Module 1. Quality Assurance for HIV Rapid Testing:

Purpose: To provide an overview of the quality management system so that participants will adopt a broad systems view toward quality for HIV rapid testing. Furthermore, they will understand where errors may occur in the rapid testing process and their responsibilities in preventing and detecting them.

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| Pre-requisite  Modules | Good understanding of country HTS program and quality management systems for HIV rapid testing |
| Module Time | 3hours and 10 minutes |
| Overall 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 |
| Resources | PowerPoint slides, pointer, prepared flipchart, and markers. |

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| **Slide #** | **Title** | **Teaching Points** |
| 1 | Quality Assurance for HIV Rapid testing | DISPLAY this slide before you begin all four activities for this module. Make sure participants are aware of the transition into a new module. |
| 2 | Content Overview | REVIEW the content overview one by one as shown on the slide. |
| 3 | Quality assurance Cycle | EXPLAIN the quality assurance cycle.  To ensure quality testing, reporting, pre- and post-testing counseling a quality management system should be implemented. The diagram above shows the steps of quality assurance that should occur in a continuous cycle to implement the quality management system:   * Plan/Develop - Planning through engaging leadership, establishing national QA coordination team, defining roles and responsibilities, reviewing and developing QA, financing, and staffing policies * Implement – through training and certification of test providers, site accreditation, supportive supervision, adequate quality/process control, documentation/record-keeping and ensuring a robust supply chain. * Monitor/Feedback/Improve – evaluating quality through post-market surveillance and External Quality Assessment (EQA), using data for decision-making, making improvements, undertaking advocacy and communication, and increasing ownership |
| 4 | Why is the Quality Assurance Cycle important? | EXPLAIN to participants that clients receive accurate test results within a reasonable time period based on key factors stated in slide |
| 5 | Components of Quality Assurance | EXPLAIN the key components of quality assurance |
| 6 | Who is responsible for quality? | Inform the participants with this slide the following:  EMPHASIZE the responsibility as shown on the slide,  EMPHASIZE there are several HIV Rapid Kits available in the market, some are cheaper, while some are approved, majority of them are not approved by WHO/CDC. Some are reliable because they give you accurate results in the determination of HIV status, while accuracy plays a major factor, also the consistency of results between the testing kits is equally important,  EXPLAIN participant’s responsibility as health care workers or as lay persons in giving an accurate result before the HIV infection spreads within a community and also to find people with true HIV positives. Time is of the essence and less turnover time with accurate results for treatment is critical. |
| **7** | Why Do Errors Occur | ASK the participants “Why Do Errors Occur?  RELATE each error to the appropriate testing site quality system components. For example, if the error of “test kit not stored properly occurs”, ask participants which part of the quality system breaks down that caused such an error.  NOTE participant’s responses on the flip chart. |
| 8 | Section Header | Preventing Errors During 3 phases of Testing  INFORM participants that you will be reviewing the different errors that can be prevented in each phase of testing. |
| 9 | Ensuring accuracy of test results | INFORM the participants that there are 3 different phases of testing and the accuracy of the results are depended in all areas.  STATE each of the elements listed in all phases. |
| 10 | Preventing PRE-Testing Errors | ASK participants, “What are some errors that may occur during pre-testing, in the QA cycle?  GO through the bullet points one by one. As you go through, relate participant’s responses on the flip chart. |
| 11 | Preventing Testing Errors | ASK participants, “What are some errors that may occur during Rapid testing in the QA cycle?  GO through the bullet points one by one. As you go through, relate participant’s responses on the flip chart. |
| 12 | HIV Testing Algorithm | EMPHASIZE that following the national algorithm is critical to ensure the accuracy and reliability of testing.  EXPLAIN WHO recommended 3-test algorithm to increase the positive predictive value of HIV RT results as countries see an HTS positivity decrease below 5%. |
| 13 | ASANTE Job Aide | EMPHASIZE the use of job aids to ensure the test procedure is being followed.  STATE the test procedure for Asante based on the job aide |
| 14 | Preventing POST-Testing Errors | ASK participants, “What are some errors that may occur after the testing in the QA cycle?  GO through the bullet points one by one. As you go through, relate the participant’s responses on the flip chart. |
| 15 | Section Header | Comprehensive Training and Competency |
| 16 | RT and RTRI Training Components | DESCRIBE the training components for the HIV rapid test and rapid test for recent infection training which includes:   * Training package * Description of hands on practical * Competency assessment criteria |
| 17 | Multi-Tiered and Systematic Training Approach | DISCUSS the systematic training approach of TOT and cascade trainings and how it has been revised in the context of COVID |
| 18 | Training Package Content for Recency | DESCRIBE the example training package for the HIV-1 Recent Infection Surveillance. The red boxes indicates that the countries already have systems in place for the specific training component and should utilize that system |
| 19 | Record Keeping | DISCUSS the new chapter on record keeping. |
| 20 | Why is Record Keeping Important | EXPLAIN the points on the slide.   * Communicate accurately and effectively - Record keeping enables sites to be timely in reporting to program managers and site supervisors. They are used to track the number of tests performed and determine what supplies are needed. * Monitor quality system – Records allow for periodic review of testing operations. Only through the review of records can improvements be identified. |
| 21 | Guide 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. * **Ensure complete confidentiality of clients’ test results** by properly storing registers that contain HIV-related information   + Keep out of view of other clients and staff   + Keep in a locked cabinet or drawer when not in use |
| 22 | Example of Poor Record Keeping | EXPLAIN that HIV test registers have been implemented at HIV testing sites but are generally used for inventory purposes and do not adequately capture key quality assurance elements such as test kit information and individual test results. Multiple registers may be used at a testing site and the information collected is not always consistent from site to site or even within the same site. This has presented a significant challenge in identifying problems and targeting areas for improvement.  DISCUSS example of record keeping:   * Hand-written columns * No test kit information * No information on who performed the testing * Only final results entered * Final result reporting not standardized |
| 23 | Standardized HTS Test Register | To this end, the standardized HTS register was designed to capture specific information, including kit name, lot number, expiration date, and individual test results.   * Ask the audience why you would want to have the same format for all testing sites. * Emphasize the last point on the slide. Ask the audience to brainstorm possible problems that a standardized register might be able to help identify. |
| 24 | Example of a Standardized HTC Register Page | Recording page of example a standardized HTC Register page.   * Emphasize that everything can be customized to fit the needs of the country. * Emphasize the important of page totals at the bottom of each column. * Emphasize the importance of a supervisor review and signature |
| 25 | Ongoing Assessment of the Quality of HIV Rapid Testing | EXPLAIN that the standardized register can be used to monitor the quality of HIV rapid testing by:  **Monitoring Site Performance**   * EXPLAIN the chart shown. * Ask the audience: What does the top and bottom charts show? * Ask the audience: What may have caused the high discordance rate in April? * Ask the audience: How can this information help a site improve?   **Monitoring Operator Performance**   * EXPLAIN the chart shown (ask for volunteers) * Ask the audience: What does the chart show? * Ask the audience: Are the operator’s all performing well? * Ask the audience: What might have happened to cause the operator’s poor performance? * Ask the audience: How can this information help a site improve?   **Assessing an Algorithm-Is it Working?**   * EXPLAIN the chart shown (ask for volunteers) * Ask the audience: What does the chart show? * Ask the audience: Even without knowing what the algorithm is, what would you say about it? * Ask the audience: What are the next steps that a site should take? (After audience has made suggestions-click with mouse)   Ask the audience: How can this information help a site improve? |
| 26 | Recency Testing Logbook page | DESCRIBE the key QA testing elements of the recency testing logbook |
| 27 | QUALITY CONTROLS | EXPLAIN what are the positive control and negative controls,  EXPLAIN why it is important to have controls while we do HIV Rapid testing for clients |
| 28 | What is Quality control (QC)? | EXPLAIN the difference between internal and external control for HIV rapid tests and the rapid test for recent infection |
| 29 | Internal and External Controls in RTRI | DESCRIBE the RTRI controls and the reason for internal and external controls |
| 30 | Frequency of QC for RT | STATE the points on the slide. |
| 31 | Frequency of QC for RTRI | STATE the points on the slide. |
| 32 | QC Testing Instructions for RTRI | STATE the points on the slide. |
| 33 | Appropriate use and Storage of Plasma QC Specimens | STATE the points on the slide. |
| 34 | Schematic of DTS Preparation and Testing | DESCRIBE preparation of DTS QC panel |
| 35 | DTS QC and Testing Instruction for RT | REVIEW DTS QC Rehydration and Testing Instruction for RT |
| 36 | DTS QC and Testing Instruction for RTRI | REVIEW DTS QC Rehydration and Testing Instruction for RTRI |
| 37 | Rehydration of DTS Quality Control Samples Job Aid | DISCUSS DTS Rehydration process thru job aid |
| 38 | Storage and Handling of DTS QC Specimens for RT | EXPLAIN how DTS QC should be stored for HIV rapid testing |
| 39 | Storage and Handling of DTS QC Specimens for RTRI | EXPLAIN how DTS QC should be stored for RTRI |
| 40 | Maintaining QC Records | STATE the points on the slide. |
| 41 | Asante Standard QC Logbook | EXPLAIB how to document Asante QC results in a standardized logbook |
| 42 | Performing Quality Controls | EMPHASIZE documentation is important.  NOTE tat is a QC fails document and immediately repeat. Record the valid QC on the next line |
| 43 | Invalid QC Results – What Do You Do? | STATE the points on the slide. |
| 44 | Failed QC Results: What Do you Do? | DISCUSS troubleshooting steps when QC fails |
| 45 | Section Header | External Quality assessment |
| 46 | External Quality Assessment Activities | EXPLAIN the EQA terminology and two of the major component.  EXPLAIN retesting is the third component of EQA that was used in the past where every 20th specimens was collected from a client and sent to NRL for retesting. Now most countries have implemented retesting before ART initiation where a client is diagnosed as HIV positive at the initial screening (first test event) and is referred for retesting using a new specimen and tester to ensure accurate results before they are put on treatment |
| 47 | EQA Should Lead to Corrective Actions | STATE points on slide. |
| 48 | Proficiency Testing Cycle and Frequency | STATE points on slide. |
| 49 | Rapid Test for Recent Infection PT result form | DISCUSS the example of an RTRI PT result form and recommendations for integrating RTRI PT into the existing national PT program. The current ILB recommendation is to prepare 1 panel that will be distributed to all HIV testing sites participating in the program. Sites will test the samples using the national HIV Rapid Test algorithm according to the country PT program procedures. Those sites with the capacity for recency testing will additionally characterize those specimens (that are HIV-positive) for recency and can record Asante results either on a separate form or a combined HIV RT/Asante PT form. |
| 50 | Roles and Responsibilities | DESCRIBE roles and responsibilities of each partner in the PT program  Briefly DISCUSS the components of the PT pack.  REMIND participants to process the panel as if it were any other specimen.  STRESS the importance of reporting any problems that may prevent timely return of results.  EXPLAIN the benefits of reviewing the feedback report and the implementation of corrective actions. |
| 51 | Stock Management and Inventory | DISCUSS the new chapter on stock management and record keeping. |
| 52 | Stock Management Tasks | EXPLAIN the different tasks associated with the stock management |
| 53 | Inspect delivery of new orders | EXPLAIN how we are generously supposed to inspect the kits and the delivery |
| 54 | Stock Management Leads to High Quality Testing | DISCUSS how stock management can lead to high quality in the test results |
| 55 | Review | DISCUSS each bullet points after all the activities. |