

14. Voluntarism, Informed Consent, and Reimbursement

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Objective (s): To ensure that male circumcision services are carried out safely, under conditions of informed consent, and without coercion

Informed consent is a key element for any VMMC program. 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 in the appropriate ways to obtain it (see GUIDANCE DOCUMENTS 16 and 19). Adult males opting for VMMC have the right to receive full information on the benefits and risks of the procedure. Only adult male clients who have the appropriate decision-making capacity and legal status are able to give their informed consent. The informed consent process should be conducted in a language that is understood by the VMMC client and his parent or guardian, as necessary.

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 can provide assent for the surgical procedure. Those too young to understand the male circumcision procedure and provide 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 guardians. Parents or guardians who are responsible for providing consent should be given 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.

Elements of Informed Consent for VMMC Surgery

Obtaining informed consent is a process, not just a signed document. It is important that the elements below are covered in the informed consent process.

Informed consent should include the following elements:

- Purpose of the procedure
- Description of the procedure
- Explanation that male circumcision is permanent
- Potential risks and benefits
- Expected time of the procedure
- Explanation that it is a voluntary procedure
- Confirmation that the client understands the key information
- Time for questions and answers

All clients (or parents/guardians in the case of a minor) must give informed consent before a male circumcision is performed.

Consider the following items when developing informed consent procedures:

- Literacy level of clients (and parents/guardians)
- Awareness and acceptance of the individual's rights to make an informed decision
- Societal norms and pressures
- Service providers' attitudes toward the client's rights and ability to make his own decision
- Staff time available to allow time for questions and answers
- Confidentiality
- National regulations/policies
- Donor's policies

Note: Informed consent must be documented with a patient's or parent's/guardian's signature indicating that the elements of informed consent (first list of bullets above) were covered and that the signer consents to the procedure (see TOOL 22). It is also important to comply with national guidelines and laws on how to document informed consent. Generally, signed consent forms are kept with the patient charts; it is important to ensure that the national protocols—including where to file the signed consents, and how long they need to be kept—are followed.

Paying clients (in money or other material goods) to undertake VMMC is not permitted in any circumstances. Any reimbursement of money or goods given to clients must be used cautiously, to avoid coercion, including the appearance of coercion.

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 MOH 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 not distort any existing national schemes.

Benefits/Gifts Provided—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 (e.g., mobilizers should be monitored to ensure that they do not give t-shirts only to VMMC acceptors instead of to all). 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. For example, it is better to reward a team of mobilizers that exceeds expectations, so that any reward is based upon collective (vs. individual) success. The above approach limits the likelihood of coercion by separating any immediacy of reward resulting for an individual mobilizer referring a particular client. Mechanisms that may even further distance perceived or actual rewards on a per-client/per-mobilizer basis are encouraged.

Staff Compensation—Clinicians who work overtime to provide VMMC services may be compensated for their time at a scale consistent with national standards. However, clinicians should not be compensated on a per-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 mobilizers should be avoided because it can lead to possible coercive practices. For the site, estimated targets should be used for planning and/or evaluation purposes only (e.g., order estimates for commodities, staffing levels, number of outreach sites needed, site and staffing efficiency).

To ensure voluntarism and informed consent, programs should not only provide appropriate informed consent for clients, but they should also:

- Develop indicators and standards within the regular M&E practices to monitor consent delivery and guarantee client comprehension, evaluate for coercive activities, and review reimbursement procedures (see Section 11)
- Avoid practices outlined above that can be perceived to be coercive
- Give special consideration to the needs of children and/or adolescents
- Avoid numerical program objectives or staff/site performance targets or quotas