

CHAPTER 4

RECORDKEEPING, REPORTING AND QUALITY ASSURANCE



This chapter provides information on the following:

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

4.1. INTRODUCTION

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

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

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

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

Box 4.1. World Health Organization's male circumcision standards

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

Source: Reprinted from (1, 2)

Box 4.2. Role of male circumcision site manager

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

4.2. RECORDKEEPING AND REPORTING

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

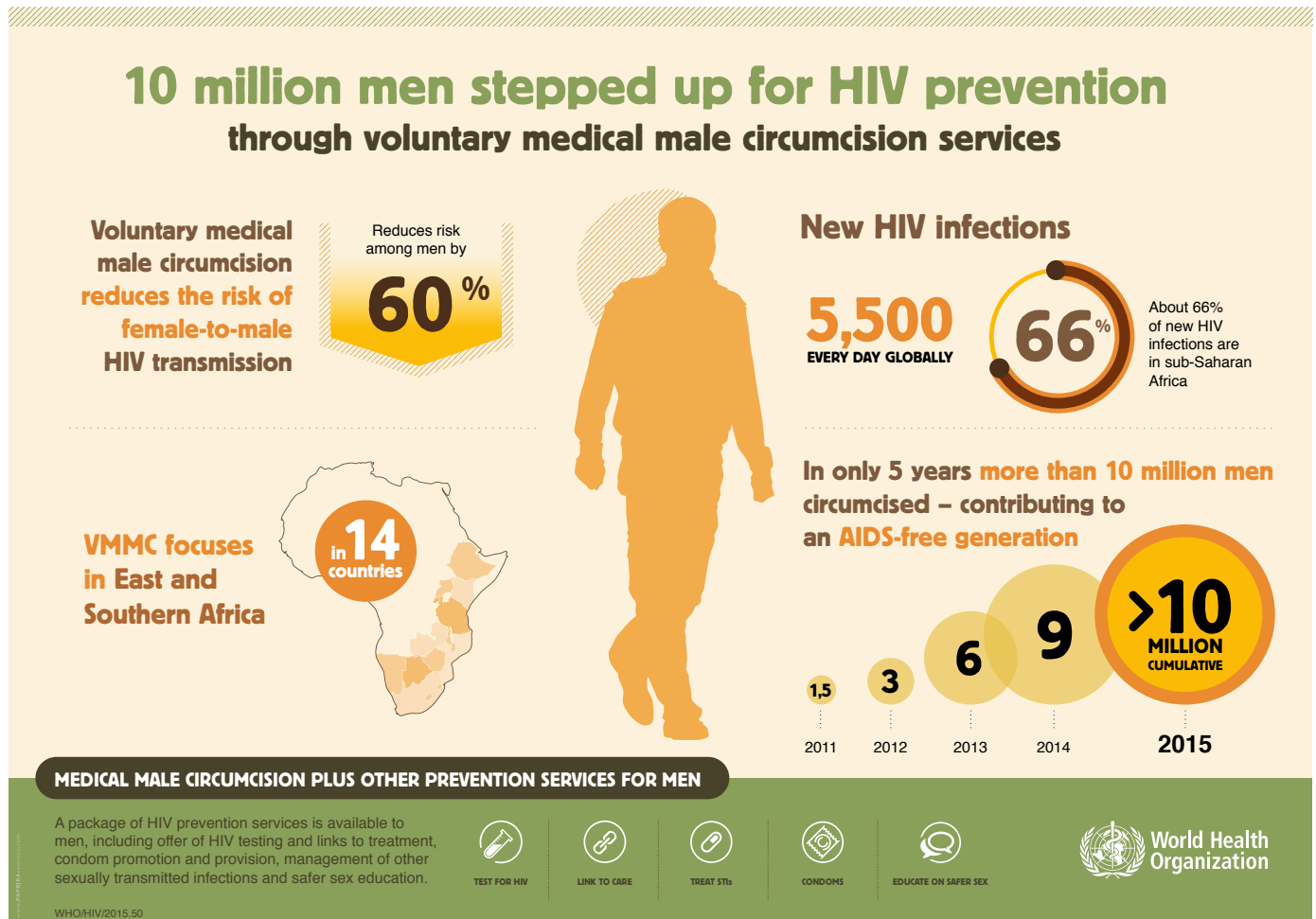
For a regional, national or international programme, information from different types of records and other data collection tools from individual male circumcision service delivery sites or programmes can be used for quality assurance purposes to do the following:

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

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

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

Fig. 4.1. HIV prevention through voluntary medical male circumcision



Source: Reprinted from (3)

4.2.1. Site records and other data collection tools

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

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

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

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

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

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

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

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

Source: Adapted from (4)

4.2.2. Reporting on adverse events

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

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

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

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

4.2.3. What are good data?

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

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

Box 4.3. Aggregated versus disaggregated data

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

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

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

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

Source: Adapted from (4)

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

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

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

4.3. MONITORING AND EVALUATION

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

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

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

4.3.1. What is a monitoring system?

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

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

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

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

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

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

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

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

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

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

4.4. QUALITY ASSURANCE

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

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

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

4.4.1. How is quality assessment done?

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

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

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

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

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

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

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

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

KEY MESSAGES

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

ANNEX 4.1. MALE CIRCUMCISION MONTHLY REPORT FORM (EXAMPLE)

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

Report by: _____

Reporting date: _____

Signature: _____

Report to: _____

ANNEX 4.2. MALE CIRCUMCISION CLIENT REGISTER FORM (EXAMPLE)

| DATE (DD/MM/ YY) | CLIENT IDENTIFICATION NUMBER | NAME (LAST NAME, FIRST NAME) | PHYSICAL ADDRESS | CLIENT CONTACT NUMBER | AGE (YEARS) | CLIENT ACCOMPANIED BY PARTNER (P), PARENT(S)/ GUARDIAN(S) (PG) OR CAREGIVER (C)] | REFERRED FROM (USE "CODE A" BELOW) |
|------------------------|------------------------------------|---------------------------------|------------------|-----------------------------|----------------|--|---|
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Code A: Referred from:

CTC = care and treatment centre, **FP** = family planning services, **OTH** = other (ask client to specify),
PITC = provider-initiated testing and counselling, **SR** = self-referral, **STI** = sexually transmitted infection clinic,
VCT = voluntary counselling and testing

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

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

1. Client's name: _____

2. Date of visit:

| | | | | | | | |
|-----|--|--|-------|--|--|------|--|
| | | | | | | | |
| Day | | | Month | | | Year | |

3. Client's ID number: _____

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

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

Treatment provided: _____

Treatment outcome: Adverse event completely resolved. _____

Adverse event partially resolved. _____

Adverse event unchanged. _____

Was patient referred? Yes _____ No _____

If yes, to where: _____

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

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

Treatment provided: _____

Was patient referred? Yes _____ No _____

If yes, to where: _____ and when: _____

Treatment outcome: Adverse event completely resolved. _____

Adverse event partially resolved. _____

Adverse event unchanged. _____

In your clinical judgement, was this adverse event:

Male circumcision related?

Not male circumcision related?

Other comments: _____

Date: _____

Name of health care provider: _____

Signature: _____

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