Module 15

Documents and Records

Purpose	To help you understand the role documents and records play in the quality system and the monitoring of programs.
Pre-requisite Modules	Module 5. Assuring Quality of HIV Rapid Testing
Learning Objectives	At the end of this module, you will be able to: ▪ Tell the difference between a document and a record ▪ Explain the rationale for following documents and keeping records ▪ Provide examples of documents and records kept at a test site ▪ Follow the procedures as prescribed in SOPs ▪ Describe how to properly keep and maintain test site documents and records ▪ Describe the types of information typically not found in a manufacturer's product insert
Content Outline	What are documents and records? Documents Why are they important? What documents should you keep? Why is it important to follow SOPs? What is the proper way to keep and maintain documents? Records Why are they important? What records should you keep? What is the proper way to keep and maintain records?
Handout	None
Notes on Customization	Provide in-country information about SOPs (who develops them, how to distribute, and process for updating), client test records, and reporting for monitoring and evaluation.

The Quality System

Documents and Records is an essential component of the Quality System. As a matter of fact, it is the backbone of the quality system.

Documents communicate the policies and procedures that should be followed at each test site. This is important for assuring consistency and accuracy at the test site.

What Are Documents and Records?

Documents are written policies, process descriptions, and procedures used to communicate information. They provide written instructions for HOW TO do a specific task.

Blank forms are also considered documents. Forms are used to capture data or information from performing a procedure.

Records are generated when written instructions are followed. In other words, after data, information, or results are recorded onto a form, label, etc, then it becomes a record.

Documents and records may be paper or electronic.

Examples of Documents and Records

Examples of documents include: country testing algorithm, safety manual, standard operation procedures (SOPs) for an approved HIV rapid test, manufacturer test kit inserts, temperature log (blank form), and quality control record (blank form).

Examples of records include: client test results, summary of findings form on-site evaluation visit, report of corrective actions, daily maintenance log (completed), stock cards and stock book (completed), and EQA specimen transfer log (completed).

Documents Are the Backbone of the Quality System

Verbal instructions often are not heard, misunderstood, quickly forgotten, and ignored. Policies, standards, processes, and procedures must be written down, approved, and communicated to all concerned.

Standard Operating Procedures (SOPs) are Documents

Standard Operating Procedures (SOPs) are documents that describe how to perform various operations in a testing site. They provide step-by-step instructions and assure consistency, accuracy, and quality.

SOPs are one type of document. Using SOPs results in reliable and consistent results.

SOPs Are Controlled Documents

Controlled documents means documents must be approved for use in-country, have document control features, and be kept up-to-date. Key features of SOPs include:

- Cover page
- Descriptive Title
- SOP number
- Version Number
- Date when SOP become effective
- Signature of person responsible for writing the SOP
- Signature of person authorizing the SOP

What SOPs Should You Keep at a Test Site?

Each test site should have on hand current/approved SOPs. Typical SOPs kept at a test site include:

- Daily routine schedule
- Country policies and algorithm
- Safety manuals (for example, safety precautions, preparation of 10% (vol / vol) bleach solution, and post-HIV exposure prophylaxis management and treatment guidelines)
- Blood collection (for example, fingerprick, venipuncture, and DBS)
- Test procedures
- EQA (for example, submission of EQA specimens to reference lab and internal assessments)
- Reordering of supplies and kits
- Equipment use and maintenance

SOPs Must Be Followed

SOPs must be followed. Not following safety precautions poses unnecessary risk to yourself, client and the environment.

Do Not Rely Solely on Manufacturer Product Inserts

Manufacturer product inserts do not provide specific information for test sites. Examples include:

- Materials required, but not in kit
- Specific safety requirements
- Sequence of tests in country algorithm
- External quality control requirements

Proper Record-Keeping Makes Quality Management Possible

Record-keeping allows a test site to:

- Communicate accurately and effectively - Record keeping enables sites to be timely in reporting to program managers and site supervisors
- Minimize error - All records must be written.
- Monitor quality system - Records allow for periodic review of testing operations. Only through the review of records can improvements be identified.
- Assist management in developing policy & plans and monitoring and evaluating programs

What Records Should You Keep at a Test Site?

It is recommended that you keep these records at your test site:

- Specimen transfer logs
- HIV request / client test result
- Lab / Test register
- Temperature logs
- Equipment maintenance logs
- Inventory records

Tips for Good Record Keeping

Here are some tips for good record-keeping:

- Understand the information to be collected. Before you record any information, make sure that you understand what is to be collected
- Record the information every time. Record on the appropriate form each time you perform a procedure.
- Record all the information. Make sure you have provided all the information requested on a form.
- Record the information the same way every time. Be consistent in how you record information.

Client Test Records

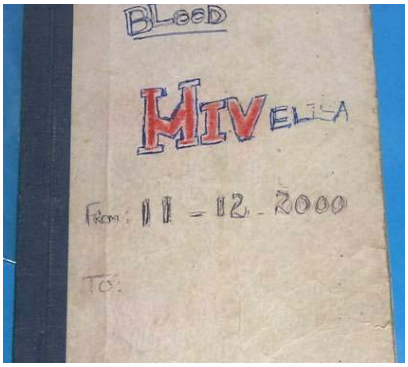
Types of information captured on test records include:

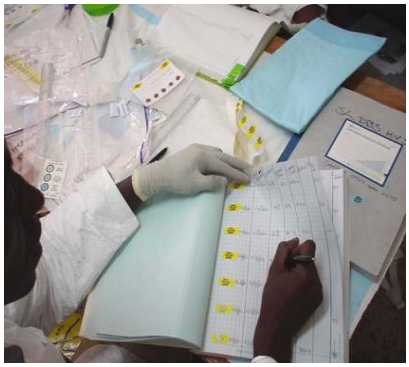
- Client/Patient ID #
- Date of test
- Results from Test 1, Test 2, and Test 3
- Repeat results
- HIV status
- Kit Name & Lot #
- Person performing test

How Long Should You Retain Client Records?

Records must be maintained secure storage for all records. The length of time you will need to store test site records will depend o your country national policies, and the availability of secure storage space at your test site.

Logbooks Are Cumulative Records of Test Site Operations





These photos of logbooks are common. Storage of logbooks and records should be kept in a manner that will minimize deterioration. Although many sites uses paper-based logbooks and records, they should be indexed so to allow for easy.

Records Should be Permanent, Secure, Traceable

Facilities where records are kept should be secure to maintain patient/client confidentiality. Procedures and mechanisms should prevent unauthorized access.

Records should be permanent, secure, and traceable. Examples of keeping records permanent include: keep books bound, number pages, use permanent ink, and control storage. To keep records secure, you need to maintain confidentiality, limit access, and protect them from environmental hazards. To keep records traceable, make sure every record is signed and dated.

Information Recorded will Feed Into Monitoring and Evaluation Systems

Records must be kept permanent, secure, and traceable because they will be used for reporting and monitoring purposes. Monitoring is the routine tracking of program information. Accurate facility records provide essential information for providing quality health care and monitoring PMTCT programs It is recommended that you analyze on a monthly basis the number of clients served and summarize the test results.

Key message

- Written policies and procedures are the backbone of the quality system
- Complete quality assurance records make quality management possible
- Keeping records facilitates meeting program reporting requirements

Module Review

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

What is the difference between a document and a record?

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What are some examples of documents and records?

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Name examples of information not found in a manufacturer product insert.

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What are some key features of SOPs?

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Module Review

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

What are some tips for good record-keeping?

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How should records be maintained?

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How are test site records reported in your country?

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