Clinical Education Initiative
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TITLE: NEW YORK STATE HIV TESTING GUIDELINE: UNDERSTANDING THE UPDATES

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New York State HIV Testing Guideline: Understanding the Updates [video transcript]

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- Hello, I'm Jeffry Kwong associate professor of nursing at Columbia University School of Nursing, a nursing champion for the New York State Department of Health AIDS Institute Clinical Education Initiative.

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Thank you for viewing the New York State's Clinical Education Initiative video on the new HIV testing guideline. This video is based on information from the Centers for Disease Control and Prevention and the New York State Department of Health AIDS Institute.

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The HIV testing guideline aligns with the first point of governor Cuomo's plan to end AIDS in New York State by identifying people with HIV who remain undiagnosed and linking them to health care. In 2010 the New York State HIV testing law was enacted to promote access to HIV screening in more clinical settings. This law was recently changed and now requires medical providers to offer HIV testing to patients who are 13 years of age and older regardless of risk behavior.

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In response to recent advances in HIV diagnostic testing technologies. The CDC and the association for public health laboratories, released a revised diagnostic testing algorithm. This offers exciting opportunities to identify patients with HIV earlier in the course of their infection. It also supports prevention,

partner notification, and treatment efforts.

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In this video we will start by reviewing the revised HIV testing algorithm. We will provide some guidance on how to interpret test results and how to deliver prevention messages based on those results. We will then close with a list of resources to support medical providers.

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The HIV diagnostic testing algorithm is intended for testing performed in a laboratory. Even if an initial screening is performed using a point of care rapid test, the full laboratory algorithm will be used to confirm preliminary positive results. The algorithm is made up of three steps. Step one is a fourth generation HIV-1, HIV-2 antigen antibody combination immunoassay. Step two is an HIV-1, HIV-2 antibody differentiation immunoassay. Step three is an HIV-1 RNA assay. Let's review each of these steps in greater detail. Step one involves the use of an HIV-1 HIV-2 antigen antibody screening immunoassay.

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Two types of screening test are currently in use for this step. One that differentiate each component and one that is a non differentiating test. Depending on the type of test used in step one the results reported to you may be simply reactive or nonreactive, or may have a result for each of the four components included in the differentiating test. HIV antigen antibody, HIV-1 antibody, HIV-1 antigen, and HIV-2 antibody. If the result from the step one test is nonreactive, no further testing is needed.

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The antigen antibody combination test is recommended as the first step in the HIV testing algorithm. However, it is important to note that some laboratories may still be using the third generation HIV antibody test for screening at step one. This test is less sensitive, meaning some cases of acute HIV may be missed. Laboratories using the HIV antibody test as the first step in the HIV testing algorithm are instructed to note this limitation in sensitivity when reporting a nonreactive antibody screening test.

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If the result of step one testing is reactive it is considered to be a preliminary positive result and the laboratory will automatically reflex to step two and conduct supplemental testing with an HIV-1, HIV-2 antibody differentiation immunoassay. Possible results from the step two antibody differentiation test include HIV-1 positive, HIV-2 positive, HIV-2 positive with HIV-1 cross-reactivity, HIV positive untypable, HIV negative, HIV-1 indeterminate, HIV-2 indeterminate, HIV indeterminate. If the result of this immunoassay is reactive for HIV-1 or HIV-2 antibodies. The interpretation is, positive for HIV-1 antibodies or positive for HIV-2 antibodies respectively. If the result of this immunoassay is nonreactive or indeterminate, the lab should reflex to the next step of the HIV testing algorithm. Step three in the HIV testing algorithm is an HIV-1 RNA assay and should be done when the result of the step two HIV antibody differentiation test is nonreactive or indeterminate. If HIV-1 RNA is detected, the final interpretation is, positive for HIV-1 and medical care should be initiated. This result may also suggest acute HIV infection. If step two was nonreactive or HIV-1 indeterminate and HIV-1 RNA is not detected during step three, the final interpretation is, negative for HIV-1 and the initial HIV antigen antibody immunoassay result was a false positive. If the step two HIV-1 HIV-2 antibody differentiation test result was HIV-2 indeterminate, HIV indeterminate, or nonreactive and the step three HIV-1 RNA was not detected. Follow up testing for HIV-2 RNA or DNA should be considered. Alternatively repeat the diagnostic algorithm in two to four weeks.

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HIV-2 viral load test are currently not commercially available. Please see the PDF accompanying this video entitled HIV-2 Guideline for more information on how to obtain these tests. When you order a laboratory based HIV test, the order should be for the full HIV diagnostic testing algorithm, but even then you can't take for granted that all indicated steps have been completed.

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For example, the HIV laboratory report to the provider will indicate a reactive step one screening test result and a negative or indeterminate step two antibody differentiation test. But there is no HIV-1 RNA test result.

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Call your laboratory to find out if the test is pending or completed. If the test was not performed for any reason, it is very important that a new specimen is collected and submitted for HIV-1 RNA testing as soon as possible.

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In summary no single test confirms the presence of HIV. As you may have noticed, the western blot test is no longer an accepted part of the recommended HIV testing algorithm. Compare the HIV testing algorithm we have just covered to the HIV testing options your organization has in place. How are they different?

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When giving a patient HIV test results, it's important to know the tests that were conducted as well as the results. If using an electronic medical record that reports HIV test results as positive or negative, you should view the actual laboratory report that shows the result of each test that was completed. It is critical to understand which test your laboratory conducts and how to interpret their results.

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Now let's review a case study that illustrates the HIV testing algorithm. Malcolm is 23 years old. He's come to see his provider because he had comdomless sex with a male partner a couple of weeks ago and is concerned about contracting a sexually transmitted infection. Malcolm shares that he has recently been experiencing fever and a case of night sweats. Malcolm's history and symptoms are suggestive of acute HIV. Based on this information, his medical provider recommends an HIV test and Malcolm agrees.

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Malcolm's medical provider knows that laboratory uses fourth generation technology in their HIV diagnostic algorithm and will reflex to an HIV-1 RNA test if indicated. The blood is drawn for HIV testing and sent off to the laboratory.

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Malcolm step one HIV antigen antibody screening test results are reactive. So the laboratory reflexes to the step two HIV antibody differentiation immunoassay to confirm the result. The antibody differentiation test result is negative. So the laboratory reflex is testing of the specimen to the step three HIV-1 RNA assay. Which detects HIV-1 in the sample. The final result comes back

to Malcolm's medical provider reporting that Malcolm is positive for HIV-1. This series of results suggest that the initial test was done while Malcolm was in the acute phase of infection prior to seroconversion.

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Identifying people earlier in the course of HIV infection is one of the benefits of using the revised algorithm. (lighthearted music)

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Now let's talk about interpreting test results. Depending on the type of laboratory tests used in step one, the results reported to you may be simply reactive or nonreactive or may have a result of each of the four components included in the differentiating test. HIV antigen antibody, HIV-1 antibody, HIV-1 antigen, and HIV-2 antibody. If the preliminary immunoassay test result is nonreactive, then the patient is considered negative for HIV-1 antigen and HIV-1 HIV-2 antibodies. If the test result is reactive, which is considered a preliminary positive, the next step is further testing in the form of the step two HIV-1 HIV-2 antibody differentiation immunoassay. The terminology for results of the anti body differentiation immunoassay differs from those of the initial immunoassay. This test will identify the presence of HIV-1 antibodies, HIV-2 antibodies, or both. If HIV-1 or HIV-2 antibodies are detected, the patient is considered positive for HIV-1 or HIV-2 antibodies respectively. If the results indicate that both HIV-1 and HIV-2 antibodies are detected, the patient is considered positive for HIV antibodies, but these antibodies cannot be differentiated and additional testing for HIV1 and HIV2 RNA or DNA is warranted. In all of these cases, medical provider case reporting is required. In a small number of cases, the test result may be nonreactive or indeterminate. Laboratory testing should reflex to an HIV-1 RNA assay. When a step three HIV-1 RNA assay is conducted, following a nonreactive or indeterminate antibody differentiation immunoassay test results, there are two possible determinations. If the RNA assay does not detect HIV-1, the laboratory will report that HIV-1 RNA was not detected. No laboratory evidence of HIV-1 infection is present at this time. This assumes that the patient has not been previously diagnosed and is not on anti retroviral treatment. If the step two result was HIV-2 indeterminate or HIV indeterminate, you should repeat the HIV testing algorithm in two to four weeks to assess for HIV-2 infection. If the RNA assay detects HIV-1 then the patient should be informed that they have acute HIV and should consider starting anti retroviral treatment immediately. Medical provider case reporting is required.

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Interpreting the multiple results from each step of the algorithm can be quite complex. In addition to providing the individual test results, the laboratory report should include a final interpretation statement based on the combined step one, step two, and step three results to help guide medical providers in clinical decision making. This statement should indicate whether the algorithm result is positive, negative, or inconclusive and provide recommendations for further testing if appropriate. Check with your laboratory if you do not see such statement on your report.

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Now let's review a case study that illustrates how to interpret results. Essie is a 45 year old woman who came to the U.S. from Nigeria a couple of years ago for work. She's come to the clinic for her annual

checkup. During the checkup Essie's medical provider offers her an HIV test which she accepts. Essie's medical provider uses an HIV antigen antibody screening test. The initial screening result is reactive, indicating that HIV antibodies or antigen have been detected. The laboratory reflexes to the second step of the HIV testing algorithm. The results of the HIV-1 HIV-2 antibody differentiation immunoassay come back positive for HIV-2 antibodies and negative for HIV-1 antibodies. Revealing that Essie's positive for HIV-2.

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Differentiating between HIV-1 and HIV-2 infection is another advantage of the updated laboratory algorithm. This means Essie will receive better care as many anti retroviral regimens are appropriate for HIV-1 infection are not effective for patients with HIV-2. Consultation with a medical provider with experience in the management of HIV-2 is recommended before initiating anti retroviral therapy in patients with HIV-2.

(lighthearted music)

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We will now review how to deliver prevention messages based on test results. A nonreactive step one screening test result indicates that no infection was detected. However, there is a window period for each type of screening test. The window period is a length of time after infection that it takes for the virus to become detectable by HIV diagnostic tests. For most third generation HIV-1 HIV-2 antibody screening tests, HIV can be detected 21 to 24 days after infection. For fourth generation HIV-1 HIV-2 antigen antibody screening tests, HIV can be detected as early as 14 days after infection.

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Patients receiving a nonreactive test result should be educated about the window period and what it means for them. When a patient presents with flu like symptoms such as fever, nausea, or diarrhea, joint or muscle pain, or other flu like symptoms, and acute HIV infection is suspected, best practice is to obtain an HIV RNA assay in conjunction with an antigen antibody combination screening test. Even with a nonreactive antigen antibody test result an RNA test should be obtained to exclude acute HIV infection. If a patient describes symptoms of acute HIV infection and was tested using an HIV-1 HIV-2 antibody screening test an RNA test should be done.

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Once again, if your patient receives a non-reactive test result through an HIV-1 HIV-2 antibody screening test and acute HIV infection is suspected, conduct an RNA test. If the laboratory used an HIV antigen antibody screening test and acute HIV infection is strongly suspected then you can either conduct an RNA test or repeat the antigen antibody test in another week. In either situation, medical providers should offer risk reduction counseling to patients on what they can do to avoid transmitting HIV.

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If test results at the second or step of a HIV testing algorithm are reactive, medical provider case reporting is required. Patients should be counseled on the meaning of their test results. In the case of a

positive test result, medical providers are required by law to make an appointment for their patient to be seen for HIV care. Again, you should provide HIV risk reduction counseling for the patient regarding how to avoid transmitting HIV to others. Finally, encourage the patient to discuss options for notifying partners, contacts, and or spouses with state or city partner services. This free resource connects patients with experienced specialists who are able to tailor a confidential notification plan to the needs of each individual.

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There are many resources available to help you in your HIV testing efforts. Information related to the CDC and the New York State Department of Health testing guidelines and revised HIV testing algorithm can be found on their websites. Additional information about HIV-2 infection can also be found on the HIV guidelines website. Partner services information and a patient education toolkit on HIV testing area also available on the New York State Department of Health website. Lastly you can call the CEI line at 1-866-637-2342. To speak with a clinician experienced in HIV testing and management. Thank you for your interest in HIV testing. New testing technologies offer a great opportunity to identify and treat people earlier in the course of HIV infection and contribute to the governors plan to end AIDS in New York State by 2020. For information on free training opportunities about HIV testing, treatment, and prevention, please visit ceitraining.org.

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