Providers are qualified and competent.
Standard 5	Clients are provided with information and education for HIV prevention and male circumcision.
Standard 6	Assessments are performed to determine the condition of clients.
Standard 7	Male circumcision surgical care is delivered according to evidence-based guidelines.
Standard 8	Infection prevention and control measures are practised.
Standard 9	Continuity of care is provided.
Standard 10	A system for monitoring and evaluation is established.

Source: Reprinted from (1, 2)

Box 4.2. Role of male circumcision site manager

The manager of a male circumcision site has a number of responsibilities. These include ensuring that: quality services are provided; records are correct, complete and consistent; and confidentiality is maintained, particularly of sensitive information, such as HIV test results.

4.2. RECORDKEEPING AND REPORTING

On an individual level, the accuracy, completeness and careful review of records help providers ensure that clients receive the safest and most appropriate care possible. Documentation in a client's records should inform several critical decisions—for example, whether the client is eligible for circumcision at a particular level of care or requires referral; which method of circumcision is best suited to him; and what other health services he may need, such as HIV care and treatment.

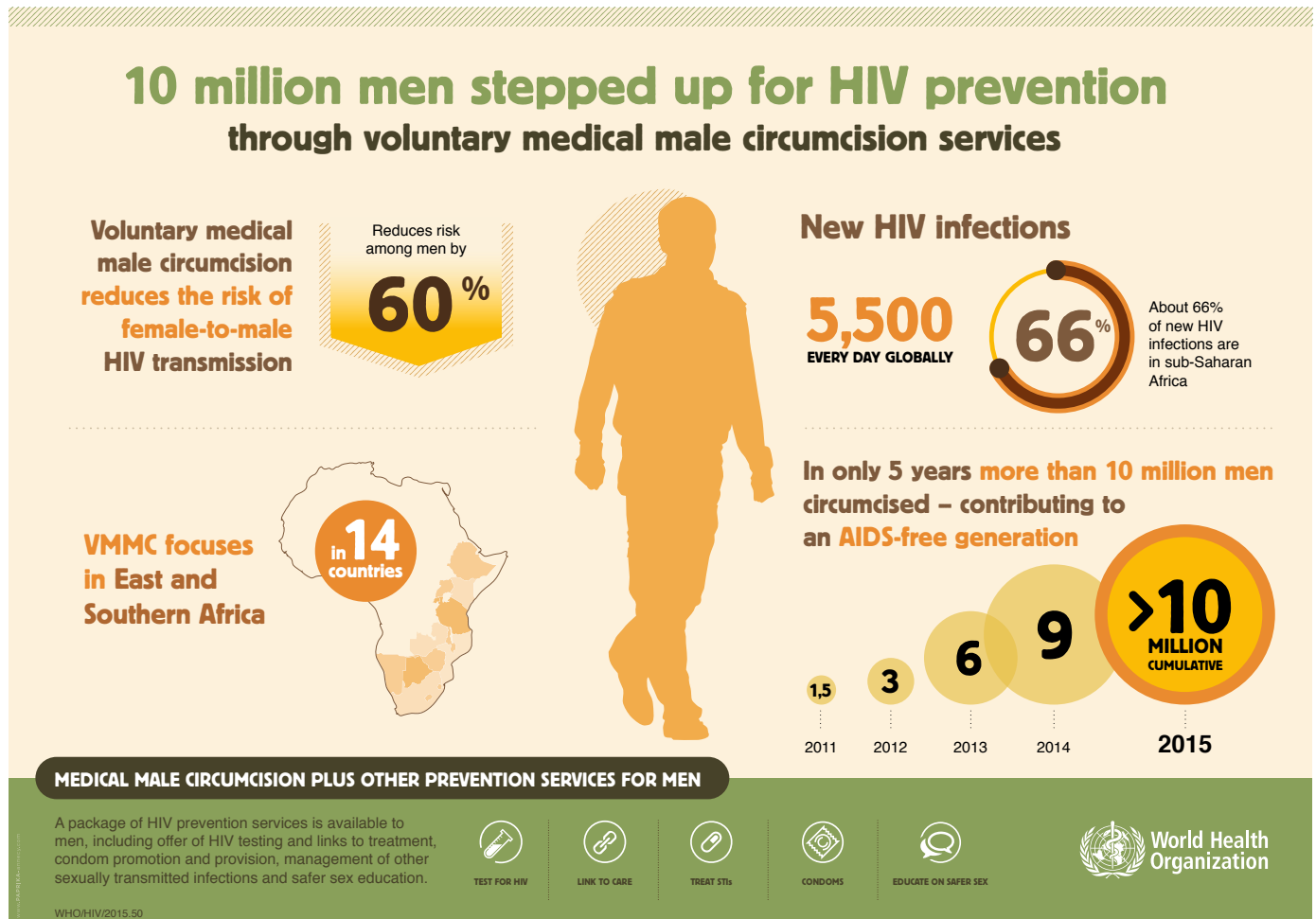
For a regional, national or international programme, information from different types of records and other data collection tools from individual male circumcision service delivery sites or programmes can be used for quality assurance purposes to do the following:

- Detect rare adverse events that would not be evident at the individual clinic or even at the regional level.
- Assess whether services are provided according to standard of care.
- Measure progress towards achieving service delivery standards or programme objectives.
- Guide decision-making and trigger actions aimed at addressing the problems identified and improving the overall quality of services.

Information gathered and collated **across regions or programmes is critical to the overall** success of the global health sector's response to HIV. Fig. 4.1 gives information about voluntary medical male circumcision and highlights one key indicator: the number of male circumcisions performed according to national standards, demonstrating the progress of male circumcision programmes. As shown in this graphic that presents data through 2015, **more than 10 million men (and 14 million through 2016) had undergone circumcision for partial protection against HIV.** Other important

indicators pertain to the minimum service package (offer of HIV testing, percentage of males circumcised who received age-appropriate, risk-reduction counselling and condom education) and service safety.

Fig. 4.1. HIV prevention through voluntary medical male circumcision



Source: Reprinted from (3)

4.2.1. Site records and other data collection tools

Collecting information to monitor adherence to standards requires the collaboration of dedicated and knowledgeable staff. The types of forms and registers used in male circumcision services vary from country to country and from health facility to health facility. Following are examples of data collection tools used in many service delivery contexts:

- appointment cards or forms
- client record forms or case notes
- counselling registers
- outpatient clinic registers
- inpatient registers
- procedure room (or minor operations theatre) registers
- health facility monthly summary reporting forms
- adverse event reporting forms

- death reporting forms
- referral forms
- referral registers
- stock control forms

Male circumcision teams are responsible for maintaining accurate, complete and timely records on all clients. A sample client record form that can be adapted to local needs and national policies is provided in Chapter 7, Annex 7.1. An example of a male circumcision monthly report form is included in Annex 4.1, and an example of a male circumcision client register form is in Annex 4.2.

Just as data can be used at the site level to support adherence to standards, they can also be reported to and used by higher-level entities within the health system or by programmes to track progress towards specific indicators. **Indicators** are specific measures that help demonstrate a programme's success or impact. Table 4.1 shows examples of key indicators for male circumcision programmes, as identified by the World Health Organization, and related monitoring and evaluation parameters. From a programmatic perspective, monitoring and evaluation contributes evidence to inform modelling that shows the impact of male circumcision on HIV infections averted, support quality improvement by identifying programme or service aspects that are either working well or need improvement, and define priorities for the future.

Managers should ensure that clinic staff have adequate time and place to complete records and that records are always completed at the time of the procedure or consultation—not later. If there is excessive workload, it can be tempting to leave record completion to a later time or at the end of the day, but leaving records to complete at a later time leads to errors and reduces the accuracy of data and quality of care.

Table 4.1. Examples of male circumcision indicators and related monitoring and evaluation parameters

INDICATORS	KEY DATA	COLLECTION TOOLS	RELEVANCE
1. Number of medical male circumcisions within the past 12 months performed according to the national standard	Age HIV status Circumcision method	Programme records Male circumcision registers	This information can help: <ul style="list-style-type: none"> • Identify groups accessing services the most and the least • Prioritize activities for the future • Evaluate success in meeting targets
2. Number or percentage of circumcised males experiencing at least one moderate, severe or serious adverse event during or following the procedure	Age Timing of adverse event (intraoperative, postoperative) Circumcision method Service site type	Programme records Male circumcision registers	This information can help: <ul style="list-style-type: none"> • Determine the safety of male circumcision programmes • Identify methods most or least likely to cause adverse events • Identify site types most or least likely to cause adverse events • Identify providers in need of training • Prioritize activities for the future • Evaluate success in meeting targets

Source: Adapted from (4)

4.2.2. Reporting on adverse events

Given that male circumcision is a surgical intervention being conducted on healthy males for personal and public health reasons, a high level of client protection is needed (5). Having accurate information on adverse events occurring with male circumcision procedures is critical to measuring progress and critical to overall success of male circumcision services and programmes (5). An adverse event is defined as “any injury, harm or undesired outcome that occurred during or following the male circumcision procedure that would not have occurred if the client had not undergone the procedure” (5). A serious adverse event describes an adverse event associated with any medical treatment that results in death, is life

threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or requires intervention to prevent permanent impairment or damage (6). In the context of male circumcision, serious adverse events nearly always occur from bleeding, infection or injury of the penis. The terms mild, moderate and severe describe the intensity of a specific adverse event (6). Prevention and management of adverse events should include the following elements:

- Conventional or device-based surgical circumcision methods and techniques should be used in accordance with this *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men*.
- Each facility should have a standard operating procedure for its referral process, which includes facility or facilities to which clients are referred, contact details and follow-up procedures for care by a medical doctor who is competent to provide male circumcision, advice and treatment or a second opinion when needed.
- Serious adverse events should be reported to the senior physician and the male circumcision national programme manager within 24 hours of discovery and then to the regional or global level. National programmes may also request notification of severe adverse events.
- Each country should have national guidelines on how to report adverse events.
- To inform about rare events, the following events should be reported to the regional or global level of the World Health Organization: all deaths and hospital admissions that occur within 30 days of circumcision; all cases of tetanus that occur within 30 days of circumcision; and all serious glans, penile or urethral injuries.

When an adverse event occurs, providers have a responsibility to report it in a timely manner to the appropriate entity by using established mechanisms. Annex 4.3 shows an example of a form used to report adverse events.

4.2.3. What are good data?

Data are facts, measurements and other variables that serve as building blocks of strategic information in the monitoring and evaluation framework. Examples of data include client's age, weight and HIV status. Monitoring and evaluation is used to make better decisions about the present and future based on what can be learnt from the past (further described below). For a monitoring system to do this, the data entered into it must be of good quality, that is, they must meet these criteria:

- Data are **accurate**. Tools should be designed to have the ability to determine the accuracy (or not) of data.
- Data are **complete**. Data gathered fulfil requirements of the data collection tool used. The appropriate data collection tool is used every time the corresponding service or event takes place. (As described below, no field is left blank. When information is unavailable or a particular question or field is not applicable, an appropriate notation is made.)
- Data are **standardized**. Data of the same type are recorded in the same way every time.
- Data are **time stamped**. The full date (day, month, year and, sometimes, time of day) when the data were collected and recorded is clearly indicated.
- Data are **relevant and appropriate for a specific use**. The data effectively serve a specific purpose (for example, provide a benefit or help avoid a problem) in the context of the services being delivered (see Box 4.3).

Box 4.3. Aggregated versus disaggregated data

To ensure that services reach people in need and that no one is left behind, strategic information needs to be usable in a way that helps the people, places and situations where interventions are needed. As building blocks of strategic information, data can be combined or separated for different uses.

Aggregated data are combined from many sources (for example, client records, registers and surveys) and summarized for a specific purpose, such as reporting or statistical analysis. For example, the total number of circumcisions performed by midlevel providers in a specific area might be more important in a given situation than knowing other specifics of each circumcison, such as the method used, age of the client or client's HIV status. Aggregated data are crucial to identify trends and patterns across health systems or programmes.

When aggregated data are separated again according to a specific variable (for example, client age) they become **disaggregated**. HIV-related data are usually disaggregated according to age, sex, key population groups, location, pregnancy and breastfeeding status. Such data allow providers and programme implementers to assess if services or programme efforts are achieving specific goals (for example, reaching younger adolescents with male circumcison services). Disaggregated data can inform decision-making and planning so that interventions more effectively reach targeted groups.

For male circumcison programmes, disaggregation by age (<10, 10–14, 15–24, 25–29 and 30+ years) can help determine the effectiveness of age-specific strategies to increase demand. Five-year age groups should be used for electronic systems. Regular or annual data extraction is recommended for reporting on these age groups in paper-based systems.

Source: Adapted from (4)

To ensure that good data are gathered and recorded, providers should do the following:

1. **Understand the data and know how to use the data collection tools.** Staff responsible for keeping records should know exactly what information is needed; for example, the method used for a client's circumcison or an adverse event associated with the circumcison. Understanding the reason for gathering certain information and how it will be used can help staff understand its importance, which should contribute to good recordkeeping practices. Staff should also receive training, as needed, in using data collection tools. Reviewing good examples of using data collection tools—and comparing them to poor examples—is a simple but effective way to help staff achieve competence in using the tools.
2. **Record data every time.** Each time a health care provider performs an activity—for example, performs a procedure, sees a client, prescribes medication, receives a test result, makes a referral or engages in another relevant activity—it should be recorded in the appropriate field on the appropriate form. The clinic should have forms for all events and services that are being monitored.
3. **Record all data.** All information requested on the monitoring forms should be provided. Doing so might require documenting what did not happen (instead of leaving the field blank)—for example, if a particular treatment was **not** provided or if a client does **not** come for a recommended follow-up visit. Through this documentation, anyone reviewing the client's record knows that the previous provider did not accidentally forget to record information—and the difference may be significant.
4. **Record data in the same way every time.** For consistency in the data entered, the same definitions, rules and tests should always be used for reporting the same type of information. It may be challenging to record data consistently, as tests and definitions change, treatments evolve and new technologies are developed. New rules or data recording practices should be developed to reflect such changes. When it is necessary to stray from data consistency, the health care provider should note the reason.

Health care providers should participate in analysing the data collected, interpreting findings and using information for decision-making. This involvement gives clinical context to the practice of keeping good records; it also gives health care providers the opportunity to appreciate the importance of recordkeeping. For example, if a particular adverse event occurs only with a certain conventional or device-based surgical circumcision method or a particular provider, then this finding may indicate that more training is needed in that particular method or for that provider.

4.3. MONITORING AND EVALUATION

The reasons for monitoring and evaluating a male circumcision service are to:

- Identify quickly any threats to patient safety.
- Investigate severe and serious adverse events or changes in patterns of adverse events.
- Detect noncompliance with set policies, guidelines and performance standards, such as client follow-up rates.
- Assess progress made towards targets and objectives at particular points in time.
- Identify possible reasons for successes and failures.
- Provide a basis for future planning.

To support the development of monitoring and evaluation systems in male circumcision programmes, the World Health Organization and the Joint United Nations Programme on HIV/AIDS have listed indicators that national programmes could consider (7). More recently, the following events were noted for immediate reporting to the World Health Organization's regional or global level to inform about rare events: all deaths and hospital admissions that occur within 30 days of circumcision; all cases of tetanus that occur within 30 days of circumcision; and all serious glans, penile or urethral injuries (8).

4.3.1. What is a monitoring system?

A monitoring system is a standardized method of data collection, data aggregation, data analysis and feedback. Collecting information to track indicators requires the collaboration of dedicated and knowledgeable staff. Information, particularly sensitive information, such as HIV test results, should be kept confidential by ensuring that there are strict data security procedures, masking personal identifiers on records (paper and electronic) as well as limiting access to these records to only those providers who need to know the information.

Health care providers need to know who is responsible for the monitoring system; record data accurately, completely and reliably; and know how and when to report information about the service or clients (see Box 4.4). Health care providers can also help those responsible for the system by providing feedback on the system, that is, how information is shared with providers, and how easy it is to complete forms accurately and reliably.

Box 4.4. Monitoring and evaluating performance in male circumcision programmes: two case studies

Male circumcision providers and clinics should use data that are gathered routinely to improve their surgical practice and overall quality of services provided. Below are two case studies that illustrate the impact of simple, everyday practices on the quality of services and health outcomes for clients.

Case study 1: Breakdown in record review protocol: how failing to review a client record led to an emergency situation

In a midlevel facility, a client's medical history was taken by one provider while circumcision was performed by another provider. When the client presented for circumcision, he reported that he had been diagnosed with haemophilia, which is a contraindication to circumcision at the clinic level. In fact, the client had been turned away from circumcision by his private doctor. The provider who took the history correctly noted that the client had a bleeding disorder but nonetheless took the chart back to the procedure room. The provider did not review the medical history before conducting the circumcision. During the procedure, the client began bleeding uncontrollably. Despite admission to a hospital and receipt of blood transfusions, the client died.

A disaster such as this should have been avoided by adhering to simple protocols for reviewing records for potential problems and by following protocols for handling records of clients with conditions that are contraindications to male circumcision or require referral or further evaluation. History taking, accurate client recordkeeping and review of client records are essential steps for ensuring that clients are safe. When client records are not used as intended, safety can be compromised. A record is only useful if it is properly used, as illustrated by the next case study.

Case Study 2: Introduction of diathermy in a male circumcision programme: how evaluation of data turned a problem around

As the volume of male circumcision clients increased in one country, a decision was made to introduce diathermy for haemostasis, a technique that involves the controlled use of electrical current to coagulate blood and achieve haemostasis. The male circumcision programme procured diathermy units and conducted training with providers. However, shortly after the introduction of diathermy, the rate of moderate and severe adverse events increased from less than 2% to over 7%. Technical advisors evaluated the reported adverse events and, based on the information provided, determined that providers were using diathermy units inappropriately.

The programme immediately suspended the use of diathermy, and the rate of adverse events returned to the baseline of 2%. The programme then conducted more extensive provider training. When diathermy was reintroduced, there was no increase in adverse events.

4.4. QUALITY ASSURANCE

For circumcision providers, commitment to safe, quality services should be top priority. Quality improvement and quality assurance help assure the provision of safe services (reducing adverse events and protecting clients and providers), adherence to relevant policies, client satisfaction, client returns for follow-up including after treatment of a sexually transmitted infection, continued demand for services and job satisfaction among providers.

Quality improvement activities involve the routine use of health and programme data (including client and facility records, training, supervision, observation of practice, etc.) to meet client and programme needs, and improve service systems and processes. **Quality assurance** activities evaluate service systems and processes against quality standards (such as those in Box 4.1) and any proposed recommendations or corrective action plans. In male circumcision services, maintaining a quality improvement process is necessary for quality assurance.

Instruction on how to implement quality improvement activities can be found in *PEPFAR's best practices for voluntary medical male circumcision site operations: a service guide for site operations (9)* and in the World Health Organization's *Male circumcision services: quality assessment toolkit (1, 2)*. The toolkit was developed specifically to assist staff in assessing the quality of their services. Facility and programme managers can also use the World Health Organization's toolkit to set up or improve male circumcision services. This toolkit includes a scoring tool to document assessment findings and measure progress towards meeting standards; it can also support external assessors to certify or accredit facilities.

4.4.1. How is quality assessment done?

A quality improvement team—internal or external to the clinic—is assembled to carry out the assessment. A better assessment may be made if the team is external to the facility being assessed; for example, team members are from other male circumcision clinics. The team may focus on gathering information related to one or more standards at a time. The assessment can be done using several different methodologies, and a combination of several approaches is necessary for a complete quality assessment. Some methods are outlined below (10):

- **Observation:** Observation is used to assess attitudes, knowledge and skills in clinical practice, including client-provider interaction, client management and surgical practice.
- **Formal and informal interviews:** One-on-one interviews may be conducted with managers, staff and clients. Some assessment questions seek staff perceptions (for example, regarding satisfaction on the job) and client perceptions (for example, regarding satisfaction with services received). These insights can also be obtained more formally through surveys (see Box 4.5).
- **Focus group discussions:** These discussions can be used to gain an understanding of attitudes, beliefs and perceptions. They are open conversations in which each participant has an opportunity to speak, ask questions of other participants and respond to the comments of others, including the facilitator, who guides the conversation and stimulates interaction among participants by asking questions on various themes.
- **Inventory:** This is an inspection process to identify availability of essential medicines, supplies and equipment, and to assess the storage and maintenance of supplies and equipment. An inventory is used to assess the condition of facilities, availability of space for performing services efficiently and safety of the environment.
- **Review of documents:** It is important to obtain and review the content of documents—such as the client register, client records, personnel files, policies, guidelines and protocols—to determine the availability and adequacy of these documents.

Box 4.5. Community surveys to aid in design of male circumcision services

At the site level, health care providers may conduct surveys for a variety of purposes, especially when gaps in the data that are available (such as population-based surveillance reports) become barriers to the design and delivery of an effective package of services. Tools used to capture survey responses should be standardized, and health care providers who administer surveys should be trained in basic survey skills.

For example, before a male circumcision campaign, male circumcision site A uses mobile units to interview hard-to-reach communities about relevant services they have received to date, and about traditions and beliefs related to circumcision. This approach can help the facility tailor male circumcision services to the community's needs and make necessary preparations to meet client demand. Questions about how clients would care for wounds may uncover practices known to be dangerous (for example, applying ash or animal dung to aid in wound healing). This information can guide providers to modify group education, counselling and postprocedure instructions to emphasize the importance of proper wound care and the dangers of applying any traditional wound healing remedy, such as animal dung or ash to wounds.

4.4.2. How to translate the quality assessment findings into action?

After completing an assessment, the quality improvement team should communicate and act on the findings as outlined below.

- **Communicating findings:** The assessment team should share findings with individuals, groups or entities who have a stake in those findings—those involved will depend on the scope and purpose of the assessment. At the facility level, stakeholders may include staff and providers, supervisor or manager, clients and the community. At the programme or health system level, stakeholders may include partners, ministries of health, donors, universities and other organizations. Before beginning the assessment, discuss and decide who should know, what they need to know and why, and how they will be informed.
- **Taking action:** Based on the findings, the assessment team should develop an action plan to close any gaps between observations (for example, how a particular circumcision procedure is being performed) and standards. The team should focus on areas where the need is greatest, such as infection control, and start with projects that can be implemented easily because working on these first will produce quick results, thereby motivating the team and clinic staff. The action plan should include specifics about how each area needing improvement will be addressed and how results of quality improvement efforts will be reported.

KEY MESSAGES

- The manager of a male circumcision site has a number of responsibilities. These include ensuring that the quality of services provided and records kept are correct, complete and consistent; staff have adequate time and place to complete records; and staff maintain confidentiality, particularly of sensitive information, such as HIV test results.
- Clinic staff should schedule periodic assessments and analyses of the clinic's data for decision-making and take actions to improve the quality of services provided.
- The accuracy and completeness of client records, and their careful review, together with proper provider training and supervision, help ensure that clients get safe care. Information from different types of records and other data collection tools employed in male circumcision service delivery sites or programmes can be used for quality assurance purposes.
- In the context of male circumcision services, quality can be defined as the degree to which providers and clinics—and the care clients receive—adhere to defined standards and expected outcomes.
- Male circumcision sites should report serious adverse events in a timely manner (generally within 24 hours) to the appropriate parties using standardized forms that adhere to national guidelines and indicators for regional or global reporting.
- Good data are accurate, complete, standardized, time stamped, relevant and appropriate for a specific use.
- The minimum set of data for male circumcision should include information gathered through client care: individual client information (including age and HIV status) and history, site type, provider type, method of circumcision, follow-up and any adverse events.
- Tools used for recordkeeping and data collection include appointment cards or forms, client record forms, counselling registers, outpatient and inpatient clinic registers, procedure room registers, health facility monthly summary reporting forms, adverse event reporting forms, death reporting forms, referral forms, stock control forms and equipment logs; other tools include observation, interviews, surveys, focus group discussions, inventory and review of other documents.
- The purpose of monitoring and evaluating a male circumcision programme is to quickly identify any threats to patient safety; detect noncompliance to set policies, guidelines and performance standards; assess progress made towards objectives at particular points in time; identify or indicate possible reasons for successes and failures; and provide a basis for future planning.
- Information on how to perform quality assessments (and quality improvement) at the facility level is available in *PEPFAR's best practices for voluntary medical male circumcision site operations: a service guide for site operations (9)* and the World Health Organization's *Male circumcision services: quality assessment toolkit* and *Male circumcision quality assurance guide (1, 2)*.

ANNEX 4.1. MALE CIRCUMCISION MONTHLY REPORT FORM (EXAMPLE)

Reporting period	
Province	
Facility name	
Supporting agency (or agencies)	
Total number of clients registered	
Total number of clients given group education	
Total number of clients offered pre-test counselling	
Total number of clients offered testing	
Total number of clients who accept HIV testing	
Total number of clients who tested positive	
Total number of HIV-positive clients referred/linked to care and treatment	
Total number of clients with sexually transmitted infections	
Total number of clients with sexually transmitted infections referred/linked to care and treatment	
Total number of clients with sexually transmitted infections who returned for male circumcision after treatment	
Total number of clients with anatomical and other contraindications to male circumcision	
Total number of clients circumcised	TOTAL =
< 10 years old	
10–14 years old	
15–24 years old	
25–29 years old	
30+ years old	
Total number of clients offered immediate postoperative care and counselling	
Total number of clients who returned and the number who did not return for follow-up on day 2	
Total number of clients who returned and the number who did not return for follow-up on day 7	
Total number of clients diagnosed with moderate, severe, serious adverse events (all deaths and hospital admissions that occur within 30 days of circumcision; all cases of tetanus that occur within 30 days of circumcision; all serious glans, penile or urethral injuries)	

Report by: _____

Reporting date: _____

Signature: _____

Report to: _____

ANNEX 4.3. MALE CIRCUMCISION ADVERSE EVENT REPORTING FORM (EXAMPLE)

This is a sample reporting form that is intended to be revised to meet local needs. For guidance on managing and reporting adverse events, refer to Chapter 10 and the *Adverse event action guide for voluntary medical male circumcision (VMMC) by surgery or device, 2nd edition, August 2017 revision (5)*.

1. Client's name: _____

2. Date of visit:

Day			Month			Year	

3. Client's ID number: _____

Instructions: Check (✓) appropriate box for any adverse events.

ADVERSE EVENT	DESCRIPTION	SEVERITY	✓
A. During surgery			
Pain	Client reports pain that is 3 or 4 on the 0–10 pain scale.	Mild	
	Client reports pain that is 5 or 6 on the 0–10 pain scale.	Moderate	
	Client reports pain that is 7 or more on the 0–10 pain scale.	Severe	
Excessive bleeding	There is more bleeding than usual, but it is easily controlled.	Mild	
	Bleeding requires pressure dressing to control.	Moderate	
	Blood transfusion or transfer to another facility is required.	Severe	
Anaesthetic-related event	Client has palpitations, vasovagal reaction or vomiting.	Mild	
	Reaction to anaesthetic is treated in the clinic, but the client is not transferred to another facility.	Moderate	
	Client has anaphylaxis or other reaction that requires transfer to another facility.	Severe	
Excessive skin removed	Skin is tight but will resolve as skin stretches after the surgery.	Mild	
	This adverse event adds time or material needs to the procedure (for example, extra sutures).	Moderate	
	Reoperation or transfer to another facility to correct the problem is required.	Severe	
Damage to the penis	There is mild bruising or abrasion, but it does not require treatment.	Mild	
	There is bruising in or abrasion of the glans or shaft of the penis, requiring pressure dressing or additional surgery.	Moderate	
	Part or all of the glans or shaft of the penis is severed.	Severe	

Treatment provided: _____

Treatment outcome: Adverse event completely resolved. _____

Adverse event partially resolved. _____

Adverse event unchanged. _____

Was patient referred? Yes _____ No _____

If yes, to where: _____

ADVERSE EVENT	DESCRIPTION	SEVERITY	✓
B. Less than one month after surgery			
Pain	Client reports pain that is 3 or 4 on the 0–10 pain scale.	Mild	
	Client reports pain that is 5 or 6 on the 0–10 pain scale.	Moderate	
	Client reports pain that is 7 or more on the 0–10 pain scale.	Severe	
Excessive bleeding	At a routine follow-up visit, dressing is soaked through with blood.	Mild	
	Client has bleeding that requires a special return to the clinic for medical attention.	Moderate	
	Client has bleeding that requires surgical re-exploration, blood transfusion or referral to another facility.	Severe	
Excessive skin removed	Client is concerned, but there is no discernible abnormality.	Mild	
	Skin is tight, but additional operative work is not necessary.	Moderate	
	Reoperation or transfer to another facility for management is required.	Severe	
Insufficient skin removed	Foreskin partially covers the glans when it is extended.	Mild	
	Foreskin still partially covers the glans, and reoperation is required.	Moderate	
Swelling/haematoma	There is more swelling than usual, but there is no significant discomfort.	Mild	
	There is significant tenderness and discomfort, but surgical re-exploration is not required.	Moderate	
	Surgical re-exploration is required.	Severe	
Damage to the penis	There is mild bruising or abrasion, but this does not require treatment.	Mild	
	There is bruising in or abrasion of the glans or shaft of the penis, requiring pressure dressing or additional surgery.	Moderate	
	Part or all of the glans or shaft of the penis is severed.	Severe	
Infection	Erythema is more than 1 cm beyond the incision line.	Mild	
	There is purulent discharge from the wound.	Moderate	
	There is cellulitis or wound necrosis.	Severe	
Tetanus	Tetanus is clinically diagnosed.	Severe	
Delayed wound healing	Healing takes longer than usual, but no extra treatment is necessary.	Mild	
	Additional nonoperative treatment is required.	Moderate	
	Reoperation is required.	Severe	
Appearance	Client is concerned, but there is no discernible abnormality.	Mild	
	There is significant wound disruption or scarring, but it does not require reoperation.	Moderate	
	Reoperation is required.	Severe	
Problems urinating	Client has transient complaint that resolves without treatment.	Mild	
	Problem requires special return to the clinic, but no additional treatment is required.	Moderate	
	Referral to another facility for management is required.	Severe	

ADVERSE EVENT	DESCRIPTION	SEVERITY	✓
One or more month after surgery			
Infection	There is erythema or traces of serious discharge or infective process noted at the wound margin; no medication is required, but wound hygiene must be improved.	Mild	
	There is discharge from the wound, painful swelling with erythema or elevated temperature, which require oral antibiotics.	Moderate	
	There is cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotic therapy.	Severe	
Delayed wound healing	Healing takes longer than usual, but no extra treatment is necessary.	Mild	
	Additional nonoperative treatment is required.	Moderate	
	Reoperation is required.	Severe	
Appearance	Client has complaints in the absence of discernible abnormal scarring/disfigurement.	Mild	
	There is significant scarring or other cosmetic problem, but it does not require reoperation.	Moderate	
	Reoperation or transfer to another facility is required.	Severe	
Excessive skin removed	Client is concerned, but there is no discernible abnormality.	Mild	
	Skin is tight, but additional operative work is not necessary.	Moderate	
	Reoperation or transfer to another facility is required.	Severe	
Insufficient skin removed	Prepuce extends over the coronal margin, but less than one third of the glans is covered when the penis is in a flaccid state.	Mild	
	Foreskin still partially covers the glans when the penis is flaccid, and reoperation is required.	Severe	
Torsion of penis	Torsion of penis is observable, but it does not cause pain or discomfort.	Mild	
	Torsion of penis causes mild pain or discomfort, but additional operative work is not required.	Moderate	
	Torsion of penis requires reoperation or transfer to another facility.	Severe	
Erectile dysfunction	Client reports an occasional inability to have an erection.	Mild	
	Client reports a frequent inability to have an erection.	Moderate	
	Client reports a complete or near complete inability to have an erection.	Severe	
Psychobehavioural problems	Client reports mild dissatisfaction with the circumcision, but there are no significant psychobehavioural consequences.	Mild	
	Client reports significant dissatisfaction with the circumcision, but there are no significant psychobehavioural consequences.	Moderate	
	Client attributes significant depression or other psychological problems to the circumcision.	Severe	

Treatment provided: _____

Was patient referred? Yes _____ No _____

If yes, to where: _____ and when: _____

Treatment outcome: Adverse event completely resolved. _____

Adverse event partially resolved. _____

Adverse event unchanged. _____

In your clinical judgement, was this adverse event:

Male circumcision related?

Not male circumcision related?

Other comments: _____

Date: _____

Name of health care provider: _____

Signature: _____

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CHAPTER 5

INFECTION PREVENTION AND CONTROL



This chapter provides information on the following:

- basic concepts of infection prevention for male circumcision services
- key components of standard precautions
- the importance of and steps for hand hygiene
- appropriate usage of personal protective equipment for male circumcision
- safe injection practices—safe handling of hypodermic needles, sharps and syringes, and safe use of syringes with safety features
- key steps involved in properly processing and decontaminating instruments and other items
- safe handling and disposal of infectious waste materials and used disposable kits
- resources for providing post-exposure prophylaxis

5.1. KEY CONCEPTS AND PRACTICES

Infection prevention and control practices are vital to protect clients and clinic staff from exposure to infection. Preventing and controlling infection in clients is essential for both their safety and the public's acceptance of the male circumcision procedure. A major concern in all clinics (not only in male circumcision clinics) is the potential transmission of bloodborne pathogens, such as hepatitis B virus, hepatitis C virus and HIV, to other clients or health care workers. The risk of acquiring hepatitis B virus due to an unsafe injection was 6% to 30%. The risk of acquiring hepatitis C virus infection due to a needle-stick (sharps) injury was 0.5%, and the risk of acquiring HIV after a needle-stick (sharps) injury was estimated at 0.3–0.6% (that is, transmission of three–six HIV infections for every 1 000 such injuries) (1). In general, if measures taken are sufficient to prevent hepatitis B virus transmission, they will also prevent all other bloodborne infections, including hepatitis C virus and HIV.

In health care facilities, most instances of infection transmission can be prevented through the application of **standard precautions** (2, 3). Standard precautions are a set of good practices known to prevent and control the transmission of infection and include (2–4) the following:

- hand hygiene
- use of personal protective equipment
- environmental cleanliness, including safe management of blood or bodily fluid spills
- decontamination of medical devices, patient care items and equipment
- safe use, handling and disposal of needles, syringes and sharp instruments
- proper disposal of all clinical waste
- aseptic practices
- respiratory hygiene
- safe management of linens

This chapter describes the standard precautions most relevant to male circumcision services. These precautions should be implemented at all times.

Immunization is another effective strategy for reducing the risk of infection transmission in the workplace. In many countries, hepatitis B vaccination is mandatory or strongly recommended for health care workers because this protects the

workers and clients. Clinic managers should ensure that clinics follow national protocols regarding hepatitis B vaccination of providers.

Even with standard precautions and mandatory immunization for health workers in place, accidents can occur. In the event of accidental exposure, such as a needle-stick (sharps) injury, clinics are urged to manage occupational exposure to bloodborne pathogens, such as hepatitis B virus, hepatitis C virus and HIV, by following a well-defined protocol that includes 1) the initiation of post-exposure prophylaxis as soon as it is safe to do so, and 2) the completion of the recommended 28-day course of post-exposure prophylaxis (see Box 5.1). There are many challenges to providing effective post-exposure prophylaxis, including early provision and adherence to the full course of the treatment. Given these challenges, full compliance with infection prevention and control practices is still the best way to protect health care workers.

Box 5.1. What to do if there is a needle-stick (sharps) injury

Despite best efforts, needle-stick (sharps) injuries do occur. The injured health care worker must balance his/her risks with the safety of the client. The following guidelines can help health care workers address needle-stick (sharps) injuries:

- As soon as it is safe to do so (with regard to client safety), the health care worker with the needle-stick (sharps) injury should stop what he/she is doing, remove gloves, and wash both hands and the area of the needle-stick (sharps) injury with soap and plenty of water. **No** antiseptics or scrubbing brushes should be used.
- If the provider is in the middle of a male circumcision procedure, then another qualified provider should take over and complete the procedure. If no other qualified provider is present, then the injured provider should ensure that any critical step is complete (for example, any active bleeding has been stopped), wash both hands and the area of the needle-stick (sharps) injury (as described below), change gloves, and then complete the procedure.
- As soon as the health care worker with the needle-stick (sharps) injury is able to do so, he/she should inform senior staff or managers at the clinic and follow clinic protocols for managing the needle-stick (sharps) injury.
- Each clinic should have a written standard operating procedure for managing a needle-stick (sharps) injury. The standard operating procedure will vary across locations and depend on the resources available at a clinic. Each clinic should have a protocol (or standard operating procedure) that was written in consultation with the appropriate referral centre. The protocol should include clear advice about what actions the injured provider should perform to mitigate the risk of hepatitis and HIV; also, it should be in accord with national standards and take into account international guidance on avoiding exposure to bloodborne pathogens (see Annex 5.1).

5.1.1. Hand hygiene and surgical hand disinfection

5.1.1.1. Hand hygiene

Hand hygiene is part of standard precautions. Proper hand hygiene practices are one of the most important in infection prevention and control to prevent cross infections (see Annex 5.2). Standard practices for hand hygiene include thorough handwashing using nonmedicated soap and water or an alcohol-based handrub. At a minimum, before and after each new client, all health care workers should wash their hands with soap and water or use an alcohol-based handrub, as recommended by the World Health Organization's *5 moments of hand hygiene (5)*; if using an alcohol-based handrub to clean hands, then the hands must be physically clean (not visibly soiled) before using the handrub (see Annexes 5.2 and 5.3).

5.1.1.2. Surgical hand disinfection

- Steps before starting surgical hand preparation

The hands of the surgical team should be cleaned upon entering the surgical area by washing the hands with a nonmedicated soap. Surgical staff should keep nails short and avoid the use of artificial nails and/or nail polish. All jewellery (rings, watches, bracelets) must be removed from hands before entering the operating theatre. Wash hands and arms with a nonmedicated soap before entering the operating theatre area or if hands are visibly soiled. The first wash of the day should include a thorough cleaning of the area under the fingernails and subungual areas using a nail

file. Nail brushes should not be used, as they may damage the skin and encourage shedding of squamous epithelial cells from the skin. If considered essential, then a single-use sterile disposal sponge should be used (5).

- Surgical handscrubbing

World Health Organization recommends that surgical hand preparation be performed either by scrubbing with a suitable antimicrobial soap and water or using a suitable alcohol-based handrub—before donning sterile gloves and before performing the surgical procedure (6). Surgical handscrub refers to surgical hand preparation with antimicrobial soap and water. Surgical handrub refers to surgical hand preparation with a waterless, alcohol-based solution (5).

A full surgical handscrub with antimicrobial soap and water is required **at the start** of the day (see Annexes 5.4 and 5.5). After the first surgical handscrub with soap and water, repeat the handscrub without performing the step of washing hands with nonmedicated soap (noted in Section 5.1.1.1) or use an alcohol-based handrub product for surgical hand preparation (see below).

Surgical handscrub with soap and water can be performed between cases if there is any residual talc or biological fluids present after gloves are removed.

Hands should also be washed upon re-entering the area, for example, after lunch or after using the bathroom.

- Hand disinfection using alcohol-based handrub

After the first handscrub with an antiseptic soap and water, an alcohol-based handrub can be applied between surgical cases; hands must be physically clean (not visibly soiled). Follow the technique illustrated in images 1–17 in Annex 5.4 before moving to the next procedure. It is essential that after applying an alcohol-based handrub, the hands must be completely dry before putting on sterile gloves for the next procedure.

When choosing an alcohol-based handrub, health care facilities should regularly procure products with proven efficacy (that is, products that comply with European Norms, American Society for Testing and Materials International or equivalent international standards). Health care facilities should implement international recommendations and position no-touch or elbow-operated alcohol-based handrub dispensers in surgical scrub rooms. Alternatively, antimicrobial soap, clean running water and disposable or clean towels for each health care worker should be available in the scrub room.

5.1.1.3. Hand care

Frequent and repeated use of soaps and other detergents is responsible for chronic dermatitis among health care workers, and this can be reduced by the addition of humectants/emollients to hand hygiene products to help moisturize the skin. In addition, skin irritation is also found due to the presence of other ingredients, for example, antimicrobial agents, fragrances and preservatives present in the hand hygiene formulation.

Health care workers may sometimes need to use lotions or creams to soothe their skin. Some hand care products are also responsible for skin sensitization, so only suitable hand creams or lotions should be used. Use of perfumed lotions or creams can also cause dermatitis, so their use should be avoided. Lotions or creams should be supplied in small, individual-use containers that are *not* refilled. However, regular and repeated use of lotions or creams at the work site is not recommended because it can lead to greasy or slippery hands.

Dermatitis is caused by drying or allergies, and severe dermatitis causes small cracks or tears in the skin. Severe dermatitis is not common, but, when it does occur, it can increase a person's risk of acquiring an infection. Staff with an allergy or adverse reaction to hand hygiene products should use alternative products as recommended by an occupational health department or dermatologist, per the facility's protocol.

If potentially infectious blood or another bodily fluid splashes onto nonintact skin, or if there is a potentially infective sharp injury, the area should be immediately washed with water and soap; an alcohol-based handrub or any antiseptic should **NOT** be used. Then, the individual should seek advice on the need for post-exposure prophylaxis (see Annex 5.1).

5.1.2. Personal protective equipment

Personal protective equipment is designed to protect both health care workers and clients from exposure to infectious agents. This equipment works by providing a physical barrier against microorganisms, helping health care workers avoid contaminating their hands, mucous membranes and broken skin (eyes, nose, mouth and face), clothing, hair and shoes; it also helps to prevent health care workers from transmitting infections to clients and other staff. Personal protective equipment includes gloves, surgical masks, protective eyewear (face shield or goggles), cap or hair cover, apron, gown and footwear. Footwear should be enclosed and capable of protecting health care workers from injury due to accidental contact with sharps and other contaminated items. Open footwear must never be worn in the operating theatre. If there is a risk of spillage of blood or other high-risk bodily fluids, surgical waterproof boots should be worn. Plastic shoe covers should *not* be used for the purpose of protecting footwear.

In male circumcision services, the following personal protective equipment is recommended:

- **Sterile surgical gloves:** Sterile surgical gloves are used for performing the procedure and changing dressings. The use of surgical gloves does not replace the need for hand hygiene. These gloves must **not** be reused to provide care to more than one client.
- **Nonsterile examination gloves:** These are used by many health care workers when handling and examining clients before or after the procedure, for example, when doing the genital screening examination. If nonsterile gloves are used, new gloves should be used for each client. All staff must perform hand hygiene immediately **after** removing gloves and on arriving at the clinic, and they must also keep their hands clean throughout the day. Also, health care workers should perform hand hygiene after removing gloves and before having contact with a client, per the World Health Organization's *5 moments of hand hygiene (5)*.
- **Masks:** Surgical masks protect mucous membranes of the mouth and nose from coming into contact with possible splashes of blood or other bodily fluids, and they should be worn by anyone undertaking a procedure that is likely to generate such splashes. Surgical masks are designed to resist fluids and are preferred over cotton or gauze masks. The provider doing the circumcision should wear a mask because of the chance of coming into contact with splashes of blood or other bodily fluids.
- **'Theatre' (surgical) gowns:** The operating team should wear impermeable, cuffed-wrist and sterile theatre gowns. Gowns contaminated with blood or bodily fluids should be removed as soon as possible and bagged for laundering or discarded as clinical waste if they are disposable.

5.1.3. Safe handling of sharps and injection practices

All clinic staff should be trained in the safe handling of hypodermic needles, syringes and sharp instruments (sharps) (see Box 5.2).

- To prevent needle-stick (sharps) injuries, the World Health Organization's *Guideline on the use of safety-engineered syringes (7)* recommends "the use of syringes with a sharps-injury-protection feature (safety-engineered syringes), as opposed to syringes without a sharps-injury-protection feature, by health care workers delivering intramuscular, subcutaneous or intradermal injectable medications to patients." Note that it is necessary to withdraw the syringe to check that local anaesthetic is not injected into a blood vessel; therefore, it is not appropriate to use safety-engineered syringes that are designed to prevent plunger withdrawal (7).
- Needles and syringes should never be reused because of the high risk of infecting the client with bloodborne viruses, such as hepatitis B, hepatitis C and HIV.
- Hypodermic (hollow-bore) needles are the most common cause of injuries to all types of health care workers:
 - Health care workers are most often stuck by hypodermic needles during client care.
 - Cleaning staff are most often stuck by needles when laundering surgical linens or disposing of them.
 - Housekeeping staff are most often stuck by needles when disposing of infectious waste material.

- Do not recap a needle because it is safer to dispose of a needle and syringe directly into a sharps container **without** recapping. However, there may be an instance when recapping is advisable. For example, if the provider has finished giving anaesthetic and there is some medication remaining in the syringe, which may or may not be needed later during the procedure, leaving the open needle uncapped is a hazard. If a needle must be recapped, then use the one-handed needle recapping technique.
 - “Step 1: Place the cap on a flat surface like the table or counter with something firm to ‘push’ the needle cap against
 - Step 2: Holding the syringe with the needle attached in one hand, slip the needle into the cap without using the other hand
 - Step 3: Push the capped needle against a firm object to ‘seat’ the cap onto the needle firmly using only one hand.”
(8)
- Syringes with sharps-injury-protection features are available, and the World Health Organization’s *Guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings* (7) recommends that “all countries should transition by 2020 to the exclusive use, where appropriate...of [World Health Organization’s] prequalified (or equivalent) safety-engineered injection devices, including [reuse prevention] and [sharps injury prevention] devices.”

Box 5.2. Safe use and disposal of hypodermic needles and syringes

- Do not use disposable needles and syringes more than once.
- Do not disassemble the needle and syringe after use.
- Do not bend or break needles before disposal.
- Dispose of the needle and syringe together in a puncture-resistant container.

5.1.3.1. Sharps containers

Clearly labelled, puncture-proof and tamper-proof sharps safety boxes or containers (see Fig. 5.1) are a key component in efforts to keep injuries from disposable sharps to a minimum.

- Place sharps containers as close to the point of use as possible and practical (ideally, within arm’s reach) but away from busy areas. Avoid placing containers near light switches, overhead fans or thermostat controls—places where people might accidentally put their hands in them. Never place sharps containers on the floor.
- Attach containers to walls or other surfaces at a convenient height, if possible, so that staff can use and replace them easily.
- Mark the container clearly so that people will not mistakenly use it as a rubbish bin.
- Mark the fill line (at the three quarters full level). Do not shake the container to settle its contents to make room for more sharps.
- **Never** fill the containers more than three quarters full.
- **Never** attempt to empty the sharps container.

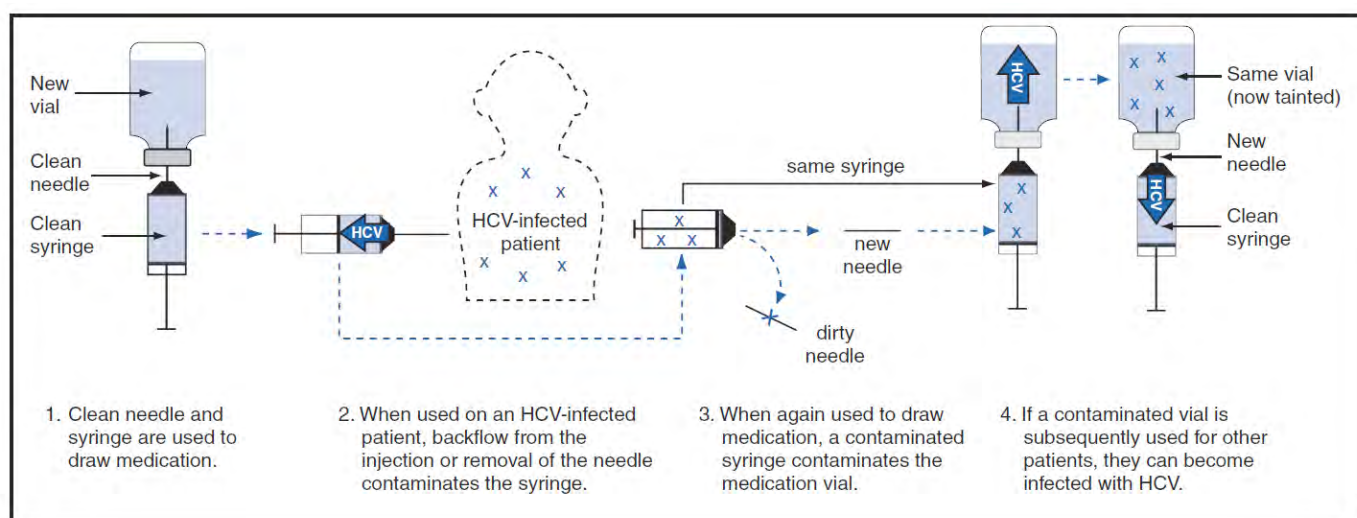
Fig. 5.1. Sample sharps container



5.1.3.2. Preventing contamination of medicine vials

The practice of reusing syringes can transmit bloodborne infections, such as hepatitis B virus, hepatitis C virus and HIV, to clients. In fact, the syringes do not have to be used on multiple patients for this to occur. Fig. 5.2 shows how bloodborne pathogens are transmitted via unsafe injection practices.

Fig. 5.2. How vials get contaminated through double-dipping



Source: (9)

Using the same syringe to inject more than one client from a multidose vial is also called **double-dipping**. Double-dipping is a dangerous and unsafe practice. In the context of male circumcision, here is a typical scenario in which this can happen after a syringe is used to draw local anaesthetic from a multidose vial and inject that medication into a client, the syringe is then reused, with or without a new needle, to draw more medication from the vial. When the same syringe is used to enter the vial, even for the same client, the entire multidose vial is contaminated. When that contaminated vial is used for the next client(s), even if **new syringes and new needles** are used, infections can be transmitted (see Box 5.3).

Syringes with reuse prevention features are available and are included in the World Health Organization's *Guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings* (7). This guidance includes the recommendation to transition by 2020 to the exclusive use of syringes with sharps-injury-protection and reuse prevention features for therapeutic injections, where appropriate. In this *Manual*, guidance to include such safety-engineered syringes for local anaesthetic injection in male circumcision has been agreed upon by the experts who developed the safety-engineered recommendation, which was based in part on a study done during male circumcision procedures (10).

Because of the need to aspirate repeatedly while advancing the needle to prevent injection directly into a blood vessel, reuse prevention syringe models used for administering local anaesthetic must permit repeated aspiration and injection

without disabling the syringe. (The disabling mechanism in such syringes may engage with deliberate activation by pressing a button, or the disabling mechanism engages automatically once the plunger is **fully** depressed. This second option may be more effective in preventing unsafe practices.) Additional desirable features for the injection of local anaesthetic include sharps injury prevention features and detachable needles (the latter to allow the use of a larger-gauge needle to draw the anaesthetic and a smaller-gauge needle to inject the anaesthetic). More information on the use of reuse prevention syringes in male circumcision and a description of a pilot experience is available (7, 10).

Box 5.3. Infection rate due to reuse of injection equipment

In 2010, estimates showed that the practice of unsafe injections caused 1.7 million new cases of hepatitis B virus, about 200 000 new cases of hepatitis C virus infections and about 25 000 new cases of HIV (1).

5.2. DECONTAMINATION AND PROCESSING OF INSTRUMENTS

Decontamination is a complex and highly specialized subject. This section provides a brief summary on the decontamination and reprocessing of reusable medical devices and patient care items or equipment. Details are given in *Decontamination and reprocessing manual for health-care facilities* (11). Decontamination is an important process for safe circumcision. It is usually undertaken by staff other than those performing the male circumcisions; however, it is important that all are aware of the decontamination process.

Decontamination is the use of physical or chemical means to remove, inactivate or destroy pathogenic microorganisms from a surface or item so that it is no longer capable of transmitting infectious particles, thereby being rendered safe for handling, use or disposal. The term is used in this document to cover cleaning, disinfection and sterilization (see Fig. 5.4 and Table 5.1).

Fig. 5.3. The decontamination life cycle



Source: reproduced by permission of the World Health Organization (11)

Table 5.1. Level of decontamination

Cleaning	The physical removal of body materials, dust or foreign material. Cleaning will reduce the number of microorganisms as well as the soil, therefore allowing better contact with the surface being disinfected or sterilized and reducing the risk of soil being fixed to the surface. Removal of soil will also reduce the risk of inactivation of a chemical disinfectant and the multiplication of microorganisms. The removal of contamination from an item to the extent necessary for further processing or for intended use.
Disinfection	The destruction or removal of microorganisms at a level that is not harmful to health and is safe to handle. This process does not necessarily include the destruction of bacterial spores.
Sterilization	The complete destruction or removal of microorganisms, including bacterial spores. Sterility State of being free from viable microorganisms. Sterilization Validated process used to render a product free from viable microorganisms.

Source: reproduced by permission of the World Health Organization (11)

5.2.1. Decontamination of instruments

All medical devices that are reprocessed, such as surgical instruments, **must be cleaned thoroughly** before they are disinfected and sterilized. Soaking medical devices in any disinfectant solution prior to cleaning or during transportation is not recommended, as there is a danger of spilling contaminated fluids and possible damage to instruments.

Used medical devices must be placed in a container or tray and kept moist until they are removed. These trays (and accompanying checklist) should be transported in a robust trolley (preferably with closed sides) to the decontamination area. Used devices should be received, checked and sorted for cleaning in the area designated for dirty devices. Cleaning is done either manually or by automated methods. Appropriate personal protective equipment must be worn.

5.2.2. Risk assessment of contaminated instruments

The risk of transferring microorganisms from instruments and equipment depends on the following factors:

- the presence of microorganisms, their number and their virulence
- the type of procedure that is going to be performed (invasive or noninvasive)
- the site in the body where the instrument, items or equipment will be used

Risk assessment for the reprocessing of medical devices was best described by Spaulding (12) and has since been modified. After thorough cleaning, the decision to disinfect or sterilize is based on whether the device is stable to heat or not. The body site where the instrument or equipment will be used or will have contact with will determine whether cleaning or high-level disinfection or sterilization is required. The Spaulding classification categorizes medical devices as critical, semicritical or noncritical, depending on the risk of infection transmission (see Table 5.2).

Table 5.2. Spaulding classification of equipment decontamination (12)

CATEGORY	DEFINITION	LEVEL OF MICROBICIDAL ACTION	METHOD OF DECONTAMINATION	EXAMPLE OF COMMON ITEMS AND EQUIPMENT IN THE MALE CIRCUMCISION CLINIC
High (critical)	Medical devices involved with a break in the skin or mucous membrane, or entering a sterile body cavity	Kills all microorganisms	Sterilization (usually heat if heat stable or chemical if heat sensitive)	Surgical instruments used for male circumcision Disposable syringes, needles and sutures supplied sterilized by the manufacturer
Intermediate (semicritical)	Medical devices in contact with mucous membranes or nonintact skin	Kills all microorganisms except high numbers of bacterial spores	High-level disinfection by heat or chemicals (under controlled conditions, with minimum toxicity to humans)	Respiratory therapy and anaesthetic equipment, flexible endoscopes, vaginal specula, reusable bedpans and urinals or urine bottles, equipment, patient bowls, etc.
Low (noncritical)	Items in contact with intact skin	Kills vegetative bacteria, fungi and lipid viruses	Low-level disinfection, that is, cleaning	Blood pressure cuffs, stethoscopes, diathermy machine leads, etc. Environmental surfaces, including the operating theatre table and other environmental surfaces

The following guidelines, which are based on the *Decontamination and reprocessing of medical devices for health-care facilities (11)*, should be followed **before** sending instruments to the sterile supply department or decontamination unit for cleaning:

- Wear personal protective equipment to protect yourself.
- Remove and dispose of items appropriately—dispose of sharps, such as scalpel blades and syringes with attached needles, and any separate needles into a sharps container.

At the end of the male circumcision procedure, the provider doing the male circumcision procedure is responsible for segregating sharps from drapes and reusable surgical instruments, and placing them into a sharps container. This is particularly important for protecting the other staff who clean instruments and dispose of drapes.

- Remove gross contamination (usually blood) from instruments by wiping them with a clean, dry cloth; precleaning (for example, by soaking or spraying) prevents contaminants from drying on devices and makes them easier to clean (11).
- Dispose of single-use circumcision devices and any other medical device according to their manufacturer's instructions for use (11).
- Use cleaning products that are appropriate for medical devices and approved by the device's manufacturer (11).
- Contain contaminated items in dedicated, fully enclosed, leak-proof and puncture-proof containers before transport (11).

5.2.3. Cleaning of instruments (reusable and single use) (11)

Cleaning is the first and most essential step in reprocessing surgical instruments after they have been used. It is the removal of visible soil, organic and inorganic materials from objects and surfaces. Cleaning must happen before disinfection or sterilization.

Cleaning and processing should be done in batches. Separate single-use (disposable) instruments from reusable instruments before cleaning and processing them to prevent mixing the two types of instrument. This will help ensure that single-use instruments are not reused.

Before any decontamination can take place, used devices are prepared for reprocessing at the point of use to ensure that they are safe for transport and are minimal risk to staff. This is not a substitute for cleaning. Point-of-use preparation helps prolong the life of surgical instruments, as dried blood and saline can cause the decomposition of stainless steel and make surgical instruments much more difficult to clean.

Used instruments should be cleaned as soon as possible after their use. If it is not possible to clean instruments, they should be rinsed and then soaked in water, or in water and enzymatic detergent solution (saline solution should not be used; see Box 5.4), until they can be cleaned. Prolonged soaking should be avoided.

Box 5.4. Do not soak instruments in disinfectant prior to cleaning

Soaking instruments in 0.5% hypochlorite (bleach) solution, or in any other disinfectant during transport or before cleaning, is **not** recommended for the following reasons:

- The disinfectant may damage/corrode the instruments.
- The disinfectant may be inactivated by blood and bodily fluids, which could become a source of microbial contamination and formation of biofilm.
- Transportation of contaminated items soaked in chemical disinfectant to a decontamination area may pose a risk to health care workers, resulting in inappropriate handling and accidental damage.
- Soaking may contribute to the development of antimicrobial resistance to disinfectants.

Source: (11)

Contaminated items should be contained in dedicated, fully enclosed, leak-proof and puncture-proof containers prior to transport. Soiled instruments should be opened and kept moist.

To ensure that instruments are in working order, once the instruments have been cleaned, they should be inspected for any visible damage and for proper functioning before they are further processed (see Chapter 3). Failure to properly clean an instrument may allow foreign material—in particular, old blood clots—to accumulate in hard-to-clean parts of the instrument, such as the hinge joints of forceps and scissors, or the serrations or teeth on the blades of forceps (11).

Cleaning is accomplished manually by brushing or flushing and using cleaning chemicals (neutral detergent) and water. Alternatively, the facility may have mechanical cleaning equipment, such as ultrasonic or washer disinfectors. Irrespective of what is available, reusable instruments must be thoroughly cleaned before disinfection or sterilization. Single-use instruments must be cleaned before their disposal. See *Decontamination and reprocessing of medical devices for health-care facilities* (11) for more information.

5.2.3.1. Instructions for manually cleaning instruments

- Wear thick household or utility gloves to help protect your hands.
- Wear protective eyewear, a mask and a plastic apron to prevent contaminated fluids from splashing into your eyes or onto your body.
- Use neutral detergent, if available. Do not use steel wool or abrasive cleaners, especially on metal (they cause scratches and promote rusting).
- Using a soft brush, scrub instruments **under the surface of the water** to prevent splashing; pay particular attention to small parts that may trap debris (for example, teeth, joints or screws).

- Rinse the instruments with clean water.
- Dry the instruments using a towel or allow them to air-dry.

5.2.4. Sterilization of instruments (reusable instruments only)

Sterilization is a reduction in the number of microorganisms by more than 10^6 (that is, more than 99.9999% of the microorganisms are killed). This reduction is achieved by heat and pressure in an autoclave, by the use of chemicals or by irradiation (13). Sterilization results in the destruction of all microorganisms, including bacterial endospores. Sterilization is necessary for surgical instruments, sutures or needles that will be used during male circumcision.

This section gives examples of sterilization methods appropriate for processing reusable items used for male circumcision procedures. Wet sterilization using steam is the most widely used method.

5.2.4.1. Thermal sterilization

- **Dry heat sterilization:** In this process, the item is exposed to 150°C (300°F) for 150 minutes or to 170°C (340°F) for 60 minutes in a dry-heat oven.
- **Moist heat (autoclaving, see Annex 5.6):** In this process, the recommendation is to expose the item to 121°C (250°F) for 15 minutes or to 134°C (270°F) for 3 minutes.

5.2.4.2. Chemical disinfectants

Disinfection by chemicals will destroy most microorganisms, but not bacterial spores. Chemical disinfection should only be used if heat treatment is impractical or may cause damage to the equipment. High-level disinfection refers to a process using an agent that is normally used for disinfection purposes. The outcome of a disinfection procedure is affected by the following:

- presence of organic load (bioburden) on the item
- type and level of microbial contaminant present before the item is cleaned
- concentration of disinfectant
- exposure time
- physical structure of the object
- temperature and pH of the disinfection process

In addition to the effective cleaning of items or equipment, the concentration and contact time are critical factors that determine the effectiveness of the disinfection process. Chemical disinfectants used are glutaraldehyde and peracetic acid. (Sodium hypochlorite solution, commonly known as bleach, is **NOT appropriate for high-level disinfection of instruments and must not be used, as it may damage the instruments.**) To achieve effective decontamination, it is important to follow the manufacturer's instructions for using the disinfectant to understand what items are compatible with the disinfectant and how long items should be in contact with the disinfectant. For some agents, the recommended concentration required for effective disinfection can be checked using test strips provided by the manufacturer.

5.2.4.3. Guidelines for storage of sterile packs

After sterilization, the packs are removed and allowed to cool. If there is an adequate supply of surgical trays and equipment, appropriate storage in the sterile supply department has to be provided before the packs are dispatched to the operating theatre. Proper storage of sterile instruments and equipment is essential to ensure that the product maintains its level of sterilization or disinfection. The sterile pack storage area has specific requirements:

- Sterile packs should be protected from dust, sun and rain during transportation.
- Sterilized instruments should be stored in a clean, dry and protected environment.

- Storage containers should not be made of absorbent material, such as wood.
- The area must have adequate lighting.
- The area should be free from damp, have good air circulation and have a constant temperature (no extremes) of 15–28°C.
- Storage shelves should be located at a minimum distance of 30 cm off the floor, 45 cm from the ceiling and 5 cm away from the wall.
- The shelf walls should be smooth and easy to clean.
- Access to the area should be restricted.
- The packs should be placed on open racks rather than on closed shelves. The packs should be placed as a single layer to prevent moisture accumulating between the packs.
- Labels and expiry dates should be clearly displayed.
- The pack inspection register should be clearly visible.
- The date of sterilization should be marked on the package, and the oldest packages should be used first (that is, first in, first out). Dates provide information on when the packages were sterilized but do not guarantee the sterility of the packs; therefore, the general condition of the pack should be examined before use, and packages should be inspected to verify they meet the requirements of a sterile product.
- Pack and materials should be stored so that they can be accessed without the need to move or handle other materials because the more an item is handled, the greater the chance of damage to the packaging.
- Once a sterile pack has been opened, its contents should no longer be considered sterile.
 - Providers should avoid opening sterile wrapped packs to remove only one instrument. If this has to be done, the whole pack is no longer sterile, and the remaining instruments in the pack must not be used for another client because they may transmit infection.

5.3. ENVIRONMENTAL CLEANING AND MANAGEMENT OF SPILLS (6)

5.3.1. Environmental cleaning

Between each case, thoroughly wipe clean and disinfect flat surfaces, such as the instrument trolley and operating table, that all surfaces health care workers can readily touch with their hands and surfaces that may have come in contact with the client's blood or bodily fluids. The floor should be wiped clean after any spills. At the end of each day, there should be a more thorough cleaning that includes all doorknobs, cupboard handles, all flat surfaces of floors, shelves, window ledges, tops of procedure lamps, etc. Periodically, there should be a deep cleaning that includes walls and ceilings. Staff must clean first using a detergent solution and then use the appropriate disinfectant (see Box 5.5), per local procedures and protocols, which should be consistent with recommendations and best practice for infection prevention and control. Detergent and/or disinfectant solutions must be discarded after each use (see Table 5.3).

Box 5.5. Bleach solutions for cleaning—not for high-level disinfection

Many different disinfectant solutions are available, and these solutions have varying degrees of effectiveness. In most countries, the most widely available solution is sodium hypochlorite solution (commonly known as bleach), which is a particularly effective antiviral solution. Although sodium hypochlorite is appropriate for environmental cleaning and management of spills, it is **NOT appropriate for high-level disinfection of instruments and MUST not be used on them.**

Table 5.3. General principles for environmental cleaning

- Cleaning is an essential first step prior to any disinfection process to remove dirt, debris and other materials.
- The use of a neutral detergent solution is essential for effective cleaning. It removes dirt while improving the quality of cleaning by preventing the build-up of biofilms and thus increasing the effectiveness of chemical disinfectants.
- If disinfectants are used, they must be prepared and diluted according to the manufacturer's instructions. Too high and/or too low concentrations reduce the effectiveness of disinfectants. In addition, high concentrations of disinfectant may damage surfaces.
- Cleaning should always start from the least soiled areas (cleanest) first to the most soiled areas (dirtiest) last and from higher levels to lower levels so that debris may fall on the floor and is cleaned last [...].
- Detergent and/or disinfectant solutions must be discarded after each use.
- Avoid cleaning methods that produce mists or aerosols or disperse dust, for example, dry sweeping (brooms, etc.), dry mopping, spraying or dusting.
- Routine bacteriological monitoring to assess the effectiveness of environmental cleaning is not required but may be useful to establish the potential source of an outbreak and/or for educational purposes [...].

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5.3.2. Decontamination of surfaces and larger equipment

Before starting to clean, wear appropriate personal protective equipment; then, use appropriate disinfectant solutions to reduce the bioburden and inactivate any infectious agents on surfaces, fixtures and larger equipment. Appropriate items and equipment, such as instrument trolleys, procedure tables, etc., must be cleaned and decontaminated between patients. When cleaning and disinfecting diathermy equipment, manufacturer's instructions for use should be followed. Reusable noncritical items, such as blood pressure cuffs or stethoscopes, should be checked for soiling or blood contamination. If they are contaminated, they should be cleaned and disinfected in accordance with the manufacturer's instructions for use. If there is gross soiling, particularly if there is wear and tear, then the item should be replaced.

5.3.3. Methods to clean blood spills

Splashes and drips

- Wear nonsterile gloves for this procedure.
- Wipe the area immediately with a paper towel or an absorbent cloth.
- Discard paper towel or absorbent cloth immediately as clinical/infectious waste.
- Disinfect area with 10 000 ppm of sodium hypochlorite (bleach) solution.
- Dry surface with disposable paper towels.
- Discard gloves and paper towels as clinical/infectious waste in accordance with local policy.
- Wash hands with soap and water, and dry hands immediately afterwards.

Larger spills

- All spills must be removed *gently and carefully*. *Always wear appropriate gloves*; use a single-use plastic apron if contamination of the body is likely. Use of gown, face shield, mask and goggles are *not* necessary.
- Cover the area of spill with sodium dichloroisocyanurate (NaDCC) granules (if available), or cover the spill with disposable paper towels or cloths soaked in 10 000 ppm of sodium hypochlorite solution. Leave paper towels or cloth for three to five minutes. *Do not pour* the solution directly onto the spill, as it may cause splashing and widen the area of contamination.
 - **Note:** Blood has a very high level of viscous organic matter poorly penetrated by any disinfectant and will need to be *treated as infectious even if disinfection is attempted*.
- Lift the soiled paper towels/cloths or scoop up the absorbed granules. Discard all into a clinical waste bag in accordance with local policy.
- Clean the area with water and a detergent solution.
- Wipe the surface area with fresh 1 000 ppm of sodium hypochlorite solution and rinse with water, as the sodium hypochlorite solution may be corrosive.
- Dry the surface with disposable paper towels.
- Remove gloves and plastic apron, and discard them as clinical waste in accordance with local policy.
- Wash hands with soap and water, and dry hands immediately.

5.4. SAFE HANDLING OF WASTE

5.4.1. Waste management

The purpose of waste management is to do the following:


- Protect health care workers who handle waste items from accidental injury.
- Prevent the spread of infection to health care workers and the local community.

About 15% of the waste generated in health care facilities is hazardous and requires special methods for its collection, storage, transportation, treatment and final disposition. The other 85% of waste is nonhazardous and can be recycled, treated or disposed of as regular municipal waste, but only if this waste is properly segregated at the point of care. The following waste categories are generated in the context of male circumcision:

- nonhazardous waste (general waste and recyclable waste)
- hazardous waste (infectious waste, for example, waste contaminated with blood; pathological waste, for example, excised foreskins; sharps waste, for example, needles and scalpels)

Protecting public health through waste management can be achieved by a variety of methods. These can be summarized in an order of preference called the waste hierarchy, with the most desirable method at the top and the least desirable at the base (see Fig. 5.4). The most preferable approach is to avoid producing waste as far as possible, thus minimising the quantity entering the waste stream. Where practicable, those waste items that can be safely recovered for secondary use is the next most preferable method. Waste that cannot be recovered must then be dealt with by the least preferable options, such as treatment or land disposal to reduce their health and environmental impacts (13).

Fig. 5.4. The waste management hierarchy

METHODS	Most preferable
Prevent	
Reduce	
Reuse	
Recycle	
Recover	
Treat	
Dispose	

5.4.2. Segregation and collection of waste

The appropriate waste receptacle (bags, bins, sharps boxes) should be available in each medical and other waste-producing area. This allows for segregation of waste at the point of its generation and reduces the need to carry waste through a health service area. To guide staff and reinforce good habits, posters showing the type of waste that should be disposed of in each container should be placed near the bins (that is, on the walls as appropriate).

Containers for infectious waste should not be placed in public areas because clients and other clinic visitors may use the containers and come into contact with potentially infectious waste. Infectious waste bins should be located as close as possible to where waste is generated (for example, nursing stations, procedure rooms or points of care). Placing sharps containers and segregation bins on treatment trolleys enable medical staff to segregate waste at the bedside or other treatment site.

Collection times should be fixed and appropriate to the quantity of waste produced in each area of the health care facility. Generally, pathological and infectious waste should be collected at least once per day. General waste should not be collected at the same time or in the same trolley as infectious or other hazardous waste.

Waste bags/bins and sharps containers should be filled to no more than three quarters full (or to the fill line on sharps bins when marked). Once this level is reached, they should be sealed so they can be collected. Plastic bags should never be stapled but may be tied in a knot or sealed with a plastic tag or tie. Replacement bags or containers should be available at each waste generation area.

Education and training must be provided to all health care workers who are responsible for segregating and collecting waste.

5.4.2.1. Segregation, packaging and disposing of sharps

Disposable sharp items, such as hypodermic needles, require special handling because these items are most likely to injure health care workers who handle them.

Steps for segregation and packaging of sharps in a sharps box are:

- Do not recap needles, or disassemble needles or syringes. Activate the sharps-injury-protection feature if it is present.
- Place needles and syringes to be disposed of in a puncture-resistant sharps container.
- **Close the sharps container tightly when it is three quarters full.** Be sure that no sharp items are sticking out of the container.
- Wear heavy-duty utility gloves.
- Remove the sharps container from the procedure area and place it in the storage area when it is ready for disposal.
- Dispose of the sharps container by incinerating, encapsulating or burying it.
- Remove utility gloves, and wash and dry them (wash daily or when visibly soiled).
- Perform hand hygiene.

5.4.3. Storage of waste

Waste storage areas for health care facilities should be protected from pests and the public (especially children and scavengers), with access limited to authorized personnel. Waste storage areas should be kept locked.

5.4.3.1. General nonhazardous waste storage

General nonhazardous waste should be stored and collected for disposal in the communal landfill/dumpsite or communal waste incinerator. This waste should be collected at least weekly. The waste storage area should be enclosed, paved and connected to a public road. The gate should be big enough that the collection vehicles can enter.

5.4.3.2. Infectious and sharp waste storage

The storage place must be identifiable as an infectious waste area by using the biohazard symbol. The storage floor and walls should be sealed or tiled to allow easy cleaning and disinfection. Storage times for infectious waste (for example, the gap in time between waste generation and treatment) should not exceed the following:

- in temperate climate, 72 hours in winter and 48 hours in summer
- in warm climate, 48 hours in the cool season and 24 hours in the hot season

If a refrigerated storage room is available, infectious waste can be stored for more than a week if it is kept cool at a temperature no higher than between 3–8°C.

5.4.3.3. Pathological waste storage

Pathological waste is considered to be biologically active, and gas formation during the storage should be expected. To minimise gas formation, storage places should have the same conditions as places for storing infectious and sharps waste. Where possible, waste should be stored under refrigerated conditions.

5.4.4. Waste treatment

5.4.4.1. Recycling of nonhazardous waste

Recycling or smelting is the process of turning used materials (waste) into new products. The potential advantages include reduced need for a landfill, and reduced consumption of fresh raw materials, energy-usage air pollution (from incineration) and water pollution (from landfilling). Recycling requires the organization and regular collection of waste; otherwise, large volumes of waste must be safely stored in between collections. In this case, clinics have to take special care to ensure that stored waste is not accessed by unauthorized personnel for inappropriate use. See Annex 5.7 for more information.

5.4.4.2 Treatment of hazardous waste

It is recommended that waste treatment techniques that minimise formation and release of chemicals or hazardous emissions be given priority. In general, the decontamination of infectious and sharp waste by steam (for example, by autoclaving) or other nonburn technology should preferably be used in the treatment of infectious waste (14). Sharp and infectious waste are normally treated together in the same treatment system. After collection, the sharp waste is treated by incineration or by alternative treatment technologies like autoclaving. In both cases, the needles will be decontaminated but still have a physical risk of pricking (waste handlers can be pricked after the waste is treated—but without getting infected).

5.4.4.3. Autoclaving of infectious and sharp waste

Autoclaving is the most common type of steam treatment and utilizes saturated steam, which is under pressure, to decontaminate waste (see Annex 5.6). In this process, potentially infected air that is evacuated from the autoclave is filtered effectively (for example, through a high-efficiency particulate air filter). Autoclaves operate at a temperature of 121°C to 134°C. Autoclaves that do not have an integrated shredder should ensure that the air is removed from the autoclave chamber before the waste is decontaminated (for example, by a vacuum pump), as air remaining in the waste can inhibit the decontamination efficiency of the autoclaving process.

5.4.4.4. Incineration of hazardous waste

Incineration is a high-temperature (850°C to 1 100°C) dry oxidation process that reduces organic and combustible waste to inorganic incombustible matter and results in a very significant reduction of waste volume and weight. In accordance with the Stockholm Convention (14), the best available technology should be used to achieve an emission of lower than 0.1 ng toxic equivalents per m³ of dioxin and furan. Primary measures for incinerators are two burning chambers (850°C/1 100°C); auxiliary burner; two seconds of residence time of air in the second chamber; sufficient oxygen content; and high turbulence of exhaust gases. The primary measures described here should be a minimum standard. By applying primary measures, a performance around 200 ng toxic equivalents per m³ of dioxin and furan can be achieved (14).

5.4.5. Final disposal of health care waste

The final disposal of health care waste is of the utmost importance. Failure to develop a suitable solution for the disposal of health care waste can lead to public health and environmental problems that could negate a project's environmental monitoring and mitigation plan.

General nonhazardous and hazardous waste should not be disposed of on the premises of health care facilities.

Nonhazardous waste should be collected regularly by the municipality or transported by the facility to a known and safely managed public disposal site. All hazardous waste should be treated to eliminate the hazardous properties before disposal or should be disposed in an engineered landfill designed for hazardous waste. Note that the disposal of pathological

wastes may be bound by sociocultural, religious and aesthetic norms and practices. A traditional option is the internment (burial) in cemeteries (13).

Low- and middle-income countries often lack proper facilities for the disposition of hazardous waste. Options outlined in this section may be implemented but should be considered transitional, interim solutions. Appropriate treatment and disposal of hazardous waste depends on the local conditions and regulations. This section describes briefly three internationally recognized methods of disposal of decontaminated sharp waste, disposable nonsharp metal instruments, pathological waste and ash from incineration. The most environmentally favourable option should be used wherever reasonably practicable. Each of the three methods is discussed in more detail in Annex 5.7 or in *Decontamination and reprocessing of medical devices for health-care facilities* (11). No matter the option selected, all wasted instruments **must** be decontaminated and stored appropriately before disposal.

5.4.5.1. Disposal of sharp and nonsharp metal waste

Even after decontamination, sharps waste may still pose physical risks. Waste consisting of nonsharp metal instruments must be secured to ensure that they are not reused. This waste can be disposed of in safe sharps pits on the health care facility's premises or encapsulated by mixing waste with immobilizing material, like cement, before disposal. These procedures are only recommended in cases where the waste is handled manually and the landfill for general waste is not secured.

5.4.5.2. Pathological waste disposal

Placenta pits can be effective in low-resource settings. They need to be located at specific sites to avoid contaminating the ground water, and they need to be locked and fenced for security. Natural degradation and draining of liquid into the subsoil greatly reduces the volume of waste in the pit and facilitates the inactivation of pathogens. Pathological waste may be disposed of at a landfill when no other treatment options are available. However, disposal should be in a prespecified area to prevent recyclers or scavengers coming into contact with the waste. Waste should also be covered as quickly as possible.

5.4.5.3. Disposal of hazardous ash

Fly ash and bottom ash from incineration are generally considered to be hazardous because they may contain heavy metal, dioxins and furans. These ashes should preferably be disposed of in sites designed for hazardous wastes. For example, they can be disposed of at designated cells at engineered landfills, encapsulated and placed in specialized monofill sites, or disposed of in the ground in an ash pit. See Annex 5.7 for more information.

5.4.5.4. Burying waste

In health care facilities with limited resources, burial of nonhazardous waste near the facility may be the only practical option for waste disposal. To limit health risks and environmental pollution, some basic rules should be followed:

- Restrict access to the disposal site. Build a fence around the site to keep away animals, scavengers and children.
- Line the burial site with a material of low permeability (such as clay), if available.
- Select a site at least 50 m away from any water source to prevent contamination of the water table.
- Ensure that the site has proper drainage, is located downhill from any wells, is free of standing water and is not in an area that floods.

KEY MESSAGES

- Health care workers need to follow recommended practices for preventing infection to protect their patients (clients), themselves and other health care workers from exposure to hepatitis B virus, hepatitis C virus, HIV and other infections.
- Hand hygiene greatly reduces the number of disease-causing microorganisms on hands and arms. It is the most important way of limiting the spread of infection. Hands should be washed with soap and water before each new client; otherwise, an alcohol-based handrub should be used.
- Appropriate personal protective equipment should be worn to protect both clients and health care workers from exposure to infectious microorganisms.
- Sterile gloves should be worn during the male circumcision procedure or when performing any invasive procedure. To avoid spreading infection from person to person, a new pair of gloves should be worn for each new client contact.
- All health care workers should be trained in the proper handling of sharp instruments. Hypodermic (hollow-bore) needles can cause injuries to clinic staff at all levels (for example, health care workers can be stuck by hypodermic needles during client care, cleaning and housekeeping; also, health care workers may be exposed to needle-stick [sharps] injuries when washing soiled instruments and disposing of infectious waste material).
- Health care workers should be trained to never enter medication vials with needles or syringes that have already been used in an injection—even for the same client.
- Syringes with safety features, including reuse prevention and sharps injury protection, are available, and both are appropriate for use.
- Health care workers should wear clean or heavy-duty gloves when handling contaminated items.
- Each clinic should have a written standard operating procedure for the management of anyone with a needle-stick (sharps) injury. The protocol should include clear advice about what actions the health care worker with the needle-stick (sharps) injury should take to mitigate the risk of acquiring hepatitis B virus, hepatitis C virus and HIV. Also, the protocol should be in accord with national standards and should take into account international guidance on avoiding exposure to bloodborne pathogens.
- Vaccination of health care workers against hepatitis B virus protects staff and their clients, and should be implemented in accordance with national protocols.
- Safe and environmental friendly management of waste should be performed along the complete logistic chain: segregation, transport, storage, treatment and disposal.

ANNEX 5.1. MANAGING OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS, HEPATITIS AND HIV THROUGH POST-EXPOSURE PROPHYLAXIS

Overview

Health care workers are at increased risk of accidental exposure to bloodborne pathogens—such as hepatitis B and C viruses and HIV—while providing male circumcision services.

A minimum approach to health and safety practices for health care providers and waste workers includes (11) the following:

- implementation of standardized management approaches
- compulsory vaccination for the hepatitis B virus for all health care workers, including cleaners and staff who handle medical waste
- provision of sharps disposal boxes for safe disposal of used needles, syringes and other sharps
- compliance with hand hygiene standards
- availability of appropriate personal protective equipment—mask, face shield or goggles, rubber apron and utility gloves (at the bare minimum, every health care worker handling waste should have a face shield and utility gloves)
- appointment of a clinic staff member or designated staff to additional or dedicated responsibility for infection control, including waste management

Immediately after any needle-stick (sharps) injury, the person injured should—as soon as it is safe to do so—hand over his/her duties to another provider and wash the area with plenty of soap and water. Antiseptics or caustic agents, such as bleach, should not be used. Flush any exposed mucous membranes with plenty of water. The clinic should have a system to quickly report any needle-stick (sharps) injuries to the nearest health facility that provides post-exposure prophylaxis services so that this can be given to the injured health care worker according to the national guidelines.

Managing potential exposure to hepatitis B or C (15, 16)

Steps to follow when a health care worker has potentially been exposed to either hepatitis B virus or hepatitis C virus:

STEP 1: Provide immediate care to the exposure site.

- Wash the exposed skin and any wound with soap and water.
- Flush mucous membranes with water.
- **DO NOT** use any antiseptic or caustic agents, such as bleach.

STEP 2: Consult the clinician in charge of post-exposure prophylaxis management as soon as possible (see Table A5.1.1):

The clinician who is in charge of post-exposure prophylaxis will:

- Determine the risk associated with the exposure by type of fluid and type of exposure.
- Find out whether the exposed health care worker has had a hepatitis B vaccination.
- Assess the health care worker's immune status by measuring the hepatitis B virus core antibodies and surface antibodies.
- Measure hepatitis C virus antibodies and alanine aminotransferase, and, if positive for hepatitis C virus, test for viremia to confirm current infection.

STEP 3: Evaluate the exposure source.

- Make a detailed clinical evaluation of the source.
- Determine the hepatitis B virus vaccination and immune status of the source.
- Test known sources for hepatitis B virus surface antigen and antihepatitis C virus antibodies.

Table A5.1.1. Prophylaxis after occupational exposure to hepatitis B virus

Vaccination status and antibody response of exposed provider	Treatment		
	Source is positive for hepatitis B surface antigen.	Source is negative for hepatitis B surface antigen.	Source is unknown or is not available for testing.
Previously vaccinated	No treatment	No treatment	No treatment
Unvaccinated	Single dose of hepatitis B immunoglobulin and full hepatitis B virus vaccination	Full hepatitis B virus vaccination	Full hepatitis B virus vaccination
Known responder ^a	No treatment	No treatment	No treatment
Known nonresponder ^b	Single dose of hepatitis B immunoglobulin and revaccination or second dose of hepatitis B immunoglobulin	No treatment	If the source is a known high risk, manage as if source were positive for hepatitis B surface antigen.
Antibody response unknown	Test exposed person for hepatitis B surface antibodies: If level is adequate, no treatment is necessary. If level is inadequate, give a single dose of hepatitis B immunoglobulin and hepatitis B vaccine booster.	No treatment	Test exposed person for anti-HBs: If level is adequate, no treatment is necessary. If level is inadequate, give hepatitis B vaccine booster and check titre in one to two months.

^a A known responder is a person who has an adequate level of serum antibody (hepatitis B surface antibodies ≥ 10 mIU/mL).

^b A known nonresponder is a person with inadequate response to vaccination (hepatitis B surface antibodies < 10 mIU/mL).

Managing potential exposure to HIV (17)

This section details steps to follow when a health care worker has potentially been exposed to HIV.

The current recommendations for HIV post-exposure prophylaxis aim to harmonize regimen with the current treatment regimen for adults and children (17). The key components of managing occupational exposure to HIV and up-to-date recommendations for the use of antiretroviral therapy are described below

STEP 1: Provide immediate care to the exposure site.

- Wash the exposed skin and any wound with soap and water.
- Flush mucous membranes with water.
- **DO NOT** use any antiseptic or caustic agents, such as bleach.

- Report the event to the health care provider in charge of post-exposure prophylaxis management. The report should include identification of the exposed person, the date and time of exposure, the type of fluid, nature of the exposure and details about the source, as recommended by national post-exposure prophylaxis guidelines.

STEP 2: Establish eligibility for post-exposure prophylaxis.

- Check for parenteral or mucous membrane exposure (for example, splashes to the eye, nose or oral cavity).
- Check for exposure to blood (this is the most likely situation, usually because of needle-stick [sharps] injury or, more rarely, blood-stained saliva or genital secretions because of problems with managing the airway or problems with catheterisation).
- Post-exposure prophylaxis is not indicated if the exposed health care worker is known to be HIV positive, source is known to be HIV negative or exposure is limited to intact skin.
- Testing the source of the exposure and the exposed health care worker is helpful. If this information cannot be obtained, then HIV post-exposure prophylaxis may still be given. The prophylaxis administration decision is sometimes based on an individual's concerns as well as the HIV prevalence in the community.

STEP 3: Prescribe post-exposure prophylaxis.

- Initiate post-exposure prophylaxis as early as possible, ideally within 72 hours of the exposure.
- Continue post-exposure prophylaxis for 28 days.
- Provide enhanced adherence counselling and address any drug interactions.
- Follow the World Health Organization's recommendations for post-exposure prophylaxis for HIV (see Box A5.1.1) (17).

STEP 4: Follow up.

- Provide follow-up for adherence and any side effects of antiretroviral treatment, and address any other questions that individual may have.
- Arrange for an HIV test to be undertaken three months after the exposure.
- Link HIV care and treatment, including preventive measures for protecting others, in case HIV test results are positive.
- Provide additional counselling and other preventive interventions as needed and if test results are negative.

There are many challenges to providing effective post-exposure prophylaxis, including early provision of and adherence to the full course of post-exposure prophylaxis. In a global review of adherence to post-exposure prophylaxis, only 56% of the people completed the full 28-day course (17). Given these challenges, full compliance to infection prevention and control practice remains the best option to protect health care workers.

Box A5.1.1. The World Health Organization's recommended daily dosage of antiretroviral therapy for 28 days for adults and adolescents (17)

An HIV post-exposure prophylaxis regimen with two antiretroviral agents is effective, but three drugs are preferred.

Recommended backbone regimen:

- Tenofovir (TDF) 300 mg once a day + lamivudine (3TC) 300 mg once a day (or 150 mg twice daily)

OR

- Tenofovir (TDF) 300 mg once a day + emtricitabine (FTC) 200 mg once a day

Recommended third drug:

- Lopinavir/ritonavir (LPV/r) 400 mg/100 mg twice a day

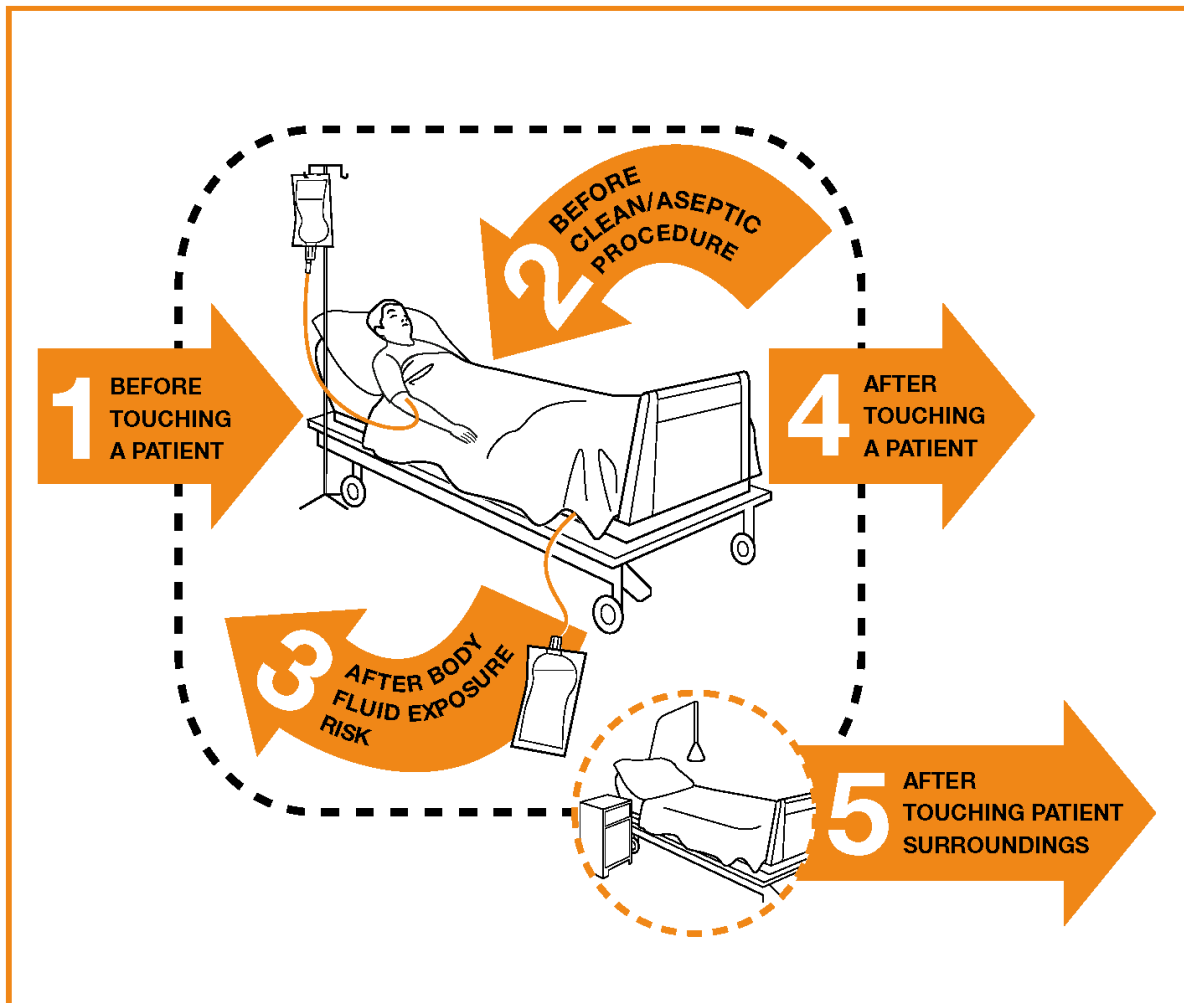
OR

- Atazanavir/ritonavir (ATV/r) 300 mg + 100 mg once a day

Raltegravir (RAL), darunavir/ritonavir (DRV/r) or efavirenz (EFV) can be considered as alternative options, depending on drug availability.

Note: Some national guidelines may recommend different antiretroviral agents to those listed above, in particular dolutegravir (DTG). The World Health Organization will be issuing updated post-exposure prophylaxis guidelines in 2018, which will reflect the potential use of dolutegravir and possibly other agents.

ANNEX 5.2. MY 5 MOMENTS OF HAND HYGIENE

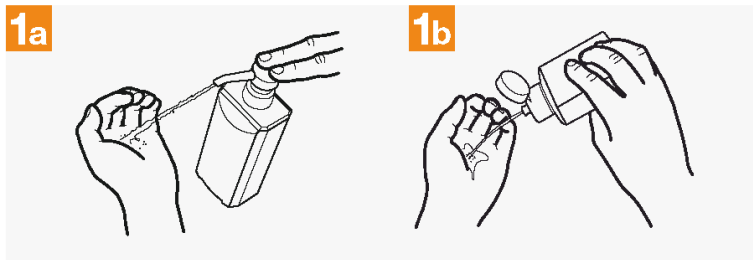


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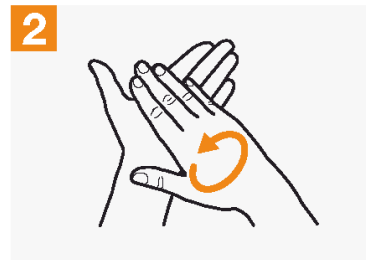
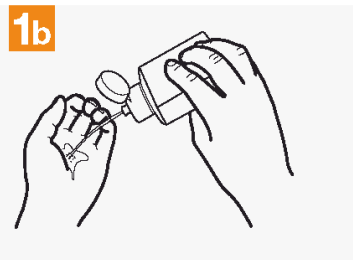
ANNEX 5.3. HAND HYGIENE TECHNIQUE WITH ALCOHOL-BASED FORMULATION

Hand Hygiene Technique with Alcohol-Based Formulation

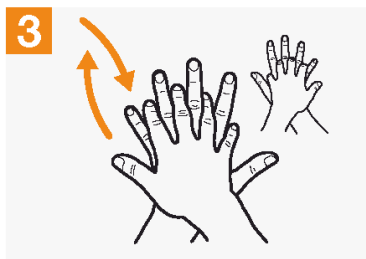
 Duration of the entire procedure: 20-30 seconds



1a Apply a palmful of the product in a cupped hand, covering all surfaces;



2 Rub hands palm to palm;



3 Right palm over left dorsum with interlaced fingers and vice versa;



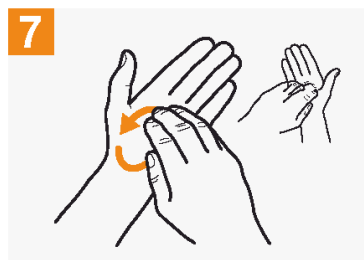
4 Palm to palm with fingers interlaced;



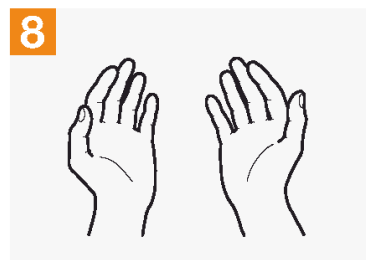
5 Backs of fingers to opposing palms with fingers interlocked;



6 Rotational rubbing of left thumb clasped in right palm and vice versa;



7 Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;



8 Once dry, your hands are safe.

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ANNEX 5.4. SURGICAL HANDRUBBING TECHNIQUE

Surgical Handrubbing Technique

- Handwash with soap and water on arrival to OR, after having donned theatre clothing (cap/hat/bonnet and mask).
- Use an alcohol-based handrub (ABHR) product for surgical hand preparation, by carefully following the technique illustrated in Images 1 to 17, before every surgical procedure.
- If any residual talc or biological fluids are present when gloves are removed following the operation, handwash with soap and water.



1 Put approximately 5ml (3 doses) of ABHR in the palm of your left hand, using the elbow of your other arm to operate the dispenser.



2 Dip the fingertips of your right hand in the handrub to decontaminate under the nails (5 seconds).



Images 3-7: Smear the handrub on the right forearm up to the elbow. Ensure that the whole skin area is covered by using circular movements around the forearm until the handrub has fully evaporated (10-15 seconds).



Images 8-10: Now repeat steps 1-7 for the left hand and forearm.

11 Put approximately 5ml (3 doses) of ABHR in the palm of your left hand as illustrated, to rub both hands at the same time up to the wrists, following all steps in images 12-17 (20-30 seconds).

12 Cover the whole surface of the hands up to the wrist with ABHR, rubbing palm against palm with a rotating movement.



13 Rub the back of the left hand, including the wrist, moving the right palm back and forth, and vice-versa.

14 Rub palm against palm back and forth with fingers interlinked.

15 Rub the back of the fingers by holding them in the palm of the other hand with a sideways back and forth movement.

16 Rub the thumb of the left hand by rotating it in the clasped palm of the right hand and vice versa.

17 When the hands are dry, sterile surgical clothing and gloves can be donned.

Repeat this sequence (average 60 sec) the number of times that adds up to the total duration recommended by the ABHR manufacturer's instructions. This could be two or even three times.



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ANNEX 5.5. SURGICAL HAND PREPARATION^a

RECOMMENDATION
<p>The panel recommends that surgical hand preparation be performed either by scrubbing with a suitable antimicrobial soap and water or using a suitable ABHR before donning sterile gloves. (<i>Strong recommendation, moderate quality of evidence</i>)</p>
RATIONALE FOR THE RECOMMENDATION
<p>The GDG noted that surgical hand preparation is vitally important to maintain the lowest possible contamination of the surgical field, especially in the event of sterile glove puncture during the procedure. Appropriate surgical hand preparation is recommended in the WHO <i>guidelines on hand hygiene in health care (1)</i> issued in 2009 and in all other existing national and international guidelines on the prevention of SSI.</p> <p>Moderate quality evidence shows the equivalence of handrubbing with an ABHR and handscrubbing with antimicrobial soap and water for surgical hand preparation for the prevention of SSI.</p>
REMARKS
<p>The available evidence on SSI as an outcome is limited to three RCTs. The trials compared handrubbing (with alcohol-based preparations) vs. handscrubbing (with PVP-I, CHG or plain soap) for surgical hand preparation and showed no significant difference between the two methods.</p> <p>Evidence from additional studies using the bacterial load on participants' hands as the outcome demonstrated that some ABHR formulations are more effective to reduce colony-forming units than scrubbing with water and antimicrobial or plain soap. The relevance of this outcome to the risk of SSI remains uncertain and the GDG considered this as indirect evidence and concluded that the recommendation could not be developed based on this surrogate outcome. Only evidence from RCTs with an SSI outcome was taken into account for the recommendation development.</p> <p>The WHO hand hygiene guidelines recommend preferably using "a product ensuring sustained activity". It was assumed that the sustained activity ensured by certain products (for example, CHG) was desirable, but there was no evidence that these products were more effective in directly reducing the risk of SSI. In the absence of such evidence, the GDG decided not to make any recommendations on specific products with or without a sustained effect and it emphasized the need to define what is considered a "suitable" product.</p> <p>The hands of the surgical team should be clean upon entering the OR by washing with a non-medicated soap. Once in the operating area, repeating handrubbing or scrubbing without an additional prior handwash is recommended before switching to the next procedure.</p> <p>It should be kept in mind that the activity of ABHRs may be impaired if hands are not completely dried before applying the product or by the handwashing itself. Hence, surgical handscrub and surgical handrub with alcohol-based products should not be combined sequentially (1).</p> <p>When choosing ABHR, health care facilities should regularly procure products with proven efficacy (that is, complying with European norms or those of the American Society for Testing and Materials or equivalent international standards) to implement this recommendation and position no-touch or elbow-operated dispensers in surgical scrub rooms. Alternatively, antimicrobial soap, clean running water and disposable or clean towels for each health care worker should be available in the scrub room.</p> <p>In LMICs where ABHR availability is limited, WHO strongly encourages facilities to undertake the local production of an alcohol-based formulation according to WHO guidance, which has been demonstrated to be a feasible and low-cost solution (1, 2).</p>

REMARKS (CONTINUED)

Skin irritation, dryness, dermatitis and some rare allergic reactions are adverse events that can occur following frequent scrubbing for surgical hand preparation. Although these are less frequent with ABHRs and more frequent with iodophors, even well-tolerated ABHRs containing emollients may cause a transient stinging sensation at any site of broken skin (cuts, abrasions). Allergic contact dermatitis or contact urticaria syndrome caused by hypersensitivity to alcohol or to various additives present in some ABHRs are rare occurrences. ABHR preparations with strong fragrances may be poorly tolerated by a few health care workers with respiratory allergies. Studies of surgeon preferences indicate a primary preference for ABHRs with a higher tolerability and acceptability, due mostly to the shorter application time required and fewer skin reactions. Care must be taken to avoid contact with the eyes when using preparations with CHG 1% or greater as it may cause conjunctivitis or serious corneal damage. Ototoxicity precludes its use in surgery involving the inner or middle ear. Direct contact with brain tissue and the meninges should be avoided. The frequency of skin irritation is concentration-dependent, with products containing 4% most likely to cause dermatitis when used frequently for antiseptic handwashing. True allergic reactions to CHG are very uncommon (1).

Alcohols are flammable and health care workers handling alcohol-based preparations should respect safety standards.

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^a Refer to source for works cited in the table.

ANNEX 5.6. DISINFECTION BY STERILIZATION, IN LINE WITH THE WORLD HEALTH ORGANIZATION'S GUIDANCE

Sterilization by autoclaving (pressured steam) is the preferred option for reusable surgical instruments. In some settings, high-level disinfection is the only acceptable alternative to sterilization. Disinfection is less effective than sterilization because although it destroys most microorganisms, it does not destroy spores (particularly tetanus spores). High-level disinfection can be achieved using either steam or chemical disinfectants. Chemical disinfectants are generally used for heat-sensitive instruments and equipment that are used in critical procedures, and which cannot be sterilized using heat. Chemical disinfection can be achieved by soaking instruments in 2% glutaraldehyde or 0.55% peracetic acid.

To determine how long an item should be immersed in pressured steam, follow the item's manufacturer's instructions for use; time for a given item varies according to concentration and pH. Chemical disinfectants must be used in a well-ventilated room; health care workers should wear personal protective equipment and follow the manufacturer's instruction for using the disinfectant. Thorough cleaning of instruments is **essential** before they are disinfected and sterilized to ensure removal of blood or caked organic matter, which may harbour spores or bacteria.

ANNEX 5.7. SPECIFICATIONS OF WASTE MANAGEMENT PROCEDURES ADAPTED (11)

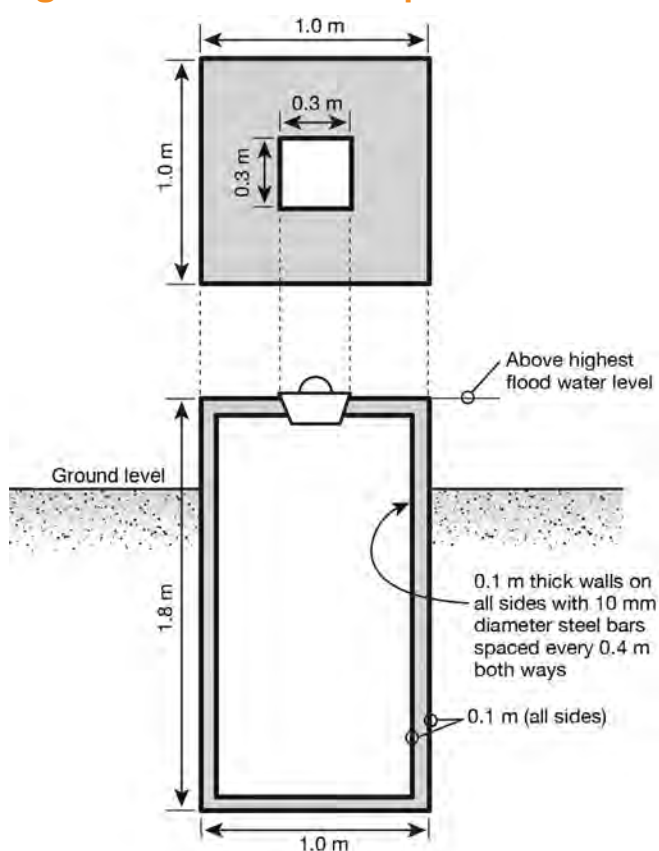
A5.7.1. Sharps pit or concrete vault

Before deciding on the pit or concrete vault method of disposal, the likely volume of waste that will be deposited should be considered. If single-use safe syringes suitable for local anaesthesia are available, it is likely that a sharps pit or concrete vault will not be big enough or will fill up too quickly because the whole syringe has to be disposed of with the needle.

A5.7.1.1. Constructing a sharps pit or concrete vault (see Fig. A.5.7.1)

- Dig a pit (minimum size of 1 m × 1 m × 1.8 m) that does not reach the ground water level. Make sure the pit is large enough to accommodate sharps and instruments for an estimated period of time. The site must be isolated and at least 30 m away from dwelling units and sources of ground water supply.
- Construct the concrete walls and slabs of the pit. Provide the slab with an opening or manhole for easy deposition of collected sharps and syringes. The manhole should be extended a few centimetres above the soil's surface to overcome infiltration of surface water.
- Deposit inside the pit or vault the collected safety boxes filled with used sharps and other instruments.
- Install a security fence around the site.
- When full, fill the vault or pit with concrete to seal.

Fig. A.5.7.1. Construction specifications



A5.7.1.2. Handling waste to be buried in the pit or vault

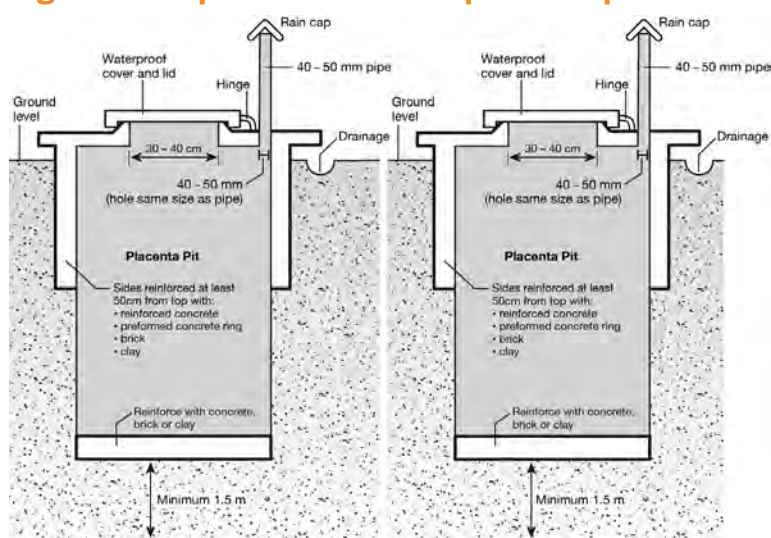
- Wear the required personal protective equipment, including reusable utility gloves, apron, protective shoes and face protection.
- Remove the decontaminated nonsharp metal instruments from the secure storage area. To reduce the potential for cross-contamination, keep the decontaminated nonsharp metal instruments separated from other contaminated waste that is not going to be buried. Place the waste in a rigid plastic container or wheelie bin.
- Carefully transport the instruments in the rigid plastic container or wheelie bin to the pit or vault.
- Slowly pour the instruments into the pit or vault.
- Clean the rigid plastic container or wheelie bin using standard cleaning procedures.

A5.7.2. Pathological waste pit

Pathological waste pits need to be located at specific sites to avoid contaminating the ground water, and the pits need to be locked and fenced for security. Natural degradation and draining of liquid into the subsoil greatly reduces the volume of waste in the pit and facilitates the inactivation of pathogens. Pathological waste may be disposed of at a landfill when no other treatment options are available. However, disposal should be in a prespecified area to prevent recyclers or scavengers coming into contact with the waste. Waste should also be covered as quickly as possible.

Below are the structural characteristics of a pathological (or placenta) waste pit (see Fig. A5.7.2):

- This pit encloses and secures organic material, the components of which degrade during aerobic bacterial processes. It is important that enough air can float into the pit for the biodegrading process and to avoid smelling its effects. This can be solved by placing an air pipe into the pit. The pipe should rise above the pit (about 1 m over ground) and should be covered with a fly grid to prevent insect breeding inside the pit.
- The upper part of the pit should be made of concrete and should be accessible by a pathway made of concrete.
- The feeding door of the pit should be made of metal and be located in the middle of the pit, thereby ensuring the most effective distribution of waste in the pit. The bottom of the pit should be compressed soil—if possible, clay.
- The depth and width of the pit depend on the geological structure of the ground. Proposed dimensions are 3 m deep, 1.5 m wide and 1.5 m long ($3 \times 1.5 \times 1.5 \text{ m} = 6.75 \text{ m}^2$).
- The pit should be fenced and locked to avoid unauthorized access.

Fig. A5.7.2. Specifications of a placenta pit

There should be two pathological waste pits next to each other. Periodically, the waste should be covered with a layer of soil. After the first compartment is filled to 80% of its capacity, it should be closed, and the second one should start to be filled. As the second one fills, the first pit's content has decomposed and the volume has reduced by 60%, so the first pit can be filled again.

A5.7.2.1. Operation of a placenta pit

Health care workers handling placentas and operating the placenta pit should:

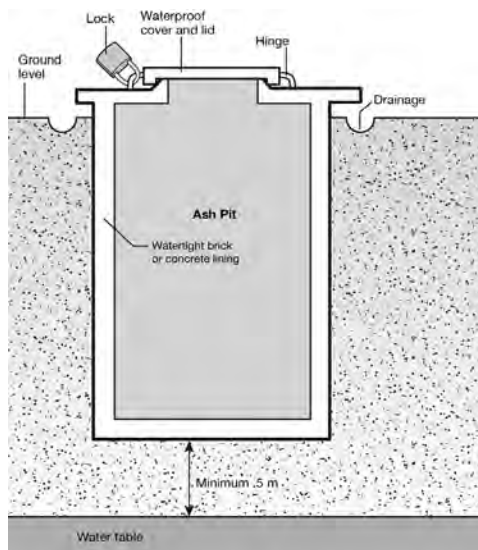
- Wear appropriate personal protective equipment to avoid any accidental exposure to blood and bodily fluids.
- Perform hand hygiene before and after wearing personal protective equipment.
- Dispose of the organic waste into the pit immediately when it arrives at the pathological waste pit.
- Make sure that the pit's lid is always shut when it is not in use.
- Disinfect the empty organic waste bins with a 0.1% sodium hypochlorite (bleach) solution. Rinse the bins with clean water, and then clean them with water and soap. (Do not mix sodium hypochlorite and soap together.)
- Close the pit down when the level of the organic waste is about 0.5 m underneath the slab. Put a thick layer of wood ash on top of the organic waste and top up with compacted soil if the pit is closed permanently.

Most organic waste will decompose into harmless matter, so it is possible to empty a pit that has been closed down for at least two years. The general public may find the removal of these remainders offensive. Take particular care to avoid injuries with sharps that have accidentally been discarded in the organic waste pit. A new permanent burial place, such as a landfill, should be found for the remaining organic waste.

A5.7.3. Ash disposal pit

Ash from incineration is considered to be hazardous because it may contain heavy metals and other toxic materials. Ash should be disposed of properly in hazardous waste sites, such as in engineered landfills, encapsulated and buried, or disposed of in an ash pit (see Fig. A5.7.3). Health care workers handling ash should wear appropriate personal protective equipment (for example, utility gloves, plastic apron, goggles and mask or N95 respirator).

Fig. A5.7.3. Specifications of an ash pit



A5.7.4. Recycling and smelting of decontaminated disposable instruments

- Transport will collect the decontaminated instruments according to a schedule arranged by the central or regional warehouse manager, recycling or smelting facility and transport company or contractor, where applicable.
- The instruments will be collected with a consignment or chain-of-custody form. It is the responsibility of the central or regional warehouse manager to check the consignment or chain-of-custody form against the removed instruments, record the details on the form and sign the form accordingly. The transport company or contractor assumes responsibility for the waste once it leaves the premises.
- The driver will deliver the instruments to the recycling or smelting facility, where the facility's representative will sign the consignment form and then assume final responsibility for them.

A5.7.5. Encapsulation

- Care and precautions should be taken to avoid cutting hands when placing decontaminated single-use instruments in the drums. It is important to wear the appropriate personal protective equipment, such as thick rubber gloves, apron, protective shoes (steel-toed boots) and goggles.
- Once a drum is filled to 75% of its capacity, a mixture of lime, cement and water (15:15:5%) is added, and the drum is filled to capacity. A larger quantity of water may sometimes be required to attain a satisfactory liquid consistency.
- Steel drum lids should then cover the drums and be sealed by spot welding the seams.
- The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste. For ease of movement, the drums may be placed on pallets that can then be put on a pallet transporter.

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CHAPTER 6

EDUCATING AND COUNSELLING CLIENTS, AND OBTAINING INFORMED CONSENT



This chapter provides information on the following:

- the role and content of group education and individual counselling in male circumcision services
- the skills required to educate and counsel clients on male circumcision services, including HIV testing and prevention
- the unique needs of adolescents in education and counselling, including age-appropriate sexual and reproductive health messages
- the skills required to encourage, but not mandate, an HIV test before the circumcision procedure
- the importance of and conditions for maintaining privacy and confidentiality of male circumcision clients
- group education and individual counselling considerations for facilities or providers offering both conventional and device-based surgical circumcision methods
- the principles of and steps involved in obtaining informed consent from clients, including from minors and other special groups

6.1. INTRODUCTION*

Health education and counselling are closely linked, but they have distinct roles in the context of supporting clients. In **health education**, the primary goals are to:

- Provide accurate information and learning experience so that individuals and communities become knowledgeable about issues relevant to their health.
- Make a positive impact on individuals' attitudes by providing current, accurate information.

Health education is delivered in group and individual formats, and includes an interactive question-and-answer component to encourage client engagement. **Counselling** is a two-way interaction (that is, a conversation) between a provider and an individual, couple or family (see Box 6.1). The goal is to support clients in making healthy, appropriate choices for themselves. This means assisting clients to examine issues that are personally relevant, such as risk behaviours; discuss their options to address any needs or problems identified; guide them to make informed decisions; and develop realistic action plans.

Box 6.1. What is counselling?

Counselling is a conversation or process of dialogue characterised by the following:

- active listening, that is, not forcing ideas or values on clients
- being respectful, empathetic and nonjudgemental, that is, not criticising clients
- empowering clients, that is, not telling them what to do
- supporting the rights of clients, that is, not taking responsibility for their actions or decisions

* Adapted from (1)

For education and counselling to be most effective, providers must work to establish a trusting relationship with clients by being respectful, empathetic and nonjudgemental at all times. Communication skills required for effective group education and individual counselling are in Annex 6.1. Prioritize the information that needs to be delivered at each visit so clients are not overwhelmed by too much information at one time (see Box 6.2).

Box 6.2. Do not overwhelm clients by giving them too much information at one time

Prioritize education and counselling messages that are critical to protect the client's right to informed consent/assent and to ensure that he is safe during and after the procedure. Giving too much information at once can reduce the client's ability to understand it, making it more difficult for the client to make healthy, informed choices. Other health or related services may be mentioned or even recommended. However, unless they are integral to male circumcision, they should not be the focus of the education and counselling until the procedure is complete, the client is recovering normally, and a critical discussion about wound care and continued HIV risk reduction has taken place. Other ways to introduce a client to these services, without overwhelming him, are to give him an information sheet about services available, send messages about special health events to his cellphone or post such information on waiting area walls.

6.2. EDUCATION, COUNSELLING AND CLIENT FLOW

Plan and prioritize education and counselling so that sufficient opportunity for these critical services is incorporated at appropriate stages into the male circumcision process. In male circumcision, as in other health services, education and counselling are usually integrated rather than being separated from other aspects of care. For example, in some settings, most preprocedure counselling may occur while the client is being screened for his eligibility to undergo the procedure because both counselling and screening require privacy. Also, asking a client about his sexual and reproductive health history can readily lead to a discussion about risk reduction, the need for HIV testing and other issues relevant to the decision to undergo male circumcision.

Fig. 1.1 (see Chapter 1) shows the typical order in which clients may progress through male circumcision services, where each block in the figure represents a stage in the male circumcision process. Building on that concept, Table 6.1 shows examples of education and counselling content to convey at each step throughout the provision of male circumcision services.

Table 6.1. Example of education and counselling content throughout male circumcision services

REGISTRATION AND WAITING	GROUP EDUCATION	INDIVIDUAL COUNSELLING	CLINICAL SCREENING	IMMEDIATE PREPROCEDURE CARE AND THE PROCEDURE	IMMEDIATE POSTPROCEDURE CARE	FOLLOW-UP CARE
Services provided at the site Minimum service package and male circumcision methods available at this health care facility	Basic information about male circumcision as part of a comprehensive HIV prevention strategy HIV testing Sexually transmitted infections Condoms Male circumcision procedure (including risk and method options if applicable) Follow-up care, including wound care and tetanus risk Other services available locally	Individual risk assessment and risk reduction plan Choice and method of male circumcision HIV testing and post-test counselling Reinforce key HIV risk reduction messages that are tailored to the client If required, refer for post-test services (for example, HIV treatment, sexually transmitted infection treatment, family planning services, immunization) Tetanus toxoid-containing vaccination Wound care Informed consent/assent	Choice of method, depending on eligibility Re-emphasize messages covered in individual counselling Address questions and fears about the procedure Explanation of contraindications, and referrals if contraindication noted	Informed consent/assent Choice of method Re-emphasize messages covered in individual counselling Wound care Address questions and fears about procedure	Wound care Abstinence during wound healing Condoms Risk reduction and additional HIV prevention measures Warning signs of complications that require early return to the clinic Follow-up care schedule Information about how to contact the clinic or providers in the event of an emergency or complication	Wound care Abstinence during wound healing Condoms Risk reduction and additional HIV prevention measures Warning signs of complications that require early return to the clinic Continued follow-up care Referral of client to other relevant services

6.2.1. Considerations for group education in male circumcision

Group education sessions allow clients to enter into individual counselling with a general understanding of the circumcision procedure (for example, benefits, risks and partial protection against HIV) and other components of the male circumcision package, such as HIV testing. In turn, individual counselling sessions can be better tailored to each client and may be shorter, which is an advantage in busy clinics. Group education needs to be conducted in a quiet place. It is beneficial to separate education sessions for men from those for adolescent boys (especially if they are not yet sexually active) to address needs specific to each group. It has been shown that offering only combined sessions, where adolescent boys and men are educated together, may deter the men from actively participating and asking questions.

During group education for male circumcision services, educators should provide basic information about the role of this procedure in a comprehensive HIV prevention strategy. If both conventional and device-based surgical circumcision methods are available, then information should be given about these different methods and the circumstances when some males may not be eligible for circumcision at all. Finally, there should be information about follow-up care, including postprocedure wound care, abstinence during the healing period and warning signs.

Although information provided during group education sessions should cover certain core information as described in Table 6.1, the content may differ slightly from one facility or health care provider to another based on local needs. For example, in a setting where traditional male circumcision is prevalent, the educator may spend more time discussing differences between the traditional and the conventional or device-based surgical circumcision methods. National programmes can prioritize topics to cover and emphasize or add to educational sessions. Educators should also consider the local cultural context to determine how best to accommodate different age groups. Likewise, adolescent boys may not understand the relevance of messages designed especially for men, as these messages do not reflect typical adolescent perspectives and life situations.

6.2.2. Considerations for individual counselling in male circumcision

The aim of counselling in male circumcision services is to support the client in his decision about undergoing this procedure and receiving an HIV test (if he has not already been tested). Counselling should also assist the client to identify ways to reduce his risk of acquiring HIV or transmitting the virus to others, and understand the importance of accessing post-test support services if needed. Preprocedure and postprocedure counselling—and follow-up care services—are also critical to reduce the risk of adverse events and encourage healthy outcomes. Individual counselling needs to be conducted in a confidential manner.

The provider should ensure that the client, his sexual partner(s) and, if the client is a minor, his parent(s)/guardian(s) have the information they need to make an informed decision about undergoing circumcision and receiving HIV testing. Once the client has been fully screened and determined to be eligible for circumcision at the clinic, and depending on his age and methods available at the clinic, counselling can guide him to choose a conventional or device-based surgical circumcision method—provided either he or his parent(s)/guardian(s), if he is a minor, consent and sign a document to record this consent. National guidelines should be followed with respect to the legal age at which a client can consent to male circumcision and HIV testing. It is also good practice to encourage minors to sign their assent documents.

The male circumcision counsellor should consider different strategies and approaches for building trust and gaining confidence of clients who differ by age, cognitive and physical development, HIV status, life situation and other factors. Tailoring messages to each client may be particularly effective because it shows the client that the provider has been paying attention to him. For example, the provider may emphasize the importance of HIV testing to a client whose HIV status is unknown, or may emphasize the importance of regular retesting to a client who is HIV negative and who has behaviours that put him at risk for HIV infection. All clients should know that male circumcision offers no direct protection to their sexual partners against acquiring an HIV infection.

6.3. CONFIDENTIALITY AND PRIVACY

Clients may be uncomfortable sharing their sexual and reproductive health concerns or history. There is a strong social pressure to conform, and considerable social stigma persists about behaviours or conditions perceived as unusual, bad or wrong. An atmosphere of trust is essential to encourage clients to discuss their sexual and reproductive health needs. Absolute assurance of confidentiality and privacy is an important aspect of a quality health service and supports the effectiveness of education and counselling. **Confidentiality means that health care providers protect and do not share a client's personal information**—except for minors because their information is shared with their parent(s)/guardian(s).

It is an individual's right to decide when and with whom to share information about his health. Client information should be kept confidential, and a client's records should be safely secured. **Privacy means ensuring that interactions with the client are neither seen nor heard by anyone who is not accompanying or directly interacting with the client.** Providers should assure clients about confidentiality and privacy, and adhere to the following guidelines:

- Individual counselling sessions should be held away from other clients, so the client being counselled cannot be seen or heard.
- When a client is asked to share information that is personal or sensitive in nature, no one else should be able to hear what he is saying (aural privacy). This need for privacy may occur during any stage of male circumcision services, for example, while receiving the HIV test or during counselling, screening or the circumcision procedure.
- Each client should be given an opportunity to discuss issues with the health care provider without his sexual partner(s) present (or, if the client is an adolescent boy, without his parent[s]/guardian[s] present). Providers should not ask the client in front of his sexual partner(s) or parent(s)/guardian(s) if he would like one-on-one time because the client may say no to avoid potential conflict. Instead, health care providers should create a few moments of privacy as part of their routine.
- If parent(s)/guardian(s) have the legal right to be present at all times, then providers should discuss with the parent(s)/guardian(s) the reasons for needing to see the adolescent boy in private; providers should obtain the adolescent boy's permission to have this private discussion. Information that the minor is embarrassed to share in front of parent(s)/guardian(s) may be important to learn to ensure that he receives the best care possible.

In the context of male circumcision services, HIV counselling (especially post-test counselling on an HIV test result) and preprocedure and postprocedure counselling should be conducted in a room that offers both aural and visual privacy to ensure that the HIV test result, sexual history and other private information are neither seen nor heard by other clients or providers. Although it can be challenging in facilities with multiple surgical bays or procedure rooms, a male circumcision team should pay special attention to ensure that each client has privacy in order to maintain the client's confidence in the care delivered. This confidence may play an important role in supporting continued and increased demand for circumcision services.

6.4. CONTENT OF MALE CIRCUMCISION GROUP EDUCATION, INCLUDING HIV PREVENTION

The following **objectives** (see sections 6.4.1–6.4.3) of male circumcision group education are adapted from the US President's Emergency Plan for AIDS Relief's best practices (2). Specific messages are in Annex 6.2.

6.4.1. Group education objective 1: general information on male circumcision as part of an HIV prevention strategy

Male circumcision clients should be provided with information about the following:

- **HIV, specifically:**
 - how HIV is transmitted
 - actions to reduce client's risk of acquiring or transmitting HIV (using condoms, and avoiding risky situations and multiple sexual partners)
 - HIV testing (options)
 - meaning of an HIV test result
 - timing of the proposed male circumcision procedure, depending on the client's age (that is, 10 years and older), HIV status and information obtained during screening
 - post-test support services (as appropriate), including, as relevant, antiretroviral treatment or the use of pre-exposure prophylaxis for the prevention of HIV
- **Male circumcision and overview of the circumcision procedure, specifically:**
 - the male circumcision service package and its benefits
 - what to expect during the circumcision procedure
 - risks before, during and after the procedure (adverse events)
 - the offer of partial protection against HIV, so there is still a need for a comprehensive HIV prevention strategy based on individual risk
 - conventional or device-based surgical circumcision methods available at the clinic, including advantages and disadvantages of each method (see Box 6.3)
 - eligibility criteria for circumcision—emphasizing exclusion criteria for circumcision at the clinic level—including bleeding disorders or haemophilia, pathologic phimosis and other conditions
 - postprocedure wound care (giving only a brief introduction but expounding on it after the procedure)
 - tetanus toxoid-containing vaccination, according to the national policy

Box 6.3. Specific male circumcision method considerations

If device-based surgical circumcision methods are not available at a site, there is no need to discuss this method.

If conventional and device-based surgical circumcision methods are available at the site, the provider may not be able to determine the method best suited for the client before screening. Therefore, information given on the different methods of circumcision can be basic until the client undergoes screening. Once the client's eligibility has been assessed, then more detailed information should be given about the method best suited to that client. If the client's screening indicates that he is eligible for either the conventional or device-based surgical circumcision method, then the client's preference can be taken into account. For example, some clients may prefer a device-based surgical method because there is no need for injection of local anaesthetic, while others may prefer the conventional surgical method, as they do not want to wear a device for a week.

6.4.2. Group education objective 2: specific information about circumcision screening and the procedure

Providers should convey general messages that help inform discussions during counselling sessions (see Annex 6.2. for details), such as the following:

- Male circumcision involves the removal of the foreskin, primarily to reduce a male's risk of acquiring HIV infection. The procedure also reduces a male's risk of contracting or developing other conditions, and it may also help him maintain better hygiene.
- Male circumcision provides only partial protection against HIV, as it reduces the risk of acquiring HIV through sexual intercourse by approximately 60–70% (3). Other risk reduction measures should be applied, including correct and consistent condom use based on individual risk.
- A man who has HIV can have the procedure if he is clinically well. However, male circumcision will not reduce this man's risk of transmitting HIV to his sexual partner(s).
- Screening will help confirm whether a client is eligible for male circumcision and may also determine the most suitable method. Screening is necessary because a small number of men have conditions that make it necessary to refer them to specialists for advice on circumcision.
- A client who has no documented evidence of receiving the full five to six doses of tetanus toxoid-containing vaccine may receive one dose of it before or at the time of male circumcision, depending on the circumcision method used and national tetanus vaccination policy. When the circumcision is performed using a device-based method—where the foreskin remains in situ for some days, presenting a higher risk for tetanus, such as through the use of an elastic collar compression method—then a client should be adequately protected against tetanus by immunization with tetanus toxoid-containing vaccine. If the client does not have documentation of the five to six doses of tetanus toxoid-containing vaccination, or he has documentation of three infant doses or one dose during adolescence or adulthood, then one booster dose must be given at least two weeks before device placement, or the client must receive two doses of the vaccine at least four weeks apart, with the second dose at least 14 days prior to device application (see Chapter 7, Box 7.3).
- Good postprocedure guidance reduces risks related to male circumcision (see Box 6.4):
 - Follow-up visits are critical to ensure proper wound care and assess healing.
 - Clients should abstain from sexual activity (including sexual intercourse and masturbation) for six weeks after conventional surgical circumcision or seven weeks after device-based surgical circumcision.
 - "...Not everyone will adhere to the abstinence recommendation, and for these clients, information about levels of risk should be made available so that those choosing to resume sex early can do so in a way that poses the least risk to them and their partners" (2). Condoms should be provided, as they reduce transmission of HIV and other sexually transmitted infections, and they are also useful to protect the newly healed wound.
 - Postprocedure care during the recovery period and until the skin has healed requires hygienic wound care, including the use of clean water. If the water supply is likely to be contaminated, water should be boiled and then cooled before use.
 - Traditional medicines and home remedies with substances such as soil, ash or animal dung should **NOT** be applied to the wound or healing skin.

Box 6.4. Talking to your client about sexual activity during the first six weeks postprocedure

Abstaining from masturbation and sexual activity for six weeks after circumcision is important for normal wound healing. Although this issue will be discussed in detail after the procedure, clients should understand some basic facts before undergoing circumcision. Tell your client:

- The safest approach to protect your health and the health of others is to completely abstain from sexual activity for six weeks.
- If you are absolutely unable to abstain from sexual activity, masturbation poses less risk than sexual intercourse, though it may mean that your wound takes longer to heal (longer than six weeks).
 - If you are wearing a device, you should abstain from all sexual activity, including masturbation, to avoid the device displacing, detaching or tearing off—and to avoid injuring your sexual partner(s). After the device is removed, you should make every effort to abstain from sexual activity for another six weeks.
- Until the wound heals completely, use a condom if you have sex with anyone, including with your regular partner. Clinics should supply condoms and provide information on other places to obtain them. Even after the skin has healed, the tissue of the circumcision wound does not have full strength for some months after the operation; condoms help protect the wound.

6.4.3. Group education objective 3: questions, answers and demonstration

- Address common concerns or fears, such as fear of the procedure, pain and injectable anaesthesia.
- Demonstrate correct male condom use.
- Prepare clients for having a more detailed discussion on male circumcision and HIV/AIDS during individual preprocedure counselling and the HIV test.

As discussed in Chapter 2, because male circumcision is a platform for reaching adolescent boys and men about HIV prevention, this service provides an opportunity to facilitate discussions on:

- gender norms (healthy versus unhealthy),
- sexual and reproductive health and rights, and
- harmful use of alcohol or other substances.

On the day of the procedure, it is important to keep to a minimum any discussion of issues that are not directly related to circumcision, HIV testing and condom use. Follow-up visits provide an excellent opportunity to continue education and counselling initiated before the circumcision, as well as to facilitate appropriate referrals.

6.5. MALE CIRCUMCISION PREPROCEDURE COUNSELLING FOR ADOLESCENT BOYS AND MEN

The following are **objectives** of male circumcision counselling:[†]

- Respond to the client's questions and concerns about the procedure.
- Reinforce key HIV risk reduction messages tailored to the client's individual needs, age and other relevant circumstances.

[†] Adapted from the *US President's Emergency Plan for AIDS Relief best practices guide (2)*

- Assess the client's ability to follow postprocedure guidance. For the sexually active client:
 - Identify factors that can support or hamper his ability to comply with the prescribed abstinence period, such as relationship status, ease of communication with sexual partner(s) and previous condom use.
 - Discuss risk reduction strategies, such as masturbation and condom use, to use if abstinence is not possible.
- Assess the client's understanding of wound care instructions. This is best done by giving instructions and then asking questions to check the client's understanding.
- Ensure that clients are making an informed decision without coercion or pressure. Allow clients and/or their parent(s)/guardian(s) to make their own informed decision on whether or not to choose male circumcision. (Details on obtaining informed consent/assent follow this section.)
- Respect the client's decision if he declines to undergo circumcision. Explore reason(s) for the refusal, reinforce the benefits of circumcision and invite the client to return for male circumcision services at a later date.
- Provide the client who is choosing to undergo circumcision with additional information on the conventional or device-based surgical circumcision method(s) available at the clinic. If there is more than one method for which a client is eligible, then help him select one (see Table 6.2).
- Obtain informed consent/assent for HIV testing, tetanus toxoid-containing vaccination (as applicable per country protocol) and male circumcision at the clinic (once screening is complete and the client is found eligible for the procedure).
- Offer HIV testing services before circumcision. For those who decline HIV testing, repeat the offer of the test during follow-up visits.
- Conduct appropriate post-test HIV counselling based on the client's HIV status and individual risk factors. Refer the client for other HIV-related post-test services as applicable.
- Adolescent boys who learn they are HIV positive may need additional counselling and support. Their parent(s)/guardian(s) will also need to be included in at least part of their counselling session.

Annex 6.3 has additional guidance on how to provide HIV testing and counselling services.

Table 6.2. Key information on conventional or device-based surgical circumcision methods

TOPIC	CONVENTIONAL SURGICAL METHODS	SOME DEVICE-BASED SURGICAL METHODS
Eligibility for clients who are under 18 years old	May be performed on males who are at least 10 years old, except forceps-guided method is not suitable for males under 15 years old or who have adhesions	Some types of devices may have limited eligibility for use in younger adolescent boys (10–14 years old) (see manufacturer's instructions for use)
First follow-up visit	Two days (for bandage removal)	Seven days (for device removal; device must be worn for seven days)
Second follow-up visit	Seven days	Usually 14 days
Anaesthesia	Local anaesthetic injection	Topical anaesthesia or local anaesthetic injection, depending on the type of device used (see manufacturer's instructions for use)
Sutures	Yes	No
Moderate or severe adverse events	Less than 2%	Less than 1%
Wound healing postprocedure	Six weeks after surgery	Six weeks after device removal
Recommended time for sexual abstinence	Six weeks or longer if wound not healed	Seven weeks (seven days while wearing device <i>and</i> six weeks for wound healing) or longer if wound not healed
Cosmetic	Suture marks may be apparent but fade with time	Good cosmetic results with the two World Health Organization prequalified device methods

6.6. INFORMED CONSENT/ASSENT FOR CIRCUMCISION AND HIV TESTING

Male circumcision is an elective invasive procedure with potential adverse events and complications. It is the provider's ethical and human rights obligation to give accurate and appropriate information to a client and to obtain his informed consent/assent. Informed consent/assent is more than having a client sign a document to record his agreement to undergo circumcision. It is the process of ensuring that clients or their parent(s)/guardian(s) understand the procedure and its associated benefits and risks, and voluntarily—freely and without coercion or pressure—make an informed decision to undergo the circumcision procedure. Only clients who have appropriate decision-making capacities and legal status as adults can give their informed consent to medical care (4). In the case of a minor, his parent(s)/guardian(s) must sign the consent document; providers should also seek the assent of minors. Providers should review local laws regarding the age at which consent can be given for male circumcision. Consent/assent must be documented (1).

Because male circumcision services help individuals learn their HIV status, education and counselling should address simultaneously both HIV testing and male circumcision procedure. The World Health Organization's 5 Cs approach for HIV testing services follows in Section 6.6.3, and key HIV testing messages are in Annex 6.3.

6.6.1. Essential elements of informed consent/assent

The following elements should be included in the process to obtain the client's informed consent/assent.

- **Assess the capacity of the client to understand** and make his decision about circumcision based on information provided (see Box 6.5). For clients who are minors or who have mental illness or developmental delays, which could interfere with their understanding of male circumcision and its role in HIV prevention, the decision about the procedure must be made by parent(s)/guardian(s). Clients who are hearing-impaired or have a language barrier need an interpreter present during the consent/assent process to ensure that they understand the information relayed.

Box 6.5. Ensure client's understanding

Every effort should be made to ensure that the person who will undergo male circumcision **understands** the information provided to the best of his ability, **chooses** to undergo the procedure freely and **gives** his informed consent/assent freely. If health care providers assess that the client is intoxicated by alcohol or under the influence of drugs, then the decision about circumcision should be deferred until the client is fully able to comprehend the information given.

- **Provide information.** Clients—and their parent(s)/guardian(s), as applicable—should be given information in everyday, local language. They should be informed about **all** major risks and benefits of male circumcision and the implications of HIV testing (if HIV testing is part of the package of care offered).
- **Ask checking questions, or ask the client to summarize what he has learned**, to assess his understanding of the information provided.
- **Assure the client that he is free to choose** whether or not to become circumcised. If there is any indication that the client is not ready to provide consent/assent, advise him to think about it for a few days before making a decision. Younger clients who are legal minors should be aware of their rights to give or refuse assent to undergo male circumcision—even if their parent(s)/guardian(s) have given informed consent.
- **Obtain consent/assent at the appropriate time.** Once clients have been educated and counselled, found eligible for circumcision through a clinical screening (see Chapter 7), received answers to any questions and decided to undergo the circumcision procedure, ask them to sign a consent/assent document. If the client is a minor, ask the parent(s)/guardian(s) to sign a consent document and the minor to sign an assent document. For clients who are illiterate, verbal consent/assent is acceptable but should still be documented (see Box 6.6).

Box 6.6. Documenting consent/assent when the client cannot read or write

Provider should follow national laws about obtaining consent/assent. Unless otherwise specified by national law, the following principles apply:

- Oral consent/assent is acceptable from clients who are illiterate because they cannot read or sign informed consent/assent forms.
- The informed consent/assent process requires providers to ensure that 1) the information they provide to clients is in a form the client understands, and 2) a literate witness is available to sign on behalf of the client to document that he has given oral consent.
- In addition to the signature of a literate witness, clients who are illiterate should document their agreement to proceed with circumcision by placing their thumbprint on the consent/assent form.
- Whenever possible, clients should choose their own literate witness.

6.6.2. Informed consent/assent from adolescent boys

Young adolescents (10–14 years old) and minors (usually defined as under 18 years old) need special consideration when obtaining informed consent/assent. Members of the male circumcision team should know how to respond to an adolescent boy's request for circumcision in a way that respects the boy's confidentiality but does not put the health care provider in conflict with the law. Special considerations and opportunities relevant to obtaining consent/assent when working with adolescents follow:

- **Providers need to know the legal age at which an adolescent is allowed to give consent/assent to undergo the circumcision procedure** because this age may vary by country and by service or procedure. Younger male circumcision clients should be asked for their identification cards to confirm their age. For example, in some countries, an adolescent boy may be able to give consent/assent for HIV testing or receive condoms at an age younger than the age at which he can consent/assent to a surgical procedure such as circumcision. The ministries of health and national medical or nursing associations should be able to provide information on national rules and regulations.
- Providers also need to know how to engage the client's parent(s)/guardian(s) in the consent/assent process while respecting the rights of the client. **If a client is not yet able to give consent for the circumcision procedure, his parent(s)/guardian(s) must provide written consent after receiving complete information about the procedure.** Every effort should be made to confirm that the person providing consent on behalf of the minor is truly the minor's parent(s)/guardian(s). The minor's parent(s)/guardian(s) should also be encouraged to base their decision on the best interests of the child.
- Even if the law does not allow a minor to give his own consent, circumcision providers should take special care to explain the risks and benefits to him in a way that is appropriate for his age and mental capacity so he comprehends the message. If the minor has sufficient cognitive capacity, **he should receive the opportunity to give or withhold assent** to the procedure. If a minor does not give assent, then circumcision should not proceed. An offer should be made to provide further information to him and his parent(s)/guardian(s), and to arrange a visit at a future date.
- Male circumcision services also offer an opportunity to make contact with adolescent boys (and their partners) and provide them with information and counselling on sexual and reproductive health. Adequate time should be allowed for education and counselling before and after the circumcision, but the focus of the interaction should remain on information related to circumcision and its outcome. Adolescent boys should be encouraged to return after the procedure, not just for follow-up but also for further education, counselling and referral to other services based on their individual needs.
- With regard to postprocedure counselling and proper wound care, it is advisable to provide informational materials and to counsel the adolescent boy with his parent(s)/guardian(s) present. Although it is recommended that the provider speak to the adolescent boy alone, if possible, the parent(s)/guardian(s) should be informed on how to support the minor to avoid infection and adverse events.

Informed consent from a minor's parent(s)/guardian(s) is documented on a separate form. The individual counsellor and the male circumcision team should ensure that the client has been properly informed (for example, about the procedure, its risks and benefits, and the need for continued condom use); the information has been given in a way that is understandable to the client and his parent(s)/guardian(s) (for example, by using their local language); and the client has had a chance to ask questions. The client should then be given time to reflect on what he has learned before being asked to sign the consent/assent document (see the sample consent form for adolescent boys and men in Annex 6.3).

6.6.3. The World Health Organization's 5 Cs approach for HIV testing services[‡]

The following 5 Cs principles, set forth by the World Health Organization, should be adhered to for HIV testing services:

- consent
- confidentiality
- counselling

[‡] Adapted from (5)

- correct test results
- connection (linkage to prevention, treatment and care services)

Coerced testing is never appropriate, whether that coercion comes from a health care provider, an employer, person with authority (such as immigration services), sexual partner(s) or family member. **The 5 Cs apply to HIV testing in all circumstances** and are discussed below.

6.6.3.1. Consent/assent

Clients who receive HIV testing must give informed consent/assent to be tested and counselled (see Box 6.7). Verbal consent/assent is sufficient; written consent/assent is not required. Clients should be informed of the process for HIV testing and counselling and of their right to decline testing.

Box 6.7. Essential information needed to obtain informed consent/assent

- Describe the purpose of the male circumcision procedure.
- Describe the procedure and its duration.
- Explain that male circumcision is permanent.
- Explain potential risks and benefits of male circumcision.
- Explain that it is a voluntary procedure.
- Evaluate the client's understanding of the key information provided.
- Allow time for the client to ask questions and receive answers.

6.6.3.2. Confidentiality

The HIV testing process must be confidential. The discussion between the provider conducting the HIV test and the client cannot be disclosed to anyone else without an expressed consent/assent from the client to do so. Confidentiality should be respected, but it should not be allowed to reinforce secrecy, stigma or shame. Counsellors should discuss, among other issues, whom the client may wish to inform about the test result and how he would like this communication done. The client should be counselled that sharing his test result with a sexual partner(s), family member, another trusted person and health care provider is often highly beneficial to the client's mental health (that is, enables social support) and will help identify others who need HIV testing.

6.6.3.3. Counselling

HIV pre-testing information can be provided in a group setting, but all clients should have the opportunity to ask questions in a private setting if they request it. All HIV testing must be accompanied by appropriate and high-quality post-test counselling based on the specific HIV test result. Quality assurance mechanisms as well as supportive supervision and mentoring systems should be in place to ensure that the provision of high-quality counselling is achieved.

6.6.3.4. Correct test results

HIV testing providers should strive to achieve high-quality testing services, and quality assurance mechanisms should ensure that people receive correct diagnoses. Quality assurance may include both internal and external measures that should be supported by the national reference laboratory. All clients who receive HIV-positive diagnoses should be retested to verify their diagnoses before initiation of HIV care or treatment.

6.6.3.5. Connection

Linkage to prevention, treatment and care services should include effective and appropriate follow-up, including long-term prevention and treatment support. Providing HIV testing in an area where there is no access to care or poor linkage to care, including antiretroviral therapy, has limited benefits for those who have to live with HIV.

6.7. MALE CIRCUMCISION POSTPROCEDURE COUNSELLING FOR ADOLESCENT BOYS AND MEN

The counsellor should ask questions to ensure that the client—and, if he is a minor, his parent(s)/guardian(s)—understands the postprocedure instructions and follow-up appointment schedule. Detailed information on postprocedure counselling for each follow-up visit is in Chapter 10, but the primary objectives and key messages for postprocedure counselling follow:

- confirming that the client understands wound care instructions and the need for clean clothing, and has the means for contacting clinical staff with any questions
- counselling the client to keep the wound dry for the first 24–48 hours while the dressing is in place
- counselling the client to use clean water (bottled or boiled and cooled) to wash the wound until the skin heals
- ensuring that the client understands that he must not apply any substance to the wound that was not prescribed by his circumcision provider because the use of traditional medicines, ashes, dung and home remedies can result in a dangerous infection, including tetanus
- describing to the client the signs and symptoms of adverse events, recommendations for contacting clinic staff and when to return to the clinic when an adverse event is suspected (see Chapter 10)
- determining the client's ability to comply with the prescribed follow-up schedule, including transport to the male circumcision clinic or to a clinic near the client's residence, given his work or school schedule and family commitments
- counselling clients and their sexual partners on the necessity for abstinence from sexual intercourse, including masturbation; if abstinence is not possible, counselling on the need for condom use during the healing period and offering recommendations to improve compliance with abstinence or mitigate an elevated risk of acquiring or transmitting HIV infection
- reinforcing to clients the partially protective benefit of male circumcision against HIV infection and the need to reduce risk behaviours that increase exposure to HIV and other sexually transmitted infections
- discussing effective prevention options, such as using condoms correctly and consistently, having sexual partners tested, reducing sexual partners, taking pre-exposure prophylaxis and engaging in other HIV prevention measures
- providing clients with written wound care instructions
- repeating to clients the wound care instructions at each follow-up visit, especially at the 48-hour visit, as this may be the time when the dressing is removed, thereby presenting the first opportunity for potential application of traditional remedy to the wound

KEY MESSAGES

- Group education supports counselling services and provides the bulk of information about HIV testing services, HIV prevention and male circumcision. It reduces the need for intensive, individualized pre-test HIV counselling.
- Individual preprocedure and postprocedure counselling is used to respond to the client's questions and concerns about the procedure; reinforce key HIV risk reduction messages tailored to the client; and educate the client about proper wound care, hygiene and the importance of abstinence while the wound is healing.
- Male circumcision providers have a duty to ensure that voluntary and informed consent/assent is obtained from the client before the procedure is performed, and maintain the client's confidentiality and privacy.
- Providers must work to establish a trusting relationship with clients by being respectful, empathetic and nonjudgemental towards them at all times.
- Clients need to be reminded of the partial protective effect of male circumcision against acquiring HIV infection and the need for continued correct and consistent condom use, as well as other risk reduction measures.

ANNEX 6.1. COMMUNICATION TECHNIQUES[§]

Various communication techniques may be used strategically to assure a supportive environment that meets the needs of an individual and results in a positive client experience. Using different types of communication—including nonverbal or the use of body language, eye contact and active listening—is as important as verbal communication. Establishing a confidential relationship that is conducive to sharing information between the provider and the client, from the start, is important to help a client feel welcome and at ease. For example, the provider can do the following:

- greeting the client by name
- introducing themselves by name to the client
- making eye contact with the client
- shaking hands with the client, if appropriate
- being friendly and welcoming to the client
- having empathy for and being nonjudgemental with the client
- engaging in nonverbal communications with the client

Other basic communication skills to use when talking with clients include active listening, acknowledging feelings, asking questions and summarizing what the client says.

Active listening involves paying attention to a client in a way that shows respect, interest and empathy (more on this below). Active listening is paying attention to the content of the client’s words and the feelings and worries expressed in his tone of voice, facial expression and posture.

Acknowledging feelings is a communication skill that has to do with the emotional layer of a conversation. The purpose of acknowledging feelings is to let a client know the provider recognizes and understands his feelings on the topic being discussed. It involves identifying the emotion a client seems to be feeling, based on the client’s words, facial expression, body language and other nonverbal cues. Most health care providers are good at giving information and are often tempted to solve emotional situations through the provision of information. However, most people need to have their feelings acknowledged and discussed before they are able to truly hear and receive information. Ignoring or making light of a client’s feelings can cause him to stop communicating and stop hearing what is being said. The following types of phrases can acknowledge a client’s feelings:

- It seems to me you are feeling...
- It sounds like you...
- What I hear you saying is...

It is important that providers use language they are truly comfortable with so that the conversation sounds genuine and not awkward.

Asking questions can enrich a conversation, yet the way questions are asked influences the responses given. Open-ended questions are those that cannot be answered with a simple yes-or-no answer. They usually begin with how, what or why—for example, “will you say a little more about why you think that?” or “how did you feel when that happened?” Open-ended questions help people open up and express their feelings, encourage more detailed conversations and give clients more control over what they wish to share. Asking skilful open-ended questions will help providers learn about clients without clients feeling interrogated. Closed-ended questions, on the other hand, often prompt a short, yes-or-no type of an answer that can sometimes lack details needed to better care for the client.

[§] Reproduced from (2)

Summarizing pulls together conversational threads, so the client can understand the whole picture; it also helps to ensure that the client and provider understand each other correctly. This process helps the provider identify the next steps the client should take.

Encouraging can affirm a client's decision to undergo male circumcision. Remind the person throughout his visit that by choosing circumcision, he is demonstrating responsibility for his health, health of his loved ones and health of the society, in general. Remind him that male circumcision is safe and effective, and that he can help assure his own smooth course by complying with the simple care and recovery guidelines provided. Also remind him that the temporary pain/discomfort and inconvenience involved will lead to a lifetime of benefits.

Maintaining confidentiality is always important in clinical settings. Every provider is ethically bound to keep confidential all personal information about clients who are under their care. When clients trust that their personal disclosures to providers are confidential, they are less likely to withhold important information and more likely to seek support for what concerns them most.

Showing empathy is the act of seeing the world through another person's eyes and understanding how that person feels from their point of view. It is a characteristic of an encouraging and trusting relationship, and the ability to relate is essential to supporting clients. It is possible to feel empathy for someone even if there is disagreement with the decision they make. The ability to empathize with clients goes hand-in-hand with having respect for them. Respect for the client and his situation is a requirement for all effective communication.

Therefore, providers should do the following:

- protect confidentiality
- remain nonjudgemental
- enable clients to explore their feelings
- provide clients the information they need to make informed decisions
- assist clients in making decisions but not make decisions for clients
- facilitate referrals as needed

A good communicator has the following characteristics:

- kind, understanding and supportive
- able to exercise confidentiality
- responsible, a good listener and easy to talk to
- open and nonjudgemental
- always available
- aware of when to speak and when to listen
- helpful and caring
- trustworthy
- respectful of clients
- knowledgeable on the subject

ANNEX 6.2. CORE CONTENT AND KEY MESSAGES FOR MALE CIRCUMCISION EDUCATION AND COUNSELLING¹

GENERAL DESCRIPTION OF HIV AND AIDS	
Provide the client with general information on HIV and AIDS and risk reduction. Key messages include:	<ul style="list-style-type: none"> • HIV causes AIDS. • Even when people living with HIV feel and look healthy, they can pass the infection to other people. • Persons diagnosed with HIV can live a long and healthy life by taking antiretroviral treatment, in addition to other care and support services.
MODES OF TRANSMISSION	
Identify the most common methods of HIV transmission and the hierarchy of risk associated. Key messages include:	<ul style="list-style-type: none"> • HIV is transmitted or passed into the body in four body fluids: <ul style="list-style-type: none"> • Semen (exchanged through sexual intercourse via vaginal, anal or oral penetration) • Vaginal fluids (exchanged through penile or oral intercourse) • Blood (exchanged through sharing contaminated injection equipment, open sores or wounds, or infected blood transfusions) • Breast milk (exchanged through lactation to feeding infants) • The most common way to get HIV is by having sexual contact without a condom with an HIV-positive person.
KNOWN RISK FACTORS FOR HIV	
Identify behaviors, physical characteristics and other factors that put persons at an elevated risk of contracting HIV. Key messages include:	<ul style="list-style-type: none"> • Behaviors that increase the chance of contracting HIV: <ul style="list-style-type: none"> • Not using condoms during sexual intercourse • Having more than one sexual partner • Use of unclean needles • Physiological factors that increase the chance of contracting HIV: <ul style="list-style-type: none"> • The presence of other sexually transmitted infections (STIs) or sores on or around the genitals • Not being circumcised • Someone may have HIV and not know it if he/she: <ul style="list-style-type: none"> • Has not been tested recently for HIV • Does not know his/her partner(s)'s HIV status or if his/her partner(s) have ever been tested

¹ Reproduced with permission from (2)

RISK REDUCTION METHODS

Recommend specific actions that clients and secondary audiences can take to reduce the risk of HIV transmission. Key messages include:

- Always use condoms when having sex, including anal and vaginal intercourse.
 - Condoms are available at the VMMC site, as well as at (these other places within the community).
- If you have more than one sexual partner, consider reducing your number of sexual partners.
- Men who do not have HIV should consider getting circumcised.
- Know your HIV status and know your partner's (or partners') HIV status.
 - Testing regularly for HIV can help ensure timely access to HIV treatment should you become infected and reduces the risk of transmitting HIV to your sexual partner(s).
 - Consider testing for HIV again with your partner(s) to make it easier to share your HIV results with each other (both negative and positive).
 - After you both test, agree with your partner(s) not to have sex with others, to avoid STIs, including HIV.
- Confidential HIV testing and STI screening are part of VMMC services. HIV testing is optional and, while recommended, is not a requirement to receive VMMC services. If you have an STI, you will receive treatment and be asked to come back another day for the surgery. If you choose not to test now, you can test after the procedure or on the day of your follow up visit.
- If you are HIV-positive, being linked with ongoing care and accessing antiretroviral treatment will better enable you to live a healthy life and reduce the risk of transmitting HIV to your sexual partner(s).

VMMC BASIC FACTS

Benefits, link to HIV prevention, partial protection and more. Key messages include: [...]

- VMMC is the removal of the foreskin to reduce males' risk of acquiring HIV infection through heterosexual intercourse.
- VMMC can be performed by surgical procedure or by use of a device (see section on Devices).
- There are cells in the inner layer of the foreskin that are near to the surface through which HIV can enter the body more easily. During circumcision, this part of the foreskin is removed. After circumcision, the remaining part is less likely to tear and more difficult for HIV to penetrate.
- In addition to reducing the risk of acquiring HIV, circumcised men are at lower risk of contracting other STIs like syphilis and gonorrhoea.
- Circumcised men are at lower risk of infections of the urinary tract system and cancer of the penis.
- Circumcised men might find it easier to maintain cleanliness of the penis and improved hygiene.
- VMMC offers only partial protection against acquiring HIV.
- Circumcised men still need to practice safer sexual practices after VMMC. Correct and consistent condom use is critical, and particularly, if for any reason you have sex before you are fully healed.
- VMMC does not directly protect your partner(s) from HIV, but it decreases your risk of getting HIV and giving it to them, and it reduces the risk of cervical cancer for female partners.
- HIV-positive men can be circumcised, but VMMC will not reduce the risk of transmitting HIV to their partners. There is a window of a few weeks after circumcision before the healing is complete when the risk that an HIV-infected man could transmit the virus to a sexual partner actually increases. It's important to take steps to reduce this risk.[...]
- In sites where both standard VMMC surgery and devices are available, group education sessions should include information about the different options for male circumcision, including the benefits and risks of each method. Please see section on Devices for more information.

POST-OPERATIVE CARE AND THE HEALING PERIOD

Note: this topic is first introduced here during group/general education discussion and will be reinforced with more detail during the immediate post-operative counseling.

Provide clients and their partners with detailed information on the importance of abstinence from sexual activity, including sexual intercourse and masturbation, during the six-week healing period after VMMC. Offer recommendations to improve compliance with abstinence and for those who raise concerns about complying, suggest that they discuss other strategies to reduce HIV transmission risk with the counselor during the individual session. Emphasize the importance of compliance to post-operative follow-up visits and following the provider's instructions on wound care and hygiene. Key messages include:

- The doctor will send you home after VMMC with tablets to be taken for pain relief after surgery/device male circumcision.
- You will be sent home with instructions on caring for your wound and when to come back for follow-up appointments. It is very important that you follow all of these instructions.
- Abstinence from all sexual intercourse and masturbation for six weeks after surgery or male circumcision device removal is strongly required.
 - For HIV-negative men, sexual intercourse during the six-week healing period increases the risk of acquiring HIV.
 - For HIV-positive men, sexual intercourse during the six-week healing period increases the risk of transmitting HIV to sexual partner(s).
- If you are absolutely unable to abstain for the entire healing period, masturbation poses less risk than sexual intercourse (though, it may result in a longer time for the wound to heal).
- Condoms are available at the VMMC site and will be offered at client's discharge.
- Discuss the six-week abstinence period with your partner(s) before and after the VMMC procedure.
- Do not put any herbs, cow dung or any other substances on the wound. It should be kept dry.

DEMONSTRATE PROPER CONDOM USE [...]

Conduct condom demonstration (if possible, for male and female condoms) according to national guidelines. Include the use of props, such as penis models, in the demonstration. If appropriate in the group setting, ask clients to demonstrate proper condom use on the penis model.

ANNEX 6.3. HIV TESTING SERVICES**

Male circumcision services offer an important opportunity to help individuals learn their HIV status, so HIV tests should be consistently offered in male circumcision programmes. Education and counselling will address HIV testing and male circumcision services at the same time; key messages are highlighted in this section. The 2015 updated HIV testing services guidelines (5) state that since most people now receive their HIV test results on the day of the test, it is no longer necessary to offer intensive, individual HIV pre-test counselling; in fact, doing so may create barriers to service delivery. Pre-test information can be provided through posters and group education. It is important to document informed consent/assent for the test and follow national guidelines and training standards for providing HIV testing services. Self-testing is also a recommended approach.

A6.3.1. Post-test counselling for clients who test negative for HIV

Where appropriate and according to the age of the HIV-negative client, post-test counselling should include the following:

- explanation of test results and HIV status
- education on methods to prevent HIV
- provision of male condoms (at least), female condoms (if available) and lubricant
- emphasis on knowing the status of sexual partner(s), and availability of counselling and testing services for partners and couples
- referral and linkage to relevant HIV prevention services, including male circumcision and pre-exposure prophylaxis for people at substantial, ongoing HIV risk
- retesting dependents on risk exposure

Because HIV transmission through a wound may occur more readily, emphasize the need to abstain from any sexual activity during the six-week postprocedure healing period. Abstinence helps the wound heal and prevents exposure to HIV.

A6.3.2. Post-test counselling for clients who test positive for HIV

Clients who are positive for HIV may be in shock and unable to absorb the education or counselling needed. They will need follow-up counselling and linkage to HIV care and treatment, including screening for tuberculosis. If feasible, it may help to accompany them to the clinic where HIV treatment is available (see Box A6.3.1). If clinically eligible for male circumcision, an HIV-positive client should be able to access male circumcision services if he chooses to do so, although he may want to establish his clinical condition (for example, viral load) and ensure that he is stabilized on antiretroviral therapy before undergoing the invasive procedure.

If parent(s)/guardian(s) are not present when a minor tests positive for HIV, you must wait for the parent(s)/guardian(s) to be present before delivering the test results. Consider the national HIV test guidelines for minors.

** Adapted from (1)

Box A6.3.1. Post-test counselling for clients who test positive for HIV

Emphasize to the client that any sexual contact during the six weeks following circumcision and/or until the wound is completely healed greatly increases the risk of transmitting HIV to his sexual partner(s).

- Explain test results and the diagnosis.
- Give the client time to consider the results and cope emotionally.
- Discuss the client's immediate concerns.
- Identify someone in the client's social network who can provide support.
- Provide clear information on antiretroviral therapy, benefits for maintaining health, reducing risk of HIV transmission and starting treatment.
- Make an active referral with a specific time and date for starting antiretroviral therapy.
- Discuss barriers to care and arrange follow-up for any clients unable to enrol in HIV care and treatment on the day of their diagnosis.
- Provide information on how to prevent HIV transmission, including reduced transmission risk when virally suppressed on antiretroviral therapy, and provide male and female condoms and lubricant.
- Discuss possible disclosure of test result to others, and risks and benefits of this disclosure, particularly among couples or partners. Offer couples counselling to support the disclosure.
- Encourage and offer partners, children and other family members HIV tests.
- Assess risk for intimate partner violence; discuss steps to ensure safety.
- Assess the client's or his partner's (or partners') risk of suicide, depression and other mental health consequences as a result of the diagnosis.
- Provide additional referrals for prevention, counselling, support and other services (for example, tuberculosis screening and referral, sexually transmitted infection screening and treatment, and contraception).
- Encourage the client to ask additional questions.

ANNEX 6.4. SAMPLE CONTENT FOR CIRCUMCISION CONSENT/ASSENT FORMS

Consent form for adult male clients to sign

Circumcision helps prevent a man from acquiring HIV and some other infections, and makes it easier to keep the penis clean during washing. However, during and after the operation, something can go wrong—this happens to about one in 50 men (6–10). The most common problems are bleeding, infection or pain, but these problems are almost always easy to treat and almost always get better completely. Very rarely, there may be a severe infection, including tetanus, which may lead to death (less than one for every 1 million people) (11).

My name is _____, and I am asking that male circumcision (removal of my foreskin) be done on me under local anaesthesia. I give you my permission to do this procedure.

Signature Date.....

(Client requesting male circumcision)

My name is _____. I am the **counsellor/provider** who has given information to the above client. I have given information about:

- definition of male circumcision,
- benefits of male circumcision,
- male circumcision procedure,
- risks of male circumcision,
- preparing for male circumcision,
- what to do after male circumcision,
- what to do about any adverse events or problems after male circumcision,
- an emergency contact number and information about where to go in an emergency, and
- importance of using condoms after male circumcision.

I have given the client an opportunity to ask me questions about all of the above topics. I have asked the client some questions to make sure that he understands the information I gave. To the best of my assessment, the client is capable of giving consent and has enough information to decide whether to proceed with male circumcision (removal of the foreskin).

Signature

Date

(Counsellor/provider)

Consent form for parent(s)/guardian(s) to sign

Circumcision helps prevent a man from acquiring HIV and some other infections, and makes it easier to keep the penis clean during washing. However, during and after the operation, something can go wrong—this happens to about one in 50 men (6–10). The most common problems are bleeding, infection or pain, but these problems are almost always easy to treat and almost always get better completely. Very rarely, there may be a severe infection, including tetanus, which may lead to death (less than one for every 1 million people) (11).

Name of parent(s)/guardian(s):

Contact address:

Phone number:

Name of client:

Consent

I am the client's parent(s)/guardian(s). I am asking you to do a male circumcision (removal of foreskin) on my son/ward under local anaesthesia. I give you permission to do this procedure.

Signature

Date.....

(Parent(s)/guardian(s) requesting male circumcision on behalf of a minor)

Assent form to sign by counsellors/providers

If the client is a minor and the parent(s)/guardian(s) have provided informed consent, the provider should sign below to indicate that assent was also obtained.

My name is _____. I am the **counsellor/provider** who has given information to the above client. I have given information about:

- definition of male circumcision,
- benefits of male circumcision,
- male circumcision procedure,
- risks of male circumcision,
- preparing for male circumcision,
- what to do after male circumcision,
- what to do about any adverse events or problems after male circumcision,
- an emergency contact number and information about where to go in an emergency, and
- importance of using condoms after male circumcision.

I have given the client an opportunity to ask me questions about all of the above topics. I have asked the client some questions to make sure that he understands the information I gave. To the best of my assessment, the client has enough information to decide whether to proceed with male circumcision (removal of the foreskin), **is capable of giving assent and has given assent.**

Signature

Date
(Counsellor/provider)

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CHAPTER 7

PREPROCEDURE SCREENING OF CLIENTS AND PREPARATIONS FOR THE CIRCUMCISION PROCEDURE



This chapter provides information on the following:

- screening clients for male circumcision: obtain a focused history from the client requesting services; identify history of and need for tetanus toxoid-containing vaccination; and perform a focused physical examination, including an examination of the male genitalia
- understanding the anatomy of the penis, including the surface and internal anatomy
- identifying, through history taking and physical examination, the contraindications for performing male circumcision at the clinic level
- selecting the correct conventional or device-based surgical circumcision procedure based on the client's age, any contraindications for circumcision and the client's preferences for a circumcision method
- performing preprocedure preparations for male circumcision
- using or adapting the World Health Organization's *Surgical safety checklist (1)*, which has been modified for male circumcision, when screening clients and undertaking preprocedure preparations

7.1. SCREENING ADOLESCENT AND ADULT CLIENTS

The circumcision team needs to ensure that the client is eligible for the conventional or device-based surgical circumcision procedure and that there are no absolute contraindications to circumcision in a clinic staffed with a team of midlevel providers doing the procedure. To make this determination, a provider should take a focused medical history and perform a focused general examination, including a detailed examination of the penis. Male circumcision clients must undergo this screening before they can provide informed consent/assent to undergo the procedure and choose an available circumcision method (where applicable).

If a client presents with contraindications to the procedure, he should be referred to a specialist, district hospital or higher level of care (see Box 7.1). If a client presents with comorbidities that pose increased risks (for example, acute malarial illness, diabetes or hypertension), the procedure should be delayed until the condition is resolved or well managed (see Section 7.5). A number of conditions listed in Table 7.1 (see Section 7.5), such as a minor degree of penile warts, are not contraindications to circumcision done at the clinic level. In such cases, whether the circumcision can be performed at a clinic will depend on the experience of the provider performing the procedure. If there is any doubt about a client's eligibility, he should be referred to a specialist, district hospital or higher level of care.

Box 7.1. Establishing referral pathways

As discussed in Chapter 2, male circumcision providers should establish referral pathways so that there are no bureaucratic obstacles to client referrals. Male circumcision staff should work together with specialists and staff at referral centres to agree on protocols for receiving and treating clients; **when in doubt, refer the client to a specialist, district hospital or higher level of care.** In turn, specialists and staff at referral centres should appreciate the skill level of staff at the male circumcision clinic but also recognize that there is difficulty in assessing some cases. In the event of an inappropriate referral, specialists should provide supportive feedback to educate male circumcision clinic staff and to encourage good care and safe practice. The specialist should bear in mind that it is safer to refer too many clients than too few.

Adolescent boys seeking male circumcision services may be at very different stages of intellectual, physical, psychological and social development, even among those who are of the same age. They may also differ in terms of their sexual behaviour, roles and responsibilities within the family and community, and in their transitions into adulthood. Providers need to be aware of and responsive to these differences in development (2). Below are key considerations for screening adolescent boys:

- For all underage adolescent boys, as they may know less about their personal and family medical history, providers should attempt to obtain the medical history both from the client and his parent(s)/guardian(s).
- The physical and developmental maturity of the adolescent client should be considered by the provider when taking a medical history and performing a physical examination. For younger and less mature adolescent boys, special care needs to be taken to explain screening procedures in an age-appropriate way.
- If there is a conflict between the adolescent's wish for privacy and the presence of his parent(s)/guardian(s), this may be managed by using a curtain to screen the examination area. However, sometimes more complete privacy is required, for example, when asking questions about sexual activity.
- Assessment of the adolescent boy's foreskin and penile development is necessary to choose an appropriate method of circumcision. The forceps-guided surgical method should not be used in adolescent boys under 15 years of age or any male who has adhesions—or any male whose tip of the glans cannot be clearly identified by palpating the foreskin—because of difficulty identifying the glans and the risk of glans amputation. Also, circumcision using some devices may be contraindicated if there is tight phimosis, which is often the case in younger adolescent boys. For any device being considered for an adolescent client, the provider should ensure that the device is prequalified by the World Health Organization and should consult the device manufacturer's instructions for use.

7.2. INITIATION OF SCREENING

Circumcision screening may be the first opportunity for a one-to-one interaction between the trained health care provider and the client. At this time, the provider should begin recording observations in the client's record, if such documentation has not yet started (see sample record form in Annex 7.1), and confirm:

- The client's name, address and cellphone number are in the chart.
- The client's chart has the correct chart number (this is especially important in places where many clients will have the same or similar names).
- The client knows that male circumcision is a conventional or device-based surgical procedure (see Box 7.2) to permanently remove the foreskin.
- The client knows that he is free to choose circumcision or not, and the choice is voluntary.
- The client has been informed about the risks, benefits and limitations of male circumcision, as described in Chapters 1 and 6.
- There is documented evidence in the chart of tetanus toxoid-containing vaccination.
- Depending on his age, the client has received HIV counselling and has been offered testing.

Box 7.2. Screen to identify circumcision method

In clinics where both conventional and device-based surgical circumcision methods are available, specific information about risks and benefits of the method(s) suitable for the particular client will depend on the screening. Therefore, information about a particular method can be given only after screening has been done and the method of choice has been selected (see Section 7.5).

Screening should be performed in privacy and before the client is in the procedure room. The provider should assure the client of the confidentiality of all information gathered. Findings from both the history taking and examination need to be documented in the client's record at the time of taking the history.

7.3. TAKING A HISTORY

A focused medical history should be taken to determine any:

- contraindications to circumcision done at the clinic level,
- indication to defer circumcision, and
- specific client needs that require further evaluation—either at the clinic or through referral to an appropriate specialist service or higher level of care.

When the client is an adolescent, efforts should be made to obtain the medical history from both the client and his parent(s)/guardian(s) because the adolescent may not know fully his own or the family's medical history. The medical history should assess general health and reproductive and sexual health, as discussed below.

7.3.1. General health

- Ask whether the client has any **current health problems**. Ask about any **illness in the client's family**. Ask about any **previous surgical operations** the client has had.

Taking a careful history enables the provider to identify conditions that contraindicate circumcision at the clinic level and/or require specialist referral. (A description of these conditions is integrated below and presented in Table 7.1, Section 7.5) **Note that a client's eligibility for circumcision at a clinic staffed by midlevel providers will depend on findings from the completed assessment.**

- **Ask about tetanus toxoid-containing vaccination.** If the client is an adolescent, ask his parent(s)/guardian(s)—follow guidelines in Box 7.3.

Identifying clients who need tetanus toxoid-containing vaccination is a critical safety measure in male circumcision services. Tetanus is a serious but preventable condition that may occur if tetanus spores contaminate wounds. If the client has no documented evidence of vaccination or is not adequately vaccinated, the provider should offer the client vaccination as indicated by national policy and based on the client's vaccination status and circumcision method selected.

Box 7.3. Guidelines for protection against tetanus—key to safe male circumcision

The primary goal of tetanus toxoid-containing vaccination is to reduce the risk of tetanus following circumcision, including the tetanus risk related to specific methods, poor hygienic conditions and wound practices. In low- to middle-income countries, many male circumcision clients have incomplete vaccinations and are not protected against tetanus. **Based on national policy, circumcision method and screening findings**, the provider should determine the protocol below that is relevant for the client.

For use of a method where foreskin is left in situ and removed several days after application, such as the elastic collar compression method, ALL clients need tetanus toxoid-containing vaccination prior to device placement if they do not have documentation indicating receipt of five tetanus toxoid-containing vaccine doses. For those clients with documented evidence of having received three infant doses, or one dose during adolescence or adulthood, a tetanus toxoid-containing vaccine booster is needed at least two weeks before device placement. For all other adolescent boys and men, a minimum of two doses are needed, with the first dose at least six weeks prior to device placement and the second dose needed four weeks later—at least two weeks prior to device placement.

For all other conventional surgical circumcision methods, national tetanus toxoid-containing vaccination policy should be followed. **Unless a client has documented evidence of having received the full five or six doses (three primary plus three child and adolescent booster doses) of tetanus toxoid-containing vaccine, the World Health Organization advises giving at least a single dose of tetanus toxoid-containing vaccine before or at the time of male circumcision, depending on national policy, practices and tetanus burden. The World Health Organization recognizes that this single dose will provide varying (or no) antibody protection, depending on the client.**

In a client who has never received any tetanus toxoid-containing vaccination, a single dose will **not** protect against tetanus.

In a client who received a three-dose infant series or a previous dose in adolescence or adulthood, a tetanus toxoid-containing vaccine booster dose should be given. A dose on the day of circumcision will provide increasing level of antibodies. Giving a booster dose 14 days (but at least seven days) before the male circumcision procedure will provide more adequate protection.

Clients who will not have received five full doses, even with a dose at the time of male circumcision, should also be encouraged to seek another tetanus toxoid-containing vaccination (at least four weeks after a first dose, at least six months after a second dose and at least one year after third and fourth doses).

Sources: Adapted from (3–5)

- Ask about **acute conditions**. If the client is suffering from an acute disorder, such as an infection or febrile illness, the circumcision procedure should be deferred until the problem has been resolved.
- Ask about a **known or suspected bleeding disorder** (for example, haemophilia) or anaemia. Take particular care to ask about bleeding disorders (see Box 7.4 for specific questions) because they will be encountered at the clinic level and are easily missed. A client with a bleeding disorder requires assessment, preparation and care that would only be available at a tertiary care hospital or a national referral hospital. If the client has a known or suspected bleeding disorder, he should be referred to the district hospital or higher level of care.

Identifying and referring clients with possible bleeding disorders is a critical safety measure in male circumcision services because excessive bleeding is a serious but preventable complication. Even if the client has not been diagnosed with a bleeding disorder, the provider should pay careful attention to the client's responses to questions (not just those about bleeding) and other findings throughout the screening because they may point towards an undiagnosed bleeding disorder.

Box 7.4. Questions to help identify bleeding disorders or increased risk of bleeding

Assessing for haemophilia, other bleeding disorders or increased risk of bleeding helps to ensure that the male circumcision procedure is safe for clients who may have a bleeding disorder. In a clinic staffed by midlevel providers, the questions in **bold type** below are the most important and should be asked of all clients. The other questions may be asked of the client, depending on what the client has already reported about his general health.

- 1. Do you have or have you ever had any of the following?**
 - nosebleeds or bleeding gums
 - minor cuts bleeding longer for you than for other people
 - joint swelling or bruising after falls (more than usual bruising with injury)
 - bruises with lumps (more than usual bruising with injury)
 - liver or kidney disease
 - a blood or bone marrow disorder
 - a high or low platelet count
- 2. Have you or a blood relative (anyone you are directly related to in your family) ever needed medical attention for a bleeding problem or were told you have a bleeding disorder or problem?**
 - during or after surgery
 - with dental procedures such as tooth extractions
 - with trauma
- 3. Do you have a female blood relative who has heavy menses or has had severe bleeding after childbirth?**

If any of the responses to questions 1–3 suggest that the client has haemophilia or another bleeding disorder, or if there is a family history of bleeding disorders, the client should be referred to the district hospital or higher level of care.

- 4. Do you take any medicines or herbal remedies? Have you ever had any injections?** If the client answers yes, compare what the person is taking against medicines or herbal remedies known to alter blood clotting. These include the following:
 - aspirin (especially aspirin in combination with green tea)
 - other nonsteroidal anti-inflammatory drugs (**Note:** there are a large number of these anti-inflammatory drugs and many different trade names for each compound; examples of such compounds include celecoxib, diclofenac, ibuprofen, indomethacin, mefenamic acid, naproxen, rofecoxib and salsalate.)
 - anticoagulants (blood thinners), such as warfarin or heparin

If the client is at increased risk of excessive bleeding because of medications he is taking, he should be referred to the district hospital or higher level of care.

If a client who has previously answered no to the above questions has significant postprocedure bleeding, then it is worth asking the questions again, as the client or a family member may remember additional information.

Source: Adapted from (6)

- Ask about **other chronic illnesses**. Ask about any known illness, such as HIV, tuberculosis, malaria, diabetes or hypertension. The points below explain why these illnesses are relevant to circumcision.
 - **HIV and/or tuberculosis:** If the client is clinically well (regardless of CD4 count), HIV and/or tuberculosis are not contraindications to circumcision performed in a clinic staffed by midlevel providers. Questions for active tuberculosis should, however, be considered (for example, history of cough of more than two weeks, coughing up blood, weight loss, fever and night sweats) in settings where HIV and/or tuberculosis is common, or where such questions are required by national standards of care (7).
 - **Diabetes:** The World Health Organization's diagnostic criteria for diabetes are fasting plasma glucose ≥ 7.0 mmol/L (126 mg/dl) or 2-h plasma glucose ≥ 11.1 mmol/L (200 mg/dL) (8). Global prevalence of diabetes is increasing, including in sub-Saharan Africa, and type 2 diabetes accounts for well over 90% of diabetes in this African region. The reported prevalence of type 1 diabetes, the type of diabetes more likely to be seen in young persons, is low and ranges from four per 100 000 persons in Mozambique to 12 per 100 000 persons in Zambia (9).
 - In the context of male circumcision, diabetes is rarely seen in the population of young, fit males, who make up the vast majority of male circumcision clients. Treated diabetes is not a contraindication to male circumcision, but clinical judgement is needed to determine whether the client should be referred to the district hospital or higher level of care. As diabetes increases the risk of infection and delayed wound healing, clients with untreated diabetes should have male circumcision deferred until they are on adequate treatment and have good control of their blood glucose levels. If the client gives a history of diabetes, the provider should check the client's blood sugar and continue to circumcision if the level is under the criteria listed above.
 - **Hypertension:** Routine measurement of pulse and blood pressure may be difficult to interpret because of client anxiety due to the upcoming procedure, and what is measured may not be reflective of a true baseline. Chronically elevated blood pressure—defined by the World Health Organization as systolic blood pressure > 140 mmHg and diastolic blood pressure > 90 mmHg—has long-term health concerns, but elevated blood pressure at this level is not a contraindication to male circumcision. Chronic hypertension is rare in young, fit adolescent boys and men seeking male circumcision, whereas anxiety due to the upcoming procedure is common. When an elevated blood pressure is noted, the client should be reassured. Recheck the blood pressure after a period of time (30 minutes), which may give a lower reading.

If national recommendations exist regarding diagnosis and management of hypertension, they should be followed. If such recommendations do not exist, one published approach suggests a cut-off to elective surgery if the systolic pressure is 180 mmHg and diastolic pressure is 110 mmHg, and to refer the client for hypertension management; if the blood pressure is lower than these cut-offs, circumcision can proceed (10). For guidelines on the measurement of adult blood pressure and management of hypertension before elective surgery, see *The measurement of adult blood pressure and management of hypertension before elective surgery: joint guidelines from the Association of Anaesthetists of Great Britain and Ireland and the British Hypertension Society* (10).

Clinic staff could recheck a client's blood pressure during follow-up visits; after several measurements, if the blood pressure remains elevated, staff should refer the client to follow up at a health centre.

- Ask questions about **alcohol or drug use or mental health problems**. Whether circumcision can be done at the clinic level will depend on whether the client can understand male circumcision and give valid consent/assent, and also whether his condition will allow him to comply with postoperative wound care instructions. This will depend on the severity of his problem and whether there is family support. If there are doubts about whether he can give consent/assent or comply with instructions, then clinic circumcision should not be done, and it is also likely that hospital or specialist circumcision should not be done.
- Ask about **other conditions** (these will depend on the local setting, for example, it may be appropriate to screen for diseases such as schistosomiasis or sickle cell anaemia).
- Ask about **medicines, injections and allergies**.
 - Ask whether the client is taking any medicines or having any injections. Most adolescent boys and young men are not routinely taking medicines (prescribed, herbal or bought in a store or pharmacy) or having injections. If they are, then they should be questioned in more detail about the conditions for which they are taking the medicines.

- Sometimes, clients will say they have no illnesses because they do not see themselves as ill, but questioning them about medications or injections can lead to the discovery of a condition (such as haemophilia or diabetes) the client has not disclosed when asked about general health.
- Questions about medicines may also help identify clients who are at increased risk of bleeding (for example, because of regular use of a nonsteroidal anti-inflammatory drug, as discussed in Box 7.4).
- Ask about any known **allergies to medicines, iodine, chlorhexidine or latex**. If the client discloses a history of allergy, the provider should assess whether it is practical to proceed with circumcision in the clinic given what supplies are available in the clinic. For example, if the client is allergic to latex and if the clinic has a supply of nonlatex surgical gloves, then it is still possible to proceed with circumcision in the clinic. If the provider is able to proceed, then that provider should check the clinic protocol for dealing with anaphylactic shock and check that clinic emergency resuscitation supplies are available and unexpired. The reason to do this is because, although rare, someone who has a known allergy may have other unknown allergies. If it is not possible to proceed with the circumcision in the clinic because of a lack of appropriate supply, then the client should be referred to a specialist unit.

7.3.2. Reproductive and sexual health

- Ask whether the client is sexually active and, if so, whether he has been sexually active within the past three months. Do not assume that younger, immature adolescent boys are not sexually active, but take particular care to ask about sexual activity in a sensitive way, with respect to privacy, to help avoid embarrassing the client. Knowing if a client is sexually active will help provide relevant instructions on wound healing and will also indicate the need to assess for sexually transmitted infections.
- Ask the client about the presence of current genital infection, ulcer or penile discharge. If the client reports symptoms that require further evaluation, the circumcision procedure should be deferred until the condition has been diagnosed and treated, either at the clinic or through referral to a specialist or higher level of care.
- Ask the client about problems with penile erection or any concerns about the genitals or sexual function. The provider should assess whether the client is seeking circumcision to help a sexual function problem. If so, the client should be referred to a specialist because male circumcision does not generally help sexual function disorders. Assess whether the client would like to be circumcised even though he has been told it is not likely to resolve his sexual function problem.

7.4. PHYSICAL EXAMINATION

The objective of the physical examination is to discover contraindications to circumcision in the clinic, indications to defer circumcision and the male circumcision method(s) most appropriate for the client. Where possible, physical examination should be performed in privacy and before the client is in the procedure room. For adolescent boys accompanied by parent(s)/guardian(s), the wishes of the adolescent should be respected unless there is a legal requirement to defer to the wishes of the parent(s)/guardian(s). Special consideration for adolescents, especially those who are younger, should be taken to ensure that they understand what happens during circumcision (see Chapter 6).

- If the client is not in good general health or has a condition that requires further evaluation or treatment, circumcision should be delayed until the problem has been treated and/or the client's condition has improved. Refer the client to a specialist, district hospital or higher level of care, as appropriate.
- If the client shows signs of immunodeficiency (for example, severe unexplained weight loss, unexplained recurrent opportunistic infections or needing bed rest for at least half the day), the client should be referred to the district hospital or higher level of care.

7.4.1. Focused general examination

Vital signs and overall appearance: It is good medical practice to note the client's pulse and blood pressure. In the context of adolescents and young men who typically seek male circumcision, any abnormality in pulse or blood pressure is infrequent. Depending on local disease prevalence, clinics may vary in their practices related to measurement of vital signs. Note the following:

- any **vital signs** measured (see Box 7.5)
- the client's **weight** (for purposes of anaesthesia dosage)
- any **signs of anaemia or other illnesses**
- the health of **the skin**:
 - **Skin lesions:** The client should be examined for skin lesions, such as wounds or jigger (*Tunga penetrans*) infections, which may put him at risk for tetanus. Jigger infestations are common in tropical and subtropical areas of East Africa but occur throughout much of the world. If there is an infected wound or tungiasis, then clinical judgement should decide whether to defer circumcision until the wound has healed and tetanus toxoid-containing vaccination provided. If the decision is to defer, arrange for follow-up.
 - **Keloids:** The presence of keloids should be noted. If there is significant or widespread keloids, the client should be referred to a district hospital or a higher level of care.

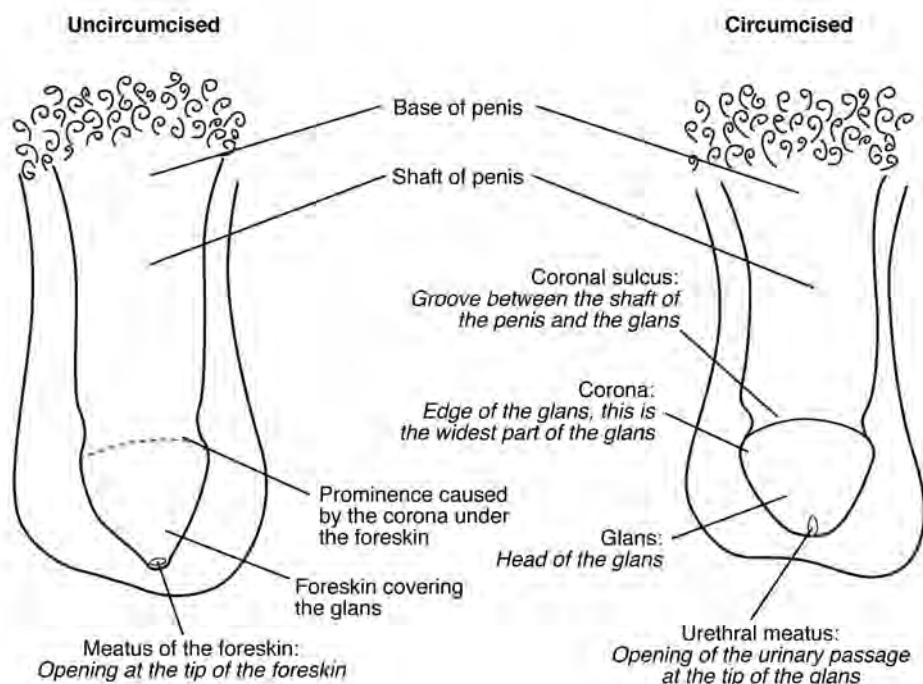
Box 7.5. Practice point on blood pressure contraindications

High or low blood pressure may be contraindications to circumcision (see Table 7.1 in Section 7.5). Commonly, high systolic blood pressure is a manifestation of anxiety. National guidelines should be followed when a client is found to have hypertension. In cases of low blood pressure, the client should be asked when he last had something to eat (and, if necessary, given some food and drink) and whether he has had a long journey to the clinic. If low blood pressure persists, the circumcision should be deferred and the client should be seen again on another occasion (arrange for follow-up).

As described in the next section, a good understanding of normal penile anatomy is necessary for safe male circumcision.

7.4.2. Examination of the penis: surface anatomy

Providers who will do circumcisions should understand the surface anatomy of the penis and also the relationships among the glans, coronal sulcus, foreskin, frenulum, frenular artery and course of the urethra (see Fig. 7.1–7.2).

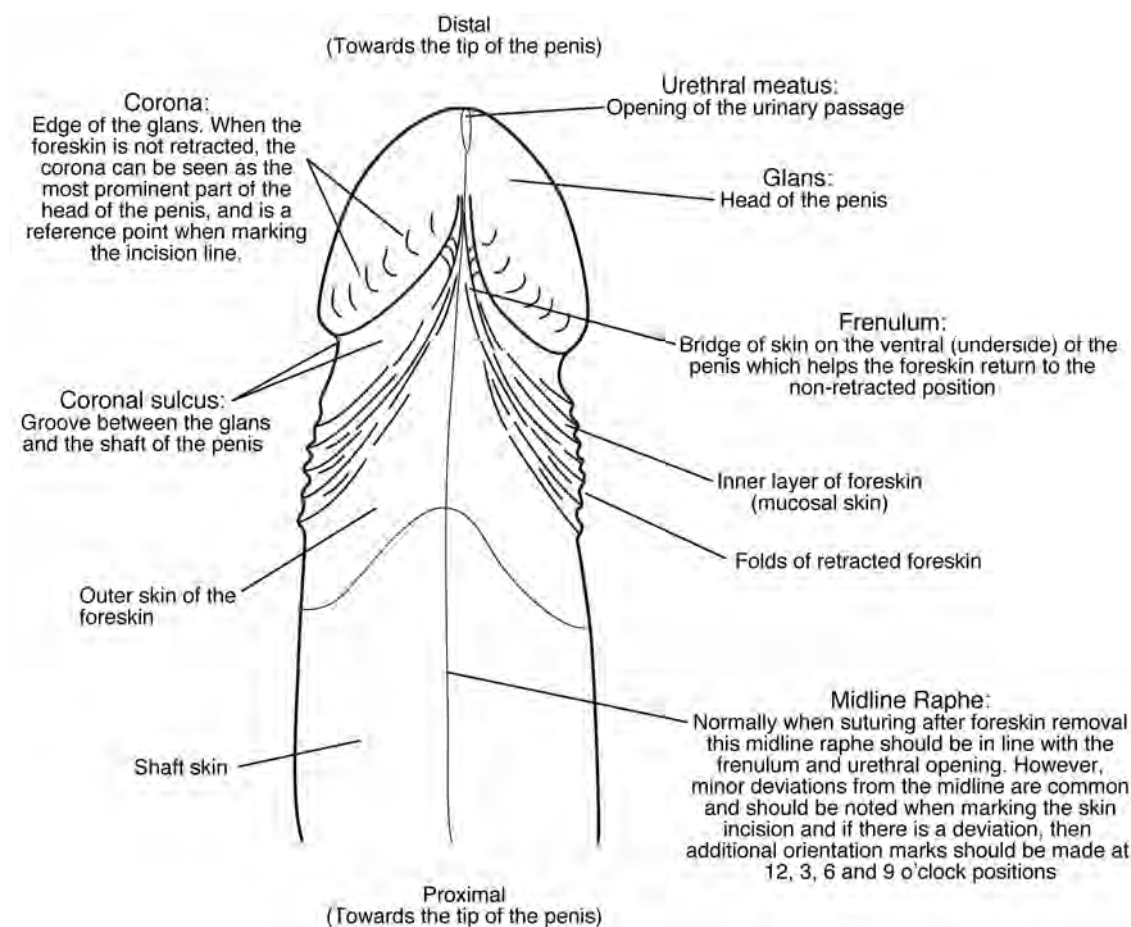
Fig. 7.1. Surface anatomy of the penis (uncircumcised and circumcised)

The penis has a shaft, a head (glans) and a neck, the narrower area between the shaft and glans. At the junction of the neck and the glans—the narrowest area—is the coronal sulcus. In the uncircumcised client, the glans and coronal sulcus are covered by the foreskin. The foreskin is the fold of skin that covers the glans when the penis is soft. When the penis is erect, the foreskin pulls back and uncovers the glans. In the midline of the underside of the penis, there is a band of skin—the frenulum—that helps the foreskin return to its usual position. The foreskin has an outer, thicker layer of keratinized skin and an inner, thinner layer of delicate skin called the mucosa.

The urethra (urinary passage), which is also lined by mucosal skin, opens at the tip of the glans. The urethral meatus (the urinary opening) is normally at the tip of the glans, but minor variations are common (see Section 7.4.3.1). The urethral meatus is normally in line with the opening at the tip of the foreskin (the foreskin meatus). There is great variation in the length of the foreskin and the width of the foreskin meatus. In younger men, the foreskin meatus is often narrow and the foreskin is relatively long.

The ventral (under surface) of the penis has a midline raphe (that is, a seam between the two parts), which is normally in line with the frenulum and urethral opening. Minor deviations of this raphe from the midline are common, and any deviation should be carefully noted because the raphe is used to line up the skin before suturing during circumcision. Any deviation from the midline should be noted in the client record and brought to the attention of the provider who will be doing the circumcision. This finding and its implications for the procedure are discussed in Chapter 9 (see Section 9.5.3).

Fig. 7.2. View of the ventral surface (underside) of the penis with the foreskin retracted to show the frenulum and coronal sulcus

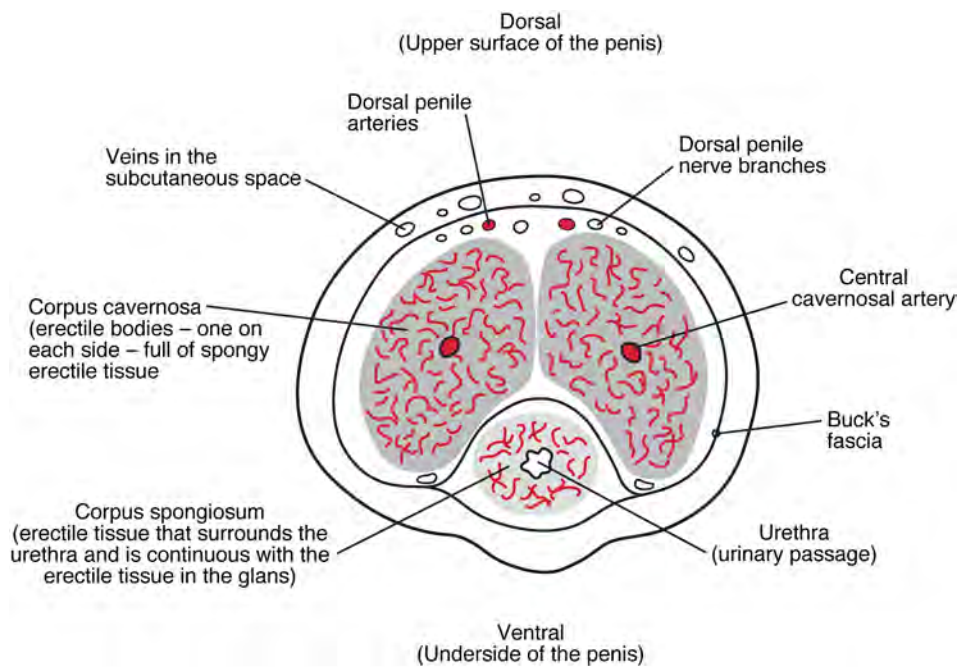


The frenulum is a fold of mucosal skin running between the glans and the foreskin on the ventral side (underside) of the glans and penis. The frenulum is extremely sensitive and is often the last area to become numb after the administration of local anaesthetic and dorsal nerve or ring block. The frenulum has a blood vessel—the frenular artery—running in its margin. The urethra runs close to the surface along the ventral side of the shaft of the penis. The urethra is close to the surface at the base of the frenulum and close to the frenular artery. It is important not to cut too deep at the base of the frenulum because this poses a risk of injuring the corpus spongiosum. More information about this error and how to avoid it is in Chapter 9 (see Section 9.6.1).

7.4.3. Internal anatomy of the penis

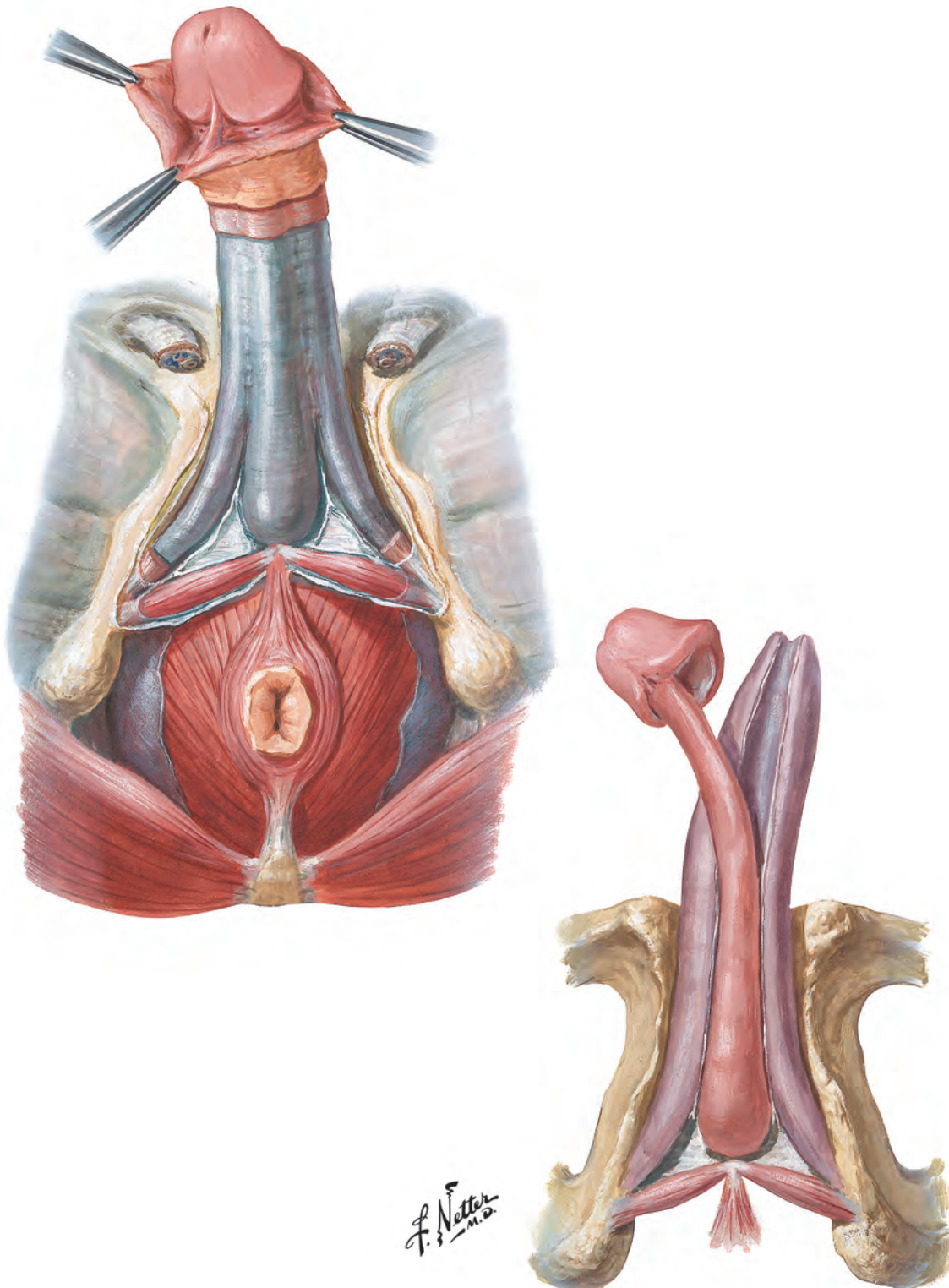
In addition to knowing the surface anatomy of the penis, the provider who is going to do circumcisions should understand the internal anatomy (see Fig. 7.3–7.4). The penis comprises three interconnected erectile bodies: the twin corpora cavernosa and the corpus spongiosum (that is, the erectile tissue that surrounds the urethra). This erectile tissue continues and expands at the distal end (tip) of the penis to form the glans, which is like a helmet across the ends of the corpora cavernosa. The erectile tissue of the penis has a rich blood supply and becomes filled with blood during erection. The twin corpora cavernosa are responsible for a rigid penis erection. The corpus spongiosum contributes to engorgement of the glans and some expansion of the girth of the penis but does not contribute strongly to its rigidity. It is important not to inject anaesthetic into the corpora cavernosa. More information about this error and how to avoid it is given in Chapter 9 (see Section 9.4.2).

The penis has a plentiful blood supply from the internal iliac arteries in the pelvis via the pudendal arteries (see Fig. 7.5). These arteries, in turn, divide to give rise to the dorsal penile artery on each side and an artery in the centre of each erectile body. In addition, there are many small arteries linking these larger arteries.

Fig. 7.3. Cross-section of the penis^a

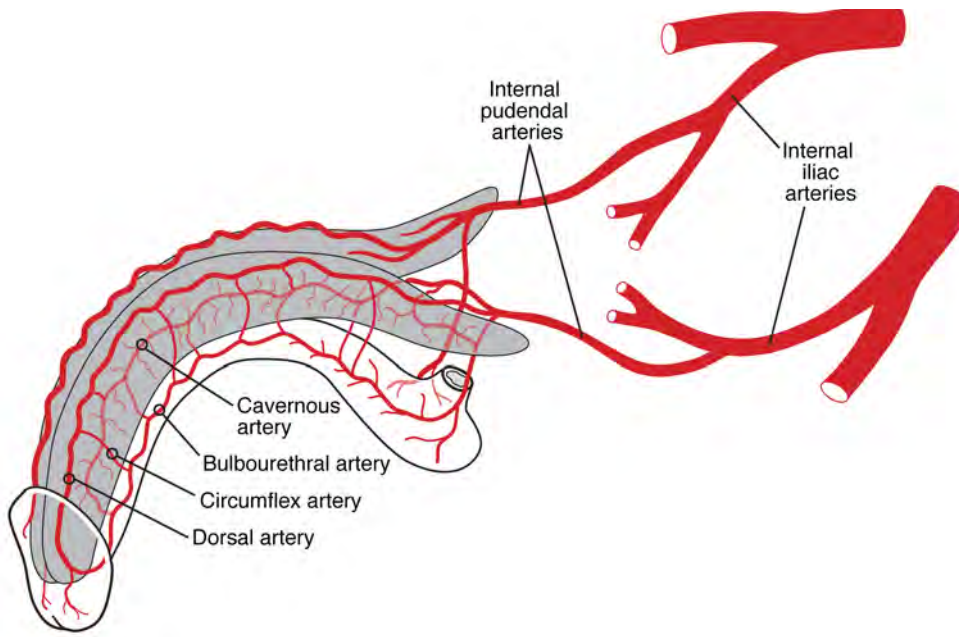
^a The erectile bodies (corpora cavernosa), the urethra and its erectile tissue (corpus spongiosum) are held together by a tough penile fascia known as Buck's fascia.

Fig. 7.4. Anatomy of the erectile tissue of the penis^a



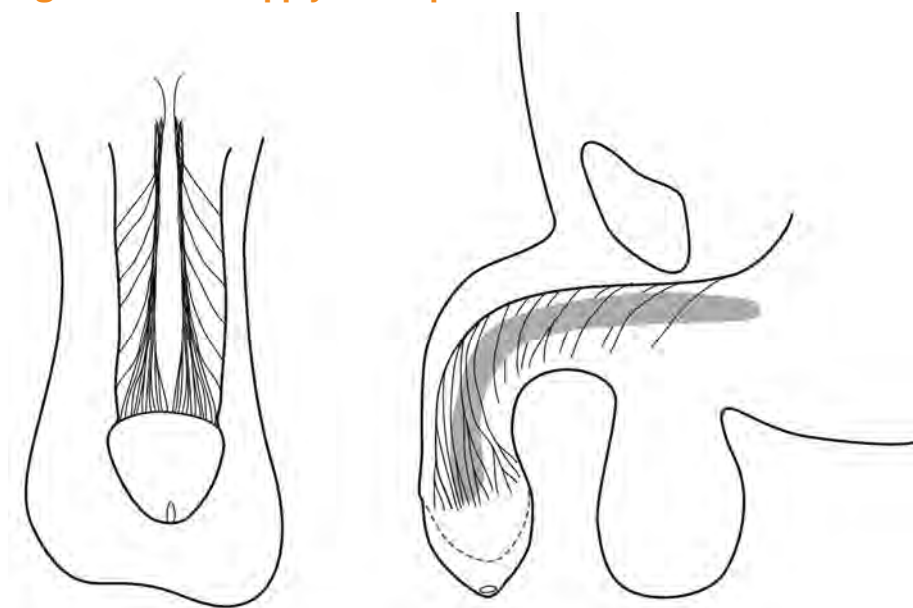
^a Illustration used with permission of Elsevier Inc. All rights reserved.

Fig. 7.5. Arterial blood supply to the penis



The dorsal penile nerves are located on the dorsal aspect of the penis, slightly to the side of the midline and deep within the penile fascia (see Fig. 7.6). At the base of the penis, these twin nerves are relatively compact, but they emerge from under the pubic bone at the 01:00 o'clock and 11:00 o'clock positions and fan out as they run towards the glans. Hence, in a dorsal penile nerve block, most of the local anaesthetic is injected at the 01:00 o'clock and 11:00 o'clock positions at the base of the penis. There is variation in these nerves and, unless the anaesthetic for the dorsal nerve block is placed well under the pubic arch, early lateral branches may be missed. A ring block involves a complete ring of local anaesthetic around the base of the penis in order to block all branches. Proper injection of local anaesthesia is discussed in more detail in Chapter 9 (see Section 9.4).

Fig. 7.6. Nerve supply to the penis



7.4.3.1. Variations from normal

This section lists the variations from normal that may be seen and their relevance to male circumcision.

- **Deviations of the midline raphe:** Normally, the frenulum, urethral meatus and median raphe are in line with one another, but deviations from the midline are quite common. Ideally, these should be detected during screening, but the provider doing the circumcision should also check the anatomy before beginning the procedure. These deviations do not interfere with penile function but may make it difficult to align the skin when suturing during the circumcision procedure. Wrong alignment (or misalignment) can lead to torsion (twisting forces) during an erection. This complication can be avoided through proper technique, as described in Chapter 9.
- **Variations in the urinary opening (urethral meatus):** The urethral meatus should be at the tip of the glans. Minor variations in the position of the urethral meatus in relation to the tip of the glans are common and do not require any treatment if the client is able to pass urine freely, has a straight penile erection and has a urethral opening within 0.5 cm of the apex of the glans (see Box 7.6). More severe displacements of the urethral meatus (hypospadias and epispadias) are described below (also see Table 7.1).
 - If hypospadias is identified, circumcision should not be done because the foreskin will be needed by the specialist to make a plastic surgery repair.
 - If the urethral meatus is in the corona or frenulum, the foreskin is bifid, the glans looks bent or the client complains of bent erections, then circumcision should not be done. If there is any doubt, the client should be referred to a specialist.

Box 7.6. Normal variations and malformations or conditions

It is important to distinguish between normal variations and malformations or conditions that are contraindications for male circumcision procedures performed in a clinic by a midlevel provider. In the more severe malformation known as hypospadias, the urethral opening is on the underside of the glans in the corona or frenular area, or on the underside of the shaft of the penis. Hypospadias may be associated with incomplete formation of the foreskin (bifid foreskin) and a downwards bend of the glans called *chordee*—it produces a downwards bend when the penis is erect.

- **Curvature of the penis:** Few penises are completely straight when erect, with curves commonly seen in all directions (up, down, left and right). Circumcision will not correct the curvature. If the client complains of curvature of his penis that is interfering with his ability to have sexual intercourse, he should be referred to a specialist. It helps if he takes photos of his erection to show to the specialist.
- **Pearly penile papules:** These are raised bumps of somewhat paler colour around the base (sulcus) of the glans, which typically develop in clients aged 20–40 years; about 10% of all men are affected. These papules may be mistaken for warts but are not harmful or infectious, do not require treatment and do not interfere with circumcision.
- **Fordyce’s spots:** These small, raised, yellowish-white spots are 1–2 mm in diameter and may appear on the penis. They are common, do not require treatment and do not interfere with circumcision.
- **Sebaceous prominences:** These raised bumps, similar to Fordyce’s spots, can appear on the shaft of the penis, located at the sebaceous glands. They are normal and do not interfere with circumcision.
- **Phimosis:** This is the inability to retract the foreskin fully. Physiological phimosis is normal in infancy and prepubescence. Pathological phimosis is rare in adolescent boys and young men (see Box 7.7).

Box 7.7. Pathological versus physiological phimosis

Phimosis is tightness of the foreskin that makes it difficult or impossible to retract the foreskin.

Physiological phimosis is normal in prepubescent boys, infants and younger men who are not engaging in sexual activity. In this case, the foreskin meatus is tight, and there are fine adhesions between the foreskin mucosa and the glans. With advancing maturity, increasing penile girth and the onset of sexual activity, the foreskin becomes looser and more easily retractable. Physiological phimosis is a contraindication to forceps-guided surgical circumcision and also to certain device-based surgical circumcision methods (for any device being considered, see its manufacturer’s instructions for use).

Pathological phimosis is an abnormality (usually scar tissue) that makes it difficult or impossible to retract the foreskin. Pathological phimosis is a contraindication to forceps-guided surgical circumcision and also to certain device-based surgical methods (see its manufacturer’s instructions for use); it can only be addressed by first doing a dorsal slit.

7.5. CONTRAINDICATIONS TO MALE CIRCUMCISION AT THE CLINIC LEVEL

Various abnormalities may be detected during screening (for photos, see Annex 7.2) and, depending on what is found, circumcision may be undertaken by a midlevel provider in a circumcision clinic or the client may be referred to a specialist. Also, some abnormalities may preclude one or more methods of circumcision (see Table 7.1 for various conditions that may be encountered during screening and for guidance on their appropriate management; some of these conditions are also discussed in the text that follows the table.)

7.5.1. Sexually transmitted infections and genital abnormalities

Identification and treatment of sexually transmitted infections is an important HIV prevention strategy; therefore, all males presenting for male circumcision should undergo screening for sexually transmitted infections. They should also be examined for any genital abnormalities that make them ineligible for male circumcision at the clinic level. Ideally, sexually transmitted infections should be treated at the male circumcision clinic. If this is not possible, they should be referred to the appropriate sexually transmitted infection clinic. Clients should be encouraged to return for male circumcision once the sexually transmitted infection has been successfully treated.

Clients with genital abnormalities should be referred for specialist opinion and treatment where indicated. Male circumcision facilities should follow the national sexually transmitted infection diagnosis and treatment guidelines, and,

depending on location of nearby clinics that treat sexually transmitted infections, facilities should stock essential drugs to treat these infections.

- **Acute sexually transmitted infections**

- **Genital ulcer disease:** Open sores and pus- or fluid-filled bumps on genitals are among the findings that may indicate this condition—often caused by a sexually transmitted infection—and should be investigated and treated. Once treatment has been completed, the client may be eligible for circumcision by a midlevel provider at a clinic.
- **Urethral discharge:** Abnormal (clear or purulent) fluid coming from the urethra, often caused by a sexually transmitted infection, should be investigated and treated. A sample of urethral discharge should be collected during genital examination for possible laboratory testing.

Once treatment has been completed, active follow-up of the client is important, and they should be prioritized for circumcision because the presence of an acute sexually transmitted infection (genital ulcer disease or urethral discharge) is objective evidence of high-risk behaviour.

- **Penile warts:** Penile warts can cause a lot of bleeding during the circumcision procedure. Whether the circumcision can proceed will depend on the extent of the warts. Also, penile warts may indicate malignancy. It is usually possible to proceed with circumcision if there are one or two small warts on the foreskin because these will be removed with the foreskin. However, if there are extensive warts, circumcision is best undertaken in a specialist facility where diathermy is available.
- **Chronic paraphimosis:** In this condition, the foreskin is permanently retracted, thickened and swollen, and the client will indicate that this is a long-standing problem. The client should be referred to a specialist.
- **Other chronic disorders of the penis and foreskin:** For conditions such as filariasis (a parasitic infestation that blocks the lymph ducts and prevents drainage), the client should be referred to a specialist.
- **Scar tissue at the frenulum:** Sometimes young men suffer from repeated tearing of the frenulum. This can result in thick scar tissue in the frenulum area and may make circumcision and related healing more difficult. If there is a scarred frenulum, device-based surgical methods of circumcision should **not** be used. Conventional surgical circumcision may be performed by an experienced provider (see Chapter 9, Section 9.6.4).
- **Balanitis:** This is an inflammation of the foreskin and the glans of the penis. The condition occurs most often in adolescent boys and men who have not been circumcised and who have poor personal hygiene. Dead skin cells, smegma (a white substance excreted by small glands around the corona of the glans penis) and bacteria accumulate under the foreskin. Symptoms of balanitis include redness or swelling, itching, rash, pain and foul-smelling discharge. Factors that predispose males to balanitis or cause the condition include the following:
 - pathological phimosis (see Box 7.7)
 - dermatitis—this is an inflammation of the skin with irritation, itching and rash, often caused by an irritating substance or an allergic reaction to chemicals in certain products, such as soaps, detergents, perfumes and spermicides
 - infection with the yeast *Candida albicans*, which can result in an itchy, spotty rash
 - certain sexually transmitted infections (including gonorrhoea, herpes and syphilis) can produce symptoms of balanitis
 - diabetes—glucose (sugar) in the urine becomes trapped under the foreskin and serves as a breeding ground for bacteria
- **Other obvious visible pathology:** A circumcision provider will quickly learn to recognize appearances of the normal penis and the appearances of common pathologies, such as penile warts, ulcers or penile discharge. There are, however, a large number of rarer conditions. When a provider encounters a new or unusual condition, then the provider should refer the client to a specialist or take a photograph and consult with a specialist. Annex 7.2 has photographs of some, but not all, of the rarer conditions that may be seen.

- **Other abnormalities of the genitalia**, such as scrotal or testicular swellings, may be detected during screening. Although these are not contraindications to male circumcision, specialist advice is needed to exclude testicular cancer, which, although rare, occurs in younger males (aged 15–45 years).

Table 7.1. Contraindications to male circumcision and management in the clinic

CONDITION	MANAGEMENT, INCLUDING ADVICE ABOUT CIRCUMCISION METHOD
<i>Illness and infections</i>	
Acute illness	Defer circumcision until the illness has been treated by an appropriate provider.
Uncontrolled diabetes	Defer circumcision until the diabetes has been treated by an appropriate provider, and follow that provider's advice about when it is safe to do the circumcision.
Uncontrolled hypertension	Defer circumcision until the hypertension has been treated by an appropriate provider, and follow that provider's advice about when it is safe to do the circumcision.
Active infection	Defer circumcision until the infection has been treated by an appropriate provider.
Uncontrolled HIV or untreated tuberculosis	Defer circumcision until the HIV or tuberculosis treatment has been started by an appropriate provider. Device-based surgical circumcision, using any device, should not be done because there are no clinical data to confirm safety in the presence of these infections.
Urethral discharge	Defer circumcision until the discharge has been treated by an appropriate provider.
Penile warts involving foreskin and glans	Do not undertake circumcision in the clinic; instead, refer to a specialist centre.
Known, untreated sexually transmitted infections (for example, syphilis, gonorrhoea, chancroid)	Defer circumcision until the infection has been treated by an appropriate provider, and follow that provider's advice about when it is safe to do the circumcision. Once treatment has been completed, actively follow up with the clients and prioritize for the circumcision because the presence of an acute sexually transmitted infection (genital ulcer disease or urethral discharge) is objective evidence of high-risk behaviour.
Penile warts confined to the foreskin	If the warts are confined to the foreskin so that they will be removed with the foreskin during circumcision, male circumcision can be done in the clinic if the provider is experienced. Device-based surgical circumcision should not be done.
Balanitis associated with phimosis	Refer to a specialist centre. Circumcision should not be done in the clinic. (It is often necessary to do circumcision in the presence of active balanitis, even before it resolves, because pus gathers under the tight foreskin; the infection will not resolve until it is incised and the pus can freely drain.)
Yeast infection (<i>Candida albicans</i>)	Defer circumcision until the infection has been treated by an appropriate provider.
Dermatitis involving the penile shaft or foreskin	Defer circumcision until the condition has been diagnosed by an appropriate provider, and follow that provider's advice about when it is safe to do the circumcision.

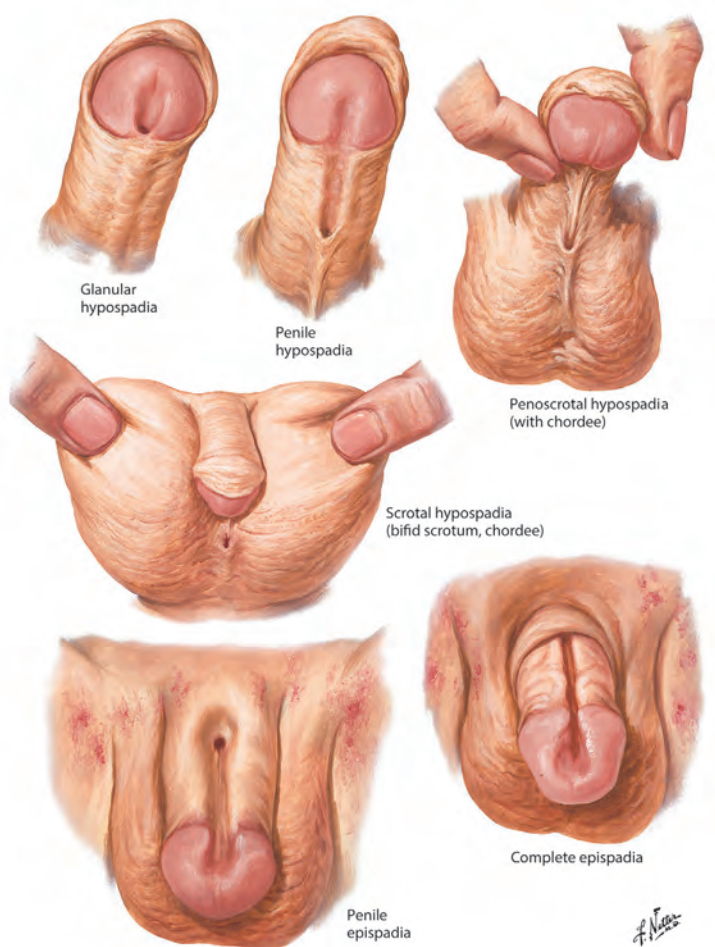
CONDITION	MANAGEMENT, INCLUDING ADVICE ABOUT CIRCUMCISION METHOD
<i>Penile anatomical abnormalities (birth abnormalities and acquired abnormalities)</i>	
Epispadias (rare)	Refer to a specialist centre. Circumcision should not be done in the clinic. (Foreskin is needed for plastic surgery repair.)
Hypospadias (with or without chordee, with or without bifid foreskin)	Refer to a specialist centre. Circumcision should not be done in the clinic. (Foreskin is needed for plastic surgery repair.)
Opening of urethral meatus near but not at tip of glans (glanular hypospadias), with no chordee and with normal foreskin	Where there is doubt, there should be referral to a specialist centre. However, glanular hypospadias has been reported more frequently from some clinics, and, depending on the experience of the provider, circumcision may be undertaken at the clinic level. (Also, depending on the frequency of this problem, the management protocol should be discussed with the specialist or referral centre to avoid clients being sent back and forth between facilities.)
Phimosis caused by scar tissue at the apex of the meatus	Refer to a specialist centre, generally. However, if the scar tissue is confined to the tip or the foreskin (and is seen nowhere else), circumcision using only the dorsal slit method may be undertaken at the clinic level, depending on the experience of the provider.
Chronic paraphimosis	Refer to a specialist centre.
Scar tissue involving the foreskin and glans (<i>balanitis xerotica obliterans</i>)	Refer to a specialist centre. Scar tissue often produces a poor cosmetic appearance (before circumcision); unfortunately, this appearance will not improve after circumcision. Circumcision may be done by a specialist.
Scar tissue involving the frenulum	Refer to a specialist centre, generally. The forceps-guided method of surgery and device-based circumcision methods should not be used. Circumcision may be undertaken at the clinic level, depending on the experience of the provider (see Chapter 9, Section 9.6.4).
Penile cancer	Refer to a specialist centre. This finding is rare in young men seeking male circumcision services.
Other penile abnormalities (for example, micropenis, bifid penis)	Refer to a specialist centre, generally. These findings are rare, but if the penis looks abnormal or if the provider has any doubt about whether to circumcise or about how to do so safely and correctly, the client should be referred.
Scrotal swelling	Refer to a specialist centre for diagnosis and management. Note that a rare cause of scrotal swelling is testicular cancer; this condition occurs in men aged 15–45 years.
<i>Conditions seen in younger adolescents with less developed genitalia</i>	
Physiological phimosis in younger adolescents	Physiological phimosis is often associated with fine adhesions between the glans and the foreskin, and is normal in younger adolescents. Circumcision can be undertaken at the clinic level, but the forceps-guided surgical method should not be used. Also, some device-based methods of circumcision should not be used (see manufacturer's instructions for users).
Less developed penis in younger adolescents, making it difficult to palpate the glans (this will include most under the age of 15 years)	Circumcision can be undertaken at the clinic level, but the forceps-guided surgical method should not be used in adolescent boys under 15 years of age or any male who has adhesions—or any male whose tip of the glans cannot be clearly identified by palpating the foreskin—because of difficulty identifying the glans and the risk of glans amputation. Also, device-based surgical methods of circumcision should not be used unless the clinic has appropriate, smaller device sizes.

7.5.2. Hypospadias and epispadias

Hypospadias and epispadias are birth defects in which the urinary opening (urethral meatus) is in the wrong place. These defects occur during the formation of the penis.

- Clients whose urethral meatus is on the underside of the penis (hypospadias) or on the upper side of the penis (epispadias) must not be circumcised at the clinic level because the foreskin may be needed in a repair operation (see Fig. 7.7).
- More severe degrees of hypospadias, where the urinary opening is in the frenular area (coronal hypospadias or on the shaft of the penis), are associated with a short urethra. The short urethra causes a downwards bend of the glans and penis, particularly when the penis is erect (chordee). Also, the foreskin is split and does not fully form across the frenular area.
- Minor variations in the urethral meatus cause difficulties in deciding whether the client should be referred to specialist, district hospital or higher level of care. If there is any doubt, it is best to refer. Such variations include a wider-than-normal meatus and glanular hypospadias, where the meatus extends more than usual towards the frenulum but not as far as the frenulum.

Fig. 7.7. Glanular hypospadias, shaft hypospadias and shaft epispadias^{a,b}



^a Also, see photo in Annex 7.2.

^b Illustration used with permission of Elsevier Inc. All rights reserved.

7.5.3. Pathological phimosis

In pathological phimosis, scar tissue makes it difficult or impossible to retract the foreskin. Pathological phimosis caused by scar tissue is relatively uncommon in a young male population accessing male circumcision services. It is important to distinguish between physiological immaturity and pathological phimosis (see Box 7.7) and among different characteristics of pathological phimosis because they may help determine the most appropriate course of action. The safe protocol for clients with pathological phimosis is to refer to a higher level of care, but there may be exceptions, depending on whether the provider who will be doing the circumcision is experienced in the dorsal slit method. Whether all or some clients with pathological phimosis should be referred will depend on the severity of the problem and the skill of the provider who will be doing the circumcision.

- If the scar tissue is confined to the apex of the foreskin and seen nowhere else, the dorsal slit method of circumcision can be undertaken by a midlevel provider in a circumcision clinic if the provider is experienced.
- If there is phimosis and also a history of penile discharge or repeated infections (balanitis), the client should be referred to a specialist. Thick adhesions between the glans and foreskin may also require referral to a specialist.
- If the scar tissue also involves the glans or urethral meatus, the client must be referred to a specialist because the cause of the scarring is likely to be the more severe condition of lichen sclerosus (*balanitis xerotica obliterans*).

7.6. PREPROCEDURE PREPARATIONS

7.6.1. Timing of consent or assent

Appropriate timing of the consent/assent process and client education on the different male circumcision methods that are available will vary among clinics. The timing will also depend on clinic protocols and whether the clinic offers a choice of methods. In general, it makes sense to undertake the screening before documenting the consent/assent—by having the client or his parent(s)/guardian(s) sign the consent/assent form. This is because screening will, in many cases, determine the most appropriate method for circumcision. For example, although general information about all methods offered at the clinic may be given through group education, it is not appropriate to give detailed information about specific device methods to a younger adolescent boy if screening shows that the use of that device is unsuitable for him (for any device that is being considered, see its manufacturer’s instructions for use).

Clients—and their parent(s)/guardian(s)—can only give proper informed consent/assent when they have chosen (or been recommended) a suitable method and when that method has been explained to them. Even when all preparations are complete, **a client may withdraw consent/assent at any time**. The provider should try to reassure any client who expresses doubt about undergoing circumcision, but, whether the client is an adult or adolescent, the provider should respect the client’s decision.

7.6.2. Use of a surgical safety checklist

By following a few critical steps, health care providers can minimize the most common and avoidable risks that endanger the lives and well-being of surgical patients. The checklist provided in Annex 7.3 identifies three phases of an operation or procedure, each corresponding to a specific period in the normal flow of work:

- before the induction of anaesthesia (sign-in phase);
- before the incision of the skin (in-the-procedure-room phase); and
- before the patient leaves the procedure room (sign-out phase).

In each phase, a checklist coordinator must confirm that the surgery team has completed the tasks listed before going ahead with the procedure. This checklist is a modified version of the World Health Organization’s *Surgical safety checklist (1)*. The full version of this surgical checklist is in use worldwide and makes a strong contribution to safe surgery. This version has been adapted for male circumcision and may be further adapted to fit local practice. Using the checklist is

particularly important in those facilities where other types of surgery are performed in the same procedure room as the one used for male circumcision.

7.6.3. Client preparations

Ideally, on the day of the circumcision, the client should thoroughly wash his genital area and penis with clean water and soap, retracting the foreskin and washing under it. He should wear clean, tight-fitting underwear. For clients who are unable to wash at home, there should be washing facilities in the clinic.

If the pubic hair is long and likely to get in the way of surgery or device application or interfere with the dressing, scissors should be used to cut the hair slightly shorter but not close to the skin—leaving about 0.5 cm of hair. This should be done before the client enters the procedure room. The client can do this at home on the day of the procedure, or it can be done at the clinic. **Shaving is not recommended because it can increase the risk of surgical site infection.**

The client should be given the opportunity to empty his bladder before going into the procedure room.

7.6.4. Hand hygiene, surgical hand preparation and protective clothing

Before entering the procedure room, anyone who will touch the sterile surgical field, touch the sterile surgical instruments, touch the wound, or apply or remove circumcision devices should:

- Remove any artificial nails or nail polish.
- Remove all jewellery, and ensure that nails are trimmed or filed.
- Make sure that hands and nails are not visibly soiled.
- Wash hands and arms up to the elbow with a nonmedicated soap.
- Perform a surgical scrub using an antiseptic handwash solution (see Box 7.8).

Box 7.8. Definition of surgical hand antiseptic, surgical hand preparation and presurgical hand preparation

Antiseptic handwash or antiseptic handrub is performed preoperatively by the surgical team to eliminate transient flora and reduce resident skin flora. Such antiseptics often have persistent antimicrobial activity. Surgical handscrubbing or presurgical scrubbing refers to surgical hand preparation with antimicrobial soap and water. Surgical handrubbing refers to surgical hand preparation with a waterless, alcohol-based handrub (11).

Surgical hand preparation will not sterilize the skin but will decrease the bacterial load and risk of wound contamination from the hands. Each surgical hand preparation with medicated soap should take three to five minutes and should be done at the start of a session of circumcision procedures. If more than one circumcision is planned for the day, hand cleansing with an alcohol-based preparation can be done between procedures (see Fig. 7.8). If hands are visibly soiled, they should be washed with soap and water. The surgical team should **clean their hands by washing them with a nonmedicated soap** before entering the surgical area, such as at the beginning of the surgical day, or re-entering the surgical area after leaving it, for example, for lunch or using the bathroom. The five moments of hand hygiene should be followed in addition to a surgical scrub (11).

Fig. 7.8. Surgical handrubbing technique

Surgical Handrubbing Technique

- Handwash with soap and water on arrival to OR, after having donned theatre clothing (cap/hat/bonnet and mask).
- Use an alcohol-based handrub (ABHR) product for surgical hand preparation, by carefully following the technique illustrated in Images 1 to 17, before every surgical procedure.
- If any residual talc or biological fluids are present when gloves are removed following the operation, handwash with soap and water.



1 Put approximately 5ml (3 doses) of ABHR in the palm of your left hand, using the elbow of your other arm to operate the dispenser.



2 Dip the fingertips of your right hand in the handrub to decontaminate under the nails (5 seconds).



3



4



5



6



7

Images 3-7: Smear the handrub on the right forearm up to the elbow. Ensure that the whole skin area is covered by using circular movements around the forearm until the handrub has fully evaporated (10-15 seconds).



8



9



10



11



12

Images 8-10: Now repeat steps 1-7 for the left hand and forearm.

Put approximately 5ml (3 doses) of ABHR in the palm of your left hand as illustrated, to rub both hands at the same time up to the wrists, following all steps in images 12-17 (20-30 seconds).

Cover the whole surface of the hands up to the wrist with ABHR, rubbing palm against palm with a rotating movement.



13

Rub the back of the left hand, including the wrist, moving the right palm back and forth, and vice-versa.



14

Rub palm against palm back and forth with fingers interlinked.



15

Rub the back of the fingers by holding them in the palm of the other hand with a sideways back and forth movement.



16

Rub the thumb of the left hand by rotating it in the clasped palm of the right hand and vice versa.



17

When the hands are dry, sterile surgical clothing and gloves can be donned.

Repeat this sequence (average 60 sec) the number of times that adds up to the total duration recommended by the ABHR manufacturer's instructions. This could be two or even three times.



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Organization

7.6.4.3. Gloves and other protective wear

After scrubbing, put on sterile operating gloves, taking care not to contaminate the sterile outer surface of the gloves (see Fig. 7.9). Gloves should be of the correct size because using gloves that are too small or too large increases the risk of glove perforation. Wearing two layers of gloves (double-gloving) is not recommended in the context of male circumcision. Remove sterile gloves carefully (see Fig. 7.10).

Surgical gloves prevent transmission of HIV, hepatitis and other infections that are transmitted by contact with blood and bodily fluids (see Box 7.9). However, there is always a possibility that a glove will be accidentally punctured. If this happens during the circumcision procedure, promptly remove the glove, clean and decontaminate hands with an antiseptic, and put on a new sterile glove. If the glove has leaked as a result of the puncture, rescrub before putting on new gloves. Client safety is of primary concern and must not be compromised. Change gloves only when it is safe for the client. For example, if the client is bleeding, control the bleeding with an artery forceps before changing the punctured glove. Once clean gloves are in place, then stop the bleeding with suture ligation or diathermy as appropriate.

Box 7.9. When providers should not perform circumcisions

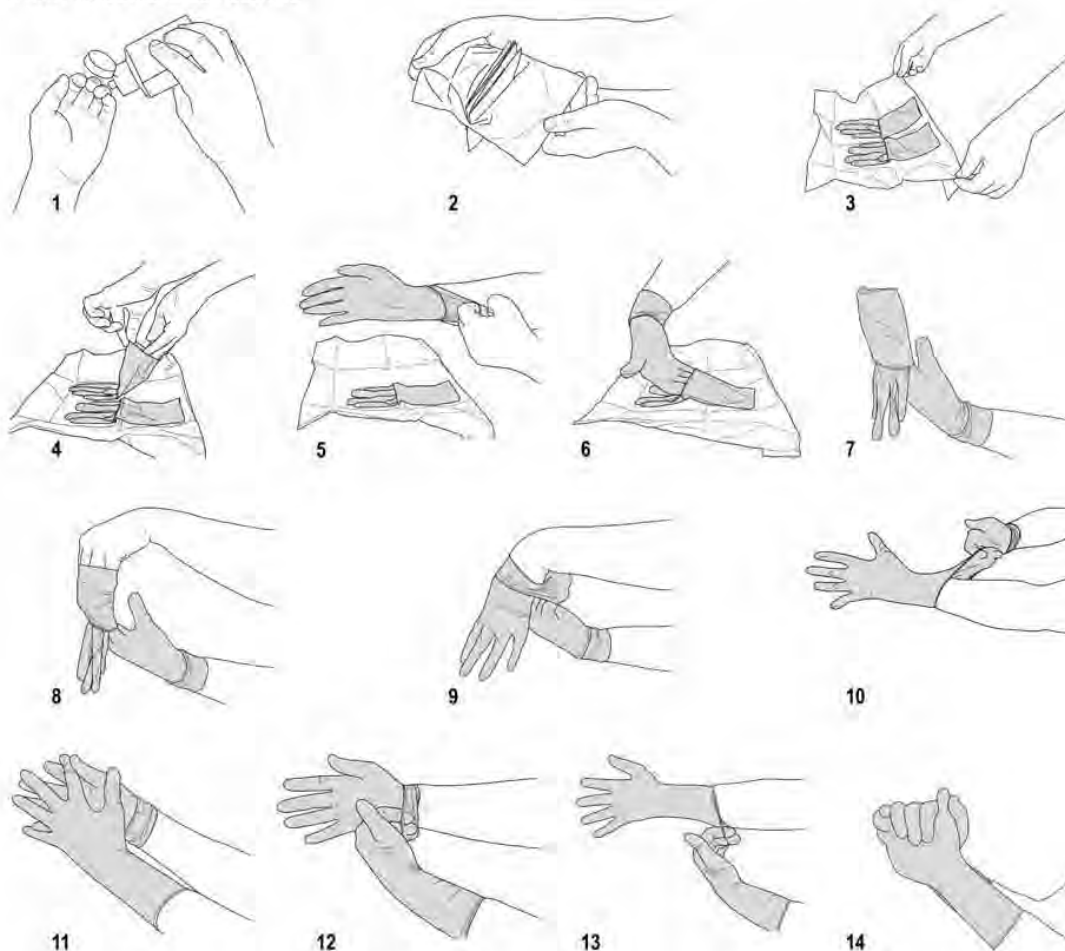
Providers should not perform circumcisions if they have any open wounds, scabs or ulcers on their hands or arms. Such injuries must fully heal before the provider returns to performing conventional or device-based surgical circumcision duties.

Whether to use a gown: A surgical gown is recommended, although some providers wear sterile operating gloves without a sterile gown. It is less expensive to only use gloves, and this is the practice in many clinic settings. The provider who is doing the procedure should, in any case, wear a clean theatre uniform (scrub suit, cap and suitable footwear). If a surgical gown is not used, including in the case of device placement or removal, both the provider who is doing the procedure and the provider's trained assistant should wear a new, clean apron for each case. Aprons protect clothes from splashes of blood and bodily fluids during the circumcision procedure and should be replaced between clients.

Face masks and protective eyewear: Face masks are recommended during circumcision because they reduce the client's exposure to droplet contaminants if the provider who is doing the procedure coughs or sneezes. The face mask also prevents the provider's mouth from being exposed to any spray of blood and bodily fluids from the circumcision site. Eyewear is also recommended during surgery because of risks of an accidental splash of blood onto the face. For those who wear glasses, no additional protection is needed; for others, particularly those who are less experienced in doing circumcision, consideration should be given to providing nondisposable, nonprescription eyeglasses. These eyeglasses must be cleaned and disinfected, per local protocol, before they are used by another provider. Eyewear is not considered necessary for most device-based surgical circumcisions.

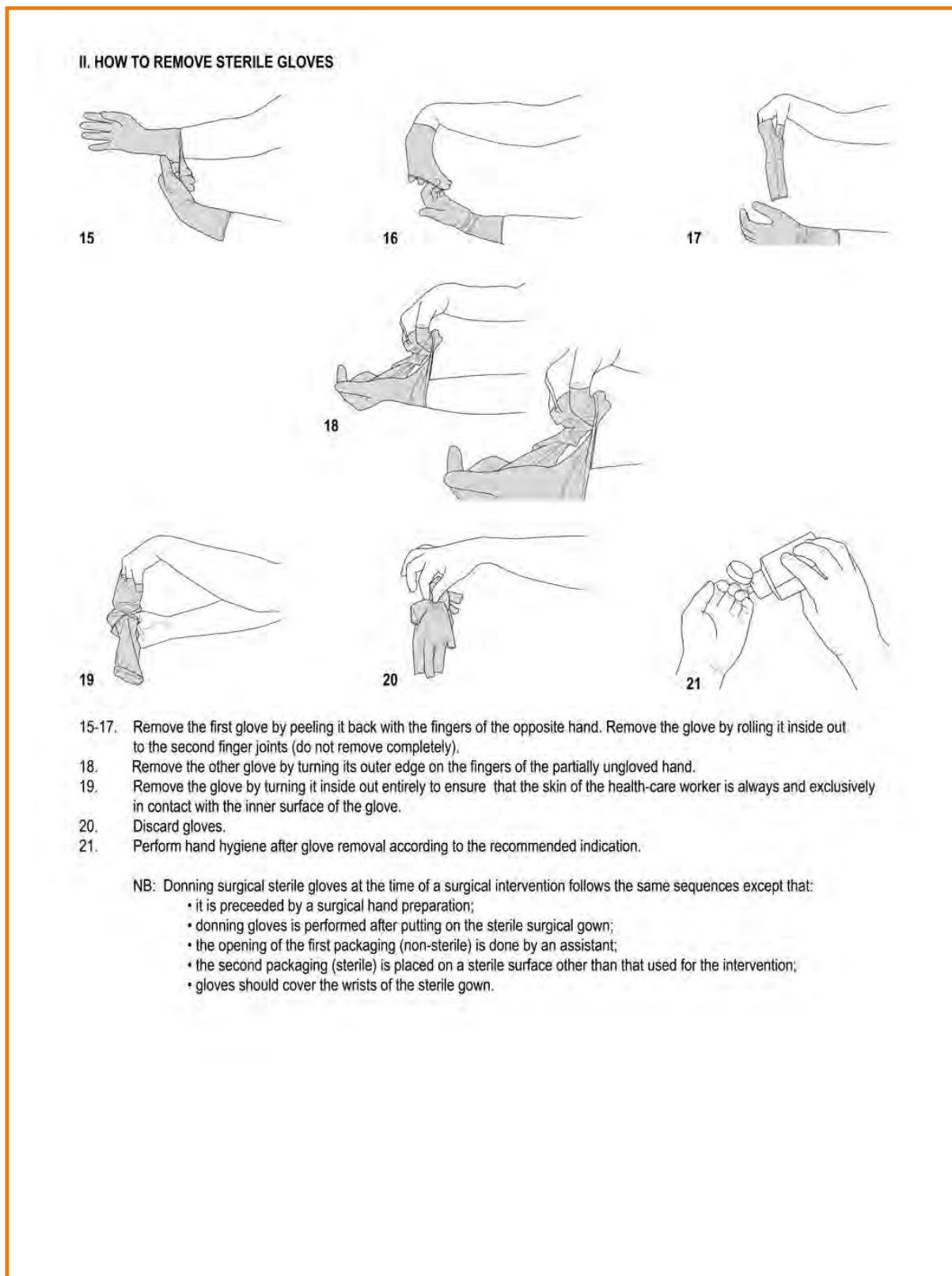
Fig. 7.9. Putting on surgical gloves

The purpose of this technique is to ensure maximum asepsis for the patient and to protect the health-care worker from the patient's body fluid(s). To achieve this goal, the skin of the health-care worker remains exclusively in contact with the inner surface of the glove and has no contact with the outer surface. Any error in the performance of this technique leads to a lack of asepsis requiring a change of gloves.

I. HOW TO DON STERILE GLOVES

1. Perform hand hygiene before an "aseptic procedure" by handrubbing or hand washing.
2. Check the package for integrity. Open the first non-sterile packaging by peeling it completely off the heat seal to expose the second sterile wrapper, but without touching it.
3. Place the second sterile package on a clean, dry surface without touching the surface. Open the package and fold it towards the bottom so as to unfold the paper and keep it open.
4. Using the thumb and index finger of one hand, carefully grasp the folded cuff edge of the glove.
5. Slip the other hand into the glove in a single movement, keeping the folded cuff at the wrist level.
- 6-7. Pick up the second glove by sliding the fingers of the gloved hand underneath the cuff of the glove.
- 8-10. In a single movement, slip the second glove on to the ungloved hand while avoiding any contact/resting of the gloved hand on surfaces other than the glove to be donned (contact/resting constitutes a lack of asepsis and requires a change of glove).
11. If necessary, after donning both gloves, adjust the fingers and interdigital spaces until the gloves fit comfortably.
- 12-13. Unfold the cuff of the first gloved hand by gently slipping the fingers of the other hand inside the fold, making sure to avoid any contact with a surface other than the outer surface of the glove (lack of asepsis requiring a change of gloves).
14. The hands are gloved and must touch exclusively sterile devices or the previously-disinfected patient's body area.

Source: (13)

Fig. 7.10. Taking off surgical gloves

Source: (13)

KEY MESSAGES

- Client assessment should include focused history taking and physical examination, including a male genital examination.
- During this process, particular care should be taken to identify bleeding disorders and tetanus toxoid-containing vaccination status of the client.
- Before circumcision, clients should be assessed for contraindications to surgery and to identify conditions that need treatment or referral. If there is any doubt, the client should be referred to a district hospital or higher level of care. It is safer for the client if providers refer clients too often rather than refer too seldom.
- Providers should have established referral pathways with specialists or higher levels of care identified in advance of any circumcision procedure. Each referral centre's contact details need to be known, readily available and kept up to date.
- Specialists and staff at referral centres should appreciate the skill level of staff at the male circumcision clinic but also recognize that there is difficulty in assessing some cases. In the event of having received an inappropriate referral, the referral centre should educate the clinic, be supportive of clinic staff, and encourage good care and safe practices—bearing in mind that it is always safer to refer too many clients than too few.

ANNEX 7.1. SAMPLE MALE CIRCUMCISION CLIENT RECORD FORM

Some of the questions in this form may not be relevant or appropriate in all settings. Therefore, male circumcision clinics should customize the form to suit their individual capacity and protocols, and the needs of the local population.

General information

1. Name: _____

2. Address: _____ Cellphone no.: _____

3. Date of visit:

Day/Month/Year: ____/____/____

4. Client ID number:

--	--	--	--	--	--	--	--

5. Hospital ID number (if different from above):

--	--	--	--	--	--	--	--

6. Date of birth:

Day/Month/Year: ____/____/____ Age: ____ Years

7. Client is referred by:

- a. Self or parent(s)/guardian(s)
- b. Family planning clinic
- c. Voluntary testing and counselling centre
- d. Urology clinic
- e. Outpatient department
- f. Nongovernmental organization
- g. Other (specify) _____

8. Marital status:

- a. Single
- b. Married
- c. Divorced/separated
- d. Other (specify) _____

9. Tribe/ethnicity: _____

10. Religion:

- a. Buddhist
- b. Christian
- c. Hindu
- d. Jewish
- e. Muslim
- f. Other (specify) _____

11. Primary indication for circumcision (circle one):

- a. For partial protection against HIV
- b. Social or religious
- c. Personal hygiene
- d. Phimosis
- e. Paraphimosis
- f. Erectile pain
- g. Recurrent balanitis
- h. Preputial neoplasm
- i. Other (specify) _____

12. Client is sexually active: Yes No
(Activity within past three months?)**13. Previous contraceptive use:**

- a. None
- b. Condoms
- c. Vasectomy
- d. Other (specify) _____

14. HIV test date and location:

- a. HIV test offered? Yes No
- b. HIV test performed? Yes No
- c. HIV test result: Positive Negative
- d. Post-test counselling given? Yes No
- e. If test result positive, linked with treatment and care? Yes No

Medical history

15. Does the client have evidence of sufficient tetanus toxoid-containing vaccination?

Yes No

If yes, record dates of past tetanus toxoid-containing vaccinations:

If no:

a. Tetanus toxoid-containing vaccine offered? Yes No

b. Tetanus toxoid-containing vaccine given? Yes No

c. Next dose planned? If so, for when? _____

16. Does the client have a history of any of the following?

a. Haemophilia or bleeding disorder? Yes No

(Self or family history [blood relative] of diagnosis, or signs or symptoms of bleeding disorder, for example, more bleeding or bruising than normal)

b. Diabetes? Yes No

17. Is client currently being treated for any of the following?

a. Anaemia Yes No

b. Diabetes Yes No

c. HIV Yes No

d. AIDS Yes No

e. Other (specify)_____ Yes No

18. Does client have any known allergy to medications, iodine or latex? Yes No

If yes, specify: _____

19. Has client had a surgical operation? Yes No

If yes, specify nature, date and any complications: _____

20. Does the client report having any of the following symptoms?

- a. Urethral discharge Yes No
- b. Genital sore (ulcer) Yes No
- c. Pain on erection Yes No
- d. Swelling of the scrotum Yes No
- e. Pain on urination Yes No
- f. Difficulty in retracting the foreskin Yes No
- g. Concerns about erection or sexual function Yes No
- h. Keloids Yes No
- i. Other (specify) _____ Yes No

21. Physical examination (general)

- a. Vital signs:
- Body temperature: _____
- Blood pressure: _____
- Pulse rate: _____
- Respiratory rate: _____
- b. Weight: _____
- c. Open wound (for example, jigger): _____
- d. Other: _____

22. Physical examination of genitals**23. Any significant abnormality on general genital examination?**

- a. Epispadias (rare) Yes No
- b. Hypospadias (with or without chordee, with or without bifid foreskin) Yes No
- c. Opening of urethral meatus near but not at tip of glans (glanular hypospadias), with no chordee and with normal foreskin Yes No
- d. Phimosis caused by scar tissue at the apex of the meatus Yes No
- e. Chronic paraphimosis Yes No
- f. Scar tissue involving the foreskin and glans (*balanitis xerotica obliterans*) Yes No
- g. Scar tissue involving the frenulum Yes No
- h. Penile cancer Yes No
- i. Other penile abnormalities (for example, filiarisis, micropenis) Yes No
- j. Scrotal swellings Yes No

24. Examination of penis:

- | | | |
|--|---------------------------------|-----------------------------------|
| a. Physiological phimosis in younger adolescents | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| b. Smaller penile size in younger adolescents, making it difficult to palpate the glans (this will include most under the age of 13 years) | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| c. Uncontrolled hypertension | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| d. Active infection | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| e. Uncontrolled HIV or untreated tuberculosis | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| f. Urethral discharge | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| g. Penile warts involving foreskin and glans | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| h. Penile warts confined to the foreskin | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| i. Genital ulcers | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| j. Known, untreated sexually transmitted infections (for example, syphilis, gonorrhoea, chancroid) | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| k. Balanitis associated with phimosis | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| l. Yeast infection (<i>Candida albicans</i>) | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| m. Dermatitis | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |
| n. Filiarasis | <input type="checkbox"/> Normal | <input type="checkbox"/> Abnormal |

25. Contraindications

If any contraindications to circumcision are found, please indicate below or, if other, specify:

If contraindications are found during the screening, please check any of the following findings, which may indicate a need for further evaluation or treatment, or referral to a specialist or higher level of care, as described in Table 7.1.

<p>A. Illness and infection</p> <p>Acute illness <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Uncontrolled diabetes <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Uncontrolled hypertension <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Active infection <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Uncontrolled HIV or untreated tuberculosis <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Urethral discharge <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Penile warts involving foreskin and glans <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Penile warts confined to the foreskin <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Genital ulcers <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Known, untreated sexually transmitted infections <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Balanitis associated with phimosis <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Yeast infection (<i>Candida albicans</i>) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Dermatitis <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Filiariasis <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Good general health <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>B. Penile abnormalities</p> <p>Epispadias (very rare) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Hypospadias <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Opening of urethral meatus near but not at tip of glans (glanular hypospadias) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Phimosis caused by scar tissue at the apex of the meatus <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Chronic paraphimosis <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Scar tissue involving the foreskin and glans (<i>balanitis xerotica obliterans</i>) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Scar tissue involving the frenulum <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Penile cancer <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Other penile abnormalities (for example, filariasis, micropenis) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Scrotal swellings <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>C. Conditions in younger adolescents</p> <p>Physiological phimosis in younger adolescents <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Smaller penile size in younger adolescents, making it difficult to palpate the glans <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Physiological phimosis in younger adolescents <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
--	---	--

26. For any of the contraindications marked Yes in Question 25, please describe the treatment plan:

- a. Was client referred to a specialist? Yes No
- b. If so, to whom? _____
- c. Did you treat the client on site for the condition? Yes No
- d. Is the client able to rescreen for male circumcision eligibility in the future? Yes No
- e. If yes, at what date can the client return for rescreening? _____

Eligibility for circumcision procedure

27. Has client given informed consent/assent for circumcision? Yes No

28. Is client eligible for circumcision at the clinic? Yes No

If yes, proceed to Question 30.

29. If client is ineligible today, list the contraindication from the table above (Question 25) here:

If other reason, describe: _____

Circumcision procedure

30. Preprocedure medications: _____

31. Anaesthetic agent and dose used:

- Lidocaine/lignocaine alone _____
- Bupivacaine and lidocaine/lignocaine _____
- Topical local anaesthetic cream _____

32. Iodine skin prep: Yes No *If no, explain:* _____

33. Type of anaesthesia: Local (penile ring block) Dorsal nerve block
 Other (specify) _____

34. Type of surgical circumcision procedure done:

- Dorsal slit method Forceps-guided method
- Sleeve method Other method (for example, device-based surgical circumcision)

If other method, specify device, indicate name, size of device, lot number: _____

35. Date of conventional circumcision procedure or device placement:

Day/Month/Year: _____/_____/_____

36. Provider name: _____ Assistant name: _____

37. Start time: _____ End time: _____ Duration: _____ minutes

38. Pain during the procedure requiring further administration of anaesthetic: Yes No

39. Postprocedure medications: _____

40. Postprocedure written and verbal instructions given: Yes No

If client is a minor, was parent(s)/guardian(s) provided with written and verbal instructions? Yes No

41. Details of follow-up plan: _____

Follow-up visit scheduled—date #1: _____

Follow-up visit scheduled—date #2: _____ (if applicable)

Follow-up visit scheduled—date #3: _____ (if applicable)

Complications (14)

42. Intraoperative complications (during surgery or prior to discharge from clinic)

If complications are found during the postprocedure follow-up, check any of the following findings. They may indicate a need for further evaluation or treatment, referral to a specialist/higher level of care or emergency care. Refer to **Chapter 10 (see Annex 10.3)** for managing adverse events and the *Adverse event action guide for voluntary medical male circumcision by surgery or device, 2nd edition (13)*.

Adverse events diagnosed? Yes No

If yes, indicate the adverse event and severity.

COMPLICATION	MILD	MODERATE	SEVERE
Excessive bleeding			
Infection			
Wound disruption			
Pain			
Scarring/disfigurement			
Torsion of penis			
Insufficient skin removal			
Excess skin removal			
Injury to penis			
Excess swelling of penis/scrotum, including haematoma			
Problem with voiding (urinating)			
Sexual complications/undesirable sensory changes			
Anaesthesia-related event			

Follow-up

43. First follow-up visit:

Day/month/year: _____/_____/_____

Postoperative (one to six days after surgery and discharge from clinic)

Adverse events diagnosed? Yes No

If yes, indicate the adverse event and severity.

COMPLICATION	MILD	MODERATE	SEVERE
Excessive bleeding			
Infection			
Wound disruption			
Pain			
Scarring/disfigurement			
Torsion of penis			
Insufficient skin removal			
Excess skin removal			
Injury to penis			
Excess swelling of penis/scrotum, including haematoma			
Problem with voiding (urinating)			
Sexual complications/undesirable sensory changes			
Anaesthesia-related event			

44. Healing normal? Yes No

If no, specify: _____

45. Additional treatment/care given? Yes No

If yes, specify: _____

46. Further follow-up planned? Yes No

If yes, specify: _____

47. Second follow-up visit:

Day/month/year: _____/_____/_____

Postoperative complications (seven or more days after surgery and discharge from clinic)Adverse events diagnosed? Yes No

If yes, indicate the adverse event and severity.

COMPLICATION	MILD	MODERATE	SEVERE
Excessive bleeding			
Infection			
Wound disruption			
Pain			
Scarring/disfigurement			
Torsion of penis			
Insufficient skin removal			
Excess skin removal			
Injury to penis			
Excess swelling of penis/scrotum, including haematoma			
Problem with voiding (urinating)			
Sexual complications/undesirable sensory changes			
Anaesthesia-related event			

48. Healing normal? Yes No

If no, specify: _____

49. Additional treatment/care given? Yes No

If yes, specify: _____

50. Further follow-up planned? Yes No

If yes, specify: _____

51. Third follow-up visit:

Day/month/year: _____ / _____ / _____

Postoperative complicationsAdverse events diagnosed at third follow-up visit? Yes No

If yes, indicate the adverse event and severity.

COMPLICATION	MILD	MODERATE	SEVERE
Excessive bleeding			
Infection			
Wound disruption			
Pain			
Scarring/disfigurement			
Torsion of penis			
Insufficient skin removal			
Excess skin removal			
Injury to penis			
Excess swelling of penis/scrotum, including haematoma			
Problem with voiding (urinating)			
Sexual complications/undesirable sensory changes			
Anaesthesia-related event			

52. Healing normal? Yes No

If no, specify: _____

53. Additional treatment/care given? Yes No

If yes, specify: _____

54. Further follow-up planned? Yes No

If yes, specify: _____

ANNEX 7.2. ABNORMALITIES THAT MAY BE ENCOUNTERED DURING SCREENING

Fig. A7.2.1. Urethral fistula (previous failed repair operation)^{a,b}



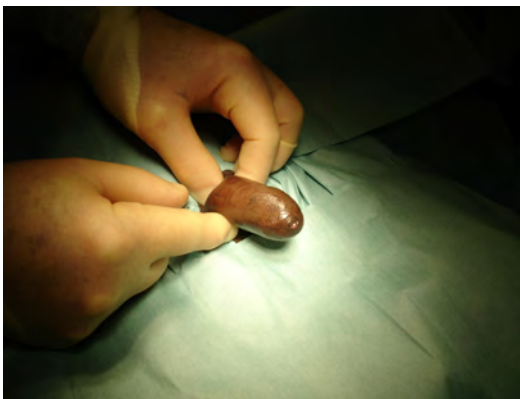
^a This client requires a referral to a specialist.
^b Photo courtesy of Mr. L. Stewart

Fig. A7.2.2. Coronal hypospadias^{a,b}



^a This client requires a referral to a specialist.
^b Photo courtesy of Jhpiego/Adrian Musiige

Fig. A7.2.3. Pathological phimosis caused by scar tissue at the tip of the foreskin^{a,b}



^a This client could have circumcision at the clinic level if the provider is experienced in doing the dorsal slit method, but the client may need a referral.
^b Photo courtesy of Professor Kasonde Bowa, Lusaka

Fig. A7.2.4. Chronic paraphimosis^{a,b}



^a This client requires a referral to a specialist.
^b Photo courtesy of Professor Kasonde Bowa, Lusaka

Fig. A7.2.5. Balanoposthitis^{a,b}

^a This client should have treatment before male circumcision and may need a referral.

^b Photo courtesy of Jhpiego

Fig. A7.2.6. Urethral discharge^{a,b}

^a This client should have treatment before male circumcision and needs a referral to a sexually transmission infection clinic.

^b Photo courtesy of Jhpiego

Fig. A7.2.7. Penile warts^{a,b}

^a This client needs referral to a higher level of care.

^b Photo courtesy of Adam Groeneveld

Fig. A7.2.8. Scarring of foreskin and glans caused by lichen sclerosus^a

^a Photo courtesy of Brian Birch, UK

Fig. A7.2.9. Preputial ulcer^{a,b}

^a This client should be referred to a specialist for diagnosis.

^b Photo courtesy of Professor Kasonde Bowa, Lusaka

Fig. A7.2.10. Primary syphilis^{a,b}

^a This client should be referred to a specialist for diagnosis.

^b Photo courtesy of Jhpiego

Fig. A7.2.11. Chancroid^{a,b}

^a This client should be referred to a specialist for diagnosis.

^b Photo courtesy of Jhpiego

Fig. A7.2.12. Gross keratinisation^{a,b}

^a This client should be referred to a specialist for diagnosis.

^b Photo courtesy of Professor C. Lei Kuching, Malaysia

Fig. A7.2.13. Penile cancer^{a,b}

^a This client should be referred to a specialist for diagnosis.

^b Photo courtesy of Professor Kasonde Bowa, Lusaka

ANNEX 7.3. SURGICAL CHECKLIST

Surgical or device circumcision safety checklist—modified from the World Health Organization’s <i>Surgical safety checklist and implementation manual (1)</i>					
Before the client lies on the procedure table		Before the provider starts the procedure (giving the anaesthetic, incising the skin or applying a device)		Before the client leaves the procedure room	
Sign-in phase		In-the-procedure-room phase		Sign-out phase	
Client has confirmed	Identity That he has come for circumcision (this is relevant if other types of surgery are done in the same procedure room)	Provider doing the procedure	Has introduced himself/herself by name	Nurse verbally confirms with team:	Name of client recorded in procedure room log
	That he has completed the consent/assent process (has been given information and has agreed to circumcision) by signing consent form				
Anaesthesia safety check	The client’s weight has been recorded, and starting and maximum doses of local anaesthetic agent have been calculated.	Anticipated critical events	Discovery of contraindication to circumcision after anaesthetic has been given (more likely in young adolescent) If this happens, follow clinic protocol.	Provider doing the procedure and nurse:	Check dressings.
Screening safety check (review screening document)	Known allergy?				
Does the client have:	Known bleeding disorder or history of prolonged bleeding?	Anticipated critical events	Inadequate anaesthesia If necessary, give more anaesthesia.	Provider doing the procedure and nurse:	Review concerns for recovery and management of client.
	Adequate tetanus immunization?				
Supplies check	Sterile instrument kits (or necessary instruments and supplies) available				
	Sutures available				
	Device stock sizes available				

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CHAPTER 8

BASIC SURGICAL SKILLS REQUIRED FOR SAFE CIRCUMCISION



This chapter provides information on the following:

- preparing a sterile operating field and maintaining sterility
- handling tissue safely
- handling needles and other sharp instruments safely
- placing surgical stitches (sutures)
- tying knots
- stopping bleeding by vessel ligation, suture transfixion or diathermy (haemostasis)
- setting up and safely using diathermy

8.1. INTRODUCTION

Surgical skill is the basis of safe surgery, irrespective of the type of surgery undertaken or the method used. Providers performing any of the conventional or device-based surgical circumcision methods discussed in this *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men (Manual)* need to be trained (see Box 8.1) and competent in all of the skills described in this chapter so that they can perform safe, high-quality male circumcisions. Having incompetent providers can lead to adverse effects and even loss of life in the people they are trying to help.

Box 8.1. Circumcision providers must be trained

Circumcision providers or those providing surgical backup for conventional or device-based surgical circumcision methods must be trained and competent in basic surgical skills.

The conventional or device-based surgical circumcision methods described in the 2009 edition of this *Manual* were based on assumptions that diathermy for haemostasis would not be available in most settings and that providers would control bleeding through vessel ligation and sutures. However, observation has shown that diathermy is more widely used than previously thought.

Diathermy can be used to stop minor bleeding if there is equipment and a provider skilled in the machine's setup and use. Providers who are competent in diathermy must also be competent in stopping the bleeding without using diathermy because severe bleeding cannot be controlled with diathermy, and there may be instances when the diathermy machine is unavailable or does not work. Therefore, this chapter describes other surgical techniques (vessel ligation and sutures) for haemostasis, which are a vital part of the circumcision provider's basic surgical skill set.

8.2. BASIC SAFETY MEASURES

In this section, the following topics are discussed: achieving and maintaining a sterile operating field, handling tissue safely, and handling needles and other sharp instruments safely during the conventional or device-based surgical circumcision procedure.

8.2.1. Preparing and maintaining the sterile operating field

The circumcision provider and anyone assisting them must always be aware of the sterile operating field and should adhere to the following infection prevention precautions and principles:

- Good aseptic technique should be used because it helps prevent wound infection.
- Everyone involved in the procedure should do the following:
 - Face the sterile operating field and be aware that everything to the side and back of those involved is not sterile.
 - Keep their hands in view, holding them upward and to the front of their bodies (that is, towards the sterile field).
 - Take care not to drop their hands to their sides.
 - Take care not to touch anything that is not in the sterile field.
- Anyone who is not directly involved in the procedure (that is, anyone other than the provider and their trained assistant) should not touch the sterile field.

When stitching sutures, care must be taken to keep suture material within the sterile field; otherwise, the loose end of the suture may accidentally move out of the sterile field and touch an area that is not sterile, particularly if the sterile drape is too small. If any instrument, suture or another item is contaminated during the procedure, it should be replaced with a sterile counterpart.

It is common to see mistakes in basic safety measures to protect the sterile operating field. These dangerous errors can be prevented through awareness and reminders of correct practice. Repeating correct practices over time can help establish them as habit.

Skin preparation and draping are described in Chapter 9.

8.2.2. Safe handling of tissue

In circumcision, safe handling of tissue is critical to achieve a good outcome. The following are guidelines for correct practice in handling tissue:

- Handle tissue gently. Handling it too firmly may crush the tissue and delay healing, which increases the risk of infection and worsens scarring.
- Use dissecting forceps (tweezers or pickup forceps) to hold the skin edges when suturing the circumcision wound; do not use artery forceps.
- Take the minimum piece of tissue needed.
- Hold the tissue firmly enough to prevent slippage, but do not apply excessive force.
- Place haemostatic sutures accurately, taking care to avoid inserting the needle too deeply into the surrounding tissue. Avoid pulling skin sutures too tight because this damages the tissue and can cause necrosis. This is particularly important for haemostatic stitches in the region of the frenulum and the 06:00 o'clock frenular skin closure stitch—necrosis in this region can cause urethral fistula (necrosis of tissue between the urinary passage and skin causing leakage of urine in the frenular area). The tension should be sufficient to bring the skin edges together so that they are just touching; there should be no gap between the edges, and the skin should not blanch or pucker.
- When suturing, ensure that the skin edges do not overlap because overlapping delays healing and gives a poor cosmetic result.

8.2.3. Safe handling of needles and other sharps

Handle sharps in a way that helps avoid injury. Sharps include needles, scalpel blades, disposable diathermy points and any other sharp instruments. The following are guidelines for correct practice in handling sharps:

- Sharps should always be taken or picked up using instruments; they should never be handled using fingers. Also, sharps should not be passed directly from one person to another; they should be placed on a sterile tray and taken or picked up using an instrument. These instructions apply to everyone who might come into contact with sharps, for example, the provider doing the procedure, any assistant or nurse, and anyone else in the procedure room.
- It is often necessary to reposition a needle while it is in the needle-holding forceps. Surgical providers should learn how to use dissecting forceps to reposition the needle. The correct technique should be emphasized during surgical training.
- Sutures should not be picked up or mounted on the needle using fingers. Rather, suture packets should be opened in such a way that the needle can be grasped with forceps or taken directly using the needle-holding forceps.
- At the end of the procedure, all sharps should be safely disposed of in a safety box. It is the responsibility of the provider doing the procedure to ensure that needles and other sharps are put into the safety box. If the provider doing the procedure neglects this duty, sharps—in particular, suture needles—are often accidentally bundled up with sterile drapes, and needle-stick (sharps) injuries often occur in staff who dispose of or launder drapes.

8.3. TYING SURGICAL KNOTS

Surgical knots are used to tie vessel ligatures and make sutures. Although knots can be tied by hand, it is better to tie the knots using instruments because this uses less suture material and has a lower risk of causing needle-stick (sharps) injury.

8.3.1. Square knot and surgeon's knot

The basic knot used in most surgical situations is a square knot with two or three throws (see Fig. 8.1). An alternative to use in particular situations is the surgeon's knot (see Fig. 8.2), which is the same as a square knot but with a double twist at the first throw. This double-twist knot is useful if the suture material is slippery or if there is some tension when placing the skin stitch because the knot can be gradually tightened to achieve the correct tension and help stop the slipping.

Fig. 8.3 shows the steps for making a two-throw square knot. To tie a surgeon's knot using instruments, follow the steps in Fig. 8.3 but, at Step 3, make a double-twist knot (see Fig. 8.2) instead of a single-twist knot.

Fig. 8.1. Square knot with two throws (A) and with three throws (B) (shown here to ligate a blood vessel)

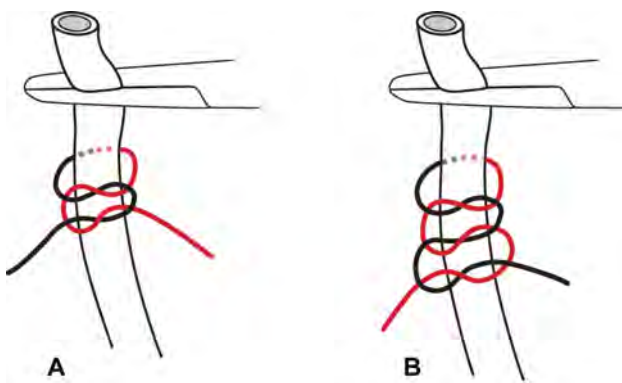
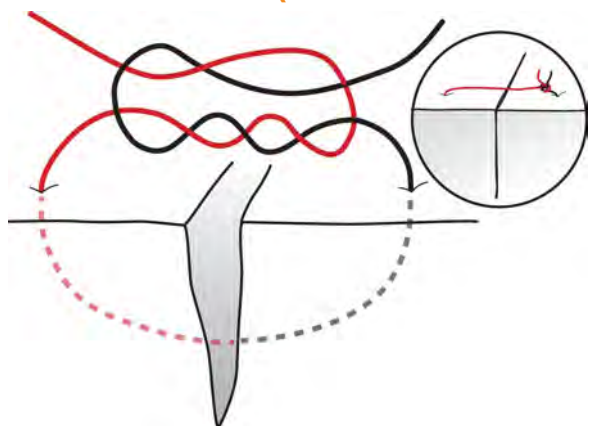
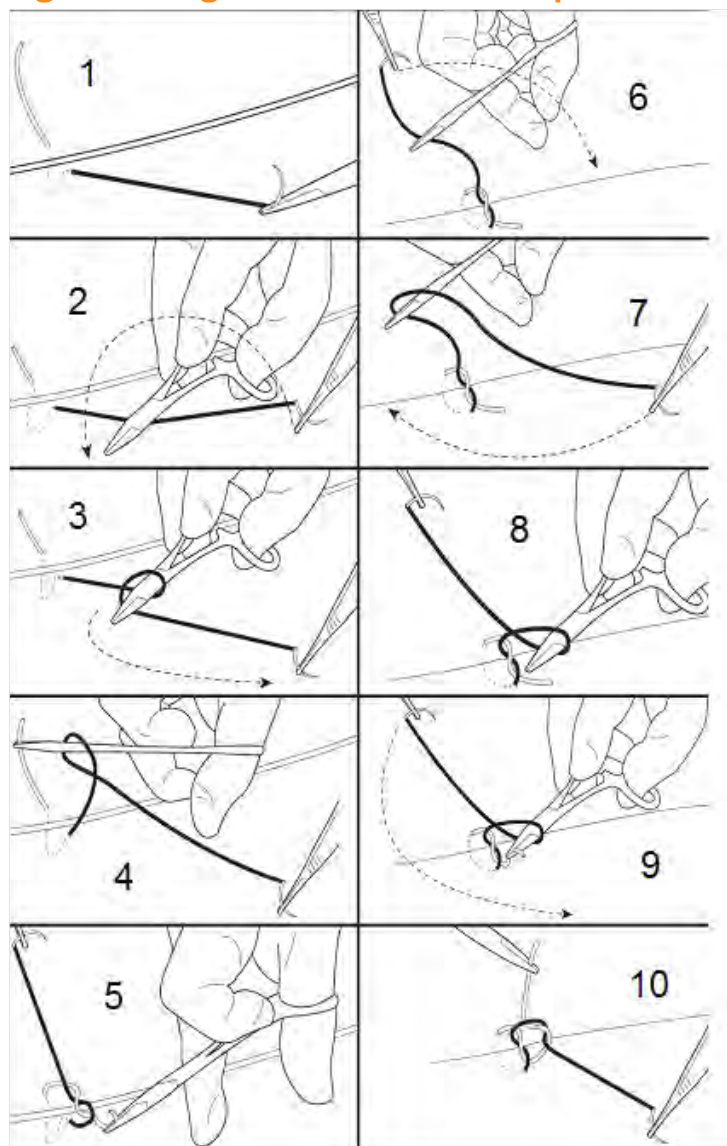


Fig. 8.2. Surgeon's knot with a double-twist knot at the first throw and a single-twist knot at the second throw (shown here for a skin stitch)^a



^a The inset shows that the knot should be tied in such a way that it overlies the skin side of the incision, not actually over the incision line.

Fig. 8.3. Using instruments to tie a square knot^a



^a The same process is used to tie a surgeon's knot (see Fig. 8.2), with a double-twist knot replacing the single-twist knot shown here in Step 3.

8.3.2. Cutting sutures

Once the knot has been tied, the ends (called the ears of the knot) should be cut approximately 3 mm from the knot. If the suture is cut too close to the knot, the knot is likely to come undone. If the suture is cut too far from the knot and the suture is subcutaneous, the excess suture material increases the chance of infection or nodule formation.

8.4. STOPPING THE BLEEDING

Minimizing blood loss is part of good surgical technique and safe medical practice—it reduces the risk of complications and the need for interventions that bring additional risks. This is particularly the case for clients who are anaemic; ideally, such clients should not be circumcised in the clinic but should be referred to the district hospital or a higher level of care. Minimizing blood loss also reduces contamination of items in the sterile field, such as instruments and operating drapes, and doing so reduces the risk of transmitting bloodborne infections, such as hepatitis B or C virus and HIV, to clinic staff who clean instruments and dispose of or launder drapes.

The following surgical techniques are used to reduce blood loss:

- **Compression:** Control oozing of blood by applying pressure over the surface with a gauze swab for two to three minutes. This will usually stop the bleeding and help identify blood vessels that have been accidentally cut and are bleeding profusely (referred to as bleeders), thereby requiring ligation or diathermy.
- **Temporary occlusion of blood vessels:** Control the bleeding from individual vessels by applying an artery forceps (see Fig. 8.4), taking care not to grasp too much tissue. An alternative technique is to pick up the vessel using dissecting forceps and then apply an artery forceps (see Fig. 8.5).
- **Tying and underrunning:** The simplest procedure is to tie the vessel below the artery forceps (see Fig. 8.1). Ensure that the tie is securely in place and not liable to slip off (for example, during a penile erection in the first few days after the operation). If there is any doubt about the security of the tie, it is better to use the underrunning technique (see Fig. 8.6). The steps for underrunning and tying are as follows:
 1. Secure the bleeding vessel with an artery forceps.
 2. Pass the suture needle beneath the blood vessel (but not too deep) and pull through, leaving enough suture material for the tie.
 3. Pass the suture beneath the vessel a second time, pull gently to occlude it and tie a knot as described in Section 8.3.1.

Fig. 8.4. Artery forceps applied to occlude a blood vessel

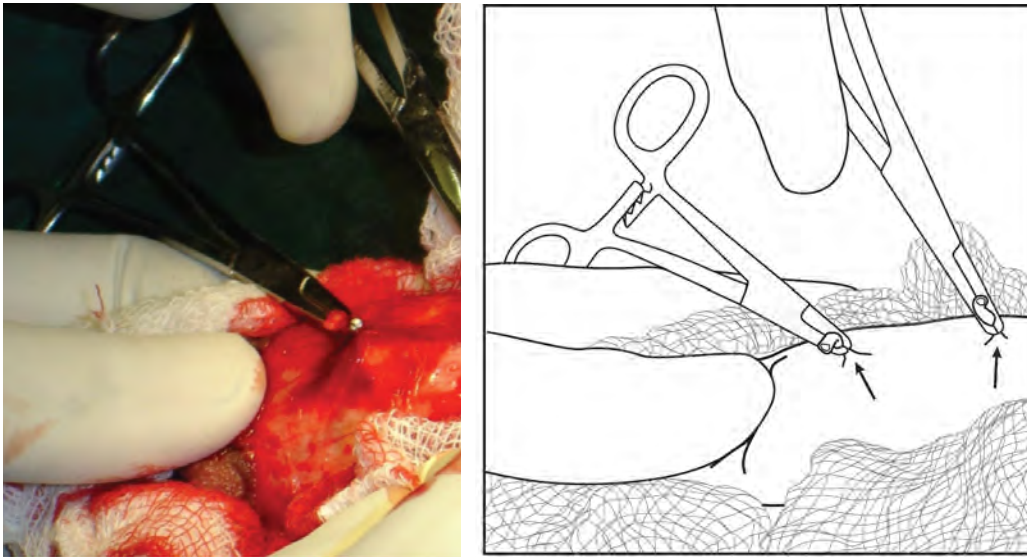


Fig. 8.5. Picking up a blood vessel with dissecting forceps (A) to facilitate accurate placement of the artery forceps (B)

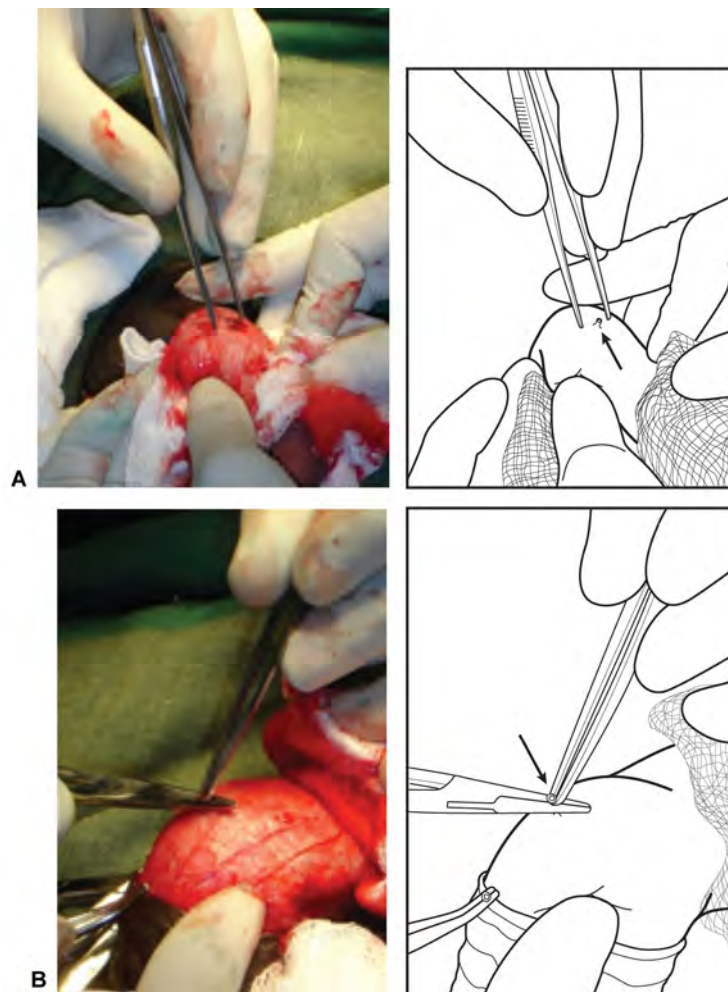
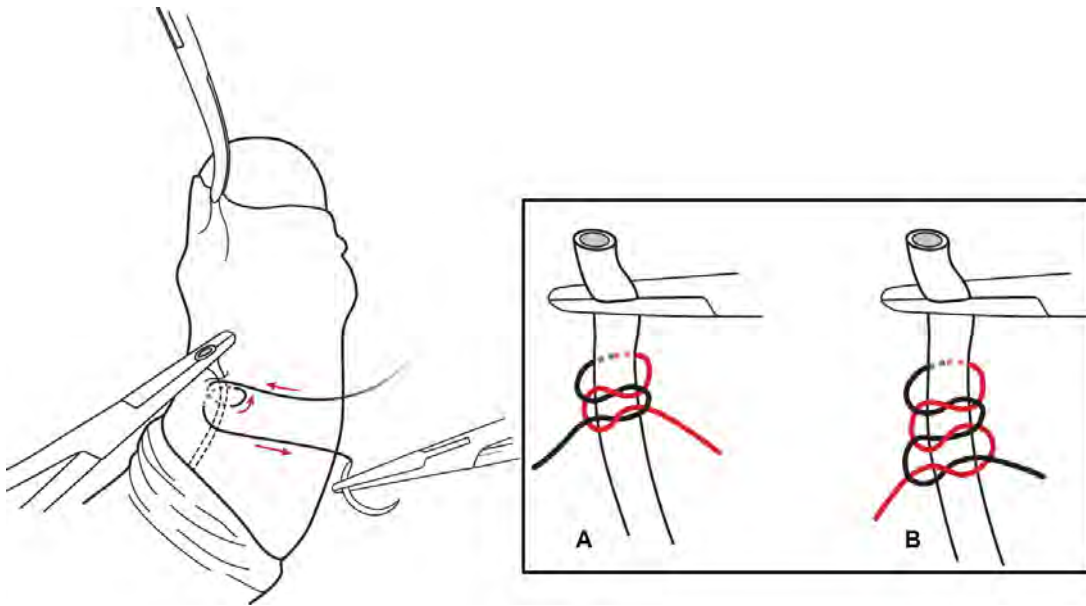


Fig. 8.6. Underrunning a blood vessel and tying the suture with a two-throw (A) or three-throw square knot (B)



8.4.1. Haemostasis

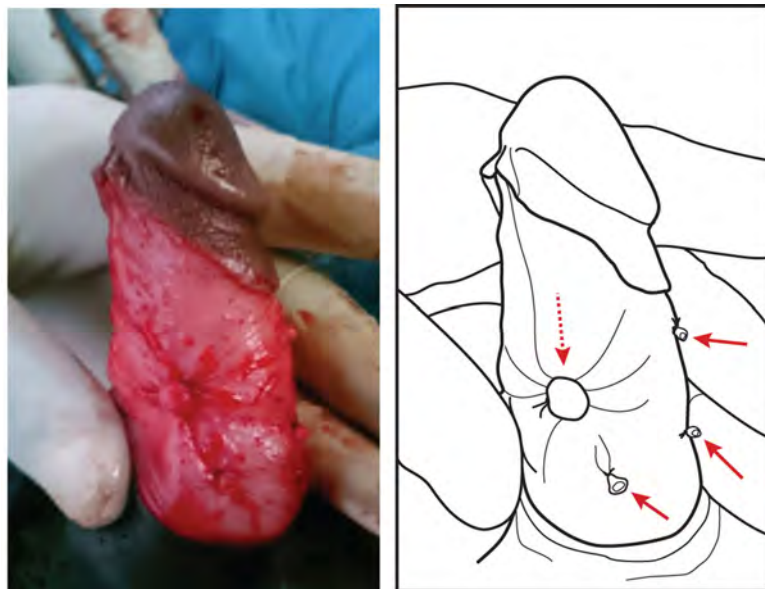
Bleeding that occurs after circumcision can lead to severe postprocedure complications. Such bleeding generally arises from a failure to control bleeding from vessels on the penile shaft. However, many providers focus more on bleeding from the skin edges; hence, it is important to correct this error of focus. The following guidelines are correct practices to use to prevent bleeding after circumcision:

- Following the removal of foreskin, pull the remaining skin towards the base to expose the whole penile shaft. At this stage, use a small, clean and dry swab to look for any bleeders that may have retracted under the skin. It is typical to find two or three such bleeding points on the shaft. These may be picked up at the tip with an artery forceps, then cauterized or ligated as described above.
- When bleeding is persistent, compression of the penile shaft, which is applied for at least five minutes, is effective in stopping most of the bleeding, thereby making it easier to see any major bleeders.
- Before starting to close the skin, always take a final look at the penile shaft and skin edges for any bleeding. Bleeding on the skin edges is less troublesome and will be controlled by both the skin sutures and compressive wound dressing.
- Bleeding from the frenulum (the fold of skin between the shaft of the penis and the foreskin in the 06:00 o'clock position) is a frequent problem and often difficult to manage. The frenular artery runs close to the base of the frenulum, and the risk of troublesome bleeding is reduced by taking particular care to cut the frenulum closer to its attachment to the foreskin and to avoid cutting the base of the frenulum where it is attached to the shaft of the penis. The frenular artery can be ligated, as described above, after pulling the skin down the shaft (see Chapter 9, Fig. 9.14–9.15). Care must be taken not to place this suture too deep because the urethra is immediately below; sutures placed too deep will enter the urethral wall and can cause tissue necrosis, resulting in a hole between the urethra and the outside skin (urethral fistula). If this happens, it can lead to lifelong disability, so all providers need to be especially alert to this potential problem.
- A troublesome minor adverse event is the formation of subcutaneous nodules under the skin of the shaft of the penis, which is caused by an excess of suture material or by the inclusion of too much tissue in the ligature during haemostasis. In some cases, these nodules are not bothersome enough to require surgical removal. The risk of developing subcutaneous nodules can be reduced by effective haemostasis (see Fig. 8.7):
 - Pick up bleeding vessels accurately and precisely. Do not take large pieces of tissue.

- Use 3/0 or 4/0 sutures, and tie surgical or square knots correctly using no more than three throws.
- Tie knots correctly, and avoid too many throws; this is especially important if polyglactin (Vicryl Rapide™) is used. This material becomes very slippery when wet, and if knots are not tied correctly, they come undone.

Finally, cut sutures accurately to leave a 3 mm ear (the cut end of the suture).

Fig. 8.7. Haemostatic ligature that has gathered too much tissue^a



^a Shown here is an example of a haemostatic ligature that has gathered too much tissue (red-dotted arrow) and will probably result in the formation of a subcutaneous nodule. Vessels should be picked up accurately, as shown in Fig. 8.4–8.6.

8.4.2. Using diathermy safely

Bleeding can be stopped by using diathermy to cause coagulation. However, diathermy requires a secure electricity supply and may not be available in some facilities; hence, providers who undertake conventional or device-based surgical circumcision should be skilled at performing the procedure and stopping the bleeding without diathermy. All techniques described in this *Manual* can be undertaken safely without using diathermy.

There are two types of diathermy: monopolar and bipolar. Bipolar diathermy is safer than monopolar diathermy but has some disadvantages: tips of the diathermy forceps can become charred, and diathermy forceps can stick to the tissue, thereby reducing their efficacy and requiring them to be cleaned frequently with a scratch pad. Thus, monopolar diathermy is widely employed and, when used correctly, is easier to perform than the bipolar procedure.

Safe diathermy requires the provider doing the procedure to understand diathermy, the machine connections, the power settings and surgical technique, and to apply that knowledge.

8.4.2.1. Diathermy machine setup

The setup for a diathermy machine is described in Annex 8.1. The provider undertaking the procedure is responsible for understanding the equipment and knowing the recommended connections and power settings for the diathermy machine's proper use in each clinic or procedure room where they work—and in the context of conventional or device-based surgical circumcision. The provider also needs to check that the connections and settings are correct before undertaking a circumcision. For male circumcision, only coagulation power settings are needed. If the diathermy machine has both cutting and coagulation outputs, the cutting power output should be switched off. If the machine has a blend switch to enable simultaneous application of coagulation and cutting outputs, this blend setting should be switched off.

The provider doing the procedure must take particular care when working in an unfamiliar facility or with an unfamiliar diathermy machine, or both. Machine settings vary for different surgical procedures. Hence, in an unfamiliar facility, or in a facility or room where other types of surgical procedures are performed, the provider doing the surgery should:

- Ask appropriate clinic staff about the normal or usual machine settings.
- Ensure that the coagulation and cutting outputs are correct.
- Ensure that the cutting current and blending setting are turned off.

Further generic guidance on this subject cannot be given in this *Manual* because of the variety of different diathermy machines. Refer to the diathermy machine's instructions for use for specific details.

8.4.2.2. When not to use diathermy

Diathermy is not appropriate in certain situations:

- Diathermy should not be used on a penis that is very small. This precaution applies to many boys aged less than 14 years because they are not yet physically mature.
- If the vessel lumen can be seen, diathermy is best avoided because a visible lumen indicates a larger blood vessel and more potential for excessive bleeding. In this situation, bleeding should be stopped with an artery forceps and ligation or underrunning the vessel (as described above in Section 8.4).
- Avoid the use of diathermy close to the incision edge or the skin surface because this can result in a full-thickness burn and an area of necrosis. These effects increase the chances of wound healing problems, including wound rupture along the surgical border (dehiscence), wound infection and delayed healing.
- Do not use diathermy at the frenulum. The urethra is close to the base of the frenulum, and diathermy of the frenular artery can cause a burn through the urethral wall. This may result in urethral fistula (urine coming out of the wound at the site of the frenular stitch, usually some days after the operation). It can take a few days for diathermy-related urethral fistula to appear because the full thickness of the burn through the urethral wall takes time to necrose and thin out. Once this happens, the fistula may become apparent.

8.4.2.3. Safe diathermy surgical technique

Whichever method of diathermy is used (bipolar or monopolar), the provider should take great care and should be trained and skilled in safe diathermy surgical technique. Most diathermy-related adverse events are caused by errors in technique (see Box 8.2). The following are guidelines for good practice when using diathermy:

- Accuracy and precision are important. When using diathermy, identify the correct vessel (the bleeder) and apply the forceps as precisely as possible. Best results will be obtained if the blood vessel is between the diathermy forceps with minimal other tissue. Do not grasp large pieces of tissue. Once the vessel has been accurately picked up, slightly lift the vessel before applying the current to confine the burn to the vessel. Take care not to pull too hard because small vessels may tear.
- Apply the diathermy current for a short time (about one to two seconds). If this does not stop the bleeding, reapply the forceps with greater precision. If the current is applied for too long, it will cause a large, deep burn that predisposes the client to infection, delayed wound healing, excess scar tissue and complications, such as a urethral fistula.
- Avoid traction on the penis. For diathermy to work, the point of greatest electrical resistance must be the tissue at the tip of the diathermy forceps. The provider doing the procedure must not pull on the penis while applying diathermy. Traction on the penis can narrow the base of the penile shaft, making that the point of greatest electrical resistance rather than the tissue at the tip of the diathermy forceps. In the worst case, this can result in a burn at the base of the shaft and loss of the entire penis. This dangerous situation is more likely to occur if the penis size is small (for example, in younger or less mature adolescents) or if the provider doing the procedure makes serious errors of technique, such as taking too large a piece of tissue with the diathermy forceps; pulling on the penis to get a better view, thereby channelling the current through a narrow area at the base of the penis; or applying the current for too long.

Box 8.2. Errors in diathermy technique

Errors in diathermy surgical technique can lead to serious complications. Therefore, it is important to be aware of common errors and understand how to avoid them; it is also important not to use diathermy in situations where it is contraindicated.

- Do not use diathermy when the penis size is small because there is a risk of a burn at the base of the penis, which can lead to a loss of the entire penis.
- Diathermy is best used on small (or narrow) vessels. If the vessel lumen is large enough to be seen, then the vessel should be picked up accurately and ligated because diathermy on such large vessels results in less secure haemostasis.
- Apply the diathermy accurately and with precision, taking the minimum amount of tissue in the forceps.
- Avoid prolonged application of the current.
- Avoid creating large burns, and avoid diathermy at the skin edges because extensive damage and burnt skin predispose the client to infection and delayed healing.
- Avoid diathermy at the frenulum because of the risk of a deep burn into the urethra, which can cause urethral fistula.
- Use diathermy only after receiving special training in its technique.
- All staff should take care not to trip on any cables on the floor; if this happens, then the cable connections and plug should be checked.
- All equipment, including cables and plugs, should be periodically inspected for fraying or insulation damage.
- All diathermy equipment should be serviced and tested according to manufacturer's instructions for use.
- Single-use diathermy pencils and single-use dispersive plates should not be reused.
- Do not ignore, lower the volume of or mute the audible beeps or alarm on the diathermy equipment—these sounds alert staff to equipment malfunction.
- Ensure that the machine is set up properly, in terms of connections and settings, to prevent adverse events resulting from a faulty machine connection.

8.5. PLACING SUTURES

The goal of suturing is to achieve apposition without tension and with correct skin orientation. Too much tension in any type of skin suture increases the likelihood that the suture will cut through and disrupt the wound. Information on suture material and the type of needle to use is in Box 8.3, followed by information on basic suturing techniques.

Box 8.3. Choice of suture material and needle

Determining the ideal suture size is a compromise between ensuring that there is adequate tensile strength and minimizing the amount of foreign material introduced into the body.

- Large suture sizes to tie blood vessels produce a more unsightly scar and can lead to small, persistent lumps.
- A fast-absorbing suture material should be used. These materials include polyglactin 910, which has been treated for a more rapid breakdown (Vicryl Rapide™), or chromic catgut (although, this is becoming less available).
- Standard (that is, not fast-absorbing) polyglactin sutures are listed as standard supplies by the United Nations Population Fund and United Nations Children's Fund (1, 2). Use undyed polyglactin to prevent a tattoo marking on the skin. The size of the polyglactin should be 3/0 or 4/0.

The suture may be mounted on a taper-cut, reverse cutting needle that is 3/8 of the circle. The taper-cut needle passes more easily through the skin; however, it also easily tears the skin on the inner aspect at the corona. For younger adolescent boys with soft skin, a round-bodied needle is often sufficient.

8.5.1. Different types of suturing techniques

This section describes the following suture techniques: simple interrupted, mattress, vertical mattress and horizontal mattress.

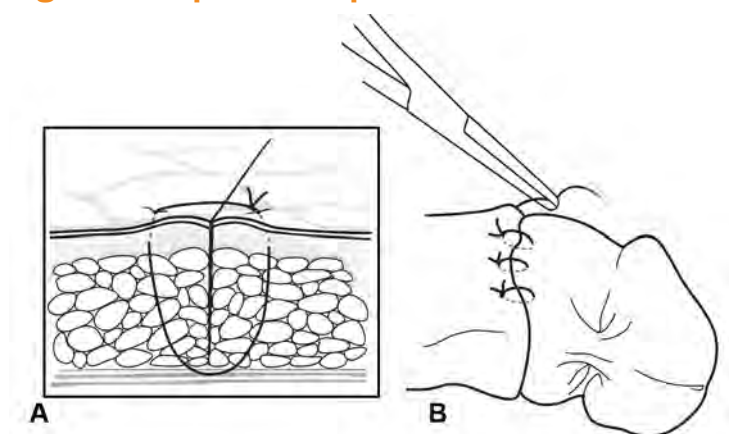
8.5.1.1. Simple interrupted suture

The simple interrupted suture is the simplest type of stitch and yields good apposition results.

1. Pass the point of the needle through the skin at 90° to the skin surface, and exit at the same angle (see Fig. 8.8[A]).
2. When suturing the penile shaft skin to the mucosal cuff, ensure that the knots are on the penile shaft side of the incision (see Fig. 8.8[B]).
3. Use as few simple interrupted sutures as possible between the 03:00, 06:00, 09:00 and 12:00 o'clock mattress sutures—typically two or three interrupted sutures (see Fig 8.11). This technique will result in a total of about 12–16 sutures.

The nearer to the skin edges the needle goes in, the better the apposition of the skin edges but higher the risk of the stitch cutting out. If stitches are placed too far from the wound's edge, there is a risk of inversion (burying) of the skin edges, which results in poor healing. **Hence, a combination of simple and mattress sutures is recommended.**

Fig. 8.8. Simple interrupted suture^a



^a(A) The suture is in place, holding the edges of the skin together. Source: (3). (B) Simple sutures close the circumcision incision—note that the knots are placed overlying the penile shaft skin and not overlying the mucosal cuff.

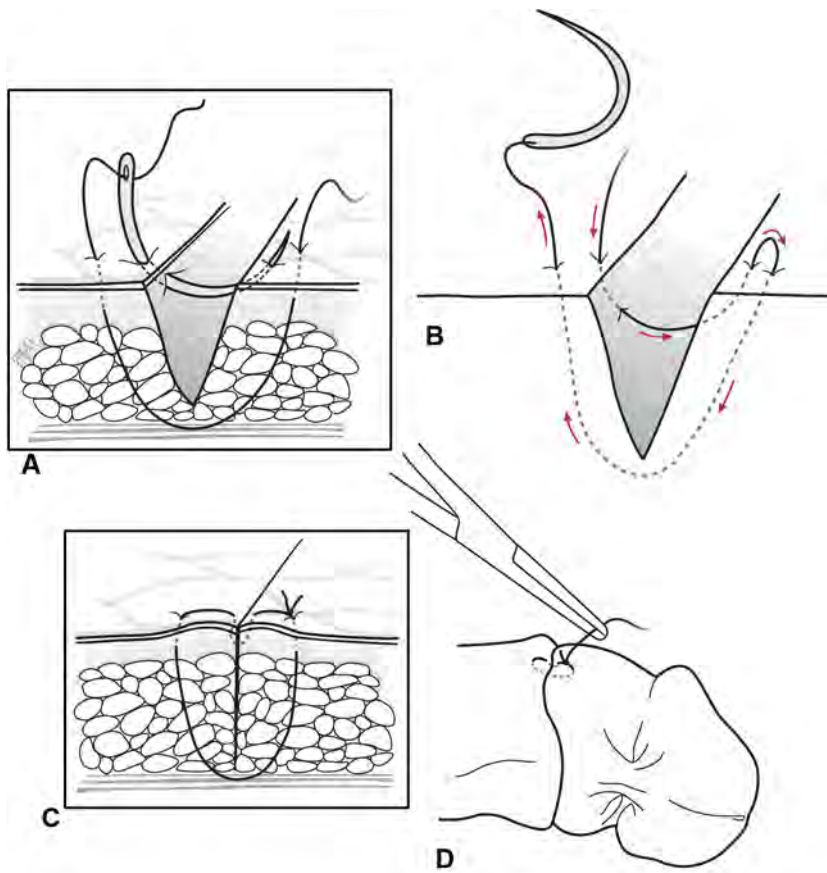
8.5.1.2. Mattress suture

Mattress sutures give a more precise apposition of the wound edges and reduce the risk of burying the skin edges. They are more complex than simple interrupted sutures; therefore, they require more time to put in.

8.5.1.3. Vertical mattress suture

The vertical mattress suture is illustrated in Fig. 8.9.

1. Start the first bite approximately 4–5 mm from the incision edge and pass to the same position on the other side of the wound.
2. Start the second bite approximately 1–2 mm from the incision edge, on the same side of the incision where the needle has just exited the skin. Pass the needle through the skin between the exit point and the wound edge, in line with the original entry point.
3. From this point, take a small bite; the final exit point is in a similar position on the other side of the wound.
4. Tie the knot so that it does not lie over the incision line. This suture approximates the subcutaneous tissue and the skin edges.

Fig. 8.9. Vertical mattress suture^a

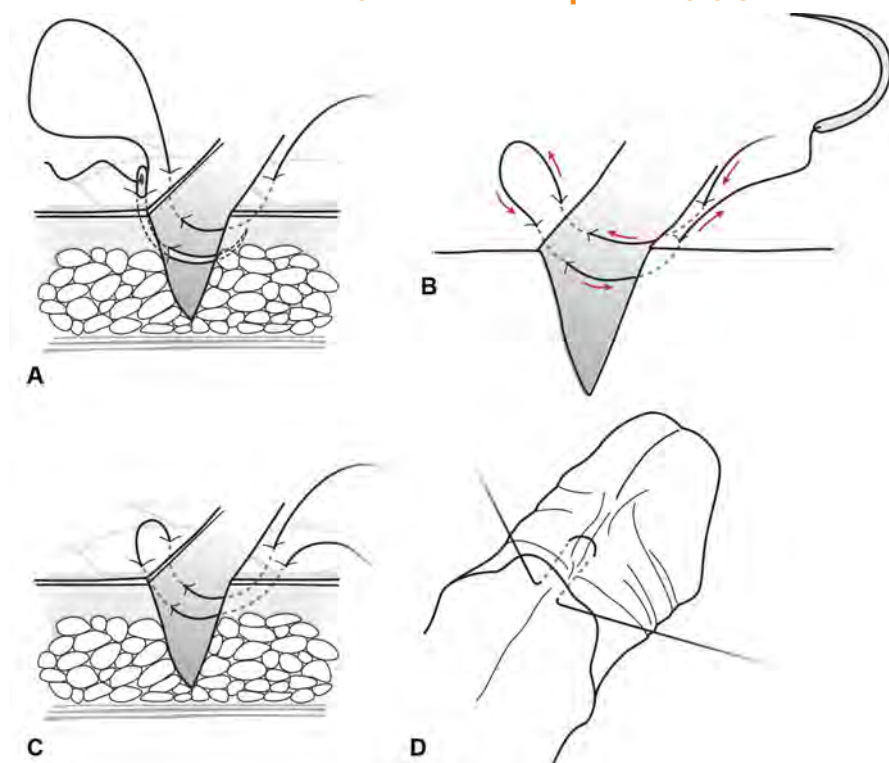
^a Vertical mattress suture technique (A,B); vertical mattress suture holding the skin edges and subcutaneous tissues together (C); and vertical mattress suture in the 09:00 o'clock position (D)

8.5.1.4. Horizontal mattress suture

This horizontal mattress suture is illustrated in Fig. 8.10.

1. Make two sutures beside one another. Align the first stitch across the wound; begin the second stitch on the side where the first ends.
2. Tie the knot on the side of the original entry point.
3. Use a horizontal mattress suture in the 06:00 o'clock position (frenulum), but keep the suture shallow. Great care must be taken to avoid placing the suture into deep layers, as the urethra is near the surface at the 06:00 o'clock position. Deep sutures can cause necrosis, resulting in urethral fistula—urethral fistula can be difficult to repair and may result in a lifelong problem.

Fig. 8.10. Horizontal mattress suture technique (A, B and C) and the horizontal mattress suture at the frenulum (06:00 o'clock position) (D)



8.5.2. Closing the circumcision wound

When suturing the circumcision wound, vertical mattress sutures should be placed in the 03:00, 09:00 and 12:00 o'clock positions (taking the frenulum at the 06:00 o'clock position; see Fig. 8.11), and a horizontal mattress suture should be placed at the 06:00 o'clock frenulum position. The 03:00, 09:00 and 12:00 o'clock mattress sutures are needed to ensure that the circumcision's wound edges do not invert (fold inwards).

The 12:00 o'clock vertical mattress suture is best placed as the first suture and the 06:00 o'clock frenulum horizontal mattress suture as the second suture. It is important to ensure that the midline raphe is in line with the frenular ridge and urethral meatus (if the raphe is naturally centred, see note below), and that there is an equal amount of skin on each side (see Box 8.4). If the ends of the 12:00 and 06:00 o'clock sutures are left long, they can be held with forceps and used to display the incision to be sutured (see Fig. 8.11).

Box 8.4. Note on alignment

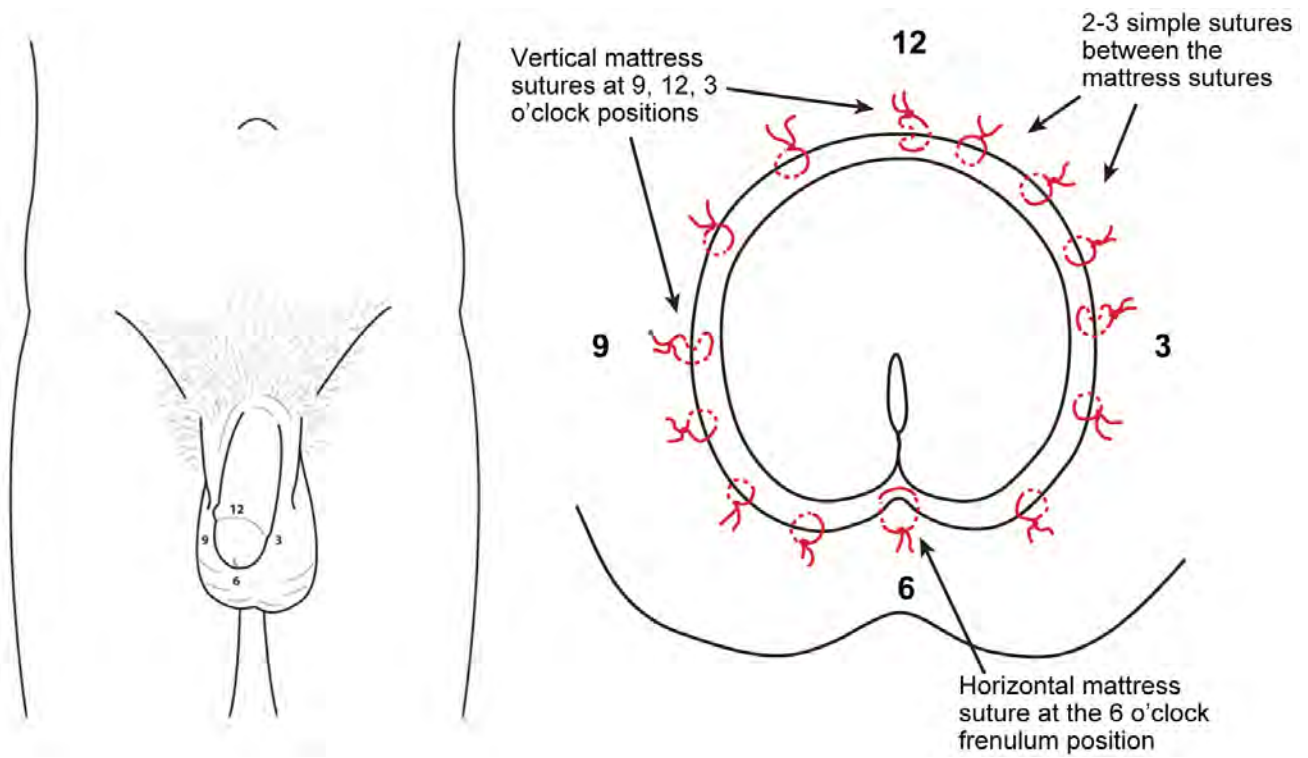
Normally, the raphe on the ventral aspect of the penis is in the midline and can be used for orientation. Alignment is achieved by lining up the midline raphe, frenulum and the urethral meatus. However, it is common for the raphe to be off-centre, so it helps to make additional marks to realign the skin when suturing (see Chapter 9, Fig 9.9).

In clients with a raphe not in the midline, extra alignment marks should be placed at the 03:00, 06:00, 09:00 and 12:00 o'clock positions when the circumcision line is marked, so the skin can be accurately realigned when the sutures are placed (see Chapter 9, Fig. 9.9). Using these orientation marks, mattress sutures should be placed at the 06:00 and 12:00 o'clock positions and then at the 03:00 and 09:00 o'clock positions. These mattress sutures should be placed first, before placing the remaining sutures. The tension and number of sutures must be just enough to achieve accurate apposition of the wound edges and avoid tissue strangulation.

8.5.3. Closing the suture wound and avoiding common problems with surgical technique

- Mark the line of the incision carefully. If the ventral raphe is not in the midline, extra alignment marks should be placed at the 03:00, 06:00, 09:00 and 12:00 o'clock positions when the circumcision line is marked, so the skin can be accurately realigned when the sutures are placed (see Chapter 9, Fig. 9.9).
- Take care with haemostasis.
 - If you can see the vessel lumen, then it is best and safest to avoid diathermy; instead, accurately pick up and tie the bleeder using proper technique.
 - If using diathermy, take small accurate pieces of tissue, and use the minimum burst of current.
 - If underrunning or ligating a blood vessel with sutures, avoid catching large pieces of tissue. Do not use excess knot throws, and do not leave long knot ears.
- Do not use too many sutures. Use about 12–16 sutures in total. This means the use of four mattress sutures with two or three simple sutures between each of the mattress sutures, that is, between the 12:00 and 03:00 o'clock positions, the 03:00 and 06:00 o'clock positions and so on.
- Make vertical mattress sutures at the 12:00, 03:00 and 09:00 o'clock positions for aligning and everting the skin.
- Make a horizontal mattress suture at the 06:00 o'clock position for haemostasis at the frenulum. Take care that the suture does not penetrate the urethra, which is near the surface in the 06:00 o'clock position. Do not pull sutures too tight. The skin edges should be together but not puckered. Too much tension cuts off the blood supply and increases the chance of tissue necrosis and infection.
- Tie the knots properly—use either a two-throw or three-throw square knot, or a double-throw and single-throw surgeon's knot.
- When using diathermy, use only the coagulation functions. Switch off all other functions, such as cutting, blending or fulguration. When the diathermy machine seems not to work, stop. Do not use diathermy at the frenulum because it can cause a burn through the urethral wall, which may result in a urethral fistula. The patient must only be in contact with the diathermy forceps and the diathermy plate (dispersive electrode). Ensure that the patient's skin is not in contact with any metal parts of the operating table to prevent the client experiencing an electric shock or skin burns.

Fig. 8.11. Orientation and positions of the horizontal and vertical mattress sutures, and the intervening simple interrupted sutures



KEY MESSAGES

- The provider and any assistant undertaking circumcision must always be aware of the sterile operating field. They should also adhere to standard precautions and principles to ensure that proper infection prevention and control practices are followed.
- Proper handling of tissue is critical to achieve a good outcome of the circumcision procedure. Handle the tissue gently because handling it too firmly may crush the tissue and delay healing, thereby increasing the risk of infection and worsening the scarring.
- Handle sharps in a way that helps avoid needle-stick (sharps) injury. Sharps include needles, scalpel blades, disposable diathermy points and any other sharp instruments.
- Minimizing blood loss is part of good surgical technique and safe medical practice. It reduces the risk of complications and need for interventions that bring additional risks. Minimizing blood loss also helps reduce the risk of contaminating the sterile field.
- Bleeding can be stopped by coagulation using diathermy. Safe diathermy requires the provider to understand and apply knowledge of the machine's electrical connections and power settings, and to know safe diathermy surgical technique.
- Even if diathermy is available, providers who undertake male circumcision should be skilled at stopping bleeding without diathermy. Surgical techniques for reducing blood loss are compression, temporary occlusion of blood vessels, and tying and underrunning.
- The goal of suturing (placing surgical stitches) is to achieve apposition without tension and with correct skin orientation. Too much tension in any type of skin suture increases the likelihood of cutting through the skin, resulting in wound disruption. Basic suturing techniques include simple interrupted sutures and mattress sutures (that is, the vertical mattress suture and the horizontal mattress suture).
- Particular care needs to be taken with haemostasis and suturing in the 06:00 o'clock frenular position, as the urethra is near the surface. Deep burns from diathermy or sutures placed too deeply, which catch the urethral wall, can result in tissue necrosis and urethral fistula (hole between the urethra and the outside).

ANNEX 8.1. DIATHERMY SETUP AND CONNECTIONS

Surgical diathermy is the use of high-frequency alternating current to produce heat with minimal stimulation of muscles and nerves, which occurs at frequencies below 20 000 Hz. Anaesthesia is necessary because the heat produced causes severe pain.

The main advantage of using diathermy for male circumcision is that it makes the procedure quicker; however, the provider doing the procedure must understand the diathermy circuit. Most diathermy units require electricity through a wall socket. If the electrical supply is unreliable, it is especially important that the provider is competent to undertake circumcision without the use of diathermy.

A8.1.1. Settings

Diathermy machines may have a number of different output settings. Depending on the output frequency and power, the current will cause the tissue to burn or vaporize. When the diathermy machine is set to coagulation, the current will yield a burn sufficient to stop bleeding from small blood vessels. When the machine is set to cutting, the current will vaporize tissue and produce a cutting effect, similar to using a scalpel. Some machines have a third setting called fulguration, in which the current will cause widespread superficial burns. There may also be a blending function that allows cutting and coagulation currents to be applied together.

Use only the coagulation function in diathermy machines, and switch off all other functions, such as cutting, blending or fulguration.

A8.1.1.1. False (dangerous) electrical circuits to earth (earth leakage)

When the diathermy machine seems not to work, stop.

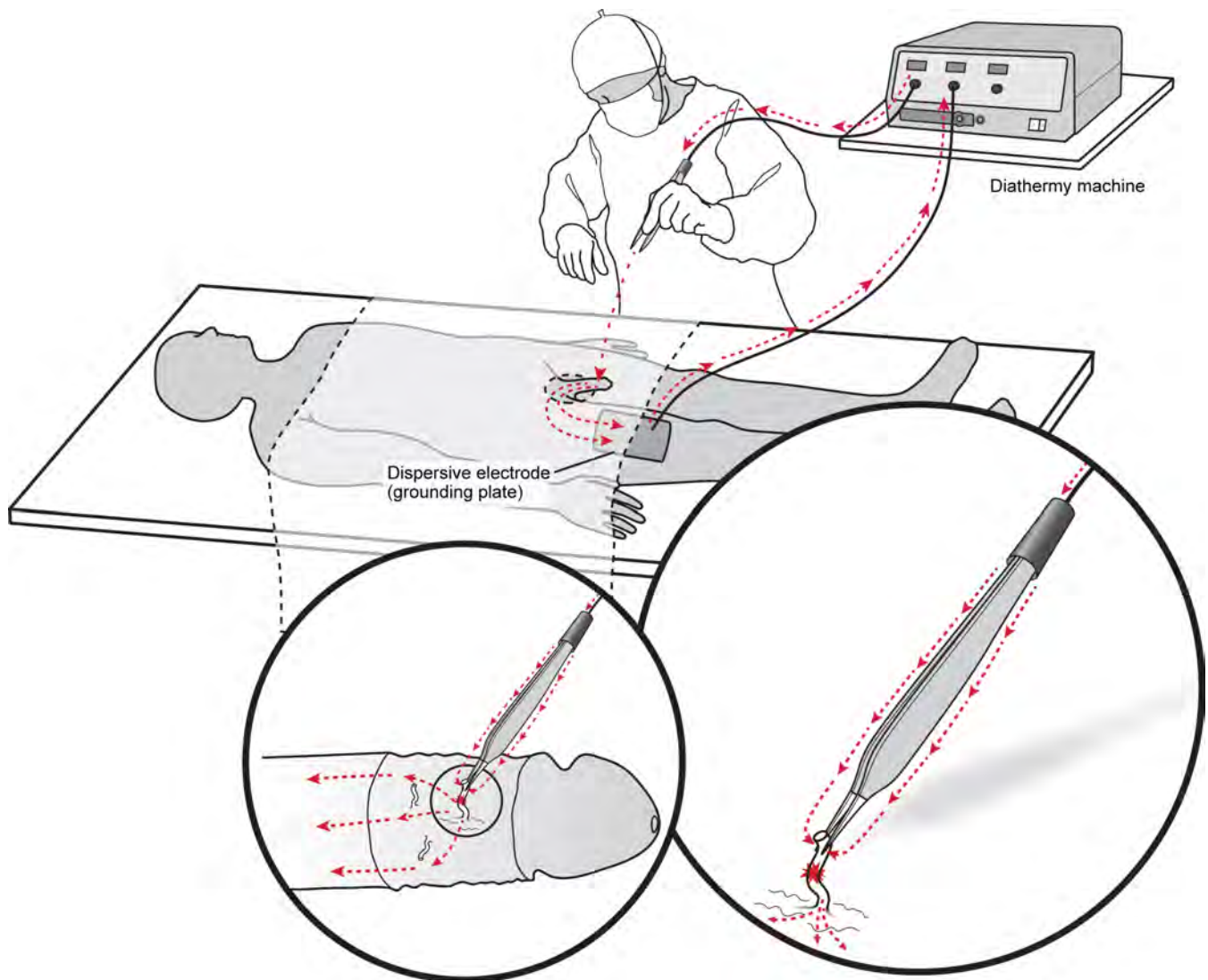
The patient must only be in contact with the diathermy forceps and the diathermy plate (dispersive electrode). The electrical current must only flow through the dispersive electrode (diathermy plate) back to the diathermy machine. The patient must not be in contact with any other material that will conduct electricity. Ensure that the patient's skin is not in contact with any metal parts of the operating table to prevent a false electrical circuit flowing from the diathermy forceps through the client's body and then through the client's skin. Otherwise, this false electrical current can result in the client experiencing an electric shock or skin burns.

To avoid any problems, the surgeon using the diathermy has the responsibility to ensure that the dispersive electrode (diathermy plate) has been placed correctly and that no other part of the client's skin is in contact with anything that will conduct electricity. The risk of a false circuit to earth is less with bipolar diathermy than monopolar diathermy, but it can happen with both methods. If there is a false circuit to earth, then this may cause the diathermy to seem as if it is not working because the energy is causing a burn at the skin that is (wrongly) in contact with the metal instead of the skin at the tip of the diathermy forceps.

A false circuit to earth is sometimes referred to as grounding, but the terms earthing or earth are used instead of ground or grounding to avoid confusion with the dispersive electrode (diathermy plate), which is also sometimes confusingly called the grounding plate.

A8.1.2. Monopolar diathermy

In monopolar diathermy, the current flows from the machine to the diathermy forceps that is held by the provider doing the procedure. The current then runs through the client's body to a dispersive electrode and back to the diathermy machine (see Fig. A8.1.1).

Fig. A8.1.1. Monopolar diathermy circuit

The effect of the coagulating diathermy current will occur at the point of greatest electrical resistance, which should be the tip of the diathermy forceps, where the diathermy forceps (tweezers) pick up a blood vessel. The dispersive electrode (diathermy plate) should be applied to bulky tissue as near to the surgical site as practical—usually the outer aspect of the upper part of the leg or under the buttock.

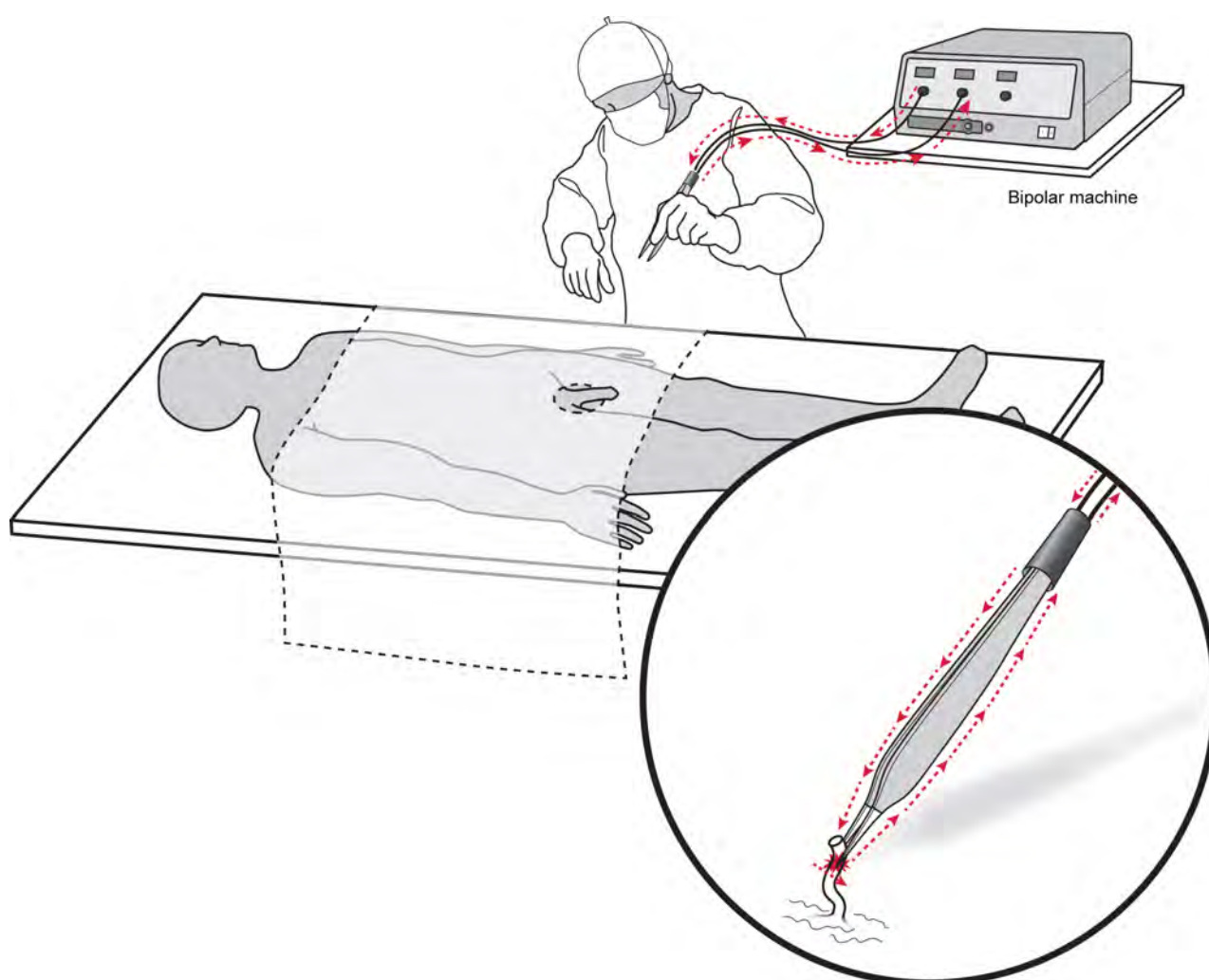
Dispersive electrodes may be reusable and held in place by bandages or disposable and stick-on fasteners. Particular care needs to be taken with the use of antiseptic cleaning agents and the placement of the dispersive electrode plate. The client's skin should be dry at the site of plate application. If antiseptic is accidentally spilled onto the plate of the dispersive electrode, then a new dry plate should be applied to a new area of dry skin. Also, the plate should not be applied to an area that is too hairy because this may prevent proper contact between the plate and skin; it is occasionally necessary to shave hair.

Care must be taken with diathermy technique. There is a risk that if the penis is put on traction at the same time as a large piece of tissue is taken with the diathermy forceps, then the base of the penis could be the point of greatest electrical resistance. When the current is channelled to the base of the penis, it could cause coagulation at that point rather than at the tip of the diathermy forceps.

A8.1.3. Bipolar diathermy

In bipolar diathermy, the current flows between two prongs of the diathermy probe, which is connected to the diathermy machine (see Fig. A8.1.2). There is no electrical circuit that flows through the client's body, and there is no need for a dispersive electrode (diathermy plate). Nevertheless, as with monopolar diathermy, care should be taken to ensure that the patient is not in contact with any metal because this contact can cause electricity to leak to the earth, thereby creating the potential for the client to experience electric shock or skin burn. Bipolar diathermy is safer than monopolar diathermy, but it is slightly harder to stop bleeding with bipolar diathermy and to use the technique effectively. If the current application is prolonged, charred tissue can stick to the diathermy forceps, and this can cause rebleeding when the forceps are pulled away. This charring reduces the effectiveness of the diathermy unless the diathermy forceps are frequently cleaned with a scratchpad.

Fig. A8.1.2. Bipolar diathermy circuit



A8.1.4. Diathermy setup precautions

- Do not use diathermy if the client has a pacemaker.
- Use correct diathermy surgical technique, as described in Section 8.4.2.
- Ensure that the client is not in contact with any metal because this can cause earth leakage. Many modern diathermy machines have an earth leakage detection circuit that automatically switches off the machine if there is any leakage of electrical current to earth. Earth leakage is less of a problem with bipolar diathermy.
- Be careful not to spill any liquid on the diathermy machine. Do not store bottles of cleaning fluids or anything else on top of the diathermy machine.
- Apply the diathermy plate (dispersive electrode, grounding plate) correctly:
 - Ensure that the diathermy plate has a broad area of contact with the skin. The plate should be applied to bulky tissue, such as the upper leg muscle, and as near to the surgical site as practical. Well-vascularized muscle conducts electricity well, but bone does not.
 - Ensure that the skin is clean and dry. Moisture on the skin may prevent proper sticking of disposable adhesive grounding places.
 - Shave hair if necessary.
 - Do not apply the diathermy plate over bony prominences to avoid burning the skin between the skin and the plate.
 - Use the whole of the diathermy plate, and do not cut a diathermy plate down in size. Many modern monopolar machines have circuitry to ensure that the diathermy plate has been properly applied. If the plate has not been properly applied, the machine alerts the user when the plate has become disconnected and prevents the machine from activating if a fault is detected.
- Do not pull on the machine's electrical cables.
- Be familiar with the safety features of the machine in use.
- Be familiar with the power settings normally used for diathermy in conventional or device-based surgical circumcision. Do not increase the power settings. If anyone asks to increase power settings, stop and check everything. A call to increase power settings is a red flag; it indicates a likely faulty connection and a risk of burning or incorrect diathermy surgical technique, especially taking too large a piece of tissue in the diathermy forceps.
- If the machine does not work when activated, check everything, as outlined below:
 - Check that only a small piece of tissue is being held and that the penis is not under tension.
 - Ensure that the connections are correct. On some old machines, it is possible to connect the diathermy plate (dispersive electrode) to the active output, but most modern machines have specially shaped plugs that make this impossible.
 - Check that the diathermy plate is in good contact with the client. One of the most common causes of diathermy burns is a poorly applied diathermy plate with only a narrow area of contact between the plate and the client; this can result in a skin burn at the site of contact with the diathermy plate.
 - If it seems that the connections are properly made, then check that the power is switched on at the wall plug and that the plug is working. Also, check that there has not been a power cut.
 - Check that the client is not in contact with any metal; many diathermy machines have an automatic power shut off if there is any earth leakage.

- If there is power in the machine and connections seem to be correct, then a lead may be faulty. Try replacing the various leads:
 - lead between the diathermy forceps and machine
 - diathermy plate (many machines have circuitry that shuts off when they detect faulty diathermy plate application or connection, or both)
 - lead between the diathermy plate and diathermy machine.
- If none of these measures solves the problem, then complete the procedure without diathermy and send the diathermy machine for repair.
- If there has been any malfunction of the diathermy machine, then, at the end of the procedure, the provider doing the procedure should check the client for adverse events, especially for burns at the site of the diathermy plate.

A8.1.5. Tips for using diathermy

- Know the diathermy machine, and be familiar with the normal settings. Read the manufacturer's instructions for use.
- Remember that the need to increase power settings is a red flag that something is wrong.
- Remember that most diathermy-related adverse events occur because of poor diathermy surgical techniques, such as the lack of accuracy or prolonged application of current.
- Know what to do if the diathermy machine does not work when it is activated.

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CHAPTER 9

CIRCUMCISION METHODS FOR ADOLESCENT BOYS AND MEN



This chapter provides information on the following:

- preparations for the circumcision procedure
- local anaesthesia for male circumcision
- step-by-step process for three conventional methods of surgical circumcision for adolescent boys and men: forceps-guided, dorsal slit and sleeve resection
- variations in technique necessary when there is phimosis or scarring of the frenulum
- devices used for male circumcision

9.1. INTRODUCTION

By the time the client is in the procedure room, several important services and preoperative actions will have already been undertaken. The client has been found eligible for circumcision at the clinic or facility level and an appropriate method has been selected (as applicable). The client—or his parent(s)/guardian(s)—has provided consent/assent (see Box 9.1). In addition, the necessary equipment and supplies have been prepared for the circumcision procedure.

Box 9.1. Reminder on consent/assent

Even after all preparations are complete, **a client may withdraw consent/assent at any time**. While the provider can try to reassure any client who expresses doubt about the procedure, ultimately, whether the client is an adult or adolescent, the provider should respect the client's decision.

There are several different methods for conventional or device-based surgical circumcision. The most appropriate method for a particular client depends on many factors:

- capacity of the clinic or facility to provide the method, that is, the skill level of the provider who will be doing the procedure and the availability of supplies and equipment required;
- medical eligibility of the client for the method, based on a focused history and physical examination, including a detailed examination of the penis and assessment of penile development; and
- client's preferred method (depending on medical eligibility), as feasible.

This chapter describes three widely used conventional or device-based surgical circumcision methods for adolescent boys and men: forceps-guided, dorsal slit and sleeve resection. These surgical techniques were also described in the 2009 edition of this *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men (Manual)*. At that time, these techniques were chosen on the basis of extensive experience worldwide and their use in three randomized controlled trials of male circumcision in Kenya, South Africa and Uganda. In this edition of the *Manual*, the three techniques have been slightly modified because of the experience of more than 10 million adult and adolescent male circumcisions performed in East and Southern Africa.

Male circumcision device methods recommended by the World Health Organization (see Box 9.2) are also efficacious, safe and acceptable methods of male circumcision among healthy men in the context of HIV prevention (1). Devices are also prequalified through the World Health Organization for quality assurance. This *Manual* provides only limited information on devices. Providers who perform male circumcision using device-based surgical circumcision methods should know which methods are recommended and receive manufacturer-accredited training for the proper use of a particular device method. Thereafter, they should also consult the manufacturer's most recent instructions for use of the device because device-based methods are relatively new and manufacturer's instructions for use frequently change to keep up to date with user experience.

Box 9.2. Devices prequalified by the World Health Organization

For current information about male circumcision device recommendations and those prequalified by the World Health Organization, visit these webpages:

<http://www.who.int/hiv/topics/malecircumcision/en/>

http://www.who.int/diagnostics_laboratory/evaluations/PQMCdevices_list/en/

9.2. SAFE SURGERY

9.2.1. Key safety principles for male circumcision services

Providers doing male circumcision procedures should keep the following in mind:

- Male circumcision is an elective procedure performed on a healthy adolescent boy or man for partial protection from HIV.
- Male circumcision presents a different situation from performing a medically necessary procedure on someone who is ill, when the risk of possible adverse events is balanced against harm caused by the illness (or resulting from not doing the procedure).
- Client safety is a top priority in the context of male circumcision as part of a comprehensive HIV prevention strategy.

To ensure that client safety is a top priority, the provider doing the male circumcision, and the provider's managers or supervisors, should apply the following principles:

- **Competence in basic surgical skills is key.** The most important component of safe surgery is having proper training in basic surgical skills (see Chapter 8) and in one or more of the specific methods described in Chapter 9.
- **Necessary supplies, equipment and other resources are available and ready for use.** These include materials needed for providing safe, appropriate and routine services, and managing any adverse events.
- **Allowing enough time is critical.** Overly hurried surgery is associated with an increase in adverse events. Most surgical methods require about 20–30 minutes per procedure. Allowing adequate time for safe surgery can be a problem when there is pressure to undertake a large number of procedures, but the provider doing the procedure must always put the client's safety first. This is particularly important if there are difficulties in stopping bleeding during a procedure.
- **Proper sterile technique and infection prevention save lives.** Anyone who touches the client during the procedure or comes into contact with any of the supplies, equipment, materials or waste from the screening or examination should be trained and skilled in performing standard infection prevention practices, as well as those practices specific to male circumcision. These specific practices are in the procedures regarding actions to take before, during and after the male circumcision (see Chapters 8–10). They are also presented in more detail and in a broader context in Chapter 5.
- **Providers should know the limits of their expertise.** The provider doing the circumcision procedure should know his or her limits. Everyone on the team should work to create an environment where those doing the circumcision are supported and encouraged to seek advice or backup at any time. If something goes wrong, the provider doing the procedure should let others know about it and receive encouragement to get another trained provider to help—and not try to hide the problem. Problems are much easier to manage in a supportive environment, where asking for help is encouraged and where there is backup. Adverse events are often made worse by panicked attempts to overcome problems without help.

- **It is safer to have a trained assistant.** Having a trained assistant helps to keep the surgery safe for the client, reduces the chance of the sterile area becoming contaminated and reduces stress if there is any difficulty with the procedure.
- **Use the World Health Organization's safe surgery checklist to improve client safety.** Using the World Health Organization's safe surgery checklist has improved the safety of surgery throughout the world. A version of this checklist was adapted for male circumcision and is in Chapter 7. The use of the checklist is particularly important in any clinic or facility shared by male circumcision services and other services, such as family planning or general surgery, where other types of surgery are done, and, particularly, where other types of surgery are done in the same procedure room as the one used for male circumcision.

Adverse events, while rare, can negatively influence the uptake of male circumcision services in the community, particularly if these incidents are not appropriately managed.

9.2.2. Circumcision-specific skills

The provider who is doing the procedure should be trained and skilled in basic surgical skills (see Chapter 8) and in skills specific to the method of male circumcision that he or she will be performing. These are highlighted below and presented in more detail in this chapter. The basic surgical skills are the following:

- Prepare the skin and drape the client before the procedure (see Section 9.3).
- Give injectable local anaesthesia using subcutaneous ring block or dorsal nerve block, or both (see Section 9.4).
- Retract the foreskin and manage adhesions (see Section 9.5.1).
- Mark the line for circumcision (see Section 9.5.2).
- Realign tissue and skin after the procedure (see Section 9.5.3).
- Avoid damaging the urethra by having proper understanding of the anatomy of the frenulum and knowing the relationship between the frenulum and the underlying urethra (see Section 9.6.1).
- Perform the forceps-guided method of circumcision (see Section 9.6.1).
- Perform the dorsal slit method of circumcision (see Section 9.6.2).
- Perform the sleeve resection method of circumcision (see Section 9.6.3).
- Dress the wound (see Section 9.7).
- Ensure that there is good recordkeeping and reporting (see Section 9.8).

9.3. SKIN PREPARATION AND DRAPING

9.3.1. Skin preparation

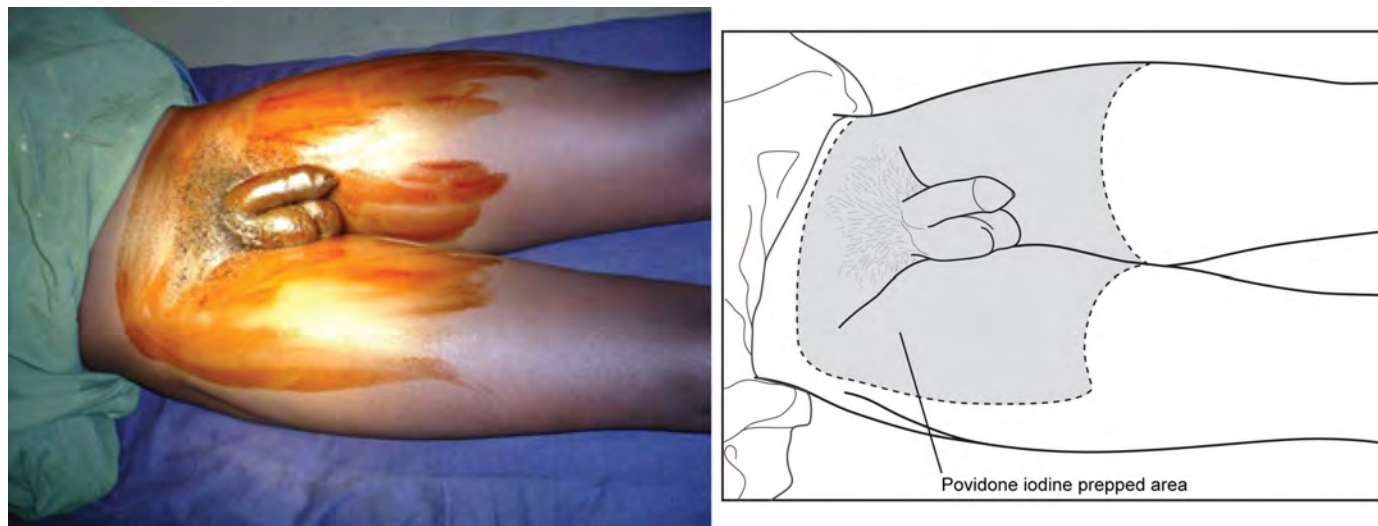
Before the client's skin is prepared, his genital area should be washed with soap and clean water to remove all visible dirt and debris. If he has not done so at home, this should be done at the clinic or facility. Cleaning is an essential step, as antiseptics will not be effective without thorough cleaning. Cleaning may be done with clean exam gloves. Prepare the skin with povidone iodine aqueous solution, starting with the glans and the shaft of the penis, and then moving out to the periphery (see Fig. 9.1). If the client has a history of allergy to iodine, use an alternative solution, such as chlorhexidine gluconate. Cleaning should be gentle. Holding the penis with a gauze swab, retract the foreskin to clean the glans. If there are adhesions, then give the client anaesthesia at this time; go back and clean the glans and coronal sulcus after the anaesthesia has worked (that is, after it has taken effect).

The areas prepared with antiseptic include the penis, scrotum, adjacent areas of the thighs and lower part of the abdomen (suprapubic area), so there is no risk that the provider doing the procedure will touch unprepared skin. Repeat the

procedure so that the skin area is prepped two more times (three total). The cleaned penis should not be placed on skin that is not prepared (for example, abdomen or thigh).

After the third wash, the wet antiseptic solution should remain on the skin for at least two minutes and allowed to dry.

Fig. 9.1. Preprocedure skin preparation with povidone iodine^a

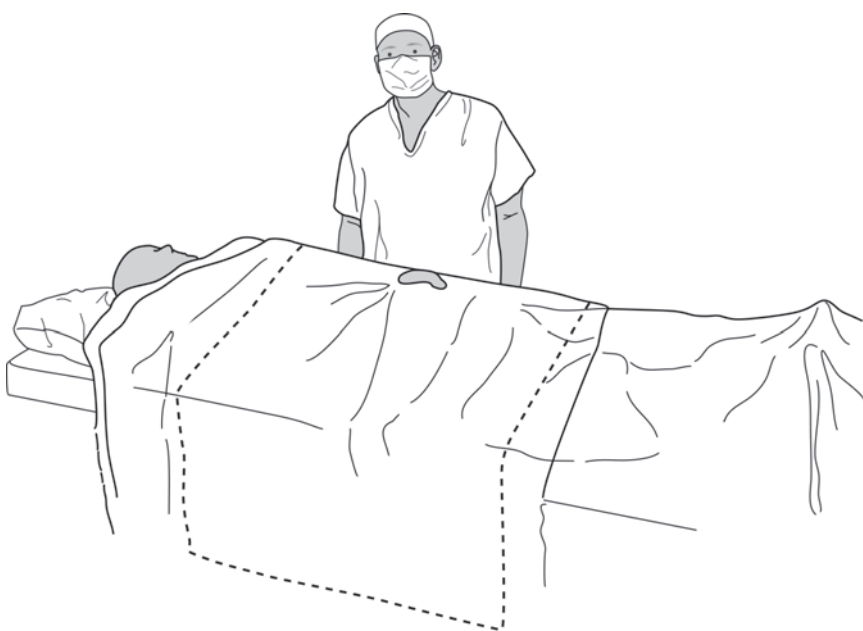


^a Photograph © R. Bailey, Kisumu Project

9.3.2. Draping

Draping provides a sterile operative field and helps prevent wound contamination. Before covering the client with sterile drapes, the provider doing the procedure (and any trained assistant) should carry out hand preparation, put on a sterile apron and put on sterile gloves. Only the operative area and the area where the anaesthesia will be administered should be left uncovered. A single drape with a hole for the penis (O-drape) (see Fig. 9.2) is better than four drapes secured with towel clips. The drape should cover the entire knee-to-chest area to provide an adequately large sterile field. The drape edges that hang below the procedure table are not sterile.

Fig. 9.2. Draping for male circumcision^a



^a The minimum sterile field is shown by the dotted lines in the drawing.

9.4. LOCAL ANAESTHESIA

When using a conventional surgical method, injection of a local anaesthetic agent(s) is recommended. Local anaesthesia is simpler, safer and less expensive than general anaesthesia; also, the client can return home on the same day as the procedure. There are two possible techniques for injecting penile local anaesthesia: subcutaneous ring block or dorsal nerve block. These techniques may be supplemented by local infiltration at the frenulum.

Topical anaesthetic cream can be used for circumcision with some device methods (see the manufacturer's instructions for use for the specific device).

9.4.1. Dose of injectable local anaesthetic agent(s)

The local anaesthetic agent(s) most often used is plain lidocaine/lignocaine 1% or 2%, alone or in combination with plain bupivacaine 0.25% or 0.5%. Bupivacaine may be used in clients aged 10 years and older, regardless of weight. The selection of drug concentration is typically made by the ministry of health for the overall national male circumcision programme; thus, providers may not have a choice about whether to use 1% versus 2% lidocaine/lignocaine or 0.25% versus 0.5% bupivacaine. If there is a choice (particularly, if the client is small), it may be better to use the lower concentration—such as 1% lidocaine/lignocaine with or without 0.25% bupivacaine—because this will allow for a reserve of volume to be available if a repeat injection is needed. Also, with this approach, there is less risk of exceeding the maximum dose. The disadvantage of a lower concentration is that it takes longer to work, and the provider doing the procedure must allow time for the anaesthesia to work.

Both lidocaine/lignocaine and bupivacaine are amide local anaesthetic agents and have similar central nervous system toxicity and cardiac toxicity—although bupivacaine has higher cardiac toxicity than lidocaine/lignocaine. Because the toxic effect is the same for these two agents, their toxicity will be additive when combined. The maximum dose of lidocaine/lignocaine that can safely be given alone is 3 mg/kg of body weight. Bupivacaine is more potent, and the maximum dose that can be given is 1.5 mg/kg of body weight—although use of bupivacaine alone is not recommended. The advantage of lidocaine/lignocaine is that it works rapidly (fast onset). Bupivacaine is more expensive than lidocaine/lignocaine and takes longer to work, but the anaesthesia lasts longer. Combinations of lidocaine/lignocaine and bupivacaine have been used in several million male circumcisions in East and Southern Africa, with dosage in accordance with the *Adverse event action guide, 2nd edition (Guide)*. This *Guide* gives the maximum recommended dose of lidocaine/lignocaine combined

with bupivacaine as 2 mg/kg of lidocaine/lignocaine and 0.5 mg/kg of bupivacaine (2). Tables 9.1–9.4 give examples of starting volumes and maximum volumes, and these tables are helpful guides to ensure that the maximum dose is not exceeded. It is good clinical practice to initially administer a starting dose and move to the maximum dose *only* if needed.

Table 9.1. Maximum doses of lidocaine/lignocaine (1%) local anaesthetic agent(s)

SAFE LOCAL ANAESTHETIC DOSING—STARTING ^a AND MAXIMUM ^b VOLUMES 1% LIDOCAINE/LIGNOCAINE		
Weight in kg	Starting volume	Maximum safe volume
20–29 kg ^c	4 mL	Additional 2 mL to TOTAL of 6 mL
30–39 kg	6 mL	Additional 3 mL to TOTAL of 9 mL
40–50 kg	8 mL	Additional 4 mL to TOTAL of 12 mL
More than 50 kg	10 mL	Additional 5 mL to TOTAL of 15 mL
^a Starting dose of lidocaine/lignocaine is 2 mg/kg. ^b Maximum safe dose of lidocaine/lignocaine is 3 mg/kg. ^c For those weighing less than 30 kg, use 5 mL syringe so that volumes can be measured accurately. Starting volume is usually adequate; increase to <i>maximum</i> volume (dose) only if it is required for pain control up to the <i>maximum</i> .		
WARNING: Lidocaine/lignocaine with adrenaline (lidocaine/lignocaine with epinephrine) or bupivacaine with adrenaline (bupivacaine with epinephrine) should never be used for male circumcision surgery because of the risk of ischaemia (vessel constriction) of the whole penis, particularly if the penis is small. Also, the use of lidocaine/lignocaine with adrenaline (lidocaine/lignocaine with epinephrine) or bupivacaine with adrenaline (bupivacaine with epinephrine) may delay the onset of bleeding from blood vessels that require ligation or diathermy.		

Source: (2)

Table 9.2. Maximum doses of lidocaine/lignocaine (1%) and bupivacaine (0.25%) local anaesthetic agents

SAFE LOCAL ANAESTHETIC DOSING—STARTING ^a AND MAXIMUM ^b VOLUMES MIXTURE OF 1% LIDOCAINE/LIGNOCAINE AND 0.25% BUPIVACAINE 1:1 MIXTURE (EQUAL VOLUMES OF EACH)		
Weight in kg	Starting volume ^c (1:1 mixture)	Maximum safe volume (1:1 mixture)
20–29 kg	3 mL of each (6 mL total)	Additional 1 mL of each drug to TOTAL of 8 mL (maximum 4 mL of each)
30–39 kg	4 mL of each (8 mL total)	Additional 2 mL of each drug to TOTAL of 12 mL (maximum 6 mL of each)
40–50 kg	5 mL of each (10 mL total)	Additional 3 mL of each drug to TOTAL of 16 mL (maximum 8 mL of each)
More than 50 kg	5 mL of each (10 mL total)	Additional 5 mL of each drug to TOTAL of 20 mL (maximum 10 mL of each)
^a Starting dose of lidocaine/lignocaine is 1.5 mg/kg and bupivacaine is 0.3 mg/kg. ^b Maximum safe doses of lidocaine/lignocaine is 2.0 mg/kg and bupivacaine is 0.5 mg/kg. ^c Starting volume is usually adequate; increase to maximum volume (dose) only if required for pain control up to the maximum. To improve provider efficiency through minimizing numbers of syringes needed, starting doses have been kept at or below 10 mL and maximum doses at or below 20 mL.		
WARNING: Lidocaine/lignocaine with adrenaline (lidocaine/lignocaine with epinephrine) or bupivacaine with adrenaline (bupivacaine with epinephrine) should never be used for male circumcision surgery because of the risk of ischaemia (vessel constriction) of the whole penis, particularly if the penis is small. Also, the use of lidocaine/lignocaine with adrenaline (lidocaine/lignocaine with epinephrine) or bupivacaine with adrenaline (bupivacaine with epinephrine) may delay the onset of bleeding from blood vessels that require ligation or diathermy.		

Source: (2)

Table 9.3. Maximum doses of lidocaine/lignocaine (2%) local anaesthetic agent

SAFE LOCAL ANAESTHETIC DOSING—STARTING ^a AND MAXIMUM ^b VOLUMES 2% LIDOCAINE/LIGNOCAINE		
Weight in kg	Starting volume	Maximum safe volume
20–29 kg ^c	2 mL	Additional 1 mL to TOTAL of 3 mL
30–39 kg ^c	3 mL	Additional 1 mL to TOTAL of 4 mL
40–50 kg	4 mL	Additional 2 mL to TOTAL of 6 mL
More than 50 kg	5 mL	Additional 2 mL to TOTAL of 7 mL

^a Starting dose of lidocaine/lignocaine is 2 mg/kg.
^b Maximum safe dose of lidocaine/lignocaine is 3 mg/kg.
^c Use 5 mL syringe so that volumes can be measured accurately.
Starting volume is usually adequate; increase to *maximum* volume (dose) only if required for pain control up to the *maximum*.

WARNING: Lidocaine/lignocaine with adrenaline (lidocaine/lignocaine with epinephrine) or bupivacaine with adrenaline (bupivacaine with epinephrine) **should never be used** for male circumcision surgery because of the risk of ischaemia (vessel constriction) of the whole penis, particularly if the penis is small. Also, the use of lidocaine/lignocaine with adrenaline (lidocaine/lignocaine with epinephrine) or bupivacaine with adrenaline (bupivacaine with epinephrine) may delay the onset of bleeding from blood vessels that require ligation or diathermy.

Source: (2)

Table 9.4. Maximum doses of lidocaine/lignocaine (2%) and bupivacaine (0.5%) local anaesthetic agents

SAFE LOCAL ANAESTHETIC DOSING—STARTING ^a AND MAXIMUM ^b VOLUMES MIXTURE OF 2% LIDOCAINE/LIGNOCAINE AND 0.5% BUPIVACAINE 1:1 MIXTURE (EQUAL VOLUMES OF EACH)		
Weight in kg	Starting volume (1:1 mixture)	Maximum safe volume (1:1 mixture)
20–29 kg ^c	1 mL of each (2 mL total)	Additional 1 mL of each drug to TOTAL of 4 mL (maximum 2 mL of each)
30–39 kg ^c	2 mL of each (4 mL total)	Additional 1 mL of each drug to TOTAL of 6 mL (maximum 3 mL of each)
40–50 kg	3 mL of each (6 mL total)	Additional 1 mL of each drug to TOTAL of 8 mL (maximum 4 mL of each)
More than 50 kg	4 mL of each (8 mL total)	Additional 1 mL of each drug to TOTAL of 10 mL (maximum 5 mL of each)

^a Starting doses of lidocaine/lignocaine are: lidocaine/lignocaine 1.5 mg/kg / bupivacaine 0.3 mg/kg
^b Maximum safe doses of lidocaine/lignocaine is 2 mg/kg and bupivacaine is 0.5 mg/kg.
^c Use 5 mL or smaller syringe so that volumes can be measured accurately.
Starting volume is usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

WARNING: Lidocaine/lignocaine with adrenaline (lidocaine/lignocaine with epinephrine) or bupivacaine with adrenaline (bupivacaine with epinephrine) **should never be used** for male circumcision surgery because of the risk of ischaemia (vessel constriction) of the whole penis, particularly if the penis is small. Also, the use of lidocaine/lignocaine with adrenaline (lidocaine/lignocaine with epinephrine) or bupivacaine with adrenaline (bupivacaine with epinephrine) may delay the onset of bleeding from blood vessels that require ligation or diathermy.

Source: (2)

9.4.2. Safe injection of local anaesthetic agents

The provider doing the procedure has the responsibility to personally check the vial of anaesthesia, ensure that the correct agent at the correct concentration has been selected and check the expiry date. It is important to verify that the anaesthesia is clear—has no visible particles in it (which may suggest that the vial is contaminated)—and does not contain epinephrine (adrenaline). **Always** check the vial.

Once the needle is in place in the base of the penis, the provider should aspirate the syringe to make sure that no blood has entered the syringe. If blood enters the syringe, do not inject the anaesthetic agent(s); move the needle to a new location and aspirate again. This ensures that the anaesthetic agent(s) is not injected into a blood vessel, corpora cavernosa or corpus spongiosum. **Repeat aspiration each time the needle is moved and before any additional anaesthetic agent(s) is injected.**

Another method for injecting local anaesthetic is to fully insert the needle, aspirate to ensure that the needle is not in a blood vessel and then inject as the needle is withdrawn. With this method, it is important to inject only while the needle is being withdrawn. If the needle stops moving, then the injection must stop. Before resuming the injection, repeat aspiration to ensure that the needle is not in a blood vessel.

9.4.3. Additional analgesia

Best practice is to give the client oral analgesia (for example, 500 mg tablet of paracetamol) 30 minutes before the procedure so that the oral agent is absorbed and effective as the anaesthesia wears off. Another dose of oral analgesia can be given for the client to take before he goes home.

9.4.4. Local anaesthetic techniques

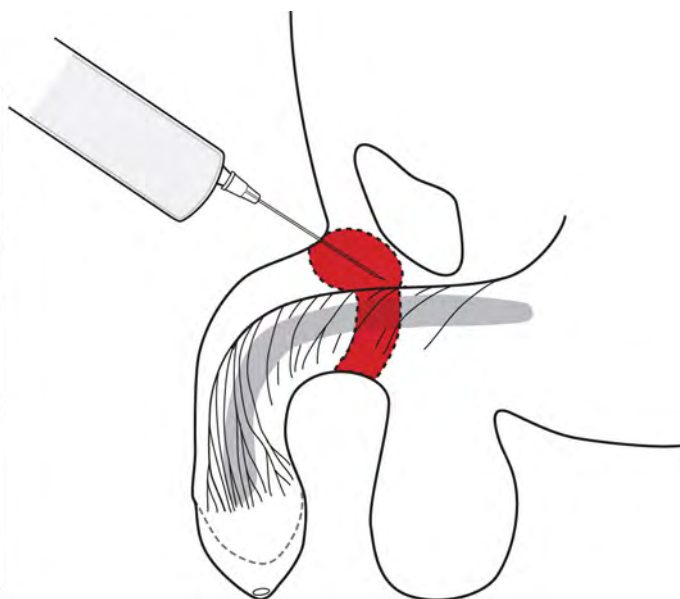
9.4.4.1. Subcutaneous ring block technique

The subcutaneous ring block technique involves administering local anaesthesia around the base of the shaft of the penis, thereby creating a subcutaneous ring of anaesthetic agent (see Fig. 9.3). This technique helps prevent any injury to the underlying penile tissue while achieving adequate control of pain on the skin of the shaft.

- Using a fine-gauge needle (23–27 gauge), first inject approximately 0.1 mL of anaesthetic agent(s) subcutaneously at 12:00 o'clock.
- Next, without withdrawing the needle, advance the needle into the subdermal space, making sure that the needle is freely mobile. At this point, aspirate the syringe and, if there is no blood, inject 2–3 mL of anaesthetic agent(s) to block the dorsal penile nerves.
- Then, advance the needle subcutaneously around each side of the penis, aspirate the syringe and, if there is no blood, inject small additional amounts of anaesthetic agent(s) to complete a half-ring of anaesthesia around the dorsal half of the shaft (see Section 9.4.4.2).
- To complete the block, make additional punctures at the 03:00 o'clock and 09:00 o'clock positions to continue the ring of anaesthesia around the ventral half of the shaft. If a puncture is made at the 06:00 o'clock position, there is a risk of urethral injury and injecting into a vessel.

Once the anaesthesia has been injected, **wait for a minimum of five minutes** (timed by a clock) before beginning the male circumcision. A common mistake is to start the procedure before the anaesthesia has had time to work. Test sensation before starting the procedure by gently pinching the foreskin with an artery forceps. If there is any residual sensation, wait for an additional two to three minutes and test again. If there is still sensation, give more local anaesthesia, taking care not to exceed the maximum safe dose (see Tables 9.1–9.4).

Fig. 9.3. The ring of local anaesthetic agent(s) after injections have been made during the ring block technique^a

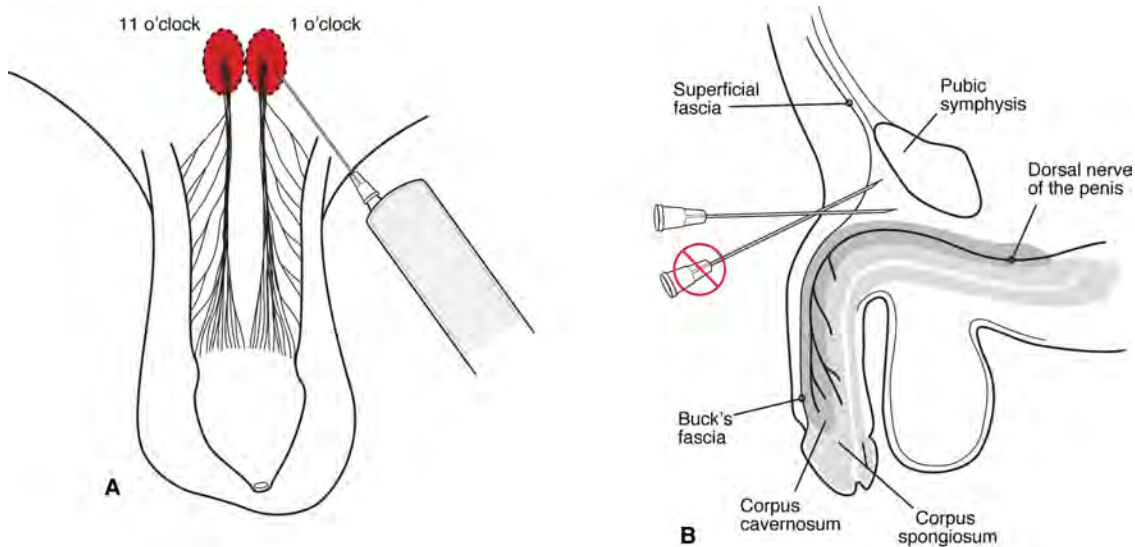


^a Photograph © R. Bailey, Kisumu Project

9.4.4.2. The dorsal nerve block

In this technique, the anaesthetic agent(s) is deposited close to the dorsal nerve (see Fig. 9.4). This gives quick and safe pain control. A fine-gauge needle (21–27 gauge) should be used.

- STEP 1.** Give two injections at the 11:00 o'clock and 01:00 o'clock positions on the dorsum of the penis in the subpubic angle.
- STEP 2.** Direct the needle at a 45° angle to the shaft. This improves the success rate of the block and reduces the risk of injury to the underlying penile structures.
- STEP 3.** Advance the needle in each of these positions (11:00 o'clock and 01:00 o'clock) to a depth of about 3 cm so that the anaesthesia is adjacent to the nerve before it branches.
- STEP 4.** Aspirate the syringe to ensure that the needle is not in a blood vessel.
- STEP 5.** Deposit the anaesthetic agent(s) close to the dorsal nerve of the penis.
- STEP 6.** Wait five minutes after giving the injection—timed by the clock—for the anaesthesia to take effect. A common mistake is to start the procedure before the anaesthesia has had time to work.

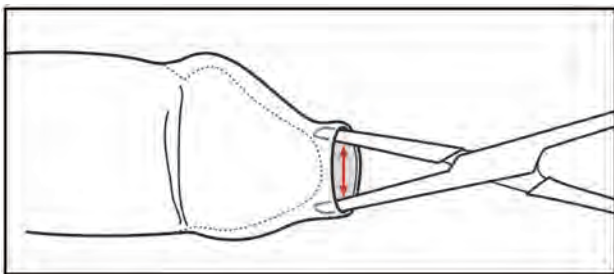
Fig. 9.4. Injection of local anaesthesia for the dorsal nerve block^a

^a (A) Injections are made at the 11:00 o'clock and 01:00 o'clock positions. (B) The needle is angled to inject under the symphysis pubis.

9.5. PREPARING THE PENIS FOR SURGERY

9.5.1. Retraction of the foreskin and managing adhesions

Retracting the foreskin is a step that is common to all methods of male circumcision described in this *Manual*. After effective local anaesthesia has been achieved, fully retract the foreskin. If the opening (or aperture) of the foreskin is tight, it may be necessary to dilate it with a pair of artery forceps (see Fig. 9.5), but this is not usually necessary in adults and older adolescents. Take care to **just stretch the opening of the foreskin** and not to push in the forceps too far. Pushing in the forceps too far increases the risk that the tip of the forceps enters the urethral meatus and causes injury to the urethra and glans. If the dilatation causes minor tears in the skin near the tip of the foreskin, this is not a problem, as the foreskin is going to be removed; however, tears in the urethral meatus can be the start of a lifelong problem because subsequent scarring can cause urethral stricture and urinary obstruction.

Fig. 9.5. Dilatation of the aperture of the foreskin^a

^a Note: Tips of the forceps are positioned within the aperture of the foreskin, and care has been taken not to allow the tip of the forceps to accidentally enter the urethral meatus.

In younger adolescents, adhesions are common; they are nearly always physiological and not pathological. Adhesions can usually be separated easily by applying gentle pressure on them using a moist gauze swab or a blunt probe (see Fig. 9.6). If the adhesions are hard or if trying to separate them causes bleeding, then they are more likely to be pathological than physiological. The provider may decide to abandon the procedure and refer the client to an experienced surgeon or specialist. Hard scar tissue adhesions with phimosis, which prevent retraction of the foreskin and chronic balanitis, are more likely to be seen in older men but can occur (rarely) in children following balanitis in infancy.

Fig. 9.6. Retracting the foreskin to fully expose the glans, corona and coronal sulcus, and to separate any adhesion^a



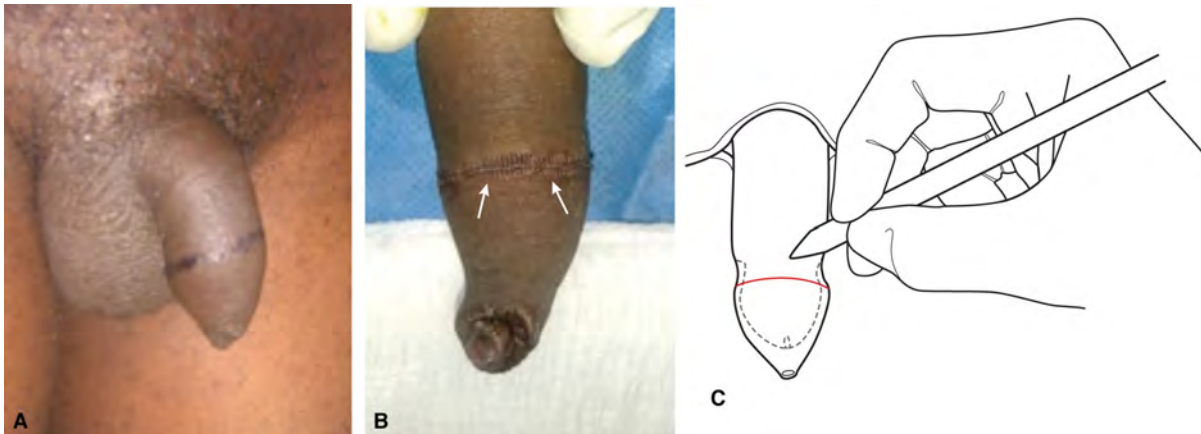
^a Photograph © R. Bailey, Kisumu Project

9.5.2. Marking the line of the male circumcision

Marking the line of the male circumcision is another step common to all conventional or device-based surgical methods described in this *Manual*; however, the placement of the line depends on the circumcision technique used. It is important to mark the line of male circumcision to avoid excess or insufficient skin removal. With the foreskin in a natural resting position, indicate the intended line of the incision with pinch marks or a marker pen for the surgical technique that will be used. Surgical marker pens are available in bright blue, and this colour shows well when the skin is deeply pigmented.

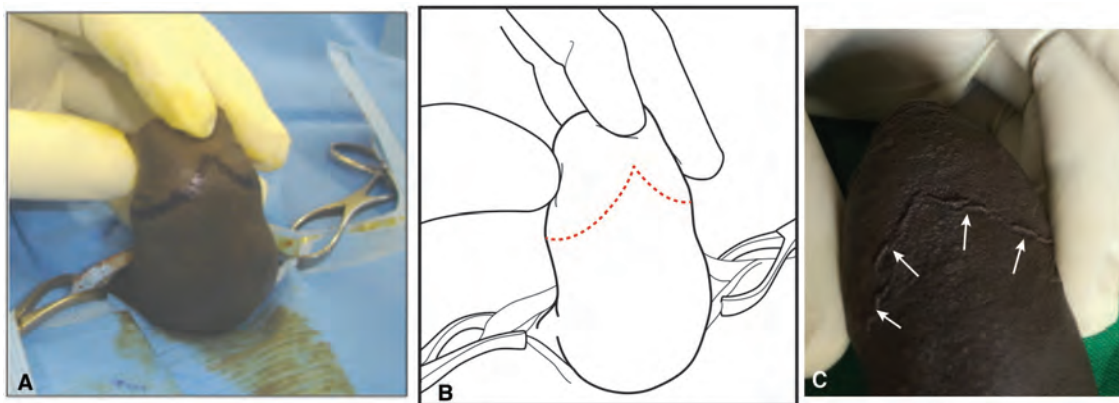
With the foreskin in the resting position and not under any traction, mark the line just distal to the prominence of the corona (see Fig. 9.7). If the line is marked too far proximally, an excessive amount of foreskin may be removed, making the placement of sutures difficult. For the sleeve resection and dorsal slit procedures, make a V-shaped mark on the ventral side (frenular side), with the point of the V towards the glans (see Fig. 9.8). For the sleeve resection method, also mark a second line of incision.

If a marker pen is not available, dabs of gentian violet may be applied with a blunt probe, the tip of an artery forceps or another sterile instrument. A further alternative is to make pinch marks with toothed forceps, but this method is slightly more traumatic; if this type of marking is used, make the incision just proximal to the pinch marks, so the tissue damaged by the pinch marks is excised with the foreskin.

Fig. 9.7. Marking the male circumcision line^{a,b}

^a (A and C) The mark is made just distal (further towards the tip of the penis) to the prominence of the coronal ridge. (B) If a marking pen is not available, small pinch marks can be made with forceps.

^b Photographs © Kasonde Bowa, Adrian Musiige and Whyson Mkandawire

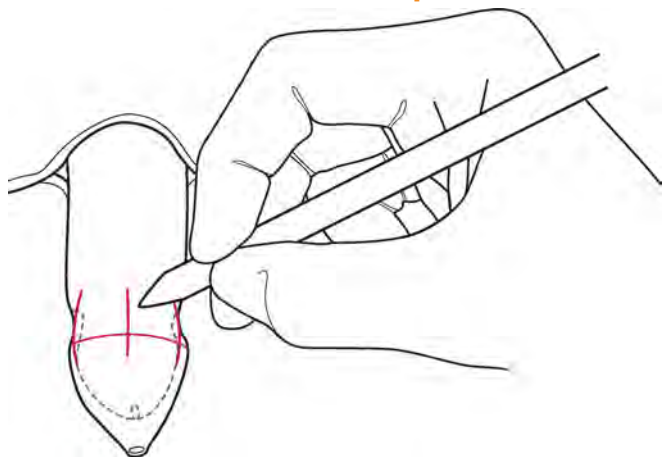
Fig. 9.8. Marking the V-shaped line^a

^a When marking before the sleeve and dorsal slit procedures, mark a V-shaped line with the apex of the V pointing towards the glans and frenulum. This V-shaped mark is not needed for the forceps-guided method, because the forceps guide the line of the incision.

9.5.3. Making realignment markings

After the removal of the foreskin and haemostasis, it will be important to ensure that the skin of the shaft can be realigned to its original position and that there is no torsion of the shaft skin in relation to the glans. Alignment can usually be achieved by lining up the frenulum and urethral meatus with the line of the midline raphe on the shaft of the penis (see Fig. 9.15). However, the raphe is commonly not in the midline; therefore, after cleaning, draping and giving local anaesthesia—but before making any incision—check the position of the midline raphe. If the raphe is not in the midline, or is difficult to see, then, in addition to marking the line of the male circumcision, make additional orientation marks (see Fig. 9.9) at the 12:00, 03:00, 06:00 and 09:00 o'clock positions so that the skin can be accurately realigned when the sutures are placed. Providers who are less experienced in doing circumcisions may find alignment markers helpful for achieving proper alignment, regardless of the position of the raphe.

Fig. 9.9. Additional skin orientation markings at the 03:00, 09:00 and 12:00 o'clock positions (shown), and 06:00 o'clock position (not shown), to help with alignment during suturing^a



^a Make additional skin orientation marks if the midline raphe is off-centre or difficult to see. These additional skin orientation markings also help if the provider is less experienced.

9.6. METHODS OF MALE CIRCUMCISION

Table 9.5 shows the advantages and disadvantages of four conventional or device-based surgical methods of male circumcision. All methods produce good results in the hands of a competent provider.

Devices can potentially reduce the time required to do a circumcision procedure and require no suturing. Another major advantage of some devices is that there is no need for local anaesthetic injection. However, there is a need for a surgical backup if device-specific complications occur. Limited information about devices is provided in Annex 9.1. (See also the manufacturer's instructions for use for each device.)

Table 9.5. Comparison of conventional and device-based surgical circumcision methods: advantages and disadvantages

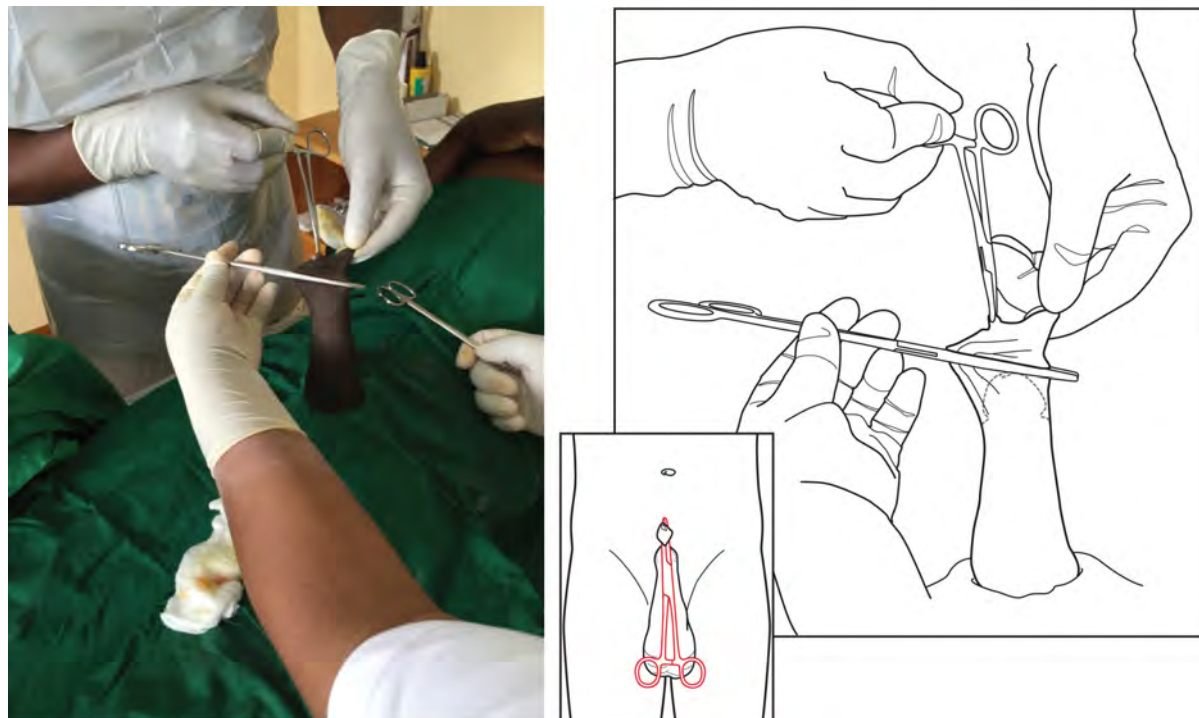
METHOD	ADVANTAGES	DISADVANTAGES
Forceps-guided	<ul style="list-style-type: none"> • Quick to learn • Faster than other methods of conventional surgery 	<ul style="list-style-type: none"> • Leaves a wider (approximately 1.5 cm) cuff of mucosal skin proximal to the corona • Glans not visualized during surgery • Should not be used in adolescent boys under 15 years of age or any male who has adhesions—or any male whose tip of the glans cannot be clearly identified by palpating the foreskin—because of difficulty identifying the glans and the risk of glans amputation
Dorsal slit	<ul style="list-style-type: none"> • Used for medical reasons, such as phimosis • Glans visualized during surgery 	<ul style="list-style-type: none"> • Slower to do and longer to teach than forceps-guided • Small risk of urethral meatus injury
Sleeve resection	<ul style="list-style-type: none"> • Excellent cosmetic outcome • Minimizes risk of removing too much or too little skin because incisions on external and inner (mucosal) layers of the foreskin are marked • Can be almost bloodless • Glans well visualized 	<ul style="list-style-type: none"> • Slower and more technical than other methods • Longer to teach
Some devices that are worn for one week	<ul style="list-style-type: none"> • Simple and quick to apply compared with surgical methods • Easier for a less-skilled provider • Reduced risk of bleeding compared with surgical methods • No stitches • Some applied with topical anaesthetic agent(s) 	<ul style="list-style-type: none"> • Need to be worn for one week • Completion of procedure requires a second visit • Brief sharp pain common at time of removal • Necrosis if foreskin retained for one week while the device is in place <ul style="list-style-type: none"> • Necrosis of the foreskin may cause an unpleasant odour and an increase in anaerobes, which increases the risk of infection, including tetanus in clients who are insufficiently vaccinated. Vaccination is required. • Need clinics or facilities to manage device-specific complications <ul style="list-style-type: none"> • For example, for some devices, there is a need for immediate, onsite surgical backup if the device slips off during application. If a device displaces in the days after the application, there is a need for surgical backup within six to 12 hours.

9.6.1. Forceps-guided method of male circumcision

The forceps-guided method **should not be used** in adolescent boys under the age of 15 years or in any male who has adhesions—or in any male whose tip of the glans cannot be clearly identified by palpating the foreskin—because of difficulty identifying the glans and the risk of glans amputation.

- STEP 1.** Prepare skin, drape skin and administer anaesthetic agent(s), as described earlier in this chapter.
- STEP 2.** Retract the foreskin and separate any adhesions, as described earlier in this chapter.
- STEP 3.** Mark the line of the incision and skin orientation marks, as described earlier in this chapter.
- STEP 4.** Grasp the foreskin at the 03:00 o'clock and 09:00 o'clock or 06:00 o'clock and 12:00 o'clock positions with two artery forceps. Place these forceps on the natural apex of the foreskin to help ensure that there is equal tension on the inside and outside surfaces of the foreskin. If this is not done correctly, there is a risk of leaving too much of the inner (mucosal) layer of the foreskin or removing too much skin on the shaft (see Fig. 9.20).
- STEP 5.** Put sufficient tension on the foreskin to pull the skin mark so that it is just distal to the glans. Taking care not to catch the glans, apply a long, straight forceps across the foreskin just proximal to the mark, with the long axis of the forceps going from the 12:00 o'clock to the 06:00 o'clock position. Before completely locking the forceps (see Fig. 9.10), feel the glans to check that it has not been accidentally caught in the forceps; then, lock it until the click sound is heard. If there is any doubt about whether the glans has been caught in the forceps, do not proceed with the forceps-guided method.

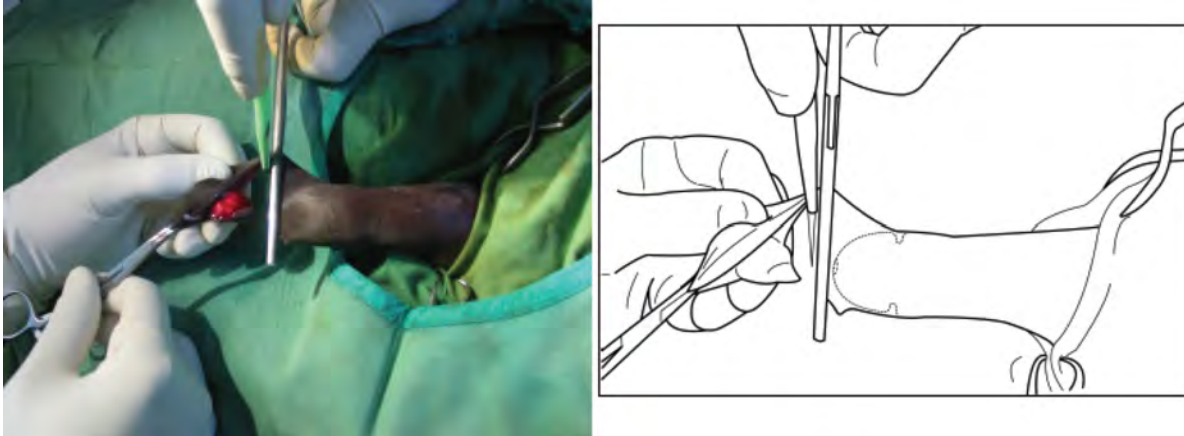
Fig. 9.10. Placing the forceps to guide the male circumcision^a



^a Take care not to catch the glans in the forceps. The forceps is slightly angled so that the line of the forceps is parallel to the line of the coronal sulcus. Place the forceps in the 06:00 o'clock to 12:00 o'clock orientation (inset).

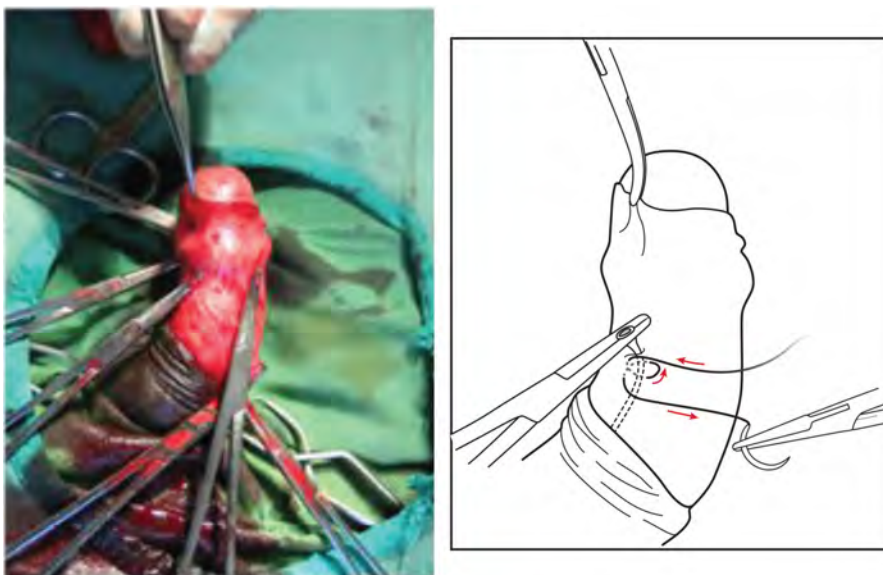
STEP 6. Using a scalpel, cut away the foreskin flush with the distal side of the forceps (the side of the forceps towards the outside or tip of the foreskin) (see Fig. 9.11). **Cutting in one smooth, decisive motion is safer and leads to better cosmetic outcomes.** The forceps protects the glans from injury; nevertheless, particular care is needed at this stage.

Fig. 9.11. Forceps-guided method: cutting off the foreskin



STEP 7. Pull back the skin to expose the raw area. Using a dry gauze swab, compress the area for two to three minutes. Clip any bleeding vessels with artery forceps. Take care to catch the blood vessels as accurately as possible and to not grab large amounts of tissue. Larger blood vessels should be underrun with a suture and ligated. Take care not to place haemostatic stitches too deeply (see Fig. 9.12). Diathermy, if it is available, may be used for smaller blood vessels.

Fig. 9.12. Applying artery forceps to blood vessels to stop bleeding, and using a suture to underrun the blood vessel



STEP 8. (Optional, extra step) The forceps-guided method leaves a broader cuff of mucosal skin than other surgical methods, and many providers trim this to leave a narrower cuff. **If this additional step is done, do not trim too close to the coronal sulcus. Leave approximately 0.5–0.6 cm of cuff, so sutures can be safely placed (see Fig. 9.13).** Also, **do not trim close to the base of the frenulum, as this makes it difficult to control bleeding from the frenular artery (see Box 9.3).**

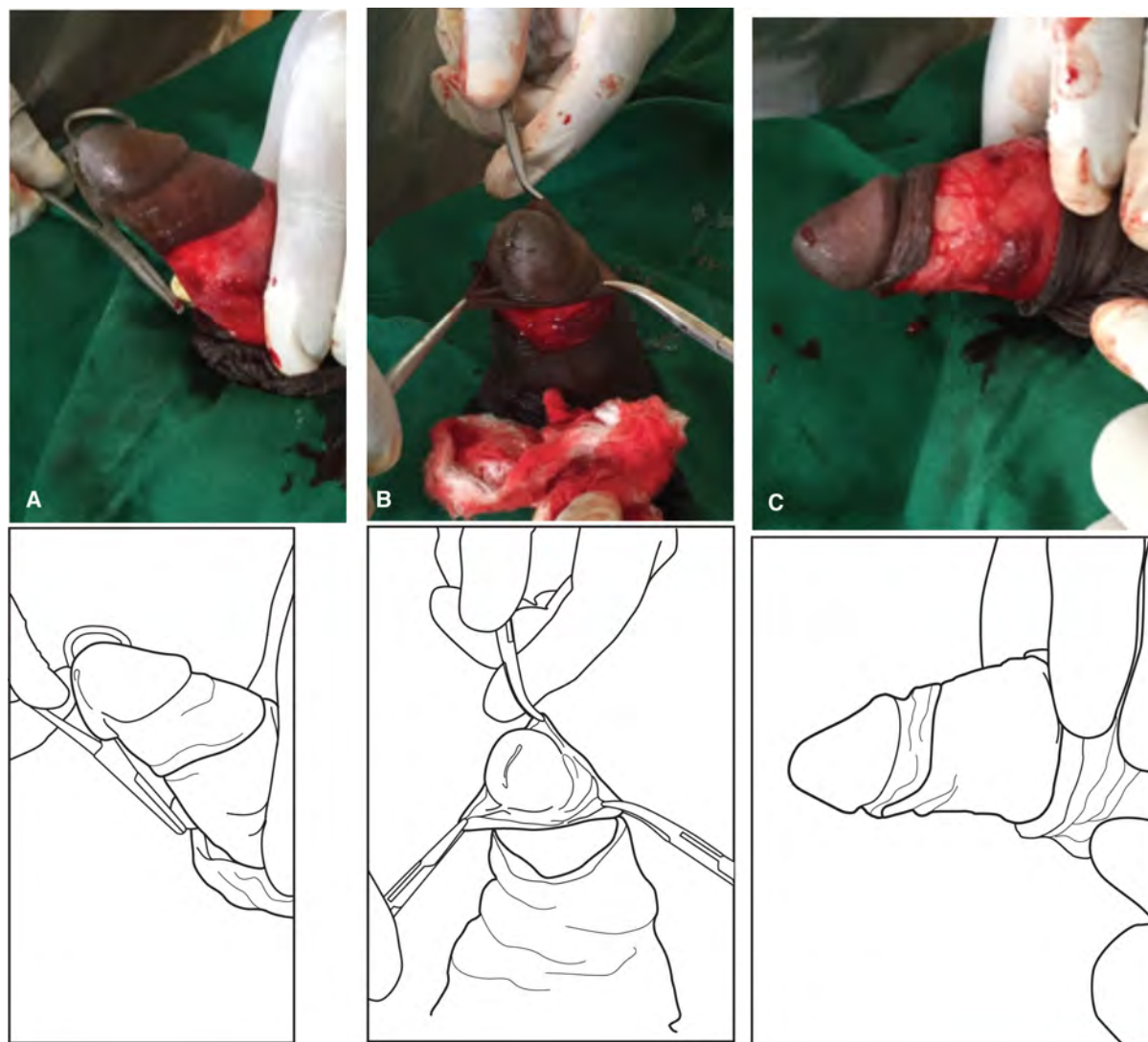
Box 9.3. Management of bleeding in the frenular area

When managing bleeding in the frenular area or on the ventral side of the penis, take great care when stopping the bleeding from the frenular artery so as not to injure the urethra. Damage to the urethra may cause tissue breakdown and a hole between the urethra and the skin surface (urethral fistula). If this occurs, it can be very difficult to treat. The following precautions should be taken:

- Avoid the use of diathermy, as this can burn into the underlying urethral wall and cause tissue necrosis.
- If there is bleeding from the frenular area, control bleeding with pressure using a gauze swab. Then, accurately locate the bleeding vessel, accurately apply artery forceps and ligate or transfix the vessel. If transfixion is used, take care to avoid using thick suture material, including big chunks of tissue in the suture and passing the suture into deeper layers. This is important because the urethra is near the skin's surface in the area immediately under the frenulum. If a suture passes too deeply, then it may enter the urethral wall and cause damage, which may result in tissue breakdown and a urethral fistula.

Normally, the horizontal mattress frenular suture (see Step 9) stops minor bleeding. Again, when placing this suture, do not include deep layers and accidentally catch the urethral wall.

Fig. 9.13. Optional, extra step in forceps-guided method^{a,b}



^a (A) Appearance of the inner layer (mucosal layer) cuff after removal of the foreskin; (B) application of a curved forceps to stabilize the cuff prior to trimming with scissors; (C) the cuff after trimming with scissors.

^b Photographs © Augustino Hellar

STEP 9. Place a horizontal mattress suture at the frenulum (see Fig. 9.14). When placing the frenulum suture, take care not to take too deep a bite because the urethra is just underneath the base of the frenulum (see Box 9.3; see Chapter 7, Fig. 7.2). Also, take care to align the midline skin raphe with the line of the frenulum (see Fig. 9.15). For clients with an off-centre raphe, see Box 9.4.

Fig. 9.14. Horizontal mattress suture at the frenulum (06:00 o'clock position)

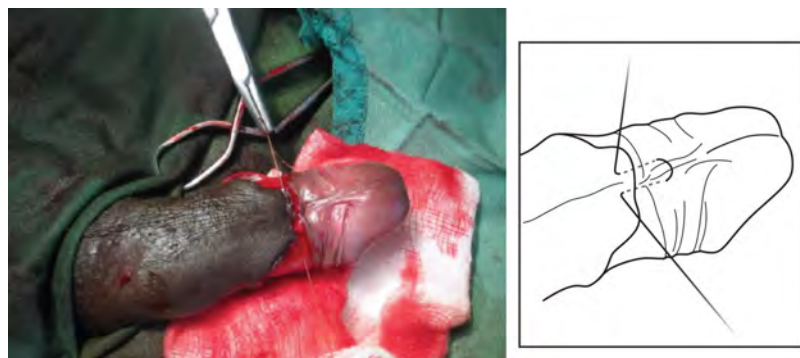
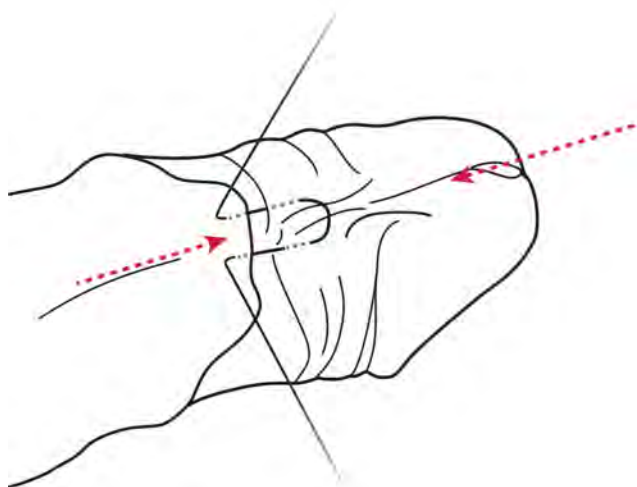


Fig. 9.15. Arrows showing the alignment of the midline skin raphe on the shaft of the penis with the line of the frenulum^a



^a The urethra is close to the surface in the 06:00 o'clock position, and this suture must not be placed too deeply.

Box 9.4. A good frenulum stitch

- Do not take too deep a bite because the urethra is just below the base of the frenulum.
- Take care to properly align the frenulum and the midline: misaligning the frenulum and the midline can result in misalignment of the whole male circumcision closure.
- Avoid tightening the suture. If the suture is too tight, it can cause an area of ulceration or necrosis at the frenulum.
- Avoid injuring the urethra. Always remember that the urethra is very close to the skin surface at the frenulum. Do not stitch too deeply, and avoid injuring the urethra.

STEP 10. Place a vertical mattress suture opposite the frenulum, in the 12:00 o'clock position (see Fig. 9.16). Place the suture so that there is an equal amount of skin on each side of the penis, between the 12:00 o'clock and 06:00 o'clock positions. (The technique of vertical mattress suture is shown in Chapter 8, Fig. 8.9.) Place two further vertical mattress stitches in the 03:00 o'clock and 09:00 o'clock positions (see Chapter 8, Fig. 8.11).

On the horizontal mattress suture, it is helpful to leave a long end at the frenulum (at the 06:00 o'clock position). On the vertical mattress suture, it is helpful to leave a long end in the opposite side (at the 12:00 o'clock position). The long ends of the sutures can be held by an assistant using artery forceps to stabilize the penis during suturing (see Fig. 9.17). There is no need to leave a long end of suture for the vertical mattress sutures placed at the 03:00 o'clock and 09:00 o'clock positions. These long ends are cut short at the end of the procedure once all the other skin stitches are in place.

Fig. 9.16. Placing a vertical mattress suture at the 12:00 o'clock position

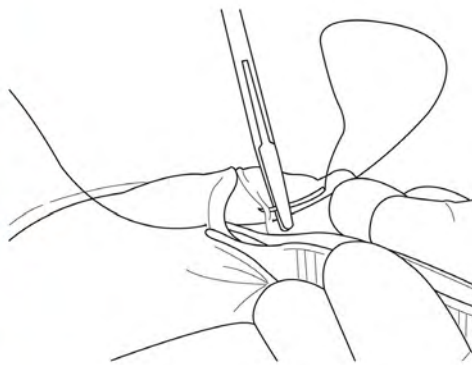
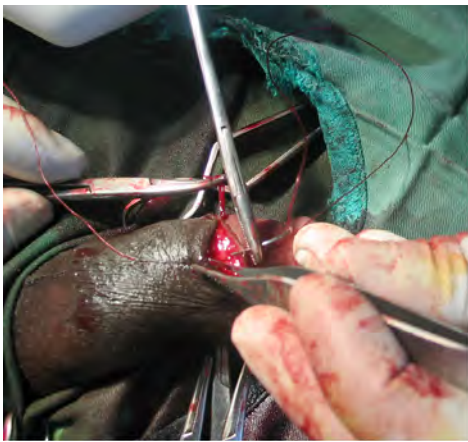
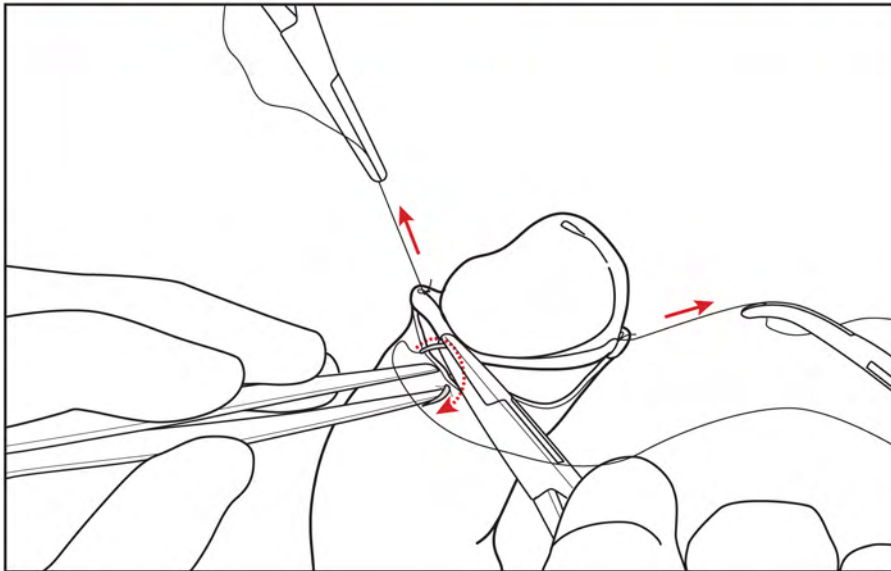
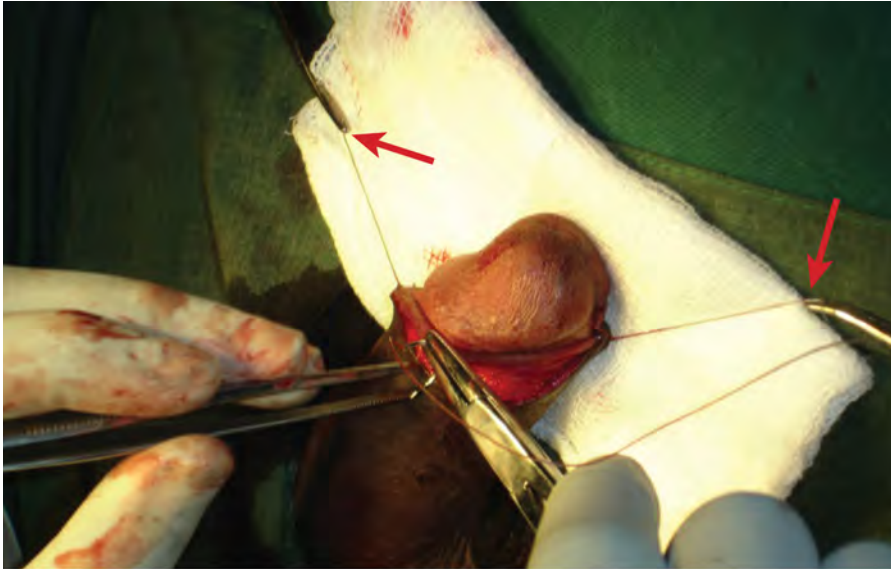


Fig. 9.17. Stabilizing the penis during suturing^a

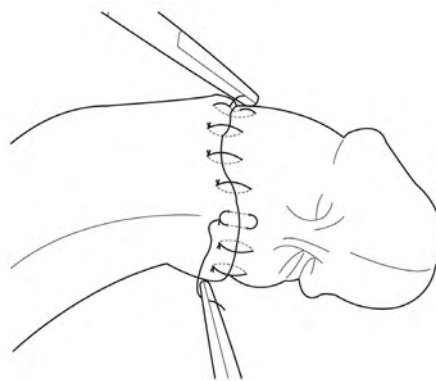


^a The penis is stabilized by an assistant holding two artery forceps (see arrows) attached to the long end of the sutures at the 06:00 o'clock and 12:00 o'clock positions.

STEP 11. After placing sutures at the 06:00, 12:00, 03:00 and 09:00 o'clock positions (principal sutures), place two or three simple sutures in the gaps between them (see Fig. 9.18). (The technique of simple interrupted sutures is shown in Chapter 8, Fig 8.8.)

Depending on the skin pigmentation, there may be a strong contrast between the colour of the penile shaft skin and the remaining mucosa (see Fig. 9.18). With time, the exposed mucosal skin will become darker and the contrast less marked.

Fig. 9.18. Placement of simple sutures between the mattress sutures^a



^a Two or three simple sutures are placed between the principal mattress sutures (which are at the 12:00, 03:00, 06:00 and 09:00 o'clock positions).

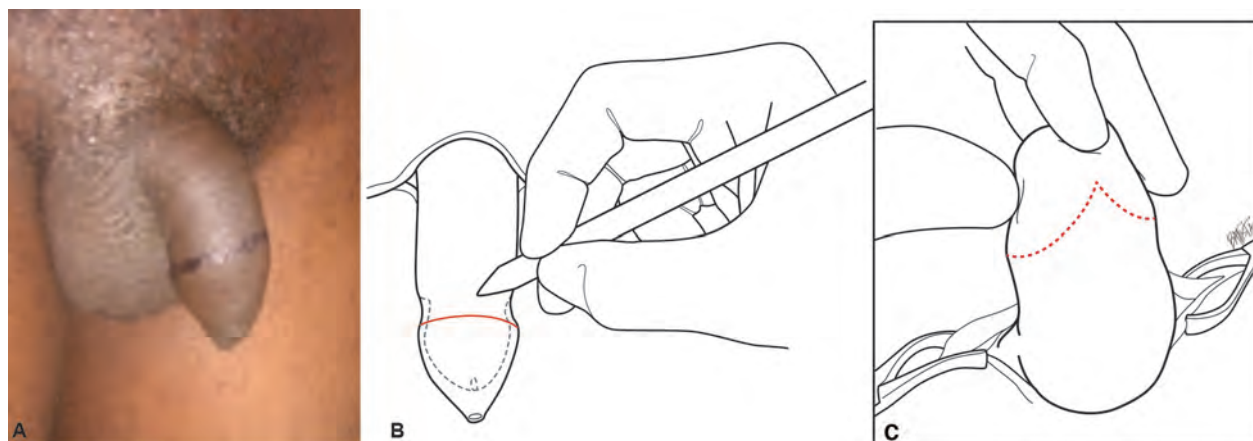
STEP 12. Once the procedure is finished, check for bleeding. If there is bleeding and care has been taken with shaft haemostasis, then the bleeding is likely to be from the skin edges. Sometimes, it is necessary to place an extra simple skin stitch, but bleeding from the skin edges typically stops within a short period of time after pressure has been applied to it with a gauze swab. If bleeding seems to be coming from deeper in the wound, then remove a few or all of the skin stitches and reinspect the penis shaft to locate the source(s) of the bleeding. **There is often pressure to finish a procedure quickly, but time spent on stopping the bleeding is valuable. It is always better to make sure bleeding has stopped than to take a risk.** Once bleeding has stopped, apply a dressing to the wound (see Section 9.7).

9.6.2. Dorsal slit method of male circumcision

STEP 1. Prepare skin, drape the skin and administer anaesthesia, as described earlier in this chapter.

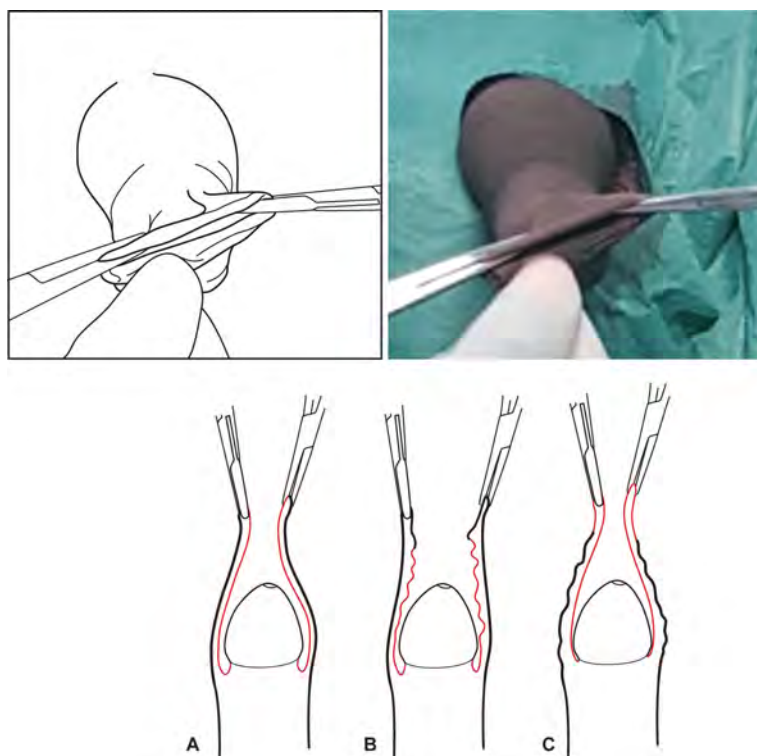
STEP 2. Retract the foreskin and remove any adhesions, as described earlier in this chapter.

STEP 3. Mark the intended line of incision (see Fig. 9.19). Make the skin mark just distal to the prominence of the corona (further towards the tip of the penis). The mark should have a V shape on the ventral side (frenular side), with the point of the V towards the glans. Note the line of the ventral midline raphe, and if there is any deviation from the midline, make additional orientation marks at the 03:00, 12:00 and 09:00 o'clock positions.

Fig. 9.19. Marking the incision line for the dorsal slit procedure^a

^a Photograph © Kasonde Bowa

STEP 4. Apply artery forceps at the 03:00 o'clock and 09:00 o'clock positions, to the apex of the foreskin meatus. Take care to apply the artery forceps to the foreskin so that there is equal tension on the inner and outer aspects of the foreskin (see Fig. 9.20). The purpose of this step is to ensure that there is correct tension on the inner and outer parts of the foreskin.

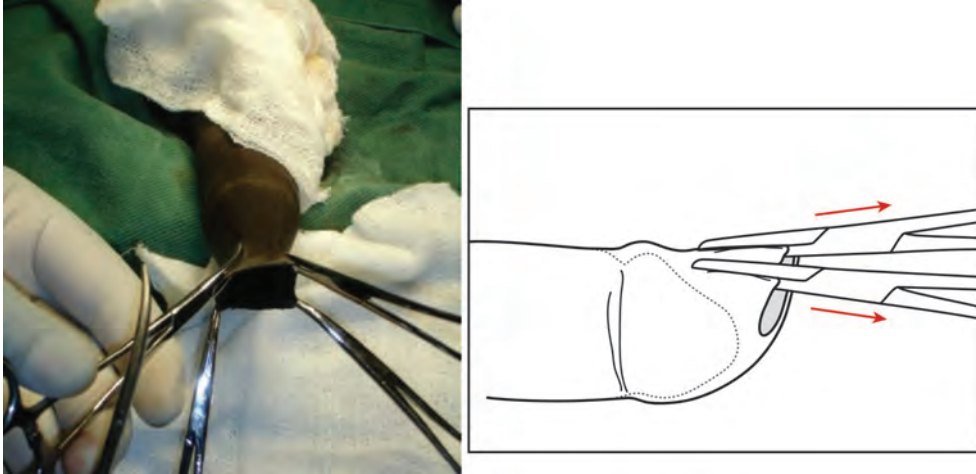
Fig. 9.20. Applying forceps to the foreskin^{a,b}

^a Apply the forceps to the tip of the foreskin with equal tension on the outer skin and the inner (mucosal) skin. (A) Forceps correctly applied to tip of foreskin; (B) forceps incorrectly applied, taking too much outer skin; and (C) forceps incorrectly applied, taking too much inner (mucosal) skin.

^b Photograph © Dr. Josephine Otchere-Darko

STEP 5. Keeping tension on the previously applied 03:00 o'clock and 09:00 o'clock forceps, place two artery forceps on the foreskin at the 11:00 o'clock and 01:00 o'clock positions (see Fig. 9.21) by taking 1–2 cm of foreskin between the forceps' blades (Fig. 9.21). Check that the inside blades of the two artery forceps are lying between the glans and foreskin, and the blades have not been inadvertently passed up the urethral meatus.

Fig. 9.21. Placing artery forceps at the 11:00 o'clock and 01:00 o'clock positions^{a,b}

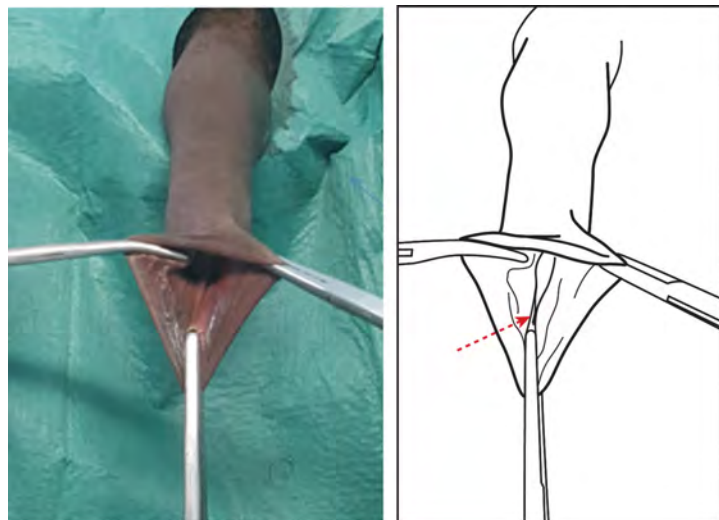


^a The drawing shows forceps applied at the 11:00 o'clock and 01:00 o'clock positions. In the photo, forceps at the 11:00 o'clock and 01:00 o'clock positions are held apart to display the area where the dorsal slit is going to be made (between these forceps). Note the 03:00 o'clock and 09:00 o'clock tensioning forceps are not shown in the drawing.

^b Photograph © Dr. Josephine Otchere-Darko

STEP 6. Keeping the 11:00, 01:00, 03:00 and 09:00 o'clock forceps in position, apply forceps at the 6:00 o'clock position, so as to take a 1 cm bite of foreskin (typically); however, exactly how much bite to take depends on the length of the foreskin. The tip of the inside blade of the forceps at the 06:00 o'clock position should nearly reach the fold of the frenulum, and the tip of the outside blade of the forceps should nearly reach the apex of the marked V on the marked line of incision. It is important that the 06:00 o'clock forceps be placed accurately and not too far in because the cut to remove the foreskin should be made between the inner layer of the foreskin and the frenulum—NOT between the base of the frenulum and the shaft of the penis. Provided the 06:00 o'clock forceps is placed correctly, the cut will be in the right place. If the cut is made too close to the base of the frenulum, then there is increased risk of bleeding from the frenular artery, which is difficult to control, thereby leading to the risk of urethral damage during attempts to control this bleeding. Once the 06:00 o'clock forceps is in position, the 03:00 o'clock and 09:00 o'clock tensioning forceps can be removed, thereby leaving three forceps in position—11:00, 01:00 and 06:00 o'clock (see Fig. 9.22).

Fig. 9.22. Forceps at the 06:00 o'clock position, with the inner blade nearly reaching the fold of the frenulum (see arrow)^{a,b}

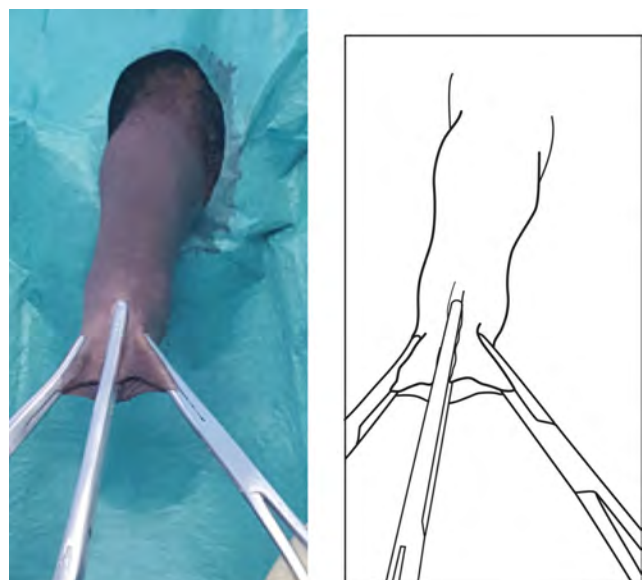


^a The forceps at 11:00 o'clock and 01:00 o'clock positions are under tension to display the interior of the foreskin meatus.

^b Photograph © Dr. Josephine Otchere-Darko

STEP 7. Between the two top artery forceps (11:00 o'clock and 01:00 o'clock), apply forceps at the 12:00 o'clock position and close it tightly to crush the line of the dorsal slit. This crushing helps to reduce bleeding when the dorsal slit is made (see Fig. 9.23).

Fig. 9.23. Applying forceps at 12:00 o'clock position to crush the foreskin before making the dorsal slit^{a,b}

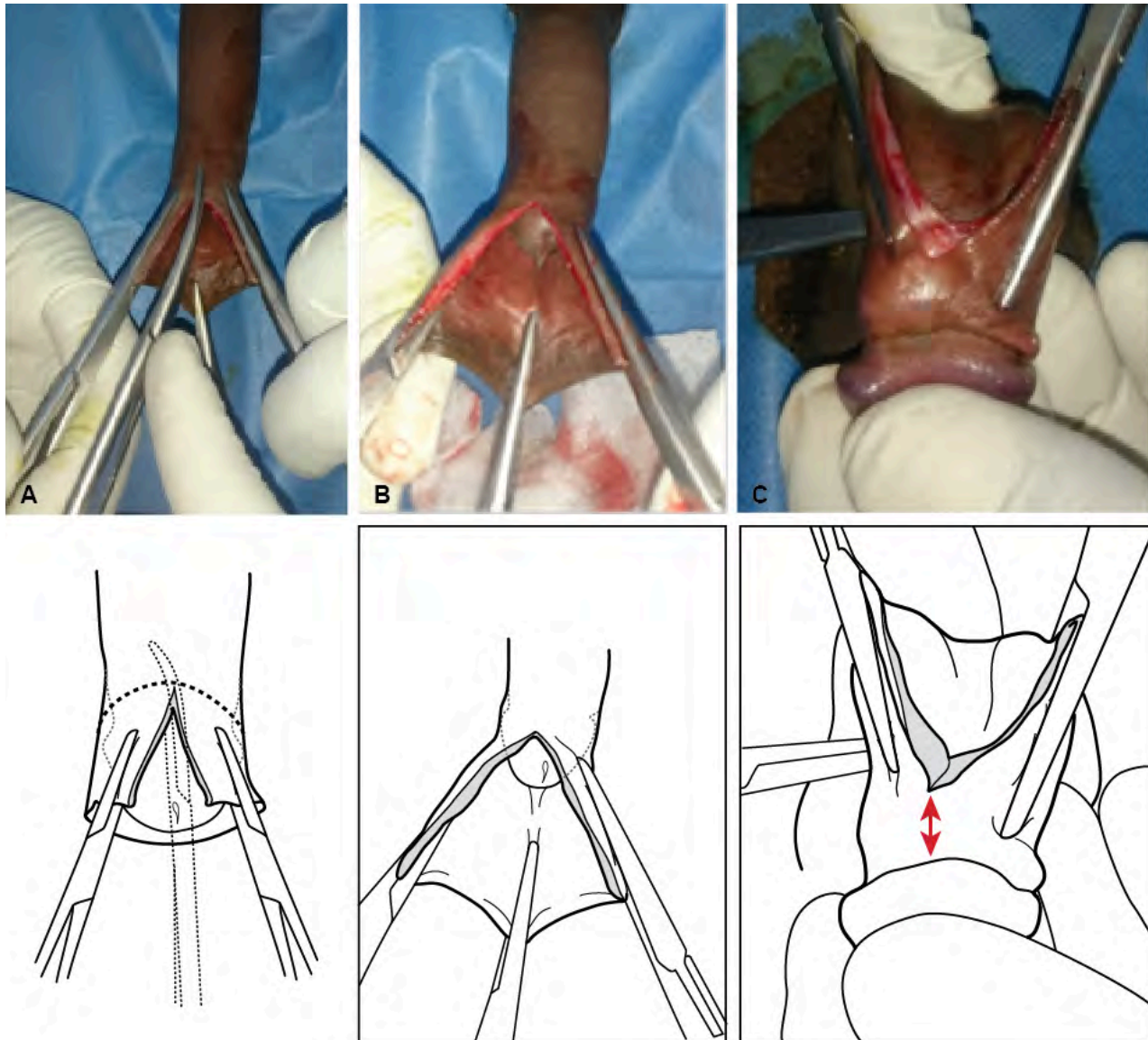


^a Note that the forceps at the 06:00 o'clock position is not shown.

^b Photograph © Dr. Josephine Otchere-Darko

STEP 8. Remove the 12:00 o'clock crushing forceps and, using dissection scissors, make a cut along the middle of the crushed foreskin (the dorsal slit) up to the previously marked incision line (see Fig. 9.24). This is best done in two stages: 1) make part of the dorsal slit cut; 2) check inside and outside to note the position of the dorsal cut, in relation to the outer marked male circumcision line and with respect to the width of the mucosa, proximal to the coronal sulcus—and then cut further as necessary. The ideal cuff of mucosal skin left behind is **approximately 0.5–0.6 cm**. Do not cut the mucosal side too near the coronal sulcus and glans; take care to leave sufficient mucosa to take the sutures.

Fig. 9.24. Cutting the dorsal slit^{a,b}



^a (A) Cutting the dorsal slit; (B) dorsal view of completed dorsal slit; and (C) inside view showing dorsal slit reaching and leaving **approximately 0.5–0.6 cm** cuff of inner layer (mucosal).

^b Photographs © Dr. Josephine Otchere-Darko, Adrian Musiige and Whyson Mkandawire

STEP 9. Follow instructions in this step, which is a modification of the one in the 2009 edition of this *Manual*, to make the circumferential cut to remove the foreskin (see Box 9.5).

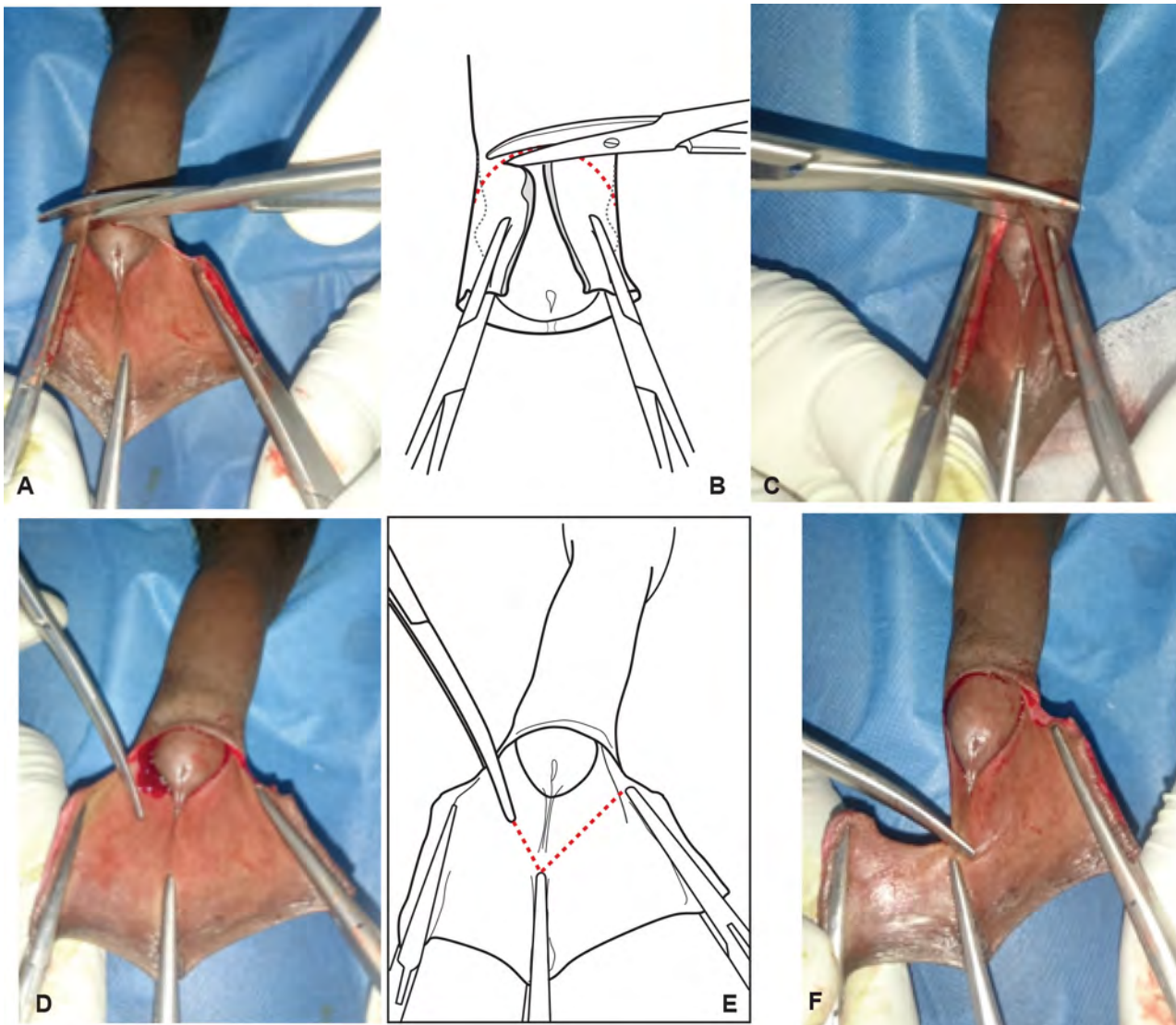
Box 9.5. Step modified from 2009 edition of this *Manual*

The dorsal slit technique described in this *Manual* is slightly modified from the technique described in the 2009 edition of this *Manual*. The modified technique is recommended because it reduces the chance that the foreskin will be cut too close to the coronal sulcus, a problem encountered with the previously described method. (In the 2009 version, the technique described a simple freehand cut without the forceps at the 06:00 o'clock position or ventral V marking.)

Starting at the 12:00 o'clock position, the circumferential cut is made using scissors, first in one direction and then the other, so just over half of the foreskin is cut free.

- Take care to follow the marked skin incision line and also to leave **approximately 0.5–0.6 cm** cuff of mucosa adjacent to the coronal sulcus.
- Once the dorsal half of the foreskin is cut free, the cut then continues towards the frenular ridge (see Fig. 9.25). The direction of the cut changes to make a V shape that corresponds to the line drawn previously, reaching the apex of the V shape at the frenular ridge and the tip of the forceps at the 06:00 o'clock position.
- Note that the foreskin is kept on traction by the assistant. Again, care must be taken to leave **approximately 0.5–0.6 cm** cuff of mucosa and to not get too close to the coronal sulcus. The change of direction at the frenular ridge at 06:00 o'clock is important as it helps to ensure that the cut is away from the base of the frenulum. If this is not done, then there is increased chance of difficulty in controlling bleeding from the frenular artery—and the risk of urethral injury when attempts are made to control bleeding.

Fig. 9.25. Cutting of the circumferential at the foreskin^{a,b}

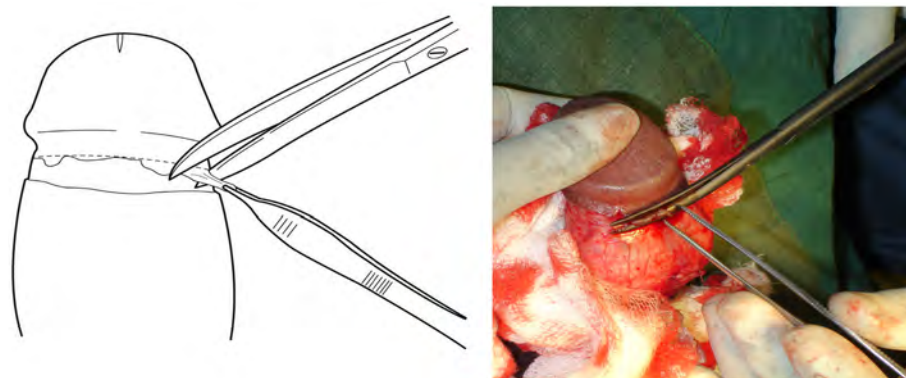


^a Starting at the 12:00 o'clock position, the circumferential cut is made using scissors, first in one direction (A, B) and then the other (C), so just over half of the foreskin is cut free. Once the dorsal half of the foreskin is cut free, the cut then continues towards the frenular ridge (D). The direction of this cut changes to make a V shape, corresponding to the red dotted lines (and the V shape of the outer skin mark [D, E]). Photograph D shows the start of the V-shaped cut. Photograph F shows the cut reaching the apex of the V shape at the frenular ridge (note that the cut is well way from the base of the frenulum, thus reducing the chance of bleeding from the frenular artery).

^b Photographs © Adrian Musiige and Whyson Mkandawire

STEP 10. If necessary, trim the mucosal edge if it is uneven. However, if care was taken to display and visualize the mucosa and outer aspects of the foreskin when making the circumcision cut, then the edge of the cut will usually be straight. If any ragged edges remain, they can be trimmed (see Fig. 9.26); however, always take care to leave **approximately 0.5–0.6 cm** of skin proximal to the corona for suturing. Also, take care to not trim or cut into the deeper tissue of the shaft of the penis, particularly in the area of the frenulum.

Fig. 9.26. Trimming the inner (mucosal) layer of the foreskin



STEP 11. Stop any bleeding, and proceed with suturing, as described in Steps 7–11 of the forceps-guided method.

STEP 12. Check again for bleeding and manage as needed, as described in Step 12 of the forceps-guided method. Once there is no bleeding, apply a dressing (see Section 9.7).

9.6.2.1 Tips for dorsal slit male circumcision

- When resecting the foreskin, keep looking at the inner foreskin to ensure that not too much skin is removed.
- Take particular care at the 06:00 o'clock frenular position.

9.6.3. Sleeve resection method of male circumcision

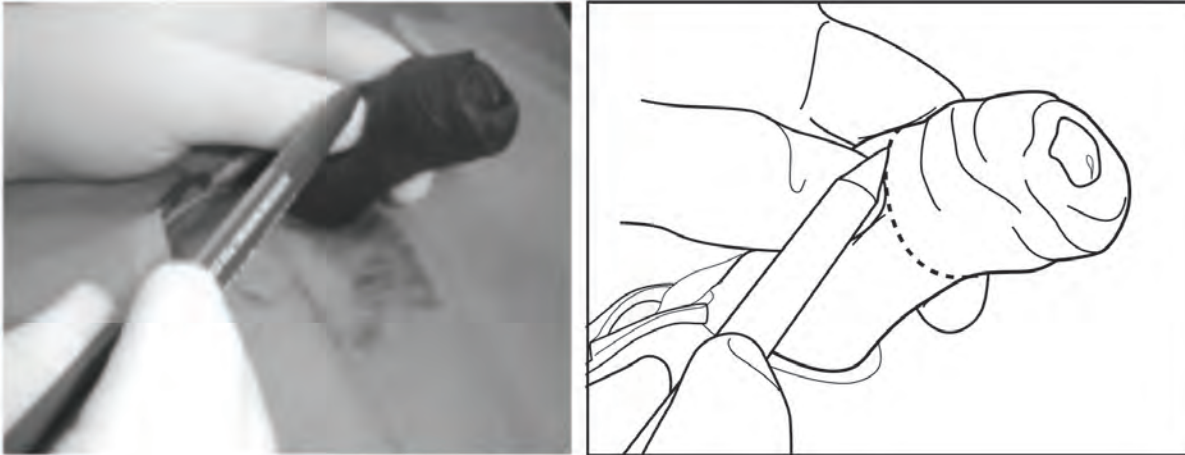
The sleeve resection method requires a higher level of surgical skill and takes slightly longer than other methods. If diathermy is available, the procedure can be virtually bloodless, and the cosmetic results are better than with the other two techniques. However, there is more room for surgical error either by cutting too far into deeper tissue when making the two circular incisions or by cutting too deeply when dissecting the skin flap free.

STEP 1. Prepare skin, drape the skin and administer anaesthetic agent(s), as described earlier in the chapter.

STEP 2. Retract the foreskin and remove any adhesions, as described earlier in the chapter. If the foreskin does not retract easily, it may be necessary to make a partial dorsal slit, as described earlier in the chapter (see Fig. 9.24).

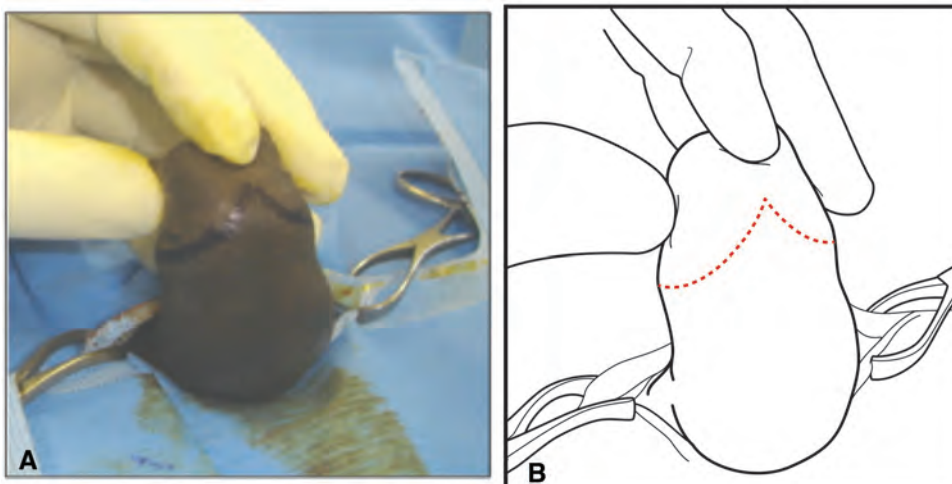
STEP 3. The sleeve resection technique is unique in that two separate lines of incision must be marked, referred to here as the outer and inner lines of incision. First, mark the intended outer line of the incision (see Fig. 9.27) and, if necessary, draw orientation marks, as described earlier in the chapter. The skin mark should be made just distal to the prominence of the corona (that is, further towards the tip of the penis). On the ventral side (frenular side), the mark should have a V shape, with the point of the V towards the glans (see Fig. 9.28).

Fig. 9.27. Marking the line of the outside cut, at or just below the corona^a



^a Photograph © R. Bailey, Kisumu Project

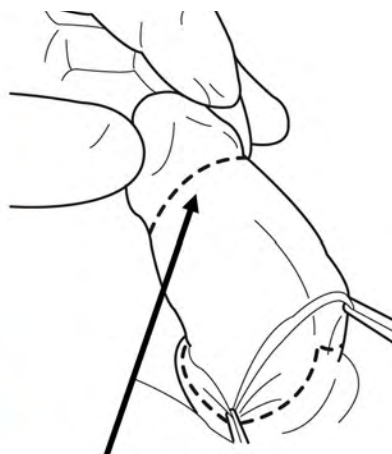
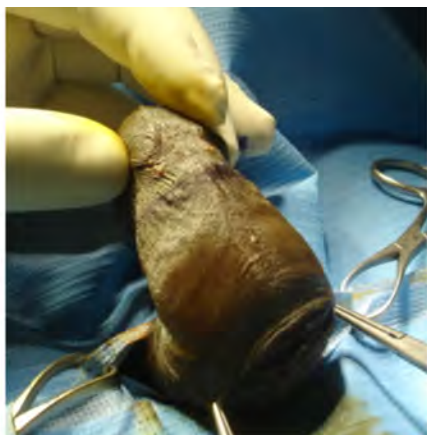
Fig. 9.28. Marking the V on the ventral side of the penis^{a,b}



^a A V-shaped mark is drawn on the ventral side (underside) of the penis; the point of the V-shaped mark is towards the frenulum. Provided the midline raphe is in the midline, the apex of the V-shaped mark should correspond with the line of midline raphe.

^b Photograph © Professor S. Watya

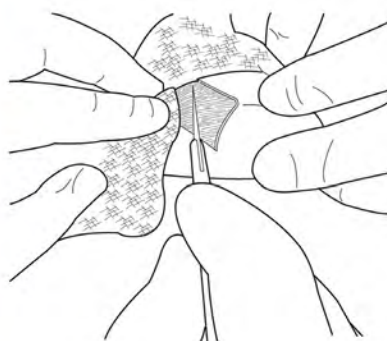
STEP 4. Retract the foreskin and mark the inner (mucosal) incision line 1–1.5 cm proximal to the corona. At the frenulum, the incision line crosses horizontally (see Fig. 9.29).

Fig. 9.29. Marking the inner incision line^a

^a Photograph © Professor S. Watya

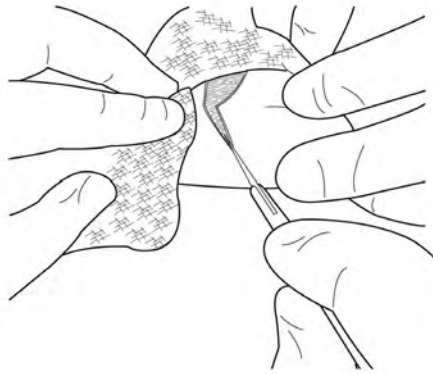
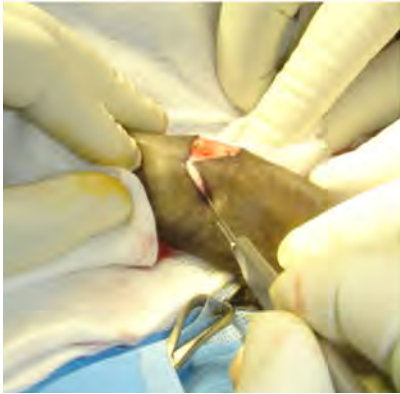
STEP 5. Using a scalpel, make incisions along the marked lines, taking care to cut through the skin to the subcutaneous tissue but not deeper (see Figs 9.30–9.32). As the incision is made, the assistant should retract the skin and keep it under tension with a moist gauze swab. Keeping proximal and distal tension to stretch the skin causes the skin to separate as soon as it is cut and lessens the risk of making too deep a cut.

An artery forceps should be applied to any vessel that is bleeding significantly; the vessel should then be tied or secured with an underrunning suture. Bleeding from small vessels can be stopped with diathermy, if available. If the cut has not been made too deeply, most bleeding will be from the edges of the skin and can be stopped by placing a simple pressure over the bleeding with a gauze swab; diathermy should not be used near the skin edge.

Fig. 9.30. Incising along the marked line^a

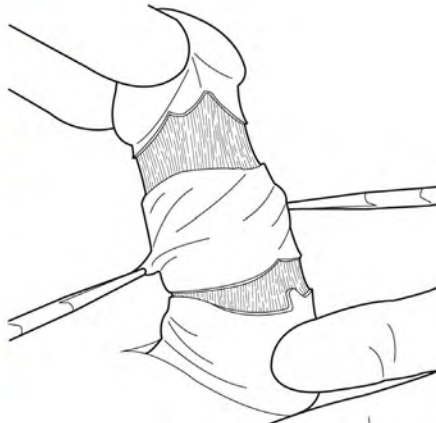
^a Photograph © Professor S. Watya

Fig. 9.31. Incising the V-shaped line on the underside of the penis^a



^a Photograph © Professor S. Watya

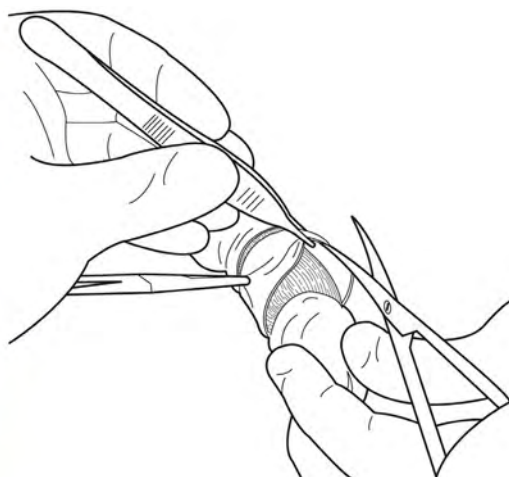
Fig 9.32 Completed incisions leaving a sleeve of foreskin^a



^a Photograph © Professor S. Watya

STEP 6. Using a pair of scissors, cut the skin vertically between the proximal and distal incisions at the 12:00 o'clock position (see Fig. 9.33).

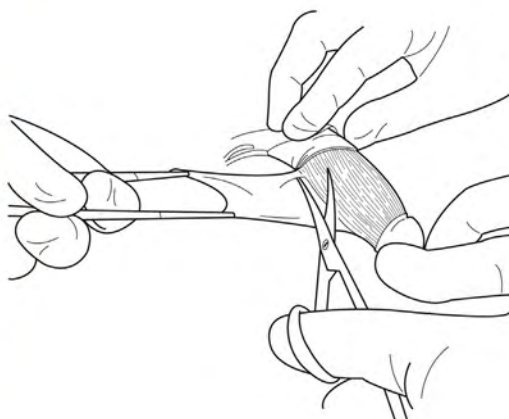
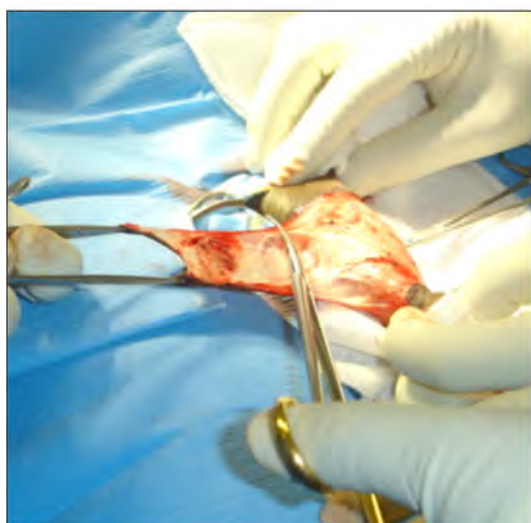
Fig. 9.33. Cutting the skin between the outer and inner incisions^a



^a Photograph © Professor S. Watya

STEP 7. Hold the sleeve of the foreskin under tension with two artery forceps and dissect the skin from the shaft of the penis using dissection scissors. The plane of dissection should be just beneath the skin and the superficial connective tissue, leaving the deeper fascia (Buck's fascia) in place (see Fig. 9.34).

Fig. 9.34. Dissecting the sleeve of skin away from the shaft of the penis^a



^a Photograph © Professor S. Watya

STEP 8. Stop any bleeding and close the skin incision with sutures, as described in Steps 7–11 of the forceps-guided method.

STEP 9. Check for bleeding again, and manage bleeding as needed, as described in Step 12 of the forceps-guided method. Once there is no bleeding, apply a dressing (see Section 9.7).

9.6.4. Variations in technique needed when there is phimosis or frenular scarring

The techniques described in this *Manual* assume that the foreskin and frenulum are normal. However, circumcision can be undertaken at the clinic level in the presence of minor abnormalities, provided that the circumcision team has sufficient experience. Any abnormalities should be detected in the preprocedure examination of the penis, which should include full retraction of the foreskin. Two abnormalities—phimosis and tight or scarred frenulum—are common indications for medical circumcision and require a slight variation in technique, as outlined below.

9.6.4.1. Phimosis

Phimosis is a narrowing of the aperture or opening of the foreskin to the extent that the foreskin cannot be retracted. The tip of the foreskin may appear white because of scar tissue. If the scar tissue is extensive, then the man is not eligible for circumcision at the clinic level and should be referred to a higher level of care.

- The first step in all circumcision procedures is to mark the foreskin with the line of incision. If the **sleeve resection method** is used, the phimosis will prevent retraction of the foreskin, meaning that the second line of incision near the corona cannot be marked. In this case, a small dorsal slit should be made, just long enough to allow the foreskin to be retracted. Once retracted, any adhesions can be separated and any debris under the foreskin can be removed with a gauze swab soaked in povidone iodine or chlorhexidine. Once all adhesions have been removed, the second line of incision on the foreskin near the corona can be marked, and the circumcision procedure can proceed as usual.
- In the **forceps-guided and dorsal slit methods**, the line of incision is marked on the outer aspect of the foreskin in the normal manner. However, with minor degrees of phimosis, it may be necessary to make a small dorsal slit to allow full retraction and cleaning under the foreskin before proceeding with the procedure. The forceps-guided method should not be used if the foreskin cannot be retracted.

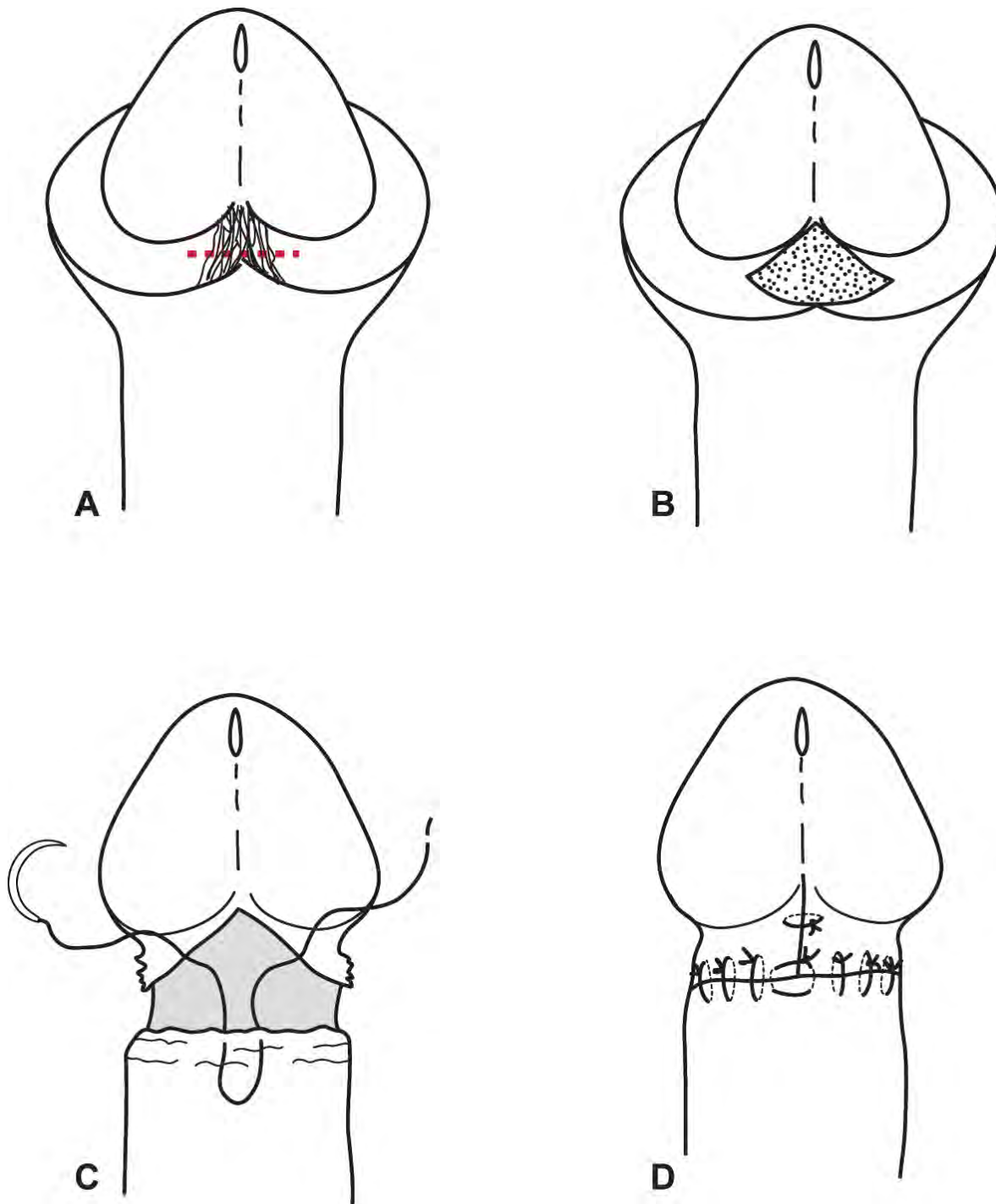
9.6.4.2. Tight or scarred frenulum

All males have a band of tissue (the frenulum) on the ventral side of the penis, just below the glans. Usually, the frenulum does not interfere with retraction of the foreskin. During early sexual experiences, the frenulum may be stretched as the foreskin is retracted, and minor tears are a frequent problem. Such tears can heal, leaving inelastic scar tissue, which tightens and makes further tearing and scarring more likely. The problem can be seen when the foreskin is retracted during physical examination. Instead of the normal colour frenulum, a tight band of white tissue is seen (see Fig. 9.35[A]). This restrictive frenular band can easily be corrected during circumcision.

To correct the restrictive frenular band, spread the foreskin open and retract it ventrally to put the band under tension. Using dissection scissors, snip the band at its centre, taking care not to injure the urethra, which is just under the frenulum. Control any bleeding from the frenular artery by careful tying or by underrunning. After the frenulum has been cut, there will be an inverted, V-shaped defect (see Fig. 9.35[B]).

The circumcision can then be performed as usual, except that the penile skin should not be sutured up to the apex of the frenular defect because this will cause increased tension on the ventral side. This tension can cause curvature of the penis or make erection or coitus uncomfortable. Instead, close the V-shaped defect by placing the frenular suture 1–2 cm (depending on age of the client and penis size) back from the apex of the V-shaped defect, taking in both sides of the defect (see Fig. 9.35[C]). The V-shaped incision is thus converted into an inverted T (see Fig. 9.35[D]). The defect overlying the frenulum is closed with one or two transverse sutures (only one shown in Fig. 9.35[D]), and the rest of the circumcision wound is closed as for a normal circumcision.

Fig. 9.35. Variation in technique if the frenulum is tight or scarred



9.7. DRESSING

A standard penile dressing technique is used for the forceps-guided, dorsal slit and sleeve resection methods. Once all bleeding has stopped (as described in the final step of each surgical method used), place a piece of petroleum jelly-impregnated gauze swab around the wound. Place a dry, sterile gauze swab over the one already placed and secure both gauzes in position with adhesive tape. Strap the penis to the lower abdomen using adhesive tape or other means (for example, close-fitting underwear); this helps to minimize oedema (tissue swelling) in the first 24–48 hours postprocedure. Do not apply the dressing too tightly or too loosely. A very tight dressing will cause discomfort, difficulty in passing urine and oedema of the glans, and could potentially restrict the blood supply—causing necrosis of the glans (see Fig. 9.36).

Fig. 9.36. Standard dressing



The dressing should be left on for 24–48 hours. The use of adhesive tape has the advantage of applying mild, constant pressure while allowing the penis to stay in place. From this point, the client will undergo postprocedure assessment and counselling before going home.

Ideally, after the designated period of time has passed, the client should return to the clinic or facility where the male circumcision was done to have the dressing removed and the wound assessed for normal healing. Depending on the clinic or facility and other circumstances, arrangements may be made for him to go to another clinic or facility for postprocedure follow-up and dressing removal.

9.8. RECORDKEEPING AND REPORTING

Good documentation is a critical part of any service provision, even more so when the service provided carries any risk of harm to the client. Be sure to document service provision by using required client forms and review documentation provided by others carefully. On the day of male circumcision, record in the procedure room log the name of the client, date and type of procedure performed; do this before the client leaves. Refer to Chapter 4 for detailed guidance on recordkeeping and reporting.

9.9. TIPS

9.9.1. For safe use of local anaesthetic agent(s)

- A new needle and syringe must be used on each occasion local anaesthetic agent(s) and be withdrawn from the local anaesthetic vial.
 - Do not double-dip into a multidose vial (that is, do not insert a used needle or a used syringe attached to a new needle to re-enter the vial). If further anaesthetic agent(s) is needed, **use a new needle and new syringe**. Double-dipping with a needle or syringe that has already been used (even on the same client) will cause blood contamination in the entire vial.

- With each movement of the needle, aspirate the syringe to ensure that the needle is not in a blood vessel, the corpora cavernosa or corpus spongiosum.
- The recommended starting dose of the anaesthetic agent(s) is sufficient in most cases.

Do not exceed the weight-based maximum safe dose of local anaesthetic agent(s); maximum dose of lidocaine/lignocaine (1% or 2%) when given alone is 3 mg/kg of body weight. When lidocaine/lignocaine and bupivacaine are combined, the suggested maximum dose of lidocaine/lignocaine is 2 mg/kg of body weight, and the suggested maximum dose of bupivacaine is 0.5 mg/kg of body weight.

- Select safety-engineered syringes (also known as autodisable syringes) if possible. Various features are available, but some of these are not compatible with safe, local anaesthetic techniques. Features that prevent reuse are to be encouraged as long as they do not interfere with the provider's ability to aspirate to check for blood (to ensure that the needle is not in a blood vessel, the corpora cavernosa or corpus spongiosum) (3).

9.9.2. For safe dosage of local anaesthetic agents

- Two percent lidocaine/lignocaine is likely to give better anaesthesia than 1% lidocaine/lignocaine.
- One percent lidocaine/lignocaine is good for small clients; 2% lidocaine/lignocaine is good for large clients.
- Breakthrough pain can be controlled by an additional block at the base of the penis.

9.9.3. For achieving adequate anaesthesia during male circumcision

- The penis can be anaesthetized for male circumcision surgery using the dorsal nerve block or the subcutaneous ring block. Either technique gives good anaesthesia provided that the technique is done well.
- For skilled providers, a combination of dorsal nerve block and subcutaneous ring block achieves excellent and quicker anaesthesia. In this situation, the dorsal nerve block is done first. Care must be taken not to exceed the maximum safe anaesthetic dose.
- Before beginning the procedure, it is important for the provider doing the procedure to know the recommended starting dose and the maximum dose based on the client's weight (see Tables 9.1–9.4).
- Lidocaine/lignocaine acts quickly while bupivacaine lasts longer. A combination of both agents gives the best immediate (preprocedure) and postprocedure anaesthesia.
- Ensure that the anaesthetic needle is in the correct plane.
 - The tip of the needle should be mobile as it lies in the loose subcuticular tissue.
 - There should be no resistance to the injection of anaesthetic agent(s). If it is difficult to inject the anaesthetic agent(s), it is likely that the tip of the needle is embedded in the thick, fibrous tissue (tunica albuginea) that covers the erection chambers (corpora cavernosa).
 - The provider should always aspirate the syringe before injecting anaesthetic agent(s) to make sure the needle is not in a blood vessel.
- It is important for the provider doing the procedure to allow sufficient time for the anaesthetic agent(s) to work.
- Before beginning the procedure, it is important for the provider doing the procedure to ensure that the client's penis is anaesthetized by testing the client's sensation to pain.

9.9.4. For forceps-guided male circumcision

- Forceps-guided method should not be used in adolescent boys under 15 years of age or in any male who has adhesions—or in any male whose tip of the glans cannot be clearly identified by palpating the foreskin—because of difficulty identifying the glans and the risk of glans amputation.

- With forceps-guided male circumcision, try to avoid trimming the inner mucosa. If it is necessary to trim the inner mucosa, use a pair of scissors—do not use anything else.
- Before closing the forceps to flatten the foreskin, use fingers to massage the glans away from the clamp line and to ensure that the glans is also free of the arterial clamp. There have been a number of instances of glans injury (laceration or partial amputation) in younger adolescents.

9.9.5. For wound dressing

- Use a clean, simple dressing.
- Avoid making the dressing too tight.
- Elevate the penile shaft with tight underwear or strapping (for example, an adhesive tape).
- Counsel the client to keep the dressing on for 24–48 hours.

KEY MESSAGES

This chapter gives step-by-step instructions for performing a circumcision on an adult or an adolescent male. It covers tissue handling, skin preparation, local anaesthesia, the circumcision itself, suturing and dressing of the wound. Three conventional surgical methods are described: forceps-guided, dorsal slit and sleeve resection. Mechanical action of male circumcision devices is also described, as well as the reference to information on devices that have been recommended and prequalified by the World Health Organization for use in public health programmes (see Annex 9.1).

- Surgical male circumcision should be done using local anaesthesia and using the dorsal nerve block or the subcutaneous ring block, or both.
- The dorsal slit method can be used for any age, but the forceps-guided should not be used in adolescent boys under 15 years of age or in any male who has adhesions—or in any male whose tip of the glans cannot be clearly identified—because of difficulty identifying the glans and the risk of glans amputation.
- The marking of the incision site is vital to ensure that the correct amount of foreskin is removed (not too much and not too little).
- Gentle and accurate tissue handling reduces tissue trauma and the consequences of trauma, which are infection, delayed healing and scarring.
- Good haemostasis using vessel ligation, transfixion sutures or accurate diathermy reduces postprocedure adverse events.
- To achieve a good cosmetic outcome, suture the wound carefully. Do not use too many sutures, and ensure that there is correct tension (not too tight or too loose) while suturing.

ANNEX 9.1. DEVICES FOR MALE CIRCUMCISION

Devices can be described according to their mechanism of action and circumstances when they are used (1). Devices that are in situ (remain in place) are applied to the foreskin; part or all of the device is in situ and is removed at a second visit some days after application (usually seven days).

Surgical assist devices are used to achieve male circumcision surgery in place of some or all of the standard surgical instruments; at the end of the procedure, no part of these assist devices remains in contact with the client's body (2, 4).

A9.1.1. In situ devices

In situ devices work by compressing the foreskin between two surfaces, thereby stopping bleeding and allowing the foreskin to be removed at the time of device placement or after necrosis of the foreskin has occurred (at about one week).

There are two main types of in situ devices for adults: clamp devices and elastic collar compression devices. Clamp devices include the subcategories of collar clamp and vice clamp. The mechanism of action for both clamps consists of rapid, tight compression between hard surfaces to achieve haemostasis. Compression is sufficient to prevent slippage of tissue from the device, such that the foreskin can be removed at the time of or soon after device application. Part of the device or the entire device is left in situ for more than 24 hours (usually one week). Good anaesthesia is required because the sudden tight compression is painful. This pain suppression is achieved by an injection of a local anaesthetic. However, new data are becoming available on the use of topical anaesthetic agent(s) and placement of the device after waiting 20–40 minutes for the topical anaesthesia to take effect.

With elastic collar compression devices, the mechanism of action consists of slow compression between an elastic ring and a hard surface. Compression is sufficient to occlude circulation and produce tissue ischaemia. Part or all of the device and the foreskin are left in place for more than 24 hours (usually one week), thereby causing ischaemic necrosis of the foreskin. At the time of this *Manual's* publication, the foreskin should not be removed at the time of application of the device because the safety is not yet demonstrated (to prevent slippage and bleeding without the foreskin remaining). Such devices can be applied with a topical anaesthetic agent(s) and without the need for an injected local anaesthetic agent(s).

Advantages of using device-based surgical circumcision compared with conventional surgical methods:

- shorter procedure time
- less provider skill needed
- limited bleeding
- lower risk of glans or urethral injury compared with surgical methods
- provides a guide for the circumcision, reducing the chance of too much or too little skin removal
- easy to train providers on using the device
- good final cosmetic result

Disadvantages of using device circumcision:

- Client must wear the device for one week. This may interfere with work and other activities.
- Second visit is needed to remove the device and, depending on the device type, the necrotic foreskin.
- During screening or even in the procedure room, some clients are found to be ineligible for device circumcision. For these clients, either circumcision should be provided using surgical methods on the same day or the circumcision should be deferred to another day. Clients whose procedure is deferred need to come back on another occasion to the same or a different clinic or facility for surgical circumcision.

- Surgical backup is needed to deal with device-related adverse events, and providers need to be familiar with the management of device-related adverse events, for example, the gross penile swelling that may occur if device displacement happens 24–48 hours after placement of the elastic collar compression clamp.
- Elastic collar compression devices, where the foreskin remains in place for one week, may cause an unpleasant odour (because of the necrosing foreskin) and an increase in anaerobic growth in the space between the prepuce and glans; the anaerobes may increase the risk of infection, including tetanus, in clients who are insufficiently vaccinated. Clients must be adequately vaccinated prior to the method.
- Because the device has to be worn for one week and healing only starts after device removal, healing requires about one more week.
- The wound after device circumcision tends to be slightly wider than after surgical circumcision, with some healing by secondary intention.
- There is a need for men to abstain from sexual intercourse until the wound has completely healed, and this process takes at least one week longer with device circumcision. Men should be provided with condoms during the recovery period and advised to use condoms as soon as they resume intercourse because this will protect the newly healed wound.

A9.1.2. Devices prequalified by the World Health Organization

The World Health Organization reviews evidence to inform recommendations on the use of male circumcision methods as well as prequalification of a male circumcision device, which means that the device has undergone an assessment process to determine safety, acceptability, performance and quality of the manufacturing system (5). The device should be applied and removed in accordance with the manufacturer's instructions for use. Prequalification status of a device can be seen on the World Health Organization's website (6).

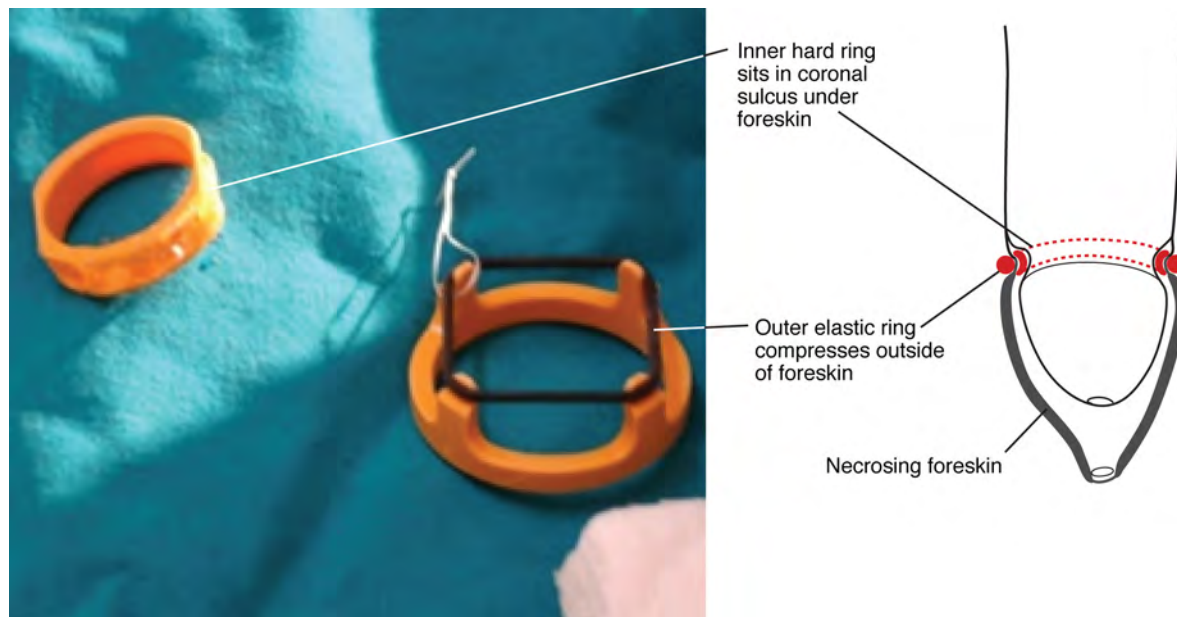
After a device has been designated as prequalified, there is continued monitoring (postmarket surveillance) of the device. From time to time, the manufacturer, in consultation with the World Health Organization, may make changes to the device instructions to improve the device's use. Also, if new risks or adverse events are identified, a field safety correction notice may be issued by the manufacturer and the instructions for use updated. This means that, at all times, the instructions for use issued by the manufacturer are kept current and should be referred to by all who provide conventional or device-based surgical circumcision. Providers in every clinic or facility should periodically review these instructions for any circumcision device they use. Each device comes with a set of instructions, and providers should always consult the latest version—not rely on older filed copies—because small improvements are constantly being made.

A9.1.3. Elastic collar compression device (see Fig. A9.1.1)

The elastic compression type of device cannot be used in circumcising clients with a very tight prepuce or where adhesions prevent full retraction of the foreskin. In practice, the device often cannot be used for younger adolescent boys because there is often a relatively tight prepuce and also physiological adhesions between the glans and foreskin. One study found about 50% of 13-year-old adolescent boys were ineligible for circumcision with this specific device method (7). The proportion of clients ineligible for circumcision with this device decreases with increasing age and maturity. Among eligible clients, this device is effective and safe, provided that the manufacturer's instructions for use are followed and the client is vaccinated against tetanus (8).

Generally, device application is quick and straightforward, and there is no need for immediate surgical backup at the time of the application. However, if the device displaces or the client removes his device, this can produce extreme penile swelling; in this situation, there is a need for backup surgical clinics or facilities within six to 12 hours of the problem becoming apparent. Severe swelling, including skin ulceration, is more likely if the device is displaced or removed more than six hours after but within the first 48–72 hours of its application (2). Device displacement after 72 hours is less likely to cause severe swelling, but there may be bleeding (2). Normally, the client has to return to the clinic six to seven days after the device was applied for the device to be removed. After device removal, wound healing takes about six additional weeks, and there is a need for wound care and dressing during this period.

Fig. A9.1.1. Elastic collar compression male circumcision device^a



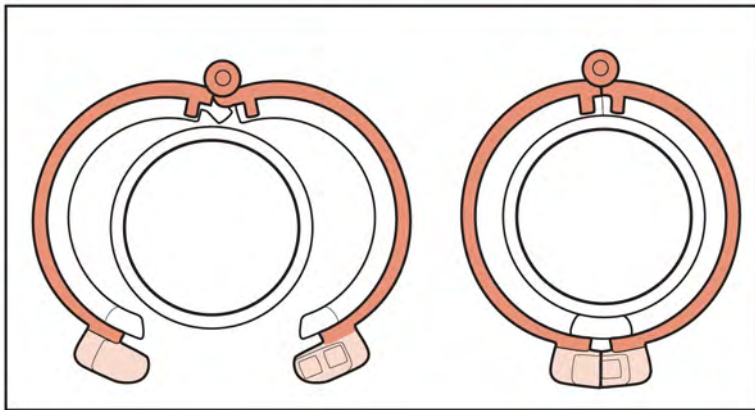
^a The photograph (left) shows the inner grooved ring (separate) and the outer elastic compression ring mounted on the device applicator. The drawing (right) shows the site of device placement in relation to the glans and foreskin. The device is worn for one week, and the device and foreskin are removed at a second visit that occurs one week after device placement.

A9.1.4. Collar clamp device (see Fig. A9.1.2)

The collar clamp device has been found to be safe for use in adolescents boys and men, provided that the manufacturer's instructions for use are followed. Refer to the manufacturer's instructions for use regarding age or other indications.

Because the foreskin is removed with this device at the time of its application, there is a need for surgical backup on site if the device slips off during or after the application procedure, and after the foreskin has been cut off. If this happens, there is an open wound and a need for immediate surgical haemostasis (Chapter 8, Section 8.4.1). If providers are well trained in applying the device, slippage during application is a rare event. Normally, the client has to return six to seven days after the device's application for its removal.

Fig. A9.1.2. Collar clamp male circumcision device



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CHAPTER 10

POSTOPERATIVE CARE AND MANAGEMENT OF ADVERSE EVENTS DURING AND AFTER CIRCUMCISION



This chapter provides information on postoperative (postprocedure)^a care, including the following:

- immediate postprocedure monitoring
- emergency and unscheduled follow-up
- routine follow-up at 48–72 hours, seven days and six weeks
- follow-up education and counselling, to be reinforced at every visit
- special considerations for younger adolescent boys
- special considerations for clients who have device-based procedures
- general information and guidance about dealing with adverse events

^a Postprocedure and postoperative are used interchangeably throughout this Chapter.

10.1. IMMEDIATE POSTPROCEDURE CARE

The client should remain at the clinic for at least 30 minutes after the procedure because it is during this period that continued bleeding is most likely to become apparent. During the operation, small blood vessels spasm when cut, and this temporarily stops bleeding. Shortly after the operation, when the spasm has stopped, the bleeding becomes apparent again, often when the client is in postoperative recovery and has started to move around. If the client has had a device applied (or removed), then he may be observed in a clinic area while seated. If he has had surgical circumcision and is in pain or has other symptoms (for example, fainting or low blood pressure), then he should remain lying down. During this time period, other components of immediate postprocedure care may or may not be provided. Postprocedure protocols for circumcision clients may vary among clinics. However, the essential components of immediate postprocedure care are the following:

- monitoring the client closely (minimum of 30 minutes)
- giving postprocedure analgesia (for example, paracetamol)
- giving the client wound care instructions and other essential advice
- scheduling follow-up visits
- completing the client's medical record
- arranging for the transfer of the client's records, as applicable

10.1.1. Close monitoring for 30 minutes after the procedure

10.1.1.1. All clients

After the circumcision is complete, the client should move to another area for observation. He may need gentle assistance. If he is feeling faint, then he should be kept in the procedure room or kept lying down on a trolley. The facilities for recovery areas will vary between clinics. In the recovery area, the client should be kept comfortable (according to the climate) and have his concerns addressed. Monitoring should be documented, and the client's clinical record should be completed.

For the first 30 minutes after the circumcision, the client should be assessed and closely monitored. This includes the following:

- observing the general condition of the client
- monitoring his breathing, pulse and blood pressure twice before he goes home
- checking the wound dressing for oozing or bleeding
- asking the client if he has pain or any other concerns (see Box 10.1)

Box 10.1. Postprocedure pain and other concerns

An abnormal amount of pain may indicate possible complications, even if nothing is apparent on clinical examination. If there are any concerns about the client's postprocedure recovery, then he should remain at the clinic for a longer period of observation.

10.1.1.2. Clients who have had device application or device removal

Follow-up procedures on a client depend on what device was used and should occur according to the manufacturer's instructions for use.

When using a device where the foreskin is removed at the time of device application, if device displacement happens soon after placement, there could be severe bleeding. The client may require immediate surgical treatment to stop the bleeding.

In situ devices for male circumcision generally remain in place for about seven days after their application. Limited information on two such devices is provided in Chapter 9. However, **providers should consult the device's manufacturer's instructions for use for step-by-step instructions on how to apply and remove the device; instructions are device specific and may be updated periodically by the manufacturer.**

After device removal, follow-up care for the wound is similar to that given to clients who have had conventional surgical circumcision. For clients who have had device-based surgical circumcision, the first follow-up event is at seven days, and further follow-up occurs at **seven days and again at six weeks after device removal.**

The device can become displaced after its application but before the scheduled removal. There have been instances when a client has removed a device by himself.

- If displacement happens, this can be an urgent situation depending on **when it happens** and **the type of device** used. Men who undergo device circumcision should be warned not to try to remove the device. They should be advised that if the device does become displaced, they must return immediately to the clinic.

10.1.2. Providing immediate postprocedure instructions and advice

10.1.2.1. Content overview

The client should receive postprocedure instructions before the client goes home after circumcision. After conventional surgery and after device removal, provide the client instructions for wound care. After conventional surgery, device placement and device removal, there is a need to provide advice about activities that are permitted and activities that must be avoided, including special messages about penile erections and sexual activity, importance of follow-up care and warning signs that indicate the need to seek immediate medical attention. All of these instructions should be reinforced at each subsequent follow-up visit. Follow-up visits are an opportunity to offer HIV testing to any client who previously did not want to be tested.

10.1.2.2. How to give instructions and advice

Postprocedure messages should be given through an education and counselling approach. This means that the client is given information and also assisted in applying the messages to his own circumstances. Instructions to the client should be given verbally; it is helpful if these instructions are also given to anyone who is with him (for example, a family member). In addition to verbal instructions, written instructions should also be given (Annex 10.1).

It is important to ensure that these messages are relevant to the client—that they fit his individual needs and circumstances. Ensure that verbal and written language used to deliver instructions is simple, concise, specific and nonmedical. Use common, understandable and everyday words and terms, such as red, painful, swollen and medicine to stop pain—not words like signs of infection, oedema or analgesia, etc. Information sheets should be pilot-tested on the target client group and amended as necessary to improve clients' understanding. This is to ensure that information is meaningful to clients and in the context of the local culture. Information may need to be translated into the local language or dialect. Separate information sheets may be needed for adolescent clients. These sheets should contain information appropriate to the client's age, maturity or literacy level—as well as to the parent(s)/guardian(s) if the client is a minor.

10.1.2.3. Ensuring client understanding, encouraging compliance

For all clients (adults and adolescents), the following practices are effective to ensure that clients understand the critical messages about wound care and other aspects of recovery:

- Ask the client to repeat the wound care instructions. Ask the client questions to check his knowledge and understanding, for example, *What will you do if the bandage [dressing] falls off?*
- Correct any mistakes in the client's understanding, as this helps in both understanding and reinforcing this critical information. When correcting mistakes, do so in a nonjudgemental way, for example, *I am sorry. I do not seem to have explained that clearly enough. What I am trying to tell you is that you should **not** use any other type of medicines or put anything else on your wound.*

Here, the provider has not blamed the client for his lack of understanding about home remedies (including traditional practices and medicines). This approach is more supportive and may encourage client compliance.

- When giving information to a younger adolescent, be mindful of his overall maturity and be sensitive to his privacy and possible embarrassment with the information received.

10.1.2.4. Considerations for adolescent clients

Instructions must be given to the adolescent as well as his parent(s)/guardian(s). Providers need to be sensitive to the age and development of adolescents, as well as their inhibitions and understanding, when discussing penis hygiene, care of penis dressings, penile erections and adolescent sexuality (see Box 10.2). All adolescent boys, even those who look young and immature, will have nocturnal penile erections and may experience pulling pain—and some may be sexually active. Therefore, providers must give advice about penile erections and sexual abstinence to all adolescent clients. Arrangements should be made so that adolescent boys are in an environment where they feel at ease and can take in information and ask questions (see Annex 10.2).

Box 10.2. Be sensitive when giving postprocedure instructions to adolescents

Adolescents are often reluctant and embarrassed to discuss penile wound dressings, penile erections and sexual activity. Depending on their maturity, some adolescents may not understand some of the issues. It is important for both the adolescent and his parent(s)/guardian(s) to receive wound care instructions. Use of picture books and peer educators may be helpful in communicating with adolescents.

10.1.3. Immediate postprocedure instructions and advice—messages

10.1.3.1. Wound care and dressings

Messages about taking care of the wound are critical, especially in the early part of recovery, when the wound is most vulnerable to infection and potential problems are most likely to occur. Good care and early recognition of any possible problem can improve an outcome.

Messages should include the following:

- **Do not apply any home remedies (including traditional practices and medicines) to the wound at any time following any male circumcision procedure or following device placement or removal.** This is a very important instruction and should be emphasized at each visit. Some clients and/or his parent(s)/guardian(s) may be tempted to apply home remedies later on in the healing process because of perceived delay in healing. Clients should know that **all home remedies** are potentially dangerous because they risk introducing tetanus and other potentially deadly infections (see Box 10.3).
- Keep the dressing in place until the first clinic visit at 48–72 hours.
- Keep the wound and dressing dry.
- Do not wet the dressing when bathing.
- Once the dressing is off, allow only clean (or boiled then cooled) water to touch the wound.
- Do not pick or scratch the wound.
- If the dressing comes off at home or gets wet, the client should follow the clinic's specific protocols. (Clinic protocol may vary for instructing clients to come back to the clinic or for providing clients with sterile dressing to take home. What is done will depend on where the clinic is located in relation to where the client lives, the facilities available in the client's home and the provider's assessment of the client's ability to comply with instructions.)
- Do not remove the wound dressing to urinate. (Note: If there is any abdominal strapping to elevate the penis, the strapping tape will need to be removed before urination, and the client will need to be shown how to do this.)
- Wear clean and well-fitting underwear to help keep the dressing in place.

Box 10.3. Warning against home remedies

Customs and traditions are powerful and should be addressed with sensitivity. It is worth taking the time to explain to clients, as well as parent(s)/guardian(s) of clients who are minors, why it is critical to avoid using any home remedies, traditional practices and medicines. In discussing such remedies:

- Explain to the client that many men (or adolescent boys) like him have had circumcision in the past and that some of them have used home remedies.
- Explain that we now know that these home remedies:
 - do not help in wound healing;
 - often make healing take longer;
 - may cause infections; and
 - may result in tetanus, which can result in death if the client has not received tetanus toxoid-containing vaccine.
- Ensure that the client understands the circumcision wound will heal best and quickest if he carefully follows the clinic's instructions.

10.1.3.2. Other key messages

As outlined below, aside from wound care and dressing, postprocedure education and counselling includes instructions and advice about activity and lifestyle changes, penile erections, sexual activity, pain management (analgesics) and warning signs that require immediate medical attention.

- **Activity and lifestyle changes during the recovery period**

Because the client will be able to return home a short time after the procedure is done, it is important to discuss protecting his wound and overall well-being in the context of his lifestyle and the activities in which he is normally engaged. Advice should be given both about what to do and what not to do. For example, depending on the client's occupation, he may have to stay home from work. The client should also be advised to avoid any activities likely to disrupt the wound, such as riding a bicycle or playing sports (including school sports). Generally, contact sports and activities such as swimming should be avoided until the skin has completely healed and the underlying wound has had time to strengthen—this normally takes between two to three months. The client should be given clear information about when it is likely that he will be able to resume sports activities or return to work.

- **Penile erections and sexual activity**

Advice should be given about penile erections and the need to abstain from sexual activity (see Box 10.4).

- *Penile erections*

After the onset of puberty, all males have nocturnal penile erections typically four to five times per night while sleeping, and these usually do not cause the man to wake up. These erections are normal and have nothing to do with sexual stimulation; they happen because of periodic high flow of blood into the penis to keep the erectile tissue healthy. Most men wake in the morning with an erection, which quickly subsides once the client gets up, walks around and passes urine.

After circumcision, nighttime and morning erections often cause pain because they pull on the skin stitches and cause the man to wake up. The pain usually causes the erection to subside; this relaxes the tension on skin stitches, and the pain goes away. If an erection persists, it helps to get up and walk about because this diverts blood from the penis into the leg muscles and helps the erection subside more quickly. It is also helpful to empty the bladder frequently. When clients are given these explanations, most choose not to take an analgesic for these brief episodes of pain.

Messages should include the following:

- Having **nighttime and morning erections will not harm the wound**. In fact, they help the penis to heal properly by straightening out any folds in the skin that may be present when the penis is soft.
- **Having an erection does not mean that he can safely engage in sexual activity before the wound has healed**. Engaging in sexual activity (masturbation and sexual activity with another person) causes more pull on the wound and may result in damage and delayed healing.
- *Special considerations for adolescents*

Providers need to be sensitive to the maturity level of the adolescent boy, whatever his actual age. It is important to remember that, despite the appearance of physical immaturity, penile erections start early in puberty; therefore, younger adolescents also need to be given advice about pain they may feel during nocturnal penile erections.

- *Sexual activity (see Box 10.4)*

Although most adolescent boys or men do not attempt sexual activity soon after circumcision, studies show that between 5% and 30% do attempt to have sex. Advice should be given on the day of the circumcision and then reinforced at each subsequent clinic visit.

Messages should include:

- Sexual activity should be avoided until the wound has healed. Sexual activity before the wound has healed increases the risk of acquiring HIV or infecting his partner if he is HIV positive because the virus may pass through the open wound. Penile erections in response to sexual stimulation or sexual activity, such as masturbation, will cause pain because of the pull created on skin stitches; therefore, the client should avoid any sexual stimulation.
- If a client does have sexual activity at any time during the six-week period after circumcision, he **MUST** always use a condom because of the increased **risk of acquiring HIV during wound healing**—and especially if the skin has not fully healed. After this six-week period, clients should be encouraged to continue using condoms **for another few months** so that the wounded tissue has time to strengthen; even once the skin has healed, the wounded tissue is still not fully healed for months.
- Masturbation may also damage the wound and delay healing; the client should try to abstain from masturbation until the skin and wound are healed.
- **Male circumcision does not give complete protection against HIV, and the client should always use condoms when having sex with someone new or when engaging in any risky sexual situation.**

This advice about sexual activity should be repeated when the client comes for follow-up at 48–72 hours and at any subsequent visit.

- *Special considerations for adolescents when discussing sexual activity*

Younger adolescents may be engaging in sexual activity and usually do not wish to share this information with their parent(s)/guardian(s). Providers need to be sensitive to confidentiality issues because it is usually necessary to have privacy. This may be difficult in some clinic settings because parent(s)/guardian(s) may want to be present. Clinic providers should make necessary arrangements to ensure that there is privacy and, if necessary, exclude parent(s)/guardian(s) because it is more essential to provide the information and advice.

- *Special considerations for clients who have had a device procedure*

- All clients should be advised to abstain from sexual activity, especially during the week the device is worn and during recovery after device removal; all clients should be encouraged to share this information with their partners. Noncompliance can lead to complications. Clients who have had a device placed should be counselled that having sexual intercourse, especially during the week after placement, can cause the device to be torn off or displaced, which could result in serious injury that **may require urgent surgery**.
- The circumcision team needs to be sensitive to the possibility that a client has not told his partner that he is having device-based surgical circumcision. The team should encourage the client to find ways to keep his partner informed or can offer to meet with the client's partner to explain the importance of abstaining from sexual intercourse, especially during the week after device placement.
- Clients who have had circumcision with any device that remains in place should take care not to catch the device in his clothing and accidentally pull it. Over the course of wearing the device for one week, sometimes there are areas of partial detachment, proximal to the ring. Adolescent boys and men should be counselled that this may happen and that snagging the ring could cause tearing, bleeding or device displacement. They should also be counselled that if this happens, they must return to the clinic.

Box 10.4. Advice about penile erections and sexual activity—summary

- Adolescent boys and men have several erections during their sleep, and most wake with an erection.
- Erections might cause pain for a few days or nights after the circumcision.
- This pain usually goes away as the erection does.
- Erections will not harm the wound and may aid in healing, but the client should avoid sexual stimulation during this time.
- If the client has a regular partner, it helps the client to comply if the partner knows that the client has been advised to avoid sexually stimulating situations until the wound has completely healed.
- Sexual activity should be avoided until the wound is healed (usually about six weeks). Masturbation and sexual intercourse can cause damage to the wound or exposed skin.
- In addition to injuring the wound or skin, sexual intercourse during the six weeks following the circumcision increases the risk of acquiring HIV because the virus may get into the body through any parts of the wound that have not healed. If the client engages in sexual intercourse before the six weeks are over, he must wear a condom to protect the wound and skin, and to avoid acquiring HIV.
- After the six-week period, clients should be encouraged to continue to correctly and consistently use condoms.
- Male circumcision does not give complete protection against HIV. Even after full recovery from circumcision, clients should always use condoms when having sex with someone new or when engaging in any risky sexual situation.
- Information on sexual activity should be reinforced at every postprocedure visit.

- **Pain management during the recovery period**

Pain during recovery should be mild and easily controlled by a supply of analgesics that can be routinely given on the day of the circumcision for the client to take home. Brief pain during nighttime erections is common and does not usually require analgesic medication. The onset of more severe pain at any time during the follow-up period may indicate infection or bleeding, and the client should be seen in the clinic. If the client needs more analgesics than those given on the day of the circumcision, this may signal complications; the client should be seen and assessed. Note that the onset of pain during the first 48 hours is more likely to be an indication of bleeding or haematoma, whereas the onset of pain after 48 hours is more likely to indicate the onset of infection.

- **Warning signs**

The client should be urged to seek immediate medical attention if he experiences any of the following:

- fever
- feeling ill
- hardness or stiffness of the abdomen
- stiffness of the jaw or fits (that is, convulsions), or both
- continued bleeding from the wound that does not stop or gets worse
- swelling and tenderness on or around the wound
- onset or worsening of pain, or throbbing pain in what was a relatively pain-free, healing wound
- skin discolouration
- bad smell coming from the dressing or wound

- swelling or tenderness in the groin (painful inguinal glands)
- pus from the wound
- difficulty passing urine
- client worries about the wound

The provider should specify exactly where the client should go (and provide contact information, such as telephone number and address, particularly if referring the client to a place other than the clinic where he was circumcised).

10.1.4. Additional postprocedure care

In addition to close monitoring and instructions, the following should be done before the client leaves the clinic:

- The client should be given a supply of analgesics and any other medication according to clinic protocols. It should be ensured that a responsible adult is available to accompany the client home (this is of particular importance for clients who are below the age of consent/assent).
- Arrangements should be made for a follow-up appointment 48–72 hours later. The client should be told exactly when and where to go for follow-up.
 - ***Special considerations for clients who have had a device procedure***

Clients who go home wearing a device should also be given a written card or information sheet with specific information about the type of device they have. They can show this to other health care providers in case they have to attend another health care facility. This handout should include contact details of the clinic where the device procedure took place so that other health care providers know how to find out more if needed. This is important because male circumcision devices are new, and most health care providers will not know what they are or how to manage them.
- For any circumcision method, document the visit in the client's medical record. Include any complaints, diagnoses, treatment or referral, and include any comments.
- Finally, the client should be told to contact the clinic or return to the clinic if there is any unexpected or adverse event(s). He should be given clinic contact details including a telephone number. If the follow-up visit will take place at another facility, the client should be given a card to give to the follow-up provider (see Box 10.5).

Box 10.5. Transfer of client records

All of the client's records should be kept at the facility associated with provision of circumcision services. If the follow-up visit will take place at another facility, the client should be given a card to give to the follow-up provider. The card should indicate the following:

- date of the procedure
- type of procedure
- medicine(s) given
- name of referring provider
- any special instructions

If it is necessary to transfer the client's records, a copy should be made and the original records kept at the facility where the surgery took place. For a sample referral form, see Chapter 4.

10.2. EMERGENCY AND UNSCHEDULED FOLLOW-UP VISITS

Normal triaging principles should apply, with priority given to emergency follow-up visits.

- Providers should assess carefully for adverse events in clients who come to the clinic for an unscheduled follow-up visit, and these clients should be seen immediately.
- Staff should be alert to the possibility of excessive bleeding or infection.
- If the client is feeling unwell, even if nothing obvious is found on clinical examination, a problem may become apparent if the client is observed in the clinic or given another follow-up appointment the next day.
- All facilities should have a pre-established emergency referral protocol, and this should be followed if there is a need to send the client to a referral centre.

The steps below should be followed at an emergency follow-up visit.

- Examine the client immediately. Check all areas related to his complaint.
- Read the medical record, if available.
- Measure and record vital signs, including temperature, especially if infection is present or suspected.
- Ask the client about the sequence of events since the operation. Ask about any problems during the surgery or in the recovery period, how problems developed, any increase in discomfort, and any medication or other treatments obtained. Note tetanus toxoid-containing vaccine status.
- Consult with clinic team members to decide the best management for the client.
- Arrange for treatment of any problems that can be handled on an outpatient basis.
- Refer the client to a higher level of care for treatment of potentially serious complications (see adverse events below).
- Note on the client record all problems and actions taken, including the specific adverse event(s) diagnosed and their severity. Follow national protocols on severe adverse event reporting.
- Inform the facility where the male circumcision was performed about the client's emergency follow-up visit (if applicable).

10.2.1. Routine follow-up visits at 48–72 hours, seven days and six weeks

Clients should be advised to attend follow-up visits to further encourage good wound care, assess for any complications and promptly treat adverse events (see Box 10.6). This is also an opportunity to provide HIV testing, information on other health conditions or referrals.

It is a good idea if the provider who does the procedure also sees the client at follow-up. This is because there may have been minor variations in technique particular to that client. Also, if there are any adverse events, this is an opportunity for the actual provider to consider any improvements to their practice, clinic protocols or both.

Quality care at follow-up visits prevents and reduces harm from adverse events; therefore, the client should be seen by an experienced clinician, and less-experienced providers should be mentored. It is impossible to predict everything that might be encountered at follow-up, and even experienced providers may have questions. Clinic culture should encourage staff to ask a colleague, more experienced provider or even a specialist at a referral centre when necessary. If the client goes to a different health care facility for follow-up, it is important for staff at that facility to be trained to do a careful follow-up examination and to report any complications to the facility where the circumcision took place. In outreach or campaign settings where providers come to a site and leave when the campaign is over, it should be the responsibility of the outreach or campaign providers to train the local providers on the basics of adverse event management in male circumcision, including common complications and how to classify and manage them, when to refer the complications, and how to record and report the complications. The outreach or campaign providers should leave the local providers with the

necessary tools and arrangements for diagnosing and treating minor complications, and for reporting and referring more serious complications.

Box 10.6. Need for follow-up visits

Data from public health male circumcision programmes in East and Southern Africa show the importance of follow-up visits (1). Failure to attend follow-up visits results in late identification of adverse events, poorer management of adverse events and poorer outcomes. Programmatic strategies to improve a client's attendance at follow-up visits include:

- reinforcing the importance of follow-up visits with clients during counselling, as a way to empower the client to take charge of his health;
- highlighting issues that may arise if follow-up visits are not attended;
- identifying and helping to mitigate client barriers to attend follow-up visits, including providing transport, reimbursing transport costs, writing a letter to the employer on behalf of the client or a provider visiting the client (for example, a provider visiting a school where there has been circumcision outreach);
- sending text message reminders or making phone calls; and
- using community health workers or community members to remind patients of follow-up visits.

The recommended follow-up schedule after surgical male circumcision is first follow-up visit at 48–72 hours, second visit at seven days and final visit at six weeks. Device circumcision follow-up visits have the same schedule as surgical circumcision; in this case, the second follow-up visit at seven days is for device removal.

At all routine follow-up visits (Box 10.7), providers should treat any adverse events (complications) or wound healing problems found during the examination, or refer the client to a higher level of care if needed.

- Additional follow-up visits (more frequent than the routine follow-up schedule) may be required so that adverse events or wound healing problems can be more closely monitored and managed. Reinforce the importance of these visits.
- Ask the client if he has any concerns or questions, and respond appropriately.
- Reinforce key messages.
- Make sure the client knows where to go for review if complications arise.
- Document the follow-up visit in the client's medical record. Include any complaints, diagnoses, treatment or referral, and include any comments.

Box 10.7. Routine follow-up visits

The following should be done at all routine follow-up visits:

- Reinforce the need for safe and responsible sexual behaviour. Abstinence during wound healing should be encouraged. If client is unable to abstain, encourage less risky forms of sexual activity (for example, masturbation).
- Remind the client that male circumcision provides partial protection.
- Remind the client that condoms should be used consistently and correctly for HIV prevention.
- Give the client condoms (and lubricant if available), and reinforce instructions about correct condom use. In the case of adolescent boys or men who may not be familiar with condoms, it may be helpful to demonstrate condom application using a model.
- If risky sexual behaviour has been identified during counselling, then reinforce advice about safer behaviour.
- Assess and discuss with the client whether and when repeat HIV testing is appropriate based on the client's risk behaviours. If the client refused HIV testing precircumcision, offer him HIV testing at all follow-up visits.

10.2.1.1. First routine follow-up visit at 48–72 hours (after surgery or after device removal)

At the first clinic visit, which occurs 48–72 hours after the circumcision procedure, the dressing should be removed, the wound inspected and a new dressing put in place as needed. If the client has questions, these should be addressed. If any problems or adverse events are identified, these should be managed as described later in this chapter. Instructions about wound care—that sutures are absorbable and do not need to be removed—abstinence from sexual activity and condom use should be reinforced.

1. Ask the client if there have been any problems:

- active bleeding
- excessive swelling
- severe pain in the penis or genital area
- inability to pass urine, or severe pain when passing urine
- fever
- tightness of chest
- rigid muscles or neck stiffness (lockjaw)
- any unusual skin colour, such as very dark or black, or unusual odour
- If the client complains of pain at this time, it may indicate the onset of infection. Normally, there is little pain during the first two to three days after circumcision; the exception is the brief episodes of pulling pain during penile erections (discussed above). Wound pain or increasing or throbbing pain at 48–72 hours is a red flag that indicates a potential problem.
- If the client complains of feeling ill, consider rare serious adverse events, such as sepsis or tetanus.
- Reinforce to clients (and caregivers) not to use home remedies to aid in healing. Remind clients to follow self-care instructions and use medications only as provided or prescribed at the clinic.

2. Gently remove the wound dressing. If the dressing has dried, it should be gently dabbed with antiseptic solution, such as aqueous chlorohexidine, until it softens. It can then be removed gently. It is important not to disrupt the wound by pulling at a dressing that adheres to it (see Fig. 10.1).

Fig. 10.1. Circumcision dressings



3. Examine the client, and look for signs of potential problems. Examples include the following:
 - active bleeding
 - excessive swelling (note if any swelling is localized to one part of the wound or shaft of the penis, or generalized)
 - gaping of the wound
 - blisters or sloughing of skin (note if blisters or loss of skin are immediately adjacent to the wound or on the shaft of the penis, and note if there is skin discolouration, redness extending beyond the wound edges, dark or black areas adjacent to the wound, or any other abnormality of skin colour)
 - discharge of pus from the wound
 - fever
 - rigid muscles or neck stiffness (lockjaw)
 - burns or blisters at the site of application of the diathermy plate (if diathermy was used, particularly if the man has pain in that area)
4. Provide any new care or treatment instructions. Give (or prescribe) medicines if applicable. Generally, it is not necessary to give any further supply of analgesic tablets. If the client asks for further analgesics, this may indicate pain caused, for example, the onset of wound infection, and the need for an earlier follow-up appointment.
5. Repeat and emphasize instructions and key messages about wound care and healing:
 - The client is encouraged to bathe using clean water. Every day, the client should gently wash the genital area with clean water.
 - The client should use medications only as provided or prescribed by the clinic.
 - The client should not use home remedies to aid in healing.
 - The client should wear clean clothing and avoid getting the wound dirty. The client should avoid touching the wound and putting anything on the wound.
 - After this six-week period, the client should be encouraged to continue to use condoms for another few months so that the wound tissue has time to strengthen.

6. Provide further HIV prevention and risk reduction information:
 - Male circumcision provides partial protection against HIV, and condoms should be used consistently and correctly for HIV prevention. Give the client condoms (and lubricant if available), and reinforce that condoms should be used consistently and correctly.
 - Review individual risk plans during postprocedure visits. Ask clients how they are doing in implementing behaviour changes and handling challenges identified during individual counselling sessions.
 - If necessary, discuss with the client whether to repeat HIV testing (or be tested for HIV, if not already done) based on the client's history and risk behaviours. Clients who have previously refused HIV testing should be offered the opportunity to test for HIV at this and all subsequent follow-up visits.
 - The client should abstain from sexual activity for six weeks after the surgery (or device removal) to help the wound heal properly and avoid complications. If the client chooses to have sexual activity during the first six weeks postsurgery or six weeks after device removal, masturbation poses the least risk. If he cannot abstain from sexual intercourse with a partner, he **must** use a condom because there may be a heightened risk of HIV transmission during the wound healing period; the condom also protects the wound.
7. Make sure the client knows where to go for follow-up if complications arise. Review with the client signs that he should look out for that may indicate a problem.
8. Schedule the next follow-up visit (for seven days postsurgery or device removal, or sooner if needed).
9. Document the follow-up visit in the client's medical record. Include wound healing progress, any problems (complaints, diagnoses), any treatments prescribed or referrals made. Include any additional notes or comments.
10. Report any adverse events according to the national or programme requirements—see (2) (*note that this guide may change, so refer to the online version for current information*).

10.2.1.2. Second routine follow-up visit at seven days (after surgery or after device removal)

At the second routine follow-up visit (seven days), care provision will include the same steps as described for the first visit but with some differences (**bolded below**).

1. Ask the client if there have been any problems, with particular attention to pain, as this may indicate infection.
2. Gently remove the wound dressing. (**Normally, the client will no longer have a dressing to remove.**)
3. Examine the client and look for signs of potential problems.
4. **Re-emphasize bathing and wound care instructions for the 48-hour visit**, and provide any new care or treatment instructions. Give (or prescribe) medicines if applicable.
5. Repeat and emphasize instructions and key messages about wound care, healing and HIV prevention.
 - **A new focus may be advising the client on when it is safe to return to work or resume sports activities.**
 - The client should be reminded to abstain from sexual activity for six weeks after the surgery (or device removal) to help the wound heal properly and avoid complications. If the client chooses to have sexual activity during the first six weeks postsurgery or six weeks after device removal, masturbation poses the least risk. If he cannot abstain from sexual intercourse with a partner, he **must** use a condom, as there may be a heightened risk of HIV transmission during the wound healing period; the condom also protects the wound.
 - Provide further HIV risk reduction care as feasible and applicable.

- If necessary, discuss with the client whether to repeat HIV testing (or be tested for HIV, if not already done) based on the client's history and risk behaviours. Clients who have previously refused HIV testing should be offered the opportunity for HIV testing at this and all follow-up visits.
6. Make sure the client knows where to go for follow-up if complications arise. Review with the client the signs that he should look out for that may indicate a problem.
 7. Schedule the next follow-up visit (**for six weeks postsurgery or six weeks after device removal, or sooner if needed**).
 8. Document the follow-up visit in the client's medical record. Include wound healing progress, any problems (complaints, diagnoses), any treatments prescribed or referrals made. Include any additional notes or comments.
 9. Report any adverse events according to national or programme requirements—see (2) (*note that this guide may change, so refer to the online version for current information*).
 10. If there are no problems with wound healing and recovery, this visit may be used as an opportunity for additional health information or referrals for relevant services.

10.2.1.3. Third routine follow-up visit at six weeks (postsurgery or after device removal)

At the third routine follow-up visit (six weeks), care provision will include the same steps as described for the first and second visits but with some differences (**bolded below**).

1. Ask the client if there have been any problems.
2. Examine the client and look for signs of potential problems.
3. Provide any new care or treatment instructions. Give (or prescribe) medicines if applicable.
4. Repeat and emphasize instructions and key messages about wound care, healing and HIV prevention.
 - **A new focus at this time may be advising the client on when it is safe to resume sexual activity. Although it is usually safe to resume sexual activity at this time, the new skin and wound on the penis will still be delicate and easy to tear. Clients should be encouraged to continue to use condoms for another few months so that the new tissue has time to strengthen.**
 - **Also, as is always advised, clients should always use condoms when having sex with someone new or when engaging in any risky sexual situation. Using a condom prevents HIV because the circumcision offers only partial protection.**
5. Assess the client's knowledge of how to use a condom consistently and correctly (ideally, have the client demonstrate on a model).
 - Provide further HIV risk reduction care as feasible and applicable (for example, if the client is known to engage in risky behaviour, offer opportunities for further HIV testing and re-emphasize advice about reducing multiple and concurrent partnerships). Clients who have previously refused HIV testing should be offered the opportunity to test for HIV at this and all subsequent follow-up visits.
 - Make sure the client knows where to go for follow-up if complications arise.
 - Discuss with the client signs that may indicate a problem.
6. Provide tetanus toxoid-containing vaccine as indicated per national protocol.
7. Schedule additional visit(s) only as needed.

8. Document the follow-up visit in the client's medical record. Include wound healing progress, any problems (complaints, diagnoses), or any treatments prescribed or referrals made. Include any additional notes or comments.
9. Report any adverse events according to national or programme requirements—see (2) (*note that this guide may change, so refer to the online version for current information*).
10. If there are no problems with wound healing and recovery, this visit may be used as an opportunity for additional health information or referrals for relevant services.

10.3. MANAGEMENT OF ADVERSE EVENTS: GENERAL GUIDANCE

This section describes clinic management of adverse events and when referral should be made to a higher level of care. See also *Adverse event action guide for voluntary medical male circumcision by surgery or device* for compiled information on adverse events and the clinic-level response.

10.3.1. Keeping the client informed

If a complication occurs during or after the circumcision, the circumcision team must keep the client—and, in the case of a minor, his parent(s)/guardian(s)—informed. For adult clients who give permission, it helps to keep his family informed. Anxiety and fear of the unknown add to the client's distress caused by an adverse event. The client (and others, as described) should be given a clear explanation about the problem (exactly what is happening) and about the plan for managing it.

For example, a complaint of increasing penile pain and fever four to five days after surgery is indicative of wound infection. If there are signs of infection on examination, the client should be given antibiotics and the situation reviewed after 24–48 hours, depending on the severity of the condition. In these circumstances, the client (and his family) should be told the following:

- **what** the problem is: *There is an infection.*
- **how** it will be managed: *Antibiotics are needed to treat it.*
- **when** the situation will be reviewed: *You (or he) should return to the clinic on [date].*

The client may also want to know why the problem happened. Providers should do their best to answer questions in a way that satisfies the client but does not make the situation worse. Describing the potential cause in general terms is better than trying to explain what might have happened when the exact cause is not known. For example, saying, "*Infection can happen when germs come into contact with the wound*" is more helpful than saying, "*This happened because you got the dressing wet*" or providing any other explanation not based on fact. It is important for providers to maintain trust and to enlist clients and their families as partners in ensuring the best outcome.

Sometimes, fear of blame inhibits providers from giving clear, accurate information. Experience with postsurgical adverse events from all over the world suggests that prompt disclosure of accurate information makes adverse events easier to manage because it helps to improve client cooperation and reduce stress for everyone involved.

10.3.2. Advance arrangements with a referral centre

Many adverse events can be managed in the clinic setting, but occasionally emergency transfer or specialist advice is needed. There should be standing arrangements with the nearest referral centre so that there are no bureaucratic obstacles when urgent or nonurgent referral is required. This also applies when the circumcision clinic is located within a district hospital. The contact details of the referral centre should be readily available. When strengthening or establishing national or local circumcision services, adequate funding for referrals should be included as part of the cost of the circumcision service.

10.3.3. Emergency transfer to a higher facility

When there is a need for emergency transfer, the following general rules apply:

- The client and his family should be given a full explanation of what the problem is and what is being done to address it.
- A clear note should be sent with the client to the referral centre in order to ensure that the provider who receives the client has the information he or she needs to respond quickly and appropriately. Do not rely on someone remembering a telephone conversation because that person may not be on duty when the client gets to the referral centre.
- The client should be told not to eat and, depending on the duration of transport, not to drink because a general anaesthetic may need to be given at the referral centre. Any accompanying family member should also be given this information.
- The clinic staff should follow up with the referral centre to make sure the client arrives at the centre and to answer any questions the referral team may have.
- Depending on the reason for transfer, the following additional measures need to be observed:
 - **If the transfer is because of low blood pressure in association with local anaesthetic toxicity or some other undefined cause**, the client should be transferred by ambulance while he is lying flat on his back on a stretcher. An intravenous fluid infusion should be set up in the clinic and maintained during the transfer. If the client is unconscious but breathing—and depending on facilities and expertise—maintain the breathing with an airway; if there is no spontaneous breathing, use an Ambu bag.
 - **If the transfer is because of uncontrolled bleeding**, the client should be transferred by ambulance while he is lying flat on his back on a stretcher. Uncontrolled bleeding should be managed during the transfer by manual compression with gauze. The provider will need to go with the client. An intravenous infusion should be set up in the clinic and maintained during the transfer.
 - **If the transfer is going to take several hours**, then the client should have a urinary catheter inserted. In facilities that are a long distance from a referral centre, providers should be taught how to catheterize, and catheters should be available.

10.3.4. Management of adverse events

In parallel with the first edition of this *Manual* being in use, an *Adverse event action guide for voluntary medical male circumcision by surgery or device* has been developed jointly by Population Services International; the College of Surgeons of East, Central and Southern Africa; and the US Centers for Disease Control and Prevention, with inputs from the World Health Organization (2). This second edition has been updated to reflect experiences from 10 million circumcisions.

In simple terms, an adverse event is something that has gone wrong. An adverse event is: “Any injury, harm or undesired outcome that occurred during or following the male circumcision procedure that would not have occurred if the client had not undergone the procedure at that time. This includes not only events related to any error in screening or medical practice, but those in which no error occurred” (2). An adverse event may happen because someone made a mistake or because of reasons not known or well understood.

10.3.4.1. Provider’s role in preventing adverse events

The provider’s role in preventing adverse events involves the following:

- The provider should carefully screen and note indicators of bleeding disorders or any other relevant medical history that might deem the client ineligible for male circumcision (or the client may need to be referred to a specialist to consider his circumcision options).
- Normally, young men are not taking any medications or receiving any injections. If they are, clinic staff should take particular care to find out what medications or injections are being taken or given, and why.

- Ensure that the client has had tetanus toxoid-containing vaccination, per national protocols and dependent on method. This may mean advising the client to return for circumcision at a later time.
- Check local anaesthetic supplies. Only give the starting dose appropriate for the client's weight, thereby avoiding local anaesthetic toxicity by not exceeding the maximum dose. Aspirate the syringe before injecting the antibiotic to avoid injecting the agent directly into a blood vessel. Use a new syringe and a new needle if there is a need to draw up further anaesthetic from a multidose vial.
- Carefully select the circumcision procedure, particularly for a younger adolescent boy who is likely to be less developed physically. The forceps-guided surgical circumcision method is **NOT** indicated for those adolescents who have not yet matured physically. Use of devices should follow manufacturer's instructions for use.
- Practice good antiseptic technique and wound care.
- Practice good surgical technique, with particular emphases on marking the circumcision suture line and handling tissue gently and with precision.
- The provider should know what actions can reduce or increase the risk of complications. For example, damage to the urethra may occur from stitches that are placed too deeply, or a deep diathermy burn may leave a hole in the urethral wall, with urine coming out through the wound (urethral fistula).
- Take the time to make sure that clients understand wound care instructions, especially the need to avoid home remedies (including traditional practices and medicines).
- Reinforce the importance of abstinence from sexual activity for six weeks after the surgery (or device removal) to help the wound heal properly and to avoid complications. If the client chooses to have sexual activity during the first six weeks after surgery or removal of the device, counsel the client that masturbation poses the least risk. If he cannot abstain from sexual intercourse with a partner, he **must** use a condom because of a heightened risk of HIV transmission during the wound healing period; the condom also protects the wound.
- Have the client repeat wound care and healing instructions, or ask him questions to check his knowledge and understanding of instructions. If the client complies, this will help to reduce the risk of the most frequent adverse event, which is wound infection.

10.3.4.2. Programme manager's or clinic supervisor's role in preventing adverse events

The programme manager's or clinic supervisor's role in preventing adverse events includes the following:

- ensuring that providers have good training in infection prevention and control, including antiseptic technique, injection safety and wound care;
- ensuring that providers have good training in surgical technique, with particular emphasis on marking the circumcision suture line and also handling tissue gently and with precision;
- not imposing unrealistic targets for performing a certain number of circumcisions in a day—a hurried surgery increases the risk of adverse events, such as infection or bleeding, because of rough tissue handling or insufficient attention to accurate haemostasis;
- making sure sufficient time is allowed for the circumcision team to provide complete postprocedure care, including wound care and healing instructions;
- making sure that clients are not hurried home before being given appropriate care and instruction; and
- monitoring for adverse events and learning from review and discussion to improve performance.

10.3.4.3. Photographs

In the case of adverse events or other unexpected findings or developments, it is often helpful to take photographs. Photographs taken at intervals and after the event can help determine whether the problem is getting better or worse. This can be particularly helpful with suspected wound infections, any skin discolouration or other suspected problems,

such as the start of Fournier's gangrene. Also, photographs of abnormalities detected at screening—for example, before circumcision, there were equivocal variations in the position of the urethral meatus—can be helpful when discussing with a specialist whether the client needs to be referred to a higher level of care. Photographs of wound problems can also help in discussions with specialists at the referral centre.

If clinic staff wish to take photographs, they should explain to the client the reason for the photograph. They will also need the consent/assent of the client before taking photographs (or, for minors, the consent of their parent[s]/guardian[s]). Care should be taken to ensure that the use of and access to these photographs are strictly limited to purposes for which and individuals to whom the client has consented. The photographs should be destroyed once they are no longer needed.

10.3.4.4. Emergencies and basic life support

Providers performing circumcision should be up to date with basic life support skills, including the management of cardiac arrests, haemodynamic imbalances, reactions to medications and hypoglycaemia. Sites performing circumcision should be equipped with the necessary emergency equipment, pharmaceuticals and emergency standard operating procedures (see (2) for a list of essential commodities for managing emergencies).

10.4. DIAGNOSIS AND MANAGEMENT OF SPECIFIC ADVERSE EVENTS

To diagnose and manage adverse events—occurring during the circumcision procedure, postprocedure and during the wound healing period—refer to:

- Population Services International (PSI)/College of Surgeons of East, Central and Southern Africa (COSECSA)/Centers for Disease Control and Prevention (CDC). Adverse event action guide for voluntary medical male circumcision by surgery or device, 2nd edition, August 2017 revision. PSI, COSECSA and CDC; 2016 (<https://www.malecircumcision.org/resource/adverse-event-action-guide-voluntary-medical-male-circumcision-surgery-or-device-2nd>, accessed 15 September 2017).

This guide is provided in Annex 10.3; it is the version revised in August 2017.

Note that this guide may change over time; therefore, it is best to refer to the online version (see link above) for the most current guideline.

KEY MESSAGES

- Postprocedure care after male circumcision includes clinical assessment and provision of instructions to the client immediately after the procedure and at 48–72 hours, seven days and six weeks after the surgery or after device removal. The client must be educated on how to care for and protect the wound, what to expect, and signs of potential problems to look for and what to do if they arise. The postprocedure care period should also be used to reinforce the importance of having safer sex and engaging in risk reduction practices, as discussed with the client during preprocedure counselling and education. Additional follow-up care after the six-week period must be available as needed. Possible complications (adverse events) of male circumcision include excessive bleeding, formation of haematoma, infection, an unsatisfactory cosmetic effect, lacerations of the penile or scrotal skin and injury to the glans.
- Rarely, tetanus and gangrene can occur. Because they are potentially life-threatening, all clinic staff should be trained to recognize these problems.
- Certain complications can be managed in the clinic. For others, the client may need to be referred to a higher level of care.
- Complications related to the use of circumcision devices are mainly related to device displacement. The risk for displacement depends on the device but can be reduced by properly placing the device and counselling the client not to snag or pull on the device. Infection is another possible complication and can be avoided by ensuring good training for providers in infection prevention and control, and by encouraging the client to adhere to wound care instructions.

ANNEX 10.1. SAMPLE INSTRUCTIONS AFTER CONVENTIONAL OR DEVICE-BASED SURGICAL CIRCUMCISION OR AFTER DEVICE REMOVAL

- After the procedure, rest at home for one to two days. This will help the wound to heal.
- Return to the clinic to have the dressing removed 48–72 hours after surgery (see the specific time and place below.)
- For best results, come back to the clinic again one week and six weeks after the operation.
- Be sure to follow the instructions on this sheet!
- **What to expect and warning signs:**
 - You may have some minor pain or discomfort, but you should not feel ill.
 - If you feel unwell or develop fever, then you should come back to the clinic (see details below).
 - You may have a little pain or swelling around the wound. This is normal.
 - Pain or discomfort should decrease. If pain becomes worse, if there is pus, if the wound starts to smell or if you are worried about your wound, then you should return to the clinic to have your wound checked (see details below).
- **How to take care of your wound at home:**
 - Keep the wound dry. You may bathe, but do not let the dressing get wet. Once the dressing is off, allow only clean (or boiled then cooled) water to touch the wound.
 - **Do not put any home remedies on the wound.**
 - The swelling may settle down better if you lie down for part of the day.
 - Keep your penis elevated to prevent swelling for at least 24 hours.
 - Do not pull or scratch the wound while it is healing.
- **Activities to delay or avoid:**
 - Do not go back to work (or school) until clinic staff say you can.
 - Do not do any sports, swimming or vigorous activities until clinic staff say you can. If you play a particular sport, ask the clinic staff when it is safe to resume.
 - **Do not have sexual intercourse or masturbate for six weeks.**
 - If you are unable to abstain from sexual activity during the first six weeks of healing, masturbation (although not recommended) is safer than having sexual intercourse.
 - If sexual intercourse cannot be avoided during the six-week healing period, you must wear a condom because the wound is not fully healed, thereby placing you at higher risk for acquiring HIV (and potentially transmitting HIV if you are HIV positive). (Clinic staff will advise you about where to get condoms.)
 - It is best to use condoms to protect the wound for every act of sexual intercourse for at least six months; even after the skin has healed, the wound tissue is not fully strong underneath the skin.
- **Return to the clinic or call the clinic immediately if:**
 - You notice increased bleeding from the surgical wound.
 - The pain or swelling at the surgical wound gets progressively worse.
 - You develop a fever within one week of surgery.
 - You have difficulty passing urine.

- You have pain in the lower abdomen.
- You have stiffness in your abdomen or jaw.
- The wound is discharging pus.
- Wound edges are coming apart.

Remember, you will also be asked to come back to the clinic 48–72 hours, one week and six weeks after your circumcision, and a health care provider will check to see how your wound is healing. If you have problems between these visits, then contact the clinic for advice.

Clinic information:

Clinic address: _____

Hours of operation: _____

Clinic phone number: _____

After-hours phone number: _____

Your next appointment is:

Day: _____

Date: _____

Time: _____

Place: _____

Once again, please follow these instructions to help your wound heal and to keep yourself healthy and safe. Your health, safety and satisfaction are our goal!

ANNEX 10.2. SPECIAL CONSIDERATIONS FOR PROVIDING FOLLOW-UP SERVICES TO YOUNGER ADOLESCENT BOYS

Tips for follow-up care of younger adolescent boys:

- Encourage the adolescent client to enlist a trusted individual to support his healing process and attendance at follow-up visits.
- When it comes to wound care, adolescents may not understand or follow instructions. While this guidance should be directed to adolescents, when possible, parent(s)/guardian(s) should also be educated about wound care.
- The young client and his parent(s)/guardian(s) should be advised to carefully follow clinic instructions about wound care and to not use any home remedies. It should be explained that experience from a large number of circumcisions in his country has shown that the best chance of achieving quick healing is to follow the clinic's instructions. Using any home remedy has been shown to delay healing and is sometimes dangerous.
- In providing information about penile erections and sexual activity, keep in mind that younger adolescents may be engaging in sexual activity and may not wish to share this information with their parent(s)/guardian(s). Providers must respect the client's confidentiality and privacy. It may be necessary to give advice about sexual activity in private, and this may be difficult in some clinic settings; nevertheless, clinics should make arrangements for this to occur.

Additional information on special considerations for communicating and caring for adolescents is provided in Chapters 2 and 6.

ANNEX 10.3. ADVERSE EVENT ACTION GUIDE FOR VOLUNTARY MEDICAL MALE CIRCUMCISION BY SURGERY OR DEVICE, 2ND EDITION, AUGUST 2017 REVISION

The entire guide follows the references section on the next page.

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Adverse event action guide for voluntary medical male circumcision by surgery or device, 2nd edition

Adverse Event Action Guide

For Voluntary Medical Male Circumcision (VMMC) by Surgery or Device
2nd Edition, 2016



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ONLINE ACCESS

An electronic version of this guide is available on the Clearinghouse on Male Circumcision for HIV Prevention: <http://www.malecircumcision.org>

Table of Contents

SECTION 1-INTRODUCTION TO THE ADVERSE EVENT ACTION GUIDE	6
PURPOSE.....	6
AUDIENCE	6
UPDATES IN THE SECOND EDITION	6
ORGANIZATION OF THIS GUIDE.....	7
SECTION 2-ADVERSE EVENT DEFINITION, CLASSIFICATION AND REPORTING	8
ADVERSE EVENT DEFINITIONS	8
ADVERSE EVENT SEVERITY	9
ADVERSE EVENT TIMING.....	9
ADVERSE EVENT RELATEDNESS	11
OVERVIEW OF ADVERSE EVENT IDENTIFICATION, MANAGEMENT AND REPORTING	13
REPORTING AND MONITORING ADVERSE EVENTS.....	14
ADVERSE EVENT MONITORING AND INVESTIGATION	16
DETERMINING REPORTING RESPONSIBILITIES.....	16
SECTION 3-TREATMENT GUIDELINES FOR ADVERSE EVENTS IN MALE CIRCUMCISION.....	18
GENERAL INFORMATION	18
EXCESSIVE BLEEDING	19
INTRA-OPERATIVE (OR PRIOR TO DISCHARGE FROM CLINIC) BLEEDING OR BLEEDING DURING DEVICE PLACEMENT OR WEARING.....	20
ALGORITHM FOR PREVENTION AND MANAGEMENT OF ACUTE BLEEDING AFTER MC	22
POST-OPERATIVE EXCESSIVE BLEEDING OR EXCESSIVE BLEEDING DURING DEVICE WEARING, DURING DEVICE REMOVAL OR AFTER DEVICE REMOVAL.....	25
INFECTION.....	29
TETANUS	31
WOUND DISRUPTION	36
PAIN	38
INTRA-OPERATIVE PAIN.....	38
POST-OPERATIVE PAIN.....	40

SCARRING/DISFIGUREMENT/POOR COSMETIC RESULT; INJURY TO PENIS.....	42
SCARRING/DISFIGUREMENT	43
TORSION OF PENIS	45
INSUFFICIENT SKIN REMOVAL.....	47
EXCESS SKIN REMOVAL	51
INTRA-OPERATIVE EXCESS SKIN REMOVAL	52
POST-OPERATIVE EXCESS SKIN REMOVAL.....	53
INJURY TO PENIS	54
INTRA-OPERATIVE INJURY TO PENIS.....	58
POST-OPERATIVE INJURY TO PENIS.....	60
OTHER ADVERSE EVENTS: EXCESS SWELLING OF PENIS/SCROTUM INCLUDING HAEMATOMA, PROBLEM WITH VOIDING (URINATING), OTHER	62
EXCESS SWELLING OF THE PENIS/SCROTUM INCLUDING HAEMATOMA.....	62
PROBLEM WITH VOIDING (URINATING)	67
SEXUAL DIFFICULTIES OR EFFECTS/UNDESIRABLE SENSORY CHANGES	70
DEVICE DISPLACEMENT	73
ANAESTHESIA-RELATED EVENTS.....	76
SYSTEMIC TOXICITY FROM LOCAL ANAESTHESIA	76
LOCAL INJECTED ANAESTHETIC DOSING	77
ANAESTHETIC DOSING CHARTS.....	79
EMERGENCY MANAGEMENT.....	85
ANAPHYLAXIS TO LOCAL ANAESTHETIC AGENTS	85
VASOVAGAL REACTION.....	86
HYPOGLYCEMIC REACTION	86
OCCUPATIONAL EXPOSURE	87
SAFE INJECTION TECHNIQUE	88
PREVENTING INJECTION-RELATED INFECTIONS.....	88
SECTION 4-APPENDICES.....	90

Appendix 1: ADVERSE EVENT RECORDING AND REPORTING	91
Appendix 2: ADVERSE EVENT TIMING.....	92
Appendix 3: ADVERSE EVENT CLASSIFICATIONS AND DEFINITIONS: DURING SURGERY, DURING DEVICE PLACEMENT OR PRIOR TO DISCHARGE FROM VMMC CLINIC.....	93
Appendix 4:ADVERSE EVENT CLASSIFICATIONS AND DEFINITIONS: POST-OPERATIVE PERIOD AFTER DISCHARGE FROM VMMC CLINIC OR DURING DEVICE WEARING, DURING DEVICE REMOVAL OR AFTER DEVICE REMOVAL	95
Appendix 5: ANAESTHETIC DOSING	100
Appendix 6: ALGORITHM FOR PREVENTION AND MANAGEMENT OF ACUTE BLEEDING AFTER MC	104
Appendix 7: ALGORITHM FOR MANAGEMENT OF BLEEDING AFTER MC BY NON-MC PROVIDERS.....	105
Appendix 8: ALGORITHM FOR MANAGEMENT OF PENILE HAEMATOMA.....	107
Appendix 9: VMMC EMERGENCY MEDICAL SUPPLIES, EQUIPMENT AND MEDICINES.....	108

SECTION 1-INTRODUCTION TO THE ADVERSE EVENT ACTION GUIDE

PURPOSE

The purpose of this Adverse Event (AE) Action Guide is to:

- Reduce the incidence of AEs in medical male circumcision (MC) by providing guidance on how to avoid them
- Improve the outcomes of AEs associated with both surgical and device-related MC, by providing guidance on safe and appropriate management
- Facilitate standardized reporting of AEs
- Support monitoring of the quality of programmes and safety of voluntary medical male circumcision (VMMC) programme services

AUDIENCE

This guide is appropriate for any programme implementing MC under local anaesthesia in adolescent and adult males as part of a comprehensive HIV prevention strategy. Although this guide has been prepared for programmes supported by the US President's Emergency Plan for AIDS Relief (PEPFAR), it is hoped that it will be useful to providers in all VMMC programmes, as well as those who conduct post-operative reviews of clients but may not be trained to provide the MC procedures themselves.

UPDATES IN THE SECOND EDITION

This document has been updated from the initial version, primarily to include definitions and management of AEs associated with WHO-prequalified MC devices, as well as to provide other updates based on additional VMMC implementation experience, including AE reporting to WHO and to PEPFAR through the Notifiable Adverse Event reporting system. These updates include:

- Definitions for PrePex and ShangRing device-related AEs, the only two WHO prequalified devices at the time of writing, including an additional device-specific AE: Device Displacement
- Timing scheme for device-related AEs
- Infection chapter expanded to include tetanus and serious necrotising infection
- Reference to WHO recommendations regarding the risk of tetanus with use of the PrePex device
- Additional guidance on the prevention and management of bleeding and additional discussion on bleeding disorders
- Additional guidance on infection control through safe injection techniques and avoidance of contamination through use of multi-dose vials
- Renaming of AE "Sexual difficulties or complications/undesirable sensory changes" to "Sexual difficulties or effects/undesirable sensory changes"

- Local anaesthetic dosing charts simplified and modified to include suggested starting doses; volumes of both starting and maximum doses are limited based on syringe size
- Bupivacaine can be used with lidocaine in VMMC clients of all ages
- Additional detail on policies and responsibilities for reporting AEs
- Inclusion of references to pertinent updated guidelines (such as for post-exposure prophylaxis) and other documents
- Additional material added including an AE definition chart, algorithms for management of bleeding and haematomas, AE timing chart, anaesthetic dosing charts, and recommended emergency management supplies
- Charts within the text of the guide and as appendices that can be used to produce full colour job aids
- Addition of colour-coding to the AE charts, with yellow, pink, and orange denoting surgery, devices, and surgery and devices, respectively

ORGANIZATION OF THIS GUIDE

Reading the entire guide will result in the best understanding of classification, management and reporting of AEs. Throughout this guide, the phrase ‘male circumcision’ or ‘MC’ is used to denote the procedure of removal of the foreskin, and the phrase ‘voluntary medical male circumcision’ or ‘VMMC’ refers to the programme providing circumcision services for HIV prevention.

Section 1 is this introduction.

Section 2 gives key background information about AEs, including criteria for classifying severity (mild, moderate or severe) and timing of AEs for both surgery and device circumcisions; an overview of the process of AE identification, management and reporting; and PEPFAR-specific reporting requirements.

Section 3 gives detailed diagnosis and management information for **each specific AE type**. It will likely be of most interest to providers who manage AEs, and they should familiarize themselves with these definitions and management principles prior to providing care to VMMC clients. Each AE type has a separate chapter, which begins with general information and considerations for that AE type, including a section on “additional and special considerations for devices”. This is followed by charts providing definitions and specific management for first surgical and then device methods. In some cases these are identical, and in others they differ.

Section 4 consists of appendices that can be used as job aids, including a guide to abbreviated AE coding, condensed charts listing diagnostic criteria for all AE types, a list of recommended emergency supplies for sites performing MC, flow charts for management of bleeding or haematomas, and anaesthetic dosing charts.

SECTION 2-ADVERSE EVENT DEFINITION, CLASSIFICATION AND REPORTING

General definition for AEs related to MC: *Any injury, harm or undesired outcome that occurred during or following the male circumcision procedure that would not have occurred if the client had not undergone the procedure. This includes not only events related to any error in screening, performance, or follow-up of the procedure, but those in which no error occurred.*

AEs are inevitable with an intervention such as MC, and occurrence of an AE does not automatically imply provider error or fault. Nonetheless, much can be done to reduce the risk and severity of AEs, including:

- use of proper supplies
- use of instruments that are in good working order
- correct cleaning and sterilization of instruments
- proper training of providers and retraining as needed
- emergency supplies on site with periodic emergency training
- early recognition of and follow up of clients with AEs
- correct management of AEs
- documentation of AEs
- evaluation of AE data and institution of changes and corrections to programmes and policies as indicated
- policies empowering all staff to alert an appropriate above-site party of practices that could lead to AEs (such as use of the forceps-guided circumcision technique in adolescents under 15 years), without fear of untoward ramifications

ADVERSE EVENT DEFINITIONS

AE definitions used in this guide are based on those in the PEPFAR Monitoring, Evaluation and Reporting (MER) Indicator Guidance. Because the majority of VMMC programmes are PEPFAR-funded, discussions of reporting in this guide also include PEPFAR reporting requirements. Other definitions have been in used in some settings, and some ministries of health may require providers to use different definitions in reporting.

AE classification has three common components: **type, severity, and timing**. Severity and timing are defined here, and types are explained in detail in the management section. **AE relatedness to MC** is a fourth component that is primarily important in AE investigation and monitoring, and discussed on p.11.

In most cases, classification and definitions for surgical and device-related AEs are the same or quite similar. However, in some cases there are differences due to technique and mechanisms of action.

ADVERSE EVENT SEVERITY

AEs have been classified into three categories of severity: mild, moderate, and severe.

- **Mild** classification indicates minimal or no intervention is required beyond reassurance and observation
- **Moderate** classification relates to those AEs that are neither mild nor severe, require intervention, and are usually managed on-site
- **Severe** classification requires extensive intervention with referral or specialist input

Moderate and severe AEs are those that in the past PEPFAR has required be reported and monitored. AEs are no longer a required reporting indicator for PEPFAR MER, but moderate and severe AEs should still be the AEs of greatest interest to national reporting systems.

As VMMC programs expand into more remote areas where health care facilities have limited capacity, increasing numbers of males are presenting with AEs to facilities that are unable to provide care for mild and moderate AEs. Transfers necessitated by this situation should not automatically result in a "severe" classification: severity should instead be determined based on clinical characteristics of the AE and level of intervention required as recommended in this guide. Similarly, hospital admissions necessitated only by distance or social considerations rather than the level of care needed should not result in an automatic 'severe' classification.

This recommendation applies to device-based MCs as well: if a client presenting with an otherwise moderate AE is transferred because the site to which he presented cannot provide appropriate care (e.g. suture materials are not stocked or staff are not trained in suturing), the transfer itself does not constitute a severe AE criterion. Surgical intervention for device AEs, including circumcision, remains a criterion for severe AE.

ADVERSE EVENT TIMING

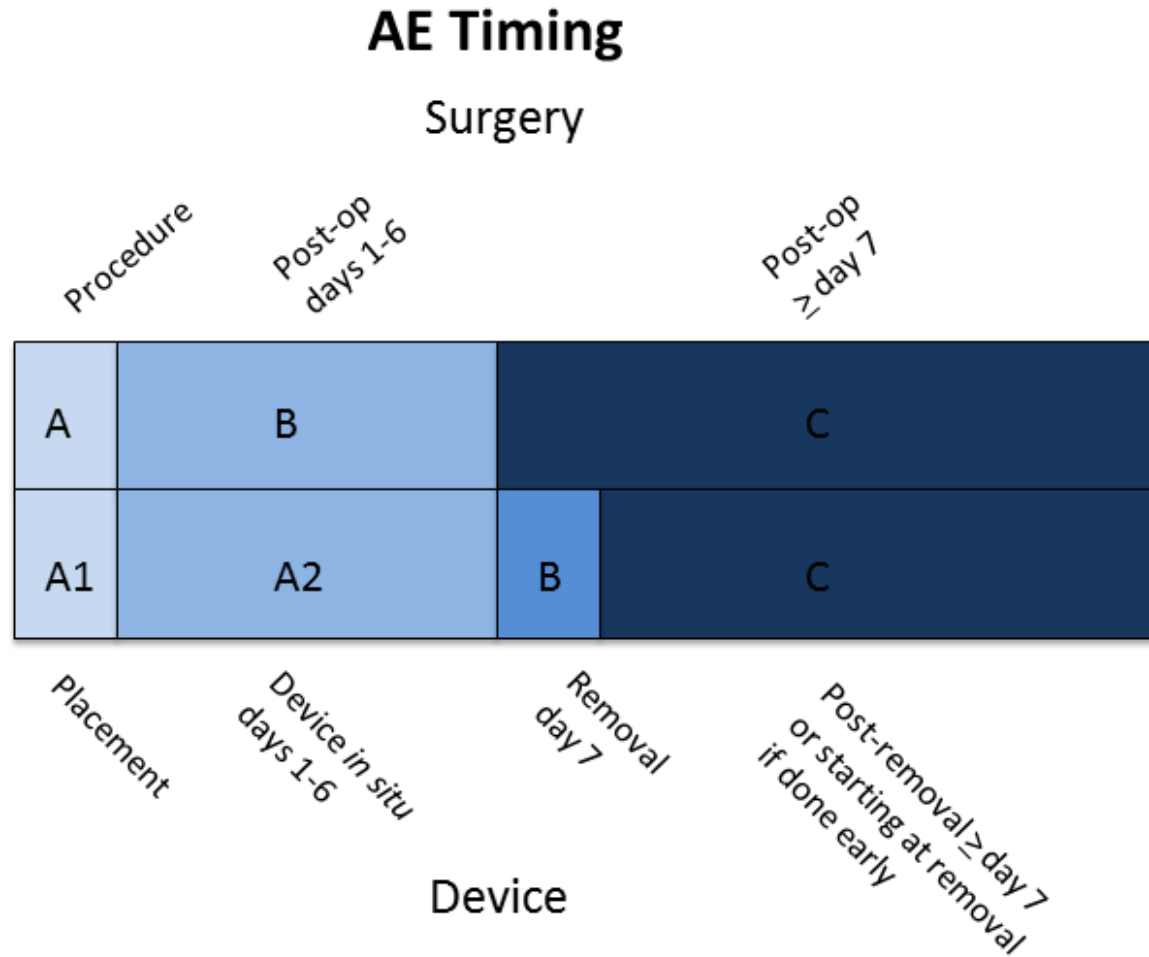
For MCs performed **surgically**, AEs are classified by their timing in relation to surgery as follows:

- A = intra-operative (AE occurs during surgery or prior to discharge from clinic)
- B = post-operative (AE occurs 1–6 days after surgery and discharge from clinic)
- C = post-operative (AE occurs ≥ 7 days after surgery and discharge from clinic)

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

- A1 = during placement of PrePex or ShangRing device
- A2 = after device placement and before removal (these AEs typically occur 1-6 days post-placement)
- B = during device removal
- C = after device removal (typically after day 7)

- If a device is displaced or removed early:
 - This should be classified as Device Displacement in the A2 period.
 - However, complications or AEs after removal of the device should be classified as C, even though the device was removed early.



This chart and a list of AE definitions are included as Appendices 2, 3 and 4.

In the diagnosis and management charts in this guide, device AEs occurring in time period A1 are addressed in the intra-operative charts, and

those occurring in periods A2, B, and C are addressed in the post-operative charts. For example, pain that occurs during device removal (B) is found in the post-operative, not intra-operative, chart.

AE timing is classified by when the first AE occurs. For example, if a client presents 8 days after surgery with an AE but gives a history of onset at day 6, timing would be classified as B, not C. The exception is injury to the penis, where the AE should be classified by when it was noted, since management can depend on how much time has passed since circumcision.

By the nature of their natural history, not all AEs can occur at all time-points. For example, scarring can only be classified as C since it cannot occur at the time of the procedure and cannot be identified in the first week after surgery, since seven days is insufficient time for scar formation.

AEs sometimes occur together and can be related (for example, wound disruption may result from wound infection). Each AE noted should be recorded as a separate diagnosis (wound infection with disruption would be recorded as 2 AEs), and the presence of one AE may affect treatment for another (e.g., wound disruption should not be closed while untreated infection is present).

With many AEs, **documentation by photographs** is very helpful in classification and monitoring progress and treatment. When photographs are obtained, client/guardian permission should or must be obtained, depending on the policy or preferences of national programmes. Permission may be written or verbal, also depending on policy or preferences of national programmes. In this guide, chapters on specific AEs indicate where repeated photographs may be particularly helpful.

ADVERSE EVENT RELATEDNESS

AEs can also be categorized with regard to relatedness to the procedure. This is most often done during an investigation process for a serious AE, rather than in routine diagnosis of common AEs. During this process, the assessed degree of relatedness to the procedure may change as new information is obtained. Relatedness does not impact management of an AE.

An AE is considered related to the procedure **if it would not have happened had the procedure not been performed. This does not necessarily imply any error or wrongdoing on the part of the provider.** For example, infection of the circumcision wound as a result of applying a traditional remedy, or displacement of a device due to sexual activity, are considered definitely related to the procedure, even though the clients did not follow instructions, as neither would have occurred had there not been MC. Neither, however, occurred because of provider error.

Regardless of being determined to be related to MC or not, all AEs should be recorded and reported, even when the AE seems to be completely unrelated (e.g., client involved in a road traffic accident 3 days after operation).

Relatedness can be classified as:

- ***Definitely related:*** Direct association with the procedure, i.e., follows a reasonable temporal sequence from the procedure and is a recognized AE of the procedure.
- ***Likely/Possibly related:*** More likely explained by the procedure, i.e., follows a reasonable temporal sequence from the procedure and is a plausible AE of the procedure, but could have another cause.
- ***Likely unrelated:*** More likely explained by other cause.
- ***Definitely unrelated:*** Clearly explained by other cause.

OVERVIEW OF ADVERSE EVENT IDENTIFICATION, MANAGEMENT AND REPORTING

In general, identification and management of an AE follows the time course depicted below.



1. **Identification:** The AE may be revealed by the client or discovered by the provider during surgery, during the post-operative observation period, or at a subsequent visit. The health care worker providing care should first identify and classify the AE. As many people own cell phones with the capability of taking and sending photographs, providers may find it helpful to have clients send photos when they call with complaints or with reports of progress. While cell phone communication and photos about healing during the post-operative period are acceptable and can be used for monitoring, all initial AE identification and treatment must be conducted through direct observation by a clinician. A list of the various types of MC-related AEs, as well as definitions of the respective severity levels, can be found in Section 2.
2. **Treatment:** Once the AE is identified and classified, the provider is encouraged to follow the treatment guidelines in this document. **The management of AEs described in this guide constitutes the basic standard of care. Where there are national protocols with enhanced standards of care, these should be used.**
 - a. Please note that the medications mentioned in this guide, specifically antibiotics, are given as examples. Local availability, drug resistance patterns, and national treatment protocols may vary. Thus, national programmes should adapt this guidance accordingly.
 - b. In most cases, management of surgical and device-related AEs is the same or similar. However, with device-related AEs, management may also include early removal of the device and/or performance of a surgical circumcision, based on clinical judgement.
3. **Referral, if necessary:** Referral to another health facility or provider (e.g., specialist doctor) may be necessary. Providers are advised to refer clients or request help with every AE that they do not feel comfortable with or capable of managing according to the treatment guidelines provided, even if the site of care is in theory equipped to handle the AE. Even when admission to a higher level of care is not called for in the management of the AE *per se*, consideration should be given to the travel conditions and distance required for return visits to the local site; sometimes transfer and admission may be needed to assure client safety and follow-up, even if not strictly medically required. Ensuring successful referrals depends on adequate planning beforehand. VMMC service delivery points should have a readily-available, up-to-date contact list of sites and appropriate specialists to which referrals can be made at any time the need arises. This list should be checked every six months to make sure that it is up to date. These providers and sites should be aware of the possibility of MC clients being referred for assistance.

4. **Reporting:** Proper reporting is important so that providers can follow-up with the client as necessary, and managers and providers can monitor the quality and safety of a programme and take actions to improve client care. Reporting should follow nationally prescribed reporting pathways and protocols. Providers and other clinic staff need to understand and follow these protocols. Site and programme managers must understand how and when to report AEs and when to inform external stakeholders. PEPFAR-funded programmes are no longer required to report all moderate and severe AEs to PEPFAR, but are still required to follow the PEPFAR Reporting Protocol for MC Client Death and Notifiable Events (see next section), and should follow any additional reporting guidance provided by national programmes and by their funding agency's in-country VMMC staff.
5. **Follow-up:** Routine follow-up ensures that clients receive sufficient care after circumcision. Providers and site managers should ensure that clients are well-informed about the importance of routine follow-up visits and when they are expected, as well as the importance of specific and additional follow-up visits when an AE has occurred. Clients with a documented AE who default on follow-up appointments should be contacted by telephone or any other appropriate means. An enquiry should be made as to their current status as well as actively encouraging them to present for follow-up review.

REPORTING AND MONITORING ADVERSE EVENTS

Reporting AEs involves passing summary information about AE rates and/or notifiable individual AEs up through designated channels to programme and/or ministry of health leadership. Monitoring can be done at any level and involves reviewing and analysing these data for trends and concerning findings.

ADVERSE EVENT REPORTING

Reports of AEs provide data necessary to conduct monitoring of service delivery, safety, programme progress and patient outcomes. AEs should be reported according to national ministry of health guidelines if present, and regardless, programmes should continue internal AE reporting for quality control. Reporting systems should include clear guidance on:

- *The severity threshold for AE reporting.* Historically, PEPFAR programmes have been required to report all moderate and severe AEs. This routine reporting is no longer required. However, “moderate and severe” can still be a useful threshold for reporting.
- *Standard AE definitions to be used,* such as the standard definitions provided in this guide. This document recommends the use of AE definitions originally provided by PEPFAR for AE reporting, but some ministries of health may require programmes to report using different AE definitions.
- *Reporting methods and timing.*
- *The expectation that AE's should be reported regardless of the appearance of relatedness;* follow-up investigations as needed will make the final determination of relatedness.

There is a subset of severe AEs for which reporting is also expected to external stakeholders such as donors, WHO, or technical advisory groups. WHO requests reporting on serious AEs, including deaths; hospital admissions to intensive care within 30 days of an MC; tetanus cases within 30 days of an MC; and serious glans, penile or urethral injuries. National Ministry of Health reporting structures should include this step at some level.

Similarly, programmes for which PEPFAR provides direct service delivery support are still required to rapidly report specific notifiable AEs through a separate PEPFAR process, under the **PEPFAR Protocol for VMMC Client Death and Notifiable Adverse Events**. The most recent version of this protocol should be followed, under the direction of the in-country VMMC staff of the funding agency. The protocol includes information on processes to ensure that appropriate parties at the country and headquarters levels are rapidly notified of any client deaths or notifiable AE, including:

- complete or partial amputation of the glans or shaft of the penis
- tetanus, including non-fatal cases
- any AE that results in disability that is likely permanent
- any AE that results in anatomic deformity that is likely permanent
- any AE that results in hospital admission for ≥ 3 days

This protocol applies to any death or notifiable AE(s) that occurs during the MC procedure or within 30 days following surgical circumcision or device removal, for any male, regardless of age, who was circumcised through services or research directly funded by PEPFAR. If there is any evidence that a death or notifiable AE occurring after the 30-day post-MC mandatory reporting period is related to the MC, this should also be reported. The list of reportable AE types may change in the future, and providers at PEPFAR-supported sites should be aware of the up-to-date requirement for AEs that need to be rapidly reported.

This reporting requirement does **not** apply for programmes receiving only technical assistance from PEPFAR. However, programmes and ministries of health are encouraged to require that all deaths and notifiable AEs be reported to them regardless of funding source, to enable more complete reporting from all service delivery points.

Admissions to a hospital for ≥ 3 days to provide care for mild and moderate AEs that are necessitated by the non-medical circumstances of the client, such as limited capacity at health care facilities near clients' home and far distances between clients' homes and health care facilities, should **not** be reported as a notifiable AE.

Implementing organizations and ministries of health should have processes in place by which providers and other staff can alert the organization (at above-site level), the funding agency, and/or the ministry of health to improper conduct that has led or could lead to AEs, such as use of forceps-guided technique in those under 15 years of age. These processes and accompanying policies should ensure there are no untoward ramifications for submitting such alerts. Field staff should be urged to use these processes whenever unsafe practices are observed.

ADVERSE EVENT MONITORING AND INVESTIGATION

Regular monitoring of reported AE data provides the necessary insight for quality assurance and improvement. All programmes should monitor the number of VMMC clients experiencing AEs as a way of measuring safety and the quality of service provision. Reports are used to calculate AE rates and, as with definitions and reporting methods, calculations of AE rates should be done using defined formulae. One such formula is:

Number of clients with at least one AE in a given time period / Number of clients with at least one post-MC follow-up visit in the same period

An AE rate above 'an acceptable level' (often considered 2% for moderate and severe AEs combined) is an indication of the need for investigation into causes of AEs and possible corrective interventions. Conversely, extremely low AE rates (near 0%) may suggest problems in the monitoring and reporting systems, such as poor follow-up rates, failure to recognize AEs, or incorrect classification of AEs. Monitoring should be conducted at multiple levels (e.g., site, region, implementing partner), so that comparisons can be made. Such comparisons allow recognition of possible problems with specific sites, regions, implementing partners, or an entire national programme, so that any needed improvements can be made at the appropriate level.

For PEPFAR-supported programmes, PEPFAR participates in investigation of reported notifiable AEs. For all programmes, it is recommended that ministries of health and/or programmes direct such investigations for all instances of severe AEs, AE clusters or high AE rates. These should include classifying AEs by relatedness to MC.

DETERMINING REPORTING RESPONSIBILITIES

In cases where multiple providers or sites are involved in a client's care, confusion can arise over who is responsible for reporting AEs. Examples would be: a client with an AE presents to the site where the procedure was performed, but requires referral to another site for management of the AE, and because of concerns about duplicate reporting, neither site reports the AE; or, a client with an AE presents to a different site from where the MC was performed, and this site is concerned about inflating its own AE rate by reporting the AE. It is important to have a single, clear policy that governs reporting responsibility. Below is an example of a possible policy. Programmes may choose to adopt some or all of the elements of the example in their policies. Regardless of the details of the policy, national programmes and implementing partners need to collaborate to develop policies for reporting of AEs that:

- ensure that all reportable AEs are reported to the national programme
- define proper reporting channels and responsibilities for reporting
- avoid duplicate reporting
- provide education on proper management, referral and reporting of AEs to all sites where men with MC-related AEs may present

Example of a policy for reporting MC-related AEs:

- When one provider performs a MC and another provider at the same site diagnoses an AE, the provider diagnosing the AE should document it and ensure it will be reported.
- When an AE is diagnosed at the site where the MC was performed, that site should report the AE, regardless of whether the client is then transferred elsewhere for care.
- When an AE is diagnosed at a site that did not perform the MC (and possibly does not perform MCs at all), as may be common in the case of campaigns or mobile services, the site that performed the MC should be notified, and it should document and report the AE. To ensure this is implemented correctly, VMMC sites should educate health posts and clinics in their catchment areas about the need to contact the MC provider in the event that a recently circumcised client presents with an AE.
- This policy requires that sites performing MCs have a standard procedure for ensuring that when one of their MC clients is diagnosed with an AE at another site and they are notified, the MC site staff reliably document the AE in the client's MC chart and report it.
- Providers at all VMMC sites sharing a catchment area (and ideally, nationally) should have a common understanding of where reporting responsibility lies, to avoid duplicate- and non-reporting.

SECTION 3-TREATMENT GUIDELINES FOR ADVERSE EVENTS IN MALE CIRCUMCISION

GENERAL INFORMATION

- Depending on level of training, knowledge and experience, providers will differ in surgical and AE management skills. Management of some AEs, especially those that are severe, requires an experienced provider. Depending on the AE and the management required, different provider skills may be needed. For example, severe injury to the penis may require management by a plastic surgeon, a complex fistula by a urologist, and tetanus by a physician skilled in intensive care. When it is recommended that an AE be managed by an experienced provider, the provider should be familiar and comfortable with the methods and skills required for managing the client's AE(s). Depending on the type of facility and its staffing, there may or may not be providers with the requisite skills present. In stand-alone facilities and those associated with primary health care facilities, it is likely that providers will NOT have the skills to manage complex or serious AEs and in these instances, clients will require referral. Decisions on whether management should be on-site or there should be client referral should be made by the provider in charge at the site, and should follow existing plans for transfer.
- Prior to discharge from the clinic after MC, all clients should be given a contact phone number to call in the event that they experience an AE or have questions.
- In instances of mobile, outreach or campaign services, trained MC providers may not always remain in the area, and clients with AEs may present to local health clinics staffed by providers not trained in MC or surgical techniques. In such situations, it is important that local providers are made aware that MC services have been provided in the community, are given contact information for the VMMC team, and are asked to call when any client recently circumcised presents with an AE.
- When AEs require surgical repair, this repair, like the circumcision procedure itself, should be done under local rather than general anaesthesia when at all possible. General anaesthesia may rarely be necessary, as in the case of prolonged surgery or extensive debridement, but should only be selected when the procedure cannot be safely performed under local anaesthesia.

EXCESSIVE BLEEDING

MC-related bleeding AEs typically occur in the first 72 hours after the procedure. Bleeding-related AEs occurring after 72 hours are often associated with new trauma to the genital area such as early commencement of masturbation or sexual intercourse, a previously unidentified bleeding vessel, or a bleeding disorder.

Bleeding related to MC is classified according to when the excessive bleeding occurs and by the extent and persistence of bleeding:

- Ongoing intra-operative or immediate post-operative bleeding (classified as A for surgery and A1 for devices)
- Post-operative bleeding (classified as B or C for surgery or A2, B or C for devices), though significant bleeding is unlikely after 72 hours
 - Bleeding related to device circumcision for PrePex and ShangRing may occur at the time of removal of the device and would be classified accordingly (i.e., as category B)

In clients with bleeding abnormalities, bleeding during or immediately after surgery is difficult to control. The most common of these abnormalities are von Willebrand disease and haemophilia. Before MC, it is important for providers to question each client or, in the case of a minor, their parent or guardian, about whether there is a history of bleeding problems in the client or the family. If there is such a history in the client or family, MC should not be undertaken under routine conditions. Instead, there should first be consultation with a specialist. It is important to remember that in some people with less severe forms of these bleeding abnormalities, the problem becomes apparent only after a medical intervention such as a medical or dental procedure. MC may be the first such procedure that some clients undergo, especially younger clients, so it may be the instance where a previously undiagnosed bleeding abnormality first becomes apparent. **As some bleeding disorders are hereditary, other family members of a client with a suspected or confirmed bleeding disorder could also be affected. Haemophilia is an inherited disorder that is passed from mothers to sons. In clients with suspected or confirmed haemophilia, brothers and cousins related through maternal aunts could also be affected and should not have MC performed until there is assurance that a bleeding disorder is not present.**

However, mild or moderate bleeding disorders are not an absolute contraindication to MC. If performed, it should be under tightly controlled conditions with experienced providers in a setting where there is access to blood or clotting factor transfusions.

Particularly in instances of mobile or campaign services, trained MC providers may not always remain in the area for follow-up, and clients with AEs may present to local health clinics staffed by providers not trained in MC or surgical techniques. Clients with bleeding may be particularly vulnerable in such situations. In addition to the general guidance above about ensuring local providers contact the MC team about AEs, local providers also need to be given specific guidance on how manage and refer clients who present with bleeding. Appendix 7 contains a flow chart for management of bleeding that can be distributed to local health care facilities and potentially displayed after VMMC campaigns or mobile services to aid local providers.

It is very important to consider a bleeding abnormality in a client with prolonged or recurrent bleeding, even if there is no prior history of this. In such cases, the client should be referred for specialist medical and surgical care. In the global VMMC programme experience, clients who have had serious consequences from bleeding events have often been those with repeated bleeding episodes and health care visits after MC who were not recognized as having a bleeding disorder. An algorithm for management of bleeding during or immediately after surgery, device placement or removal is included as Appendix 6.

INTRA-OPERATIVE (OR PRIOR TO DISCHARGE FROM CLINIC) BLEEDING OR BLEEDING DURING DEVICE PLACEMENT OR WEARING

Defined as: Oozing/swelling/haematoma/obvious bleeding during or immediately after initial surgery or during device placement and wearing

Intra-operative bleeding that is difficult to control can be due to a number of reasons.

Look for:

- An unidentified bleeding vessel, commonly occurring in the region of the frenulum. This bleeding can be difficult to stop and is best controlled with ligatures and **not** diathermy cautery, since the area of the frenulum and the underlying urethra is vulnerable to cautery-related burns and subsequent fistula development.
- **Caution:** If the identified bleeding area is in the vicinity of the urethra/frenulum, take care not to place the haemostatic sutures too deep, since there is a risk of penetrating the underlying urethra with the sutures, possibly causing a future urethral stricture or fistula.
- If a haematoma has started to form or if there is extravasation of blood into the tissue, the source of bleeding can be difficult to identify. This situation is often associated with a cut blood vessel that has retracted from the plane of the incision, or overly deep dissection with the scalpel blade or dissecting scissors into the highly vascular corpus cavernosa or other deep vascular penile tissue.
- An expanding haematoma is a sign of ongoing bleeding and should be managed as with other acute bleeding.

Excessive bleeding during surgery or immediately thereafter may increase the risk for subsequent wound infection, as bacteria easily reproduce in a hematoma; close follow-up may be needed (e.g., visits at day 2 and day 4 or 5) to ensure that infection does not develop.

Additional and special considerations for devices

With devices, control of bleeding should be managed in the same manner as with surgery. If bleeding occurs when the device is in place and is not easily controlled, the device may need to be removed to identify the source of the bleeding with surgical intervention to complete the circumcision and achieve haemostasis.

PrePex

- Bleeding with placement should not occur as there is no cutting of live tissue
- Bleeding at the time of removal is usually minimal, but can require pressure or, on occasion, placement of sutures for haemostasis

ShangRing

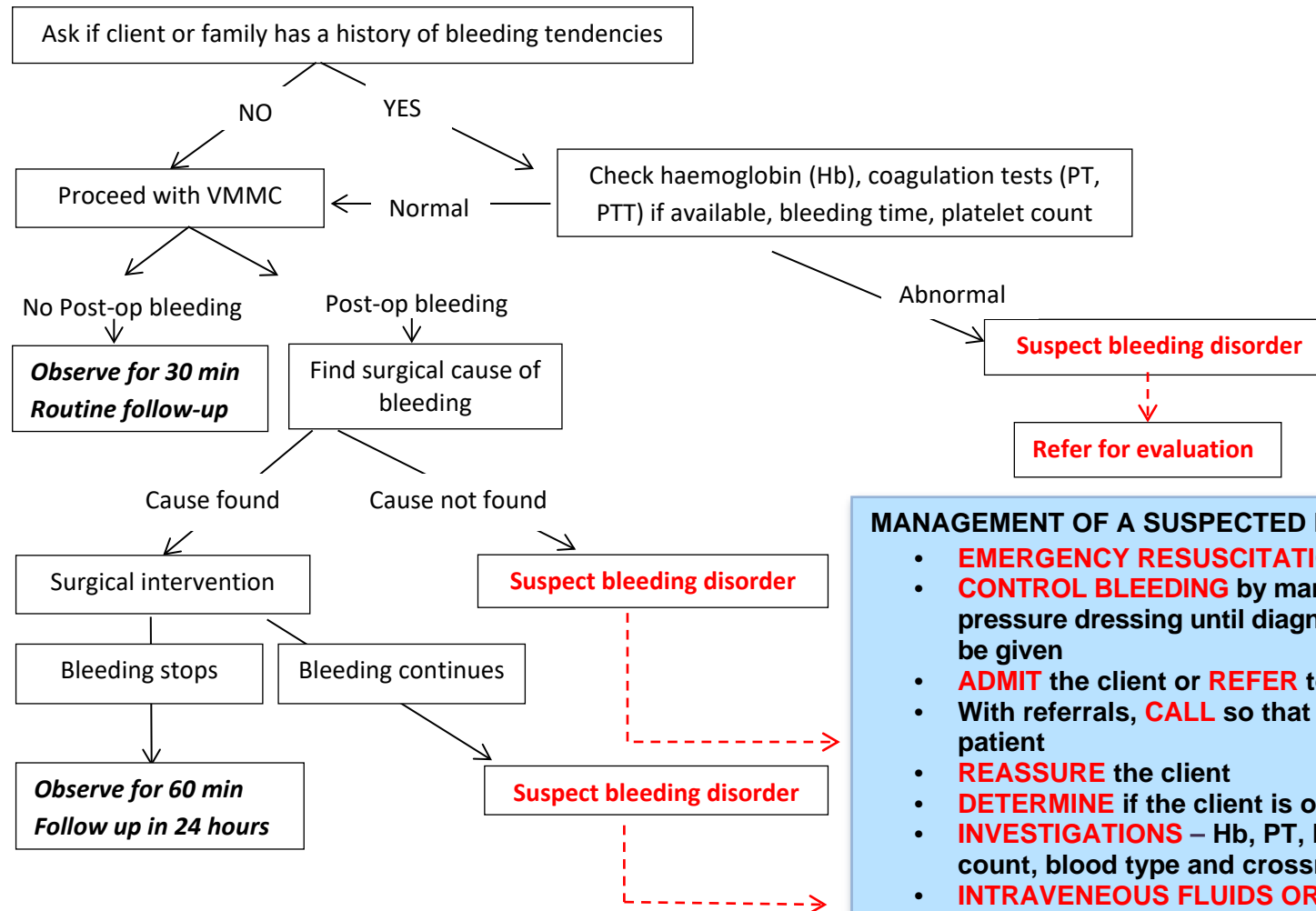
Because foreskin is removed at the time of placement, bleeding can occur with device placement if the ring is not placed properly to attain haemostasis, or if the device becomes displaced. In these instances, bleeding needs to be controlled and an emergency surgical circumcision will likely be needed.

The Algorithm for Management of Acute Bleeding after MC (below and Appendix 6) may be used for evaluation and management of bleeding during or immediately following MC. This algorithm can be adopted as needed by programmes and can be displayed in operating theatres.

In all cases:

- **Stay calm and remember that it is almost always possible to control bleeding with manual pressure onto a gauze swab over the area of bleeding. In cases of severe bleeding it may be necessary to wrap gauze around the penis and to apply manual pressure to the whole circumference of the penis. This technique can be maintained for as long as necessary, for example, while thinking about next steps or calling for assistance, or even during transfer of the client.**
- **Reassure the client.**
- **Monitor the client's blood pressure and heart rate for any signs of shock** (heart rate more than 100 beats per minute, decrease in systolic blood pressure to less than 100 mm Hg).
 - **Note:** Blood pressure may remain normal despite significant blood loss; a fall in blood pressure in a young person often occurs late and is an indication of massive blood loss.

ALGORITHM FOR PREVENTION AND MANAGEMENT OF ACUTE BLEEDING DURING AND AFTER MC



MANAGEMENT OF A SUSPECTED BLEEDING DISORDER:

- **EMERGENCY RESUSCITATION** if in hypovolemic shock
- **CONTROL BLEEDING** by manual compression and/or pressure dressing until diagnosis and definitive treatment can be given
- **ADMIT** the client or **REFER** to a higher facility
- With referrals, **CALL** so that facility can get ready for the patient
- **REASSURE** the client
- **DETERMINE** if the client is on anticoagulant therapy
- **INVESTIGATIONS** – Hb, PT, PTT, bleeding time, platelet count, blood type and crossmatch
- **INTRAVENEOUS FLUIDS OR BLOOD TRANSFUSION** if hypotensive since Hb may be normal after acute bleeding
- **MANAGE** according to the cause—e.g., Vitamin K, clotting factors, FFP, platelet transfusion etc.

Adapted from JHPIEGO

ADVERSE EVENT	MILD	MODERATE	SEVERE
<p>Description: Excessive Bleeding <i>Intra-operative or prior to discharge from clinic</i></p> <p>Surgery</p>	<p>A-BL: Intra-operative bleeding that is more significant than usual or post-operative spotting of the bandage with blood; both easily controlled.</p>	<p>A-BL: Intra-operative bleeding or bleeding that occurs prior to discharge that requires a pressure dressing to control, or that requires additional skin sutures without surgical re-exploration of the wound.</p>	<p>A-BL: Intra-operative bleeding requiring blood transfusion, transfer to another facility, or hospitalization; or post-operative bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility.</p>
<p>Description: Excessive Bleeding <i>During device placement or wearing</i></p> <p>Device</p>	<p>A1/A2-BL: Bleeding during placement that is more significant than usual or spotting of the bandage or clothing with blood; both easily controlled.</p>	<p>A1/A2-BL: Bleeding during placement that requires a pressure dressing to control without surgical re-exploration of the wound or removal of the device.</p>	<p>A1/A2-BL: Bleeding during placement that requires blood transfusion, transfer to another facility, or hospitalization; or bleeding that requires surgical exploration, removal of device, placement of sutures, hospitalization, or transfer to another facility.</p>
<p>TREATMENT</p>	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Apply pressure manually with gauze swab and maintain for 5 minutes. Use a clock to measure the time and do not lift gauze to check until time is done. • Gently remove swab. If bleeding has stopped, reapply the wound dressing. • If bleeding continues, this is a moderate AE. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Apply pressure manually while taking care not to move or displace device and maintain for 5 minutes. • If bleeding continues, this is a moderate AE. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Apply pressure manually with gauze swab and maintain for 5 minutes. Use a clock to measure the time and do not lift gauze to check until time is done. • Gently remove swab and attempt to identify the origin of the bleeding vessel. • If the wound is closed or partially closed, remove sutures since it is easy to miss a bleeding vessel under a fold of skin. • Re-administer local anaesthesia if necessary. • If the bleeding vessel is clearly identifiable, place a suture at that point and tie securely or use electrocautery for haemostasis if the bleeding area is not in the vicinity of the frenulum. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Refer to the higher-level facility. • Apply manual pressure to control bleeding during transfer of the client. • Establish intravenous access and administer crystalloid replacement fluids (e.g., sodium chloride) of 1–2 litres. • Re-exploration of the wound should be performed with good lighting and removal of all sutures so that there can be thorough inspection of the wound. • If there is excessive bleeding from the frenular artery, an underrunning haemostatic stitch should be used to occlude the artery. Avoid biting too deeply, which can damage the urethra. • If one or two re-explorations of the

ADVERSE EVENT	MILD	MODERATE	SEVERE
		<ul style="list-style-type: none"> • If the bleeding vessel is not identifiable, under-run the bleeding area by starting at a dry point and insert continuous sutures which cross the bleeding area, ending with a knot at a dry part of the surface. • For difficult frenular bleeds, place an additional vertical mattress suture. Great care is needed not to place the suture too deeply, because the urethra is near to the surface skin and can easily be damaged. • Be prepared to call for a more experienced provider and/or refer (see severe AE management). <p>FOR DEVICE</p> <ul style="list-style-type: none"> • When applying any pressure or pressure dressing to the wound, take care not to displace or move the device. • Unless the source of bleeding can be clearly identified and controlled with pressure, it is likely that the device will need to be removed and a surgical circumcision performed; this will be classified as a severe event. 	<p>wound have failed to identify a distinct bleeding vessel but the bleeding continues, suspicion for a bleeding disorder should be high. In this case, further re-exploration is unlikely to benefit the patient and may worsen bleeding. The focus should be on correcting clotting deficiencies.</p> <p>ADVANCED MANAGEMENT IN BLEEDING DISORDERS</p> <p>For clients with likely bleeding disorders treated in high-level facilities:</p> <ul style="list-style-type: none"> • In those who respond well to factor VIII, continue infusions for 7 days to allow healing and prevent rebleeding. • Re-exploration should be avoided if possible, but if necessary (e.g. to remove clots), pretreatment with appropriate clotting factors can help prevent bleeding. Consult hematology. • Hematology consultation by phone may be sufficient and helpful, if not available on site. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • As above for surgery. • The management is the same as for severe bleeding after surgery except that it will probably be necessary to remove the device and convert to a surgical circumcision.

POST-OPERATIVE EXCESSIVE BLEEDING OR EXCESSIVE BLEEDING DURING DEVICE WEARING, DURING DEVICE REMOVAL OR AFTER DEVICE REMOVAL

Defined as: Oozing/obvious bleeding after discharge from MC clinic or during or after device removal

- Prior to discharge from the clinic, all clients should be given a contact phone number to call in the event that they experience an AE or have questions. Clients should be instructed that if they experience any post-operative bleeding (or any other AE), they should call a MC provider using the contact number.
- Mild post-operative bleeding may be caused by removal of dressings, leading to some displacement/disruption of the suture margin clot or scab formation. This bleeding is usually very slow, from an identifiable location where the healing suture margin clot/scab has been disrupted. Bleeding caused by removal of a dressing or cleaning of a wound can be prevented or decreased by wetting the dressing with sterile water or saline prior to removal and avoiding removing any clot/scab.
- Moderate to severe post-operative bleeding usually presents from 6 hours after surgery through the first post-operative day, but can occur even later. It may be due to bleeding of a cauterized or sutured vessel, or a previously unidentified vessel becoming disrupted by an erection, trauma, or other external event to the area. Look for significant bleeding or a regular stream of fresh blood from the suture margin or wound, soaking dressings or underwear. If this bleeding is contained or partially contained by the suture margin or scab covering the wound, there may be accompanying swelling or underlying haematoma. This presents as swelling, bleeding, or both.
- If a client returns with a complaint of bleeding and bleeding is controlled, he should be scheduled for follow-up the next day. If a clinic visit is not possible, there should be follow-up by phone to make sure that bleeding has not recurred.
- **Any bleeding or haematoma that recurs (presents more than once) could indicate a bleeding abnormality and should be closely followed by an experienced provider trained in MC or referred for further evaluation.**
- If a client presents with post-operative bleeding, he (or his guardians, in case of a minor) should re-questioned about a personal or family history of bleeding in the event that this information was not initially collected or that because of a desire to get MC, this information was not disclosed. In the event that there is now a family or personal history of bleeding, consider referral, even if haemostasis is achieved.
- Fresh, noticeable active bleeding not controlled by a pressure dressing requires re-operation, or referral if re-operation at the site is not possible.
- Also see “Other Adverse Events” if there is swelling or haematoma.
- An algorithm for management of haematoma is included in this guide under the chapter “Other Adverse Events: Excess Swelling of Penis/Scrotum including Haematoma, Problem with Voiding (Urinating), Other” and as Appendix 8.

Additional and special considerations for devices

- If heavy bleeding is encountered at device removal, application of pressure or placement of sutures for control may be needed.
- In general, all bleeding after removal of device should be handled in the same manner as bleeding after surgical circumcision.

PrePex

- At PrePex removal, oozing may be seen when necrotic tissue is separated from the underlying healing wound. If this is a small amount of blood and the bleeding is easily controlled not requiring pressure, it does not need to be classified as an AE.
- While removing the necrotic foreskin with Harvey wire scissors, acute injury to underlying tissue is also possible, and bleeding can occur and would be classified as a category B adverse event.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Excessive Bleeding Post-operative Surgery	B/C-BL: Blood-stained dressings or underwear, no active bleeding. Small amount of bleeding from minor clot disruption when changing dressings that is controllable with new dressings or 5–10 minutes of manual pressure measured on a clock.	B/C-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure measured on a clock, and requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound.	B/C-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
Description: Excessive Bleeding During or after device removal Device	B/C-BL: Small amount of bleeding from wound with no active bleeding and is controllable with new dressings or 5–10 minutes of manual pressure.	B/C-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure or requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical exploration of the wound.	B/C-BL: Bleeding that requires surgical exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
TREATMENT	<p>FOR SURGERY</p> <ul style="list-style-type: none"> Control with new dressings or 5–10 minutes of manual pressure. Use a clock to measure the time and do not lift gauze to check until time is done. Apply a light pressure dressing and observe the client for 30 minute, using a clock to measure the time. Review in 24 hours. <p>FOR DEVICE</p> <ul style="list-style-type: none"> Management as above for surgery. 	<p>FOR SURGERY</p> <p>Note that haematomas are often best managed conservatively even when they are quite large (see section on haematoma)</p> <ul style="list-style-type: none"> Apply pressure manually with gauze and maintain for 5 minutes. Use a clock to measure the time and do not lift gauze to check until time is done. Gently remove swab and attempt to identify the origin of the bleed. If provider(s) have sufficient experience and expertise, administer local anaesthesia and examine the wound. If bleeding vessel is clearly identifiable, place a suture at that point and tie securely. If the bleeding vessel is not identifiable under-run the bleeding area by starting at a dry point and insert continuous 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> If the pressure dressing is significantly soaked with blood, the client will require surgical re-exploration. Apply manual pressure/compression over gauze swab to control bleeding. Establish intravenous access and administer crystalloid replacement fluids of 1–2 litres. If provider(s) have sufficient experience and expertise, administer local anaesthesia and explore the wound. FOLLOW UP initially daily until the clinical team assesses client's progress as satisfactory. If sufficient expertise to manage client not available on site, REFER to a higher-level facility. Apply manual pressure to control bleeding during transfer of the client. Keep client supine to avoid hanging

ADVERSE EVENT	MILD	MODERATE	SEVERE
		<p>sutures which cross the bleeding area, ending with a knot at a dry part of the surface.</p> <ul style="list-style-type: none"> • Observe the client for at least one hour and re-inspect the dressing. • Give the client the emergency contact details of the provider on call in case bleeding resumes. • FOLLOW UP initially daily until the clinical team assesses client's progress as satisfactory. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery. 	<p>penis that can result in penile engorgement and further bleeding.</p> <ul style="list-style-type: none"> • If one or two re-explorations of the wound have failed to identify a distinct bleeding vessel but the bleeding continues, suspicion for a bleeding disorder should be high. In this case, further re-exploration is unlikely to benefit the patient and may worsen bleeding. The focus should be on correcting clotting deficiencies. <p>ADVANCED MANAGEMENT IN BLEEDING DISORDERS</p> <p>For clients with likely bleeding disorders treated in high-level facilities:</p> <ul style="list-style-type: none"> • In those who respond well to factor VIII, continue infusions for 7 days to allow healing and prevent rebleeding. • Re-exploration should be avoided if possible, but if necessary (e.g. to remove clots), pretreatment with appropriate clotting factors can help prevent bleeding. Consult hematology. • Hematology consultation by phone may be sufficient and helpful, if not available in-house. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery.

INFECTION

Defined as: The condition resulting from the invasion of the body by pathogenic microorganisms

Infection-related AEs may present as soon as the second day post-operatively or post-device placement, and typically present in the first two weeks following foreskin removal (timing classification B or C for surgery, C for devices). However, problems related to effects of severe wound infections can present months, or even years, later. Wound infection severity can fall anywhere on a broad spectrum ranging from mild/moderate manifestations of wound infections, to serous wound discharge and suture margin infections, to severe wound disruption secondary to infection, abscess formation, areas of wound or skin necrosis, disfigurement and sepsis. Mild infections can be treated conservatively with local wound cleaning and dressing changes. Moderate or severe infections should be treated with systemic antibiotics. Topical antibiotics usually should not be used.

NOTE: There are separate classifications for treatment of wound disruption and scarring/disfigurement, which can often occur with wound infection, later in this section.

Look for:

- Suture or wound margin discharge that is serous or frank pus.
- Small areas of yellow slough, often around a suture itself or the wound margin, especially the area of the frenulum.
- Blistering around the incision or near the wound margin.

Inquire about:

- When the signs of infection were first noted.
- Wound hygiene and cleaning practices.
- Pain. Post-operative pain usually improves following MC. Pain that is getting worse might be a sign of infection.
- Self-administered treatment, including use of home or traditional remedies on the circumcision wound.

A localized swollen, fluctuant area (often extremely tender to palpation), warm affected area, offensive odour, and/or thick yellow discharge may indicate the presence of an abscess, which may require surgical drainage and treatment with antibiotics. If there is cellulitis, marking the line of erythema with a pen at the time of diagnosis and repeatedly at set intervals such as 1–2 hours, along with photographs if possible, may help providers determine whether the infection is advancing or improving with treatment, and how quickly.

All infected wounds should be examined for the presence of a fistula, as on occasion wound infection can lead to the formation of a fistula. Clients may present with complaints of leaking or spraying of urine. Initial treatment in such a case should be the same as if fistula were not

present. **In addition, in all instances when there is the presence of a fistula, there should be prompt referral to a specialist for evaluation and repair as needed.**

A rare but serious complication of circumcision may be necrotising fasciitis of the genitals. This is sometimes also called Fournier gangrene. This infection usually involves multiple organisms including anaerobic bacteria, can advance rapidly along tissue planes, results in necrosis of large areas of tissue, and has significant morbidity and mortality. Important points around this infection include:

- Necrotising fasciitis is a life-threatening infection where the infection can spread over hours.
- Necrotising fasciitis may be characterized by intense pain and tenderness over the involved skin.
- If necrotising fasciitis is suspected, there should be **urgent** referral to a center with capacity to manage this condition (often a district or larger hospital). This infection spreads very rapidly; a history of normal healing the day or two before presenting with evidence of severe infection might be a clue for the provider to this life-threatening emergency.
- **Mark the line of cellulitis** so as to monitor advancement of infection.
- A multimodal approach is key, centered around early and aggressive debridement and broad-spectrum antibiotics that are effective against anaerobes.
- Many cases require multiple debridement procedures.

In any case of a wound infection, especially where there appears to be presence of anaerobes as evidenced by odour, and if the client was not vaccinated for tetanus at the time of MC or already up-to-date, consider providing a tetanus booster if available and per national policy. (This will not completely mitigate risk of tetanus, but could prove useful in those who previously received a complete primary series).

Additional and special considerations for devices

Infections with use of devices are classified as A2 (during wearing) or C (after removal). Infection noted at the time of removal should be classified as A2.

If an infection develops while a device is in place, it may be deemed necessary to remove the device. As there is little experience with this situation, there is no standard practice for this decision. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), the provider will also need to decide if surgery or other interventions such as debridement are needed.

With device wounds, which heal by secondary intention, white or yellowish discharge can develop over the wound during normal healing. This granulation tissue may sometimes be confused with infection. The presence of warmth, pain and erythema (redness) are signs that can distinguish true infection.

PrePex

- With the PrePex device, in most men there is an odour resulting from the necrosis of the foreskin while the device is in place. In some cases, the odour can be intense and offensive. It is probably caused by anaerobic growth in the space between the necrotic foreskin and underlying tissue, and is not an infection. As infections caused by anaerobic bacteria can also produce a similar odour, there may be confusion between the necrotic process and infection when this device is in place. Infection is usually accompanied by warmth, pain, and erythema, which can be used to distinguish infection from the necrotic process.
- There have been several cases in which premature sloughing of some layers of the foreskin has been observed while PrePex is in place. The occurrence of this is even rarer than device displacement, so there is little clinical information to date. In several cases, part of the inner mucosa has separated from the rest of the foreskin and was seen protruding from the end of the foreskin. In a single case, this protrusion appeared as a urine-filled sac. The appearance of this is alarming but involves only the necrosing foreskin; live tissue is not affected. While this is not listed as a defined AE in this guide, it should be reported so that additional data on this rare event and its management can be gathered. If urination is obstructed, surgical circumcision may be necessary.

TETANUS

Tetanus is an acute and frequently fatal disease caused by a neurotoxin produced by the organism *Clostridium tetani*. This bacterium is commonly found in the environment in places such as warm, moist soil. The bacteria may also be found in the intestinal tract of humans and animals.

There have been rare reports of tetanus associated with both surgical and PrePex MC. Overall, the risk of tetanus following circumcision appears to be extremely low. However, the risk of tetanus, both in the context of MC and in general, may be increased by low tetanus immunisation primary series or booster coverage in adolescent and adult males, resulting in low rates of protective immunity. Following circumcision, applying home remedies that contain animal dung, plants or soil could increase the risk of tetanus because these may be contaminated with *C. tetani* spores. In several of the tetanus cases associated with MC, home remedies were applied to the MC wound. This underscores the importance of counselling clients about proper wound care, including not applying any substances to the MC wound unless instructed to do so by providers.

Diagnosis of tetanus is based on typical signs and symptoms, including:

- Headache
- Jaw cramping
- Sudden, involuntary muscle spasms, including in the neck, shoulder, or chest
- Painful muscle stiffness all over the body
- Difficulty swallowing
- Seizures
- Fever and sweating

- Hypertension
- Tachycardia (fast heart rate)

For more information, see: <http://www.cdc.gov/tetanus/about/symptoms-complications.html>

Diagnosis or suspicion of tetanus is a medical emergency requiring hospitalization at a facility capable of delivering a high level of supportive care, **including respiratory support with a ventilator. Immediate treatment with human tetanus immune globulin (TIG) is an important part of management.** Drugs to control muscle spasms, aggressive wound care and antibiotics are also important components of the management (<http://www.cdc.gov/tetanus/about/diagnosis-treatment.html>). Additional details on treatment of tetanus have been published by WHO (Current recommendations for treatment of tetanus during humanitarian emergencies: http://www.who.int/diseasecontrol_emergencies/publications/who_hse_gar_dce_2010.2/en/). Any case of suspected or confirmed tetanus should be transferred **immediately** to a facility capable of providing intense support, **even if such support is not required at the time.** Waiting until symptoms worsen and there is an acute need for support could result in death of the client. Transportation may be hazardous if transport vehicles are not well equipped to handle a sudden change of status, such as development of convulsions or respiratory distress that may commence en route. Communication with the referral facility, with agreement on a safe transfer plan, is critical.

Each tetanus case should be thoroughly investigated and reviewed for association with MC, and reported to the WHO by the ministry of health. Device manufacturers should be informed of any case after device use.

In settings where there is incomplete coverage with an infant primary tetanus series or where tetanus boosters are not up to date, the population eligible for MC may not be protected from tetanus. WHO and PEPFAR have proposed that ministries of health develop policies regarding use of tetanus vaccination and boosters in the context of MC, and have provided recommendations (<http://www.who.int/hiv/pub/malecircumcision/tetanus-male-circumcision/en/>).

In a person who has received no prior tetanus immunisation, a single dose of vaccine serves to prime the immune system but does not result in a protective antibody level, and thus there is not protection from tetanus. Even in those with at least one prior immunisation who receive a subsequent dose, substantial levels of antibody may not be seen until 7 days after the vaccination, with a maximum level by 14 days. Given this timing, revaccination of previously vaccinated clients at the time of circumcision also cannot be relied on to protect clients from tetanus. **Note: There have been at least 3 cases of tetanus in clients who received a single dose of a tetanus toxoid-containing vaccine (TTCV) at the time of either surgical circumcision or PrePex placement.**

Based on review of the most recent available program data, as of July 2016, WHO released a technical consultation update (<http://www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/>). **This advises that for circumcision with a device method that requires that the foreskin remains in situ for several days before it is removed, all clients without a documented history of**

appropriate tetanus immunization receive two doses of TTCV prior to device placement, at least four weeks apart, with the second falling at least two weeks before placement. Clients with documentation of three infant doses or one dose during adolescence or adulthood should receive a booster at least two weeks before device placement. Those with five or six documented lifetime doses given on appropriate schedules do not need additional immunization. For surgical circumcision, no changes have been made to the 2015 WHO meeting report (<http://www.who.int/hiv/pub/malecircumcision/tetanus-male-circumcision/en/>) recommending that Ministries of Health develop TTCV delivery strategies based on national TTCV schedules, practices and coverage and tetanus burden, ensuring that clients without documentation of sufficient coverage receive at least one dose of TTCV at the time of VMMC. While this dose is not expected to provide protection from tetanus during the VMMC healing period, it may help to improve the client's general protection against tetanus.

With time, additional data may become available on the risk of tetanus and circumcision with surgery or with specific device(s). Implementers and programme managers need to be aware of the latest information from WHO on device use for circumcision, available at http://www.who.int/diagnostics_laboratory/evaluations/PQMCdevices_list/en/, as well as the latest versions of device manufacturers' instructions for use (IFU). At the time of writing, IFU for PrePex and ShangRing were available at the following links:

- PrePex: <http://prepex.com/device-overview/user-manual/>
- ShangRing: http://www.who.int/hiv/topics/malecircumcision/prequal_mc_devices_2015.pdf (*IFU at end of document*)

Regardless of the approach taken to immunisation or the circumcision method, clean care including appropriate skin preparation and wound care counseling for clients is crucial, including the importance of not placing substances including traditional remedies on the wound, as this is a risk factor for tetanus.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Infection Surgery	B/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene.	B/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics.	B/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics.
Description: Infection Device	A2/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene.	A2/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics.	A2/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics.
TREATMENT	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Explain and emphasize importance of keeping the wound clean for favourable outcomes in the recovery/healing period. • Consider daily dressing changes for improved wound hygiene. • Consider treating localized areas of suture margin infection with local care including frequent dressing changes and cleaning. • Topical antibiotics should not be used. • Consider providing a tetanus booster if available and per national policy. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery. <p>Any client with symptoms suggestive of tetanus should be immediately transferred to a high level facility for support and tetanus immune globulin should be administered as soon as possible.</p>	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Explain and emphasize importance of keeping the wound clean for favourable outcomes in the recovery/healing period. • If significant discharge and pus from the suture margin/wound, or marked erythema of surrounding tissue, or elevated temperature, add oral, locally-appropriate broad spectrum antibiotics such as amoxicillin/clavulanic acid, or in accordance with national guidance or locally available drugs. • FOLLOW UP initially on a daily basis and once improvement is noted, at 2-3 day intervals until healing is complete. • Advise any client with infection to contact provider if pain or discharge worsens or he develops other symptoms such as fever. • Consider providing a tetanus booster if available and per national policy. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Infections accompanied by systemic signs such as fever, chills, and constitutional symptoms should be treated with locally appropriate, broad spectrum intravenous or intramuscular antibiotics according to national guidelines. • Elevate the penis by strapping it up against the abdominal wall. • For infections that do not improve on treatment, swab infected area and send for microbiological identification and drug sensitivity testing, where laboratory services are available. • Refer for treatment and monitoring. If debridement or abscess drainage are needed, intravenous or intramuscular antibiotics and referral to a surgical provider will be needed. • In the case of an abscess, if a delay of more than 6 hours is expected before the client is able to reach a referral location, it

ADVERSE EVENT	MILD	MODERATE	SEVERE
		<p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery. • Determine if there is need to remove the device early as part of the management of the infection, keeping in mind the risk of bleeding when a device is removed early. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), the provider will need to decide if surgery is needed. <p>Any client with any signs of a necrotising infection such as rapidly advancing erythema or infection should be suspected of having a necrotising infection and considered for referral and evaluation for aggressive surgical debridement.</p> <p>Any client with symptoms suggestive of tetanus should be immediately transferred to a high level facility for support and tetanus immune globulin should be administered as soon as possible.</p>	<p>may be useful to release 1–2 sutures in the hope that pus will drain. If no pus drains, do not further manipulate. The use of non-absorbable suture to tie or suture blood vessels can cause an abscess to persist.</p> <ul style="list-style-type: none"> • Consider providing a tetanus booster if available and per national policy. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery. • Determine if there is need to remove the device early as part of the management of the infection, keeping in mind the risk of bleeding when a device is removed early. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), the provider will need to decide if surgery or wound closure is needed. <p>Any client with rapidly advancing erythema or infection should be suspected of having a necrotising infection, and considered for referral and evaluation for aggressive surgical debridement.</p> <p>Any client with symptoms suggestive of tetanus should be immediately transferred to a high-level facility for support, and tetanus immune globulin should be administered as soon as possible.</p>

WOUND DISRUPTION

Defined as: The opening of a wound along surgical suture the wound margin, also known as wound dehiscence

- Surgical wound disruption may follow the unravelling of a suture (possibly poorly placed or tied), premature dissolution of an absorbable suture, or infection of the wound that involves swelling and separation of the edges. Too-tight knotting of the suture can cause ischaemia of the wound edges that may also later cause wound disruption. Less frequently, wound disruption may follow trauma (e.g., early resumption of sexual activity).
- Wound disruption associated with infection should be managed as described below and additionally as outlined in the chapter on infection.
- A clean, uninfected, disrupted wound can usually be re-sutured less than 48 hours after circumcision for an improved cosmetic appearance.
- Older clean disrupted wounds can sometimes also be re-sutured, including those in which infection has been successfully treated. But usually after 48 hours, disrupted wounds are contaminated or may have obvious infection. In these cases it is better not to attempt suture closure, but instead to leave the wound open to heal from within (by secondary intention). Placing sutures to close such a wound often results in infected sutures which 'cut out' through the skin, and a longer wound healing time than if the wound were left open. It requires experience and judgement to tell whether an older disrupted wound can be sutured. Clients can be reassured that the cosmetic appearance of a disrupted wound which is left open usually improves after a year.

Wound disruption associated with surgery is classified as B or C only.

Additional and special considerations for devices

- Device wounds heal by secondary intention and are different in appearance from post-surgical circumcision wounds, which heal by primary intention. By definition, wounds that heal by secondary intention are not closely apposed and there is a gap between wound edges during normal healing. This does not count as wound disruption.
- Wound disruption in the context of a device circumcision should be determined by an increasing distance between wound edges, with exposure of deeper tissues at the base of the wound.
- The severity of device wound disruption is classified based on width, rather than on length along the suture line as with surgical wound disruption.

Wound disruption associated with devices is classified as C only.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Wound Disruption Surgery	B/C-WD: Wound disruption but not extensive enough to require suturing for wound closure (<1.0 cm in length).	B/C-WD: Wound disruption extensive enough to require suturing or other clinical intervention but not surgery (≥ 1.0 cm in length).	B/C-WD: Surgical re-exploration or repair is required, or referral/transfer to another facility or hospitalization is required.
Description: Wound Disruption <i>after removal</i> Device	C-WD: Wound disruption but not extensive enough to require suturing for wound closure.	C-WD: Muco-cutaneous gap ≥ 1.0 cm in width, but no exposure of deeper tissue	C-WD: Wound disruption exposing tissue deeper than subcutaneous tissue or requiring surgical intervention such as suturing or debridement.
TREATMENT	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Generally, dehiscence measuring less than 1.0 cm in length (not width) does not require additional sutures. • Reassure client that the penis heals well and no further treatment is needed. Advise on adequate wound hygiene and follow-up. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • A gap between wound skin edges that increases in size from the time of device removal and where there is no exposure of underlying tissue does not constitute an AE. • Management as above for surgery. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • If circumcision was <48 hours ago and there are no signs of infection, apply additional sutures. • If circumcision was over 48 hours ago but wound appears clean or any infection has been successfully treated, experienced providers can consider resuturing. Leaving wound open may be preferable. • If wound disruption and infection present, clean the wound, apply daily dressing and treat with oral antibiotics such as amoxicillin/clavulanic acid, or in accordance with national guidance or locally available drugs. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Gap is measured as distance between wound edges for devices, not along the length of the wound as with surgery. • Management as above for surgery. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Refer for further treatment in a surgical unit. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery.

PAIN

Defined as: An unpleasant sensation related to the circumcision surgery, during either the surgery itself or recovery from the surgery

Pain is a difficult and subjective sensation to classify. People have different thresholds of pain, so trying to classify pain as mild, moderate, or severe is challenging. A limited amount of pain is also a normal event associated with any surgery; not all pain constitutes an adverse event.

INTRA-OPERATIVE PAIN

Surgical MC results in pain and requires control during the procedure with local anaesthesia. Usually the only pain experienced is that of the injection itself. If the local anaesthetic agent(s) is under-dosed or the procedure is lengthy, additional anaesthetic may be needed in order to manage client pain adequately. If higher-than-recommended doses of local anaesthetic are required to control pain, this may be due to inappropriate injection technique leading to administration of the drug into a blood vessel rather than into the local area, or the medication may be expired, or be of poor quality and not contain the amount of anaesthetic stated on the label.

Additional and special considerations for devices

As with surgery, use of devices for MC results in pain, and pain control is required. The course of pain with devices differs somewhat from that associated with surgery, and the pain seen with the PrePex device is different from that seen with the ShangRing.

PrePex

- As there is no cutting of vital tissue at the time of PrePex placement, there is little to no pain at that time. Mild pain often develops in the first few hours after placement and this can be controlled by the use of topical anaesthetic applied at the time of device placement. **Complaints of pain at the time of placement should be a signal to look for device misplacement.** Pain while wearing the device has been reported and in rare cases has prompted early removal. Pain at the time of removal is reported by the majority of clients and can be severe. While this pain often lasts only seconds, up to 30 minutes of pain post-removal has been reported.

ShangRing

- As currently performed, the ShangRing requires the use of injectable anaesthesia because the foreskin is removed during placement. As with surgery, there is pain associated with the injection of anaesthesia, but there should not be additional pain during the procedure.

With devices, a visual analogue score (VAS) is often used to rate pain at a single moment in time, with 0 being no pain and a score of 10 being the worst pain imaginable. Classification of severity may be based on this score. This differs from the classification method for pain associated with surgery, which is based on disability over time, making it somewhat difficult to compare pain between the two methods. Intraoperative pain (pain at placement) associated with devices is classified as A1 only.

ADVERSE EVENT	MILD	MODERATE	SEVERE
<p>Description: Pain <i>Intra-operative or prior to discharge from clinic</i></p> <p>Surgery</p>	<p>A-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure. No additional local anaesthetic is required.</p>	<p>A-PA: Pain requiring additional local anaesthesia</p>	<p>A-PA: Pain not responsive to additional local anaesthesia.</p>
<p>Description: Pain <i>Intra-operative or prior to discharge from clinic</i></p> <p>Device</p>	<p>A1-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure.</p>	<p>A1-PA: Client expresses discomfort and is not able to cooperate well with procedure.</p>	<p>A1-PA: Client rates pain as very severe.</p>
<p>TREAT</p>	<p>FOR SURGERY</p> <ul style="list-style-type: none"> Mild pain and/or discomfort is expected when one gets an injection, and therefore not medically significant, reassure client. <p>FOR DEVICE</p> <ul style="list-style-type: none"> Mild pain and/or discomfort is expected and therefore not medically significant, reassure client. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> Check the local anaesthetic vial with use of injectable anaesthesia (correct substance, expiration date). Give additional local anaesthetic while remaining within maximum safe dose. <p>FOR DEVICE</p> <ul style="list-style-type: none"> Check for misplacement of device. In the case of ShangRing, give additional local injectable anaesthetic while remaining within maximum safe dose. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> Check the local anaesthetic vial with use of injectable anaesthesia (correct substance, expiration date). If there is severe pain during anaesthetic injection or after administration, postpone procedure to another day, and investigate the cause of the pain. <p>FOR DEVICE</p> <ul style="list-style-type: none"> Check for misplacement of device. Explore reasons for pain/pain perception. Postpone procedure to another day and investigate the cause of the pain.

POST-OPERATIVE PAIN

The average surgical MC client will report pain starting 2-3 hours after surgery and for at least the first 2–3 days after his operation. This pain typically subsides with the use of over-the-counter oral analgesia and should not routinely disrupt sleep. Pain may intensify with night-time or morning erections and cause the client to awaken. This is normal as long as the pain subsides when the erection resolves. Clients should experience a daily general improvement in pain after the operation, with little to no pain or discomfort after 7–10 days. In cases of worsening pain, suspect an underlying problem such as infection.

Pain is regarded as outside of normal parameters and should be classified as an AE when one or more of the following occur:

- Pain does not resolve even with analgesia
- Sleep is significantly disrupted due to pain
- Mobility is impaired by pain and the performance of daily tasks is significantly restricted more than 48 hours after surgery
- Pain/discomfort has not improved significantly 7–10 days after surgery
- Pain gets progressively worse, not better, after surgery or device removal
- Pain is associated with another type of AE, such as infection

Providers need to use their experience, training and these guidelines to decide if there is abnormal pain beyond the expected pain associated with MC or if the pain is due to another AE, such as infection. Pain due to infection may be characterized as that which initially improved in the first days following the procedure but then worsened as the infection developed.

Additional and special considerations for devices

Pain that occurs during device removal (B) is found in the post-operative chart below.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Pain <i>Post-operative</i> Surgery	B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery.	B/C-PA: Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activities) that lasts for at least 1 day after surgery.	B/C-PA: Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activities) lasting 2 or more days after surgery.
Description: Pain <i>during wearing, at removal and after removal</i> Device	A2/B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery	A2/B/C-PA: Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting for at least 1 day after device placement or removal. For programmes that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 5-7 (on a 1-10 scale).	A2/B/C-PA: Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting 2 or more days after device placement or removal. For programmes that utilize a visual analogue scale (VAS) for rating severity of pain, a VAS score of 8-10 (on a 1-10 scale).
TREATMENT	FOR SURGERY <ul style="list-style-type: none"> Reassure client and administer oral analgesic agents such as Paracetamol (Acetaminophen) or Ibuprofen. FOR DEVICE <ul style="list-style-type: none"> Management of as above. 	FOR SURGERY <ul style="list-style-type: none"> Look for possible cause of pain, (e.g., another AE), and treat that AE. Review the analgesia being used (dosage, frequency, drug expiration). Reduce ambulation. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. In some instances, management of device-related pain may include early removal of device. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), at the time of removal, the provider will need to decide if surgery or wound closure is needed. 	FOR SURGERY <ul style="list-style-type: none"> Look for possible cause of pain, (e.g., another AE), and treat that AE. Review the analgesia being used (dosage, frequency, drug expiration). Refer to specialist. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. In some instances, management of device-related pain may include early removal of device. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), at the time of removal, the provider will need to decide if surgery or wound closure is needed.

SCARRING/DISFIGUREMENT/POOR COSMETIC RESULT; INJURY TO PENIS

Multiple events can lead to scarring, poor cosmetic result, or injury. These include poor surgical technique, post-operative infection and poor wound healing.

In this section, there are several definitions and recommendations for management given for different conditions, including:

- Insufficient skin removal
- Injury to penis (including the glans, shaft, urethra)
- Excess skin removal
- Scarring/disfigurement
- Torsion of the penis

All of these should be reported under the appropriate AE of scarring/disfigurement/poor cosmetic result. In the cases of scarring/disfigurement, torsion of the penis and insufficient skin removal, full assessment cannot be made until more than 7 days after surgery, and therefore all cases are classified as **C for both surgery and devices**. Injury to the penis and excess skin removal can be noted at the time of surgery or thereafter, and can be classified as **A, B, or C for surgery**; or **A1, A2, B or C for devices**.

These AEs are very rare and have not yet been observed after device-based circumcision.

SCARRING/DISFIGUREMENT

Defined as: A transient or permanent negative alteration in the appearance of the penis

This can only be classified as **C for both surgery and devices**, as accurate assessment of scarring is not possible before 7 days.

Scarring/disfigurement ranges from mild scarring to a gross distortion of the penis during or after the healing process. Usually the client presents after wound healing, complaining about appearance of the penis, or the provider notes the disfigurement at the follow-up visit. Always examine the client with maximum privacy and in good light, preferably natural. Determine if the problem is present all of the time or only evident during penile erection. If the problem is only evident during erection, make arrangements for the client to be examined with an erection (referral to specialist urologist). Having the client take a photo of his penis when he has an erection (such as upon waking in the morning) can be very helpful in the assessment of penile deformity or any other erection-related abnormality.

AEs that may lead to skin loss or large skin defects can lead to scarring during healing. Early referral for skin grafting in these cases can decrease scar formation.

In discussing both scarring/disfigurement, keloid formation (excessive and disfiguring scar formation) needs to be considered. Keloids are extremely rare on the penis; however, cases have been recorded in areas where there is hair (mid-shaft to base of the penis). Penile skin does not have hair in the areas involved in circumcision, and no cuts should be made in, or devices placed over, areas that have hair. If a keloid is suspected, **repair or removal should be performed only by an expert**, since further surgery could lead to increased scar formation.

Excessive tension from sutures can create a ridge with grooves where the sutures were placed. Most ridging will resolve spontaneously by 12 months; however, when the suture line is not straight, there can be persistent ridging, and management should be as described below. Subcutaneous nodules may also form on the shaft of the penis, caused by excess suture material that has been used to stop bleeding or by inclusion of too much tissue in a haemostatic suture.

There have been reports of a cosmetic effect of uneven or jagged skin edge with the dorsal slit technique of MC, as the foreskin is trimmed around the glans using multiple cuts with dissection scissors. This cosmetic result can be mitigated with careful trimming of any skin tags on the inner edge of the foreskin. Care must be taken to leave approximately 5 mm of skin proximal to the corona and not to cut deeper tissue.

Additional and special considerations for devices

None.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Scarring Surgery	C-SD: Complaints by client in the absence of discernible abnormal scarring/disfigurement.	C-SD: Discernible but re-operation not required. Usually noticed first by the client and reported to the provider.	C-SD: Discernible and requires re-operation or referral/transfer to another facility.
Description: Scarring Device	C-SD: Complaints by client in the absence of discernible abnormal scarring/disfigurement.	C-SD: Discernible but re-operation not required. Usually noticed first by the client and reported to the provider.	C-SD: Discernible and requires re-operation or referral/transfer to another facility.
TREATMENT	FOR SURGERY <ul style="list-style-type: none"> Reassure client that with healing of the wound, the appearance of the penis will improve. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> Reassure client that with healing of the wound, the appearance of the penis will improve. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> Refer to a specialist/urologist who may consult a plastic surgeon in cases of severe scarring or disfigurement. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery.

TORSION OF PENIS

Defined as: Rotation or twisting of the penis to either side of the midline that can lead to pain or discomfort with erections

Penile torsion is very rare and usually occurs when there is failure to correctly align the frenulum with the median raphe (line of fusion of the two halves of the penile skin along the underside of the penis) during surgery. There is no corresponding line on the dorsal (uppermost) side of the penis. Sometimes torsion is also caused by excess skin removal that is compensated for intra-operatively by moving the remaining skin about.

Some torsion may only be visible at the time of erection or more prominent with an erection, and therefore difficult for the provider to assess when the penis is examined in a flaccid state. Having the client take a photo of his penis when he has an erection (such as upon waking in the morning) can be very helpful in the assessment of torsion or any other erection-related abnormality.

If the torsion or misalignment of tissue is noted while applying the dressings at the end of the surgical procedure, remove all the sutures and start again. If the torsion is corrected, it need not be reported as an AE, however if a single provider needs to correct torsion multiple times, retraining should be considered. With proper surgical technique, this AE should not be seen. Since torsion of the penis noted at the time of surgery should be addressed at that time, torsion of the penis should be classified only as C.

Additional and special considerations for devices

With use of devices, assessment of torsion will be possible only after device removal, and therefore should be classified as C. In theory, since there is not separation and re-alignment of the skin, torsion should not occur with use of devices.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Torsion of penis Surgery	C-SD: Torsion present but does not cause pain or discomfort.	C-SD: Torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.	C-SD: Torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.
Description: Torsion of penis Device	C-SD: Torsion present but does not cause pain or discomfort.	C-SD: Torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.	C-SD: Torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.
TREATMENT	FOR SURGERY <ul style="list-style-type: none"> Reassure client that cases improve in appearance with re-moulding of the tissue as the penis heals. Even mild pain or discomfort disappears as the skin elongates during healing. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> Reassure client that cases improve in appearance with re-moulding of the tissue as the penis heals. Even mild pain or discomfort disappears as the skin elongates during healing. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> Refer to a specialist for potential re-operation. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery.

INSUFFICIENT SKIN REMOVAL

Defined as: A state where the skin at the coronal sulcus partially covers the glans when the penis is in a flaccid state.

Newly-trained VMMC providers are often nervous about excising too much foreskin, as this could lead to difficulty with wound closure. This may lead to an overly cautious approach regarding the amount of foreskin removed, with resultant insufficient skin removal and the outcome of a partial circumcision. Insufficient skin removal is also seen when there has been failure to fully retract the foreskin at the time of circumcision or device application; this is more likely in younger adolescents where physiological adhesions may be present.

With insufficient skin removal, the glans of the flaccid penis is partially covered by residual foreskin rather than completely exposed.

Ideally, insufficient skin removal should be noted and addressed at the time of initial surgery (time period A), so that correction can be made at that time and re-operation is not required. With the forceps-guided method, insufficient skin removal can be diagnosed based on the presence of a wide margin of inner foreskin remaining, where the shaft skin can easily be stretched to cover the glans or part of it. However, removal of a sleeve of tissue after some or most of the foreskin has been excised requires additional technical skill and should not be attempted by a provider inexperienced in this type of revision, including during revision at the time of the initial surgery. **With proper surgical technique, this AE should not be seen.**

To correctly assess the amount of foreskin excised post-operatively, providers need to observe the penis in a flaccid state once operative swelling has completely subsided and without pulling on the remaining foreskin. Therefore, **a postoperative diagnosis of this AE can only be classified as C with both surgery and devices.**

Clients with insufficient skin excision not noted at the time of the initial procedure often present dissatisfied and complain of a poor cosmetic result. Re-operation may be needed; this decision should include consideration of the fact that remaining foreskin can serve as an entry point for HIV infection and decrease the preventive effect of male circumcision. Re-operation may require a sleeve technique, and should therefore be carried out only by a provider experienced in that technique.

Additional and special considerations for devices

Improper placement can result in insufficient skin removal. As with surgical MC, if insufficient skin removal is not noted until after healing, re-operation may be needed, may require a sleeve technique, and should be carried out only by a provider experienced in that technique.

PrePex

Insufficient skin removal can result from any of several different errors or omissions in device placement.

- Commonly, mild forms of inadequate skin removal can result from marking of the circumcision line too far from the coronal sulcus (i.e., more distal from the sulcus than it should be), either all around the circumference of the penis (symmetrically) or asymmetrically. This leads to incorrect device placement with resultant insufficient skin removal. The insufficient skin removal may often not be noticed until after day 7 when oedema has subsided. Proper skin marking will decrease the risk of insufficient skin removal occurring from incorrect device placement.
 - This may also occur if the ink of the marked line is rubbed off with cleaning. Care is needed with application of topical anaesthesia with PrePex placement: anaesthetic cream should be applied only to the inner surface of the foreskin. Application of cream to the outside of the foreskin can make the skin marking difficult to see or can make the ink wipe off, leading to improper device placement.
- Less commonly, more moderate forms of inadequate skin removal can result from varying degrees of failure to push the inner ring all the way down to the sulcus. If this is noted at the time of placement, the device should be removed and replaced in the proper position.
 - This failure can be symmetrical, or asymmetrical, where the inner ring is unevenly seated in the coronal sulcus, with one side of the ring not lying in the sulcus, leading to an asymmetric circumcision with insufficient skin removal of part of the foreskin.
- Rarely, more severe inadequate skin removal can result from invagination of the foreskin, where part or all of the foreskin becomes folded upon itself with the placement of the inner ring. Invagination is caused by **failure by the provider to conduct final inspection of the inner ring** at completion of device placement to visualize the inner ring in situ. This inspection should be included in all placements prior to cutting the verification cord. Making sure there is even tension on both the external and internal surfaces of the foreskin with PrePex placement, ensuring the entire surface of the inner ring can be seen between the foreskin and the glans after placement, and that there are no areas where the surface of the ring is covered by invaginated inner mucosal surface, will prevent this problem. If invagination is recognized immediately, the device should be removed and replaced properly. In cases of severe insufficient skin removal, surgical revision is needed.
- In some cases of insufficient skin removal, the severity of the problem can be determined at the time of device removal and a decision can be made regarding the need for immediate surgical revision. In other cases, the severity of the problem may be difficult to discern due to oedema and/or presence of an eschar and the need for surgical revision should be determined after healing.

ShangRing

- If insufficient skin removal is noted at the time of placement of ShangRing, the device should be removed and there should be surgical correction. As noted above, this may require additional surgical skill and should not be attempted by a provider inexperienced in this type of revision.
- If the ring is not properly placed, insufficient skin removal may result.
- If not noted until after healing, re-operation may be needed and may require a sleeve technique, which should be carried out only by a provider experienced in that technique.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Insufficient skin removal Surgery	C-SD: Prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state.	C-SD: Prepuce partially covers glans when flaccid but surgical correction is not necessary.	C-SD: Prepuce covers most of the glans when flaccid and surgical correction is necessary.
Description: Insufficient skin removal Device	C-SD: Prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state.	C-SD: Prepuce partially covers glans when flaccid but surgical correction is not necessary.	C-SD: Prepuce covers most of the glans when flaccid and surgical correction is necessary.
TREATMENT	FOR SURGERY <ul style="list-style-type: none"> Reassure the client; no further action needed. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> The foreskin easily retracts and one-third to two-thirds of the glans is covered by the residual prepuce. The decision to re-operate should be taken in consultation with the client. Refer to experienced MC provider for re-circumcision by sleeve resection in a hospital. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> Greater than two-thirds of the glans is covered by residual prepuce or there is stenosis of the residual aperture preventing foreskin retraction. The decision to re-operate should be taken in consultation with the client. Refer to experienced MC provider for re-circumcision by sleeve resection in a hospital setting. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery.

EXCESS SKIN REMOVAL

Defined as: Removal of too much foreskin, such that there is difficulty in wound closure

Excess skin removal is a difficult and stressful complication to manage. Providers should call for assistance or transfer clients to referral centres as soon as they have concerns or are not comfortable/feel unable to deal with this adverse outcome. Skin loss or large skin defects can lead to scarring and dysfunction, but early referral for skin grafting can decrease the likelihood of these outcomes.

Extreme care should be taken to prevent excess skin removal. **Proper skin marking prior to the procedure is the best means of prevention and should be performed in each circumcision, and providers need to be well trained in this technique.**

Look for:

- Difficulty in approximating the foreskin and mucosal edges during suturing, or inability to approximate the edges.
- Tension on sutures when approximating the shaft skin and mucosal edge.

Additional and special considerations for devices

With devices, excessive skin removal has not yet been reported. It could be possible with improper placement, if the foreskin is stretched too much such that shaft skin is pulled beyond the device and removed with the foreskin (PrePex), or excessive inner foreskin is removed resulting in insufficient tissue cuff to hold the device in place (ShangRing). This should not happen with proper training.

PrePex

- There should be marking of the skin prior to procedure to assure proper placement.
- Excessive skin removal will likely only be detected after device removal, and should be classified as C.

ShangRing

- Skin marking is not used when the foreskin is everted over the device inner ring.
- If there is excessive skin removal, it is theoretically possible that there would not be enough tissue to hold the device properly in place. This has not been reported. However, should it occur, it would be classified as A1 and would be managed as with excessive skin removal encountered with surgery.
- Excessive skin removal will likely only be detected after device removal, and should be classified as C.

INTRA-OPERATIVE EXCESS SKIN REMOVAL

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Excess Skin Removal <i>Intra-operative</i> Surgery	A-SD: Tightness of skin discernible but additional sutures or mobilisation of skin not needed for skin closure.	A-SD: Tightness of the skin discernible and additional sutures or skin mobilisation needed for wound closure, but no other intervention needed.	A-SD: Provider unable to close skin; referral to another facility required.
Description: Excess Skin Removal <i>Intra-operative</i> Device	Not applicable	Not applicable	Not applicable
TREATMENT	<ul style="list-style-type: none"> • Skin tightness can resolve as skin stretches after surgery. • Follow up as needed to assess wound closure and healing. 	<ul style="list-style-type: none"> • Additional sutures by an experienced operator; if not available, cover wound with a moist dressing and refer to a higher-level health care facility and classify as severe. • Regular follow-up to ensure good wound healing and review the integrity of the suture margin. • It may be necessary to review clients 6–12 months post-circumcision after complete wound healing. In most cases, tightness with erections will resolve by this time, but a small number of cases will need referral (severe AE). 	<ul style="list-style-type: none"> • Cover the wound with a moist dressing. • Refer to a higher-level health care facility to determine need for skin graft to help close the wound.

POST-OPERATIVE EXCESS SKIN REMOVAL

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Excess Skin Removal <i>Post-operative</i> Surgery	B/C-SD: Slight tightening of the skin observed; no surgical correction needed.	B/C-SD: Pulling of scrotal skin onto the penile shaft, wound disruption or disruption of sutures due tension on stitches.	B/C-SD: Wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation.
Description: Excess Skin Removal <i>After removal</i> Device	C-SD: Slight tightening of the skin observed; no surgical correction needed.	C-SD: Pulling of scrotal skin onto the penile shaft and wound disruption.	C-SD: Wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation.
TREATMENT	FOR SURGERY <ul style="list-style-type: none"> Reassure client that most skin tightening and mild pain on erection resolves as skin on the wound stretches. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> May need to remove sutures and allow healing by secondary intention. It may be necessary to review clients 6–12 months post circumcision after complete wound healing. In most cases, tightness with erections will resolve by this time, but a small number of cases will need referral for plastic surgery (severe AE). FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> Refer to a higher-level health care facility. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery.

INJURY TO PENIS

Defined as: Injuries to the penis or complications due to the actions of the provider. Most injuries occur during the surgical procedure and are noted at that time, but sometimes injuries such as bruising are not apparent until later. **Unlike other AEs, these AEs should be classified at the time that they are noted, rather than the time they occur; hence the definition for post-operative injury to penis.**

Injuries to the penis can involve one or a combination of the following:

- Glans: a cut into the glans (laceration), or partial or total severing (amputation)
- Shaft: a cut, laceration or diathermy burn of the skin
- Urethra:
 - Fistula: a tract between the urethra and the skin, usually in the frenular area at the base of the glans, through which urine can leak
 - Immediate damage resulting in leakage of urine within the first few days of circumcision
 - Damage causing tissue necrosis over time, or a stitch through the urethra, causing development of a fistula over time. Wound infection may contribute to this process.
 - Fistulas may be most likely to form in young clients with immature penises, where the urethra lies closer to the surface than in sexually mature penises.
 - Blockage (occlusion) of the urethra resulting in difficulty or inability to pass urine
 - Immediate occlusion from a stitch around the urethra or externally around the glans, or severe swelling compressing the urethra. In the case of a stitch around the urethra, it is also impossible to pass a catheter until the stitch has been removed.
 - Damage to the urethra leading to later development of scar tissue in its wall, causing narrowing (stricture).
- Nerve damage: Severing of branches of the dorsal nerve of the penis caused by too deep a cut when removing the foreskin, and resulting in areas of numbness in the glans. When the sleeve method of circumcision is used, particular care has to be taken not to cut too deeply when making the distal ring incision.

The mechanisms of injury to the penis can include one or more of the following:

- Too deep a cut with a scalpel or scissors when removing the foreskin.
- During the forceps-guided method: partial or total amputation of the glans because of difficulty in identifying the location of the glans, leading to accidentally catching some or all of it between the blades of the guiding forceps.
- During the dorsal slit procedure:
 - Cutting too close to or deep near the base of the frenulum, damaging the urethra or its blood supply.
 - Wrong placement of the 12-o'clock crushing forceps so that the inner blade of the forceps wrongly enters the urethra, rather than the space between the foreskin and the glans

- Wrongly-placed sutures:
 - Taking too deep a “bite” or tying sutures too tightly, thus devitalising areas of tissue
 - This is a particular problem when placing sutures to control bleeding from the frenular artery, and is more likely to happen if the cut to remove the foreskin has been made too close to the base of the frenulum. This can result in the suture catching or encircling the underlying urethra and causing tissue necrosis and urethral fistula, or urethral obstruction.
 - Taking too deep a “bite” with the 6 o’clock closing suture and catching the underlying urethra in the suture. This can occur with all methods of surgical circumcision.
- Wrong diathermy technique
 - Using diathermy too close to the skin edge: this is a common mistake which causes an area of skin necrosis and predisposes to infection. Instead, providers should know that skin edge bleeding usually stops once the circumcision closing sutures have been placed and tied.
 - Prolonged use of diathermy: this causes an area tissue damage and can lead to infection or necrosis. Prolonged use of diathermy in the frenular area can result in necrosis of the urethral wall, causing urethral fistula to develop days or weeks after the circumcision.
 - There are rare reports of complete penile loss following prolonged use of diathermy. This should never happen if diathermy application is accurate, short and not used on infants or when the penis is very small. Also, if there is not immediate visible effect of the diathermy at the tip of the diathermy forceps, the surgeon should stop using diathermy (see text on diathermy in WHO manual).

Management

Prevention is the best management. It is achieved by good training and by providers being familiar with the most likely complications of the procedure that they are using. Providers should be particularly aware of:

- For forceps-guided surgical circumcision:
 - **Forceps-guided circumcision should not be used for clients aged 10-14 years or any clients with immature genitalia or severe adhesions;** other methods that directly visualize the glans (i.e., dorsal slit or sleeve resection) should be used. Forceps-guided VMMC in these clients increases the risk for severe glans damage or amputation. A crucial step in this procedure is palpation of the glans through the foreskin after the forceps has been applied to ensure that no part of the glans is trapped in the forceps before the foreskin is cut is; however, this is unreliable in young clients because of the small size of the glans.
 - This risk of glans injury exists for clients of all ages if the forceps are wrongly placed.
- For dorsal slit circumcision, lacerations of the glans, usually small and minor, can also be seen, as the surgeon uses multiple cuts to remove the prepuce with this method.

- For any method, there is risk of urethral injury when working in the frenular area. Do not cut too close to the base of the frenulum, take care when placing sutures, and do not use diathermy around the frenulum. The 6-o'clock mattress suture at the frenulum should be a horizontal (not vertical) mattress suture, and care must be taken not to incorporate deeper layers (see WHO Manual).

In general, if a simple injury occurs at the time of surgery and is recognised then or within a few hours, it should be repaired immediately if a competent provider is available. For example, an accidental cut into the skin of the shaft or glans should be sutured. However, any more extensive injury, such as amputation of the glans or urethral injury including fistulas, should only be managed by an expert surgeon. This is because early, appropriate management is crucial to preventing long-term sequelae. For example, urethral repairs done by inexperienced providers can raise the risk of stricture. Each case has to be judged depending on the extent of the injury and the proximity of expert surgical help, and potentially with the help of telephone advice. It is safer to refer too many rather than too few cases.

In the case of fistula appearing with urine leakage days or weeks after circumcision, surgical repair is very difficult and should only be attempted by a specialist in a referral centre. More often than not, repairs by a non-specialist provider fail and result in further complications such as urethral stricture, the need for multiple operations and a lifelong problem. **In the case of amputation, use of diathermy to control bleeding is discouraged,** because it is not effective in stopping bleeding from erectile tissue and can interfere with reattachment. Pressure should be used instead.

Additional and special considerations for devices

- Injury may happen any time sharp instruments (blade and Harvey wire scissors) are used.
- With devices, electrocautery is not used and burns are not a described AE. Urethral fistulas also have not been noted.
- Because the devices are made of hard plastic and are worn for 7 days, they can cause injury in the event of a blow or trauma to the genital area, such as in a motor/bicycle vehicle accident.
- As with surgery, some injuries may not become apparent immediately. Injuries noted after removal have likely been sustained during removal. Nonetheless, they should be classified as C.

PrePex

- Sharp instruments are not used for placement, so injury during placement is unlikely. At the time of removal of the necrotic foreskin, the glans cannot be well visualized initially. Care must be taken not to injure the glans with the removal scissors.
- Displacement of the device can result in swelling of the penis with formation of bullae. (See displacement section.)
- There have been several cases in which premature sloughing of the foreskin has been observed while PrePex is in place. This is very rare so there is little clinical information to date. In several cases, part of the inner mucosa has separated from the rest of the foreskin, protruding from the end of the foreskin. In a single case, this appeared as a urine filled sac. The appearance is alarming but involves only the necrosing foreskin; vital tissue is not affected. While this is not listed as a defined AE in this guide, it should be reported so that additional data on this rare event can be gathered.

ShangRing

- Injury is possible at the time of placement, during wearing, or at removal. As with surgical circumcision, care should be taken to safely excise the foreskin without injuring the glans or shaft at the time of device placement.

INTRA-OPERATIVE INJURY TO PENIS

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Injury to Penis <i>Intra-operative</i> Surgery	A-SD: Limited superficial laceration or burn injury not requiring additional dressings.	A-SD: Abrasion or small laceration of glans or shaft or small burn injury requiring prolonged intra-operative attention to treat or pressure dressing, but surgical repair not required.	A-SD: Severe laceration or severing of the glans or shaft, damage to the urethra that requires additional surgery to repair the injury, significant diathermy burn injuries.
Description: Injury to Penis <i>during placement</i> Device	A1-SD: Limited superficial injury not requiring additional intervention.	A1-SD: Abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.	A1-SD: Injury that requires surgical intervention to stop bleeding or repair.
TREATMENT	FOR SURGERY Damage caused by scalpel or cautery: <ul style="list-style-type: none"> Attend to any bleeding. If any further attention is required, reclassify. Ensure the paraffin gauze covers the affected areas with daily dressing changes until complete healing. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY Damage caused by scalpel: <ul style="list-style-type: none"> Attend to any bleeding. Apply simple sutures if the wound is small with discernible edges not involving the urethra or urethral meatus. Damage caused by cautery: <ul style="list-style-type: none"> Apply paraffin gauze dressings to small mucosal burns with daily dressing changes until complete healing. FOR DEVICE <ul style="list-style-type: none"> Management as above for surgery. 	FOR SURGERY <ul style="list-style-type: none"> Severe injuries may require both immediate and later surgery for repair. In the case of a fistula, the client should be promptly referred for specialist evaluation. Repair should not be attempted by nonspecialists. Damage caused by scalpel: <ul style="list-style-type: none"> Severe damage should be evident during surgery and should be immediately addressed by a competent provider. If necessary, bleeding can be controlled by a pressure dressing or wrapping the penis in gauze and sustained manual

ADVERSE EVENT	MILD	MODERATE	SEVERE
			<p>pressure until a competent provider arrives or during transport to a higher level facility.</p> <ul style="list-style-type: none"> • In the case of amputation, diathermy should be avoided as it is not effective in stopping bleeding from erectile tissue and can make reattachment of the severed glans more difficult. • Severed tissue should be sent with the client. The tissue should be wrapped in sterile gauze, ideally soaked in sterile saline. • Refer if necessary for treatment monitoring and evaluation. <p>Damage caused by cautery:</p> <ul style="list-style-type: none"> • Refer if necessary for treatment monitoring and evaluation especially for clients sustaining larger burns in the vicinity of the urethra. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery.

POST-OPERATIVE INJURY TO PENIS

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Injury to penis <i>Post-operative</i> Surgery	B/C-SD: Bruising or abrasion, or limited superficial laceration, or burn injury not requiring additional dressings.	B/C-SD: Significant laceration or burn injury requiring either prolonged follow-up care and attention, or repeated or additional dressings, but not requiring surgical correction or hospitalisation.	B/C-SD: Significant injury including laceration or severed portion of glans; damage to the urethra or shaft laceration with ongoing bleeding that requires hospitalization, development of a fistula, transfer or transfusion; or significant burn injury leading to significant tissue necrosis/loss. Laceration or severed tissue should be evident at the time of surgery but severe diathermy burns or even coagulation of blood in the whole penis may not be evident until a day or two later. In the case of diathermy urethral injury, leakage of urine through the circumcision wound may occur some days later.
Description: Injury to penis <i>during wearing, at removal or after removal</i> Device	A2/B/C-SD: Limited superficial injury not requiring additional intervention.	A1-SD: Bruise, abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.	A1-SD: Injury that requires surgical intervention to stop bleeding or to repair. Severing of the glans or shaft, injury to urethra or development of a fistula is also considered a severe AE.
TREATMENT	FOR SURGERY <ul style="list-style-type: none"> Apply paraffin gauze to affected areas and repeat daily dressing until complete healing. 	FOR SURGERY Damage caused by cautery: <ul style="list-style-type: none"> Apply paraffin gauze to affected areas and repeat daily dressing until complete healing. For burns from cautery, start on 	FOR SURGERY <ul style="list-style-type: none"> Severe AE should have been noted at the time of surgery and referred at that time. However, should there be signs of severe injury in the post-operative period, refer to a specialist.

ADVERSE EVENT	MILD	MODERATE	SEVERE
	<p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery. 	<p>prophylactic treatment with antibiotics, such as amoxicillin/clavulanic acid, or in accordance with national guidance or locally available drugs.</p> <ul style="list-style-type: none"> • Examine for the presence of a fistula and refer to a specialist for evaluation and repair. • Follow closely for signs of infection. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Attend to any bleeding. • Apply simple sutures if the wound is small with discernible edges not involving the urethra or urethral meatus. 	<ul style="list-style-type: none"> • Examine for the presence of a fistula and refer to a specialist for evaluation and repair. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery.

OTHER ADVERSE EVENTS: EXCESS SWELLING OF PENIS/SCROTUM INCLUDING HAEMATOMA, PROBLEM WITH VOIDING (URINATING), OTHER

This section includes excess swelling of penis/scrotum including haematoma, problem with voiding and any other AEs that have not been described elsewhere in this document.

EXCESS SWELLING OF THE PENIS/SCROTUM INCLUDING HAEMATOMA

Defined as: Accumulation of fluid or blood in the tissue at the site of the wound that may extend to surrounding areas

Haematoma or swelling noted at the time of surgery or device placement, or any other time prior to discharge, is an indication of acute bleeding and should be classified and managed as bleeding, A-BL for surgery or A1-BL for devices.

Some swelling is part of the natural healing process, as are small areas of bruising or haematoma at the edges of a wound. Swelling with haematoma is caused by bleeding that either has resolved or is still ongoing. Swelling or haematoma noted after surgery should be classified as B or C. If it is associated with ongoing external bleeding and/or infection, these AEs should also be reported.

With haematoma:

- Increasing swelling or extension of the haematoma into adjacent tissues indicates ongoing bleeding. Provider should carefully assess whether there is ongoing bleeding, as this may be an indication for exploration of the wound and should be managed as ongoing bleeding.
- The presence of a haematoma may be indicated by a dusky appearance of the skin, indicating underlying blood.
- Haematoma may be more localized whereas swelling from other causes may be more diffuse.
- Haematomas without active bleeding should resolve spontaneously and can be treated conservatively. Even large haematomas are often best managed conservatively, particularly if diagnosed some days after circumcision. When exploration is undertaken, the risk of infection is increased and the time to recovery is no different from conservative management. Resolution may take several weeks.
- If ongoing bleeding is suspected, the wound should be opened, explored, and managed in the same manner as post-operative bleeding.
- A large collection of blood may cause discomfort and need to be evacuated for relief, even if there are no signs of ongoing bleeding.
- Retained blood can increase the risk of infection, so a higher suspicion for infection is needed in these cases and antibiotic therapy might be indicated.
- An algorithm for management of a haematoma is below and included as Appendix 8.

A haematoma with ongoing bleeding should be reported as both haematoma and bleeding and managed as described in the bleeding chapter. An algorithm on the management of haematoma from MC is included in as Appendix 8 and on the following page.

Any haematoma that recurs could indicate a bleeding abnormality, and should be followed closely or referred for further evaluation.

With swelling **not** associated with haematoma:

- Swelling is part of the healing process and should resolve over time.
- Increasing swelling, particularly if painful, can be an indication of a problem such as infection and may be indicated by accompanying drainage from wound, surrounding erythema or warmth.
- Swelling with formation of bullae or blistering should be considered as a sign of a potential serious AE, such as a necrotising or other severe infection, and should be evaluated carefully, especially when accompanied by erythema, fever or other systemic signs.
- If infection is suspected, follow closely and consider starting oral antibiotics (see also instructions under “Infection”).

Additional and special considerations for devices

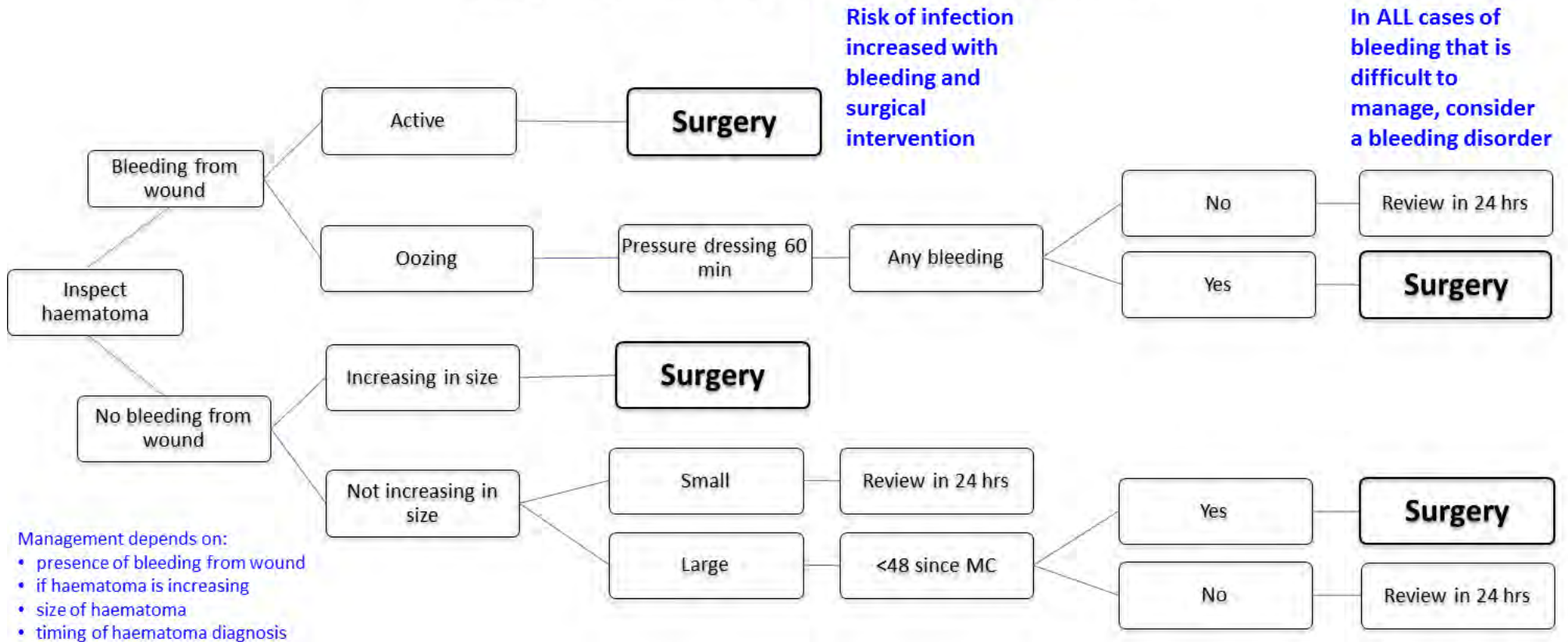
Haematoma and swelling can occur while wearing the device, with self-removal or displacement of the device, or after removal. It would be classified as A2 or C.

PrePex

- Swelling of the foreskin that occurs with device displacement or early removal should be classified as severe and requires prompt attention.
 - Swelling associated with this AE may be significant and accompanied by pain, bullae and loss of skin.
 - Usually a surgical circumcision is needed to prevent serious outcomes.
 - Because of distorted anatomy with excessive swelling, a sleeve technique may be needed for circumcision, and therefore the provider attending the client should be skilled in the technique.
 - **Under no conditions should a forceps-guided technique be used when a surgical circumcision is performed with swelling caused by device displacement.** Because the swelling makes palpation of the glans difficult, it is crucial to be able to visualize the glans to ensure it is not damaged.

Management of penile haematoma after circumcision, MC sites

Surgical exploration by experienced providers only



ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
<p>Description: Excess swelling of penis/scrotum including haematoma</p> <p>Surgery</p>	<p>B/C-OA: Mild swelling without signs of ongoing bleeding.</p>	<p>B/C-OA: Symptoms/signs that require clinical intervention, but not surgical exploration.</p>	<p>B/C-OA: Surgical exploration required to control bleeding or remove haematoma or symptoms/signs so extraordinary as to cause disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery, device placement or removal.</p>
<p>Description: Excess swelling of penis/scrotum including haematoma <i>during wearing device or after removal</i></p> <p>Device</p>	<p>A2/C-OA: Mild swelling without signs of ongoing bleeding.</p>	<p>A2/C-OA: Symptoms/signs that require clinical intervention but not surgical exploration.</p>	<p>A2/C-OA: Surgical exploration required to control bleeding or remove haematoma or symptoms/signs so extraordinary as to cause disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery, device placement or removal.</p>
<p>TREATMENT</p>	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Reassure client that haematoma/swelling will resolve spontaneously with time. • Elevate the penis by strapping it up against the abdominal wall to help the swelling resolve. A period of rest may help the swelling resolve. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery. • If PrePex device is still in place, make sure if it has not migrated from its original 	<p>FOR SURGERY</p> <p>IF ONGOING BLEEDING IS PRESENT, CLASSIFY AS SEVERE AND MANAGE ACCORDINGLY.</p> <p>IF NO BLEEDING PRESENT:</p> <ul style="list-style-type: none"> • Look for signs of infection or other causes of swelling and treat accordingly. • Elevate the penis by strapping it up against the abdominal wall to help the swelling resolve. A period of rest may 	<p>FOR SURGERY</p> <p>IF ONGOING BLEEDING IS PRESENT: (Increasing size of swelling or swelling with bleeding from the wound):</p> <ul style="list-style-type: none"> • Apply pressure manually with gauze swab and maintain for 5 minutes. • Gently remove swab and attempt to identify the origin of the bleed. • If bleeding continues, administer local anaesthesia and an experienced provider should explore the wound. If bleeding vessel is clearly identifiable,

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
	<p>placement site. If migrated from original site, additionally classify and manage as device displacement.</p>	<p>help the swelling resolve.</p> <ul style="list-style-type: none"> Swelling may take up to 3 weeks to resolve. <p>FOR DEVICE</p> <ul style="list-style-type: none"> Management as above for surgery. If PrePex device is still in place, make sure if it has not migrated from its original placement site. If migrated from original site, additionally classify and manage as device displacement. 	<p>place a suture at that point and tie securely.</p> <ul style="list-style-type: none"> If the bleeding vessel is not identifiable, under-run the bleeding area by starting at a dry point and insert continuous sutures which cross the bleeding area, ending with a knot at a dry part of the surface. Observe the client for at least one hour and re-inspect the dressing. Give the client the emergency contact details of the provider on call in case bleeding resumes. Elevate the penis by strapping it up against the abdominal wall to help the swelling resolve. A period of rest may help the swelling resolve. FOLLOW UP initially daily until the clinical team assesses client's progress as satisfactory. <p>IF NO BLEEDING PRESENT:</p> <ul style="list-style-type: none"> Look for signs of infection or other causes of swelling and treat accordingly. Elevate the penis by strapping it up against the abdominal wall to help the swelling resolve. A period of rest may help the swelling resolve. <p>FOR DEVICE</p> <ul style="list-style-type: none"> Management as above for surgery. If PrePex device is still in place, make sure if it has not migrated from its original placement site. If migrated from original site, additionally classify and manage as device displacement.

PROBLEM WITH VOIDING (URINATING)

Clients have a natural apprehension about passing urine with the freshly operated penis; however, problems with voiding may go beyond this. Problems with voiding occur when the client who tries to pass urine fails to do so or has to strain to initiate or maintain urine flow. The client will complain of one or more of:

- Inability to pass urine despite an urge to do so, after more than 6–8 hours have passed since surgery.
- Passing small amounts of urine on a frequent basis.
- Only managing a trickle following heavy straining.

This AE will be noted post-operatively and therefore should be classified as B/C or A2/C for surgery and devices, respectively.

Causes of inability to void can range from pain and apprehension to inadvertent ligation of the urethra. Common early reasons for problems voiding are insufficient fluid intake or a bandage that is too tight. Determining that the client has had enough to drink and inspecting the bandage and glans to look for impingement or ischaemic changes from an overly tight bandage are important. A bandage is too tight if one cannot insert a finger between the bandage and the skin. (This definition does not apply to a pressure dressing being used to achieve haemostasis). With moderate difficulty voiding, there may be partial obstruction, with the client either needing to make frequent visits to the toilet and passing only small amounts of urine, or straining to pass urine and being left with the sensation that the bladder is not empty.

A deep suture applied across the urethra or an inadvertent wrap of suture around the glans may cause difficulty with urination. If enough time has passed, the suture may be covered by swollen skin and difficult to visualize. In this case, removal of the bandage does not relieve symptoms and fullness in the bladder will be palpable. Difficulty urinating which develops later after the procedure may result from unrecognized laceration of the urethra during surgery, leading to urethral scarring and stricture.

In such cases, upon asking the client to pass urine, the urethra may be palpable (proximal to the blockage, it may fill with urine and bulge as urination is attempted). Catheterization may be necessary. **Use size 10–12 Fr (French Size) for boys under 12 years, and larger sizes (14-18 French) for males aged 12 years onwards.** Inability to pass a small catheter will confirm obstruction. The patient should be evaluated by an expert surgeon capable of diagnosing the cause of obstruction.

Additional and special considerations for devices

In any case of complaints of difficulty with urination when a device is in place, the device should be carefully examined to make sure that it is not causing any obstruction to the urethra or the urine stream.

PrePex

- As the foreskin becomes necrotic, the opening may narrow and cause obstruction, flow diversion or spraying of the urine stream. Complete obstruction has been reported in those with a long foreskin or who are young.
- Displacement of the elastic band from the inner ring can lead to pressure on the shaft that can in turn cause pressure on the urethra, leading to partial urethral obstruction.

ADVERSE EVENT	MILD	MODERATE	SEVERE
<p>Description: Problem with Voiding (Urinating)</p> <p>Surgery</p>	B/C-OA: NA	B/C-OA: Obstruction requiring a special return to the clinic but not surgical intervention or placement of a catheter (transient difficulty urinating that resolves on its own would not be considered an AE).	B/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment, or surgery to correct.
<p>Description: Problem with Voiding (Urinating) during wearing device or after removal</p> <p>Device</p>	A2/C-OA: NA	A2/C-OA: Symptoms that resolve with removal/repositioning of the device or dressing (transient difficulty urinating that resolves on its own would not be considered an AE).	A1/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment or surgery to correct.
<p>TREATMENT</p>		<p>FOR SURGERY</p> <ul style="list-style-type: none"> • A catheter is indicated where the client still cannot pass urine and the urethra or bladder is palpable, or the client has a painful urge to pass urine and is failing to do so and would generally be classified as severe. • However, if a catheter is required for less than 24 hours, providers may wish to classify this as a moderate AE. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Examine device to make sure it is not causing any obstruction. • With PrePex, obstruction to flow of urine caused by the necrotic foreskin can be relieved by placing a small cut in the foreskin to increase the size of the 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Refer to a specialist facility. • If urethral catheter is not possible and if the transfer is going to be long or problematic and there is sufficient onsite expertise, a suprapubic catheter may need to be inserted. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Examine device to make sure it is not causing any obstruction. • If above not present, management as above for surgery.

ADVERSE EVENT	MILD	MODERATE	SEVERE
		<p>foreskin opening, or by early device removal. The choice should be based on clinical judgement. As the necrosing foreskin is not sensitive to pain at this point, anaesthesia or analgesia should not be needed.</p> <ul style="list-style-type: none"> • If above not present, management as above for surgery. 	

OTHER: GASTRITIS

NSAIDS taken for postoperative pain relief have the potential to contribute to gastritis, ulcer exacerbation, and even perforation. These abdominal processes should be considered in postoperative clients presenting with severe abdominal pain, particularly in programmes routinely prescribing NSAIDs. Clinicians treating such clients should ask about medications used for postoperative pain.

SEXUAL DIFFICULTIES OR EFFECTS/UNDESIRABLE SENSORY CHANGES

Defined as: Undesirable sensory changes or changes in or difficulty with sexual function

Sensory changes may include complaint of a patch on the penis where sensation is abnormal, different, or absent. The report and the examination results are often subjective and may vary at different time points and with examination by different providers/practitioners. Some clients report loss of sensation; others a different sensation, or over-sensitivity to the extent that the client avoids intercourse. The diagnosis of sexual difficulties or effects is derived from the history given by the client and is very difficult to quantify. Several studies have attempted to measure sensory changes in the glans penis in both circumcised and non-circumcised males. Results have been varied and at times equivocal. It appears that initially at least, an increase in glans sensitivity occurs following circumcision due to the fact that the glans is newly “exposed”. This effect is almost always temporary and resolves with time. As this is a subjective finding and may have been present prior to circumcision, the only means to definitively determine relatedness to circumcision is by taking a sexual history at baseline prior to the procedure.

With regard to a report of undesirable sensory changes, the objective is to define the location and consistency of the undesirable sensory change. It may be helpful to draw a diagram of the penis marking the areas of sensory changes and use the diagram at each visit to determine changes over time.

Premature ejaculation is defined as an inability to delay early ejaculation and can cause significant distress in clients. Glans hypersensitivity may be part of the pathogenesis of this complex disorder. Circumcision may therefore indirectly be associated with premature ejaculation as a result of the heightened sensation. Once again, this will most likely be a temporary effect that will resolve as the glans hypersensitivity decreases. This resolution interval will vary among individuals. Studies consistently show that after circumcision the time to ejaculation is slightly longer when compared with uncircumcised men and therefore men can be reassured that premature ejaculation, common in young men, is unlikely to be made permanently worse by circumcision.

Some reports have suggested that circumcision may contribute to erectile dysfunction. However, the erectile response is a complex neuro-endocrine and vascular event relying on blood vessels and nerves in the pelvis and perineum. A circumcision does not damage these structures and therefore will not cause erectile dysfunction. In the acute setting, pain may be a physical factor inhibiting erections. This is not usually clinically apparent, as males are advised to abstain from intercourse in the acute post-operative period. At times men present for male circumcision because they have sexual dysfunction, in the hope that the procedure may resolve their problem. Taking a sexual history prior to circumcision, including a history of sexual dysfunction, can be helpful in an assessment of client complaints of sexual problems after circumcision.

Sexual complications/undesirable sensory changes cannot be assessed until there is healing and sexual activity has resumed, and therefore all are classified as C for both surgery and devices.

ADVERSE EVENT	MILD	MODERATE	SEVERE
<p>Description: Sexual Effects/ Undesirable sensory changes</p> <p>Surgery</p>	<p>C-SX: Occasional inability to have erection or dissatisfaction with sexual performance, no psycho-behavioural consequences.</p>	<p>C-SX: Post-operative changes that consistently impair or preclude sexual function for 3 to 6 months after surgery not present prior to surgery.</p>	<p>C-SX: Post-operative changes that consistently impair or preclude sexual function for greater than 6 months after surgery that were not present prior to surgery.</p>
<p>Description: Sexual Effects/ Undesirable sensory changes</p> <p>Device</p>	<p>C-SX: Occasional inability to have erection or dissatisfaction with sexual performance, no psycho-behavioural consequences.</p>	<p>C-SX: Post-operative changes that consistently impair or preclude sexual function for 3 to 6 months after surgery not present prior to surgery.</p>	<p>C-SX: Post-operative changes that consistently impair or preclude sexual function for greater than 6 months after surgery that were not present prior to surgery.</p>
<p>TREATMENT</p>	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Reassure client and explain that increased sensitivity is common for the first month or two after MC. • Explore with the client the possibility of pre-existing issues (problems pre-dating the procedure). • Where a client reports a patch with abnormal sensation, he should be advised that this problem is likely to reduce with time. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Reassure client. • Where the client complains of hypersensitivity causing premature ejaculation, local anaesthetic gels may be helpful. • In all cases where the client complains that penile sensation changes are causing an inability to obtain a firm erection, he should be referred to an expert in the management of male sexual dysfunction. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Refer all cases to a specialist. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Management as above for surgery.

DEVICE DISPLACEMENT

Defined as: Movement of MC device from original placement site to another place on the penis or movement completely off the penis. Displacements can be inadvertent, or can result from sexual activity with the device in place or from intentional self-removal. The clinical course and management of this AE should be carefully and fully documented.

Inadvertent slippage or displacement of a device can be the result of use of an incorrectly-sized device, provider error with placement (in the case of ShangRing), client manipulation of the device, or trauma to the genital area. To date, displacement has been uncommon and seen only with the PrePex device. By definition, device displacement takes place in the A2 period; consequences, like edema, take place in the C period.

PrePex

- Cases of displacement need to be evaluated by an experienced clinician.
- The signs and symptoms seen with PrePex displacement depend on the degree of ischaemic necrosis present from the device at the time of the displacement.
 - Displacement that occurs within hours of placement likely will have little consequence, as little or no ischaemia is present. In this case, the device can usually be replaced.
 - There should be reassessment to determine the proper size of device, as an incorrect size can be a risk factor for displacement.
 - If it is determined that displacement was from self-removal or because of sexual activity while the device was in place, the device should not be replaced because the risk of recurrent displacement may be high; instead, circumcision should be done through surgery.
 - Likewise, displacement at the end of the period that the device is in place may also be of little clinical consequence, as there is complete ischaemia and necrosis of the tissue by that time and the foreskin can be removed as in routine removal.
 - In the case of displacement in the first several days after placement, partial ischaemia will be present, and presentation can be dramatic. Extensive swelling of the foreskin can be present often accompanied by pain, bullae and loss of skin. These signs and symptoms above may already be present at presentation, or could develop in the hours after device displacement. Regardless, urgent evaluation is necessary, and in most cases prompt surgical circumcision is needed to prevent serious outcomes.
 - If the anatomy is distorted due to extensive swelling, a sleeve technique may be needed, and therefore the surgeon should be skilled in this technique.
 - Because there should be visualization of the glans throughout the procedure, the forceps-guided technique should not be used.
 - There have been several instances where clinicians have chosen to closely observe cases with significant swelling and delay surgery for several days, until swelling has resolved; more outcome data is needed to help define optimal management and timing of surgery.

- If in doubt about management, the conservative approach is to perform a surgical circumcision soon after the client presents with device displacement.

ShangRing

- Slippage occurs most frequently immediately after excision of the foreskin. Because control of bleeding will be needed, surgical circumcision by an experienced provider should be performed.
- Because the force on the tissue by ShangRing is greater than by PrePex, ShangRing is less likely to displace. Displacement is possible, however, with trauma or in other contexts where there is a significant pulling force on the device.
- If slippage or displacement occurs during the first few days after placement, surgery may be needed for haemostasis and wound closure. If it occurs late in the period during which the device is worn, no additional procedure may be needed, as there may be adequate haemostasis and formation of an eschar on the underlying tissue.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Device displacement	A2-DD: NA	A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal, that does not require surgical intervention to correct, because the device can be removed, repositioned, or replaced with a new device.	A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal, that requires surgical intervention to correct, or requires hospitalization or transfer to another facility to clinically manage.
TREATMENT		<p>For PrePex:</p> <ul style="list-style-type: none"> • If displacement is in within several hours of device placement, consider repositioning or replacement of device. • If displacement occurs near the day of removal (day 5 or 6), removal of necrotic foreskin and device may be all that is needed. • If device is to be removed and not replaced, and there is not a surgical circumcision, close follow-up is needed to make sure that serious signs and symptoms such as pain, swelling and bullae do not develop. <p>For ShangRing:</p> <ul style="list-style-type: none"> • For slippage immediately or soon after placement and excision of the foreskin, surgery is needed to complete the circumcision, establish haemostasis and close the wound. • For slippage or displacement later when there is adequate haemostasis and formation of an eschar, complete removal of the device may be the only management needed. • If device is removed early and there is not a surgical circumcision or wound closure, close follow-up is needed to make sure bleeding and wound dehiscence do not develop. 	<p>For PrePex and ShangRing:</p> <ul style="list-style-type: none"> • Surgical circumcision by a provider experienced in sleeve or dorsal slit technique and performing surgery in cases where anatomic landmarks may be distorted. The forceps-guided technique should not be used. • In cases where bullae or sloughing of the skin is present, consider treatment with systemic antibiotics. • Close follow-up either through admission or daily outpatient visits until swelling and bullae subside.

ANAESTHESIA-RELATED EVENTS

SYSTEMIC TOXICITY FROM LOCAL ANAESTHESIA

This is very rare and may occur with unintended intravascular administration or with administration of an excessive dose of anaesthetic. **This is one of the most serious AEs, is difficult to treat successfully, and it is essential to prevent through the following measures:**

- Ensuring correct dosing of anaesthetic agents is the most important measure to prevent anaesthetic toxicity.
 - Know the toxic dose of the local anaesthetics being used and use the lowest effective dose. Doses are weight-based and differ for different sized individuals.
 - Err on the side of lower doses, as additional anaesthetic can administered if needed.
 - Have a clearly-articulated programme policy on standardized anaesthetic dosage.
 - Have posted standardized anaesthetic dosing charts in operating theatres. Double-check doses of local anaesthetics before administration and make sure they are appropriate based on client weight.
 - Double-check concentrations of local anaesthetics before administration - both lignocaine and bupivacaine come in at least two concentrations.
- Use safe injection techniques.
- **ALWAYS aspirate before EVERY injection of an anaesthetic agent** in order to make sure the needle is not in a vessel or the corpus cavernosum.
- Describe early symptoms of local anaesthetic overdose (e.g., metallic taste in the mouth, numbness, light-headedness, dizziness, itching, or shortness of breath) to clients and instruct them to inform you immediately if they experience any effects.
- Maintain verbal contact with the client during the procedure to detect symptoms such as difficulty speaking or confusion.

Lignocaine (lidocaine) is an amide local anaesthetic. Lignocaine with Epinephrine (Adrenaline) is **absolutely contraindicated for use in the penis** because the epinephrine may cause constriction of blood vessels and compromise blood flow to tissues with end-arterial blood supply such as the penis. In some programmes, a mixture of bupivacaine (Marcaine) and lignocaine is used for local anaesthesia, because the mixture provides a longer duration of anaesthesia than lignocaine alone. The mechanism of action and toxicity of bupivacaine are the same as those of lignocaine.

The symptoms of anaesthetic toxicity affect the central nervous and cardiovascular system and tend to follow a predictable progression: Toxicity begins with numbness of the tongue and mouth, light-headedness, and visual and speech disturbances and progresses to muscle twitching, unconsciousness, seizures, respiratory arrest, and cardiovascular depression. Seizures generally will not occur with serum lignocaine levels of less than 10 mcg/ml. If oxygenation, ventilation, and cardiac output are maintained, there can be full recovery without sequelae. However, if serious central nervous system or cardiac complications develop, these can be very difficult to treat, and may require care in an intensive care unit. There is a risk of serious complications, or even death.

DEVICE

With some devices, topical rather than injected local anaesthesia is used at the time of placement and/or at the time of removal. Systemic reactions to topical anaesthetics are extremely rare, and have been reported only when the product is used over large areas of skin such as over both legs, or used on skin that is abraded. These conditions would not be expected with circumcision. Local reactions may include swelling and itching at the site of administration. AEs associated with use of local or topical anaesthetic at the time of placement should be classified as A1, and those associated with use at the time of removal should be classified as B. If systemic signs and symptoms develop, a cause other than topical anaesthetic should be sought. This AE occurs only during surgery or device placement and should be classified as A, A1 or B for surgery and device, respectively.

LOCAL INJECTED ANAESTHETIC DOSING

With regard to local anaesthetic agents, safety needs to be assured at multiple points—from the supply of products to appropriate dosing with proper injection technique and monitoring of the client—including:

- Steady supply of good-quality product so that potency is assured.
- Standardization of anaesthetic agents used; some programmes opt for use of lignocaine alone, while others use lignocaine and bupivacaine because the combination results in rapid onset of action (lignocaine) and longer duration of anaesthetic effect (bupivacaine effect lasts up to 4-5 hours after injection). However, bupivacaine is more expensive than lignocaine.
- Standardization of the concentration of anaesthetic agents used; two commonly used concentrations of lignocaine (1.0% and 2.0%) and bupivacaine (0.25% and 0.5%) are available, and there is an increased potential for dosing errors if concentrations are interchanged.
- Standardization of the ratio of volumes of anaesthetic agents used; the simplest and most commonly used ratio is 1:1.
- Standardization of the amount of anaesthetic used; weight-based dosing is optimal, especially for lower weight clients; some programmes find that above a certain weight cut-off (such as 40 kg) a fixed dose provides adequate pain control for all clients.
- Standardization of the mixing process of the combination of anaesthetic agents.
- Use as small a syringe as possible for dosing the local anaesthetic. Drawing small volumes of fluid into large syringes is may result in measurement errors and more precise measurement of volume is possible in a smaller syringe. For example, with a total volume of 4 ml, it may be best to use 5 ml syringe; for a total volume of 8 ml, a 10 ml syringe may be the best size to use.
- Waiting an adequate time for the effect of the anaesthetic agent(s) to occur; if after an adequate period, pain control is not achieved, additional anaesthetic not to exceed maximum dose can be administered.

The maximum recommended dose is 3.0 mg/kg for lignocaine and 1.5 mg/kg for bupivacaine **when either agent is used alone**. Adequate anaesthesia can be achieved with lower doses and when the two agents are combined, such that the maximum recommended dose is 2.0 mg/kg of lignocaine and 0.5 mg/kg of bupivacaine (Table 1). To aid with calculation of weight-based dosing, milligrams per millilitre for different concentrations of both lignocaine and bupivacaine are listed in Table 2 and dosing charts are included in Appendix 5.

Volumes of maximum doses for heavier clients, particularly when using the lower concentrations of either anaesthetic, may be too large to easily administer into the relatively small anatomic space of the base of the penis. With slow instillation, injection of larger volumes may be possible. Although the recommended dosing charts have been designed to limit starting and maximum dose volumes based on standard syringe sizes, some programmes have found that all clients weighing more than 40 kg may experience adequate pain control with the use of the 40 kg dose/volume. For instance, a client weighing 70 kg may achieve adequate pain control with a dose/volume for a 40 kg client, even though a higher maximum dose/volume may be allowed. This is because the area of tissue that needs to be anaesthetized for circumcision is limited. With use of 2.0% lignocaine and 0.5% bupivacaine in a 1:1 mixture, a volume over 10 ml may not be needed in those weighing over 50 kg. Use of dorsal nerve block (with or without a ring block) may result in a quicker effect and require less volume of anaesthetic.

While safety is paramount, inadequate pain control should also not occur in the context of surgical MC. Pain during the procedure despite use of local anaesthetic should indicate a problem with medications, dose or administration technique, and should signal a need to review medications used, dosing or provider training.

Table 1: Recommended Starting and Maximum Doses for Anaesthetic Agents

Agent	Starting dose	Maximum dose
Lignocaine	2.0 mg/kg	3.0 mg/kg
Lignocaine-bupivacaine combined	1.5 mg/kg-0.3 mg/kg	2.0 mg/kg-0.5 mg/kg

Table 2: Milligrams per Millilitre of Local Anaesthetic

Agent	mg/ml
Lignocaine 1.0%	10 mg/ml
Lignocaine 2.0%	20 mg/ml
Bupivacaine 0.25%	2.5 mg/ml
Bupivacaine 0.5%	5.0 mg/ml

The anaesthetic dosing chart on the following page has been edited from its original version by adding suggested starting doses and maximum doses. For heavier weights, the maximum dose is capped at one that can be delivered in 20 ml as injection of more than this amount of fluid may prove difficult.

ANAESTHETIC DOSING CHARTS

Starting and Maximum Doses of 1.0% Lignocaine with and without Bupivacaine, by Volume

If bupivacaine to be used with lignocaine 1.0%, use concentration of 0.25% with 1:1 combination

Safe local anaesthetic dosing—starting* and <i>maximum</i> ** volumes		
1% Lidocaine		
Weight in KG	Starting volume	<i>Maximum safe volume</i>
20–29 kg***	4 ml	Additional 2 ml to TOTAL of 6 ml
30–39 kg	6 ml	Additional 3 ml to TOTAL of 9 ml
40–50 kg	8 ml	Additional 4 ml to TOTAL of 12 ml
More than 50 kg	10 ml	Additional 5 ml to TOTAL of 15 ml

*Starting dose lidocaine (lignocaine) 2 mg/kg
***Maximum safe dose lidocaine 3 mg/kg*
***For those weighing less than 30 kg, use 5ml syringe so that volumes can be measured accurately
Starting volume usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

Safe local anaesthetic dosing—starting* and *maximum*** volumes

Mixture of 1% Lidocaine and 0.25% Bupivacaine

1:1 Mixture (equal volumes of each)

Weight in KG	Starting volume (1:1 mixture)	<i>Maximum safe volume (1:1 mixture)</i>
20–29 kg	3 ml of each (6 ml total)	Additional 1 ml of each drug to <i>TOTAL of 8 ml (maximum 4 ml of each)</i>
30–39 kg	4 ml of each (8 ml total)	Additional 2 ml of each drug to <i>TOTAL of 12 ml (maximum 6 ml of each)</i>
40–50 kg	5 ml of each (10 ml total)	Additional 3 ml of each drug to <i>TOTAL of 16 ml (maximum 8 ml of each)</i>
More than 50 kg	5 ml of each (10 ml total)	Additional 5 ml of each drug to <i>TOTAL of 20 ml (maximum 10 ml of each)</i>

*Starting dose lidocaine (lignocaine) 1.5 mg/kg/bupivacaine 0.3 mg/kg

***Maximum safe dose lidocaine 2.0 mg/kg/bupivacaine 0.5 mg/kg*

Starting volume usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

To improve provider efficiency through minimizing numbers of syringes needed, starting doses have been kept at or below 10 ml and maximum doses at or below 20 ml.

Starting and Maximum Doses of 2.0% Lignocaine with and without Bupivacaine, by Volume

If bupivacaine to be used with lignocaine 2.0%, use concentration of 0.5% with 1:1 combination

Safe local anaesthetic dosing—starting* and *maximum*** volumes

2% Lidocaine

Weight in KG	Starting volume	<i>Maximum safe volume</i>
20–29 kg***	2 ml	Additional 1 ml to TOTAL of 3 ml
30–39 kg***	3 ml	Additional 1 ml to TOTAL of 4 ml
40–50 kg	4 ml	Additional 2 ml to TOTAL of 6 ml
More than 50 kg	5 ml	Additional 2 ml to TOTAL of 7 ml

*Starting dose lidocaine (lignocaine) 2 mg/kg

***Maximum safe dose lidocaine 3 mg/kg*

***Use 5ml syringe so that volumes can be measured accurately

Starting volume usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

Safe local anaesthetic dosing—starting* and *maximum*** volumes

Mixture of 2% Lidocaine and 0.5% Bupivacaine

1:1 Mixture (equal volumes of each)

Weight in KG	Starting volume (1:1 mixture)	<i>Maximum safe volume (1:1 mixture)</i>
20–29 kg***	1 ml of each (2 ml total)	Additional 1 ml of each drug to <i>TOTAL of 4 ml (maximum 2 ml of each)</i>
30–39 kg***	2 ml of each (4 ml total)	Additional 1 ml of each drug to <i>TOTAL of 6 ml (maximum 3 ml of each)</i>
40–50 kg	3 ml of each (6 ml total)	Additional 1 ml of each drug to <i>TOTAL of 8 ml (maximum 4 ml of each)</i>
More than 50 kg	4 ml of each (8 ml total)	Additional 1 ml of each drug to <i>TOTAL of 10 ml (maximum 5 ml of each)</i>

*Starting dose lidocaine 1 (lignocaine) .5 mg/kg / bupivacaine 0.3 mg/kg

***Maximum safe dose lidocaine 2.0 mg/kg / bupivacaine 0.5 mg/kg*

***Use 5ml or smaller syringe so that volumes can be measured accurately

Starting volume usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

ADVERSE EVENT	MILD	MODERATE	SEVERE
<p>Description: Anaesthesia-related event</p> <p>Surgery</p>	<p>A-AN: Mild localised allergic reaction at injection site without swelling and systemic reaction.</p>	<p>A-AN: Reaction to anaesthetic including light-headedness, nervousness, and dizziness that resolves spontaneously over a relatively short period of time and not requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities at VMMC site and no transfer to another facility or admission to hospital.</p>	<p>A-AN: Symptoms of severe systemic allergic reaction to local anaesthetic including rash, urticaria, angioedema, and shortness of breath; or symptoms of overdose of local anaesthetic including light-headedness, nervousness, confusion, dizziness, drowsiness, ringing of ears, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, bradycardia, or hypotension requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities or hospitalization to manage.</p>
<p>Description: Anaesthesia-related event</p> <p>Device</p>	<p>A-AN: Mild localised allergic reaction at injection site without swelling and systemic reaction.</p>	<p>A-AN: Reaction to anaesthetic including light-headedness, nervousness, and dizziness that resolves spontaneously over a relatively short period of time and not requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities at VMMC site and no transfer to another facility or admission to hospital.</p>	<p>A-AN: Symptoms of severe systemic allergic reaction to local anaesthetic including rash, urticaria, angioedema, and shortness of breath; or symptoms of overdose of local anaesthetic including light-headedness, nervousness, confusion, dizziness, drowsiness, ringing of ears, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, bradycardia, or hypotension requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities or hospitalization to manage.</p>
<p>TREATMENT</p>	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Stop the injection immediately and prepare to treat the reaction. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Wipe off any remaining topical anaesthetic if this was used. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Stop the injection immediately and prepare to treat the reaction. <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Wipe off any remaining topical anaesthetic if this was used. 	<p>FOR SURGERY</p> <ul style="list-style-type: none"> • Stop the injection immediately and prepare to treat the reaction. • Obtain adequate intravenous access. • Establish control of the airway and ensure adequate oxygenation. • Refer as soon as possible, keeping

ADVERSE EVENT	MILD	MODERATE	SEVERE
		<ul style="list-style-type: none"> • Management as above for surgery. • Look for other cause of signs and symptoms. 	<p>cardiopulmonary functions stable.</p> <p>FOR DEVICE</p> <ul style="list-style-type: none"> • Wipe off any remaining topical anaesthetic if this was used. • Management as above for surgery. • Look for other cause of signs and symptoms.

EMERGENCY MANAGEMENT

Emergencies are extremely rare events with male circumcision. Despite this, all sites providing VMMC services should be able to handle emergencies. Even sites providing only device services that do not involve injecting local anaesthetic may experience some of the emergency types discussed below. Preparedness includes having emergency management supplies at the site, training providers in emergency management, and having a pre-existing plan for referral of clients. The emergency management plan should include pre-identified sites to which clients with emergencies will be transferred, with current and correct telephone numbers so that in the event of a transfer, the site can be made aware of the transfer and be prepared. Sites should keep on site algorithms for emergency management and should consider posting them in operating theatres. There should also be a protocol for periodic checking of emergency medicines and supplies to make sure all required equipment is in place, in good working order and that no medications are expired. A list of supplies required or highly recommended for PEPFAR-supported sites is included as Appendix 9.

WHO has a number of guides for emergency management that may be helpful, including:

- Best practice safety protocols, including Emergency Resuscitation, Airway Management, HIV Prevention Protocols, Transportation of Critically Ill Patients: http://www.who.int/surgery/publications/immesc_best_practice/en/
- Resuscitation and preparation for anaesthesia and surgery: <http://www.who.int/surgery/publications/s16025e.pdf?ua=1>
- Generic essential emergency equipment and infrastructure/supplies for emergency and essential surgical care: <http://www.who.int/surgery/publications/s15982e.pdf?ua=1>

Several situations are mentioned in this section, including anaphylaxis, vasovagal reactions and hypoglycaemia. Vasovagal reactions and hypoglycaemia need to be recognized and not confused with anaphylaxis, as their management is different, and if treated appropriately they are not life-threatening. Reviewing this text should not substitute for emergency training.

ANAPHYLAXIS TO LOCAL ANAESTHETIC AGENTS

This is extremely rare and should not be confused with overdose of local anaesthetic. It may occur in response to the anaesthetic agent or the preservative. Anaphylaxis is likely when all of the following three criteria are met:

- Sudden onset and rapid progression of symptoms
- Life-threatening airway and/or breathing and/or circulation problems
- Skin and/or mucosal changes (flushing, urticaria, angioedema)

Treatment: Follow **A**irway-**B**reathing-**C**irculation (ABC) approach to resuscitate the client.

Note: Adrenaline (epinephrine) is the most important drug for the treatment of an anaphylactic reaction (see dosages below). Adrenaline must be readily available in clinical areas where an anaphylactic reaction could occur. **The intramuscular (IM) route is the best way to administer adrenaline to treat an anaphylactic reaction.** Monitor the client by checking pulse, blood pressure, and electrocardiogram and pulse oximetry, if available. Hydrocortisone is also used in the treatment of anaphylaxis; **however, this drug is an adjunct to adrenaline and not a substitute for it.** The onset of action of adrenaline is immediate, whereas the effect of hydrocortisone is not. Regardless of whether the client seems to improve after treatment, he requires transfer to a facility equipped to care for anaphylaxis, as relapse after several hours is possible

VASOVAGAL REACTION

This is a common effect seen during minor surgery under local anaesthetic or with other minor procedure such as obtaining a venous blood sample. It is not due to anaesthetic toxicity or allergy. Signs and symptoms are generally:

- Light-headedness/dizziness/fainting
- Nausea and vomiting
- Heart palpitations

These signs and symptoms are generally reported during or soon after the operation, and are self-limited and resolve. Treatment consists of laying the client down, elevation of legs, reassurance, close observation, and on occasion, oxygen may be required until clients recover. Vasovagal reactions should not be mistaken for toxicity to anaesthetic agents.

HYPOGLYCAEMIC REACTION

Hypoglycaemia or low blood sugar may be seen in some clients, especially if there are long waiting times for services and if they have not eaten before arrival to the VMCC site. Symptoms of hypoglycaemia can include shakiness, dizziness, sweating, and feeling faint and can mimic a vasovagal reaction. Severe hypoglycaemia can result in confusion or loss of consciousness. As with vasovagal reactions, the client should be placed in a prone position. If a glucometer (a device to measure blood sugar) is available, a blood glucose level can be measured. If the blood glucose level is documented or suspected to be low, the client should be immediately given food or drink that contains sugar. If the client is not capable of eating or drinking because of confusion or loss of consciousness, glucose-containing intravenous fluid can be administered. Once a normal blood glucose level is restored, symptoms should resolve. If not, hypoglycaemia is not the cause of the symptoms and another cause should be sought.

OCCUPATIONAL EXPOSURE

While not an emergency in the sense of needing to perform resuscitation, occupational exposure, for example from a needle stick injury, is an important risk to the provider and needs to be addressed promptly and correctly. Management of these AEs are not covered in this document.

National guidelines should always be followed and align with the Joint WH/ILO Post Exposure Prophylaxis to Prevent HIV Infection Guidance. (<http://www.who.int/hiv/pub/prophylaxis/02.pdf>)

Instances of occupational exposure need to be reported and monitored to ensure that post-exposure management was appropriate. Also, instances where a provider has more than one occupational exposure may need to be investigated and may trigger a need for retraining on surgical technique or identification of faulty instruments.

SAFE INJECTION TECHNIQUE

PREVENTING INJECTION-RELATED INFECTIONS

While the majority of local anaesthetic injections are performed safely, with little or no risk of infection, transmission of infections to clients or providers is possible if injections are not done safely. There are two types of infections which can be transmitted, both resulting from contamination of an injection needle:

- **Bacterial infections:** A needle used to inject local anaesthetic can become contaminated through contact with bacteria from any surface, including the client's skin, which can then be pulled into the syringe during aspiration.
- **Bloodborne (usually viral) pathogen infections:** A needle used to inject local anaesthetic for a client infected with HIV, Hepatitis B or C, or another bloodborne pathogen, can become contaminated with that pathogen, which can also then be pulled into the syringe during aspiration.

In both cases, if the contaminated needle or syringe is used again to access a vial, the vial can become contaminated. If the same vial is later used for another client, the infection can be transmitted to that next client. Both types of pathogens have been transmitted in this way, and outbreaks of bacterial and viral infections have been documented. Providers may be tempted to change the needle but re-use the same syringe. However, this does not remove the risk of transmission. In the case of bloodborne pathogens, a provider can also become infected if he or she is stuck by the hollow injection needle.

Key safe injection practices to prevent transmission of infections to clients or providers through local anaesthetic include:

- **Never** enter a medication vial with a previously-used syringe or needle ("double dipping").
 - If a patient needs additional anaesthesia during a procedure, use **a new needle and syringe** to draw anaesthetic and re-inject. This carries a very small increased cost, but the risks of re-use are much more significant.
- **Never** administer medications from the same syringe to more than one patient, even if the needle is changed or you are injecting through an intervening length of IV tubing.
- **Best practice is to ensure lignocaine vials are not re-used**, by disposing of them during cleanup after each MC. If a provider uses a previously-used anaesthetic vial for a client, it is impossible to know whether the vial is contaminated, for example by a prior provider who incorrectly "double-dipped" into that vial. Outbreaks of bacterial infections have been associated with use of multi-dose vials of medications, including anaesthetics.
 - If it is impossible to eliminate lignocaine vial re-use, the patient's only line of defense is to ensure no provider ever 'double-dips' into a vial. This can prevent transmission of bloodborne pathogens, though bacterial infection can still be transmitted.
- Ensure an adequate supply of extra needles and syringes for anaesthesia that can be accessed without opening an entire MC kit.

Needle stick injuries are a risk for staff. To prevent these injuries:

- **Never** recap used needles two-handed, or use fingers to pick up a suture needle exposed to blood.
- **Always** dispose of used sharp instruments in sharps containers immediately after use.
- Ensure sharps containers are available at every procedure station and not overfilled.

More information is also available from CDC (http://www.cdc.gov/injectionsafety/providers/provider_faqs.html) and the World Health Organization Safe Injection Global Network campaign (SIGN) campaign (http://www.who.int/medical_devices/collaborations/network/en/)

SECTION 4-APPENDICES

This appendix contains the algorithms, tables and figures contained and referred to in this guide. These materials may be of use to aid providers, for example with anaesthetic dosing or management of bleeding. Programmes may wish to use this material as is, or to adapt as appropriate.

Appendices include:

1. Adverse event recording and reporting chart
2. Adverse event timing
3. Adverse event classification and definitions: during surgery, during device placement or prior to discharge from VMMC clinic
4. Adverse event classification and definitions: post-operative period after discharge from VMMC clinic or during device wearing, during device removal or after device removal
5. Anaesthetic dosing
6. Algorithm for prevention and management of acute bleeding after MC
7. Algorithm for management of bleeding after MC by non-MC providers
8. Algorithm for management of penile haematoma after circumcision at VMMC sites
9. VMMC emergency medical supplies, equipment and medicines

APPENDIX 1: ADVERSE EVENT RECORDING AND REPORTING

All AEs should be reported, even if they share a related cause. For example, wound disruption that is caused by an infection should be reported as two AEs: infection and wound disruption. All AEs must be recorded and include time, type, and severity.

MOST COMMON TYPES OF AEs RELATED TO MC, NOT INCLUDING PAIN:

Bleeding related:	Infection related:
<ul style="list-style-type: none"> Excessive bleeding Haematoma 	<ul style="list-style-type: none"> Infection Wound disruption Abscess formation Scarring/disfigurement from infection
<i>Bleeding and infection cause over 95% of non-pain AEs reported.</i>	

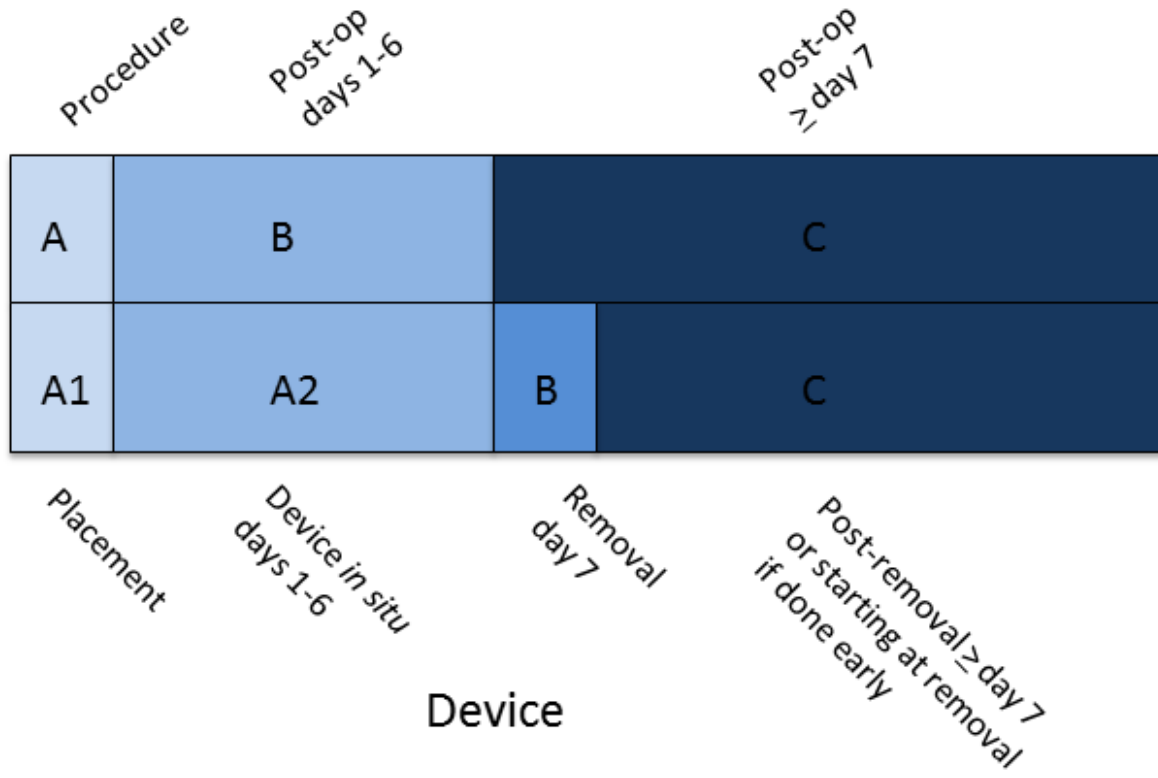
Time	Type	Severity
<p>FOR SURGERY</p> <p>A = intra-operative (during surgery or prior to discharge from clinic)</p> <p>B = post-operative (1-6 days after surgery and discharge from clinic)</p> <p>C = post-operative (≥7 days after surgery and discharge from clinic)</p>	<p>AN = Problem with Anaesthesia</p> <p>BL = Excessive Bleeding</p> <p>DD = Device Displacement*</p> <p>IN = Infection</p> <p>OT = Occupational Exposure</p> <p>PA = Pain</p> <p>SD = Scarring/Disfigurement/Poor Cosmetic Result; Insufficient Skin Removal; Excess Skin Removal; Penile Torsion; Injury to Glans or Shaft of Penis</p> <p>SX = Sexual Dysfunction/Undesirable Sensory Changes</p> <p>WD = Wound Disruption</p> <p>OA = Other AEs (Including Excess Swelling of Penis/Scrotum, Haematoma, Difficulty Urinating, Other)</p>	<p>Mild</p> <p>Moderate</p> <p>Severe</p>
<p>FOR DEVICE</p> <p>A1 = during device placement</p> <p>A2 = during week after device placement while wearing device</p> <p>B = during device removal</p> <p>C = after device removal</p>	<p>*DD is only for devices</p>	

Example of Coding: An AE coded **A-PA-Moderate** indicates moderate pain during the procedure: **A** = during procedure, **PA** = pain, **moderate**.

The following chart may aid in determining AE timing and can be displayed in clinics.

APPENDIX 2: ADVERSE EVENT TIMING

Surgery



APPENDIX 3: ADVERSE EVENT CLASSIFICATIONS AND DEFINITIONS: DURING SURGERY OR PRIOR TO DISCHARGE FROM VMMC CLINIC, OR DURING DEVICE PLACEMENT OR WEARING

ADVERSE EVENT	MILD	MODERATE	SEVERE
AN: Anaesthetic-related problem			
Surgery (A-AN) and Device (A1-AN)	Mild localised allergic reaction at injection site without swelling and systemic reaction.	Reaction to anaesthetic including light-headedness, nervousness, dizziness that resolves spontaneously and not requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities at VMMC site and no transfer to another facility or admission to hospital.	Symptoms of severe systemic allergic reaction to local anaesthetic including rash, urticaria, angioedema, and shortness of breath, or symptoms of overdose of local anaesthetic including light-headedness, nervousness, confusion, dizziness, drowsiness, ringing of ears, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, bradycardia, or hypotension requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities or hospitalization to manage.
BL: Bleeding			
Surgery	A-BL: Intra-operative bleeding that is more significant than usual or post-operative spotting of the bandage with blood; both easily controlled.	A-BL: Intra-operative bleeding or bleeding that occurs prior to discharge that requires a pressure dressing to control, or that requires additional skin sutures without surgical re-exploration of the wound.	A-BL: Intra-operative bleeding requiring blood transfusion, transfer to another facility, or hospitalization; or post-operative bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Device	A1/A2-BL: Bleeding during placement or wearing that is more significant than usual or spotting of the bandage or clothing with blood; both easily controlled.	A1/A2-BL: Bleeding during placement or wearing that requires a pressure dressing to control without surgical re-exploration of the wound or removal of the device.	A1/A2-BL: Bleeding during placement or wearing that requires blood transfusion, transfer to another facility, or hospitalization; or bleeding that requires surgical exploration, removal of device, placement of sutures, hospitalization, or transfer to another facility.
PA: Pain			
Surgery	A-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure. No additional local anaesthetic is required.	A-PA: Pain requiring additional local anaesthesia.	A-PA: Pain not responsive to additional local anaesthesia.
Device	A1-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure.	A1-PA: Client expresses discomfort and is not able to cooperate well with procedure.	A1-PA: Client rates pain as very severe.
SD: Scarring/disfigurement/poor cosmetic result; excess skin removal; injury to penis			
Surgery	A-SD: <i>Excess skin removal</i> —tightness of skin discernible but additional sutures or mobilisation of skin not needed for skin closure. A-SD: <i>Injury to penis</i> —limited superficial laceration or burn injury not requiring additional dressings.	A-SD: <i>Excess skin removal</i> —tightness of the skin discernible and additional sutures or skin mobilisation needed for wound closure, but no other intervention needed. A-SD: <i>Injury to penis</i> —abrasion or small laceration of glans or shaft or small burn injury requiring prolonged intra-operative attention to treat or pressure dressing, but surgical repair not required.	A-SD: <i>Excess skin removal</i> —provider unable to close wound; referral to another facility required. A-SD: <i>Injury to penis</i> —severe laceration or severing of the glans or shaft, damage to the urethra that requires additional surgery to repair the injury, significant diathermy burn injuries.
Device	<i>Excess skin removal</i> —NA A1-SD: <i>Injury to penis</i> —limited superficial injury not requiring additional intervention.	<i>Excess skin removal</i> —NA A1-SD: <i>Injury to penis</i> —abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.	<i>Excess skin removal</i> —NA A1-SD: <i>Injury to penis</i> —injury that requires surgical intervention to stop bleeding or repair.

APPENDIX 4: ADVERSE EVENT CLASSIFICATIONS AND DEFINITIONS: POST-OPERATIVE PERIOD AFTER DISCHARGE FROM VMMC CLINIC OR DURING OR AFTER DEVICE REMOVAL

ADVERSE EVENT	MILD	MODERATE	SEVERE
BL: Bleeding			
Surgery	B/C-BL: Blood-stained dressings or underwear, no active bleeding. Small amount of bleeding from minor clot disruption when changing dressings that is controllable with new dressings or 5–10 minutes of manual pressure measured on a clock.	B/C-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure measured on a clock, and requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound.	B/C-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
Device	B/C-BL: Small amount of bleeding from wound with no active bleeding and is controllable with new dressings or 5–10 minutes of manual pressure.	B/C-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure or requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound.	B/C-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
DD: Device Displacement			
Device	A2-DD: NA	A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal that does not require surgical intervention to correct, either because the device can be removed, repositioned, or replaced with a new device.	A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal, that requires surgical intervention to correct, or requires hospitalization or transfer to another facility to clinically manage.

ADVERSE EVENT	MILD	MODERATE	SEVERE
IN: Infection			
Surgery (B/C-IN) and Device (A2/C-IN)	B/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene.	B/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics.	B/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics.
PA: Pain			
Surgery	B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery.	B/C-PA: Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activities) that lasts for at least 1 day after surgery.	B/C-PA: Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activities) lasting 2 or more days after surgery.
Device	A2/B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery	A2/B/C-PA: Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting for at least 1 day after device placement or removal. For programmes that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 5–7 (on a 1–10 scale).	A2/B/C-PA: Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting 2 or more days after device placement or removal. For programmes that utilize a visual analogue scale (VAS) for rating severity of pain, a VAS score of 8–10 (on a 1–10 scale).
SD: Scarring/disfigurement/ poor cosmetic result; torsion; insufficient skin removal; excess skin removal; injury to penis			
Scarring/disfigurement/ poor cosmetic result; excess skin removal Surgery (C-SD) and Device (C-SD)	<i>Scarring</i> -complaints by client in the absence of discernible abnormal scarring/disfigurement. <i>Torsion of penis</i> —torsion present but does not cause pain or discomfort.	<i>Scarring</i> -Discernible but re-operation not required. Usually noticed first by the client and reported to the provider. <i>Torsion of penis</i> —torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.	<i>Scarring</i> -Discernible and requires re-operation or referral/transfer to another facility. <i>Torsion of penis</i> —torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.

ADVERSE EVENT	MILD	MODERATE	SEVERE
	<i>Insufficient skin removal</i> —prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state.	<i>Insufficient skin removal</i> —prepuce partially covers glans when flaccid but surgical correction is not necessary.	<i>Insufficient skin removal</i> — prepuce covers most of the glans when flaccid and surgical correction is necessary.
Injury to penis Surgery	B/C-SD: <i>Injury to penis</i> -bruising or abrasion, or limited superficial laceration, or burn injury not requiring additional dressings.	B/C-SD: <i>Injury to penis</i> -significant laceration or burn injury requiring either prolonged follow-up care and attention, or repeated or additional dressings, but not requiring surgical correction or hospitalisation.	B/C-SD: <i>Injury to penis</i> -significant injury including laceration or severed portion of glans; damage to the urethra or shaft laceration with ongoing bleeding that requires hospitalization, development of a fistula, transfer or transfusion; or significant burn injury leading to significant tissue necrosis/loss. Laceration or severed tissue should be evident at the time of surgery but severe diathermy burns or even coagulation of blood in the whole penis may not be evident until a day or two later. In the case of diathermy urethral injury, leakage of urine through the circumcision wound may occur some days later.
Injury to penis Device	A2/B/C-SD: <i>Injury to penis</i> -limited superficial injury not requiring additional intervention.	A1-SD: <i>Injury to penis</i> -bruise or abrasion of the glans or shaft requiring pressure dressing, but surgical repair is not required.	A1-SD: <i>Injury to penis</i> -injury that requires surgical intervention to stop bleeding or to repair. Severing of the glans or shaft, injury to urethra or development of a fistula is also considered a severe AE.
Excess skin removal Surgery	B/C-SD: <i>Excess skin removal</i> -slight tightening of the skin observed; no surgical correction needed.	B/C-SD: <i>Excess skin removal</i> -pulling of scrotal skin onto the penile shaft, wound disruption or disruption of sutures due tension on stitches.	B/C-SD: <i>Excess skin removal</i> -wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Excess skin removal Device	C-SD: <i>Excess skin removal</i> -slight tightening of the skin observed; no surgical correction needed.	C-SD: <i>Excess skin removal</i> -pulling of scrotal skin onto the penile shaft and wound disruption.	C-SD: <i>Excess skin removal</i> -wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation.
SX: Sexual Effects/Undesirable sensory changes			
Surgery (C-SX) and Device (C-SX)	C-SX: Occasional inability to have erection or dissatisfaction with sexual performance, no psycho-behavioural consequences.	C-SX: Post-operative changes that consistently impair or preclude sexual function for 3 to 6 months after surgery not present prior to surgery.	C-SX: Post-operative changes that consistently impair or preclude sexual function for greater than 6 months after surgery that were not present prior to surgery.
WD: Wound disruption			
Surgery	B/C-WD: Wound disruption but not extensive enough to require suturing for wound closure (<1.0 cm).	B/C-WD: Wound disruption extensive enough to require suturing or other clinical intervention but not surgery, (≥ 1.0 cm).	B/C-WD: Surgical re-exploration or repair is required, or referral/transfer to another facility or hospitalization is required.
Device	C-WD: Wound disruption but not extensive enough to require suturing for wound closure.	C-WD: Muco-cutaneous gap ≥ 1.0 cm in width, but no exposure of deeper tissue	C-WD: Wound disruption exposing tissue deeper than subcutaneous tissue or requiring surgical intervention such as suturing or debridement.

ADVERSE EVENT	MILD	MODERATE	SEVERE
OA: Other AEs, Excess swelling of penis/scrotum including haematoma; difficulty urinating; other			
Surgery (B/C-OA) and Device (A2/C-OA)	<p><i>Excess swelling</i>—mild swelling without signs of on-going bleeding.</p> <p><i>Other</i>—N/A.</p>	<p><i>Excess swelling</i>—symptoms/signs that require clinical intervention, but not surgical exploration.</p> <p><i>Other</i>—other adverse events related to surgery that result in disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 4 days after surgery but not more than 7 days.</p>	<p><i>Excess swelling</i>—surgical exploration required to control bleeding or remove haematoma or symptoms/signs so extraordinary as to cause disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery or device placement or removal as pertinent.</p> <p><i>Other</i>—other AE(s) related to the surgery that result in disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery or device placement or removal, or result in hospitalization or referral/transfer to another facility.</p>
Difficulty urinating Surgery	NA	B/C-OA: Obstruction requiring a special return to the clinic but not surgical intervention or placement of a catheter (transient difficulty urinating that resolves on its own would not be considered an AE).	B/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment, or surgery to correct.
Difficulty urinating Device	NA	A2/C-OA: Symptoms that resolve with removal/repositioning of the device or dressing (transient difficulty urinating that resolves on its own would not be considered an AE).	A1/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment or surgery to correct.

APPENDIX 5: ANAESTHETIC DOSING

Starting and Maximum Doses Of 1.0% Lignocaine with and without Bupivacaine, By Volume

If bupivacaine to be used with lignocaine 1.0%, use concentration of 0.25% with 1:1 combination

Safe local anaesthetic dosing—starting* and *maximum*** volumes

1% Lidocaine

Weight in KG	Starting volume	<i>Maximum safe volume</i>
20–29 kg***	4 ml	Additional 2 ml to TOTAL of 6 ml
30–39 kg	6 ml	Additional 3 ml to TOTAL of 9 ml
40–50 kg	8 ml	Additional 4 ml to TOTAL of 12 ml
More than 50 kg	10 ml	Additional 5 ml to TOTAL of 15 ml

*Starting dose lidocaine (lignocaine) 2 mg/kg

***Maximum safe dose lidocaine 3 mg/kg*

***For those weighing less than 30 kg, use 5ml syringe so that volumes can be measured accurately

Starting volume usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

Safe local anaesthetic dosing—starting* and *maximum*** volumes

Mixture of 1% Lidocaine and 0.25% Bupivacaine

1:1 Mixture (equal volumes of each)

Weight in KG	Starting volume (1:1 mixture)	<i>Maximum safe volume (1:1 mixture)</i>
20–29 kg	3 ml of each (6 ml total)	Additional 1 ml of each drug to <i>TOTAL of 8 ml (maximum 4 ml of each)</i>
30–39 kg	4 ml of each (8 ml total)	Additional 2 ml of each drug to <i>TOTAL of 12 ml (maximum 6 ml of each)</i>
40–50 kg	5 ml of each (10 ml total)	Additional 3 ml of each drug to <i>TOTAL of 16 ml (maximum 8 ml of each)</i>
More than 50 kg	5 ml of each (10 ml total)	Additional 5 ml of each drug to <i>TOTAL of 20 ml (maximum 10 ml of each)</i>

*Starting dose lidocaine (lignocaine) 1.5 mg/kg/bupivacaine 0.3 mg/kg

***Maximum safe dose lidocaine 2.0 mg/kg/bupivacaine 0.5 mg/kg*

Starting volume usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

To improve provider efficiency through minimizing numbers of syringes needed, starting doses have been kept at or below 10 ml and maximum doses at or below 20 ml

Starting and Maximum Doses of 2.0% Lignocaine with and without Bupivacaine, by Volume

If bupivacaine to be used with lignocaine 2.0%, use concentration of 0.5% with 1:1 combination

Safe local anaesthetic dosing—starting* and *maximum*** volumes

2% Lidocaine

Weight in KG	Starting volume	<i>Maximum safe volume</i>
20–29 kg***	2 ml	Additional 1 ml to TOTAL of 3 ml
30–39 kg***	3 ml	Additional 1 ml to TOTAL of 4 ml
40–50 kg	4 ml	Additional 2 ml to TOTAL of 6 ml
More than 50 kg	5 ml	Additional 2 ml to TOTAL of 7 ml

*Starting dose lidocaine (lignocaine) 2 mg/kg

***Maximum safe dose lidocaine 3 mg/kg*

***Use 5ml syringe so that volumes can be measured accurately

Starting volume usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

Safe local anaesthetic dosing—starting* and *maximum*** volumes

Mixture of 2% Lidocaine and 0.5% Bupivacaine

1:1 Mixture (equal volumes of each)

Weight in KG	Starting volume (1:1 mixture)	<i>Maximum safe volume (1:1 mixture)</i>
20–29 kg***	1 ml of each (2 ml total)	Additional 1 ml of each drug to <i>TOTAL of 4 ml (maximum 2 ml of each)</i>
30–39 kg***	2 ml of each (4 ml total)	Additional 1 ml of each drug to <i>TOTAL of 6 ml (maximum 3 ml of each)</i>
40–50 kg	3 ml of each (6 ml total)	Additional 1 ml of each drug to <i>TOTAL of 8 ml (maximum 4 ml of each)</i>
More than 50 kg	4 ml of each (8 ml total)	Additional 1 ml of each drug to <i>TOTAL of 10 ml (maximum 5 ml of each)</i>

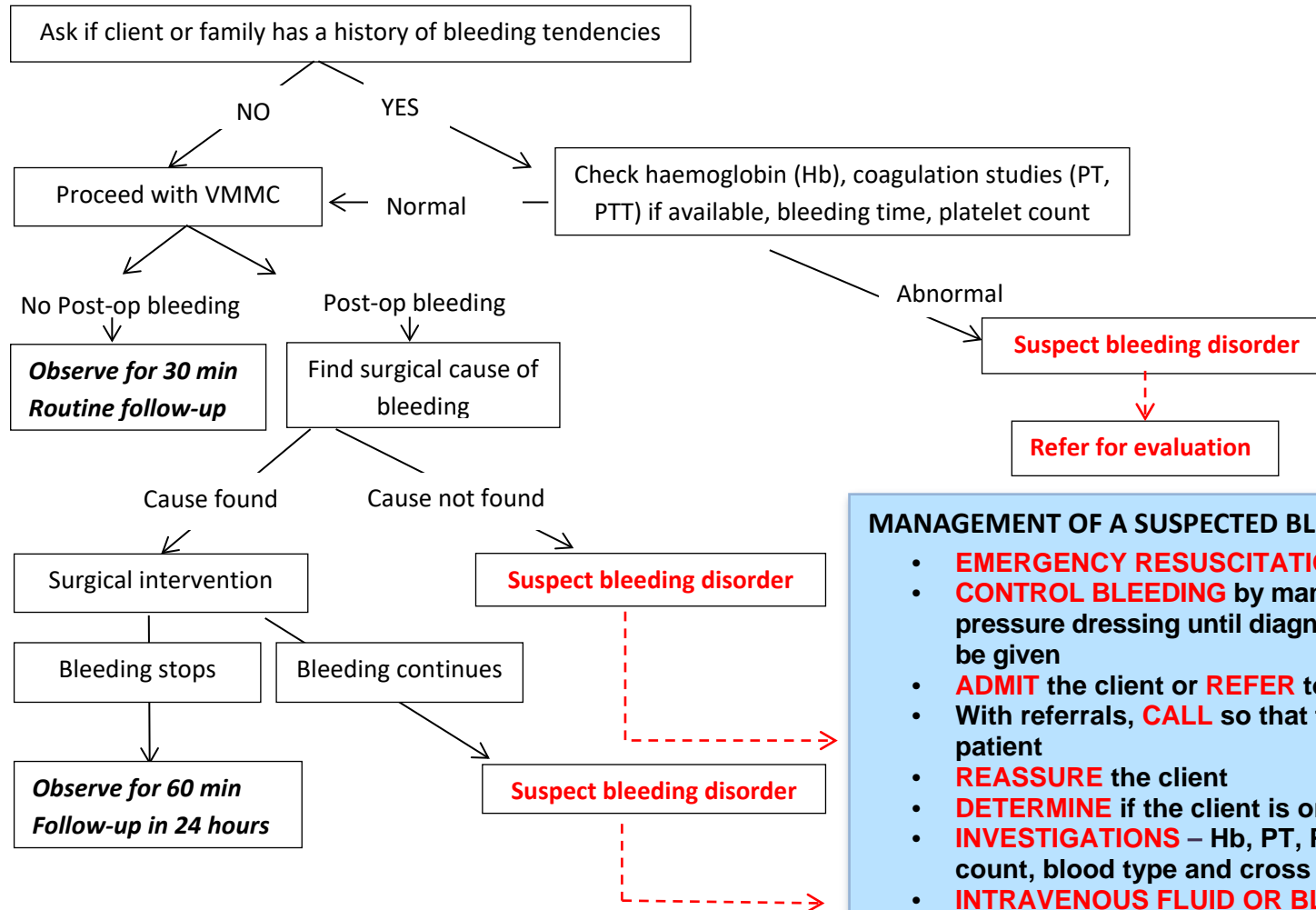
*Starting dose lidocaine 1 (lignocaine) .5 mg/kg/bupivacaine 0.3 mg/kg

***Maximum safe dose lidocaine 2.0 mg/kg/bupivacaine 0.5 mg/kg*

***Use 5ml or smaller syringe so that volumes can be measured accurately

Starting volume usually adequate; increase up to *maximum* volume (dose) only if required for pain control up to the *maximum*.

APPENDIX 6: ALGORITHM FOR PREVENTION AND MANAGEMENT OF ACUTE BLEEDING DURING AND IMMEDIATELY AFTER MC, BY MC PROVIDERS



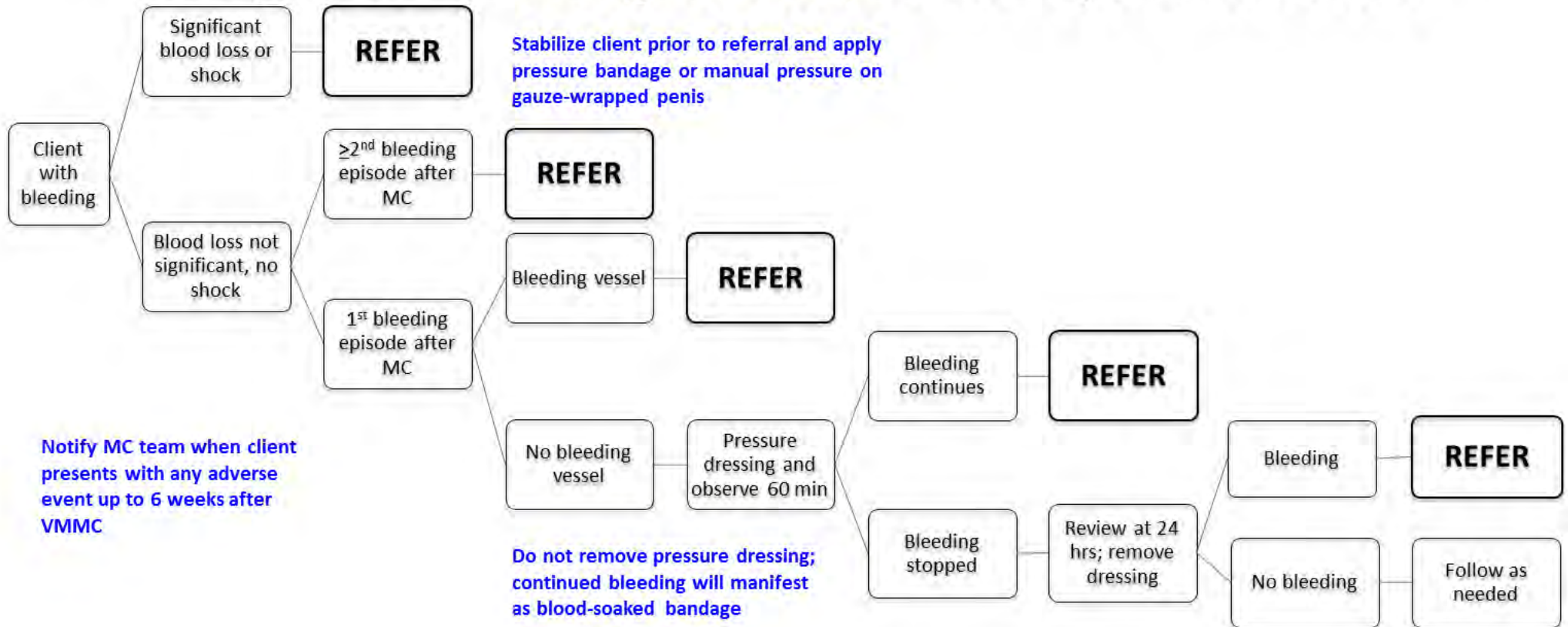
MANAGEMENT OF A SUSPECTED BLEEDING DISORDER:

- **EMERGENCY RESUSCITATION** if in hypovolemic shock
- **CONTROL BLEEDING** by manual compression and/or pressure dressing until diagnosis and definitive treatment can be given
- **ADMIT** the client or **REFER** to a higher facility
- With referrals, **CALL** so that facility can get ready for the patient
- **REASSURE** the client
- **DETERMINE** if the client is on anticoagulant therapy
- **INVESTIGATIONS** – Hb, PT, PTT, bleeding time, platelet count, blood type and cross match
- **INTRAVENOUS FLUID OR BLOOD TRANSFUSION** if hypotensive since Hb may be normal after acute bleeding
- **MANAGE** according to the cause—e.g., Vitamin K, clotting factors, FFP, platelet transfusion etc.

Adapted from JHPIEGO

APPENDIX 7: ALGORITHM FOR MANAGEMENT OF BLEEDING AFTER MC, BY NON-MC PROVIDERS

Management of Bleeding After MC, Community Health Centres



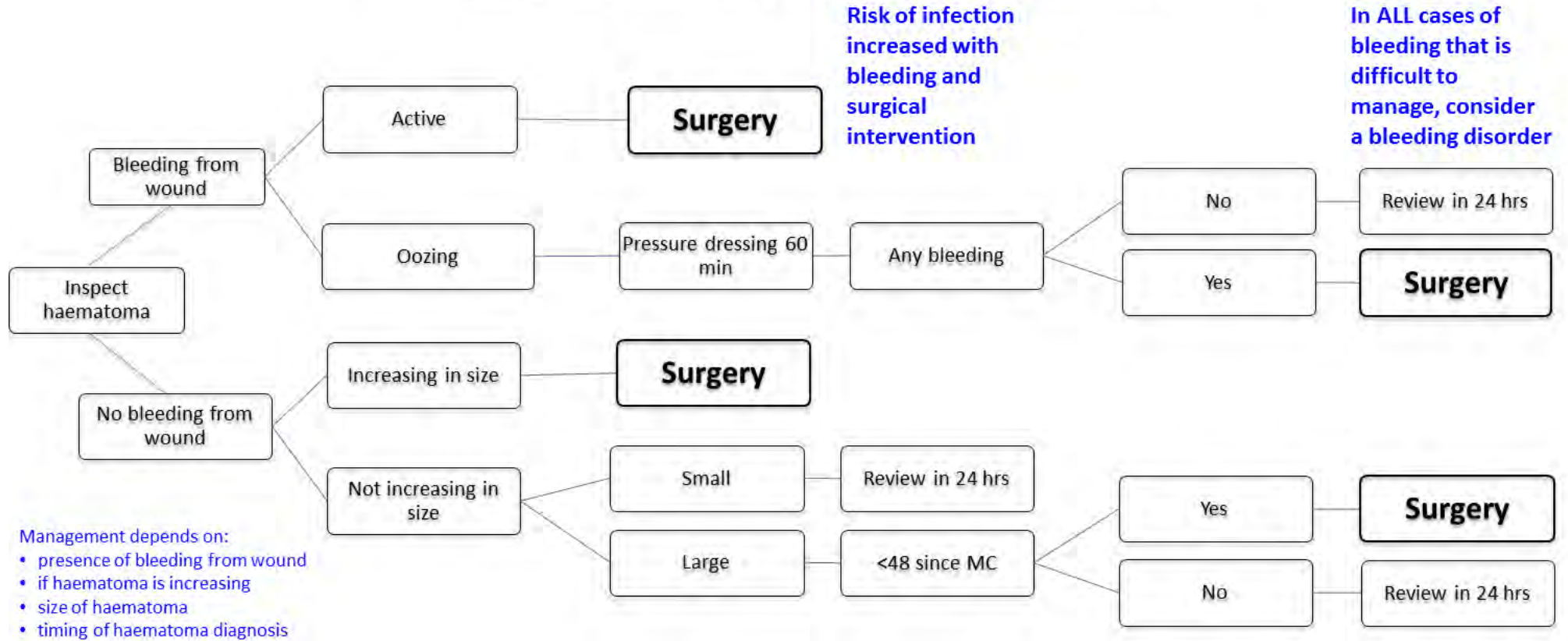
In ALL instances of post-operative bleeding:

- **Each time a client presents with bleeding, check vital signs; if there is any indication of haemodynamic compromise, stabilize as possible and urgently refer.**
- **Obtain history from client/guardians about when bleeding started and estimated of blood loss.**
- **Ask client/guardians about trauma or other events that may have led to bleeding.**
- **Note if bleeding appears to be from a discreet area or vessel or from a large area of the surgical wound-diffuse bleeding more likely with a bleeding abnormality.**
- **Refer if there is a bleeding vessel identified as the source of bleeding. If staff with adequate surgical training and skill are available at the facility, may be managed onsite.**
- **Question client/guardian about a personal or family history of bleeding. (History may not have been obtained initially or client/guardian may have been reluctant to reveal history).**
- **Contact VMMC team to report AE during the time that the client is in clinic.**
- **When considering follow-up of a client with a bleeding, there should be consideration of travel distance and conditions required for a return visit. Difficulties, such as the need to walk considerable distance to the clinic may necessitate admission to a health care facility.**

APPENDIX 8: ALGORITHM FOR MANAGEMENT OF PENILE HAEMATOMA

Management of penile haematoma after circumcision, MC sites

Surgical exploration by experienced providers only



APPENDIX 9: VMMC EMERGENCY MEDICAL SUPPLIES, EQUIPMENT AND MEDICINES

REQUIRED		HIGHLY RECOMMENDED
1. Stethoscope	9. Three sizes of oropharyngeal airways	17. Glucometer
2. Sphygmomanometer	10. Two sizes of syringes (2ml and 10ml)	18. Glucometer strips
3. Normal saline (sodium chloride solution for infusion; 0.9% NaCl)	11. Two sizes of needles (G21 and G23)	19. Paediatric blood pressure cuff
4. Tourniquet	12. Bags and masks (e.g., Ambu-bag) One child size One adult size	
5. IV infusion tubing	13. Exam gloves	
6. Three sizes of IV catheters (G18-green, G20-pink, G22-blue)	14. Alcohol swabs	
7. Adrenaline (unexpired)	15. Gauze	
8. Hydrocortisone (unexpired)	16. Adhesive tape (strapping)	

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