EDUCATIONAL COMMENTARY – PREVENTING THE TRANSMISSION OF HIV/AIDS

Learning Objectives

Upon completion of this exercise, participants will be able to:

- state the approximate number of new cases of HIV diagnosed per year in the United States.
- discuss the Centers for Disease Control and Prevention (CDC) guidelines for HIV testing.
- describe the four rapid assays currently approved by the Food and Drug Administration (FDA).

AIDS is one of the deadliest epidemics of modern times, causing the deaths of more than 22 million persons worldwide. In the United States, 500,000 people have died of AIDS, and more than 1 million persons live with HIV/AIDS, according to estimates by the Centers for Disease Control and Prevention (CDC). About 25% of those are unaware that they are infected. Since the advent of antiretroviral drugs in the 1990s, the death rate for HIV-infected individuals has decreased significantly, but the number of new cases reported has continued to increase to over 40,000 per year. Approximately 50% to 70% of new sexually transmitted cases involve relationships with individuals who do not know their HIV status. Behaviors such as unprotected sexual intercourse with an infected person, multiple sex partners, and the use of nonsterile needles for illegal drugs increase the risk of infection with HIV. Statistics on AIDS diagnosis, deaths, and infected persons in the United States are provided in the Table.


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<tbody>
<tr>
<td>AIDS diagnoses</td>
<td>38,016</td>
<td>38,513</td>
<td>39,728</td>
<td>39,775</td>
<td>44,198</td>
<td>956,666</td>
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<td>Deaths of persons with AIDS</td>
<td>16,980</td>
<td>16,641</td>
<td>17,404</td>
<td>17,453</td>
<td>16,316</td>
<td>530,756</td>
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<tr>
<td>Persons living with AIDS</td>
<td>331,512</td>
<td>353,384</td>
<td>375,707</td>
<td>398,029</td>
<td>425,910</td>
<td>NA</td>
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Source: Centers for Disease Control and Prevention, Atlanta, GA ([http://www.cdc.gov/hiv/resources/factsheets/At-A-Glance.htm](http://www.cdc.gov/hiv/resources/factsheets/At-A-Glance.htm)). The values given for category titled “Persons living with AIDS” each year are cumulative.

Because a vaccine for HIV is not available, the only hope of reducing its spread is through preventive strategies. Treatment of HIV-infected women during labor and delivery and their newborns immediately after delivery has significantly reduced cases of congenitally transmitted HIV. Strict adherence to safety guidelines by healthcare workers as well as administration of prophylactic antiretroviral drugs after occupational exposure have also been important in reducing new HIV cases. In addition to its epidemiological studies and educational programs, the CDC is conducting clinical trials of pre-exposure prophylaxis in populations at high risk. The studies are designed to evaluate the safety and efficacy of
administering daily anti-retroviral drugs for the prevention of HIV infection. However, testing remains an important component of all HIV prevention strategies.

2006 CDC Guidelines

In September 2006, the CDC revised its guidelines regarding HIV testing of adults, adolescents, and pregnant women. The major revisions include the following recommendations:

1. All patients in health care settings should be tested for HIV unless the patient declines testing.
2. Individuals at high risk for infection should be screened for HIV at least once annually.
3. General consent for medical care is sufficient for HIV testing. A separate written consent is not necessary.
4. All pregnant women should be screened for HIV unless the patient declines testing.
5. Screening should be repeated in the third trimester in areas with elevated rates of HIV infection among pregnant females.
6. Prevention counseling should not be required with HIV testing.

These new guidelines have been implemented in an effort to reduce barriers to testing and ultimately reduce the transmission of the disease. More than 200,000 individuals in the United States are unaware that they are infected. By increasing the numbers of individuals tested for HIV, health officials aim to increase the numbers of individuals who know their HIV status, and thereby reduce disease transmission. Studies show that among persons tested in public health settings using conventional HIV antibody assays, only 30% to 40% return for their results. This problem prompted the development of rapid HIV tests. Instead of assays requiring hours or days to report, the results can be available in 20 minutes or less. The 4 rapid HIV assays approved by the United States Food and Drug Administration are listed and briefly described here.

Four Rapid Assays

1. OraQuick Advance Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, PA). This test is performed on whole blood, plasma, or oral fluid. No refrigeration of reagents is required. These factors allow the testing to be performed outside the traditional laboratory, thus making testing possible in public health clinics or third-world countries. The ability to test oral fluid increases the willingness of some individuals to be tested. When used on fingerstick blood, this assay is classified as a waived test by the Clinical Laboratory Improvement Amendments (CLIA).
2. Uni-Gold Recombigen HIV Test (Trinity BioTech, Bray, Ireland). This test assays whole blood, serum, or plasma for antibodies to HIV-1 only. Results are available in 10 to 12 minutes. When testing whole blood samples, it is classified as a waived test and may be performed in non-traditional settings.

3. Reveal Rapid HIV-1 Antibody Test (MedMira, Halifax, Nova Scotia). This test is performed on serum or plasma. Because a centrifuge is required to separate the serum or plasma from the cells, it is not as adaptable to settings outside the traditional laboratory. Results are available in about 3 minutes. The CLIA classifies this test as moderately complex.

4. Multispot HIV1/2 Rapid Test (Bio-Rad Laboratories, Redmond, WA). The Multispot HIV1/2 Rapid Test detects both HIV-1 and HIV-2 infection and can also differentiate between the two. It is classified as moderately complex and is not appropriate for non-traditional testing sites.

The OraQuick, Uni-Gold, and Reveal assays consist of test cartridges that contain nitrocellulose paper in a testing area that has been impregnated with recombinant or synthetic HIV envelope proteins. If the patient has antibodies to these proteins, which are HIV antigens, the antibodies will attach, forming an antigen-antibody complex. Colorimetric reagents are added to detect the presence of any antigen-antibody reaction. The Multispot assay is similar but is a more complex procedure consisting of several additional reagents.

If a positive result occurs with any of these assays, it is considered a preliminary positive. A preliminary positive sample does not require further screening with the traditional enzyme immunoassay (EIA). Instead, a more specific assay, such as a Western Blot or immunofluorescent assay, is performed to confirm the diagnosis of HIV infection. As a result, individuals may leave testing sites before this testing is complete, knowing they may be infected with HIV. Those who fail to return for the results of confirmatory testing continue to be a challenge.

Summary
Rapid testing for HIV infection is a helpful tool in reducing the spread of HIV. These assays are less expensive than the traditional enzyme immunoassay screening tests, and the results are available much faster. Additional advantages to the patient include better access to testing, including availability in nontraditional testing sites, and the less-traumatic acquisition of specimens for testing. Health officials hope that the availability of this type of testing will encourage high-risk individuals to submit to testing and that knowledge of their HIV status will reduce the behaviors that have been identified in spreading the disease.
EDUCATIONAL COMMENTARY – PREVENTING THE TRANSMISSION OF HIV/AIDS (cont.)

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