PrePex

Reference Manual

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Ministry of Health Rwanda
Rwanda Military Hospital-PrePex Center of Excellence
World Health Organization
Jhpiego
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Acknowledgments

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From the Ministry of Health Rwanda/Rwanda Biomedical Center:

Placidie Mugwaneza
Eugene Rugira
Vincent Mutabazi
Chaste Karangwa

From the Rwanda Military Hospital/PrePex Center of Excellence:

Jean Paul Bitega
Leon Ngeruka M.

World Health Organization (WHO)

Jules Mugabo

Jhpiego

Tigistu Adamu Ashengo, Jhpiego USA
Raymond Bandio, Jhpiego Tanzania
Julia Bluestone, Jhpiego USA
Kelly Curran, Jhpiego USA
Augustino Hellar, Jhpiego Tanzania
Rajab Kakaire, Jhpiego Lesotho
Nancy Kiplinger, Jhpiego USA
Mehebub Mahomed, Jhpiego Mozambique
Beata Mukarugwiro, Jhpiego Rwanda
Jabbin Mulwanda, Jhpiego Zambia  
Adrian Musiige, Jhpiego Botswana  
Eugene Rugwizangoga, Jhpiego Rwanda  
Jovite Sinzahera, Jhpiego Rwanda  
Alison Trump, Jhpiego USA  
Ronald Wandira, Jhpiego Botswana  
Jérémie Zoungrana, Jhpiego Rwanda

Other contributors:

Erick Baganizi, Drew Cares International, Rwanda  
Hagit Freud, Circ MedTech, Rwanda  
Antoine R. Gasasira, CDC, Rwanda  
Col. Ben Karenzi, Rwanda Military Hospital  
Sifuni Koshuma, MOH Tanzania  
Lior Levert, Circ Med Tech, Rwanda  
Maguy Mbabazi, DCI, Rwanda  
Thabo Mashigo, CHAPS, South Africa  
Pacifique Mugenzi, Rwanda Military Hospital  
Concessa Mukamusoni, Society for Family Health, Rwanda  
León Ngeruka, Rwanda Military Hospital  
Josephine Otchere-Darko, CHAPS, South Africa  
Christopher Samkange, Zimbabwe VMMC Program  
Sinokuthemba Xaba, Zimbabwe VMMC Program  
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# Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<td>AE</td>
<td>Adverse Event</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>MC</td>
<td>Male Circumcision</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
</tr>
<tr>
<td>MOVE</td>
<td>Model(s) for Optimizing Volume and Efficiency</td>
</tr>
<tr>
<td>NSAID</td>
<td>Nonsteroidal Anti-inflammatory Drug</td>
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<tr>
<td>PEP</td>
<td>Post-Exposure Prophylaxis</td>
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<tr>
<td>PSP</td>
<td>PrePex Sizing Plate</td>
</tr>
<tr>
<td>RMH</td>
<td>Rwanda Military Hospital</td>
</tr>
<tr>
<td>SAE</td>
<td>Severe Adverse Event</td>
</tr>
<tr>
<td>SRH</td>
<td>Sexual and Reproductive Health</td>
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<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on AIDS</td>
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<tr>
<td>VMMC</td>
<td>Voluntary Medical Male Circumcision</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Introduction

In 2013, the World Health Organization (WHO) pre-qualified the PrePex™ device as a safe device to be used for voluntary medical male circumcision (VMMC). Subsequent approval was provided by the US Food and Drug Administration. PrePex has emerged as the most promising method to use to scale up VMMC services in the Eastern and Southern Africa region. Use of this device in scaling up VMMC in WHO priority countries could result in millions of VMMC procedures being performed in a short period of time, hence reaching WHO’s goal of circumcising 80% of eligible men in these countries and reducing new HIV infections.

The Rwanda Military Hospital established a PrePex Centre of Excellence where providers come from around the world to learn how to use the new PrePex device. Because many providers must now be trained to perform the procedure safely in their respective countries, a standard training package was needed to ensure quality training across programs, thus meeting international norms and standards.

This PrePex Learning Resource Package was developed after a series of consultative workshops with experts in the field. The workshops included master trainers in the VMMC program, principal investigators in the PrePex safety studies, experts in training and teaching methodologies, managers of programs that are scaling up VMMC services, technical experts from the manufacturing company, and clinicians who provide services using the PrePex device.

The PrePex Learning Resource Package includes evidence-based methodologies and approaches to training that will make training more interesting and stimulating to providers. Most importantly, it focuses on the skill development so that providers can offer safe VMMC services to clients using the device.
Overview

Evidence suggests that reaching a goal of 80% VMMC coverage in five years and sustaining it thereafter would avert more than 3.6 million adult HIV infections in the next 15 years and benefit as many as 20.3 million adult HIV-negative men for HIV prevention purposes.¹ In the long term, there is an indirect benefit to women when the majority of men in a community are circumcised, because it reduces the incidence of HIV among the entire population. In addition, women with circumcised partners have lower rates of other sexually transmitted infections (STIs), such as human papillomavirus, which may later lead to cancer of the cervix.

Achieving the 80% coverage target for VMMC is proving challenging with conventional male circumcision (MC) methods, but circumcision with devices such as PrePex™ shows greater potential. The PrePex MC procedure was validated for safety and efficacy in Rwanda in September 2011. That same year, the study team started training teams from other countries who were interested in piloting PrePex. Five teams successfully performed 590 PrePex MC procedures.

For the procedure to be performed safely, providers need to be trained to competency in performing circumcision with the PrePex method. PrePex teams, which include a PrePex operator and an assistant, must be trained in a validated PrePex course.

Rwanda Military Hospital’s PrePex Center of Excellence developed a training course to certify PrePex teams to perform safe and effective PrePex MC procedures. The course was modified by a team of experts to improve its content and provide better guidance to trainers from other sub-Saharan African countries. This learning resource package for the course was pretested in Rwanda in August 2015, and following the pretest, changes were incorporated. The package will be accredited for use in PrePex training programs worldwide.

The PrePex training course was developed by PrePex experts, both physicians and nurses, whose combined experience includes more than 10,000 successful PrePex MC procedures. The training lasts four days and is followed by a short period of supervision to verify that the providers are performing the procedure correctly and safely.

Chapter 1: Introduction to Circumcision for HIV Prevention

Chapter Objectives
At the end of this chapter, participants should be able to:
1. Define male circumcision.
2. Describe the relationship between male circumcision and HIV.
3. Demonstrate the public health impact of scaling up voluntary medical male circumcision in priority countries.

Introduction
What is male circumcision?
Male circumcision (MC) is the surgical removal of the foreskin covering the end of the penis so as to permanently expose the glans (or head of the penis). It is one of the oldest and most common procedures, practiced worldwide for various reasons, including religious, cultural, social, and medical indications.

Figure 1. Example of Uncircumcised and Circumcised Penises

MC is also known as voluntary medical male circumcision (VMMC) when it is offered to males (adults, adolescents and infants) who have been informed of the health benefits and risks associated with the procedure, and have consented to it themselves or through their guardians.

The benefits of MC include: reduced risk of urinary tract infections in childhood; reduced risk of ulcerative sexually transmitted diseases in adulthood; protection against penile cancer; reduced risk of cervical cancer in female sex partners; and prevention of balanitis (inflammation of the glans),
posthitis (inflammation of the foreskin), phimosis (inability to retract the foreskin) and paraphimosis (inability to return the retracted foreskin to its original location).

**VMMC and HIV Infection**

VMMC constitutes an important intervention in the biomedical prevention of HIV infection. The World Health Organization (WHO) and Joint United Nations Programme on AIDS (UNAIDS) recommended VMMC in a clinical setting as a component of the comprehensive preventive strategy against HIV (WHO/UNAIDS, 2007). Following these recommendations, some countries in sub-Saharan African were earmarked for scale-up of this additional strategy. These are countries with low prevalence of MC and high prevalence of HIV, as shown in Figure 2. This followed evidence from the randomized clinical trial that demonstrated the protective effect of approximately 60% for HIV uninfected men from an infected woman [1–3].

**Figure 2. VMMC-Targeted Countries with High HIV Prevalence and Low MC Prevalence**

There’s biological evidence in the effectiveness of removing the foreskin in reducing a man’s risk of HIV acquisition. The foreskin contains a high density of HIV target cells, its inner layer is thin and prone to tears and injuries, it’s highly vascularized, and uncircumcised men have a higher risk of sexually transmitted infections (STIs), including HIV.

However, modeling studies have demonstrated the need for 80% coverage of MC to achieve reduction of HIV from 30% to 10%. One such study by Nagelkerte et al. showed that increased uptake of VMMC services in countries with high HIV prevalence and low MC coverage could lead to substantial reductions in HIV transmission and prevalence over time, not only for the men themselves but also in the entire population [4].
Public Health Impact of VMMC Scale-Up

VMMC is a one-time procedure that offers partial protection from HIV for the lifetime of a client, making it a high-impact intervention with excellent value. Impact and costing estimates from mathematical models suggested that if we achieve scale-up of VMMC to reach 80% coverage among males 15–49 years old in the priority countries by 2015 and maintained that level until 2025, we would avert 3.4 million, or 22%, of new HIV infections in the 10-year period. While the scale-up would cost US$1.5 billion by 2015, it would result in net savings (because of averted treatment and care costs) amounting to US$16.5 billion [5].

Figure 3. Number of MCs Needed by 2015: 20.3 Million

This graph shows the number of men who needed to be circumcised in the priority countries by 2015. A total of 20.3 million men needed to be circumcised in Eastern and Southern Africa to reach 80% coverage.
The impact of scaling up VMMC to 80% in the priority countries will avert 3.36 million new HIV infections through 2025 and result in net savings (due to averted treatment and care costs) amounting to US$16.51 billion.


**Challenges of VMMC Scale-Up to Date and Ways to Overcome Them**

MC is a resource-intensive program. While reasonable time and funds have been spent on capacity-building for implementation, the uptake of the VMMC program has remained rather low. Most VMMC procedures are surgical; using either of the methods (forceps-guided, dorsal slit, and sleeve circumcision methods), procedure times are approximately 15–30 minutes, excluding anesthesia, and involve suturing and control of bleeding. To overcome some challenges related to VMMC, some revised approaches have been proposed following implementation research, including establishment of dedicated VMMC service sites in high-volume districts, adoption of the MOVE model (Model for Optimizing Volume and Efficiency) for service delivery, introduction of circumcision devices to improve efficiency, and use of mobile services.

**Potential of MC devices to simplify VMMC service delivery**

One such device for simplifying VMMC service is the PrePex™ device, which has been studied in Botswana, Rwanda, and Zimbabwe. Potential advantages of the PrePex device include: injectable, local anesthesia is not needed, no suturing is required, and placement and removal are quick, with both procedures requiring eight minutes. Acceptability in pilot studies has been high, which may improve the overall uptake of MC services. The PrePex device has been pre-qualified by WHO to be used on adult males over 18 years of age. The studies on adolescents and children are ongoing.
Who can be trained to perform MC using the PrePex device?
This training approach introduces the technique of performing MC using the PrePex device. It is intended for medical doctors and nurses. Surgical skills have been found to make it easier for learners to acquire the knowledge and skills needed to become proficient with the PrePex device; however, prior surgical experience is not a requirement for PrePex training.

Minimum package of VMMC services as recommended by the WHO
- Group education on VMMC and HIV
- Individual VMMC counseling and informed consent
- HIV counseling and testing
- Pre-operative physical exam including STI screening
- MC procedure conducted by trained VMMC providers, using either surgical or device methods
- Promotion and provision of condoms
- Immediate post-operative review and counseling
- Two post-operative follow-up visits (48 hours, 7 days)

Chapter Summary:
- VMMC reduces the risk of HIV heterosexual transmission from an infected woman to a man by 60%.
- Scaling up VMMC in priority countries with low MC rates and high HIV prevalence would prevent new infections and save billions of dollars in treatment costs in the future.
- A number of approaches have been proposed to overcome challenges faced during VMMC scale-up.
Chapter 2: The PrePex Circumcision Device

Chapter Objectives:
At the end of this chapter, participants should be able to:
1. Describe the PrePex device and functions of its parts.
2. Describe the action mechanism of the PrePex device.

The PrePex Device
The PrePex device is manufactured by Circ MedTech Limited, is certified CE-Class IIa in the European Union, and has been approved by the U.S. Food and Drug Administration. As mentioned previously, the device has been pre-qualified by WHO to be used on adult males over 18 years of age. The studies on adolescents and children are ongoing.

Description of PrePex Device Parts
Components of the PrePex Device
The PrePex device consists of an inner plastic ring, outer elastic ring, placement ring, and verification thread. There is also a sizing plate with five holes of different sizes to guide the selection of the device size. All components were created for single use and disposal.

Figure 5. Components of the PrePex Device

The inner ring has a circular shape, with two rounded sides and two flat sides. This design is important for the placement and removal of the device. During device placement, the rounded sides are aligned to the two lateral sides of the penis while the flat sides are at the dorsal and ventral sides of the penis.
The placement ring is fashioned with four legs, with a notch at the top of each leg. The notches help hold the elastic band during the placement and the legs allow for easy release of the elastic band onto the foreskin during placement.

The verification thread is intended to correct for elastic ring misplacement, if needed.
Figure 8. PrePex Sizes
Five PrePex sizes A (smallest), B, C, D, and E (largest) are currently available, and smaller sizes will be available soon.

- Single use, one per client

Figure 9. PrePex Sizing Plate (Single Use)
Mechanism of Action

The PrePex device is a non-surgical medical device for males found eligible for circumcision using PrePex. The device works by compressing the foreskin with two rings to block circulation distally (i.e., blood flow is cut off to the part of the foreskin in front of the position where the device is placed). The client wears the device for seven days during which time the foreskin becomes necrotic (dies off). The dead foreskin is then removed, followed by removal of the device.

Chapter Summary:

- The PrePex device is a simple device that can accelerate scale-up of VMMC so as to reach the highest number of men possible in the shortest period of time.
- The PrePex device is made up of different parts, each of which serves a particular purpose in completing the PrePex circumcision.
- The PrePex device causes the foreskin to die off through compression of the foreskin with two rings.
Chapter 3: Client Education and Counseling

Chapter Objectives:
At the end of this chapter, participants should be able to:
1. Provide sexual and reproductive health (SRH) information to clients seeking VMMC.
2. Describe the importance of group education and counseling on VMMC services and the key messages to be given during a group education session.
3. Educate and counsel clients and/or parents (or guardians) about the PrePex method of MC.
4. Describe the informed consent process.

Group Education on SRH and MC
Health education increases awareness and favorably influences attitudes and knowledge related to improving personal health. Group education is used to support individual counseling by giving clients basic information about MC before attending an individual counseling session. Counselors can then work with clients, partners of clients, and/or clients’ parents on specific issues related to MC or SRH in general. Group education allows the individual counseling session to be shorter, which is an advantage at busy clinics. The local cultural context should be considered when providing group education.

Key Messages for Group Education Session

General information on VMMC and HIV infection
- Explain what MC is. Outline the benefits and risks, and describe how the surgical and PrePex VMMC procedures are performed and what happens afterwards.
- Emphasize that MC does not provide complete protection against HIV infection. Males should be encouraged to use other proven HIV prevention measures even after undergoing MC.
- Explain that circumcised men can become infected and can pass on HIV infection to their sexual partners.
- Emphasize that following circumcision the man MUST abstain from any form of sexual activity, including masturbation, until the wound has completely healed.
- Discuss the importance of knowing one’s HIV status. Explain how HIV is transmitted, how a person can protect himself or herself from HIV infection, and where people with HIV infection can find support.
- Explain that clients with an STI have a greater risk of becoming infected with, and transmission of, HIV and that MC would reduce the risk of contracting STIs.
- Emphasize the importance of avoiding HIV infection and outline different ways of reducing the risk of acquiring the infection.
- Describe the measures that the service takes to ensure that client records are kept confidential, and provide assurance that confidentiality will be maintained.
Ensure the client that the decision to proceed and receive MC services is a voluntary one. If at any time he would like to withdraw from receiving MC, his decision will be respected.

MC as part of broad reproductive health needs of men

- Emphasize that, like women and girls, men and boys have SRH needs.
- Emphasize that only condoms, consistently and properly used, protect against STIs, HIV, and unwanted pregnancy. Other methods of contraception, even those that are highly effective in preventing pregnancy, do not protect against STIs, HIV, or possible future infertility.
- Emphasize that men should treat women as equal partners in decision-making related to SRH.
- Emphasize that men should support the SRH of women and the well-being of their children, with equal regard for female and male children.
- Underscore the importance of not perpetrating gender-based violence, especially against women and girls. Emphasize that responsible men do not force or coerce their partners to have sex against their will (rape).

Emphasize the differences between surgical and PrePex VMMC procedures

- Clients should be informed that circumcision can be performed using either a surgical method or using the PrePex device.
- Clients not eligible for circumcision using the PrePex device will be provided surgical circumcision options.
- For clients undergoing circumcision with the PrePex device, injectable anesthesia as is usually used with surgical circumcision will not be used, nor will stitches.
- Following PrePex circumcision, the device is left on the foreskin (penis) and the foreskin and device are removed after 7 days.
- During surgical circumcision, the foreskin is removed during the initial procedure under anesthesia, the wound is stitched, and a dressing applied.
- The client must abstain from intercourse until the wound has healed completely, irrespective of the method used for circumcision.

Counseling on PrePex Circumcision

Basic Facts about Counseling

In counseling for MC using the PrePex method, the provider ensures that the client (if the client is a child, his parents) has all the information he needs to make a decision about undergoing the procedure. Counseling also covers a component of HIV counseling, which concentrates on helping clients reduce their risk of becoming infected with HIV, or for those already infected, how to avoid transmitting the virus to others.
**Client Information Provided during Individual Counseling Session**

<table>
<thead>
<tr>
<th>1. What is PrePex circumcision?</th>
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<tbody>
<tr>
<td>PrePex is a device used to conduct circumcision, which is defined as the removal of the foreskin, the fold of skin covering the head of the penis.</td>
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<table>
<thead>
<tr>
<th>2. Who will do the procedure?</th>
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<tr>
<td>Trained health care providers will do the procedure.</td>
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<tr>
<th>3. Who is eligible for the PrePex procedure?</th>
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<tr>
<td>It will be determined whether clients are eligible for circumcision using the PrePex method, depending on relevant information obtained during the history-taking and examination done as part of the screening process. Eligibility criteria include:</td>
</tr>
<tr>
<td>• Good general health</td>
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<tr>
<td>• No past history of bleeding disorders</td>
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<tr>
<td>• Suitable foreskin</td>
</tr>
<tr>
<td>• Absence of genital anomalies, e.g., STIs, genital infections</td>
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<tr>
<th>4. Are there alternatives to the PrePex procedure if a client is not eligible?</th>
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<tr>
<td>Yes, the alternative to the PrePex procedure is the surgical method of MC.</td>
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<tr>
<th>5. How is the PrePex procedure done?</th>
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<tr>
<td>During the PrePex MC procedure, the health care provider cleans the skin of the penis and surrounding areas with an antiseptic solution. Sizing of the penis is done using a single-use PrePex sizing plate (PSP) to determine the appropriate size to be placed over the client’s penis. An anesthetic cream is applied to cause numbness (to minimize pain) and the procedure then begins with placement of the PrePex device by the health care provider and an assistant. The placement of the PrePex device takes about 3 minutes and the device stays in place for 7 days.</td>
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<tr>
<th>6. Post-procedure care of the penis?</th>
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<tbody>
<tr>
<td>Instructions to follow after the operation:</td>
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<tr>
<td>The client is advised:</td>
</tr>
<tr>
<td>• Not to move the PrePex device, not even through clothes. Emphasize that touching the device while urinating or bathing must not cause any movement of the device. Any movement of the device may require a surgical circumcision.</td>
</tr>
<tr>
<td>• To return for removal of the device on the 7th day after placement. Early removal may result in complications.</td>
</tr>
<tr>
<td>• Not to remove the device and not to let anyone other than a trained provider remove the device.</td>
</tr>
<tr>
<td>• To report or return to the MC center where he had the device placed if any unexpected complications arise, such as uncontrollable pain or the device becomes displaced.</td>
</tr>
<tr>
<td>• Not to pull on the foreskin in case the device becomes partially detached.</td>
</tr>
<tr>
<td>• To abstain from sexual intercourse and masturbation when the device is on the penis, so it will not move out of place.</td>
</tr>
</tbody>
</table>
7. **Things to expect after the PrePex circumcision procedure:**

After the PrePex circumcision procedure, the client may experience the following, which are considered normal:

- Pain during the week he’s wearing the device; he should take the supplied painkiller tablets to control the pain.
- The foreskin distal (in front of) on the elastic ring will become darker and dry.
- An unpleasant odor may occur while wearing the device. To abate this, the client is advised to practice good hygiene by regular cleaning and to avoid the collection of urine under the foreskin.
- Some partial skin detachments along the elastic ring.

The client is advised to:

- Bathe normally and keep the inner foreskin clean by rinsing it thoroughly (holding the source of water close to the penis and directing the water stream to the foreskin opening) without touching and/or displacing the device in any way.
- Return on day 7 or any time he experiences any problems.

8. **What to expect after the PrePex device has been removed?**

Below is some of what the client may experience after removal of the PrePex device:

- Abstain from sex for 6 weeks even with a condom.
- Urinate and experience erections as usual.
- Keep the protection (bandage) dry. Keep the bandage on your penis for 2 days and return to the clinic to have the dressing removed.
- After removing the bandage, wash your penis gently every day with soap and clean water. DO NOT rub the soap directly on the circumcision area, make bubbles or foam from the soap in your hands and apply it on the circumcision area. Dry your penis carefully with a clean cloth.
- Do not put any substances on the wound. Some people wrongly put animal dung, soil, and other things to quicken healing. These substances have infectious organisms in them that could cause severe illnesses including tetanus. Simple cleaning as described previously will help the wound heal quickly.
- Leave the large band of necrotic tissue that exists and do not remove it; this is your body’s natural protection, it will fall off itself in time.
- Position your penis in an upward position whenever you can (shift your penis up inside your pants), and be cautious not to press on the wound.
- Keep the circumcision wound clean—this is very important.

9. **Report any unexpected situation**

Very few problems are experienced with PrePex circumcision; however, return to the clinic immediately if you have any of these problems:

- Severe pain
- Swelling on penis or testicles
- Difficulty urinating (passing urine)
- A wound or bleeding on the penis
- Any health problem that worries you—even if it has nothing to do with the circumcision (dizziness, headache, fever, pain, pain in lower stomach area).

PHONE OR COME TO THE CIRCUMCISION CENTER IF YOU HAVE ANY QUESTIONS.
Informed Consent for PrePex Circumcision

General Information

Clients must give informed consent before PrePex circumcision is performed. Health care providers should give clients all the information they need to make a fully informed decision, including:

- Give an explanation, in plain language, of PrePex circumcision and the nature of the procedure. The client should be informed of the risks and benefits of the procedure and of other ways to reduce the risk of HIV infection.
- Provide information about other circumcision methods if they do not want to be circumcised with the PrePex device.
- Stress the importance of the device remaining in place for 7 days, the need to avoid activities that might displace the device, and the necessity for prompt follow-up by a trained provider should the device become displaced.
- Inform the client that they MUST not remove the device.
- Explain clearly the need to return on day 7 to have the device removed by a trained provider, or earlier if there are concerns.
- Evaluate whether the client understands the information provided.
- Evaluate the client’s capacity to make necessary decisions.
- Assure the client that he is free to choose whether or not to be circumcised using the PrePex method. If there is any suggestion that the client is not ready to give consent, advise him to reflect on it for a few days.
- Ask clients who decide to undergo PrePex circumcision to sign a consent document.

The goal of this consent process is to ensure that the clients understand the PrePex circumcision procedure. At the same time, they should be given the opportunity to make use of other SRH services.

Only clients who have appropriate decision-making capacity and legal status can give their informed consent to medical care.

When a child (usually defined as a person under the age of majority under national law, though some countries allow consent for certain types of medical care to be given by minors) lacks the legal status required to provide independent, informed consent, or lacks the capacity to appreciate the risks and benefits associated with the procedure, written consent based on full information must be obtained from the parents or legal guardian. The parents or legal guardian should make the decision according to the best interests of the child.
Documenting Informed Consent for PrePex Circumcision

The PrePex circumcision team should ensure that the client has been informed about the risks and benefits of MC, and that the information has been given in an understandable way, using an everyday local language.

The information provided verbally should be backed up by written information sheets in the local language. After receiving this information, the client should be encouraged to ask questions. He should then be given time to reflect on his decision before being asked to sign the consent document.

Chapter Summary:

- Providers should have general knowledge of the SRH needs of clients seeking VMMC.
- Group education is used to support individual counseling. Clients receive basic information about MC using the PrePex device.
- Providers have a duty to: a) ensure that voluntary and informed consent is obtained from each client before the procedure is performed; b) maintain confidentiality; and c) provide services without discrimination.
Chapter 4: Client Screening for PrePex Circumcision

Chapter Objectives:
At the end of this chapter, participants should be able to:
1. Understand the importance of screening clients before the PrePex procedure.
2. Describe key points of history taking and the physical examination for all clients undergoing the VMMC procedure.
3. Identify contraindications to PrePex circumcision.

Introduction
All clients requesting circumcision, including with the PrePex device, must be screened to ensure that they are suitable for the particular circumcision method and to detect any contraindications and or conditions that may require treatment or referral. There might be clients with findings either in the history or examination that may preclude them from receiving circumcision with the PrePex device, but may be able to proceed with surgical circumcision.

To ensure that a client’s assessment is complete, these steps should be followed: conduct history taking, perform a physical examination, and assess the foreskin for suitability or ease of placing the PrePex device. The Golden Rule for screening clients prior to a PrePex circumcision is: “If anything is found to be unusual with the client’s health or at penile examination, then circumcision with the PrePex device must not be performed.”

Prior to screening a client, the provider prepares the necessary materials, including medical non-sterile gloves, an examination couch/bed, and waste receptors, which allow waste to be separated. It’s important to ensure privacy in the place where a client’s history is being taken and examination performed. The provider then invites the client in and introduces the purpose of the screening.

History Taking
When taking the medical history, ask the client about the following:

- Current general health
- Currently taking any medicines, with special emphasis on anti-coagulant medications, chronic use of NSAIDs
- Any known allergies to medicines, latex, plastic or antiseptics
- History of bleeding disorders or anemia
- Any current genital infection, ulcer or penile discharge
- Any problems with penile erection or any other concerns about sexual function
- Any known medical conditions for which he may be receiving treatment such as diabetes, hypertension, HIV
- History of immunization against tetanus and, if available, when the last dose was received
Physical Examination

During the general examination of the client, consider the client’s general state. It’s important to check the client’s vital signs, including weight, blood pressure, pulse, and temperature (refer to the examination section on the client record form). Look for the presence of any wounds on the client’s body.

Genital examination

Ask the client to lower his pants and stand in front of you for genital examination. Ensure adequate exposure prior to examination. If available, the client may be asked to lie on an examination couch/bed.

Check for the following:

- Abnormal structure of the penis and foreskin; does the client have a partial circumcision?
- Genital rash, sores, redness, or warts.
- Squeeze the head of the penis. Is there a discharge?
- Any abnormal swelling on the penis or scrotum.
- Check for the suitability of the foreskin for PrePex MC by pulling it back over the glans (retraction), does it return to its natural position? Pull foreskin sideways gently. Check if it’s flexible enough for PrePex? Is the opening wide enough to insert the inner ring? See Figure 11.
- Pull back the foreskin and examine the frenulum for any adhesions? Other abnormalities?
- Inspect the position of the urinary opening (which should be at the tip of the penis).

Note: Some of the findings from the examination in the above text box may preclude circumcision with the device as shown in the table to follow.

Figure 11. Examination of Foreskin for Suitability

Note: The eversion of the foreskin opening to determine width of the opening.

Following the examination, ask the client to get dressed and then explain your findings:
1. **If the client is OK:**
   - Complete the Client Card with your conclusions, sign and date it.
   - Send the client to the procedure room.

2. **If NOT OK:**
   - Complete the Client Card with your conclusions, sign and date it.
   - Explain to the client what you have found in your examination.
   - Explain that he cannot have PrePex circumcision during that visit (e.g., will he need surgical MC or other treatment or be able in the future to have PrePex after re-examination?).

**Conditions That May Render a Client Unsuitable for PrePex Circumcision Method**

- Active infectious disease
- History of bleeding disorders
- Allergies to latex/plastic/antiseptics
- Reported/confirmed diabetes or hypertension and other chronic medical conditions which in the assessment of the provider, is not well controlled
- Acute disease (e.g., fever)
- Abnormalities of the penis (e.g., abnormal structure of the penis, from birth or an accident) such as tight or torn frenulum, hypospadias, epispadias
- Active disease or infection of the penis
- STI
- Damaged foreskin or non-intact foreskin
- Genital swelling
- Abnormalities of the foreskin such as phimosis, paraphimosis, and pathological adhesions
- Clients with wounds on the body may defer circumcision until the wounds heal (to follow the national policy)
- A client whose penis is either too small or too large for the available PrePex sizes
Tetanus immunization for clients who are eligible, according to country-specific guidelines

Mitigating the risk of tetanus infection through vaccination for all circumcision procedures and other wounds is advised. The primary goal of a tetanus vaccination in the context of VMMC for HIV prevention is to reduce risks associated with the circumcision procedure and its wound, including overcoming poor hygienic practices. Tetanus vaccination would also contribute to further expanding the WHO vaccination recommendation for children, adolescents, and adults to reduce the risk of tetanus in unprotected adolescents and adults. Tetanus vaccines are highly efficacious. At a minimum, unless an individual has received the full five-dose series of tetanus toxoid-containing vaccine (TTCV), it is advised that a single dose of TTCV be added at the time of MC, recognizing that this dose will provide varying levels of protection for each individual.

The vaccination history of men presenting for circumcision is frequently limited, but if such information is available it should be used to determine the individual's vaccination needs and
override population-level considerations. Men opting for VMMC by any method have the right to receive full information on the benefits and risks of the procedure, including the risk of tetanus infection, and protection offered by tetanus vaccination.

**Number and timing of vaccine doses and level of protection in the context of MC**

It is uncertain exactly where and when the highest risk of *C. tetani* inoculation occurs, the timing for germination, or the release of toxins on which tetanus toxoid acts. With use of an elastic collar compression device, if *C. tetani* spores are present at the time of placement or while in situ, it may take 24 to 48 hours for *C. tetani* spores to germinate and bacteria to multiply within the anaerobic environment. The first symptoms of tetanus disease after circumcision or device placement among the cases so far reported occurred between 8 to 12 days. Immunological kinetics vary but suggest the following:

- **A booster** dose in a primed individual should be given at least 7 days and ideally 14 days before the VMMC procedure (conventional surgery or device placement) for adequate protection.

- Providing a dose in a primed individual at the time of device placement or procedure may allow the development of partial protective immunity through production of antibodies within approximately 96 hours and increasing antibody levels to their maximum in 1 to 4 weeks.

- In a **vaccine-naive** individual, a single priming dose would be inadequate to induce protective antibody levels. Thus, two doses of the TTCV 4 weeks apart, with the second dose ideally 14 days before the VMMC procedure, would be needed for protection of such individuals.

In summary, the following advice on **vaccination options with TTCV should be followed, along with the criterion for infection prevention through rigorous surgical skin preparation and good wound care education regardless of circumcision method.**

At a minimum, unless an individual has received a full five dose series of TTCV, a single dose of TTCV should be added at the time of MC, recognizing that this dose will provide varying levels of protection for each individual.
Table 1. Vaccination Options with TTCV

<table>
<thead>
<tr>
<th>Tetanus vaccination status of clients to be circumcised (assumed to be unknown at the individual level though it should be queried and when available vaccination should be based on individual history)</th>
<th>Level of protective immunity provided to the individual</th>
<th>Options for TTCV of the individual prior to circumcision procedure</th>
</tr>
</thead>
</table>
| 1. In countries or subnational areas where clients are likely to be fully vaccinated against tetanus (based on population policies and coverage levels), including:  
  - all 3 infant doses of TTCV, plus 2 to 3 subsequent TTCV boosters OR  
  - 2 doses of TTCV in adolescence or adulthood, with a 3rd dose in the past five years | Clients likely have protective immunity | No need for a further booster dose of TTCV prior to VMMC, but a dose could be provided for longer-term protection |
| 2. In countries or subnational areas where clients are likely "primed" against tetanus (based on population policies and coverage levels), meaning they have had at least 1 previous dose of TTCV | 1 TTCV booster at the time of VMMC cannot assure protective immunity against tetanus, but may contribute to protection from disease or reduced severity of disease | • Ideally, provide the single TTCV booster dose 14 days prior to VMMC  
• At a minimum, provide a TTCV booster dose at the time of VMMC  

For longer-term protection against tetanus from any wound, encourage VMMC clients to return for the VMMC follow-up visit at 4 to 6 weeks and provide another dose of TTCV; encourage a booster dose after 1 year |
| 3. In countries or subnational areas where clients are likely "not primed", also known as vaccine naive (based on population policies and coverage levels), meaning they have never received any TTCV | An individual likely has no protective immunity against tetanus | Provide 2 TTCV doses at least 28 days apart. **On first encounter, provide a first TTCV dose**  
• Ideally provide the second TTCV dose at least 14 days prior to VMMC  
• If the second TTCV dose is provided at the time of VMMC, limited protection may be provided during the first week post VMMC while antibody levels are increasing  

**At a minimum**, provide a TTCV dose at the time of circumcision, recognizing that no protection is provided with only 1 dose  

**For longer-term protection**, encourage individual to receive a third dose in 6 months and additional doses subsequently 1 year apart |
Chapter Summary:

- **Client screening aims to identify clients who are suitable for circumcision using the PrePex device and those who are not.**
- **History taking and physical examinations, including genital examination are key steps in the screening procedure.**
- **To mitigate the risk of tetanus following MC, providers MUST ascertain the immunization status of each client as per national guidelines.**
- **Proper screening of clients prior to circumcision with the PrePex device will greatly affect the ease of the procedure and may affect the outcome of the procedure.**
- **In some circumstances, clients with contraindications to PrePex circumcision may still be eligible for surgical VMMC.**
- **It is important for all providers to be able to identify conditions that may preclude circumcision using the PrePex device.**
- **If there is any doubt as to suitability for PrePex circumcision, the client should be referred to a specialist or provided the option of one of the surgical methods.**
Chapter 5: Placement of the PrePex device

Chapter Objectives:
At the end of this chapter, participants should be able to:
1. Understand and perform the steps during placement of a PrePex device for MC.
2. Recognize problems that may arise during placement of the device and how to deal with them.
3. Understand the key information to give to clients after placement of the device.

PrePex Placement Procedure
Before starting the procedure, cross-check to ensure that right client has been referred. Cross-check the client’s record form to ensure that the screening was conducted and no contraindications found. Informed consent must be obtained and the form signed.

During the device placement, the following precautions must be considered by the operator and assistant:

Tissue handling:
- Handle penis and foreskin gently, especially when stretching the foreskin.
- Avoid client discomfort and damage to tissue.
- Use only fingers to stretch foreskin, NOT instruments.

Essential Instruments and Materials for PrePex Placement:
- 2 pairs of medical non-sterile gloves
- Antiseptic in dispensing bottle; as per national guidelines of 10% povidone-iodine (caution: iodine allergy)
- 3 gauze sheets in the following sizes: 7.5 cm x 7.5 cm/10 cm x 10 cm
- 1 PrePex single-use sizing plate
- Skin marker
- 1 gm anesthetic cream; preferably lignocaine of 5% concentration
- PrePex devices in all 5 sizes (A to E)
- Scissors to cut the verification thread
- Waste receptacle
- Pain medication, e.g., ibuprofen
Sizing of the Penis

Using a single-use PSP, measurement under the sulcus is done by sliding each opening of the PSP over the glans and placing it directly under the coronal sulcus. This should be done 3 times without pulling the penis. The appropriate size is the opening that fits best, not too loose and not too tight (see Figure 13 below). Correct sizing of the penis is important because if an incorrect size is chosen, it could result in:

- Pain during erection when the PrePex device is too small
- Failure/difficulty to insert the inner ring because the PrePex device is too big

Figure 13. Sizing of the Penis

The assistant then chooses the PrePex device based on the sizing outcome (A, B, C, D or E).

Note: If the diameter of the penis under the coronal sulcus is too large and cannot fit in the E opening or if it is too small and cannot precisely fit into the A opening, then do not perform the PrePex procedure, and refer the patient for surgical circumcision.
Skin Preparations

Prepare the skin with antiseptic solution (10% povidone-iodine solution is the recommended antiseptic) (caution: iodine allergy):

- Soak a piece of gauze in the povidone-iodine solution or antiseptic solution. The application should be done at least 3 times and then wait 2 minutes, in the case of iodine, before the procedure or device placement.

- When applying the solution, start with the glans penis and foreskin, and then move to the shaft of the penis and the groin. The extent of skin preparation is advised to go up to just below the umbilicus and mid-way to the thighs.

- Retract the foreskin and clean the glans to the sulcus, the inner and outer foreskin, and the penile shaft. Scrub well and remove all residual dirt using the antiseptic solution, as shown in Figure 14 below.

- Dry with a clean gauze if necessary.

Figure 14. Steps for Skin Preparation

1

2

3

Marking the Circumcision Line
Marking the insertion point of the elastic ring or circumcision line is important to avoid complications of insufficient or excessive skin removal. The foreskin is stretched to ensure that the inner part has no hidden folds and then let it rest again in its natural position. Some uncircumcised men have a very lax foreskin, which is partially retracted in the resting position. In such cases, it is better to apply a little tension to the foreskin before marking the circumcision line. However, it is important not to pull the skin too hard before marking the line, as this will result in too much skin being removed. A circumferential mark is made along the coronal sulcus about 0.5 cm below the corona starting on the dorsal (back) side of the penis. Another mark, in a V-Shape, pointing toward the frenulum is made on the ventral side of the penis. The apex of the V should correspond with the midline raphe, ensuring that the V is not too sharp (see Figure 15 below). This is to avoid damage to the frenulum.

Figure 15. Marking the Circumcision Line

Ensure that the marked circumcision line is clear for the PrePex procedure. If the marking is not clearly visible, do not perform the procedure. Before continuing with the procedure, it is very important to mark the line again if it is not visible.
Loading of the Elastic Ring over the Placement Ring

The right PrePex size is selected and the elastic ring is put in place by either putting the elastic ring first on 2 adjacent placement ring notches, then moving circumferentially OR putting the elastic ring first on 2 opposite placement ring notches, then applying to the remaining notches. The operator chooses the method she or he is comfortable with.

Figure 16. Loading of the Elastic Ring over the Placement Ring

Placement Ring (with Elastic Ring) Inserted on the Penis

Placement ring loaded with elastic ring is placed at the base of the penis with the elastic ring facing the glans.
Application of Lidocaine 5% Dermal Cream

Retract the foreskin and apply a quantity of the anesthetic cream equal to the end of a fingertip on the shaft (inner foreskin) and sulcus area. Once the anesthetic cream has been applied, there is no need to wait for it to take effect, the procedure may continue.

The penis is positioned in the normal anatomical position, as shown below next to a wall clock in Figure 19.
These next steps should be performed by two trained providers:

- The first person (the operator) grasps the foreskin at 6 and 12 o’clock.
- With the thumb and index fingers of both hands the operator stretches the foreskin open to allow insertion of the inner ring below the skin of the shaft by the second person (the assistant).
- The operator uses dry gauze to ensure a good grip. Ensure that the foreskin is opened wide enough by viewing the sulcus area, thus assuring there will be no doubly entrapped foreskin.
- Inform the client that there may be brief discomfort.
- The assistant holds a curved side of the inner ring and inserts the inner ring all the way down to the sulcus and then presses the opposite side of the inner ring down to the sulcus also. If the ring is not pushed all the way down, it may cause suboptimal circumcision results.
- During the insertion of the inner ring, the assistant must insert the inner ring with its flat parts toward the dorsal and ventral sides of the penis, ensuring that one of the flat sides is in the area of the frenulum and the other flat side is on the opposite side of the frenulum.

**Caution:** When introducing the inner ring through the foreskin opening, be very careful not to harm the foreskin. If it’s hard to introduce the inner ring, do not force it and do not perform the procedure.
Steps for placement of the inner ring:

- Grasp foreskin closed to secure the inner ring and then bring the placement ring up to align the elastic ring with the inner ring groove.

- Once the elastic ring and inner ring are aligned, support the placement ring with one hand, and, with the other hand, adjust the foreskin so that the marked circumcision line is exactly underneath the elastic ring.

- Adjust the foreskin from beneath each of the four legs of the ring by pulling the skin down. When the alignment is confirmed, then the elastic ring is released into the inner ring groove. It is important to explain to the client that he may experience a bit of discomfort when the elastic ring is released onto the skin.

- Fix the placement ring using 4 fingers of your non-dominant hand in the space between each of the 4 placement ring legs and hold the elastic ring and inner ring together. With the thumb and finger of your dominant hand, gently release the elastic ring from the placement ring one point at a time, from the notch onto the foreskin. Check that the elastic ring is on the foreskin and lying perfectly in the groove of the inner ring and above the marked circumcision line.
Adjust the foreskin to align it with the elastic ring at the circumcision line by gently pulling the proximal shaft skin and check if the device is correctly in place by looking beneath the foreskin. The inner ring should be in place in the sulcus and the elastic ring exactly in the groove of the inner ring.

Explain your actions to the client and cut the verification thread. Make sure there is no invagination before cutting the verification thread.

Discard the placement ring.

Complete client records and give post-operative instructions to the client.

Show the client the ring before he leaves the room.

Challenging Situations That Might Occur during Placement and Appropriate Solutions

1. **Problem: Narrow foreskin**
   Even with good screening, the operator may not be able to insert the inner ring due to narrow (borderline) and inflexible foreskin.
Foreskin opening too narrow and inflexible to allow insertion of the inner ring.

Solution:

- Do not use excessive force when inserting the inner ring. **Be very careful not to harm the foreskin.**
- If the foreskin is too narrow, amend the client’s card with the reason for failure of placement and suggest surgical circumcision as an option.

2. **Problem: Inaccurate placement**

   When verifying whether the placement has been done correctly (immediately after the placement), you may see that it has not been placed correctly. This may be due to one of the following reasons:

   - Elastic ring is not lying over the circumcision line
   - Inner ring is not placed low enough inside the foreskin
   - Inner ring is not on the sulcus line
   - There is an invagination of the foreskin

Solution: Replacement procedure:

- Pull the verification thread, which will pull the elastic ring off the penis. Once the elastic ring is off, start the procedure again and follow the placement steps as described above. Perform the placement procedure with a new device.

3. **Problem: In case of small penis size**

   If the size of the penis is smaller than size A of the sizing plate and a size A ring cannot be safely inserted, do not perform the PrePex procedure.

Solution:

Update the client’s card with the reason for failure of placement and send the client for surgical circumcision.

4. **Problem: In case of large penis size**

   If the size of the penis is larger than size E of the sizing plate, do not perform the PrePex procedure.

Solution:

Update the client’s care with the reason for failure of placement and send the client for surgical circumcision.

5. **Problem: Inner ring becomes dislodged while adjusting the foreskin**

   If the inner ring becomes dislodged while the operator adjusts the foreskin to the circumcision line, the inner ring and elastic ring are then no longer aligned one on top of the other.

Solution:

Work slowly and evenly all around the penis.

Make sure you perform the adjustment below each point of the 4 legs of the placement ring.
Follow-Up and Counseling of Clients after Device Placement

After the PrePex device has been successfully placed, the client should be discharged through an exit group counseling session. On referring the client to a group discharge counseling session, the following should be clearly observed:

- Complete the client’s card after the placement procedure with your name and date;
- Ask the client to get dressed and send him with his signed card to the post-placement counseling room; and
- Make sure the client does not leave without a discharge session.

Post-placement counseling session for clients following PrePex circumcision

Provision of instructions following the device placement may be done for a group of clients (where feasible) or for an individual client. The post-placement counseling session will take place in a designated room by a PrePex-trained counselor. The client(s) will receive the post-placement information leaflet and pain management medicine, and will have the opportunity to discuss the important information listed below with the counselor.

Important points to be discussed:

1. Explain to the client that he must **not move** the device at all for any reason, even if it is causing discomfort. Explain the risks of dislodging the device, such as the possibility of infection.
2. If the device **moves out of place**, recommend that the client contact the circumcision center immediately.
3. Explain to the client that if he must contact and **return to the clinic, or go to an alternative clinic**, immediately if he experiences any of the following symptoms (also, he should mention to clinic staff that he recently underwent the MC procedure):
   - Severe pain
   - Swelling of penis or testicles
   - Device moves out of position
   - A wound or bleeding on the penis
   - Difficulty in passing urine
   - Parts of the foreskin separate from the penis within the first 4 days (separation is normal 5–7 days after placement)
   - Any health problems such as dizziness, fever, or pain, which may or may not be related to the circumcision
4. Provide contact details to the client (in case of complications).
5. Make sure the client is given an appointment date and time for removal of the device. Emphasize that he must return on time—in 7 days—for the removal procedure or he risks complications.
6. Indicate to the client he may notice smells on days 4–7, as a result of the natural necrosis process, and that these are **NORMAL**.

7. Explain that it is normal to have erections; recommend that he urinate frequently because erections usually go down after urination. Emphasize that the client must not touch the device!

8. What to expect in the next few hours and days after the procedure:

   - Foreskin will feel completely numb over the next few hours.
   - Foreskin will become darker, then black and dry.

9. Normal washing is allowed and even required! The provider explains how to do this properly.

10. No sex or masturbation at all allowed—not even with a condom—until 6–7 weeks post placement.

11. Advise the client not to touch the device: it will hurt more! Touching the device may harm the penis.

12. Give tablets of ibuprofen 400 mg as pain management for the upcoming 7 days. Advise the client to take the tablets as instructed.

13. Encourage the client to share the information leaflet with his partner.

**Key information to emphasize:**
- No sex or masturbation at all—not even with a condom—until 6–7 weeks post placement.
- Client must not move the PrePex device, **not even through his clothes**.
- Client must not try to remove the PrePex device.
- Warn the client that he will have to go through **surgical circumcision if he moves the device**.

The client must return to the health professional for assistance.

**Chapter Summary:**
- PrePex placement requires an operator and an assistant to follow the steps described to correctly place the device on a client.
- It is important to ensure that the client does not move the device while wearing it, and also abstains from sex and masturbation.
- Clients must be given discharge information after placement to ensure that the device stays in situ until removal.
Chapter 6: Removal of the PrePex Device

Chapter Objectives:
At the end of this chapter, participants should be able to:
1. Understand and perform the steps involved for removal of the PrePex device.
2. Recognize challenges that may arise during the removal procedure and how to handle them.
3. Understand the key information to give to the client after device removal.

Removal of the PrePex device is conducted on day 7 after placement. To ensure that the removal procedure goes smoothly, necessary preparations should be made, with all required tools and materials on hand. During the procedure, only the operator handles the client’s penis. The assistant prepares and handles the tools. It is recommended that the provider explains to the client the basic steps of the procedure.

Essential PrePex Removal Tools and Materials

- Pair of medical gloves
- Antiseptic in dispensing bottle
- Gauze sheets
- Sterile kit containing: 1 artery forceps, 1 Harvey wire scissors, 1 spatula
- 1 scalpel
- 1 non-adherent (not sticking) dressing

It is mandatory to use only adequately sterilized removal instruments. Using instruments that have not been adequately sterilized may lead to infection.

Removal tools and materials

- Artery forceps to hold the foreskin firmly in place while cutting.
It is recommended that the scissors (Harvey wire scissors) be used to remove the necrotic foreskin, which is very tough to cut. The scissors used for this purpose have blunt edges and serrated blades, specifically designed to cut tough tissue like the dried necrotic foreskin.

Spatula to remove inner ring. The spatula is a specialized tool to assist with removing the inner ring although it is not always needed. Sometimes the inner ring can be removed without using it, depending on the status of the circumcision wound.
During removal

Skin preparation:

- Prepare the skin with antiseptic solution (10% povidone-iodine solution is the recommended antiseptic) (caution: iodine allergy). Next, use wet gauze to clean the necrotized foreskin, inner ring area, and shaft of the penis. If iodine is being used, the iodine should be applied at least 3 times, allowing 2 minutes for the iodine to dry before proceeding.

- Before removing the foreskin, it is recommended that you pull the penis and foreskin gently upward to separate the foreskin from the glans. You may drip fluids (e.g., antiseptic solution) through the foreskin opening to enhance the separation.

Figures 27. Skin Preparation during Removal

1.  
2.  

If the foreskin opening is too narrow and stiff and does not allow scissors to be inserted, use the forceps to gently dilate the opening.

- Some edema (swelling) may occur, which is normal, as long as it is local and not observed all over the genitals. Handle the penis gently and carefully.

- Make sure you take care not to injure the urethra during the introduction of the Harvey wire cutting scissors into the meatus or lacerate the glans by not holding the foreskin far enough away from it when cutting.
Positions on the glans

Figure 28. Positions on the Glans

Cutting the Foreskin

- Before starting to remove the foreskin, make sure the penis is at its proper position to be able to correctly apply the scissors and the forceps.

- Pull penis up, placing forceps at 2 o’clock (transfer to left hand) and scissors at 3 o’clock.

- Cut the foreskin vertically first toward the elastic ring and then at an angle, spirally, to the line where the inner ring is visible. Make sure to cut the foreskin as close to the elastic ring as possible.

- When you reach the inner ring, cut as close to the inner ring as possible, so that the tip of the inner ring becomes fully visible. While cutting, avoid holding the penis at area immediately next to the position of the device and do not pull on the forceps with which the necrotic skin is being held because these actions cause the client discomfort.
Figure 29. Steps for Cutting the Foreskin

3

After the inner ring is fully exposed, minimal foreskins should be visible. If necessary, trim the cut edge clean and straight.
Removing the Elastic Ring
The elastic ring should be removed only after the foreskin has been removed, following these steps:

- Use a sterile scalpel to cut the elastic ring placed over the flat part of inner ring on the side that is opposite the frenulum.
- Make sure you do not cut the elastic ring on the same side as the frenulum. Before removing the scalpel from packet, explain to the client that you will be cutting the elastic, not the skin.
- The elastic ring is only cut at the flat part of the inner ring using the slip over fashion.
- Take care not to harm the viable skin and discard the elastic ring.

![Figure 30. Removing the Elastic Ring]

Removing the Inner Ring
This is a very sensitive step during the removal process of the PrePex device and also causes pain. You need to be gentle and do it as quickly as possible to minimize pain.

- Before removing the inner ring, thoroughly disinfect the area of the inner ring, the necrotic foreskin around it, and the glans with a locally recommended antiseptic and gauze.
- The inner ring should be pulled out on a curved side using the spatula; avoid the frenulum area.
Partial separation of the necrotic foreskin may occur; in such cases, extra care should be taken when extracting the inner ring to minimize pain of the separation area.

Cut the inner ring with a cutter before discarding it to avoid reusing it.

After removal of the inner ring, clean the circumcised penis with antiseptic solution, examining it to make sure there is no oozing; if oozing is observed, apply pressure with the clean gauze for a few seconds. Then do the following:

- Dress the circumcised penis with a standard non-adherent pad.
- Instruct the client not to get the dressing wet and to return for follow-up after 48 hours.
- Instruct the client to wash the penis and the wound area normally after dressing is removed.
- Instruct the client to contact the MC clinic in case of any concerns.
- Instruct the client to abstain from sexual intercourse and masturbation for 6 weeks after removal of the device, and explain that those actions may lead to disruption of the wound, which will cause a delayed healing.
- Explain to the client the importance of using condoms when he resumes sexual intercourse, and that circumcision does not offer total protection against HIV infection.
- Educate the patient on the risks and potential damage to the wound and to his general health if he uses traditional or non-authorized substances (e.g., animal feces, soaps, organic substances, like butter, powders, herbs and honey) on the wound.
Dressing of the Wound

Dressing of the wound after the removal of the inner ring is very crucial, and should be done as follows:

- Apply direct pressure with gauze for several seconds to make sure oozing stops completely.
- DO NOT dress the wound before you make sure there is no oozing!
- Clean area with an appropriate antiseptic solution (caution: be aware of possible allergic reaction and solution concentration!).
- Place dressing around the wound, use Micropore (adhesive tape) at the top of the dressing to seal it. Do not seal it too tightly (can cause discomfort and even necrosis of the glans).
- Make sure the urethra opening is not covered by the dressing.
- Position the penis upward and instruct the client to keep this position.

Challenges with the PrePex Removal Procedure

Sometimes the removal procedure might not be as straightforward as described above. Some cases may need special attention during removal, such as those described below.

Partial Separation of the Foreskin from the Penis

Partial separation of the foreskin from the penis often happens at the frenulum.

Suggested approach for such cases:

- Take extra care during the removal of the inner ring.
- Ask the client to indicate which areas are painful and avoid them as you work.
- Do not use the spatula in areas identified to be painful.
Figure 33. Example of Partial Separation of the Foreskin from the Penis

Necrotic Foreskin Sticks to Glans
Suggestions for approaching this challenge:

- Use gauze to drip antiseptic/normal solution into the necrotic opening.
- Keep gently moving the foreskin up and down, so the antiseptic drips into the foreskin, separating it from the glans.

Figure 34. Example of Necrotic Foreskin Sticks to Glans

Early Device Removal
If the client returns to the clinic and can no longer bear the device, the operator can consider removing the device after a thorough assessment of the foreskin necrosis; the provider should reinforce the counseling and strongly advise the client to wait until 7 days.

Removal Days—General Note
Optimal removal day has been found to be day 7, exactly 1 week post placement. However, removal can be done with no harm on day 6 if the client requests early removal due to pain, discomfort, smells or other reasons.
Follow-Up and Counseling of Clients after Device Removal

After removal of the PrePex device and appropriate dressing of the wound, the client may be discharged after attending an exit counseling session, which may be provided on a group or individual basis. On referring clients to a discharge counseling session, the following should be clearly observed:

- After the removal procedure, the client record form should be completed.
- Ask client to get dressed and send him with his signed card to the counseling room.
- Make sure the client does not leave without attending a discharge session.

Post-Removal Discharge Counseling Session

Self-care

The discharge session will take place in a designated room by a PrePex-trained counselor, the client will receive the post-removal information leaflet, and discuss with the important information with the counselor, including the following topics:

1. **Explain to the client how to care for the wound:**
   - Keep the dressing dry!
   - MUST return for follow-up after 2 days or any time if any concerns.
   - Remaining foreskin will dry and fall off within 1 to 2 weeks.
   - Wash gently, do not rub, use soap and clean water daily.
   - Dry carefully.
   - Handle with care for 2 weeks or until the skin has grown back nicely over the wound.

NB: In some programs, clients are given additional dressings to take home and instructed on how to dress the wound (taking care not to contaminate the wound and cause an infection).

2. **Clients should be clearly instructed not to have sex or masturbate for 6 weeks (not even with a condom) because this may**
   - Disturb the wound and delay healing.
   - Increase the risk of infection including HIV.

3. **Clients should be given clear information, using simple and understandable language, on how to deal with complications that may arise. The client MUST come to the circumcision center or any nearby clinic, if they have any concerns.**

**Chapter Summary:**

- It is important for providers to follow the steps described in this chapter to be able to remove the device correctly.
- Clients need to be given wound care information and counseling on abstinence after device removal to ensure proper wound healing and reduced risk of acquiring HIV.
Chapter 7: Identification and Management of Adverse Events

Chapter Objectives:
At the end of this chapter, participants should be able to:
1. Describe potential adverse events (AEs) and side effects of PrePex MC and their management.
2. Demonstrate appropriate recognition and decision-making to manage AEs.

Definitions
Side effects and AEs may occur with any procedure or medical treatment. In PrePex circumcision, they must be identified quickly and managed properly. The aim of this chapter is to acquaint the PrePex provider with definitions for these occurrences as well as descriptions of side effects and AEs that may follow PrePex circumcisions.

What is a side effect of circumcision?
This is an expected symptom/effect of a healing wound in any MC procedure. Following PrePex circumcision, the following side effects may happen: oozing, localized edema, clear exudate from the wound, and slough formation.

What is an AE?
An AE is any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medical treatment and/or procedure regardless of whether it is considered to be related to the medical treatment/procedure. An AE is any injury, harm, or undesired outcome during or following the MC procedure that would not have occurred if the client had not undergone the procedure at that time. Following PrePex circumcision, AEs encountered may include: site bleeding, diffuse penile edema, productive exudate, diffuse penile hematoma, incision site infection and related symptoms, and injury to the penis.

AE Severity
AEs have been classified into three categories of severity—mild, moderate, and severe—to provide a clear spectrum of AEs. The moderate and severe AEs are the only ones that need to be reported and monitored. Below is an explanation of each category.

- Mild classification: minimal or no intervention required beyond reassurance and observation
- Moderate classification: neither mild nor severe, require intervention, and are usually managed on site
- Severe classification: extensive intervention required with referral or specialist input. In addition, severe AEs also include any event that:
  - Results in death
- Is life-threatening
- May result in permanent disability or incapacitation (including deformity)
- Requires intervention to prevent permanent disability or incapacitation (including deformity)
- Requires hospitalization or referral to a specialist for higher-level care or intervention

**AEs Outcomes/Consequences**

AEs can have a number of outcomes, from resolution with no morbidity or permanent damage to outcomes that may include lengthy recovery periods and may result in permanent damage such as scarring.

**Side Effects of PrePex Circumcision**

1. **Oozing from the wound**
   This is defined as a discharge of red serum from the wound. It commonly happens after removal of the device and the common site of oozing is the frenular area. Therefore, before dressing the wound, it is important to wait and see if there’s any oozing. Below are pictures demonstrating oozing from the wound edges following removal of the PrePex device.

   **Figure 35. Example of Oozing from the Wound**

   Management:
The oozing from the wound can usually be stopped with short-term applied pressure, with no further action required. However, if the application of pressure does not stop the bleeding, suturing may be considered if any bleeding vessels are identifiable.

2. **Localized edema**
   Localized edema is an accumulation of fluid beneath the skin in the wound area. It is by far the most common side effect following PrePex circumcision and usually happens 2–7 days after removal of the device. Below are photos demonstrating edema localized to the frenular area following removal of the device.
Figure 36. Example of Localized Edema

Management:
No treatment is necessary for localized edema. It should resolve itself within a few days. Explain to the client what it is, that it is common, and show him how to perform compression at home to diffuse the fluids.

Recommendation: To avoid this swelling, advise the client to elevate the penis in his underwear to prevent fluid accumulation. These same instructions apply for the after-placement procedure.

1. Clear exudate
   Clear exudate refers to discharge of a clear fluid from the wound, which may be visible on the dressing or underwear. The photo below shows an example.

Figure 37. Example of Clear Exudate
Management:
The client should be encouraged to:

- Wash with soap and water once a day
- Change underwear once a day

If the discharge continues for 3 days, replace the dressing with a dry one, which will help absorb the discharge.

1. **Slough formation**
   White, yellowish-like exudate over the exposed granulating tissue may appear on day 9 up to day 14. (Common in ~10% of the clients). See photos below for examples.

![Figure 38. Examples of Slough Formation](image)

Management:
No form of treatment is required for slough. The client should be encouraged to wash the penis normally with water and soap.

It’s also important to explain to the client that this effect IS NOT AN INFECTION and no treatment is required.
AEs of PrePex Circumcision

AEs of PrePex circumcision include:

1. **Site bleeding:**
   Site bleeding is when there is active bleeding from the wound that cannot be stopped by direct pressure of 30 seconds.

   **Treatment:**
   The bleeding vessel must be identified and ligated with sutures or another medical intervention made by the physician.

2. **Diffuse penile edema**
   Diffuse penile edema is accumulation of fluid beneath the skin, not limited to the wound area but visible all over the genitals (swelling of penis and scrotum). It’s important to rule out other possible causes of swelling such as infections. The photo below shows an example of a diffusely edematous penis following PrePex circumcision.

   **Figure 39. Example of Diffuse Penile Edema**

   ![Diffuse penile edema](image)

   **Treatment:** A thorough evaluation should be done to effectively rule out other probable causes of the swelling. If there is no identifiable cause for the swelling, ibuprofen or another nonsteroidal anti-inflammatory drug should be prescribed for the client. It may also be necessary to prescribe an antibiotic in cases where other signs of an infection exist.

1. **Productive exudate**
   Productive exudate is when there is a discharge of a cloudy fluid from the wound. This kind of exudate is consistent with more severe infections, and is commonly referred to as pus. Below is a photo of a client with exudate.

   **Treatment:** Clean the wound with an antiseptic solution and place a dry dressing on it.
2. **Device displacement**

Device displacement is when the device moves from the position in which it was placed. This could happen spontaneously in case where an incorrect placement, in particular an invagination, was performed. In such cases, the device could be displaced during an erection.

In most of the cases, however, the device gets displaced during manipulations by the client or a third party such as during sex or masturbation or deliberate removal.

**Figure 40. Example of Outcomes of Device Displacement**

To mitigate such risks, it is essential to explain to the patient that he should not move the device even if he experiences pain or discomfort and that he should not masturbate or have sex.

If there’s displacement of the device with or without edema, the patient should return to the clinic as soon as possible and the provider should perform surgical circumcision to avoid complications.

3. **Pain**

The client may experience pain when the device is on the penis, but could also experience it during or after removal of the device. Scenarios likely to cause pain include:

During placement:
- When inserting the inner ring too hard or deep
- Stretching the foreskin too widely

Mild to strong pain mostly occurs during removal when:
- The penis is swollen
- The wound is fully exposed
- Touching the inflamed area
- Pulling the foreskin with the forceps during cutting
- Cutting the elastic ring; often followed by a feeling of relief
- Extracting the inner ring
- First dressing is being removed

If the client experiences pain at home, he should take the supplied painkillers. If the pain is uncontrollable, the patient should be advised to return to the MC clinic to be evaluated and clinically managed. Pain medication stronger than the routinely prescribed ibuprofen may then be considered, ranging from a topical lidocaine cream/spray to injectable anesthesia through a dorsal penile nerve block, in rarer cases.

4. **Disturbance of urine flow**
   The client may notice a change or difficulty in their voiding. This could be caused by incorrect placement, for example, one of the device parts may obstruct the urethral outlet. For clients who have a long foreskin, the tip may close during necrosis. The clients should be advised to gently stretch the foreskin, without manipulation of the device.

There are also some other possible risks that may occur such as:

- If the inner ring is not pushed all the way down to the sulcus level, this may lead to insufficient skin removal.
- If the circumcision line is not marked according to the recommendations, this may lead to removal of too little or too much skin.
- Penile injury during foreskin removal due to the incorrect use of the wire scissors.

For VMMC programs, providers MUST classify AEs that clients present with according to the severity and these must be recorded on the client record forms.

The table below highlights the classification criteria for the commonly documented AEs and device hazards
## Classification of AEs and Device Hazards

### Table 2. Classification of AEs and Device Hazards

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Description</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Pain score of 8 or more not requiring anesthesia</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Requires anesthesia</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Not controlled by additional anesthesia</td>
<td>Severe</td>
</tr>
<tr>
<td>Difficulty in applying the device</td>
<td>Could not apply device; determined as contra indicated; no harm to tissue or subject</td>
<td>No AE</td>
</tr>
<tr>
<td></td>
<td>Had to push unusually hard, but no harm to tissue or subject and no change to procedure</td>
<td>No AE</td>
</tr>
<tr>
<td></td>
<td>The device cut through the foreskin, with or without minor bleeding, no change in procedure</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>The device cut through the foreskin, with or without minor bleeding, and requiring a change to surgical method</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>The device cut through the foreskin, causing significant bleeding and requiring a change to surgical method</td>
<td>Severe</td>
</tr>
<tr>
<td>Pain / Discomfort</td>
<td>Not requiring intervention beyond painkiller or anesthetic cream</td>
<td>Not AE</td>
</tr>
<tr>
<td></td>
<td>Requiring early device removal by PrePex operator or by client</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Requiring early device removal and anesthesia</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Not controlled by device removal or additional anesthesia</td>
<td>Severe</td>
</tr>
<tr>
<td>Device displacement / spontaneous detachment</td>
<td>Device displacement with no clinical consequences, or complete spontaneous detachment, or patient removed device himself with no adverse clinical consequences</td>
<td>Not AE</td>
</tr>
<tr>
<td></td>
<td>Device displacement requiring replacement</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Device displacement requiring surgical intervention</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Displacement or detachment and penile damage present</td>
<td>Severe</td>
</tr>
<tr>
<td>Early device removal (i.e., 4 days or less with the device)</td>
<td>Device removed due to pain, swelling or bleeding</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Device removed due to pain, swelling or bleeding requiring surgical intervention</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Device removed and penile damage present</td>
<td>Severe</td>
</tr>
<tr>
<td>Adverse Event</td>
<td>Description</td>
<td>Severity</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Edema</td>
<td>More edema than usual, but not causing any discomfort to the patient</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Moderate edema causing the patient discomfort, though managed with conservative measures</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Severe edema, causing the patient discomfort, uncontrolled with conservative measures</td>
<td>Severe</td>
</tr>
<tr>
<td>Hematoma</td>
<td>Mild contained hematoma, not requiring any treatment</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Hematoma requiring surgical drainage/exploration but no evidence of active bleeding</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Rapidly expanding hematoma suggesting active bleeding requiring surgical exploration or referral</td>
<td>Severe</td>
</tr>
<tr>
<td>Pain</td>
<td>Pain score of 6 or less lasting for less than 2 minutes</td>
<td>Not AE</td>
</tr>
<tr>
<td></td>
<td>Pain score of 8 or more lasting for over 2 minutes</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Requires anesthesia</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Not controlled by additional anesthesia</td>
<td>Severe</td>
</tr>
<tr>
<td>Excessive bleeding</td>
<td>More bleeding than usual, but easily controlled</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Bleeding that requires suture to control</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Blood transfusion or transfer to another facility for management required</td>
<td>Severe</td>
</tr>
<tr>
<td>Edema</td>
<td>More edema than usual but not causing any discomfort to the patient</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Moderate edema causing the patient discomfort, though managed with conservative measures</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Severe edema, causing the patient discomfort, uncontrolled with conservative measures</td>
<td>Severe</td>
</tr>
<tr>
<td>Hematoma</td>
<td>Mild contained hematoma, not requiring any treatment</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Hematoma requiring surgical drainage/exploration, but no evidence of active bleeding</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Rapidly expanding hematoma suggesting active bleeding requiring surgical exploration or referral</td>
<td>Severe</td>
</tr>
<tr>
<td>Adverse Event</td>
<td>Description</td>
<td>Severity</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Infection</td>
<td>Pain and erythema with no obvious swelling</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Painful swelling with erythema or elevated temperature or purulent wound discharge</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Cellulitis or wound necrosis</td>
<td>Severe</td>
</tr>
<tr>
<td>Device removal difficulties</td>
<td>Difficult removal, with pain score of 8 or more lasting for over 2 minutes</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Difficult removal, with abrasion of shaft or glans</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Difficult removal, requiring injection of local anesthetic or requiring up to three sutures post-removal</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Difficult removal, requiring more than three sutures</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Difficult removal, with penile damage</td>
<td>Severe</td>
</tr>
<tr>
<td>Damage to the penis</td>
<td>Mild bruising or abrasion, not requiring treatment</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Bruise or abrasion to the glans or shaft of the penis requiring pressure dressing or surgery to control</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Portion or all of the glans or shaft of the penis severed</td>
<td>Severe</td>
</tr>
</tbody>
</table>

**Chapter Summary:**
- There are some events that will occur following PrePex circumcision that are expected, which are usually referred to as side effects. However, any unexpected event following PrePex circumcision shall be treated as an AE.
- AEs are classified according to their severity as mild, moderate, or severe.
- Most AEs are easily managed and do not require referral to centers outside of where the MC was performed.
- AEs include site bleeding, swelling, device displacement, pain, infection and disturbance of urine flow, differential sloughing of the foreskin layers.
Chapter 8: Basic Infection Prevention Concepts

Chapter Objectives:
At the end of this chapter, participants should be able to:
1. Describe the standard precautions in infection prevention.
2. Understand the steps involved in instrument processing.
3. Explain proper waste management practices.
4. Discuss PEP following injury during MC.

Introduction
Health care workers should follow recommended practices for preventing infection in order to protect themselves, other health care workers, and their patients from exposure to HIV and other infections. Below are recommended infection prevention practices.

- Wash hands with soap and water after each procedure; otherwise, use an alcohol-based handrub. 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.

- Wear appropriate personal protective equipment to protect clients and staff from infectious microorganisms.

- Wear sterile gloves during circumcision procedures or when performing any invasive procedure. A new pair of gloves should be worn for each new client contact in order to avoid spreading infection from person to person. During the placement of the PrePex device, however, non-sterile gloves are used.

- Train all staff in the proper handling of sharp instruments. Hypodermic (hollow-bore) needles can cause injuries to clinic staff at all levels: workers can be stuck by hypodermic needles during patient care, cleaning, and housekeeping. Staff may be exposed to needle-stick and sharps injuries when washing soiled instruments and disposing of infectious waste material.

- When handling contaminated items support staff should wear clean or heavy duty gloves.

- Instruments and other reusable items can transmit diseases if not properly decontaminated, cleaned, sterilized, or subjected to high-level disinfection.

- High-level disinfection destroys all microorganisms, except some bacterial endospores. Sterilization destroys all microorganisms, including bacterial endospores.

- Proper waste management is important for preventing accidental injury to people who handle waste items and for preventing the spread of infection to health care workers and the local community.

- Post-exposure prophylaxis (PEP) for HIV with antiretroviral drugs may reduce the risk of infection after exposure to HIV. It will be effective only by starting it as soon as possible, within 72 hours after exposure, and by adhering to the full course of treatment.

- PEP for hepatitis B with immune globulin can reduce the risk of hepatitis B infection. Consideration should be given to vaccinating all health workers against hepatitis B.
Basic Concepts

Infection prevention measures in MC programs have the following primary objectives:

- Prevent infections in men having surgical procedure.
- Minimize the risk of transmitting HIV and other infections to clients and health care staff, including cleaning and housekeeping staff.

A major concern in MC programs is the potential transmission of blood-borne pathogens, such as HIV and hepatitis B and C viruses, to health care workers or patients. The risk of acquiring HIV from an HIV-infected person through a needle-stick injury is estimated at 0.3% (3 HIV infections for every 1,000 injuries). The risk of acquiring hepatitis B virus infection, after being stuck with a needle that has been used on a person with hepatitis B infection, ranges from 6% to 37%, with an average of 18%. Finally, the risk of acquiring hepatitis C infection after being stuck with a needle that has been used on a person infected with hepatitis C is 1.8%.

Most instances of transmission of infection in health care facilities can be prevented through the application of standard precautions. In the circumcision clinic, standard precautions, as described below, should be applied to all clients at all times, regardless of their infection status.

Standard Precautions

Standard precautions are practices aimed at preventing and controlling infection. They include the use of personal protective equipment, designed to protect health care workers and patients from contact with infectious agents.

Remember the following points:

- The minimum requirement is that providers must wash their hands with soap and water or use a handrub after each procedure.
- Alcohol-based handrubs do not remove soil or organic matter. Washing with soap and water is recommended between the use of handrubs.
- Staff who frequently wash their hands or use an alcohol-based handrub should use hand lotions and creams regularly to minimize dryness of the skin and reduce the risk of irritant contact dermatitis. Staff with an allergy or adverse reaction to alcohol-based handrubs should use other handrubs or soap and water. If potentially infectious blood or other body fluid is splashed on non-intact skin, or if there is a potentially infective percutaneous injury, do not use alcohol-based solutions or strong disinfectants. Instead, wash the affected area with water and soap and seek advice on the need for PEP.

Hand hygiene is a requirement for PrePex procedures as it applies to other procedures.
Personal Protective Equipment

Personal protective equipment (PPE) provides a physical barrier against microorganisms, helping providers to prevent the contamination of hands, eyes, clothing, hair, and shoes, and the transmission of infections to patients and other staff. PPE includes gloves, masks, protective eyewear (face shield or goggles), cap or hair cover, apron, gown, and footwear (boot or shoe covers).

PPE should be used by health care workers who provide direct care to patients; support staff, including medical aides, cleaners, and laundry staff; and family members who provide care to patients. The ensemble of PPE worn by staff should be appropriate to the level of potential exposure (to both staff and patients). Reusable PPE (e.g., plastic aprons) should be decontaminated according to the manufacturer’s instructions or laundered according to the protocol of the health care facility.

Generally, for MC procedures, the following PPE is recommended.

Gloves: The use of gloves does not replace the need for hand hygiene by either handwashing or use of handrubs. Gloves should be worn during and after each procedure. Gloves should not be reused to provide care to more than one patient.

Masks (optional): Masks protect the mucous membranes of the mouth and nose from possible infections, as well as reducing the risks of transmission of infections from the health care worker. They should be worn by anyone undertaking a procedure that is likely to generate splashes of blood, blood products, and body fluids. Surgical masks are designed to resist fluids and are preferable to cotton or gauze masks. The use of masks is optional as their benefit during minor procedures is questionable.

Aprons: Aprons made of rubber or plastic provide a waterproof barrier to keep contaminated fluids off of the health worker’s clothing and skin. Staff should wear aprons when cleaning instruments and other items used for patient care.

Immunizations

Certain vaccines, e.g., hepatitis B vaccine, can be useful in protecting health care workers against diseases that they may be exposed to during their work. Follow the protocols of health facility regulations on immunization.
# Table 3. WHO Immunizations Guidelines for Clients against Tetanus

<table>
<thead>
<tr>
<th>Tetanus vaccination status of clients to be circumcised (assumed to be unknown at the individual level though it should be queried and when available vaccination should be based on individual history)</th>
<th>Level of protective immunity provided to the individual</th>
<th>Options for TTCV of the individual prior to circumcision procedure</th>
</tr>
</thead>
</table>
| **1.** In countries or subnational areas where clients are **likely to be fully vaccinated** against tetanus (based on population policies and coverage levels), including:  
  - all 3 infant doses of TTCV, plus 2 to 3 subsequent TTCV boosters OR  
  - 2 doses of TTCV in adolescence or adulthood, with a third dose in the past 5 years | Clients likely have protective immunity | No need for a further booster dose of TTCV prior to VMMC, but a dose could be provided for longer-term protection |
| **2.** In countries or subnational areas where clients are **likely “primed”** against tetanus (based on population policies and coverage levels), meaning they have had at least 1 previous dose of TTCV | 1 TTCV booster at the time of VMMC cannot assure protective immunity against tetanus, but may contribute to protection from disease or reduced severity of disease | • Ideally, provide the single TTCV booster dose 14 days prior to VMMC  
• At a minimum, provide a TTCV booster dose at the time of VMMC |
| For longer-term protection against tetanus from any wound, encourage VMMC clients to return for the VMMC follow-up visit at 4 to 6 weeks and provide another dose of TTCV; encourage a booster dose after 1 year |
| **3.** In countries or subnational areas where clients are **likely “not primed,”** also known as vaccine naive (based on population policies and coverage levels), meaning they have never received any TTCV | An individual likely has no protective immunity against tetanus | Provide 2 TTCV doses at least 28 days apart. **On first encounter, provide a first TTCV dose**  
• Ideally provide the second TTCV dose at least 14 days prior to VMMC  
• If the second TTCV dose is provided at the time of VMMC, limited protection may be provided during the first week post VMMC while antibody levels are increasing |
| At a minimum, provide a TTCV dose at the time of circumcision, recognizing that no protection is provided with only one dose |
| For longer-term protection, encourage individual to receive a third dose in 6 months and additional doses subsequently 1 year apart |

---

**PrePex Reference Manual**
Safe Handling of Sharps

All clinic staff should be trained in the safe handling of sharp instruments. Hypodermic (hollow-bore) needles are the most common cause of injuries to all types of clinic workers.

- Health care workers are most often stuck by sharps during patient care.
- Cleaning staff are most often stuck by sharps when washing soiled instruments.
- Housekeeping staff are most often stuck by sharps when disposing of infectious waste material.

Disposal of Sharps

Sharps should be disposed of into clearly labelled, puncture-proof, and tamper-proof sharps safety boxes or containers. These are a key component in efforts to keep injuries from disposable sharps to a minimum. General points in the correct use of sharps containers:

- 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, where people might accidentally put their hands into them.
- Attach containers to walls or other surfaces, if possible, at a convenient height, so that staff can use and replace them easily.
- Mark the containers clearly so that people will not mistakenly use them as rubbish bins.
- 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.
- Never attempt to empty a sharps container.

Processing of Instruments, Environmental Cleaning and Management of Spills

Soiled instruments and other reusable items can transmit infection if they are not properly reprocessed. Effective and safe reprocessing includes decontamination of instruments and equipment immediately after use, cleaning to remove all organic matter and chemicals, and high-level disinfection or sterilization of instruments used in normally sterile critical sites, i.e., within the body, in sterile tissue, cavities, or the bloodstream. Before sterilization, all equipment must be decontaminated and then cleaned to remove debris. Sterilization is intended to kill living organisms. Disinfectant solutions are used to inactivate any infectious agents that may be present in blood or other body fluids. They must always be available for cleaning working surfaces, equipment that cannot be autoclaved, and non-disposable items, and for dealing with any spillages involving pathological specimens or other known infectious material.

For decontamination, used instruments should routinely be soaked in a chemical solution (0.5% chlorine) for 10 minutes before cleaning. Decontamination decreases the viral and bacterial burden of an instrument but does not clean debris from the instrument or sterilize it. The purpose of decontamination is to reduce the risk to those who have to handle the instruments during further cleaning. Decontamination is not a sterilizing process and must not be used as a substitute for sterilization.
There are many disinfectant solutions and their effectiveness varies. In most countries, the most widely available disinfectant is sodium hypochlorite solution (commonly known as bleach or chloros, JIK), which is a particularly effective antiviral agent.

For cleaning, all used instruments and equipment must be treated with detergent and water before being subjected to high-level disinfection or sterilized. Otherwise, organic matter may prevent adequate contact with the disinfectant or sterilizing agent. Organic matter may also bind and inactivate chemical disinfectants.

Instructions for manual cleaning:

- Wear thick household or utility gloves.
- Wear protective eyewear, mask, and plastic apron, if available, to prevent contaminated fluids from splashing into your eyes or onto your body.
- Use liquid soap, if available. Do not use abrasive cleaners or steel wool, especially on metal (they cause scratches and increase the risk of rusting).
- Using a soft brush, scrub instruments under the surface of the water to prevent splashing, paying particular attention to any teeth, joints, or screws.
- Rinse the instruments with clean water.
- Dry the instruments with a towel or allow them to air-dry.

High-Level Disinfection

High-level disinfection destroys all microorganisms except some bacterial endospores. It is usually used for heat-sensitive instruments and equipment that is used in critical sites, but cannot be sterilized. High-level disinfection is the only acceptable alternative to sterilization for heat-sensitive surgical instruments. There is no single ideal disinfectant. Different grades of disinfectant are used for different purposes. However, glutaral (glutaraldehyde) is generally the most appropriate chemical for high-level disinfection. It must be used under very strictly controlled conditions, in a safe working environment, and the manufacturer’s handling instructions must be strictly followed.

In situations where sterilization is not possible for equipment used for circumcision, high-level disinfection is the next best acceptable method of instrument processing. However, for instruments to be used during PrePex removal, only sterilization is recommended.

Sterilization

Sterilization is the destruction of all microorganisms, including bacterial endospores. Sterilization can be achieved by either physical or chemical methods. It is necessary for medical devices that will be used in sterile body sites and can be achieved using:

- High-pressure steam (autoclave) or dry heat (oven);
Chemicals, such as ethylene oxide or formaldehyde, or glutaraldehyde if left for 10 hours; and
- Radiation.

Sterilization of all surgical instruments and supplies is crucial in preventing HIV transmission.

All viruses, including HIV, are inactivated by high-pressure steam sterilization (autoclaving) for 20 minutes at 121–132°C, or for 30 minutes if the instruments are in wrapped packs.

Items that have been sterilized must be properly stored to ensure that they do not become recontaminated.
- The storage area should be clean, dry, and free of dust and lint.
- The temperature should be kept at approximately 24°C and the relative humidity at less than 70%, if possible.
- Sterile packs and containers should be stored 20–25 cm off the floor, 45–50 cm from the ceiling and 15–20 cm from an outside wall.
- Do not use cardboard boxes for storage of sterile items, as they shed dust and debris and may harbor insects.
- Mark the date of sterilization on the package and use the oldest packages first (i.e., first in, first out). Dates serve as an indicator of when packs should be used, but they do not guarantee the sterility of the packs. It is therefore necessary to examine the general condition of packs.

**Safe Disposal of Infectious Waste Materials**

The purpose of waste management is to:
- Protect people who handle waste items from accidental injury.
- Prevent the spread of infection to health care workers and the local community.

Tips for safe handling and disposal of infectious waste:
- Place waste in plastic or galvanized metal containers with tightly fitting, color-coded covers that differentiate infectious from noninfectious waste.
- Place all disposable sharps in designated puncture-resistant containers.
- Place waste containers close to where the waste is generated in a position convenient for users.
- Ensure that equipment used to hold and transport waste is not used for any other purpose.
- Regularly clean all waste containers with a disinfectant (0.5% chlorine solution), then wash with water and soap, rinse with water only, and allow containers to air-dry.
- When possible, use separate containers for waste that will be treated or that will be disposed of in a particular manner. In this way, workers will not have to handle and separate waste by hand.
Disposing of Sharp Items
Disposable sharp items, such as hypodermic needles, require special handling. They are the items most likely to injure the health care workers who handle them. If these items are disposed of in a municipal landfill they become a danger to people in the community.

Burning Waste Containers
Burning destroys waste, kills any microorganisms, and is the best method of disposing of contaminated waste. It reduces the bulk volume of waste and also ensures that items cannot be scavenged and reused.

Encapsulating Waste Containers
Encapsulation is the easiest way to safely dispose of sharps containers. When a container is three-quarters full, pour cement (mortar), plastic foam, clay or other similar material into it until it is completely full. After the material has hardened, seal the container and dispose of it in a landfill or bury it.

Burying Waste
In health care facilities with limited resources, the burial of waste (such as excised foreskins) near the facility may be the only practical option for waste disposal. To limit health risks and environmental pollution, the following basic rules should be followed:

- Restrict access to the disposal site. Build a fence around the site to keep animals and children away.
- Line the burial site with a material of low permeability (e.g., clay), if available.
- Select a site at least 50 meters 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.

Post-Exposure Prophylaxis
Health care workers may be accidentally exposed to blood and other body fluids that are potentially infected with HIV, hepatitis virus or other bloodborne pathogens. Occupational exposure may occur through direct contact of non-intact skin with potentially infected blood or body fluids, from splashes into the eyes or mouth, or through injury with a used needle or sharp instrument. PEP can help to prevent the transmission of pathogens after such an exposure.
Managing occupational exposure to hepatitis B, hepatitis C, and HIV

The immediate response to exposure to blood or other fluids that are potentially infected with hepatitis B virus, hepatitis C virus or HIV are summarized here (more details should be available in routine standard protocols in a facility).

**Step 1:** Provide immediate first-aid care to the exposure site:

- If a splash or a spill occurs on the skin, wash the area immediately with soap and water. Do not use caustic agents, alcohol, or bleach because they will irritate the skin and may increase the risk of infection. Do not apply a dressing.
- If a splash or a spill occurs in the eyes, nose, mouth, or on any mucous membrane, rinse the area with clean water for at least 10 minutes.
- If an injury has been caused by a potentially contaminated sharp, wash the area with soapy water and allow the wound to bleed freely (do not squeeze) for a while. Then give normal first aid.

**Step 2:** Evaluate the risk by determining the type of fluid (blood, visibly bloody fluid, or other potentially infectious fluid), the severity and type of exposure (percutaneous or needle-stick, mucous membranes, intact, or non-intact skin) and the source of infection.

**Step 3:** If the source person is identified, it is important to obtain information on her or his hepatitis and HIV serostatus, and, if positive, to conduct an evaluation of the clinical status and treatment history:

- Assess the risk of infection, using available information.
- The source person may be tested only with her or his informed consent.
- Do not test discarded needles or syringes for virus contamination.
- After the result, refer the health care worker to receive PEP if available in the same facility (according to national guidelines). The client should be linked to care and treatment services if this is the first time.

**New Updates on Wound Care from WHO Consultation Meeting on VMMC and Tetanus (March 2015)**

- There needs to be careful attention to clean care of the wound after circumcision. This includes clear and understandable wound care and genital hygiene instructions, return to a medical facility for the removal of dressings, re-evaluation of wound healing progress, and clear instructions about returning to the health care facility for post-procedure care, and, in particular, urgently when specific symptoms suggestive of tetanus or other infections are noted.
- Community education about the dangers of applying potentially *C. tetani* containing substances (such as animal dung poultices, herbal remedies) to wounds should be undertaken as well as an assessment of local wound care practices.
For clients being circumcised with the PrePex device:

- Providers must fully retract the foreskin without forcing, thoroughly clean and disinfect under the foreskin with povidone-iodine prior to device placement, as noted above; disinfect the skin before cutting away necrotic foreskin, again before removing the elastic and inner rings, and after removal of the rings prior to applying the dressing.

- Clients presenting for device placement on whom full retraction of the foreskin cannot be done easily should be offered conventional surgical circumcision under local anesthesia as this will allow a small dorsal slit to be made and any adhesions to be broken to allow proper cleaning and disinfection before the conventional surgical procedure.

**Chapter Summary:**

- Standard precautions must be observed so as to minimize the risk of infection transmission from clients to health workers and vice versa.
- Clients must be assessed for their immunization status against tetanus and if required they should receive tetanus immunization before circumcision with the PrePex device.
- While placement of the device is a clean procedure, the removal procedure should also be done under sterile conditions.
- Sterilization is recommended for the removal of instruments.
- Waste disposal practices are similar to other surgical procedures.
Chapter 9: Monitoring and Evaluation

Chapter Objectives:
At the end of this chapter, participants should be able to:
1. Describe the importance of record keeping for monitoring and evaluation.
2. Describe the characteristics of good data.
3. Describe tools used for record keeping.
4. Demonstrate proper record keeping.
5. Report AEs using standardized forms.
6. Analyze and use data for decision-making.

Introduction
Record keeping is a key responsibility of health care workers in any health facility. The accuracy and completeness of the records provide much-needed data that can be processed to obtain important information to guide program implementation and decision-making. As the old saying goes, “If it is not written down, it did not happen.”

Types of forms and registers used in VMMC vary from country to country and from health facility to health facility. The following are examples of such data collection tools:

- Appointment cards or forms
- Client record forms or case notes
- Counseling register
- Outpatient clinic registers
- Inpatient registers
- Theatre register
- Health facility monthly summary reporting forms
- AE reporting form
- Death reporting form
- Referral forms
- Stock control forms

The clinic manager should ensure that health care providers maintain adequate records on all clients. Records should include information on the identity of the client, the type of service provided, and any special circumstances associated with it. Sample record forms to assist with this task are given in Appendix C.
Ensuring Good Data

A monitoring system will provide useful information only if the data recorded are “good”. Clinic managers should ensure that staff are aware of the following:

- **Understanding the data.** Staff responsible for keeping records should know exactly what information is needed, for example, AEs associated with MC.

- **Recording the data every time.** Every time a staff member performs a procedure, sees a client, prescribes medication, receives a test result, or makes a referral, it should be recorded on the appropriate form.

- **Recording all the data.** All the information requested on the monitoring forms should be completed. This might require noting when a particular treatment was not provided.

- **Recording the data in the same way every time.** The same definitions, rules, and tests should always be used for reporting the same piece of information. In the long term, this may not be possible, as tests and definitions change, treatment evolves, and new technologies are developed. When it is not possible to record data in the same way, a note should be made describing the change.

It is also important for the health manager to periodically work with clinic staff to analyze data collected, interpret the findings, and provide feedback to the staff while using the information for decision-making. For example, if data analysis shows a higher than expected incidence of AEs compared to other VMMC sites, the information will serve as a basis for following up the critical steps of the VMMC procedure to identify procedural errors that may have led to this increase. Correction of such identified errors may later show a decline in the incidence of such AEs.

As a second example, if quarterly analysis of service utilization data reveals a declining patronage of the health facility, this may alert the health manager to investigate the likely reasons for such a decline. Subsequent root cause analysis may reveal a cause that can be remedied (e.g., stock-out of supplies, shortage of human resources, long waiting times, etc.) to correct the situation.

Electronic Data Storage and Reporting of Data

In some setups, electronic data storage is used. The purpose is to ensure that VMMC data are secured and easily shared among program personnel. This also facilitates easy reporting and analysis for decision-making. In addition, data stored electronically are handy during VMMC program evaluation.

Monitoring

**Monitoring is the routine assessment (e.g., daily, monthly, quarterly) of information or indicators related to ongoing activities.**
Monitoring helps to:
- Track progress toward program targets or performance standards; and
- Identify aspects of the program that are working according to plan and those that are in need of adjustment.

**Evaluation**

*Evaluation is the measurement of how much things have changed as a result of the interventions implemented.*

There are, of course, many factors that can cause things to change. A formal evaluation tries to demonstrate how much a specific intervention contributed to an observed change.

**Why do we need to monitor and evaluate VMMC programs?**

The purpose of monitoring and evaluating a MC program is to:
- Assess progress made at particular points in time;
- Assess progress towards set objectives;
- Detect non-compliance with set policies, guidelines, and performance standards;
- Quickly identify any threats to patient safety;
- Provide feedback on whether targets are being met;
- Identify reasons for successes and failures; and
- Provide a basis for future planning.

**Monitoring Systems**

Collecting information to track indicators requires the collaboration of dedicated and knowledgeable staff. Obtaining and reporting the required information represent an extra burden of work, and may even be impossible unless an effective monitoring system is in place. This implies:
- All those involved know what information is needed and by whom.
- The tools needed to collect the information are available.
- All those involved know how and when to report the information.
- One person is responsible for making sure the system is working by ensuring that indicators are up to date, records are being properly kept, and data are reported to appropriate partners.
The person responsible for the monitoring system must keep clinic staff informed about what needs to be recorded and reported. He or she must also adjust monitoring tools to reflect the information required.

**Monitoring Performance in Male Circumcision Programs**

Figure 41 is a graphic representation of how monitoring through routine data collection can help identify how program performance (represented by the thick arrow) relates to program objectives, using as an example the cumulative number of circumcisions performed per month.

**Figure 41. Monitoring and Evaluation of Program Performance in Relation to Program Objectives**

**Methods of Evaluation**

Evaluation can be done by:

- Reviewing available records and reports (client record forms, clinic register, theatre register, AE forms, drug inventory forms, referral forms, etc.);
- Conducting supervisory assessments;
- Having staff conduct self-assessments;
- Conducting peer assessments;
- Obtaining feedback from clients (e.g., through exit interviews); surveying community perceptions of the service; and
- Comparing the clinic’s services with those of other facilities.
The development of a functional monitoring system is a responsibility of the Ministry of Health; however, effective implementation involves full participation of managers, monitoring and evaluation staff, and clinicians. Data that require strict confidentiality should be treated as such.

**Using Monitoring Information for Intervention-Related Decision-Making**

In the context of record keeping and monitoring, information is good only if it can be used. Data that cannot be used should not be collected. Each and every facility should be able to analyze the data and utilize the information for decision making to improve the quality of the services.

**Chapter Summary:**

- VMMC site has a number of responsibilities.
- These responsibilities include:
  - Ensuring that good quality data are correct, complete, and consistent;
  - Records are safely stored;
  - Ensuring quality of services provided; and
  - Ensuring secure maintenance of confidential and sensitive information.

- Clinic staff should periodically analyze their own data for decision-making and to improve the quality of services being provided.
Appendix A. Sample Group Education Guide

Below is a sample script that shows how a group education session might be conducted. The script should be adapted to the specific situation in the clinic or region. The text in italics contains instructions for the group educator.

Hello, my name is____________________, and I am a______________________ here at this clinic. As you may know, at this clinic we provide the following services for men and give you some more information regarding VMMC:

- Information and education on MC (including the management of post-operative complications);
- MC for men who choose to have the procedure;
- Information and counseling on sexual intercourse, safer sex, and health problems related to the reproductive system;
- Diagnosis and management of sexually transmitted infections;
- Counseling and testing for HIV and AIDS and referral for care and support;
- Contraceptive methods, such as pills, injectables, vasectomy, tubal ligation, used with condoms, prevent both pregnancy and infections (dual protection);
- MC offers partial protection, thus using condoms correctly and consistently, reducing the number of sexual partners, delaying the start of sexual relations, avoiding penetrative sexual intercourse, and avoiding unsafe injections is important;
- MC like any other surgical procedure can be associated with adverse events or complications though we do everything we can to reduce this risk;
- We always advise clients to avoid sexual intercourse or masturbation for the first 6 weeks after circumcision, and to use a condom during sexual intercourse until the wound has completely healed (at least 6 months). It is always best to use a condom whenever there is any risk of HIV infection.
- At this clinic, both surgical and PrePex MC can be performed as a day procedure, with the provision of medication to relieve any pain;
- Explore any existing myths, for example, the PrePex procedure is associated with castration of animals because of the elastic ring; other people think that circumcision can cause or cure impotence (failure of erection) or reduce sexual pleasure; and
- Ask if anyone present has any question?

Summary
We have talked about the different services that are available for you today. What services are of interest to you today? If you are worried that you may be infected with an STI or HIV, or if you want to be tested, counseling and testing services are available here, too. If you want to register yourself or your son for circumcision, please let us know. We will be very pleased to assist you in any way you wish.

Please take some of the information leaflets we have here. They may answer other questions that you may have. Thank you for your attention.
### Appendix B. Screening Guidance

<table>
<thead>
<tr>
<th>Check</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Abnormal <strong>structure</strong> of the penis and foreskin?</td>
<td></td>
</tr>
<tr>
<td>2. Genital rash, sores, redness, or warts?</td>
<td></td>
</tr>
<tr>
<td>3. Squeeze the head of the penis. Is there a discharge?</td>
<td></td>
</tr>
<tr>
<td>4. Any abnormal swelling on the penis or scrotum?</td>
<td></td>
</tr>
<tr>
<td>5. Pull foreskin sideways gently. Flexible enough for PrePex?</td>
<td></td>
</tr>
<tr>
<td>Wide enough to insert the inner ring?</td>
<td></td>
</tr>
<tr>
<td>6. Pull back the foreskin and then let it go. Does it return to its natural position?</td>
<td></td>
</tr>
<tr>
<td>7. Pull back the foreskin and examine the frenulum. Do you notice any adhesions or other abnormality?</td>
<td></td>
</tr>
</tbody>
</table>
Appendix C. Client Record Forms

Name of site/health facility:

**PERSONAL DETAILS:**

1. Client’s names: ________________________________

2. Visit date: ___/___/_____

3. Code number in HTC if applicable: ____________

4. Code number in MC register: ________________

5. Date of birth: _____/_____/_____
   Age ______ years

6. Patient’s ID: ____________________________

7. Marital status:
   a=Single, b=Married, c=Cohabiting, e=Divorced/Separated, f=Widowed

8. Address: ________________________________
   District: ________________________________
   Sector: ________________________________
   Cell: ________________________________
   Village: ________________________________
   Phone: ________________________________

9. Names of contact family: ________________________________
   Phone: ________________________________
   Relationship: Spouse, Parent, Others:

10. Education: None, Primary, Secondary, University

11. Occupation/Function: ________________________________

17. Current medications: __________________________

18. Ever Had sex: Yes / No;
   used condom: Yes / No

19. HIV history (today or within 90 days):
   Tested: Yes / No
   If yes, Date: ____/_____/_____
   where: ________________________________

20. HIV status if positive: CD4 count: ____________

21. Client given results: Yes / No

**CLINICAL HISTORY AND SCREENING:**

22. Does the client have any of the following complaints?
   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 foreskin: Yes / No
   g. Genital warts: Yes / No
   h. Others: Yes / No

23. Any bleeding problems in self or other family members? Yes/No

24. Has the client had any STIs in the last 3 months?
   Yes / No (if yes, specify condition and whether treated and where) ________________________________

25. Is patient under treatment for any of the following?
   Hypertension: Yes / No
   HIV/AIDS: Yes / No
   Diabetes: Yes / No
   Other: ________________________________

26. Has client ever had any surgical operation?
   Yes / No
   If yes, what: ________________________________
   and when: ___/_____/_____
   Any complications related to that surgery? ________________________________

27. Blood pressure: / __ mmHg.
MEDICAL HISTORY:

12. Smoker: Yes / No; if yes, number per day: ______
   Alcohol: Yes / No; if yes: bottles per day: ______

13. Allergies (drugs, rubber): ________________

14. History of headaches: Yes / No
   Fever: Yes / No

15. Any wound: Yes / No; if yes where ______

16. Tetanus immunization status: Yes / No

28. General examination findings
   Pallor: Yes / No
   Wasting: Yes / No
   Jaundice: Yes / No
   Lymphadenopathy: Yes / No
   Leg edema: Yes / No
   Check for any wound:

29. Genital examination:
   Penis: Normal / Abnormal, specify

30. Is client suitable for MC: PrePex / Surgery / C.I

31. Has client or a guardian signed an informed consent for MC?
   Yes / No

32. Booking for MC: Date: _____/_____/_____

HIV status: Pos/ Neg/ Indeterminate (no test, known HIV +)
Spouse notified Yes / No
Spouse tested: Yes / No

If contraindication, describe the reason(s): __________________________________________________________
<table>
<thead>
<tr>
<th>PrePex Method</th>
<th>Surgical Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. PrePex Placement Procedure</strong></td>
<td><strong>1. Operative notes</strong></td>
</tr>
<tr>
<td>Placement Date: <em><strong><strong>/</strong></strong></em>/_____</td>
<td>Date: <em><strong><strong>/</strong></strong></em>/_____</td>
</tr>
<tr>
<td>Placement Team: __________________</td>
<td>MC surgeon: __________________</td>
</tr>
<tr>
<td>Operator: __________________</td>
<td>Assistant: __________________</td>
</tr>
<tr>
<td>Assistant: __________________</td>
<td>Start time: ______  End time: ______</td>
</tr>
<tr>
<td>PrePex Size: ___  PrePex Lot: ___</td>
<td>Premedication: __________________</td>
</tr>
<tr>
<td>Start time: _____  End time: _____</td>
<td>Amount of local anesthesia used: __________</td>
</tr>
<tr>
<td>Dermal cream used: 5%lidocaine/ EMLA/Other specify __________________</td>
<td>Suture: chromic/vicryl/plain gut/other</td>
</tr>
<tr>
<td>Disinfectant used: __________________</td>
<td>Type of MC procedure: dorsal slit / forceps guided</td>
</tr>
</tbody>
</table>

**2. Post PrePex placement discharge session**

Discharge session performed: Yes/ No  
Blood pressure: ___/___  
Pulse: ____  
Provided: Leaflet: Yes / No  
Ibuprofen: Yes / No

**3. PrePex removal Procedure**

Removal date: _____/_____/_____  
Removal team: __________________  
Operator: __________________  
Assistant: __________________  
Blood pressure: ___/___  
Pulse: ____  
Temperature: ____  
Provided: Leaflet: Yes / No  
Ibuprofen tablets:Yes/ No

Blood pressure: ___/___  
Pulse: ____  
Postoperative medications: __________  
Complications: Yes/No  
If yes specify: __________  
Complications: Yes/No  
Fill out the form for AE  
Anticipate place of follow-up within 2 days: __________________
<table>
<thead>
<tr>
<th><strong>PrePex Method</strong></th>
<th><strong>Surgical Methods</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Complication (AE) information</td>
<td>3. Follow up visit 48 hours after MC surgically</td>
</tr>
<tr>
<td>Where any complication (AE) observed or reported: Yes / No</td>
<td>Date: <em><strong>/</strong></em>/_____</td>
</tr>
<tr>
<td>If yes specify: ____________________________</td>
<td>Name of HF: ____________________________</td>
</tr>
<tr>
<td>Timing: Placement, during device wearing, removal visit, post-removal visit</td>
<td>Blood pressure: <em><strong>/</strong></em></td>
</tr>
<tr>
<td>Date: <em><strong>/</strong></em>/_____</td>
<td>Pulse: ____</td>
</tr>
<tr>
<td>Fill out the AE report form</td>
<td>Temperature: ____</td>
</tr>
<tr>
<td></td>
<td>MC wound information:</td>
</tr>
<tr>
<td></td>
<td>Clean / Infection / Scabby / Bleeding</td>
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<td>5. Follow up 48 hours after PrePex removal</td>
<td>If yes, fill out the form for AE</td>
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<td>Date: <em><strong>/</strong></em>/_____</td>
<td>Names of MC provider: ____________________________</td>
</tr>
<tr>
<td>Name of HF: ____________________________</td>
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<td>Blood pressure: <em><strong>/</strong></em></td>
<td>Blood pressure: <em><strong>/</strong></em></td>
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<tr>
<td>Pulse: ____</td>
<td>Pulse: ____</td>
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<tr>
<td>Temperature: ____</td>
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<td>MC wound information:</td>
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<tr>
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<td>Clean / Infection / Scabby / Bleeding</td>
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<tr>
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<td>History of: Headache: Yes/No</td>
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<tr>
<td>Fever: Yes/No</td>
<td>Fever: Yes/No</td>
</tr>
<tr>
<td>Complications: Yes/No</td>
<td>Complications: Yes/No</td>
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<td>If yes, fill out the form for AE</td>
<td>If yes, fill out the form for AE Treatement provided:</td>
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<td>Names of MC provider: ____________________________</td>
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Appendix D. Important Information on Placement of the PrePex Device

Important information about wearing your PrePex device

If you have a wife or girlfriend, show her this leaflet.

What is PrePex circumcision?
Male circumcision is a medical procedure to remove the foreskin of the penis. This helps protect you from HIV and other sexually transmitted infections. PrePex is a special device used to conduct circumcision.

When you get circumcised with the PrePex device, you will come to the circumcision center two times:

At the first visit, the PrePex device is placed on the penis. After a few days, the foreskin becomes dry and dead.

Seven days later, you will return to the circumcision center to remove the PrePex device and the dead foreskin.

PrePex circumcision is done by a well-trained nurse in a few minutes.

What can I expect when wearing the PrePex device?
In the first few hours and days, the foreskin will feel completely numb. It will become darker, gradually becoming black and dry.

Parts of the foreskin might become separated from the penis about 5 to 7 days after the PrePex placement.

While wearing the PrePex device:
4. No sex or masturbation at all when device is on
5. Do not touch the device, not even through your clothes
6. Do not try to remove the device
7. Wash your penis as usual
How do I take care of my penis when wearing the PrePex device?

Come back to the hospital exactly 1 week after placement. If you return later, it will be more painful to remove.

Do not have sex or masturbate at all while you are wearing the PrePex device, not even with a condom.

Do not touch the device at all, even if it is hurting or uncomfortable. Contact your provider with any concerns.

You can urinate as usual and have erections while wearing the PrePex device. Just do not touch the PrePex device.

Wash and dry your penis carefully.

Wash your penis as usual on the outside but do not get water inside.

Do not try to retract the foreskin and clean the inside. Note that dry urine may cause a mild smell. This is normal.

If you feel any pain, take the pain reliever given to you. Take it on a full stomach.

If the PrePex device moves out of place, immediately contact the circumcision center.

Locate your penis in an up position whenever you can (shift your penis up inside your pants).

There are very few problems with PrePex circumcision. Come back to the clinic immediately if you have any of these problems:

Severe pain
Swelling on penis or testicles
Difficulty urinating (passing water)
A wound or bleeding on the penis
Any health problem that worries you, even if it has nothing to do with the circumcision (e.g., dizziness, headache, fever, pain, pain in lower stomach area, stiffness).

Phone or come to the circumcision center if you have questions.
Appendix E. Important Information after Removing the PrePex Device

If you have a wife or girlfriend, show her this leaflet.

**How do I take care of my penis after PrePex removal?**

The PrePex nurse has now removed your PrePex device and the dead foreskin, and covered the circumcision wound with a protection.

You may not have sex at all for 6 weeks, not even with a condom. If you masturbate, do not touch the circumcision area at all.

**Why no sex for 6 weeks?**

The circumcision area is still new and unhealed. This is the most risky time for HIV and other germs to enter your body if you have sex.

Information

You can urinate and have erections as usual.

The dressing must remain dry.

Keep the protection on your penis for 2 days and then remove it gently.

After removing the protection:

- Wash your penis gently every day with soap and clean water. DO NOT rub soap directly on the circumcision area; instead, make bubbles/foam from soap in your hands and apply it to the circumcision area. Dry your penis carefully.

- Leave the large band of necrotic tissue in place and not remove it. This is your body’s natural protection; it will drop off by itself in time.

- Locate your penis in an up position whenever you can (shift your penis up inside your pants). Be careful not to press on the wound.

- If you have any problems (e.g., pain, bleeding, swelling, fever, stiffness, go to the circumcision center immediately or to any other clinic.

- It is very important to keep the circumcision wound safe from germs and HIV.
**Important**
Talk to your sexual partner. Explain the benefits of PrePex male circumcision for you, your partner, and your community.

Explain that you cannot have sex for the full 6 weeks while your circumcision is healing.

You may not have sex at all for 6 weeks, not even with a condom.
If you masturbate, do not touch the circumcision area at all.

Phone or come to the circumcision center/any other clinic if you have questions or problems.
Appendix F: PrePex User Manual for Authorized and Trained Users

**Patient Preparations:**

1. Scrub the penis shaft, foreskin and scrotum area with antiseptic solution according to local guidelines.
2. Take a new, single use PrePex Sizing Plate (PSP) and select the appropriate size A, B, C, D or E by sliding each one over the glans and placing directly under the coronal sulcus, the appropriate size is the one which fits precisely (Figure 3).
3. Choose PrePex based on the sliding outcome (A, B, C, D or E).

<table>
<thead>
<tr>
<th>Type</th>
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<tr>
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<td>DW0201</td>
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<td>E</td>
<td>34mm</td>
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</table>

**Note** – If the diameter under the coronal sulcus is too large and it cannot fit into the E circle, do not perform the procedure.

**Procedure Preparation**

1. Stretch the foreskin up past the glans and release so the foreskin is in natural position.
2. Mark a circumcision line according to WHO Manual for Male Circumcision under local anesthesia ver 3.1 Dec 2009, using a standard medical skin marker (see figure 4).
3. Pull foreskin down towards body and apply 5% anesthetic cream on the exposed shaft area up to the coronal sulcus.

**Placement Procedure**

4. Place the Elastic Ring on the Placement Ring. Do not remove the Verification Thread. It is intended for correction of Elastic Ring misplacement (see figure 5).
5. Place the Placement Ring (with the attached Elastic-Ring) on penis shaft with the Elastic-Ring side facing away from the body (See figure 6).

**Figure 3**

**Figure 4**

**Figure 5**

The following steps 5 and 6 should be performed by 2 people

6. 1 person should stretch the foreskin up and to the sides for insertion of Inner Ring. Use fingers or a dry gauze for a good grip (See figure 7).

7. Another person should insert the Inner Ring with the flat sides toward the sides through the opening of the foreskin (see figure 8), landing one of the flat sides in the frenulum area. Make sure to push the Inner Ring down.

8. Push the Inner Ring over the glans and place it just below the glans (on the sulcus).
9. Hold the foreskin closed from the tip holding the Inner Ring in place (See figure 9). Advance the Placement Ring toward the glans until the Elastic-Ring is circumferentially just above the Inner Ring groove and that the two rings are aligned.
10. With one hand support the Placement Ring, with the other hand adjust the foreskin so the marked circumcision line is exactly under the Elastic Ring, adjust from beneath each of the 4 legs by pulling the skin downwards (see figure 10).

**Figure 6**

11. To place the Elastic Ring - Push the Elastic Ring off the Placement Ring at each of the 4 sides of each notch of the Placement Ring, use 4 fingers of your left hand to hold the two rings together in the space between each of the 4 legs. Work with the thumb and finger of your dominant hand to release the Elastic Ring from each notch (Figure 11).
12. Make sure the Elastic Ring is mounted directly above the Inner Ring groove and above the circumcision line previously marked. If the Elastic-Ring is not positioned as desired, use the verification thread to pull it off the ring and start the procedure again.

13. Upon proper placement of the Elastic-Ring, remove the Delivery Ring, and cut the verification thread.

14. Instruct the subject on the following when sending him home:
   a. To return for device removal after 1 week
   b. To report any unexpected situation, such as pain or device displacement
   c. Not to touch any part of the Device not even through clothes
   d. Not to pull the foreskin in case partial detachment occurs
   e. To abstain from sexual intercourse when device is on the penis and for 6 weeks after device removal and to avoid masturbation
Foreskin Removal

1. The device is removed 7 days after it has been placed.
2. Remove the foreskin using blunt edge scissors or other standard cutting tool (Figure 12).
3. Use forceps to hold the foreskin
4. Take care not to harm the glans
5. Cut the foreskin as close to the Elastic Ring as possible.

Elastic Ring Removal

1. Warning: Elastic Ring is removed only after the foreskin was cut.
2. Use a sterile scalpel 10 to pierce the Elastic Ring on the area of the flat part of Inner Ring cut as far from the frenulum as you can (Figure 13).
3. Take care not to harm the viable skin.

Inner Ring Removal

1. The Inner Ring is removed after the Elastic Ring.
2. Use sterile spatula.
3. Separate the necrotic foreskin from the Inner Ring all around.
4. Pull out the Inner Ring from one of the curved sides, avoid the frenulum (Figure 14).

Post Removal Procedure

1. Clean the penis with antiseptic solution.
2. Dress the circumcised penis with a standard non-adherent pad.
3. Instruct the patient not to wet the dressing and to remove the dressing in 2 days.
4. Instruct the patient to contact his local care provider in case of pain, infection or fever.
5. Instruct the patient to avoid sexual intercourse for 6 weeks.

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PREPEx User Manual for Authorized & Trained Users Only

Intended use: PREPEx is a single use, disposable device indicated for circumcision of adult men, defined as circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus, with minimum amount of preputial skin remaining.

Contra indications:
- Dermatitis of the penis or foreskin, allergy to rubber or plastic, non-intact skin on the penis, active genital infection, phimosis, paraphimosis, wounds under the prepuce, torn or tight frenulum, hypospadia, any active penile diseases, active infectious disease impairing health, history of bleeding disorders.

Disposal:
- Follow local, state and federal regulations with respect to environmental protection when disposing of used material.

Caution:
- This device is restricted to sale by or on the order of a physician. This device should not be used if the package integrity has been broken. Use by trained personnel only. This device should not be reused at risk of cross contamination.
- This device is intended for adults only and is not applicable for males under the age of 18.

Clinical Experience:
- For information regarding Clinical Trials see: Use of devices for adult male circumcision in public health HAV prevention programmes; Recommendations of the Technical Advisory Group on Innovations in Male Circumcision; March 2012; WHO/HIV/2012.7; World Health Organization Department of HAV/AIDS.

Environmental requirements and storage conditions:
- Storage: -10°C to 50°C, away from direct sunlight.

Overview: PREPEx includes the following items:
- Placement Ring
- Elastic Ring
- Inner Ring
- Verification Thread

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Accessories:
- The PREPEx Sizing Plate (PSP) is intended for single use for selection of appropriate device size.

The use of PREPEx requires additional tools and materials which are not supplied with PREPEx, such as: Disinfectants, Skin marker, Gauze, Anesthetic cream, Wire scissors, Forceps, Spatula, Scalpel, Wound dressing, Utility Scissors and Cather pad, Adhesive strip.

PN-00111-Rev 9, Release 01 Jan 2013
References


6. Teaching Slides; Rwanda Military Hospital PrePex Training Slides.