EDUCATIONAL COMMENTARY – RAPID TESTING FOR HIV

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Learning Outcomes
Upon completion of this exercise, the participant will be able to:

- Discuss the evolution of HIV testing.
- Name the first rapid test for detection of HIV antibodies.
- List the advantages provided by the OraSure OraQuick Rapid HIV-1 Antibody Test.
- Compare the sensitivity of rapid tests using serum, plasma, or whole blood samples with rapid tests using oral fluid.

In spite of improved treatment protocols for human immunodeficiency virus (HIV) and efforts to prevent infection, HIV/AIDS (acquired immunodeficiency syndrome) continues to be an important health issue in the United States and the world. The Centers for Disease Control (CDC) estimates that there are 850,000-950,000 persons living in the United States with HIV. Of these, 180,000-280,000 do not know that they are HIV infected. Testing for HIV remains a very important weapon in the fight against HIV.

Testing for antibodies to HIV was initiated in 1985 to protect the blood supply. Enzyme immunoassays (EIA) were developed to screen donated blood in an effort to prevent transmission of the disease to recipients of transfused blood. EIA tests have high sensitivity, which means that positive samples will produce positive results. These tests remain extremely important in the donor screening process.

The next step in HIV testing occurred when services were provided to test individuals at high risk for HIV infection. A secondary type of test was implemented because of false-positive results. To report a test positive, a confirmatory test, such as a Western Blot (WB) test or immunofluorescent antibody test (IFA) for HIV, must be performed and also found positive. These tests are highly specific, i.e., a negative specimen will yield a nonreactive result. HIV tests cannot be reported positive until both the screening and confirmatory test results are available. Therefore, the results were not available for 1-2 weeks after the patient visit.

Emphasis in research and development of HIV tests has focused on the production of assays that could be performed and reported very quickly. This is particularly important for healthcare workers who are accidentally exposed to possibly HIV-infectious body fluids and neonates of infected women who were not tested for HIV during pregnancy. Early administration of antiretroviral drugs is very effective in the prevention of infection.
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The Food and Drug Administration (FDA) approved the first rapid test in 1992. The Abbott Murex Single Use Diagnostic Systems (SUDS) HIV-1 Test can be performed in about 15-30 minutes on either serum or plasma. This test is not useful as a point-of-care test because it requires refrigeration of reagents, centrifugation of samples, and several steps in the performance of the procedure. It is a very sensitive test, but yields a high percentage of false-positive results. Reactive test results are reported immediately as probably positive to patients in high-risk environments and probably false-positive to those in low-risk categories. All positive SUDS tests require confirmation by a more specific test, such as WB or IFA. According to Tommy Thompson, former United States Secretary of Health and Human Services, “Each year, 8,000 HIV-infected people who come into public clinics do not return a week later for their results.” These rapid tests make results available to patients during their initial visits.

In November, 2002, the FDA approved the first rapid HIV test kit for detection of antibodies to HIV-1 (OraSure OraQuick Rapid HIV-1 Antibody Test) using whole blood. The test requires a drop of whole blood, which eliminates the need for a centrifuge, and the test kit may be stored at room temperature and it does not require sophisticated instrumentation. These factors allow the performance of the test outside the traditional laboratory in settings without electricity or specialized equipment, including public clinics and in third world countries where there is a high prevalence of HIV infection.

The rapid HIV test was initially classified by Clinical Laboratory Improvement Amendments (CLIA) in the moderate complexity category. It has now been changed to waived status, reducing the requirement for supervision necessary for non-laboratory professionals to perform the test in CLIA-certified settings.

Implementation of rapid testing lead to the availability of patient results in < 30 minutes. This allows immediate administration of treatment that can slow the progression of disease and prompt notification of HIV-positive patients to aid in the prevention of transmission of the infection to others. In 2003, two additional rapid HIV tests were approved by the FDA – MedMira Reveal Rapid HIV-1 Antibody Test and Trinity Biotech Uni-Gold Recombigen HIV Test.

Most cases of AIDS in the United States are caused by HIV-1. HIV-2 is rare in this country but is highly prevalent in West Africa. Cases of HIV-2 reported in the United States are usually linked to exposure in West Africa. In 2004, the Multispot HIV1/2 Rapid Test was approved for use on serum or plasma. Also in 2004, the OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test was approved as a point-of-care test. Whole blood, plasma, or oral fluid may be tested using this procedure. Using oral fluid instead of blood eases the fear many individuals have related to having their blood drawn. Oral fluid also decreases the risk to the healthcare professional. This test is not used to screen blood donors. In late 2005, several US cities reported clusters of false-positive results on OraQuick tests performed on oral fluid samples. These clusters did not occur on whole blood specimens.
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The CDC along with local and state health officials and the test kit manufacturer are investigating these reports to determine whether or not test protocols need to be modified. There have been no reported cases of HIV transmitted through saliva or oral fluid.

Rapid tests for HIV are not approved for home use. The lack of training of the public might lead to erroneous test results, but more importantly, there is concern over the lack of a mechanism for counseling or patient follow-up. The FDA has approved the Home Access HIV-1 Test kit with which the individual pricks a finger, adds the blood to a test pad, and submits the pad to a laboratory for analysis. Results are submitted anonymously and patient counseling is available.

In 2003 after consultation with the FDA, laboratory experts, and the Centers for Medicare and Medicaid Services (CMS), the CDC announced that all preliminary positive rapid HIV tests must be confirmed by WB or IFA testing, even if EIA testing results are nonreactive. Patients with negative or indeterminate WB or IFA test results must be retested 4 weeks after the initial reactive rapid test result before reporting the initial test result as a false positive.

Rapid testing for HIV has increased the number of people who know their immune status, and has allowed timely administration of antiretroviral drugs to neonates of HIV mothers and occupationally-exposed healthcare professionals. Continued development of more sensitive and specific tests will further reduce the spread of HIV infection around the world.

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