Module 15: Documents and Records

Purpose
To help participants understand the role documents and records play in the quality system and the monitoring of programs.

Pre-requisite Modules
- Module 5: Assuring the Quality of HIV Rapid Testing

Module Time
30 minutes

Learning Objectives
At the end of this module, participants 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

Module Overview

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<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
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<tr>
<td>1</td>
<td>3 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-4</td>
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<td>2</td>
<td>4 min</td>
<td>Presentation Exercise</td>
<td>Documents vs. records</td>
<td>Slide 5-7</td>
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<td>3</td>
<td>10 min</td>
<td>Presentation Discussion</td>
<td>Documents</td>
<td>Slides 8-14; manufacturer product inserts</td>
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<td>4</td>
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<td>Presentation</td>
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<td>5</td>
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<td>Presentation Q&amp;A</td>
<td>Summary Key messages</td>
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Material/Equipment Checklists
- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
- Handout: Client Test Record (please be prepared to show a form used locally)
- Manufacturer product inserts from test kits (enough copies to pass around)
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<tr>
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<th>Teaching Points</th>
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<tr>
<td><strong>Customization Notes</strong></td>
<td>In general, this module must be customized with in-country examples of documents and records and site-specific information on how to keep and maintain records.</td>
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</table>
| 1 | **Module 15: Documents and Records**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2 | **The Quality System**  
REMIND participants that Documents and Records is a component of the Lab 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. |
| 3 | **Learning Objectives**  
STATE the objectives on the slide. |
| 4 | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| **Flipchart** | WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
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| 5 | **What Are Documents and Records?**  
STATE the points on the slide and ADD the following information:  
- Documents are 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. |
| Exercise 6-7 | **Exercise: Differentiate Between Documents and Records**  
DISPLAY slide 6.  
ASK participants to look at the list on the slide for a minute and think about which item is an example of documents versus records.  
Go through each item as a group soliciting answers.  
DISPLAY slide 7 to show the correct answers (items in yellow are examples of documents and items in white are records).  
ANSWER any questions participants may have before moving on. |
| 8 | **Documents Are the Backbone of the Quality System**  
STATE the points on the slide. |
| 9 | **Standard Operating Procedures (SOPs) Are Documents that...**  
EXPLAIN SOPs are one type of document. Using SOPs results in reliable and consistent results. |
<p>| 10 | Customize slide #10 by replacing the sample SOP page on the slide with a page from a real in-country SOP. |</p>
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| 10           | **SOPs Are Controlled Documents**  
               DESCRIBE “controlled documents.”  
               EXPLAIN that 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 |
| 11-12        | **Customization Notes**  
               ADD the following in-country information about SOPs:  
               • Who develops  
               • How distributed  
               • Process for updating |
| 11           | **What SOPs Should You Keep at a Test Site?**  
               EXPLAIN each test site should have on hand current/approved SOPs. These are typical SOPs kept at a test site.  
               READ the examples on the slide. |
| 12           | **What SOPs Should You Keep at a Test Site?– Cont’d**  
               READ the examples on the slide. |
| 13           | **SOPs Must Be Followed**  
               PROVIDE examples of consequences of not following SOPs.  
               • Not following safety precautions poses unnecessary risk to self, client and the environment  
               • Reporting inaccurate results – negative impact on client and family  
               • Breach of ethical conduct |
| **Activity** | **2 minutes**    |
|              | PASS AROUND manufacturer product inserts (from test kits) for participants to examine.  
               DISCUSS what information is included in the inserts and what is not. |
| 14           | **Do Not Rely Solely on Manufacturer Product Inserts**  
               CONCLUDE the activity by pointing out the information on the slide. |
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| 15           | **Proper Record-Keeping Makes Quality Management Possible**  
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. |
| 16           | **What Records Should You Keep at a Test Site?**  
STATE the list on the slide. |
| 17           | **Tips for Good Record Keeping**  
STATE the points on the slide.  
- **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. |
| 18           | Customize slide #18 by replacing the sample client test record on the slide with a real in-country one. |
| Slide Number | Teaching Points |
|--------------|----------------|---|
| 18           | **Client Test Records**  
POINT OUT types of information captured on test records and the proper way to complete the information:  
- Client/Patient ID #  
- Date of test  
- Test 1 result  
- Test 2 result  
- Test 3 result  
- Repeat results  
- HIV Status  
- Kit Name & Lot #  
- Person performing test  
MENTION any commonly made mistakes |
| 19           | Customize slide #19 with in-country policy and information regarding record retention. |
| 19           | **How Long Should You Retain Client Records?**  
STATE points on the slide  
DISCUSS importance of maintaining secure storage for all records |
| 20           | **Logbooks Are Cumulative Records of Test Site Operations**  
EXPAND the points on the slide:  
- These photos of logbooks are common. Storage of logbooks and records should be kept in a manner that will minimize deterioration.  
- Note also that although many sites used paper-based logbooks and records, they should be indexed so to allow for easy retrieval.  
- Note the From and To Dates. |
| 21           | **Records Should be Permanent, Secure, Traceable**  
STATE facilities where records are kept should be secure to maintain patient/client confidentiality. Procedures and mechanisms should be that prevents unauthorized access. |
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| 22 | Customize slide #22 with specific in-country information related to the reporting processes:  
| | • What will be reported?  
| | • When will it be reported?  
| | • How will it be reported?  
| | • Whom will it be reported to?  
| | • How will the data be used? |
| 22 | **Information Recorded will Feed Into Monitoring and Evaluation Systems**  
| | EXPLAIN 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. |
| 23 | **Summary**  
| | ASK participants to answer the questions on the slide. |
| 24 | **Key Messages**  
| | STATE the key messages on the slide.  
| | ANSWER any questions participants may have. |