Module 5

Assuring the Quality of HIV Rapid Testing:
A Systems Approach to Quality

Purpose	To provide an overview of the lab quality system so that you will adopt a broad systems view toward quality and understand where errors may occur in the rapid testing process and your responsibilities in preventing and detecting them.
Pre-requisite Modules	None
Learning Objectives	At the end of this module, you will be able to: ▪ Explain the systems approach to lab quality and its benefits ▪ Identify the essential elements of a lab quality system and how they apply to HIV rapid testing ▪ Recognize key factors that may compromise the quality of HIV rapid testing ▪ Describe your responsibilities in preventing and detecting errors before, during, and after testing
Content Outline	The approach we take to achieve quality Essential elements of a lab quality system Quality assurance procedures at the HIV rapid testing site How you can contribute to quality before, during, and after testing
Handout	None
Notes on Customization	If a lab quality system has been established, provide specific in-country information for each component of the quality system.

What is "Quality"?

Quality is the ability of a product or service to satisfy the needs of a specific customer. You may achieve it by conforming to established requirements and standards.

An example of service would include providing and interpreting an HIV Rapid Test.

"Dining Out": A Quality Experience

Quality can be evaluated in anything we experience. You can better understand the concept of quality and quality systems by thinking about what you might experience at a fine restaurant:

Think about what you might expect for a quality experience at a fine restaurant? If your expectations as a customer are met by the restaurant, the restaurant has provided you with "quality" service.

Simply put: Quality Management is having systems in place to continually evaluate:

- What is being done
- How it is being done
- What are opportunities for improvement
- How to make changes for improvement
- What is the impact of the change/improvement

Keep the restaurant scenario in mind as you study this module.

Why Quality?
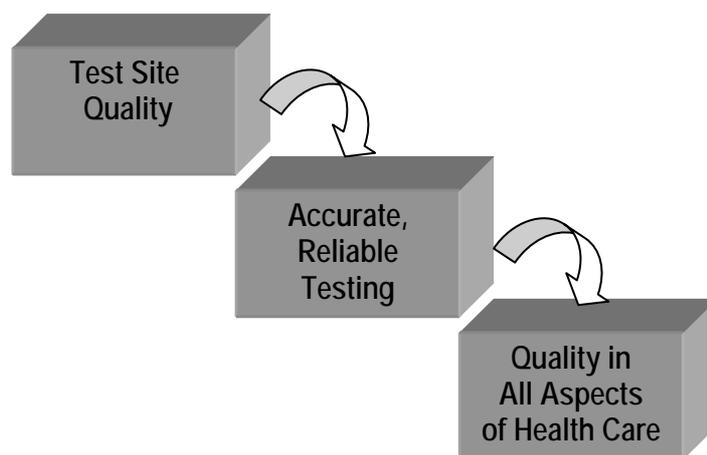
Why is quality important?

Quality at a testing site will result in accurate and reliable test results, which are essential to all aspects of patient health, including prevention, care and treatment.

A Systems Approach to Quality

The approach we take to ensure lab quality is a systems approach. A systems approach examines all components in the system, not just focusing on any one component. It places as much emphasis on identifying and describing the connections between system components as on identifying and describing the components themselves.

Let's explore the concept further by using the human body as an example. A headache may be caused by disorder in other parts of the human body system. You need to look at other parts to find out what's wrong with the head.

Similarly, to achieve total quality in the lab or testing site, you need to look at all the activities, direct or indirect, that may contribute to quality.

Definition of A Lab Quality System

A lab quality system is the organizational structure, responsibilities, processes, procedures, and resources for implementing quality management of the laboratory or testing site. In other words, it implies all activities which contribute to quality of tests, directly or indirectly.

By adopting the systems approach to lab quality, a lab quality system would encompass all activities that contribute to quality directly or indirectly.
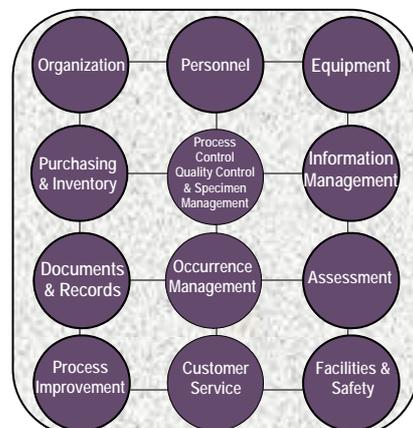
Benefits of a Quality System

A quality system to the HIV rapid testing sites has several benefits. It:

- Monitors all parts of the testing system

- Detects and reduce errors

- Improves consistency between testing sites

- Helps contain costs

The Lab Quality System

A lab quality system has 12 components. Read on to learn about each component.

Organization

Organization is the leadership or party responsible for establishing and managing the overall quality program. The quality system must start with the organization.

To ensure total lab quality, organization needs to:

- Create quality policy and standards
- Secure sufficient resources to maintain quality requirements
- Clearly define roles and accountability
- Cultivate a culture committed to quality

This component is closely linked to other components such as personnel, equipment, process improvement, and customer service.

Personnel

Personnel are the most important component in the lab quality system because it is linked to all other components. To achieve total lab quality, we need to have the right people on the right jobs all motivated and competent to perform. Consider:

- Human resource planning – What skills do you need? How many people do you need? When do you need them?

- Hiring – What is the hiring practice that will help you attract the right people? It should start with a clear job description that defines duties, responsibilities, and required skills.

- Retention – What is your plan to retain your people once they are hired? How are you going to address the issue of high turnover?

- Supervision – Supervisors are critical in that they communicate performance expectations, model proper behaviors, provide feedback, and motivate the employees. They make sure employees have the support required for performance, which includes information, tools, and consultation for problem solving.

- Training – Upon assignment to a testing site, staff must be oriented to site polices and operations. Due to method changes and frequent staff turnover, training must be provided to update employee skills. Initial and on-going competency assessment is required for all staff performing testing.

- Performance management – This entails all the activities that ensure an employees on-the-job performance. It involves goal setting, performance coaching, feedback, monitoring, appraisal, and performance improvement measures.

Equipment

Equipment used at the HIV rapid testing site may include refrigerator, freezer, and precision pipettes. Laboratories that serve as referral labs for HIV rapid testing site must ensure that equipment used is appropriate for the task and kept in optimal working order. This is achieved by:

- Selecting the right equipment. The purchasing contract should include installation and initial calibration; regular service; and training to operate the equipment.

- Setting up mechanism for regular preventative maintenance and routine calibration to ensure uninterrupted service and prolonged life span of the equipment.

- Ensuring readily available technical expertise for timely repair in case of equipment breakdown.

- Stocking up on parts that break frequently

- Establishing troubleshooting procedures

- Creating a maintenance log and regularly reviewing all documentation

- Retiring equipment properly. This involves putting up signage, removing from premise, and salvaging reusable parts.

This component is closely linked to other components such as personnel, purchasing and inventory, documents and records, and facilities and safety.

| **Purchasing and Inventory** | Purchasing is primarily handled by a central procurement and inventory process. Laboratory staff should be involved during the process of defining criteria for the materials and supplies needed. |

Purchasing and inventory involves:

- Defining criteria for products and services to be purchased

- Establishing a system to receive, inspect, accept, store incoming materials

- Maintaining proper inventory

- Developing a system to connect materials to appropriate patients, activities, or records. This is important in the event of notices from manufacturers of potential problems with specific kit lot #. You will know what lot # was used only if this information is recorded.

This component is closely linked to other components such as organization, process control, documents and records, and facilities and safety.

| **Process Control** | Process control refers to the activities and techniques performed to ensure: |

- Testing procedures are correctly performed

- The environment is suitable for reliable testing

- The test kit works as expected to produce accurate and reliable results

Process control concerns all aspects of the laboratory, not just the testing procedures. Examples include ensuring that:

- Test methods are appropriately evaluated.

- Testing sites have on hand up-to-date standard operating procedures.

- All staff follow SOPs (Standard Operating Procedures) exactly as written.

- Specimens are appropriately collected, handled/processed, stored, transported, and discarded.

- QC (quality control) is performed and monitored.

This component is closely linked to other components such as personnel, purchasing and inventory, assessment, and facilities and safety.

Documents and Records	Document and records may be paper-based or computer-based. Regardless of the format, a system must be established in order to:
	- Create standards for forms - Manage document revision, approval, and distribution - Manage patient test records - Maintain document storage, retrieval, and destruction
	This component is closely linked to other components such as purchasing and inventory, information management, assessment, and occurrence management.
Information Management	Information management refers to these activities:
	- Manage incoming and outgoing information - Establish standards for gathering information - Ensure the privacy and confidentiality of patient information
	These activities can often be facilitated by computers. If computers are used, personnel must be trained in relevant computer skills such as word processing, spreadsheet, and database.
	This component is closely linked to components such as personnel, documents and records, and customer service.
Occurrence Management	Occurrence management deals with lab problems and errors as they occur. Examples of occurrences include accidental spills or needle injuries. There must be a pre-defined approach and system for dealing with errors. For example, you should keep a record of all circumstances related to the error or problem, and corrective action taken and any communications with affected persons. This information is useful for those monitoring the testing, for any internal audits, and for use if further inquiries from patients or physicians occur.
	This component is closely linked to other components such as process control, documents and records, and customer service.

Assessment

Assessment is the periodic examining and monitoring of laboratory operations to established requirements. It involves external and internal evaluation.

It is good practice for testing sites to periodically conduct self-evaluation of their operations against quality requirements. Any gaps identified can be addressed immediately. There are two types of external evaluation or assessment.

- Testing sites may be routinely monitored in the form of supervisory visits.

- External assessments may be conducted by external agencies for accreditation purposes. This is usually done by an independent body to objectively assess compliance with established quality requirements of published standards.

This component is closely linked to other components such as organization, personnel, and process control

Process Improvement

Process improvement refers to activities designed to identify and eliminate causes of poor quality, and to reduce waste and improve efficiency by eliminating non-value added activities.

Sometimes formal studies are conducted and results are statistically analyzed. An example might be efficiency of a testing site in reporting client results. Does it take 2 hours to report a result that can be reported within 30 minutes?

But the studies don't always have to be formal. Opportunities for process improvement are everywhere if you pay attention. Here are some examples:

- You are required to dispose of sharps after each test. But the sharps container is located in a separate room from the testing area. This situation discourages testers from following the recommended safety practice and increases potential hazard if used sharps are transported to the container next door. What should you do?

- You are required to retrieve a test record or report from a given day, but it takes you a long time to sort through the piles of paper. After locating the record, there is missing information

This component is closely linked to other components such as organization, personnel, documents and records, process control, and customer service

Customer Service

Who are your customers? The patient/client, of course, is the ultimate customer. However, we must not forget the clinician, program staff, and epidemiologists. These people are our internal customers.

Everyone at the HIV rapid testing site has responsibility for providing good customer service, from the receptionist, counselor, and lab staff. Each test site should actively seek information on both internal and external satisfaction through customer surveys and interviews, and then use the data collected for process improvement. It is also a good practice to reward staff providing good service.

This component is closely linked to other components such as personnel, documents and records, process control, and process improvement

Facilities and Safety

It is important to ensure that facilities, testing and storage areas are adequate in order to produce reliable test results, e.g., monitoring testing and storage area temperatures. It is also important to provide an adequate and safe work environment.

This component is closely linked to other components such as organization, personnel, purchasing and inventory, occurrence management, process control, and customer service.

Who Is Responsible for Quality?

Quality is everyone's responsibility. For example,

- Laboratory management and program staff establish quality assurance procedures.

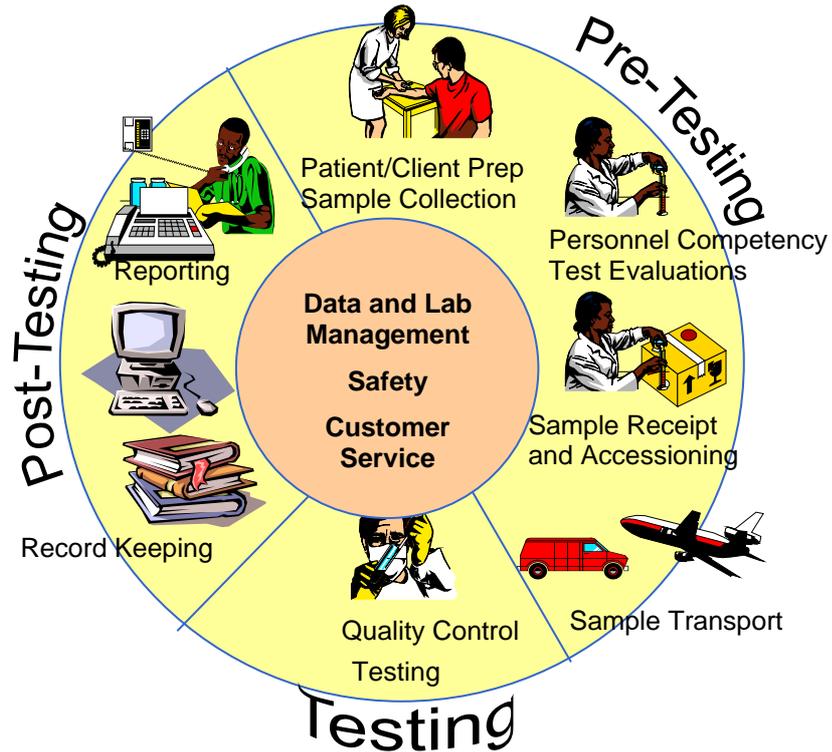- Test site personnel implement the quality assurance procedures.

How can you contribute to lab quality? You will find out more about the specific things you can do to help. But, first, let's explain how quality assurance differs from quality control.

Quality Assurance vs. Quality Control

Quality assurance (QA) is the activities that ensure process are adequate for a system to achieve its objectives. Quality control (QC), on the other hand, is the activities that evaluate a product or work result.

Examples of QA include establishing standard procedures for sample collection and defining criteria for acceptable samples. Examples of QC include analyzing known QC sample to determine if a test is valid, and deciding if a sample is acceptable for testing. As you can see, QC is part of QA.

**The Quality
Assurance Cycle**

The Quality Assurance Cycle

Pre-Testing
- Patient/Client Prep / Sample Collection
- Personnel Competency Test Evaluations
- Sample Receipt and Accessioning
- Sample Transport

Testing
- Quality Control Testing

Post-Testing
- Reporting
- Record Keeping

Center: **Data and Lab Management / Safety / Customer Service**

Quality assurance is applied throughout the testing process at all testing sites. It is not a one time event. As you can see in the graphic above, this is a continual process encompassing 3 phases and there are multiple activities associated with each phase of testing.

Why Do Errors Occur?

Errors can occur throughout the testing process. Some causes include:

- Individual responsibilities unclear
- No written procedures
- Written procedures not followed
- Training is not done or not completed
- Checks not done for transcription errors
- Test kits not stored properly
- QC, EQA not performed
- Equipment not properly maintained

The table below provides the examples of errors that may occur during the three phases of Quality Assurance Cycle, and what you can do to prevent them.

	Before Testing	During Testing	After Testing
Common Errors	• Specimen mislabeled or unlabeled • Specimen stored inappropriately before testing • Specimen transported inappropriately • Test kits stored inappropriately	• Country algorithm not followed • Incorrect timing of test • Results reported when control results out of range • Improper measurements of specimen or reagents • Reagents stored inappropriately or used after expiration date • Dilution and pipetting errors • Incorrect reagents used (i.e., using buffers from a different kit)	• Transcription error in reporting • Report illegible • Report sent to the wrong location • Information system not maintained
How to Prevent / Detect Errors	• Check storage and room temperature • Select an appropriate testing workspace • Check inventory and expiration dates • Review testing procedures • Record pertinent information, and label test device • Collect appropriate specimen	• Perform and review Quality Control (QC) • Follow safety precautions • Conduct test according to written procedures • Correctly interpret test results	• Re-check patient/client identifier • Write legibly • Clean up and dispose of contaminated waste • Package EQA specimens for re-testing, if needed

Remember, every tester is responsible for preventing and detecting errors before, during, and after testing.

Why is Quality System Important to Rapid Testing?	Even the simplest Rapid Test is not foolproof. Quality is the foundation of everything we do. A quality system:

- Sets the standard for level of quality

- Meets/exceeds customer expectations

- Provides means to prevent, detect and correct problems

- Becomes the core of a monitoring, evaluation, and improvement system

- Reduces costs

Key message

- Quality is the foundation of everything we do.
- The simplest Rapid Test is not foolproof.
- Errors can occur throughout the testing process.
- Quality is <u>everyone</u>'s responsibility.

Module Review

Find out how much you have learned by answering these questions.

Why do errors occur?

_____

_____

_____

What are some common errors that might occur with HIV rapid testing?

_____

_____

_____

Where is QA applied in a PMTCT or VCT testing site?

_____

_____

_____

What are some steps to take before, during, and after testing to assure the quality of results?

_____

_____

_____

Module Review

Find out how much you have learned by answering these questions.

Describe the impact that errors will have on the patient/client.

_____

_____

_____