

Module 4: HIV Testing Strategies and Algorithms

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| Purpose | To provide the participants with a basic understanding of how HIV rapid tests are selected for the country's algorithm and how HIV status is determined following the algorithm. |
| Pre-requisite Modules | Module 1: Overview of HIV Infection Module 3: Overview of HIV Testing Technologies |
| Module Time | 1 hour |
| Learning Objectives | At the end of this module, participants will be able to: <ul style="list-style-type: none"> ▪ Discuss the process for developing a national testing algorithm ▪ Explain how sensitivity, specificity, positive/negative predictive value relate to development of an HIV rapid testing algorithm ▪ Explain the HIV rapid testing algorithm approved in your country ▪ Determine HIV status following a particular algorithm |

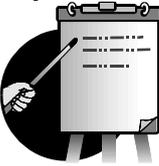
Module Overview

| Step | Time | Activity/ Method | Content | Resources Needed |
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| 1 | 2 min | Presentation | Module introduction | Slides 1-3; Prepared flipchart – content outline |
| 2 | 15 min | Presentation; Discussion | Strategies and Algorithms | Slides 4-10 |
| 3 | 20 min | Presentation; Discussion | Evaluating Test Performance | Slides 11-16 |
| 4 | 10 min | Presentation; Discussion | Testing Algorithms | Slides 17-19 |
| 5 | 5 min | Exercise | Interpreting HIV status using testing algorithm | Slide 20; Exercise Sheets: <u>Interpreting HIV Status Using Testing Algorithm</u> |
| 6 | 3 min | Presentation; Discussion | Possible Outcomes of HIV Testing | Slides 21 |
| 7 | 5 min | Q&A | Summary | Slide 22 |

Material/Equipment Checklists:

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Flipchart
- Handouts:
 - Exercise #1: Interpreting HIV Status Using Testing Algorithm
 - Exercise #2: Interpreting HIV Status Using Testing Algorithm

Teaching Guide

| Slide Number | Teaching Points |
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| 1 | <p><u>Module 4: HIV Testing Strategies and Algorithms</u></p> <p>DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.</p> |
| 2 | <p><u>Learning Objectives</u></p> <p>STATE the objectives on the slide.</p> |
| 3 | <p><u>Content Overview</u></p> <p>EXPLAIN the topics that will be covered in this module.</p> |
| <p>Flipchart</p>  | <p>WRITE the content outline on a flipchart prior to training.</p> <p>REFER to it frequently to orient participants to where they are in the module.</p> |
| 4 | <p><u>Strategies and Algorithms</u></p> <p>DEFINE Strategies and Algorithms by STATING the points on the slide.</p> |
| 5 | <p><u>Strategies and Algorithms (Cont'd)</u></p> <p>HIGHLIGHT the points on the slide</p> |
| 6 | <p><u>HIV Testing Strategies</u></p> <p>EXPLAIN parallel and serial testing can be part of any testing strategy.</p> <p>DEFINE parallel and serial testing by STATING points on the slide</p> |

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| 7 | <p><u>Testing Algorithms Should be Developed at National Level</u></p> <p>Before any test is adopted in country for use, a series of key steps must be taken.</p> <p>STATE the key steps.</p> <p>EMPHASIZE:</p> <ul style="list-style-type: none"> ▪ Because multiple tests are marketed and available in-country, each country must identify the appropriate tests for use within given environment ▪ A standardized approach to developing an algorithm must be taken. This involved building consensus and developing policy before a test is brought to national scale. |
| 8 | <p><u>Timeline for Developing National Testing Algorithm</u></p> <p>HIGHLIGHT a number of activities must be accomplished before a test is fully implemented</p> <p>EMPHASIZE the following points:</p> <ul style="list-style-type: none"> ▪ tests undergo a series of evaluations before they are adopted for use country-wide ▪ timeline for accomplishing each phase of the evaluation process is indicated on the slide |

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|  <p>TIPS</p> | <p>For lab staff and health workers, consider providing the following information on test evaluation process:</p> <ul style="list-style-type: none"> • Phase I: samples with known HIV results are tested at the laboratory using a number of different kits. The results of the rapid tests are compared with the original laboratory results. Ones that worked the best are then evaluated in phase II. • Phase II: clients are tested at a rapid testing site by the tests under evaluation, and the same sample is tested at the laboratory using laboratory tests. The results are compared, and the rapid tests that worked the best will be used in phase III. • Phase III: Is the final phase whereby certain rapid tests have been approved by the MoH and are used at rapid testing sites. <p>For participants without lab or health background, consider providing the following information:</p> <ul style="list-style-type: none"> • Samples are tested at the laboratory and at points of service by numerous kits. • The ones that work best to detect HIV infections are approved by the MoH for nation-wide use. |
| <p>9</p> | <p><u>Advantages of National Testing Strategies and Algorithms</u></p> <p>HIGHLIGHT nationally adopted testing strategies and algorithms facilitates:</p> <ul style="list-style-type: none"> ▪ Standardizing the tests used in country. Supporting a limited number of tests is more feasible and practical than many different tests. ▪ Bulk procurement facilitates cost control |
| <p>10</p> | <p><u>Key Factors in Determining a Country's Algorithm</u></p> <p>A number of factors contribute to the selection of specific tests in a country's algorithm.</p> <p>STATE the factors listed on the slide</p> |

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| 11 | <p><u>Evaluating Test Performance: Basic Terms</u></p> <p>One of the factors considered when determining a country's algorithm is the performance the tests. This performance is based on how close a test under consideration agrees 100% with the result of another test, i.e., reference method or "gold standard", also referred to as the true result or actual HIV status.</p> <p>STATE the definitions on the slide</p> <p>EXPLAIN the basic difference between Se, Sp and PPV, NPV</p> <ul style="list-style-type: none"> ▪ Se & Sp relate to the performance of the <u>test</u> capacity ▪ PPV & NPV relate to the probably of the <u>individual</u> being infected or not when the test yields a positive or negative result |
| 12 | <p><u>Calculating Sensitivity, Specificity, PPV & NPV</u></p> <p>This table provides the formulas for calculating Se, Sp, PPV, & NPV.</p> <p>A = true positives; that is the test under evaluation yields a positive result AND the "gold standard" yielded a positive result</p> <p>C = false negatives; that is the test under evaluation yielded a negative result, while the "gold standard" or true value was positive</p> <p>A+C = all people who are truly infected with HIV</p> <p>B = false positives; that is the test under evaluation yields a positive result, while the "gold standard" or true value was negative</p> <p>D = true negatives; that is the test under evaluation yields a negative result AND the "gold standard" or true value yielded a negative result</p> <p>B+D = all people who are truly NOT infected with HIV</p> |

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| 13 | <p><u>Calculating Sensitivity, Specificity, PPV & NPV (Cont'd)</u></p> <p>This table illustrates the calculation of Se, Sp, PPV & NPV.</p> <p>Evaluation of a rapid test on a panel of specimens that have been tested by the gold standard to determine actual HIV status is shown to contain HIV antibodies to 374 samples and no HIV antibodies to 626 samples.</p> <p>Of the 374 serum samples that were antibody positive, the rapid test classified 370 of the samples as positive.</p> <p>Of the 626 samples that were HIV antibody negative by the gold standard, 624 were classified by the rapid tests as not containing HIV antibodies.</p> <p>STATE the final results of Se, Sp, PPV, & NPV.</p> <p>ASK participants what does this really mean?</p> <ul style="list-style-type: none"> ▪ Test performance of the HIV rapid test under evaluation is nearly as good as the results of the “gold standard” or true value. ▪ The HIV test will yield highly accurate results <p>BUT, while these results indicated very good performance, you must also keep in mind that the performance is influenced by the makeup of the population.</p> |
| 14 | <p><u>HIV Rapid Test Performance</u></p> <p>STATE – as illustrated in the example in the previous slide, no test is 100% sensitive or 100 % specific when compared to the “gold standard”</p> |
| 15 | <p><u>How Prevalence Affects PPV & NPV</u></p> <p>If we know the sensitivity and specificity of the kit and the prevalence of HIV in the population, we can theoretically calculate the predictive value of the performed test.</p> |
| 16 | <p><u>How Prevalence Affects PPV & NPV (Cont'd)</u></p> <p>EMPHASIZE in general, the higher the prevalence, the higher the PPV. Conversely, the lower the prevalence, the lower the PPV.</p> |

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| 17 | <p><u>Testing Algorithm Describes the Sequence of Tests to be Performed</u></p> <p>DESCRIBE what a testing algorithm is. (Defined in slide title)</p> <p>EXPLAIN the rationale for using multiple tests and the implications when a client obtains an inaccurate test result:</p> <ul style="list-style-type: none"> • False positive (that is, inaccurately reported as positive) • False negative (that is, inaccurately reported as negative) <p>DEFINE the term “Discordant.”</p> |
| 18 | <p><u>Ideal Algorithm</u></p> <p>STATE the points on the slide</p> |
|  <p><i>TIPS</i> Slides 19</p> | <p>For participants without any lab background:</p> <ul style="list-style-type: none"> • Explain the algorithm slowly. Participants may have never seen an algorithm before. • Go over it step by step. Use Slide Build feature when presenting the algorithm. |
|  <p><i>Customization Notes</i> 19</p> | <p>Show country-specific testing algorithm with appropriate test names inserted.</p> |

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| <p>19</p>  | <p><u>Testing Algorithm</u></p> <p>DESCRIBE in-country test algorithm.</p> <p>EMPHASIZE testing sites must never use any kits, other than the ones described in the countries algorithm, and have been evaluated and approved for use by the Ministry of Health.</p> <p>STATE that in a parallel testing algorithm involves two tests running at the same time.</p> <p>HIGHLIGHT the following key points:</p> <ul style="list-style-type: none"> • When both tests are reactive, the final HIV result is positive. • When both tests are non-reactive, then the final HIV result is negative. • If one test is reactive and the other is non-reactive, then a third test known as a tiebreaker is performed. • The tie-breaker determines the final result – if the tiebreaker is reactive, then the final HIV result is positive; if the tiebreaker is non-reactive, then the final HIV result is negative. <p>EMPHASIZE that test 1, 2 and 3 are different rapid tests.</p> |
|  <p><i>Customization Notes</i></p> <p>20-21</p> | <p>Modify the exercises and table of possible HIV test outcomes based on your country's testing algorithms.</p> |
| <p>20</p> <p>Exercise</p> <p>5 Minutes</p> | <p><u>Exercise: Interpreting HIV Status Using Testing Algorithm</u></p> <p>REFER participants to the exercise in their manual.</p> <p>ASK participants to spend 3 minutes, working alone, on the exercise.</p> <p>DISCUSS the answers as a group.</p> |
| <p>21</p> | <p><u>Possible HIV Test Outcomes: Parallel Testing Algorithm</u></p> <p>DISCUSS the various combinations of possible HIV test results and how to interpret HIV status in each scenario.</p> <p>EMPHASIZE that all invalid test results must be repeated.</p> |
| <p>22</p> | <p><u>Summary</u></p> <p>ASK participants to answer the questions on the slide.</p> <p>ANSWER any remaining questions the participant may have.</p> |