

PEPFAR Guide to Monitoring & Reporting Voluntary Medical Male Circumcision (VMMC) Indicators

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Contents

Acknowledgments	4
Introduction	5
Monitoring and Reporting System Overview	6
Semi-Annual Program Results (SAPR) and Annual Program Results (APR)	6
National HMIS systems for VMMC	7
Electronic Data Management Systems	8
VMMC Workflow	9
Monitoring VMMC Programs	9
PEPFAR VMMC Indicators	9
Target Setting Process	11
Data Collection, Interpretation and Use	12
Method of Measurement for Indicators	17
Data Tools and Reporting Systems	17
Linkage of Facility-based Records Systems	19
Data Quality Assurance	20
Recording and Reporting VMMC-Related Data	21
Capacity Building for VMMC Reporting	25
Sample Registry and Reporting Forms for VMMC	26
VMMC Emergency Preparedness and Death Reporting Procedures	29
Conclusion	30
Additional Resources	30

List of Tables

- 1. PEPFAR VMMC Indicators from the NGI Reference Guide V1.2, February 2013
- 2. PEPFAR VMMC-Associated Indicators from the NGI Reference Guide V1.2, February 2013
- 3. Data Quality Checklist
- 4. Sample Data Fields for VMMC Data Collection
- 5. Summation and reporting periods typical of routine VMMC service delivery
- 6. Guiding Questions for VMMC data collection and reporting

List of Figures

- 1. Sample workflow and sequence of events for VMMC
- 2. Linkages between VMMC and other HIV services
- 3. VMMC recording and reporting, by reporting levels
- 4. Sample Surgery Register
- 5. Sample District/Regional Report

Appendices

- 1. PEPFAR VMMC Indicator Reference Sheets
- 2. Sample Paper Data Collection Forms
- 3. Sample Consent Form
- 4. Checklist for Assessing USG Direct Support for Service Delivery

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Introduction

Voluntary medical male circumcision (VMMC) has demonstrated in three randomized trials^{1,2,3} to reduce men's risk of HIV acquisition by at least 60%. Further studies show the effects to be sustained over time.⁴ PEPFAR is supporting VMMC activities in 14 countries, working side-by-side with partner governments, the World Health Organization (WHO), and other implementing partners in program planning and service delivery. UNAIDS/WHO issued normative guidance in March 2007, stating that VMMC should be recognized as an additional important intervention to reduce the risk of male heterosexually acquired HIV infection and that VMMC should always be implemented as part of a comprehensive HIV prevention package.⁵ Modeling studies predict that under a rapid scale-up scenario, the benefits of VMMC are likely to be large, with an average of one HIV infection averted for every nine VMMCs performed⁶. Modeling also suggests that for maximum impact, scale up of VMMC must be rapid and coverage high, prioritizing men who are sexually active or soon to become sexually active.

The Office of the U.S. Global AIDS Coordinator (OGAC) requires PEPFAR-funded implementing partners to report program indicators to demonstrate accountability for public funds and program performance. At the most basic level, indicators are comprised of data that summarize the services that were provided. In 2009, PEPFAR defined its indicators for male circumcision programs and provided definitions to guide PEPFAR implementing partners collecting the indicators. These indicators and definitions may be found in the PEPFAR Next Generation Indicator (NGI) Reference Guide⁷ (version 1.2). This document, the PEPFAR Guide to Monitoring & Reporting VMMC Indicators, is meant to go beyond the VMMC indicators. It builds upon the WHO guidance titled "A Guide to Indicators for Male Circumcision Programmes in the Formal Health Care System"⁸, providing additional information on best practices for the collection, compilation, sharing of information, and data use to ensure the indicator reporting is accurate and timely, as contractually required to receive PEPFAR funds.

The authors of the guide recognize that the collection and sharing of VMMC service information occurs within a broader context of partner country governments' health infrastructure, information systems, and data needs for evaluation and oversight. These factors vary widely by country. While this guide was

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¹ Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. *Lancet*. Feb 24 2007;369(9562):657-666.

² Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. *Lancet*. Feb 24 2007;369(9562):643-656.

³ Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, Puren A. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. *PLoS Med.* Nov 2005;2(11):e298.

⁴ Gray, R., G. Kigozi, et al. (2012). "The effectiveness of male circumcision for HIV prevention and effects on risk behaviors in a posttrial follow-up study." AIDS 26(5): 609-615.

⁵ World Health Organization, Joint United Nations Programme on HIV/AIDS. 2007. New data on male circumcision and HIV prevention: policy and program implications. Available at http://libdoc.who.int/publications/2007/9789241595988 end.pdf.

⁶ Njeuhmeli, E., S. Forsythe, et al. (2011). "Voluntary medical male circumcision: modeling the impact and cost of expanding male circumcision for HIV prevention in eastern and southern Africa." <u>PLoS medicine</u> **8**(11): e1001132.

⁷ PEPFAR Next Generation Indicator (NGI) Reference Guide Version 1.2: http://www.pepfar.gov/reports/guidance

⁸ A guide to indicators for male circumcision programmes in the formal health care system. Geneva: World Health Organization and Joint United Nations Programme on HIV/AIDS, 2009.

intentionally written with a PEPFAR focus--for PEPFAR implementing partners to aid in reporting of PEPFAR indicators--we've attempted to broaden its scope somewhat to include perspectives and needs beyond those of PEPFAR alone. That said, it is beyond the scope of this document to guide the development, adaptation, and/or implementation of a national system to collect, communicate, and receive health service information. WHO/UNAIDS/PEPFAR have provided other resources related to M&E for health services, not specific to VMMC, that may be helpful for the larger needs of partner country governments.

Monitoring and Reporting System Overview

Health management information systems (HMIS) are critical for the functioning of the health system, and any new health service introduced through a government's health infrastructure must be accompanied by the appropriate support for HMIS. Ideally, these include:

- National indicators
- Standardized national data collection tools
- Systems and protocols for data flow
- A data management system (can be electronic or paper-based, or a combination of these)

Monitoring and reporting activities that collect, aggregate, and share service provision data are an essential component of a VMMC HIV prevention program and are necessary to fulfill the indicator reporting requirements. An indicator quantifies performance and is a measurable number, proportion, percentage, ratio or rate that reports program achievements. This guide provides recommendations on how PEPFAR implementing partners collect and report requisite indicators, and how this reporting should fit into a national context of VMMC HMIS. Challenges may exist when reporting requirements differ between PEPFAR and the Ministry of Health, such as indicator reporting on a different schedule, or on a different level (i.e., facility vs. regional vs. national aggregation), with different stratifications (i.e., age strata may differ) or indicators that are entirely different. Challenges may also exist with integration of PEPFAR-indicators into national reporting systems/HMIS.

Semi-Annual Program Results (SAPR) and Annual Program Results (APR)

Annual and semi-annual reports must be submitted by PEPFAR country teams to PEPFAR according to stated deadlines. The SAPR reports on services delivered between October 1 to March 31, and the APR reports on services delivered between October 1 to September 30, corresponding with the United States Government (USG) fiscal year. Instructions regarding submission processes are provided by the incountry PEPFAR team. Country programs vary in the ways in which SAPR and APR reports are submitted: some utilize online databases while others utilize Excel spreadsheets. Additional guidance for PEPFAR reporting can be found in the NGI Reference Guide.

National HMIS systems for VMMC

In order to support sustainable provision of VMMC services, it is important to align with, and, in many cases, provide technical support for national HMIS systems. HMIS is a pillar of health service delivery, and a functioning reporting system for VMMC integrated into national HMIS is important for the success and sustainability of VMMC as a health service. The considerations provided below may be useful to PEPFAR implementing partners who may need to assist in establishing national-level HMIS for VMMC.

- Standardized indicators: The starting point for developing data collection and reporting tools for a national program is consensus on what the national program wishes to monitor in order to evaluate and plan for the scale up of VMMC. After thorough consultation, the agreed elements for monitoring need to be distilled into a concise set of national indicators. For example, a set of national indicators may encompass: service delivery statistics, such as number of males circumcised, number of males tested for HIV, number of clients experiencing a moderate or severe adverse event; training-related statistics, such as number of doctors or nurses trained on VMMC surgery or counseling; and, service availability statistics, such as number of sites offering VMMC services. Indicators may also be complex, such as measures of HIV incidence performed repeatedly to demonstrated changes in HIV incidence coinciding with VMMC scale-up. Regardless of the scope of their interests and needs, it is necessary for country programs to have a national set of defined indicators before data collection tools can be developed. This will then dictate what information should be collected, aggregated, and reported up from facilities to district, regional and national levels.
- Standardized tools: A fundamental building block of HMIS is a standardized set of data collection tools. Each facility providing services then uses the standardized tools for recording service data (e.g., data collection forms to record information about the services that each client receives, such as HIV testing, clinical screening, surgery, and follow-up). Each facility next aggregates these data into the indicators that were defined and selected. The indicators are then reported up to the next level, such as the district level. Each district level would then aggregate the indicator data for all facilities in that district and report up to the next higher level, such as the province, and so on, until data is received at the national level summarizing all services provided in the country, per the indicators. The aggregation of indicator data at the facility level typically requires detailed abstraction of information from the standardized data collection tools. Therefore, to reduce data abstracting burden on staff at the facility level, reporting summaries should be as concise as possible.
- **Diversity of indicators:** At country level, indicators in addition to those reportable to OGAC may be needed for national program planning and evaluation. UNAIDS/WHO has also provided guidance on monitoring and reporting of VMMC programs, which contains additional suggested indicators (put in reference to the WHO/UNAIDS guide). PEPFAR implementing partners should be very familiar with the PEPFAR indicators, definitions, and reporting requirements/timelines. In this way, if they are asked to assist with

development of national systems, there may be as much agreement (or at least awareness) as possible between the PEPFAR and national indicators and their reporting. It is likely that national indicators will be more detailed than PEPFAR indicators.

- Support needed for Maintaining National HMIS: In order to make national recording and reporting of VMMC indicators a functional process, it is important to train the VMMC providers on the appropriate completion of data collection tools. Facilities should also receive timely feedback on data quality in relation to completion of data collection tools, which impacts indicator reporting. Problems with erroneous and incomplete data or delayed aggregation and reporting can then be quickly remedied. Ministries of Health and Defense should be supported in their efforts to provide systematic follow-up after training and supportive supervision, to ensure quality data collection using the standardized data collection tools, in accordance with reporting deadlines.
- Reporting Schedule: In order to sustain the monitoring and reporting of VMMC, it is
 important to pre-determine a reporting schedule that defines the frequency of data
 aggregation and reporting up by facilities, district level, and provincial level offices.

The responsibility to make routine health information on VMMC flow from facility up to the national level belongs to the relevant government ministries, but PEPFAR implementing partners and other VMMC stakeholders should support the process through technical assistance from facility to national level, while completing their own nationally and internationally defined reporting requirements. It is recognized that militaries may have other established and required reporting channels.

Electronic Data Management Systems

Among countries where PEPFAR is supporting VMMC, there are some countries which have primarily electronic data management systems to handle routine health information; while others rely on completely paper-based systems. It is possible for the VMMC indicators to be effectively monitored and reported in either data management system, or a hybrid of the two.

In either paper based or electronic data management systems, VMMC monitoring will start with an individual client who will have information about his service recorded on the standardized data collection tool. In advanced electronic systems, the individual client information is entered into an electronic version of the data collection tool (similar to an electronic medical record), which then becomes part of a database at the facility level. Electronic systems should be designed to produce standardized reports such as a daily register and clinical forms, and ad hoc reports.

For electronic data management systems, computer programs should be included so that the PEPFAR and national VMMC indicators can be automatically generated for reporting up. All principles of HMIS apply to electronic or paper-based data management systems: standardized tools should be used across facilities; aggregation and reporting up should be timely (by deadlines); and, the data management system should address the indicator reporting requirements of both the partner country government and PEPFAR.

National policies and protocols governing the management of routine health data should be understood and respected by PEPFAR implementing partners. In some countries, PEPFAR implementing partners may have to apply for permission to access electronic data management systems from Ministry of Health.

VMMC Workflow

Collection of data, through the use of client records and/or registers, is required in order to aggregate and calculate VMMC indicators. The VMMC data elements may be divided into the following categories according to the workflow of VMMC service delivery (also see Figure 1):

- 1. Demographic information: registration
- 2. VMMC Education/Counseling
- 3. Individual counseling and offer of HIV testing
- 4. VMMC surgical consent
- 5. Medical history and physical examination
- 6. VMMC surgical procedure
- 7. Post-operative recovery and discharge/adverse event monitoring
- 8. Post op visits (routine and for adverse event management)
- 9. Referrals to care and treatment for HIV-positive individuals
- 10. Treatment or referral for STI care

Monitoring VMMC Programs

PEPFAR VMMC Indicators

VMMC indicators, like other PEPFAR indicators, are reported to PEPFAR twice a year in the Semi-Annual Program Results (SAPR) & Annual Program Results (APR) Reports. Refer to the section entitled 'SAPR and APR' under 'Recording and Reporting VMMC Service Delivery' for further explanation.

Similar to other PEPFAR programs, the VMMC program has specific indicators on which every PEPFAR implementing partner who supports and/or provides VMMC must report. Table 1 below presents PEPFAR's five VMMC indicators that all PEPFAR implementing partners must report. Additionally, HIV testing and counseling (HTC) services, which occur as part of PEPFAR-funded VMMC must also be reported. Associated services, like provision of post exposure prophylaxis (PEP) for occupational exposure to HIV occurring during VMMC services, is also reportable, depending on the type of PEPFAR program in the country.

PEPFAR Indicators are classified with respect to PEPFAR monitoring and reporting practices as "essential" or "recommended." The essential indicators are those which are considered to be of highest priority and crucial for basic program monitoring, accountability, and tracking of progress. Recommended indicators also provide extremely valuable information for program management and evaluation. For PEPFAR's internal operating purposes, essential indicators are further categorized as

either "reported" or "non-reported." This additional sub-categorization does not apply to collection and reporting of indicators by PEPFAR implementing partners, but rather instructs country PEPFAR offices on their obligations to forward information to OGAC. Please see the reference sheets in Appendix 1 for more information. Each country PEPFAR office uses its discretion to determine whether the recommended indicators must be reported to them by PEPFAR implementing partners.

PEPFAR implementing partners must be aware of the reporting requirements which your Funding Agency award and your country PEPFAR office require. Your PEPFAR country team will require you to report on the essential indicators. Those indicators that the local office requires you to report—whether essential or recommended—will likely appear in your SAPR / APR reporting template.

PEPFAR implementing partners should be aware in advance of reporting requirements, so that they are collecting the appropriate information to be able to report on the indicators.

Table 1. PEPFAR VMMC Indicators from the NGI Reference Guide V1.2 (as of March 2013 – please note that these indicators can change and the most recent guidance should be used)

VMMC Indicators	Required Disaggregation	Recommended Disaggregation
	Level (s)*	Level(s)*
ESSENTIAL Indicators		
P5.1.D Number of males circumcised as part of the	Age: under 1; 1-9;	HIV test result, Site
minimum package of MC for HIV prevention services	10-14; 15-19; 20-	location
within the reporting period, categorized by age	24; 25-49; 50+	
P5.2.D Number of circumcised clients experiencing at		Severity of AE, time
least one moderate or severe adverse event (AE)		of onset, and type
during or following surgery, within the reporting		of AE
period		
H2.3.D Number of health care workers who	Type of training,	All program areas
successfully completed an in-service training program	including VMMC	
RECOMMENDED Indicators		
P5.3.D Number of locations providing MC surgery as		Site location
part of the minimum package of MC for HIV		
prevention services within the reporting period		
P5.4.D Number of males circumcised within the		
reporting period who return at least once for post-		
operative follow-up care (routine or emergent) within		
14 days of surgery		

^{*}See Appendix 1 for Indicator Reference Sheets

Table 2: PEPFAR VMMC-Associated Indicators from the NGI Reference Guide (as of May 2012 – please note that these indicators can change and the most recent guidance should be used)

Associated Indicators	Required Disaggregation Level (s)*	Recommended Disaggregation Level(s)*
ESSENTIAL Indicators		
P6.1.D Number of persons provided with post- exposure prophylaxis (PEP)	Exposure type	
P8.1.D Number of the targeted population reached with individual and/or small group level HIV prevention interventions that are based on evidence and/or meet the minimum standards required	MARP type	Sex
P11.1.D Number of Individuals who received testing and counseling services for HIV and received their results	Age/Sex, and by test result	Type of counseling, and by MARP type

^{*}See Appendix 1 for Indicator Reference Sheets

Note that care must be taken to ensure the individuals receiving VMMC education at more than one location (i.e. facility and community-level) are not double-counted.

Target Setting Process

Estimating targets for program indicators is important and targets should be developed during collaborative planning and/or evaluation processes. National VMMC strategies likely include targets on a multi-year horizon or have developed annual targets and these targets should inform PEPFAR targets. VMMC targets and results are reviewed and discussed during COP reviews. Having target information available also enables analysis of trends of results and targets from prior years. PEPFAR implementing partners adhering to best practices in program planning, set targets and also will be expected to respond to PEPFAR regarding target preparation and review of the Country Operational Plan (COP). However, the use of targets for individual health care workers and community mobilizers should be avoided because it could lead to coercive practices.

Targets for program indicators should be set in advance, and adjusted when necessary. If there is no existing baseline, refer to expert opinion and research findings if available. When setting targets, factors that should be considered include: MC prevalence, HIV prevalence, population size, ability to roll-out outreach/mobile MC services, infrastructure and personnel capacity, funding levels, commodity logistics, national strategies, and donor/client expectations.

The process of calculating targets and the data used for decision-making should be documented for future reference or modification of targets. When providing justifications for targets and results in the SAPR and APR, it is important to include information about the current status of the program and factors which may be influencing the results. Revisions to targets may need to be made when there is a shift in funding, program

For in-country reporting, the PEPFAR team will want to know whether the PEPFAR implementing partner met, failed to meet or exceeded the targets set in the COP: the comment sections in the SAPR or APR should be used to explain why targets were not met or were exceeded.

objectives, or staff turnover – if these are revisions to PEPFAR targets, any changes must be negotiated with your funding agency.

Data Collection, Interpretation and Use

The following describes time points at which data should be collected in order to be able to provide programs with necessary data on VMMC clients. As can be seen in the section below, some variables on the client forms are purely *clinical data elements* and are collected as part of providing appropriate medical care for the client but do not inform indicator reporting (e.g., client weight and blood pressure). Other data elements will contribute to the reporting of indicators (e.g. age, HIV status). To minimize the documentation and reporting burden for health care providers and facility staff, it is important to be judicious in deciding the data elements that must be collected.

Demographic information is collected at client enrollment (when the client first presents to a facility or location with an interest in VMMC). For indicator reporting purposes, the age/date of birth is the most important demographic information collected, as it is used for disaggregation purposes.

Interpretation/use: Demographic information helps to understand the profile of clients who are presenting for VMMC services. Contact information may be used for follow-up of clients or for health information promotion activities such as phone-based messages, if permitted. Information on client age enables disaggregation of the indicator for number of VMMCs provided [Indicator P5.1D]. PEPFAR implementing partners should be aware of national guidelines regarding personal information of clients and restrictions about storage or access which may apply.

VMMC Counseling information is collected during group education sessions. Attendance lists should be maintained so participation at the education sessions can be tracked, especially in a community setting. The educator can fill out a report capturing information about the participants who attended (i.e. total number of attendees, age range, sex), topic covered and mode of delivery. Data elements on VMMC counseling may or may not be priority, depending on the national reporting guidelines.

Interpretation/use: Tracking participation VMMC counseling and education sessions can be used to help plan and make decisions on how well a certain target audience or age group is being reached with information on VMMC. If a small percentage of the intended audience is being reached, then plans may be adjusted to improve reach.

HIV Testing and Counseling (HTC), specifically provider-initiated testing and counseling (PITC) is required to be offered to individuals coming for service, regardless of whether or not they decide to have or meet clinical criteria to undergo VMMC. The individual's HIV status is important for the appropriate clinical care of the client. Furthermore, collecting clients' HIV test results allows indicator data to be reported and disaggregated (i.e. number of circumcisions by HIV status). HTC data are generally recorded according to national protocols, which should be well established in all PEPFAR

country programs. Caution should be taken to avoid double counting of individuals when HIV testing is reported by both testing and counseling programs and VMMC programs.

Interpretation/use: HIV status provides important information for the client and health care providers. HIV status informs proper management of clients in surgery, and provides information for the appropriate linkages and referrals of clients. Information on client HIV test results enables disaggregation of the indicator for number of VMMCs provided [Indicator P5.1D].

MC Surgical Informed Consent is provided before the MC procedure is conducted and a paper record or acceptable electronic record must be maintained with the client's signature or the parent/guardian's signature if the client is a minor.

Interpretation/use: Consent is not used for analysis, but must be documented. PEPFAR implementing partners must provide for the proper collection of informed consent, recording and storage of consent forms, in order to conform to both national and PEPFAR requirements.

Medical History and Physical Examination: Information in the medical history is collected for clinical purposes.

Clinical information is collected before the VMMC procedure is performed. It is essential that medical history information be complete in order to determine medical eligibility for MC, to avoid surgical complications and provide quality client management. All medical history including bleeding disorders, diabetes, and drug allergies should be recorded in a visible place on the client record either in a designated section or near the top so that this information is easily identifiable by the clinical team. A physical examination is also performed and recorded before the MC procedure is conducted.

Interpretation/use: Neither medical history nor physical examination data contribute to the reporting of indicators, but the information is essential for appropriate clinical care and may be drawn upon for program quality assurance/improvement, secondary analyses or research questions, given the correct ethical clearance.

Intra-operative information is collected during the VMMC procedure.

It is essential that data are collected at all points in the VMMC workflow in order to document elements of the surgical operation, conduct quality assurance, and to avoid surgical complications.

Intra-operative information on adverse events prior to discharge is used to report on the adverse event indicator. Monitoring adverse events is crucial for individual client management and program management and should be linked to good clinical care and the process of recording information at and immediately following the surgery, prior to discharge, and at each follow-up visit. Information such as time taken to complete surgery or cadre of the surgeon are not reported on, but may be of interest for program quality assurance/improvement and secondary analyses or research questions, given obtaining the correct ethical clearance.

Adverse Events (AE): AE indicators are among the most important of those monitored for VMMC programs. AEs are recorded on a standardized form. Definitions are provided in the NGI Reference Guide. The AE form collects information on the type, timing (intra or post operative), and severity of the AE. Moderate and severe AEs are reportable.

Interpretation/use: It is extremely important for PEPFAR implementing partners to track AEs (intra and post-operative) properly. AEs are examined as a proxy for safety and quality in VMMC service delivery. It is important that AEs are classified correctly (moderate and severe) according to agreed, standardized definitions as provided in the NGI Reference Guide.

Post-op/ pre-discharge information is collected during the immediate post-operative recovery period prior to the client leaving the VMMC site. While information should be collected post op in the course of good clinical care, unless there is a moderate or severe AE, the data is not required to be reported. It is essential that the client remain at least 30 minutes post-op to be monitored for any AE and provided with good clinical care.

Follow up information includes time of visit relative to surgery (48 hours, seven days, six weeks is recommended in many countries; other countries may classify as first visit, second visit and third visit). Follow up information is generally recorded in the client record, but can also be recorded directly into a register. The information includes the time of visit according to the visit schedule, what services were given (provision of condoms, removal of bandage) and any AEs observed and managed.

Interpretation/use: Follow up visits are important indicators on the extent to which clients are adhering to post-surgical care instructions. PEPFAR implementing partners are required to report on follow up visits and should have strong systems for tracking these data.

Data for HIV-positive client referrals to care and treatment should be collected. Ideally, data about the number of HIV-positive clients referred who actually enroll in HIV care and treatment should also be collected. It is recognized that many challenges exist due to weak linkages to care and loss to follow-up. Please see Linkages of Facility-based Services section below for further discussion.

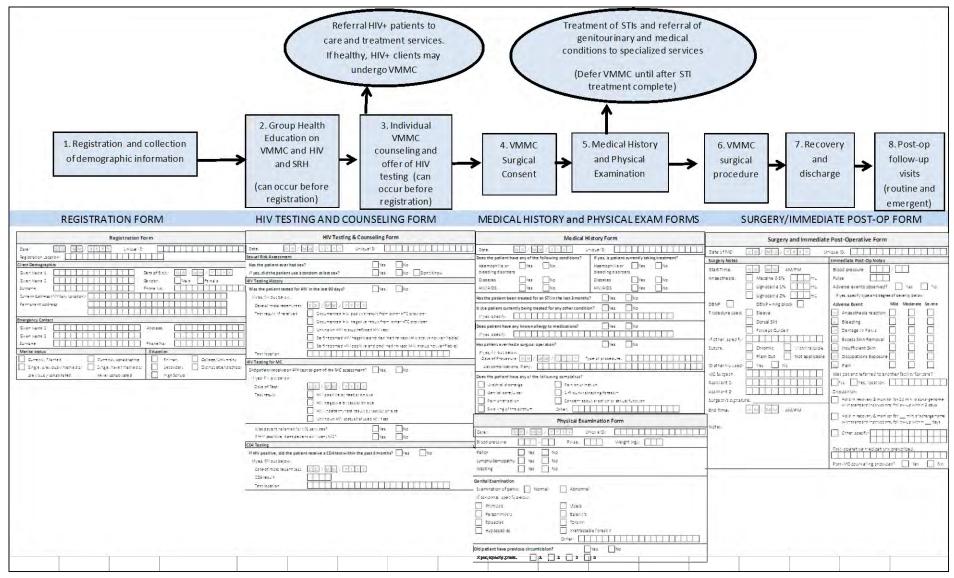
Interpretation/use: Referrals to care and treatment for HIV positive VMMC clients are important indicators to track successful integration of VMMC services into the spectrum of HIV services.

The range of data variables discussed above should be considered when designing data collection instruments such as medical records, registers, and reports. It is essential to accommodate standardized definitions to facilitate the accurate and consistent collection and reporting of data across facilities, PEPFAR implementing partners, districts, provinces, regions, and countries. If using a paper-based system, it is important to designate a person responsible for completing medical records and/or registers and aggregating data into reporting forms. Staff involved in VMMC service provision may

include the health care facility staff responsible for registering clients, HTC and VMMC counselors, peer educators, VMMC providers (i.e. doctor, nurse), anesthesiologist, & medical director/supervisor of the MC program and facility in-charge.

Figure 1 represents a sample workflow and sequence of events at a VMMC site, with corresponding data collection tools for each event. It is noted that in some countries, some of these forms may be combined.

Figure 1. Sample workflow and sequence of events for VMMC



Method of Measurement for Indicators

Below are some "methods of measurement" for the PEPFAR VMMC indicators. Refer to the NGI Reference Guide for a complete description and explanation of the method of measurement for the indicators.

P5.1.D Number of males who received VMMC as part of a minimum package of HIV prevention, categorized by age and HIV status

<u>Method of measurement:</u> The numerator can be calculated by totaling the number as an aggregate of clients having received VMMC within the reporting period, taken from monthly summaries, VMMC Registers or clients' medical records maintained by programs. There is no denominator.

P5.2.D Number of circumcised clients experiencing at least one moderate or severe adverse event (AE) during or following surgery, within the reporting period

<u>Method of measurement:</u> The numerator can be generated by summing the clients experiencing moderate and severe adverse events documented in Adverse Event Monitoring Logs, files of individual Adverse Event forms or client medical records maintained by programs. There is no denominator.

P5.3D Number of locations providing MC surgery as part of the minimum package of MC for HIV prevention services within the reporting period

<u>Method of measurement:</u> The sum of separate locations providing MC surgery as part of the minimum package of MC for HIV prevention services within the reporting period.

P5.4.D Number of males circumcised within the reporting period who return at least once for post-operative follow-up care (routine or emergent) within 14 days of surgery

<u>Method of measurement:</u> The sum of individual clients returning to the MC surgery location for postoperative follow-up care within the reporting period (by date of surgery), taken from monthly summaries, VMMC Registers or clients' medical records maintained by programs.

H2.3.D Number of health care workers who successfully completed an in-service training program within the reporting period

<u>Method of measurement:</u> The number is the sum of health care workers who successfully completed an in-service training program within the reporting period with full or partial PEPFAR support. Individuals will not count as having successfully completed their training unless they meet the minimum requirements as defined by international or national standards. In the absence of international or national standards, the minimum requirement will be determined by the PEPFAR country team. Any individual involved in safeguarding and contributing to the prevention, promotion, and protection of the health of the population may be counted in this in-service training indicator.

Data Tools and Reporting Systems

This section explains types of forms that may be used in the VMMC monitoring and reporting process and provides a description of the information that is captured. In some places, there may only be a register, and in

such places, the register not only allows for easier aggregation but it must also capture the important clinical and indicator data elements.

Facility-based client record form

Ideally, all facilities should have a client record form that is started for an individual once he enrolls in VMMC. This form should be started for all individuals who enroll regardless of whether they complete the procedure. Regardless of the format, it is important that the form collects the necessary clinical data elements and other data elements required for reporting of the indicators in a standardized manner. The forms should be organized in such a way that corresponds with the workflow and sequence of events of the VMMC process.

Facility Daily Register

The purpose of the facility daily register is to capture demographic information on all individuals that come to the site with the intention of having VMMC, and to keep track of all individuals who registered for VMMC, regardless of whether or not they received the procedure, at a specific facility. Some individuals may only receive group counseling. All individuals who register for VMMC will have a facility-based client record form and will need to be listed in the facility surgery day register.

Surgical Register (see Figure 4)

For those individuals that elect to proceed with VMMC and actually receive clinical services, information from facility-based client record forms should be entered into the facility surgery day register at least weekly. Each row in the register is for one client and contains the name of each client. The total number of individuals (rows) should be aggregated monthly at the end of each month. These total numbers should reflect the same disaggregation as in the VMMC indicators (e.g. age, HIV status).

Facility Follow-up Register

The purpose of the facility follow-up register is to capture information on frequency of follow-up visits and any adverse events.

All individuals who receive VMMC should ideally be listed in the facility follow-up register. In some cases the follow-up register and surgical register will be one register. Regardless, each row in the register is for one client. Each row contains the names of a client, one client per row. The total number of clients (rows) should be added monthly at the end of each month. The number of clients experiencing adverse events will also need to be reported according to disaggregation as in the VMMC indicators (e.g. severity, type of adverse event, timing of adverse event).

District/Regional Record (see Figure 5)

The purpose of the district/regional record is to capture and keep track of specific information on all male circumcisions performed by sites within specific districts or regions. All individuals recorded in the facility surgery and follow-up registers should be recorded in the district/regional record. Each row in the district/regional record is for one facility. The rows contain the total number of clients, including disaggregated-

level data, for each facility. The cumulated monthly numbers from each facility register should be reported to the district/region by means of summary forms. The rows should be aggregated on a semi-annual basis to reflect the total numbers of clients, including disaggregated-level data, for the district.

National Monitoring System

Chronic disease

clinic

Partner disclosure

Pre-ART

ART

Antenatal/PMTCT

All VMMC data coming from lower levels in the health system (facility, district, region/ province) will be aggregated into a national reporting system. It is likely that this will be an electronic system. The national system tracks service delivery country-wide, based on the national indicators for VMMC program rollout.

Linkage of Facility-based Records Systems

Linking VMMC to other HIV prevention interventions is essential for providing comprehensive prevention services to clients. HIV prevention interventions are intimately linked to services such as HIV testing and counseling, PMTCT interventions, treatment, evaluation and treatment for STIs, general health services and TB. Of great importance is linking HIV negative men identified in HIV testing and counseling sites or other locations providing HIV testing to VMMC services. Men identified as HIV-positive by VMMC service sites may get VMMC if they are healthy enough and should also receive referral and linkage assistance to HIV care and treatment. Figure 2 illustrates where VMMC services are linked with other types of service providers. PMTCT and ANC services may also be points of referral, to the extent that information provided to women at such sites may reach the men that they influence.

Group

Health

Education

Offer

HTC

HIV -

Referral to Care and Treatment

Physical

Exam

Treatment of STI,

Referral of genitourinary and medical conditions to

specialized services

VMMC

Procedure

FACILITIES/SERVICE SITES

HTC (HIV-)

STI diagnosis and treatment

Programs addressing male norms

Registration

VMMC

Facility

Figure 2. Linkages between VMMC and other HIV services.

Data Quality Assurance

Routine data quality assurance measures should be instituted at each point of data collection as well as at each point of aggregation (facility, partner, district, regional, national, etc.). Comparison of past-year APR results and COP targets may show inconsistencies that could be indicative of data quality problems or data entry errors. PEPFAR implementing partners should proactively conduct reviews of data no less than quarterly to assess the quality of facility level data. Table 3 below provides a sample checklist to help avoid common data errors.

Table 3. Data Quality Checklist

Data quality concern	Guiding questions
Data completeness	Are providers filling in all fields in the registers?
	Are all VMMC's being reported in the registers?
	Are facilities submitting monthly summaries consistently?
Data quality	Are fields in the form being filled out correctly?
	Are monthly summary indicators being correctly tallied from the
	registers into aggregated reports?
Data timeliness	Are summary reports being generated and sent to the appropriate level
	following reporting deadlines?
Storage / Infrastructure	Are forms, registers and reports being filed and stored properly (in
	locked storage)?
	Do facilities and districts have enough recording and reporting tools for
	their reporting purposes?

PEPFAR implementing partners and providers should expect an assessment of the data during collection and reporting, using a data quality assessment (DQA) instrument or an external quality assurance (EQA) assessment.

EQA exercises can assist national governments in monitoring VMMC service delivery programs and provide ongoing feedback on the safety and quality of services. These DQA and EQA activities will help ensure that the programs are conducted according to the best clinical practices and produce favorable clinical outcomes and public health impact.

The objectives of a VMMC EQA are to:

- Monitor PEPFAR-funded VMMC service delivery by conducting quality assurance assessments of PEPFAR implementing partners' service sites
- Assure that all PEPFAR-funded VMMC service provision meets appropriate standards and best clinical practices
- 3. Provide technical assistance and support for program improvement where needed
- 4. Build/strengthen the capacity of respective MOHs to conduct VMMC quality assurance

Current EQA tools include DQ components but do not include a complete DQA. If the program does an in-depth DQA, the objectives of the VMMC DQA are to assess:

- 1. Accuracy: Do the data measure what they are intended to measure?
- 2. Validity: Are the fields in the forms being filled out correctly?
- 3. Reliability: Are the data measured and collected the same way with the same data collection instruments over time? Are standardized data collection forms being used?
- 4. Completeness: Are all fields completed in all forms or registers or electronic systems? Are all VMMCs being reported in all necessary forms/systems? Are all follow-up visits recorded? Are all AEs recorded?
- 5. Precision: Do the data have sufficient detail? Are all weights collected and recorded?
- 6. Timeliness: Are data entered during each client's visit? Are summary reports being generated and sent to the appropriate level following reporting deadlines?
- 7. Integrity: Are the data protected from deliberate bias or manipulation for personal or political reasons?
- 8. Confidentiality: Are clients are assured that their data will be maintained according to national/international standards for data?

Recording and Reporting VMMC-Related Data

VMMC, as a service provided through the health system, must be recorded properly using standardized tools and summarized into reports which flow up a data management chain. Recording and reporting systems are in different stages of standardization in the 14 countries where VMMC programs are being rolled out.

Data collection and reporting tools, from the health facility level up to the national level, must be established in order to successfully monitor and report indicator data. It is important that data collection and reporting tools are standardized, in order to facilitate consistency in data collection and aggregation across different reporting levels and through national systems. The type of data management system--paper-based or electronic-- may cause some variability in information flow to each required reporting level. While paper and electronic systems may differ, the data elements captured must be the same and must be able to be reported as required.

Data collection and reporting tools include client record forms, registers, and periodic (monthly or quarterly) summary forms. The purpose of the summary forms is to aggregate information to be reported to the next level (such as district, regional, or national). For example, summary forms at the facility level aggregate data from clients- at a given facility for reporting to the district. Summary forms at the district level aggregate data from all facilities in a give district for reporting to the province, and so on to the national level. The reporting period may vary, but at least monthly aggregation is recommended to be able to provide rapid feedback on service delivery. Although the PEPFAR implementing partner's primary responsibility is to report accomplishments toward indicators to PEPFAR, it is also important that PEPFAR implementing partners support national health systems approaches to HMIS for VMMC Refer to Appendix 2 and Appendix 3 for sample MC data collection and reporting tools.

Collecting and analyzing only what is needed for individual client care and for facility, district and national program management is an important principle for the design of VMMC information systems. While forms may vary between countries, these guidelines encourage the use of a simplified standardized data collection system at the facility level. Table 4 provides the key data elements required for each data source. This is an example of a illustrative system, based on a data flow in which client information for the VMMC service is recorded on a client record form and is transcribed into a summarized log (summary form), which is then used to generate a monthly summary report.

The example system in Table 4 allows flexibility for additional data collection, though it's important that the previously specified minimum essential data elements not be compromised. The addition of novel data collection elements may allow for analysis for clinic and program needs, and for research, if IRB procedures are followed. While forms may vary, standardization of the data elements is critical to ensure that data can be aggregated.

Electronic systems: Health Management Information Systems (HMIS) can either be paper-based or electronic. Electronic systems can facilitate reporting, improve data accuracy and reduce the manual review/tabulation burden of paper-based systems. Electronic systems may use paper forms for data entry and back-up. For countries in which electronic medical records exist, a register may not be necessary, and the monthly summary form may be an automatically generated report. All information in an electronic database should be supported by a hard-copy source document.

The following illustrative example uses a paper-based system and includes 5 forms for recording and reporting purposes:

- 1. A client record form for collecting clinical data, including follow-up
- 2. A facility surgery day register
- 3. A facility **follow-up register**

(Note: In some cases the facility surgery day register and follow-up register might be combined into one register)

- 4. Monthly summary forms
 - a. Summary form for Facilities
 - b. Summary form for District/Province/Region

Examples are provided of each record or register and the essential minimum data elements.

To assist in the best possible collection, monitoring and reporting of VMMC indicators and ongoing program evaluation, a list of key data elements has been compiled for easy reference (see Table 4).

Table 4. Sample Data Fields for VMMC Data Collection

			Facility Register		
		Facility Register	Follow-up		
	MC Record Form	Surgery Register	Register	District Record	National Record
	ID#	ID#	ID#		
	Name, address	Name, address	Name, address		
Demographic	Date of birth	Date of birth	Date of birth		
Information	Age	Age	Age	By age	By age
	Registration date	Registration date	Registration date		
	Facility, Region	Facility, Region	Facility, Region	By facility	By district/region
	Date, ID#, Allergies,	Date, ID#, Allergies,			
	History of STI and	History of STI and			
Medical History	other conditions,	other conditions,			
	Treatments, Current	Treatments, Current			
	complaints	complaints			
Physical	Date, ID#, blood	Date, ID#, blood			
Examination	pressure, pulse,	pressure, pulse,			
Examination	genital exam	genital exam			
MC Procedure	ID#	ID#	ID#		
and Intra-	Date	Date	Date	By month	By quarter/year
Operative	Start time, end time	Start time, end time			
Information	Surgeon name	Surgeon name	Surgeon name		
mormation	Type of AE	Type of AE	Type of AE	By type of AE	By type of AE
		<u> </u>			
	ID#		ID#		
	Date		Date		
Post-Operative /	Facility		Facility	By facility	By district/region
Adverse Event	Number of days post-		Number of days	Number of days	Number of days
Information	ор		post-op	post-op	post-op
			Type of AE,	By type of AE,	By type of AE,
	Type of AE, Severity		Severity	severity	severity

Different country programs will have different reporting periods. Typically, program data is aggregated and reported on a monthly or quarterly schedule. Aggregation of the registers or records will be done by different people or by electronic systems, depending on whether systems are paper-based or electronic. For example, for the facility register, the summation of cells across days of a given month will compile the aggregate report.

Information should be routinely summed over designated time intervals then reported to the next level at predetermined reporting periods. Reporting frequencies may vary depending on the type of VMMC service delivery. While reporting for routine VMMC service delivery may be monthly, reporting during a campaign period may be more frequent (i.e. daily, weekly). Table 5 provides summation and reporting periods typical of routine VMMC service delivery. The level and information to report remain the same regardless:

Table 5. Summation and reporting periods typical of routine VMMC service delivery

LEVEL	INFORMATION TO SUM AND REPORT
Facility	# of males circumcised as part of VMMC for an HIV prevention program
	(Essential)
	Disaggregation:
	By age (Essential)
	 By HIV status, and by site location (Recommended)
	 # of circumcised males who experienced at least one moderate or severe
	adverse event during or following surgery (Essential)
	Disaggregation:
	 By severity, type and by time of onset (Recommended)
	# of males circumcised who returned at least once for post-op follow-up care
	(routine or emergent) within 14 days of surgery (Recommended)
District	 # of males circumcised as part of VMMC for an HIV prevention program
	(Essential)
	Disaggregation:
	By age (Essential)
	 By HIV status, and by site location (Recommended)
	# of circumcised males who experienced at least one moderate or severe
	adverse event during or following surgery (Essential)
	 By severity, type and by time of onset (Recommended)
	o By facility
	# of males circumcised who returned at least once for post-op follow-up care
	(routine or emergent) within 14 days of surgery (Recommended)
	 # of healthcare workers who successfully completed an in-service training
	 By cadre (VMMC and Pediatric Treatment)
	 # of locations providing MC surgery as part of the minimum package of MC for
	HIV prevention services (Recommended)
	By location type
National	 # of males circumcised as part of VMMC for an HIV prevention program
	(Essential)
	Disaggregation:
	 By age (Essential)
	 By HIV status, and by site location (Recommended)
	# of circumcised males who experienced at least one moderate or severe
	adverse event during or following surgery (Essential)
	Disaggregation:
	 By severity, type and by time of onset (Recommended)
	# of males circumcised who returned at least once for post-op follow-up care
	(routine or emergent) within 14 days of surgery (Recommended)
	# of healthcare workers who successfully completed an in-service training
	 By cadre (VMMC and Pediatric Treatment)
	 # of locations providing MC surgery as part of the minimum package of MC for
	HIV prevention services (Recommended)
	 By location type

Figure 3 is a sample flowchart of recording and reporting, by reporting levels. The district and regional reporting may vary by country according the respective provinces or regions.

Data Collection and Reporting Frequency Reporting Process Male enrolls Registration Daily VMMC procedure and VMMC Record Form Follow-up Facility level Daily Daily **Client record forms** Facility Follow-up Register Facility Surgery Day Register entered into register Monthly Monthly **Facility numbers** Facility Periodic Summary Form aggregated into OR Monthly **Summary Form** Semi-annually District/Regional level Aggregated facility **District/Regional Record** numbers reported to district/regional record Semi-annually **District numbers District Periodic Summary Form** aggregated into **Summary Form** level Annually Aggregated National district/region records **National System** reported to national system

Figure 3. VMMC recording and reporting, by reporting levels

Capacity Building for VMMC Reporting

It is likely that a PEPFAR implementing partner supporting VMMC service delivery rollout will need to assist public hospitals and clinics where they support VMMC services to ensure proper recording and reporting of VMMC indicator data. Table 6 below provides some guiding questions to assess the capacity for VMMC recording and reporting at facility and district level.

Table 6. Guiding Questions for VMMC data collection and reporting

Level	Guiding questions
Facility	Do providers understand how to fill all fields on the recording tool?
	Are providers consistently taking the time to fill in all fields in the recording tool?
	Is there a designated person in the health facility whose responsibility it is to aggregate data into summary reports?
	Do the fields in the register allow for summarization into the summary report?
	Are errors being made in tallying or aggregation?
	Are systems in place to allow for aggregating and submitting reports by
	the deadline?
District/ Region / Province	Is there a designated person at this level whose responsibility it is to
	receive and aggregate facility level reports?
	Is there a mechanism in place to follow up late or missing reports from
	facilities or districts?
	Are errors being made in aggregation?
National level	Is there a designated person or section of the Ministry of Health to receive reports?
	Is there a mechanism in place to follow up late or missing reports from districts or regions?
	Is there a system in place to assess completeness of the data?
	Is there an appropriate data management system in place to properly store and aggregate the data and produce reports?

Sample Registry and Reporting Forms for VMMC

Figures 4 and 5 below provides sample registry and reporting forms for VMMC. It is understood that country programs will likely develop national tools based on their own strategies and resources, which may or may not include the data elements in the sample tools below. The sample tools provide an example of data monitoring which go beyond the minimum requirements for PEPFAR reporting, but which also address clinical efficiency and HIV prevention interventions.

Figure 4. Sample Surgery Register

Surgery R	egister (incl	udes fol	low-up regis	ter)																																																														
Facility Nar	me:			ні	V Status														Follow-up																																															
		HIV	positive	HIV	negative			Circumcision complete											Day	of Fol	low-	ира	nd A	E pos	stsu	rgery																																								
			Self reported		Self reported						Age					AE during surgery		_		_								_		_		_				AE during surgery		_		_		_		_		_		_		_		_		_				0 pos rgery		Day	1-6) ay 7	-14	Any	
Date	Patient	Tested at Site?	date of last test (if not tested at site)	Tested at Site?	date of last test (if not tested at site)	% Tested at Site	Unknown and self reported	<1	1-9	10-14	15-19	20-24	25-49	+09	Total	Mild	Moderate	Severe	Mild	Moderate	Severe	Moderate	Severe	Mild	Moderate	Severe	Moderate	Returned for Follow- up																																						
1-Mar	Patient A	Х														0	0	0						0	0	0	0	Х																																						
	Patient B				2-Feb-12											0	0	0			() (0				0	Х																																						
2-Mar	Patient C			Х												0	0	0																																																
31-Mar	Patient Z			Х												0	Х	0			(Х	0	0	Х	0	Х	Х																																						
	TOTAL (March)	А	В	С	D	(A+C)/ (A+B+C+D)		Е	F	G	H	_	J	К	SUM(E:K)	L	М	N									0	Р																																						
EXAMPLE	TOTAL (March)	5	1	80	9	85/95		0	2	6	25	46	13	3	95	0	1	0									1	44																																						
1-Apr	Patient A																																																																	
	Patient B																																																																	
2-Apr	Patient C																																																																	
30-Apr	Patient Z																																																																	
	TOTAL (April)																																																																	

Figure 5. Sample District/Regional Report

District/I	Regional Reco	rd																																																																																																																													
DISTRICT: HIV Status															Follow-up																																																																																																																
		HIV	positive	HIV	negative			Circumcision complete										Day	of Fo	llov	v-up	and.	АЕ ро	stsu	ırgery																																																																																																						
			Self reported		Self reported							AE during surgery			_		_		_				_		_		_		_		_		_		_		_		_		_		_				_		_		_		_				_		_				_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		-		-		-				-		0 po		Da	y 1-6		Day 7	7-14	Any	
MONTH	CLINIC	Tested at Site?	date of last test (if not tested at site)	Tested at Site?	date of last test (if not tested at site)	% Tested at Site	Unknown and self reported	<1	1-9	10-14	15-19	20-24	25-49	50+	Total	Mild	Moderate	Severe	Mild	Moderate	Severe	Mild	Moderate	Severe	Moderate	Severe	Moderate	Returned for Follow- up																																																																																																			
March	CLINIC A																																																																																																																														
	CLINIC B																																																																																																																														
	CLINIC C																																																																																																																														
	CLINIC Z																																																																																																																														
	TOTAL (March	A	В	С	D	(A+C)/ (A+B+C+D)		E	F	G	Н	1	J	К	SUM(E:K)	L	М	N									0	Р																																																																																																			
April	CLINIC A																																																																																																																														
	CLINIC B																																																																																																																														
	CLINIC C																																																																																																																														
	CLINIC Z																																																																																																																														
	TOTAL (April)																																																																																																																														

VMMC Emergency Preparedness and Death Reporting Procedures

Through the implementation of VMMC programs, as of September 2012, PEPFAR had supported over 1.9 million circumcisions. As PEPFAR programs reach greater numbers of boys and men with VMMC, we can anticipate that complications or adverse events will occur at an expected frequency/rate. Surgical procedures and use of local anesthesia inherently involve risk, and while rare, severe adverse events, including death, do occur.

Life-threatening complications will occur, and though unavoidable and rare, our supported staff and sites must be prepared to manage and report them. Guidance on emergency equipment/supplies is provided by WHO and PEPFAR, and readiness assessments are specifically recommended as part of quality assurance activities. All PEPFAR agencies, implementing partners, and facilities must assess their readiness for emergency situations and ensure that they are familiar with emergency protocols. Obtaining and documenting informed consent prior to performing medical services, like VMMC, ensures that clients are fully aware of the associated risks and benefits and is crucial to enabling a high-quality, voluntary environment.

PEPFAR agencies and implementing partners must assess all VMMC service sites to verify that required emergency equipment/supplies are on-site and readily available, haven't reached their expiration date, and that staff trained in their use is always available when VMMC services are being provided. The VMMC TWG provides follow-up with the technical leads in countries to ensure that this is occurring. Sites lacking equipment, supplies, or trained staff must suspend all VMMC services until the deficiencies have been addressed. If you need technical assistance in completing these assessments, please contact any of the VMMC TWG co-chairs:

OGAC: Jason Reed: reedjb@state.gov

USAID: Emmanuel Njeuhmeli: enjeuhmeli@usaid.gov

CDC: Naomi Bock: neb2@cdc.gov

DoD: Anne Thomas: anne.thomas@med.navy.mil

There is a process for reporting client deaths that has been circulated to PEPFAR offices and VMMC technical leads that ensures the in-country PEPFAR Coordinator and the Office of the U.S. Global AIDS Coordinator are informed of all such events within 24 hours. Additional details will be made available in the next revision of this guide.

Conclusion

Monitoring and reporting of VMMC programs is integral to the success of VMMC, and is necessary for the integration of VMMC into health systems in the country. PEPFAR implementing partners are required to report on VMMC indicators, but also are tasked with assisting the national health information systems for sustainability (PEPFAR Blueprint: Creating an AIDS-free Generation, 2012). Good monitoring and reporting systems for VMMC are possible, and many country programs have made great strides in working hand-in-hand with PEPFAR teams and Ministries of Health to establish such systems.

Additional Resources

- A guide to indicators for male circumcision programmes in the formal health care system.
 Geneva: World Health Organization and Joint United Nations Programme on HIV/AIDS, 2009.
- Clearinghouse on Male Circumcision for HIV Prevention web site, 2013
 [http://malecircumcision.org]. Web site developed by FHI 360.
- PEPFAR SAPR and APR Guidance: Guiding Questions for VMMC Indicator Reporting [PEPFAR Guidance distributed to field].
- PEPFAR Blueprint: Creating an AIDS-free Generation. The Office of the U.S. Global AIDS
 Coordinator. U.S. Department of State. November 2012.
- PEPFAR Next Generation Indicator Reference Guide (Version 1.2) [Available at: http://www.pepfar.gov/reports/guidance/index.htm]
- Technical Considerations Provided by PEPFAR Technical Working Groups for FY 2013 COPS and ROPS. October 2012. [Available at:
 - http://www.pepfar.gov/reports/guidance/technical/index.htm]
- PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations [Available at:
 - [http://malecircumcision.org/resources/PEPFAR_best_practices_guide_for_vmmc.html]
- Progress in Scale-up of Male Circumcision for HIV Prevention in Eastern and Southern Africa: Focus on service delivery. Geneva: WHO, UNAIDS, 2011.
- Manual for male circumcision under local anaesthesia. WHO, UNAIDS, JHPIEGO: Version 3.1, 2009. [Available at: http://www.who.int/hiv/pub/malecircumcision/local_anaesthesia/en]