PEPFAR

U.S. President's Emergency Plan for AIDS Relief

CHAPTER TEN.

COMPREHENSIVE QUALITY ASSURANCE AND
CONTINUOUS QUALITY IMPROVEMENT

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

A Service Guide for Site Operations

Acknowledgments

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CHAPTER 10.
Comprehensive Quality Assurance and Continuous Quality Improvement

GOALS

To ensure site staff are able to:

– Provide comprehensive, high-quality VMMC services at all sites, in line with national, WHO (World Health Organization) and PEPFAR (U.S. President's Emergency Plan for AIDS Relief) standards through quality assurance and continuous quality improvement activities.

– Prioritize patient safety, maximize site-level efficiencies, and build capacity for implementation of quality methodology.

WHAT USERS NEED TO KNOW

Comprehensive quality systems encompass quality improvement/assurance (QI/QA) and external quality assessment (EQA) as well as continuous quality improvement (CQI) mechanisms. [See **WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services**, **PEPFAR External Quality Assessment (EQA) Tools**, and **USAID ASSIST Project VMMC CQI and EQA Toolkit**]. The development of a well-coordinated, comprehensive quality assurance and continuous quality improvement strategy is critical to the success of any health program scale-up plan (Massoud 2001). It is also important that this strategy is integrated into all aspects of the VMMC program right from the start of VMMC services. QA is a cross-cutting activity, linking other VMMC pillars, including leadership, management, infection control, waste management, and the VMMC minimum package of services. [See **WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services**]. Without a targeted strategy focusing on provision of high-quality VMMC services, patient safety and robust infection control practices, investments in VMMC service provision, and scale-up may not yield the anticipated results [See **WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services**]. Furthermore, the VMMC program may continue to be vulnerable to several unanticipated consequences, such as poor patient outcomes, high morbidity and mortality rates, and fear/stigma of the VMMC program, thereby potentially negating investments in demand-creation activities. [See **PEPFAR Quality Strategy**]. It is therefore important to ensure QA and CQI activities are prioritized during scale-up of VMMC programs and concerted efforts are made toward promoting integration, capacity development, routine quality monitoring, and implementation with a goal of sustainability [See **USAID ASSIST Project VMMC CQI Toolkit**].

FREQUENTLY REFERENCED INFORMATION

External quality assessment (EQA): EQA measures the extent of compliance to the minimum quality standards and performance against quality indicators and guidelines. It is often conducted by independent individuals or organizations using standard tools across a number of facilities, districts, provinces, and countries.

Continuous Quality Improvement (CQI): CQI is an integral part of how everyday services are performed. It ensures understanding of the systems and processes for doing work in order to identify any prevailing gaps. Since all activities contain two major components—what is done (content) and how it is done (process of care)—CQI is best achieved by addressing both of these components at the same time. This paradigm for QI makes organizations more efficient and able to provide quality care with increased access and decreased waste, often at less cost.

The difference between EQA and CQI: EQA is a periodic formal assessment carried out typically by outside experts to identify performance gaps against a set standard; whereas, CQI is an ongoing process, structured but potentially less formal, carried out by program staff to both identify and address inadequate performance against either external standards or their own insights to facilitate improvement.

FOR ADDITIONAL INFORMATION

Routine assessments (either internal or external) of quality should be a continuous and ongoing activity to ensure that any deviations from the expected level of quality are identified quickly and remedied. Country programs should reinforce the need for VMMC sites to conduct routine self-assessments of quality [See **USAID ASSIST Project VMMC CQI Toolkit**] on a given schedule and to implement CQI for VMMC services, as well as to facilitate EQA assessments [See **WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services** and **PEPFAR External Quality Assessment (EQA) Tools**]. It must be understood that, while EQA and CQI are separate activities, they are inextricably linked, comprising inherent synergies and latent potential (see Figure 10.1).

CQI involves a service provider-led iterative process of testing changes, initially on a small scale, through "plan-do-study-act" (PDSA) cycles, to develop solutions for the identified gaps. The series of steps to PSDA include plan a change, do, study, and act (see Figure 10.1). Once the proposed solutions are proven, they are then spread to the entire system to yield better outcomes. This is essentially a supportive process, whereby sites are assessed to gauge the extent of compliance to the minimum quality standards, performance against quality indicators and guidelines, to note identified gaps, and to put into place and monitor remedial plans and actions. Subsequently, onsite mentoring and coaching are performed and reassessments are conducted on a regular basis. Primarily CQI is aimed at bridging the gaps between the expected level of care according to national, PEPFAR, and WHO VMMC standards and actual level of care currently provided by the VMMC service sites.

EQA assessments provide an opportunity for sites to improve their performance further and to identify areas needing support.

Routine CQI assessments should occur at least quarterly and EQA exercises at least annually. Both activities should occur more frequently if serious issues are identified. However, it is important to note that regular assessments on their own do not lead to improvement. Deliberate CQI efforts should be put in place to address any gaps identified through these regular assessments. The VMMC CQI assessment tool [See **USAID ASSIST Project VMMC CQI Toolkit**] should be revised and adapted annually to meet the needs of the program and to act on any new evidence related to client safety or changes in policy.

In addition, there is a requirement for all PEPFAR-supported sites to receive SIMS (Site Implementation Monitoring System) visits. All SIMS visits are conducted by PEPFAR personnel and are categorized as a subset of the overall QA activities within the VMMC program.

Figure 10.1. Relationship between EQA, CQI, and SIMS

4. ACT
- – Integrate
- – Standardize
- – Monitor.

1. PLAN A CHANGE
- – Identify opportunity
- – Root case analysis
- – Suggest changes
- – Design the change.

QUALITY ASSURANCE

Full cycle of activities and systems for maintaining the quality of patient care.

Generally associated with the monitoring of compliance with standards.

SIMS

PLAN

ACT **PDSA** **DO**

STUDY

2. DO
- – On a small scale, implement change
- – Where you can, control setting.

QUALITY IMPROVEMENT

The combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners, and educators**—to make the changes that will lead to better patient outcomes (health), better system performance (care), and better professional development.**

3. STUDY
- – Collect data
- – Analyze data
- – Check customer satisfaction and other key indicators.

Adapted from J. Amman, SIMS training Johannesburg, November 2014

VMMC EQA ACTIVITIES

The objectives of VMMC EQA assessment visits are to:

- – Assure that all PEPFAR-funded VMMC service provision meets appropriate standards and best clinical practices.

- – Monitor PEPFAR-funded VMMC service delivery programs by conducting QA assessments of implementing partners' service sites in resource-limited settings.

- – Identify areas where technical assistance and support for program improvement is needed.

- – Identify policy issues and quality gaps that relate to clients' safety that require immediate remedy.

- – Build/strengthen the capacity of respective ministries of health (MOHs) to conduct VMMC QA.

- – Review and identify potential system-wide barriers that may impede VMMC scale-up.

An EQA assessment typically takes three to four hours per site for a team of three to four assessors. It includes direct observation of facility procedures and activities, including counseling sessions and actual VMMC surgeries, staff interviews, review of material resource inventories (e.g., supplies, medications, written materials), and a review of client registers and records. Findings from the EQA assessments are summarized by general and site-specific reports [See **EQA Country Report Template** and **EQA Site Report Template**]. The general report helps national task forces and MOHs to identify their programs' strengths and challenges. Site-specific reports help national

programs and local facilities craft specific interventions to fill gaps. The assessments yield immediate and tangible benefits, including increased partner and governmental buy-in, rapid identification of barriers to service efficiency and demand creation, and practical feedback on infection control and waste management. The EQA assessments complement existing normative guidance and routine monitoring, and they can easily be adapted to different local and health contexts.

VMMC CQI ACTIVITIES

The objectives of the VMMC CQI program are to:

– Ensure ongoing improvement within VMMC programs by identifying specific gaps and appropriate solutions which are then implemented at site level.

– Complement ongoing EQA findings to monitor PEPFAR-funded VMMC service delivery programs by conducting in-depth comprehensive baseline CQI reassessments of implementing partners' service sites.

– Ensure that all PEPFAR-funded VMMC service provision is in compliance with international appropriate standards and best clinical practices.

– Identify strengths, weaknesses, and best practices within the VMMC program.

– Build/strengthen the capacity of respective PEPFAR partners and MOH staff to conduct and sustain ongoing VMMC CQI programs.

– Promote shared learning between VMMC clinics, districts, provinces, and countries to quickly spread best practices.

The overall process of CQI includes an initial baseline assessment and feedback, followed by CQI team formation and onsite coaching and mentoring on an ongoing basis. To ensure steady progress, CQI reassessment visits should be conducted regularly, preferably every quarter. A CQI assessment (either baseline or reassessment), which is similar to an EQA visit, typically takes four to six hours per site, depending on the size of the assessment team and the services provided at site level. All CQI assessments should be conducted using standardized CQI tools aligned to the local policies and guidelines [See **VMMC CQI and EQA Assessment Toolkit**]. CQI assessments include direct observation of facility procedures and activities; staff interviews; review of material resource inventories; and review of policies, client registers, and records. Depending on the country, there are seven or eight key domains/areas consisting of several standards identified for CQI in VMMC which must be observed for completion of an assessment visit. The main domains are: (1) Leadership and Planning; (2) Management Systems; (3) Monitoring and Evaluation; (4) Registration, Group Counseling, and IEC (information, education, and communication) Material; (5) Individual Counseling and HIV testing; (6) Infrastructure, Supplies, Equipment, and Environment; (7) Medical Circumcision Surgical Procedure (preoperative, intraoperative, and postoperative tasks including client follow-up); and (8) Infection Prevention and Control, including waste management.

Findings from the CQI assessments are summarized by overall and site-specific reports, including narrative sections as well as "VMMC CQI dashboards" indicating performance levels. [See **Uganda VMMC CQI Guide** and **USAID ASSIST Project VMMC CQI Toolkit**]. The overall report helps national and regional entities and MOHs to identify their programs' strengths and challenges and implement specific system-strengthening activities. Site-specific reports help national programs and local facilities develop interventions to solve specific problems and fill gaps. The assessments yield immediate and tangible benefits, including increased partner and governmental buy-

in, rapid identification of barriers to service efficiency and demand creation, and practical feedback on infection control and waste management.

CASE STUDIES

Case Study 10.1. Continuous Quality Improvement in Uganda and South Africa

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

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

1. **WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services**

2. **PEPFAR External Quality Assessment (EQA) Tools**

3. **WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition**

4. **PEPFAR Quality Strategy**

5. **USAID ASSIST Project VMMC CQI and EQA Toolkit**

6. **EQA Country Report Template**

7. **EQA Site Report Template**

8. **Uganda VMMC CQI Guide**

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ABBREVIATIONS

ASSIST	**Applying Science to Strengthen and Improve Systems**
CQI	**continuous quality improvement**
IEC	**information, education, and communication**
IPC	**infection prevention and control**
IQA/EQA	**internal and external quality assessment**
MOH	**ministry of health**
PDSA	**plan-do-study-act**
PEPFAR	**U.S. President's Emergency Plan for AIDS Relief**
QA	**quality assurance**
SIMS	**site implementation monitoring system**
WHO	**World Health Organization**

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

Continuous Quality Improvement in Uganda and South Africa

BACKGROUND

Quality improvement has been shown to be an effective tool for ensuring the safety and quality of VMMC services. This case study describes how quality and safety problems revealed in EQA were addressed through CQI, leading to improved adherence to VMMC quality standards, improved counseling and informed consent, and higher follow-up rates.

Figure 10.1.1. VMMC EQA Dashboard

Health unit	Baseline Feb-May 2013							Jan-14							Feb-15						
	Management systems	Supplies, equipment & environment	Registration group education and IEC	Individual counseling & HIV testing	Male circumcision surgical procedure	Monitoring & evaluation	Infection prevention	Management systems	Supplies, equipment & environment	Registration group education and IEC	Individual counseling & HIV testing	Male circumcision surgical procedure	Monitoring & evaluation	Infection prevention	Management systems	Supplies, equipment & environment	Registration group education and IEC	Individual counseling & HIV testing	Male circumcision surgical procedure	Monitoring & evaluation	Infection prevention
1	30	50	0			33		70	83	67	100	91	86	91	80	100				85	100
2	20	33	0			7	92	80	67	75			87	92	80	87	80			87	92
3	40	83	0			14	84.6	80	67	100			93	100	80	100	83	80	90	78	92
4	30	50	0			18	82	90	83	83	83	80	92	100	90	83	100	100	100	93	100
5	20	33	0			14	80	80	67	83	100	80	86	85	100	100	83	100	100	86	100
6	10	50				7	70	90	83	100	100	100	93	93	100	100	100	100	100	100	92
7	40	50	50			75	60	70	83	67	83	82	86	89	90	83	100	83	100	92	96
8	50	50	25			14	77	90	100	83	100	90	86	85	90	100	83	100	90	86	85
9	60	50	83	39	64	29	92	90	100	100	82	100	100	100	100	83	100	100	100	86	100
10	20	50	50			0	33	90	100	100	83	100	92	93	100	100	100	100	90	100	92
11	33	25	0			0		80	100	100	80	80	77	75	80	80	83	90	80	100	80
12	25	33	0				70	100	83	100	80	83	100	92	100	83	100	80	83	100	92
13	60	67	75	83	81	14	80	90	67	83	100	100	86	100	80	83	100	100	100	86	83
14	70	50	25			50	80	100	83	100	100	100	93	100	90	83	100	100	100	85	83
15	60	33	25			50	90	100	84	67	100	82	67	100	100	84	100	100	97	86	93
16	30	67	100			14	58.3	100	100	100	100	100	100	100	90	83	100	100	100	93	100
17	40	83	75	100	100	14	84.6	90	83	100	100	100	100	92	100	67	100	83	100	86	92
18	70	67	100	67	100	69	75	100	67	100	100	100	100	75	100	75	100	100	100	100	80
19	40	50	0			21	100	100	83	83	100	97	100	100	100	83	83	80	97	100	100
20	60	50	0			21	92	100	83	83	83	85	93	85	100	83	83	83	85	93	85
21	70	50	0			21	77	90	67	83	94	77	100	76	90	80	83	94	80	75	83
22	80	83	100			93	100	90	100	100	100	100	100	100	90	100	100	100	90	85	100
23	70	100	100	100	100	93	100	90	84	100	100	100	100	100	100	83	100	83	97	86	100
24	70	100	100	100	100	93	100	90	100	100	100	100	93	100	100	83	100	94	100	86	92
25	60	50	100			46	100	90	83	50	83	82	50	77	90	83	100	100	91	86	85
26	60	33	50			15	76.92	90	67	84	100	85	79	92	100	67	100	100	91	93	92
27	40	83	75	100	100	75	100	90	84	100	100	91	86	100	90	83	100	100	91	79	85
28	20	50			78	15	50	90	75	50	94	87	93	70	90	75	50	94	87	93	90
29	22	67	67		47	29	85	80	67	67	83	80	93	82	90	83	83	100	91	93	92
30	40	67				38	84.6	90	67	83	100	91	93	82	90	67	83	83	70	100	100

Initial work in Uganda: In 2012, two EQAs found serious quality gaps, including lack of standardized registers, poor documentation of client informed consent, lack of emergency preparedness, and untrained providers. In response, ASSIST (Applying Science to Strengthen and Improve Systems) helped form improvement teams to identify barriers in achieving national standards, identify solutions (changes) to overcome the barriers, and test these changes, while collecting performance data to measure whether gaps were bridged. A color-coded dashboard based on compliance with 53 standard categories was used by teams to measure progress. Site staff came together for periodic peer-to-peer learning sessions to share best practices. Within less than a year of carrying out CQI, the majority of sites had achieved "green" (good) performance across the majority of the standards, and these results have been sustained into 2016, except in dropped sites where the ASISST program was not giving external support to the sites.

Introduction in South Africa: Baseline assessments were conducted at 127 sites across the country, and then a smaller group of sites were identified as needing "intensive support" to form site-level teams. These teams worked to develop and implement site-level improvement plans, empower those teams to identify gaps in service delivery, test changes to address those gaps, and use their own data to monitor improvements in quality. Two cross-provincial learning sessions were conducted to share learning across sites and provinces and to identify successful site-level changes and best practices for scale-up. In under a year, significant improvement was achieved across all eight quality standards in the intense-support sites, as highlighted in Figure 10.1.2.
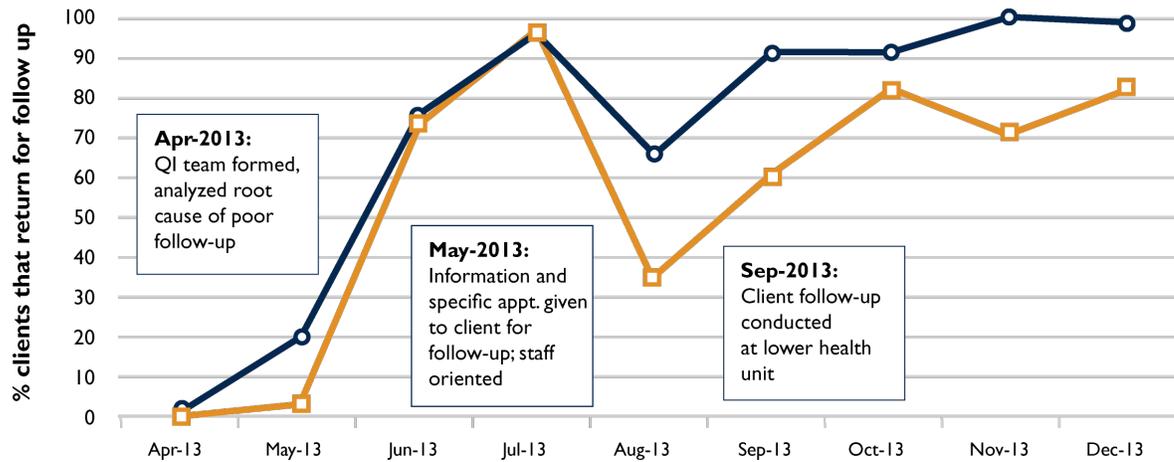
Figure 10.1.2. VMMC CQI Dashboard

| Quality Standard | Baseline (June-September 2014) | | | | | | | | | First re-assessment (Feb-May 2015) | | | | | | | | | Second re-assessment (Aug-Sept 2015) | | | | | | | |
	Average of Leadership	Average of Management	Average of M&E	Average of Group	Average of Individual	Average of Infrastructure	Average of Surgical	Average of Infection-	Sum of A-0	Average of Leadership2	Average of Management 2	Average of M&E2	Average of Group2	Average of Individual2	Average of Infrastructure2	Average of Surgical2	Average of Infection- 2	Count of R -2	Average of Leadership3	Average of Management 3	Average of M&E3	Average of Group3	Average of Individual3	Average of Infrastructure3	Average of Surgical3	Average of Infection- 3
Average across all sites	40.5	68.5	74.2	84.2	81.6	75.6	74.5	78.2	0.0	60.1	83.4	79.6	88.5	84.8	93.8	89.5	92.1	43.0	74.9	92.1	86.0	92.0	91.5	96.7	94.0	95.7

QUALITY IMPROVEMENT INTERVENTIONS AT INDIVIDUAL SITES

Using similar approaches, ASSIST has worked with individual sites to improve the quality of VMMC services, which include the following:

– Gulu Regional Referral Hospital in Uganda improved 48-hour client follow-up from initially only 2 percent in April 2013 to 99 percent. The follow-up rate at 7 days was also noted to be good at 82 percent as shown in Figure 10.1.3.

– A large private provider in Johannesburg was supported to establish a CQI team to address infection prevention and control (IPC) and waste disposal. Within eight months, the clinic improved its IPC score from 66 to 98 percent and has made the new practices part of routine VMMC service provision.

– A rural primary health care center in South Africa formed a CQI team including both Department of Health and implementing partner staff that mobilized the site staff to standardize preoperative history-taking and examination, repair infrastructure, increase privacy, upgrade staff skills in IPC and counseling, and empower mobilizers. Within 11 months, scores for surgical procedures improved from 60.6 to 96.8 percent and for IPC from 72.7 to 95.3 percent. The number of VMMC procedures performed increased from 60 to 124 per month (January–June 2015). The CQI team integrated changes into routine service provision.

Figure 10.1.3. Time Series Chart of Service Improvements

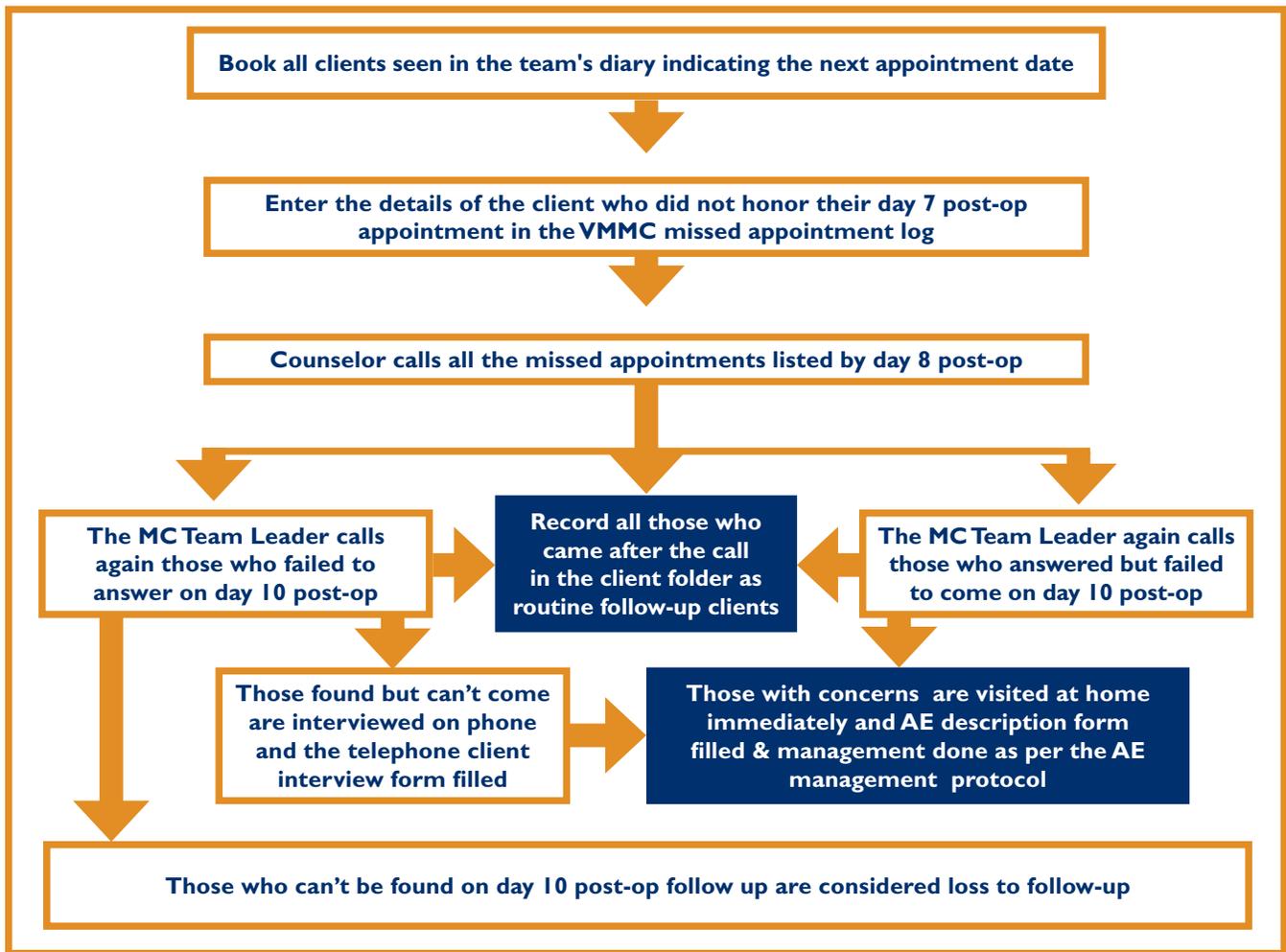|	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13
% age FU 48 hrs	2	20	76	97	66	91	91	100	99
% age FU 7 days	0	3	74	97	35	61	82	71	82
# Return 48 hr	1	27	32	773	71	69	31	77	470
# Return 7 days	0	4	31	766	38	46	28	55	388
# Circumcised	46	134	76	793	108	76	34	77	473

LESSONS LEARNED

– The Uganda VMMC CQI pilot demonstrated that site teams could be mobilized to significantly improve VMMC service quality. Broad consultation with stakeholders was vital at start-up to engage MOH and IPs. Use of simple but informative tools such as the dashboard was key.

– Implementation of CQI initiatives in VMMC programs requires patience and perseverance, but also yields tangible results. Capacitating and involving all staff in ongoing CQI initiatives allows for creativity, teamwork, increased staff motivation, and optimized service delivery.

IMPROVEMENTS TO POST-OPERATIVE CLIENT FOLLOW-UP THROUGH THE DEVELOPMENT OF TRACKING TOOLS

Figure 10.1.4. VMMC Missed Appointment Management Algorithm

IMPACT RESEARCH & DEVELOPMENT ORGANIZATION
VMMC MISSED APPOINTMENT MANAGEMENT ALGORITHM

Book all clients seen in the team's diary indicating the next appointment date

Enter the details of the client who did not honor their day 7 post-op appointment in the VMMC missed appointment log

Counselor calls all the missed appointments listed by day 8 post-op

The MC Team Leader calls again those who failed to answer on day 10 post-op

Record all those who came after the call in the client folder as routine follow-up clients

The MC Team Leader again calls those who answered but failed to come on day 10 post-op

Those found but can't come are interviewed on phone and the telephone client interview form filled

Those with concerns are visited at home immediately and AE description form filled & management done as per the AE management protocol

Those who can't be found on day 10 post-op follow up are considered loss to follow-up

Between 2010 and 2013, the VMMC client post-operative follow-up rate at all VMMC sites operated by Impact Research and Development Organization (IRDO) in 10 counties in eastern Kenya ranged from 29 to 32 percent. In November 2014, the team designed a follow-up system flow chart (Figure 10.1.4) indicating the steps to take if a client misses follow up, and a Missed Appointment Log (Figure 10.1.5) to record those who miss their appointments and to document the outcome of follow-up calls made.

Figure 10.1.5. Follow-Up Missed Appointment Log
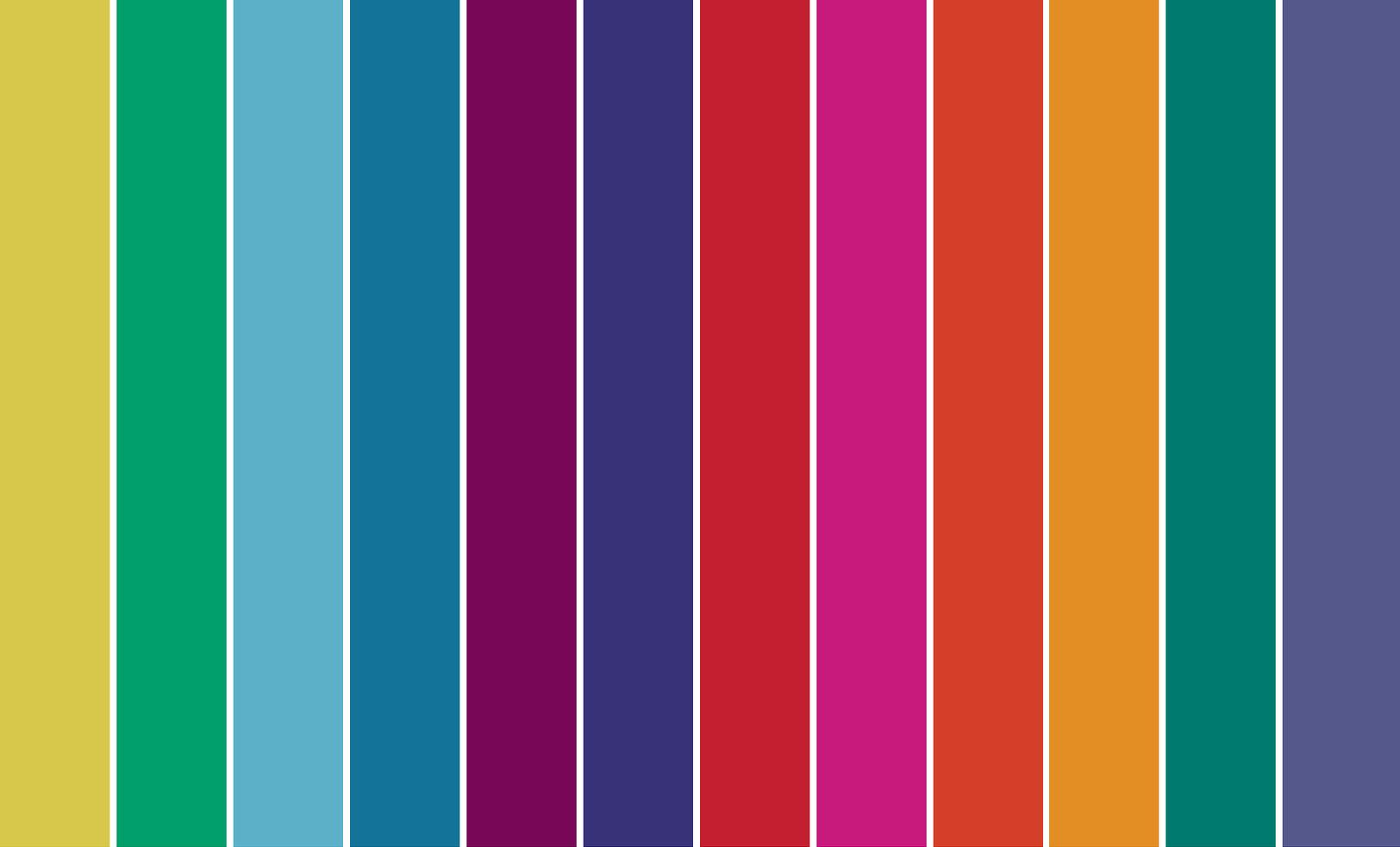
VMMC Follow-Up Missed Appointment Log

No.	Date of Missed Appointment	Client No.	Real Name	Age	Phone #	Date Called	Called By	Outcome
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		

After surgery, clients are issued a card indicating the return date and reminded to return for postoperative review on day 7, as per VMMC Kenya's policy. Those who miss follow-up on day 7 are recorded in the VMMC Follow-up Missed Appointment Log. If on day 8 the client has not come for review, the team leader advises the counselor to call the client. If by day 10 the client still has not honored the appointment, the team leader makes a second call. If the client comes after the day 8 or day 10 telephone reminder, he is recorded on the client folder as routine follow-up.

However, if the client is found on the day 10 telephone call but unable to come for review, the clinician will interview the client over the phone and complete a client telephone interview form. If issues of concern are identified, the team leader visits the client at home or in a nearby health facility for review. If the client is not reached on the day 10 telephone call and tracking through the mobilizers also fails, he will be considered lost to follow-up.

These efforts have seen an increase in follow-up rates, from an average of about 30 percent in 2010–13, to 38 percent in 2014, and to 59 percent in early 2015, nearly doubling the client postoperative follow-up rate in two years.

PEPFAR

U.S. President's Emergency Plan for AIDS Relief

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