CHAPTER TWELVE.

VOLUNTARISM & INFORMED CONSENT

PEPFAR’S BEST PRACTICES FOR VOLUNTARY MEDICAL MALE CIRCUMCISION SITE OPERATIONS

A Service Guide for Site Operations
Acknowledgments

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CHAPTER 12.
Voluntarism & Informed Consent

CHAPTER GOALS
To ensure site-level staff are able to:

- Provide accurate and comprehensible information to male clients, spouses of male clients, and guardians of minors seeking VMMC (voluntary medical male circumcision) services to help them make informed decisions.

- Obtain and document the informed consent of males (and guardians of minors) seeking VMMC services.

- Ensure clients are aware of and comprehend the risks and benefits of VMMC and that they choose the services voluntarily and without coercion.

WHAT USERS NEED TO KNOW

SUMMARY
This chapter presents the requirements of the voluntarism and informed consent (IC) process. Specifically covered are the following topics: training site staff on elements and principles of the IC process, administering and documenting IC while ensuring that clients understand the risks and benefits as well as all other information on VMMC procedures, and proper wound care practices. The chapter also discusses issues relating to parental consent and assent for minors, the national age of consent, the role of parents/guardians, obtaining consent from illiterate participants, national policies, international guidelines, and PEPFAR (U.S. President’s Emergency Plan for AIDS Relief) considerations [See UNAIDS Safe, Voluntary, Informed Male Circumcision and Comprehensive HIV Prevention Programming Guidance for Decision-Makers on Human Rights, Ethical and Legal Considerations and PEPFAR Technical Considerations for COP/ROP 2016]. Finally, two case studies are featured: one from Zambia evaluating clients’ comprehension of key concepts, social norms, and practices regarding IC and the other from Uganda on successful use of the IC process to improve the quality of VMMC services [See Evaluation of the Informed Consent Process for Male Circumcision Scale-Up in Zambia]. The chapter cites and refers the reader to many resources for additional reading.

Informed consent is the voluntary agreement of an individual—or his authorized representative who has the legal capacity to give consent—to undergo a specific medical procedure. All VMMC site staff must be trained in the principles of informed consent and the appropriate ways to obtain it. Adult males opting for VMMC have the right to receive full information on the benefits and risks of the procedure. Only adult males who have the appropriate decision-making capacity and legal status (have reached the legal age of consent) are able to give their own informed consent.
A child (as defined by national law) generally lacks the legal status required to provide independent informed consent. However, children and adolescents have the right to participate in decisions affecting their health, and therefore they should provide assent for the VMMC procedure. Those too young to understand the male circumcision procedure and provide assent, or who refuse assent, should have the procedure deferred. Assent is the expression of willingness to undergo a procedure by a person who is by definition (according to his evolving capacity and national laws) too young to give informed consent but who is old enough to understand the procedure. If assent is given, informed consent must also still be obtained from the subject’s parents or a guardian, including providing them (parents/guardians) with sufficient information regarding the benefits and risks of the procedure to determine what is in the best interest of the minor. In countries with laws that allow minors to give independent informed consent, providers must ensure that the client’s personal health history information is not disclosed to the parents without the minor’s consent.

PEPFAR policies follow local laws about consenting clients for VMMC such as age of consent, in cases where some minors under 18 years may consent for VMMC or where school representatives such as head teachers may consent on a minor’s behalf. Minors need to be accompanied when they seek VMMC services, and parents or guardians are advised to participate in all information sessions to ensure they understand the procedure very well and are able to apply the acquired information during wound care. The informed consent process should be conducted in a language that is understood by the VMMC client and his parent or guardian, as necessary.

**ILLITERATE CLIENTS**

Clients who are illiterate and therefore cannot sign the informed consent document should be provided the same information as other clients, including having the informed consent read to them. Their name and date should be well printed on the form and close to their thumbprint.

PEPFAR’s annual VMMC Technical Considerations also recommend obtaining and documenting an adult informed consent and assent/parental consent for all minors before the VMMC procedure [See PEPFAR Technical Considerations for COP/ROP 2016]. Although obtaining the written informed consent form is performed once, informed consent is actually a process that must continue throughout the duration of the procedure. Staff therefore must ensure that not only does the client offer his signature/thumbprint (or her signature/thumbprint in case of female parents of minors) on the informed consent document, but also that his continued participation to receive the procedure is still acceptable at every step of the process. All information shared with clients and across sites needs to be consistent. This information should be incorporated into a standard operating procedure, and all site staff should be well versed in appropriate information about risks and benefits of VMMC, the VMMC procedure, pre- and post-op care, HIV, sexually transmitted infections (STIs), and so on.

**ELEMENTS OF INFORMED CONSENT FOR VMMC**

Obtaining informed consent is a process, not just a signed document. Informed consent should include the following elements [Modified from Code of Federal Regulations - 45 CFR 46.116(a) and 21 CFR Part 50.25(a)]:

- Purpose and average duration of the procedure and a description of the procedure to be followed such as the type of VMMC (surgical or device and which specific one will be used on the client).

- Explanation that male circumcision is permanent.
– Explanation that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the client is entitled, and that the client may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

– A description of benefits to the client or benefits beyond the client such as indirect protection for women, reduced overall HIV transmission if more men get circumcised, and so forth.

– A description of any foreseeable risks and discomfort to the client.

– A description of recommended post-care procedures and schedules for follow-up visits.

– A statement describing to what extent the client’s confidentiality and privacy of both their records and the procedure itself is maintained.

– An explanation that VMMC can be obtained at any time and a list of alternative places where it is provided under similar or different conditions.

– Whom to contact (including phone contact and physical location) for answers to pertinent questions about the VMMC, or the VMMC minimum package of services, or in case of complications.

– Confirmation that the client understands the key information.

– Time for questions and answers.

VMMC programs and sites should not deny rights or benefits to those who do not accept VMMC, as this could pressure them into accepting VMMC services. For example, a program should not deny a person access to HIV testing services, antiretroviral therapy, or condoms if they refuse VMMC services [See UNAIDS Safe, Voluntary, Informed Male Circumcision and Comprehensive HIV Prevention Programming: Guidance for Decision-Makers on Human Rights, Ethical and Legal Considerations].

FREQUENTLY REFERENCED INFORMATION

GIFTS, REIMBURSEMENTS, AND INCENTIVES TO CLIENTS

**Paying Clients**

Paying clients or providing incentives (in money or material goods) to undertake VMMC is not permitted under any circumstances in order to avoid coercion or the appearance of coercion. Any authorized reimbursement of money or goods given to clients must be used cautiously in line with the following considerations.

**Reimbursement for Procedure-Related Expenses**

Depending on the need for overcoming barriers for VMMC uptake, countries may consider offering reimbursement for travel expenses typically incurred by clients as a result of undergoing VMMC. Such reimbursements should be set based on reasonable transport costs within the specific geographic and population context and must be monitored closely to avoid inappropriate or unethical practices, including coercion. Wage reimbursements should not be introduced in PEPFAR-supported programs unless there is strong evidence that the strategy addresses a well-
documented barrier. Programs that have documented loss of wages as a barrier to VMMC uptake must contact the ministry of health of their respective countries and PEPFAR with a proposal on how they would set rates, manage, and administer such payments to ensure that they would not represent a coercive incentive to potential clients and would not distort any existing national schemes.

STAFF COMPENSATION

Mobilizers

Peer mobilizers are often very effective in increasing demand for VMMC. Programs that use peer mobilizers must develop systems to monitor the quality of their activities to assure that recruited clients are well informed about VMMC and have not been pressured or coerced to undergo the procedure. For example, mobilizers should be monitored to ensure that they do not give t-shirts or other gifts only to VMMC acceptors; instead gifts should be given to all people interested in VMMC or all people attending a certain mobilization event.

Community mobilizers may be rewarded for exceptional performance. Programs electing to give rewards to highly successful mobilizers must take steps to prevent the coercion of clients by mobilizers who may otherwise be financially motivated to pressure individuals. Mobilizers should never be compensated on a one-to-one basis, meaning that an individual mobilizer should not receive money for each client who undergoes VMMC. Instead PEPFAR programs are required to reward a team of mobilizers that exceeds expectations, so that any reward is based upon collective (versus individual) success. The above approach limits the likelihood of coercion by separating any immediacy of reward resulting from an individual mobilizer referring a particular client. Mechanisms that further minimize perceived or actual rewards on a per-client/per-mobilizer basis are encouraged.

Site Staff

Clinicians who work overtime to provide VMMC services may be compensated for their time at a scale consistent with national standards. However, clinicians must not be compensated on a per-circumcision procedure basis, to avoid actual or perceived motivation for clinicians to coerce clients to undergo the procedure.

PROGRAM TARGETS

The use of targets for individual service providers or for mobilizers is prohibited because it can lead to possible coercive practices. For the site, estimated targets should be used for planning and evaluation purposes only (e.g., order estimates for commodities, staffing levels, number of outreach sites needed, or site and staffing efficiency). Site or district level targets need to be monitored carefully to ensure that they do not flow down to individual service providers or peer mobilizers.

To ensure voluntarism and informed consent, programs should not only provide appropriate informed consent for clients, but should also comply with the following:

- Adhere to PEPFAR indicators and standards that need to be assessed during external quality assessment (EQA), site improvement and monitoring systems (SIMS), and continuous quality improvement (CQI) to monitor consent delivery and guarantee client comprehension, evaluate for coercive activities, and review reimbursement procedures [See Chapters 8 and 10].

- Avoid practices outlined above that can be perceived to be coercive.

- Give special consideration to the needs of children and adolescents.
To evaluate the quality of informed consent provided to clients at VMMC sites, the Population Council assessed the clients’ comprehension of key concepts and social norms and practices regarding informed consent for adolescents, analyzing the clients’ experience versus their expectations [See Evaluation of the Informed Consent Process for Male Circumcision Scale-Up in Zambia]. Clients’ understanding of messages was found to differ across clients, with most clients understanding benefits more than risks. The study team recommended separation of consent from clinical record forms and advised discreet informed consent form documents that can be read to and given to clients. This chapter includes a draft sample informed consent document. This is available as a template, though adaptation is necessary to align with local regulations.

**FOR ADDITIONAL INFORMATION**

**SAMPLE INFORMED CONSENT FORM:**

**Voluntary Medical Male Circumcision (VMMC) for HIV Prevention**

Client Consent to Participate in VMMC

I____________________________(name(s) of staff administering informed consent) working for ______________________________________________________________________________________ (name and address of site/organization) will discuss with you information about VMMC including its benefits, risks, relation to HIV, and what you need to do before and after receiving VMMC.

What is VMMC?

VMMC is the surgical removal of the foreskin of the penis. It is permanent (once performed, it cannot be reversed). VMMC reduces a man’s chances of acquiring HIV by up to 60 percent. It indirectly reduces HIV infection in women once fewer men are infected by HIV. VMMC has other benefits, including improved hygiene, reduced penile cancer, reduced sexually transmitted infections, and reduced cervical cancer in female partners of circumcised men.

Why is VMMC necessary?

VMMC is recommended by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) as one of the methods for HIV prevention. At 60 percent, VMMC does not offer full protection against acquiring HIV, because a circumcised man can still become infected with HIV and can also infect others with HIV. Males from the ages of 10 years and above may receive VMMC if the health care provider determines that their health is suitable for the medical circumcision procedure. HIV-positive men may also receive VMMC, but becoming circumcised does not reverse HIV infection if a man already has HIV; however, it may offer some benefits to HIV-positive men such as improved hygiene, reduced genital ulcer disease (GUD). All eligible men seeking to get VMMC are encouraged to test for HIV, but this is not mandatory. It is recommended that all HIV-infected men, including those identified through VMMC services, be evaluated and enrolled for HIV care and treatment for their own health benefit and to prevent transmission of HIV to others.

What do I have to do after VMMC?

After surgical VMMC, you are advised to abstain from sexual intercourse for six weeks. You must return to the clinic on the 1st, 7th, and 42nd day after the procedure for review of your wound and to finally certify wound healing.
If you receive circumcision using a medical device you must return to the facility after seven days to remove the device, and you must abstain from sexual activity for six weeks after the device is removed. You should not remove the device by yourself, but instead you are to return to the VMMC provider for the removal and assessment of the wound and to get advice on wound care. You must return to the facility on the 14th and 42nd day for review and certification of wound healing.

You must rest for at least three days after VMMC (irrespective of method) to allow healing to take place normally. Strenuous exercise such as bicycle riding or lifting heavy weights may cause disruption to the VMMC wound, thus delaying wound healing or causing displacement of the device that may require surgical intervention.

You should avoid use of homemade potions, such as applying animal dung to the wound, since that may cause infections like tetanus. You should promptly return to the facility for follow-up at scheduled appointments, exercise sexual risk reduction including reducing the number of sexual partners, and use condoms upon resuming sexual activity.

What exactly is done? How long does it take?

**Surgical VMMC:** During surgical VMMC, the foreskin is removed by one of several methods including forceps-guided, dorsal slit, and/or sleeve resection. After counseling, you will be invited to enter the operating room (OR). The provider will explain the whole procedure in detail including the following steps: provider and assistant clean their hands and put on gowns and gloves; clean the penis and surrounding areas; give injection anesthesia; mark incision lines; cut along the marked lines; remove the foreskin; stop any bleeding; approximate skin edges; dress the wound and position the penis. This takes between 15 and 30 minutes. The injection comes with a little pain, but this quickly disappears as the medicine starts to work. Providers usually use local anesthesia, which means that they do not put you to sleep. As the provider starts to work, he or she will ensure that you are as comfortable as possible. The pain control from the anesthetic lasts at least one hour.

**Device VMMC by PrePex:** Once in the OR, the provider will explain the PrePex process in detail including the following steps: provider will clean hands and put on gloves; apply a local anesthetic [topical EMLA cream] to the site of the device placement (to remove pain at the site); assess the size of the penis; choose a PrePex device; place the inner ring; place the outer ring on the inner ring; assess the fit of the rings; position the penis; and give care instructions and discharge you. This takes between 7 and 15 minutes. You are advised to return to the clinic on the 7th day to remove the device and again on the 14th and 42nd day for follow-up.

**Device VMMC by ShangRing:** If you choose ShangRing and it is available at the site, the provider will explain the ShangRing procedure in detail including the following steps: provider will clean and glove hands; apply a local anesthetic [injection or topical EMLA cream] to the penis (to remove pain at site). In brief, the inner ring is placed around the penis at the coronal sulcus; the foreskin is held with four clamps and drawn over the inner ring; the outer ring is then positioned and clamped shut; and the foreskin is dissected with curved tissue scissors. The wound is cleaned with iodine and dressed with dry gauze. You are advised to keep the wound clean and dry, and to return to the clinic on the 7th day to remove the device and again on the 14th and 42nd day for follow-up.

The health provider will explain in detail the different methods and help you choose which options may be best for you. Not everyone is medically eligible for all options. Whichever procedure you choose, you will receive pain medication for up to three days. You will get additional instructions on how to take care of your circumcised penis.
Cost of VMMC

VMMC is offered to you for free. VMMC may be offered at a fee at other places such as private providers. In such places, the cost of VMMC will be discussed with the client before the VMMC is conducted. However, you will be responsible for the cost of your transport to and from the VMMC site.

Risks and Discomforts

VMMC may result in a few complications depending on the method used. For example some of these complications are as follows:

**Surgical VMMC:** Bleeding, pain, injury to the glans/shaft, swelling, discomfort (associated with sutures and sometimes dressings), or infection.

**PrePex method:** Swelling, smell, infection, post-placement pain, discomfort (associated with wearing the device), and displacement of the device.

**ShangRing method:** Placement failure, damage to foreskin, wound disruption, post-placement pain or discomfort (associated with wearing a device), infection, and displacement of the device.

To avoid and reduce these complications, the providers are well trained and careful during the entire procedure. They observe the highest level of clinical standards recommended by WHO, UNAIDS, and the Ministry of Health, including pain management and the use of appropriate medical equipment and supplies. To further reduce these undesirable effects, you are advised to follow the instructions given to you throughout the procedure and the written information sheet given to you at discharge. In case you have any complications, please inform us immediately using the contact information at the end of this document. You may need to go to the nearest health center or come back to this VMMC site if you have complications. Clients who experience placement failure or displacements of their devices before the 7th day may require surgical intervention to complete the VMMC. Fortunately, most sites can perform both surgical and device VMMC, so that there is available surgical back-up for managing any device failure of placement or displacements should these occur.

Benefits to Clients

VMMC is offered to you for free. It reduces your risk of becoming infected with HIV through sex with female partners. VMMC also confers other benefits to you: VMMC reduces some sexually transmitted infections (STIs), particularly ulcerative STIs, including chancroid, herpes, and syphilis, as well as balanitis, phimosis, and penile cancer. When many males in the population decide to become circumcised, the number of men with HIV decreases, and other people, including women, are less at risk for HIV infection. Female sex partners of circumcised men are also at less risk of cervical cancer. Note that male circumcision does not offer 100 percent protection. It reduces, but does not eliminate the risk of HIV infection among sexually active HIV-negative males.

Compensation for time and transport: VMMC is a health service; therefore, you will not be compensated for the time you spend at the site or for transport costs.

Confidentiality: Throughout the procedure, the facility ensures your privacy by restricting entry into clinical and operating rooms to staff only. All documents that have captured information about you are accessible by staff only during the provision of VMMC or follow-ups. After that, they are kept under lock and key with restricted access. This information may not be released without your written consent. However, this information is used routinely to
make progress reports about the VMMC service. Any other need to release information will follow applicable local government procedures and will not identify your name or address.

**Voluntarism:** Participating in VMMC is completely voluntary. Even if you decide now to have circumcision, you may change your mind before the procedure begins. Once the procedure begins, it cannot be reversed. The removal of your foreskin will be permanent. If you decide not to be circumcised, you will not be penalized or denied any other services by this facility or its health care providers. VMMC is also provided in other centers such as ________, ________, where you may receive it under similar conditions.

**Contact information:** If you have questions about VMMC, including questions about what we have discussed, you may ask me now…. [Pause for questions]

If you have questions later, please feel free to contact [name, contact phone or address including staff in the clinic and site manager]

**Client Rights:** The client’s rights are displayed on the walls throughout the premises. If you have questions about your rights as a participant in VMMC, or wish to obtain further information, ask questions, or discuss any concerns about VMMC with someone other than the members of this team, please contact [details of who the client may contact such as MOH staff, or head of health services at district]

**Consent**

Consent/Assent: I __________________________________________________________________________

the undersigned, have received information about VMMC and understand the benefits and risks of VMMC. I give consent/assent to be circumcised at this site.

Signature: ______________________________________

[If unable to write, provider or witness may write name of client, capture thumbprint on signature line, and describe the owner of the thumbprint. This must be witnessed below.]

Consent: I __________________________________________________________________________ (parent/guardian) have received information regarding VMMC and understand the benefits and risks of VMMC. I consent for my child/relative/friend to be circumcised at this site.

Signature: ______________________________________

[If unable to write, provider or witness may write name of client, capture thumbprint on signature line, and describe the owner of the thumbprint.]

Staff (consent administrator or VMMC provider):

Name ________________________________

_____________________________________  ____________________

Staff signature      Date
CASE STUDIES

Case Study 12.1. Evaluation of the Informed Consent Process for Male Circumcision Scale-up in Zambia

Case Study 12.2. Improving Informed Consent Administration at VMMC Sites in Uganda

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

The following documents, which are available online and in the accompanying external media (included with the hard copy version of this Guide), provide the background information or procedural guidance used for development of this chapter.

1. UNAIDS Safe, Voluntary, Informed Male Circumcision and Comprehensive HIV Prevention Programming: Guidance for Decision-Makers on Human Rights, Ethical and Legal Considerations

2. Evaluation of the Informed Consent Process for Male Circumcision Scale-Up in Zambia

3. PEPFAR Technical Considerations for COP/ROP 2016

4. Sample Informed Consent Form

ABBREVIATIONS

CQI continuous quality improvement
EQA external quality assessment
GUD Genital Ulcer Disease
IC informed consent
IP implementing partner
MOH ministry of health
OR operating room
PEPFAR U.S. President’s Emergency Plan for AIDS Relief
SIMS site improvement and monitoring systems
STI sexually transmitted infection
UNAIDS Joint United Nations Programme on HIV/AIDS
VMMC voluntary medical male circumcision
WHO World Health Organization
CASE STUDY 12.1.
Evaluation of the Informed Consent Process for Male Circumcision Scale-Up in Zambia

Between December 2009 and March 2010 the Population Council conducted an evaluation of the VMMC informed consent process with three main objectives:

1. Assess male clients’ comprehension of key concepts in the informed consent process
2. Examine social norms and practices regarding informed consent for adolescents
3. Investigate how VMMC clients (adults and adolescents) who had recently undergone circumcision felt their experiences compared to their expectations.

The Population Council’s findings (from 228 VMMC clients who participated in the comprehension assessment and 62 VMMC clients who participated in the semi-structured interviews) suggest that male circumcision clients comprehend most key concepts in the informed consent process. Areas that seemed to be understood best were the need to continue safer sex practices and aspects of wound care and healing. However, the concept of partial protection is not well understood: although many clients knew that MC reduces men’s risk of HIV by 60 percent, few seem to recognize that they are at “lower” versus “low” risk of getting HIV. In addition, many clients believe that VMMC is partially protective against HIV, but fully protective against other STIs and cervical cancer in women, and there is a lack of awareness that VMMC does not protect female partners from HIV, except indirectly. In addition, benefits seemed to be better understood than risks.

Regarding informed consent among clients participating in semi-structured interviews, all adults and all except one adolescent had chosen to undergo MC voluntarily, with many emphasizing that it had been their own choice, free from pressure or coercion. Clients were less clear about the meaning of their signature on the informed consent form; some clients thought signing the form was freeing the service providers of all liability, whereas other clients did not recall signing a form providing consent. Interviews with clients, parents/guardians, and key informants indicated that consent procedures for minors are not well understood and are not being implemented consistently. In some cases, there is a lack of awareness about the age of consent (18 and older), and in other cases, parents have a strong influence regardless of the child’s age.

The main recommendations by researchers included: (1) considering developing a discrete informed consent form for clients to sign that is separate from the other elements of the intake form; (2) or, if that is that form is infeasible, providing a laminated card that the provider could read together with the client before he signs to reinforce that he understands the risks and benefits and is agreeing voluntarily to undergo VMMC; (3) emphasizing risks and benefits equally in client information booklets; (4) reinforcing partial protection messages in settings with women; (5) making additional efforts to emphasize the lack of proven effect in reducing HIV risk among women and that protection against cervical cancer is only partial; and (6) acknowledging that most clients will experience some pain during or after VMMC surgery.
CASE STUDY 12.2.
Improving Informed Consent Administration at VMMC Sites in Uganda

In 2012 two PEPFAR-led external quality assessments (EQAs) found serious quality gaps, including lack of standardized registers, poor documentation of client informed consent, lack of emergency preparedness, and untrained providers. In response, USAID asked the ASSIST Project to support the Ministry of Health (MOH) and 10 implementing partners (IPs) to improve VMMC quality and safety in 30 sites using a continuous quality improvement (CQI) approach. ASSIST, MOH, and the IPs supported sites in forming improvement teams to identify barriers in achieving national standards, and to identify solutions (changes) to overcome the barriers and test these changes, while collecting performance data to measure whether gaps were bridged. A color-coded dashboard based on compliance with 53 standard categories was used by teams to measure progress. Figure 12.1 illustrates the dramatic change in informed consent administration from zero in March 2013 to 100 percent in July 2013 and maintenance of this high performance through the subsequent 12 months.

Figure 12.2.1. Percentage of Clients with Documented Informed Consent Prior to Circumcision

*Mean is calculated because more than half of points are 100%. Shift above mean occurs by December 2013. See Perla et al. 2011.
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