HIV/AIDS:
State Of Florida Mandatory Update
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The looped red ribbon became the universal symbol of AIDS awareness.  

Courtesy of the National Institutes of Health.
About the Author

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Objectives

Upon completion of this course, the learner will be able to:

- Identify how care and treatment of persons infected with HIV has changed since the beginning of the pandemic.
- Discuss the Center for Disease Control (CDC) 2006 recommendations for HIV testing as part of routine medical care.
- Contrast the prevalence of HIV in the US with that of Sub-Saharan Africa.
- Contrast the exposure categories for men and women in the US.
- Discuss antiretroviral medications and adherence.
- Describe postexposure prophylaxis for occupational exposure to HIV and non-occupational exposure to HIV.

Introduction

HIV/AIDS has changed dramatically in the past 25 years since the disease was identified. The first cases were reported among gay men who presented with a syndrome that included wasting, fevers, frequent acute illnesses, diarrhea, and Pneumocystis carinii pneumonia (PCP). Once diagnosed with PCP or other opportunistic infections, care was palliative with no known cause or treatment effective against their spiraling immune function.

During this time, when the cause of HIV/AIDS was not known, patients could be turned away from treatment or kept in isolation for fear of spread of the disease. In some cases health care workers refused to care for the patients due to fear of contagion and/or stigmatized them because of their sexual orientation. It may be easy to criticize those actions now, but looking back they faced a deadly disease with no known cause or cure.

We know now that HIV/AIDS was not a new disease in the 1980’s, and that cases have been identified as far back as the 1930’s although they weren’t identified at that time. HIV, a zoonotic disease, originated in Africa; recent research indicates that HIV may have been introduced to humans from apes as long ago as the early 1800s (Wrobey, et al., 2008). HIV eventually made its way to the Western world because of a combination of events including: the destruction of the rainforest, migration patterns of African natives.
from tribal lands to cities and back for trading and employment, prostitution along trade routes, and increasing availability and affordability to travel between countries and continents.

Regardless of the history of HIV development and migration, the disease as we know it in the U.S. may have turned out much differently if bureaucrats had responded more quickly to initial health reports. What was originally perceived to be isolated events among the gay population, evolved into a serious public health threat to the entire world within less than two decades. Unfortunately, the U.S. was not the only country to underestimate the threat of HIV/AIDS. Others were also slow to respond, allowing HIV to spread silently for years before cases of AIDS were identified. By the time they realized there was a problem, the damage had already been done.

The Global Picture of HIV/AIDS

Worldwide, at the end of 2007, approximately 33.2 million persons were living with HIV infection (CDC, 2008c). HIV/AIDS continues to be a political as well as a medical disease. In many ways it has evolved into two epidemics, divided by what one physician refers to as the "haves and have-nots" (Sepkowitz, 2006). In developing countries, even HIV testing may not be readily available, especially to the poor living in rural areas. This problem is compounded by the cost of HIV medications which remains well out of reach for many. Still, the outlook is not hopeless, but change will require political and financial cooperation among countries worldwide.

Of the 5 million new infections recorded globally in 2005, 3.2 million (64 per cent) were in sub-Saharan Africa (WHO, 2006a). Since the 1980s, 50 million people in Africa have been infected by HIV and 22 million have died, the majority of them in their most productive years (WHO, 2006a). Because of this, the cost of HIV/AIDS is much greater than simply medical expenses. Countries have lost more than a whole generation of teachers, political leaders, and scientists. In some African countries as many as 25-38% of adults are infected with HIV (WHO, 2006a). Life expectancy, once improving, has fallen by more than 15 years in five countries and by six-to-15 years in nine others. A child born today in Zambia can expect to live for only 32 years. In South Africa life expectancy dropped between 1995-2002 from 61.4 years to 51.4 years (WHO, 2006a).
In many cases, HIV/AIDS has destroyed the family unit leaving older children and grandparents to raise younger children. More than 12 million African children have been orphaned due to AIDS, depriving them of the love, care, and guidance normally offered by parents. Many of them are homeless and impoverished, subject to exploitation and abuse (WHO, 2006a). There were an estimated 6,800 new cases of HIV infection a day (2.5 M/year) and 5,700 AIDS related deaths globally in 2007. Most were among the poor and the oppressed.

While the greatest number of people infected with HIV/AIDS continues to live in Sub Saharan Africa, countries in the Russian Federation are also hard hit by new cases of HIV/AIDS. In 2006 the number of reported cases of HIV rose 25% over the reported number of cases the previous year. Overall estimates of intravenous drug use are 1-2% in the general population in those countries, but 5-8% among men age 30 or younger. In addition, as many as 80% of these young male drug users report not using condoms on a regular basis, increasing the likelihood of infection among sexual partners (WHO, 2008).

Figure 1. Global View of HIV Infection. 39.5 million people living with HIV in 2006

Tuberculosis (TB) is the leading cause of death among persons with HIV/AIDS in developing countries. According to the CDC (2008b) worldwide, TB is the cause of death for as many as half of the persons with AIDS. In 2007, there were approximately 33.2 million persons worldwide, living with HIV infection. In 2007, approximately 2 billion persons (one third of the world’s population) were infected with Mycobacterium tuberculosis; an estimated one third of the persons living with HIV infection are coinfected with TB (CDC, 2008b).
Similar to the burden with HIV, many people are undiagnosed and/or untreated due to the lack of health care resources. Hepatitis B (HBV) and Hepatitis C (HCV) are also significant health problems in the HIV population with an estimated 72-95% of intravenous drug users infected with HCV (WHO, 2008).

The Role of the World Health Organization in HIV/AIDS

In response to the continued increase in numbers of cases of AIDS and AIDS related deaths in Africa, the World Health Organization (WHO) introduced a strategy in 2003 called the *3 by 5 Plan*, intended to provide antiretroviral medications for 3 million persons infected with HIV/AIDS in developing countries by 2005. This plan signaled a change in strategy from primarily focusing on prevention to recognizing the role of adequate ART in preventing transmission of HIV/AIDS.

While the 3 by 5 program did not reach the goal of providing ART for 3 million people by the end of 2005, 1.3 million people were provided with treatment preventing an estimated 250,000-300,000 deaths (Merson, 2006). A new program intended to increase prevention efforts, testing, and medical care (including antiretroviral treatment [ART]) for HIV positive persons in Africa is now underway. WHO is supporting the global plan *Towards Universal Access by 2010*. Because of the continued generosity of many countries and organizations, about 30% of people living with HIV/AIDS are now receiving adequate ART (See Table 1).

### Table 1. Distribution of ART by Geographic Area

<table>
<thead>
<tr>
<th>Geographic Area</th>
<th>% of People on ART Who Need ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub Saharan Africa</td>
<td>30%</td>
</tr>
<tr>
<td>Latin America &amp; The Caribbean</td>
<td>62%</td>
</tr>
<tr>
<td>Europe &amp; Central Asia</td>
<td>17%</td>
</tr>
<tr>
<td>East, South, &amp; South East Asia</td>
<td>25%</td>
</tr>
<tr>
<td>North Africa &amp; the Middle East</td>
<td>7%</td>
</tr>
</tbody>
</table>

HIV testing is available to only about 12% of people in Africa who would like to be tested. Testing rates in Eastern Asia and Pacific and South East Asia were reported at 0.1% and 0.2% in Northern Africa and the Middle East (WHO, 2008). Recommendations to increase testing availability are also included in the new plan.

The number of women with HIV has increased and is now estimated to be about half of the global HIV population (Altman, 2008). In most cases the route of infection is heterosexual. In countries where women rely on prostitution or providing sex for food or shelter, rates have increased significantly. In some countries where women do not have equal rights with men, women choose to stay in a relationship knowing that her partner is practicing unprotected sex with other partners because she has no way for herself or her children to survive if she leaves. HIV/AIDS continues to flourish in areas where poverty and inequality exist. In some countries, as reported at the 17th International AIDS Conference (Altman, 2008), rape is used as a political weapon of terror; such atrocities further victimize women and girls by making them vulnerable to HIV infection.
WHO (2008) reports that 33% of pregnant women with HIV/AIDS in developing countries in 2007 received ART prior to or during delivery compared to 10% in 2004, significantly decreasing the rate of fetal transmission. However, only 12% of the women were continued on ART after delivery.

The Centers for Disease Control and Prevention (CDC) estimates that there have been about 1,200,000 cases of HIV/AIDS in the U.S. at the end of 2005. This number reflects an estimated 40,000 new cases per year, with as many as 25% of these cases not aware of their HIV status. The annual number of new HIV cases has remained steady for many years.

A new area of interest to prevent the spread of HIV is male circumcision. Studies have shown that male circumcision can reduce the spread of heterosexual transmission by up to 60% (WHO, 2008). Implementation of this procedure in developing countries may be limited due to religious, cultural, and financial barriers. In addition, education is needed to reinforce the fact that while circumcision can decrease the risk of transmission it is not a means of preventing infection.

While these changes are all positive, continued monetary and manpower support is needed to continue to make progress in these areas.
HIV/AIDS in the United States

The Centers for Disease Control and Prevention (CDC) estimates that there were about 1,106,400 persons living with HIV in the U.S. at the end of 2006 (2008a). Of those individuals, approximately 1 in 5 (21%) do not know they are infected. In 2008, CDC adjusted its estimate of new HIV infections because of new technology developed by the agency. For many years, the CDC estimated there were roughly 40,000 new HIV infections each year in the United States. New results shows there were dramatic declines in the number of new HIV infections from a peak of about 130,000 in the mid 1980s to a low of roughly 50,000 in the early 1990s. Results also shows that new infections increased in the late 1990s, followed by a leveling off since 2000 at about 55,000 per year. In 2006, an estimated 56,300 individuals were newly infected with HIV (CDC, 2008).

There were no dramatic changes in the demographics of persons reported to be HIV infected (See Figure 2). The greatest number of new cases is still among men, especially men who have sex with men (MSM), while the most common route of infection among women is heterosexual unprotected sex (CDC, 2008a). There has been a sharp decrease in mother to child transmission from 1,650 in the 1990’s to <200 due to routine screening of pregnant women, use of antiretroviral medication for treatment and prophylaxis, cesarean section if indicated, and avoiding breastfeeding (CDC, 2006a; CDC, 2006c).
The burden of HIV infection was disproportionate among populations. Blacks made up 12% of the adult and adolescent population in the United States in 2006, but accounted for 46.1% of persons estimated to be living with HIV. Similarly, nearly half (48.1%) of the persons living with HIV were MSM, and although not precisely known, the percentage of MSM in the general population is estimated to be much lower. Data from CDC’s National Survey of Family Growth indicate that, among males aged 15 – 44 years, 3.7% ever have had anal sex with another male, and the proportion of men who had a male sexual partner in the past 12 months was 2.9% (CDC, 2008a).

**HIV Testing**

In September, 2006, the CDC issued *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Healthcare Settings* (CDC, 2006e) for routine HIV testing during healthcare contacts. These recommendations are an outgrowth of the recommendations made by the Institute of Medicine (IOM) in 1999 to adopt a national policy of universal testing of pregnant women with patient notification (opt-out screening), eliminating requirements for extensive pretest counseling, and eliminating requirements for explicit written consent for HIV testing. Adoption of the IOM recommendations led to increased prenatal screening, and, combined with appropriate medical care, contributed to a dramatic 95% decline in perinatally acquired HIV cases. Since the IOM report, CDC along with multiple stakeholders began exploring the feasibility of adopting a similar policy for the general public, which could bring about reductions in sexually transmitted HIV (CDC, 2006e). This exploration led to the 2006 Recommendations.
Key differences in the revised *Recommendations* for patients in all healthcare settings are (CDC, 2006e; Branson, et al., 2006):

- HIV testing for patients, aged 13-64, in all healthcare settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- All patients initiating treatment for TB should be screened routinely for HIV infection.
- All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection.
- HIV testing of people at high risk for HIV infection at least once a year.
- Screening should be incorporated into the general consent for medical care; separate written consent is not recommended.
- Prevention counseling should *not* be required with HIV diagnostic testing or as part of HIV screening programs in healthcare settings.

Additional key differences in the *Recommendations* for pregnant women in healthcare settings are (CDC, 2006e):

- Including HIV screening in the routine panel of prenatal screening tests for all pregnant women, unless the patient declines (opt-out screening).
- Repeat screening in the third trimester in certain jurisdictions with elevated rates of HIV infection among pregnant women.

The *Recommendations* emphasize the importance of voluntary testing. Some may have concerns that eliminating the recommendation for separate informed consent for an HIV test could result in some patients being tested for HIV without their knowledge. Others have asserted that requiring separate, written informed consent is a barrier that makes HIV screening difficult to conduct in healthcare settings, and that removing this requirement would make widespread HIV screening feasible (CDC, 2006e).

Concerns have also been expressed over the lack of HIV prevention counseling in conjunction with HIV testing. The 2006 recommendations from the CDC continue to support prevention counseling as an intervention to help people reduce their risks for HIV, but recognize it can become a barrier to HIV testing in busy healthcare settings. The CDC still recommends that patients receive information about HIV testing, HIV infection, and the meaning of test results (CDC, 2006e).

Some of the compelling reasons for the revised *Recommendations* are (CDC, 2006e):

- An estimated one-fourth of the approximately 1 million persons in this country who are living with HIV do not know they are infected. That’s approximately 250,000 persons who could be spreading HIV to their partners unknowingly. As HIV screening becomes a more routine aspect of medical care, more people will know they are infected with HIV.
- People living with HIV can receive effective treatment, resulting in improved health and extended life, if their HIV infection is diagnosed earlier. Currently,
many people learn of their HIV infection only after they have developed symptoms (in a large study of HIV-infected persons, 44% reported they were first tested for HIV because of illness).

- Most people, after finding out they have HIV, adopt behaviors that reduce HIV transmission. Routine HIV testing may help protect the partners of persons who are living with HIV but do not know it. In theory, new sexually transmitted HIV infections could be reduced more than 30% per year if all HIV-infected persons knew of their infection and adopted changes in behavior similar to those of persons already aware of their infection.

- Routine HIV testing may reduce the stigma associated with an HIV test offered based on the healthcare provider’s perception (or knowledge) of risk. When every person gets offered an HIV test at some point in his or her health care, it should take controversy and judgment out of the test and make it a normal part of taking care of oneself.

- Providers reported that requirements for pre-test counseling and written informed consent were not feasible in emergency rooms and other busy healthcare settings.

The Recommendations are intended for healthcare providers in both the public and private sectors. These include healthcare workers in hospital emergency departments, inpatient services (including labor and delivery), correctional health care facilities, clinics including substance abuse treatment, public health, community, pediatric and adolescent, prenatal, and mental health, and other primary care settings (CDC, 2006e).

These Recommendations address HIV testing in healthcare settings only. They do not change existing CDC recommendations on HIV counseling, testing, and referral for persons at high risk for HIV who receive testing in nonclinical settings such as at community-based organizations (CDC, 2006e).

More detailed information about the revised Recommendations can be obtained at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.

Standard testing techniques use an enzyme immunosorbent assay (EIA) to screen for antibodies to both HIV-1 and HIV-2. Because EIA is sensitive but not specific for HIV, all positive EIA tests are confirmed using the Western Blot. There are three possible results from testing: positive, negative, or indeterminate. People with indeterminate results should be encouraged to be retested in three months. While the results of tests are accurate in most cases, patients with clinical symptoms that are consistent with HIV who receive negative or indeterminate results should be retested to rule out technical error.

The transition from standard to rapid testing may play an important role in early identification of HIV and slow/prevent the spread of infection. CDC estimates that many of the new cases of HIV reported each year may have resulted from exposure to blood and/or body fluids of people who are infected with HIV but unaware of their status. Some reports claim that as many as 40% of people tested for HIV do not return for their test results (Liang, et al, 2005). Another feature of rapid tests is that they are simple to do and portable, allowing testing in remote locations where no lab is available. They have been successfully used in mobile vans, storefront clinics, and at needle exchange sites.
There are two basic types of rapid tests available. One involves using a small amount of blood and the other uses saliva obtained by swabbing the oral cavity. Table 2 indicates Rapid HIV tests approved by the FDA as of February, 2008. The tests are interpreted visually and require no instrumentation or laboratory. HIV antigens are affixed to the test strip or membrane. If HIV antibodies are present in the specimen being tested, they bind to the affixed antigen. The test kit's colorimetric reagent binds to these immunoglobulins creating an indicator that is visually detectable (Greenwald, et al., 2006). Sensitivity and specificity for rapid tests are equivalent to standard test results. Negative results are considered valid unless testing was performed during the window period (define window period). Like conventional HIV enzyme immunoassays (EIAs), rapid HIV tests are screening tests that require confirmation if reactive; all positive test results must still be confirmed by a standard Western Blot (Greenwald, et al., 2006). Repeat testing is recommended in one month for indeterminate test results (Bartlett & Gallant, 2005).

### FDA Approved Rapid HIV Antibody Screening Tests

**February 4, 2008**

<table>
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<tr>
<th>FDA Approved</th>
<th>Specimen Type</th>
<th>CLIA Category</th>
<th>Sensitivity** (95% CI)</th>
<th>Specificity** (95% CI)</th>
<th>Manufacturer</th>
<th>Approved for HIV-1 Detection?</th>
<th>List Price Per Test?</th>
<th>External Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OneQuick ADVANCE Rapid HIV-1/2 Antibody Test</strong></td>
<td>Oral fluid</td>
<td>Waived</td>
<td>99.3% (98.6-99.7)</td>
<td>99.5% (99.6-99.9)</td>
<td>OneQuick Technologies, Inc. <a href="http://www.1quick.com">www.1quick.com</a></td>
<td>Yes</td>
<td>$17.50</td>
<td>Sold Separately ($3.75 each)</td>
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<td>Whole Blood (finger stick or venipuncture)</td>
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<td>98.6% (98.5-99.9)</td>
<td>100% (99.7-100)</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>Moderate Complexity</td>
<td>98.6% (98.5-99.9)</td>
<td>98.6% (99.6-99.9)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Uni-Gold Rapid HIV-1 Antibody Test</strong></td>
<td>Whole blood (finger stick or venipuncture)</td>
<td>Waived</td>
<td>100% (99.3-100)</td>
<td>99.7% (99.0-100)</td>
<td>Trinity Biotech <a href="http://www.trinitybiotech.com">www.trinitybiotech.com</a></td>
<td>No</td>
<td>$15.75</td>
<td>Sold Separately ($26.25 each)</td>
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<td></td>
<td>Serum &amp; Plasma</td>
<td>Moderate Complexity</td>
<td>100% (99.3-100)</td>
<td>99.8% (99.5-100)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Revial G-3 Rapid HIV-1 Antibody Test</strong></td>
<td>Serum</td>
<td>Moderate Complexity</td>
<td>98.8% (98.5-100)</td>
<td>99.1% (98.8-99.4)</td>
<td>Medixio, Inc. <a href="http://www.medixio.com">www.medixio.com</a></td>
<td>No</td>
<td>$14.00</td>
<td>Included</td>
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<tr>
<td></td>
<td>Plasma</td>
<td>Moderate Complexity</td>
<td>98.8% (98.0-100)</td>
<td>98.6% (98.4-98.8)</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

* "Public health*" prices for public health programs that are recipients of CDC funds for expanded HIV testing.

* *Clinical Laboratory Improvement Amendments:* CLIA regulations identify three categories of test: waived, moderate complexity, or high complexity.

* **Sensitivity** is the probability that the test result will be reactive if the specimen is a true positive. **Specificity** is the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary tables of approval for HIV-1 only. For HIV-2 information, see package inserts.

National HIV/AIDS Testing Day is an annual event held on June 27 and is sponsored by the National Association of People Living with HIV/AIDS (NAPWA-US). First held in 1996, the event is intended to promote HIV awareness and provide opportunities for HIV testing; it aims to encourage persons at risk for HIV infection to get tested and learn their status. The organization advocates for people living with HIV/AIDS, but also focuses on their role in bringing an end to the human suffering that has resulted from HIV/AIDS in the U.S. and worldwide. In 2006, the theme, "It's Better to Know," underscores the importance of being tested for HIV.
HIV Vaccine

The development of an effective HIV vaccine has eluded scientists since the beginning of the pandemic. Traditionally vaccines have been developed from live or attenuated organisms that stimulate the development of antibodies to the organism when injected into a healthy person. In this way, the immune system develops a “memory” of the invading organism and is able to mount a rapid response to prevent the organism from causing serious illness. HIV vaccine development has been complicated by the number of different viral strains and mutations. HIV mutation is encouraged by non-adherence to medication, and also by natural processes that occur during viral replication. A person may start with a virus with several mutations and within years develop a virus that is “wild type,” meaning that it has changed characteristics from the original virus. None of the vaccines currently under development use live HIV or any organisms that could cause HIV/AIDS in humans.

CDC (2007) reports more than 70 phase I and II vaccine trials have taken place in the past 15 years. Only eleven of these vaccines were tested in developing countries. Most recently, one Phase III trial was conducted in North America and Thailand among MSM and women at high risk (sex workers, partners of HIV positive spouse). The trial used VaxGen Vaccine, a recombinant vaccine given at 0, 1, and 6 months, followed by booster immunizations at 12, 18, 24, and 30 months. Unfortunately, the efficacy criteria required to continue trials was not met. Several other vaccines are being tested in the U.S. and developing countries but further testing will be needed before any product will be available for use.

Antiretroviral Medications

Prior to the advent of antiretroviral therapy (ART), HIV/AIDS was considered a terminal disease. Now, it is considered to be a chronic disease in most cases. ART is an evolving field of study with the focus on decreasing pill burden while maintaining efficacy, development of new drug classes aimed at interfering with viral replication at certain stages of the process, and development of new drugs that are efficacious in the presence of common mutations. Drug sequencing, the study of stepwise medication use designed to decrease the likelihood of resistance development to classes of drugs, has contributed to recommendations for treatment and enhanced the overall understanding of resistance development.
To date there are five classes of ART approved for use by the Food and Drug Administration (FDA). These include:

- non-nucleoside reverse transcriptase inhibitors (NNRTI),
- nucleoside reverse transcriptase inhibitors (NRTI),
- integrase inhibitors (INT),
- protease inhibitors (PI), and
- entry inhibitors (FI).

Each class was designed to interrupt the viral replication cycle at a specific stage. In addition, there are five combination pills that contain more than one medication:

- Combivir (ritonavir and epivir),
- Truvada (tenofovir and emtriva),
- Epzicom (epivir and abacavir),
- Trizivir (ritonavir, epivir, and abacavir), and
- Atripla (efavirenz, tenofovir, emtriva).

The development of drug combinations is aimed at improving adherence by decreasing pill burden.

Prezista (dauranavir) was approved by the FDA in June, 2006, making it the newest protease inhibitor (PI) to be available commercially. Prezista is dosed as one 600 mg tab along with 100 mg of ritonavir twice a day with food. Ritonavir is used to "boost" the level of Prezista and acts synergistically to maintain therapeutic drug levels. It is currently recommended for persons who have tried and failed other PI containing regimens rather than as a first line PI. Because it has a different molecular structure than other PIs, there should be an acceptable viral response to treatment. As with all medications, a thorough search should be conducted to assure there are no drug-drug interactions between Prezista and other medication, including those for HIV.

Patients should be advised to avoid concurrent dosing with other classes of medications including (but not limited to): antifungals, anti-seizure medications, antacids, coumadin, medications for GERD, antihistamines, statins for lowering cholesterol, antimigraine medications, methadone, antidepressants, and St. John’s Wort. Alcohol should also be avoided. Most common side effects are nausea, vomiting, diarrhea, headache, and rash. Patients taking Prezista have reported cases of hepatitis. Therefore, it should be used with caution in patients co-infected with chronic hepatitis C.

The most recent innovation in ART is FDA approved Atripla the first combination, once daily pill in 2006. It is a fixed-dose combination of Sustiva (effivirenz) and Truvada (a combination of tenofovir and emtricitabine). This medication should markedly reduce the complexity of HIV medication treatment, hopefully improving adherence. Atripla should be taken without food, at bedtime. The most common side effects include: headache, dizziness, abdominal pain, nausea, vomiting, and rash. Discontinuation of the treatment for HIV-1 with Atripla in patients with chronic Hepatitis B infection can result in severe flare-ups of Hepatitis B infection. Other potential serious adverse events reported for the use of Atripla’s ingredients include serious liver toxicity, renal impairment and severe depression. It should not be used during the first trimester of pregnancy due to the potential harm to the fetus. Pregnancy should be avoided by women receiving these medications (FDA, 2006).
Two additional classes of drugs have recently been approved by the FDA: integrase inhibitors and entry inhibitors. Both of these medications act at a specific site to interrupt viral replication in the CD4 cell.

**Integrase Inhibitors**

During the viral replication process, following reverse transcription, the HIV DNA migrates into the nucleus of the cell. The integrase enzyme facilitates incorporating viral genetic material into the DNA of the cell. If this process is successful the CD4 cell produces HIV virus instead of other CD4 cells. The class of integrase inhibitors is designed to interrupt this step of the viral replication cycle.

**Entry inhibitors**

These drugs act by attaching themselves to proteins on the surface of T-cells or proteins on the surface of HIV to prevent the cells from binding together. The entry inhibitor can target the gp120 or gp41 proteins on the HIV cell surface, or the CCR5 or CXCR4 receptors on the surface of the CD4 cell. If the medication is effective in preventing HIV from entering the CD4 cell, the viral replication cycle is interrupted at this stage.

Many other new and unique drugs are being developed and tested. Several are expected to receive FDA approval late in 2008. New classes of medications are especially helpful since they are designed to work in the presence of existing viral mutations. These medications, when available, will help to increase treatment options, especially for persons who are highly treatment experienced.

**Post-Exposure Prophylaxis**

There have been several changes in CDC (2005a) recommendations for post-exposure prophylaxis (PEP) after exposure to HIV. These changes are based on new scientific evidence that resulted from research focused on viral transmission following occupational and non-occupational exposures. The most current recommendations can be found at the CDC website and are available in downloadable format for use in emergency departments and medical offices.

The CDC (2005a) currently recommends PEP for occupational exposures:

PEP should be initiated as soon as possible, preferably within hours rather than days of exposure. If a question exists concerning which antiretroviral drugs to use, or whether to use a basic or expanded regimen, the basic regimen should be started immediately rather than delay PEP administration. The optimal duration of PEP is unknown. Because 4 weeks of zidovudine appeared protective in occupational and animal studies, PEP should be administered for 4 weeks, if tolerated. Combinations that can be considered for PEP include ZDV and 3TC or emtricitabine (FTC); d4T and 3TC or FTC; and tenofovir (TDF) and 3TC or FTC. In the previous Public Health Service guidelines, a combination of d4T and ddI was considered one of the first-choice PEP regimens; however, this regimen is no longer recommended because of concerns about toxicity (especially
neuropathy and pancreatitis) and the availability of more tolerable alternative regimens.

The PI preferred for use in expanded PEP regimens is lopinavir/ritonavir (LPV/RTV). Other PIs acceptable for use in expanded PEP regimens include atazanavir, fosamprenavir, ritonavir-boosted indinavir, ritonavir-boosted saquinavir, or nelfinavir. Although side effects are common with Non-nucleoside Reverse Transcriptase inhibitors, efavirenz may be considered for expanded PEP regimens, especially when resistance to PIs in the source person's virus is known or suspected. Caution is advised when EFV is used in women of childbearing age because of the risk of teratogenicity (CDC, 2005a).

For non-occupational exposures (nPEP), the recommendations are as follows:

For persons seeking care ≤72 hours after non-occupational exposure to blood, genital secretions, or other potentially infectious body fluids of a person known to be HIV infected, when that exposure represents a substantial risk for transmission, a 28-day course of highly active antiretroviral therapy (HAART) is recommended. Antiretroviral medications should be initiated as soon as possible after exposure. For persons seeking care ≤72 hours after non-occupational exposure to blood, genital secretions, or other potentially infectious body fluids of a person of unknown HIV status, when such exposure would represent a substantial risk for transmission if the source were HIV infected, no recommendations are made for the use of nPEP. Clinicians should evaluate risks and benefits of nPEP on a case-by-case basis. For persons with exposure histories that represent no substantial risk for HIV transmission or who seek care >72 hours after exposure, DHHS does not recommend the use of nPEP (CDC, 2005b).

Social Issues

Management of social issues plays a significant role in HIV care. For this reason, an integrated team of professionals is needed to meet the complex needs of patients with HIV. Issues such as substance abuse, mental health, financial needs, relationship issues, and housing can interfere with the patient’s ability to remain adherent to his medical care plan. Patient’s present to the clinic and report that they were unable to take certain doses of medication because they had been instructed to take it with food, but they had no food. Others report missing appointments or tests because no transportation was available. Specialists in the field now recognize the importance of postponing initiation of ART if possible for persons with chaotic life situations until changes can be made to optimize the likelihood of treatment success. Referrals to community based organizations, food pantries, and organizations managing subsidized housing can greatly improve the possibility of successful treatment.

Adherence

Taking ART medications at the right dose and time has been shown to promote viral suppression and reduce AIDS related mortality. Predictors of poor adherence have not changed significantly over the past several years. Because adherence often involves behavioral change, it is difficult to implement and continue. Adherence is important for two reasons: it affects the individual but also has a significant effect on public health.
People who are able to maintain an undetectable viral load are less likely to progress to AIDS. An undetectable viral load also decreases the probability of viral transmission following an exposure.

In 2005 the media reported a case of multi-drug resistant (MDR) HIV in a person living in New York City. According to media reports, the persons was recently diagnosed with HIV but had so few treatment options that progression to AIDS was rapid. Shet, et al. (2006) reported on the prevalence of ART resistant mutations transmitted on a New York City cohort of recently infected persons. Of the 112 people in the study, viral resistance was identified among 25% prior to beginning ART, while almost 10% had MDR strains of HIV. The increase of resistance was statistically significant different between 1995-1998 and 2003-2004 (p=0.04).

Resistance is a problem which could become worse if the number of cases of drug resistant virus increases. As with other drug resistant organisms such as Multi-Drug Resistant Mycobacterium tuberculosis (MDTB) and Methicillin Resistant Staphylococcus aureus (MRSA), the development of viral resistance complicates and limits treatment options. In contrast to many developing countries where antiretroviral therapy is not available, in the U.S. non-adherence, a major contributor to the development of viral resistance, continues to be a significant focus of patient care efforts. The development of natural mutations during viral replication also contributes to the development of viral resistance, but to date there is no mechanism known to interfere with that process.

Stigma

Stigma continues to be a deterrent for HIV testing and care. The previously mentioned CDC consideration of changing testing recommendations based on the rationale that offering HIV testing as a routine part of medical care may result in increased numbers of people willing to be tested and earlier identification of persons already infected.

The reasons for HIV related stigma have not changed in the past twenty years, although several reports have claimed that there is less stigma toward people with HIV/AIDS in the U.S. now than at the beginning of the pandemic. The barrier to eliminating stigma toward this population results from cumulative prejudice among many groups of people who are infected: homosexuals, intravenous drug users, minorities, and women. For that reason, change in attitudes will be difficult and HIV related stigma will probably persist as a problem for years to come.

Social Support

Social support has been related to improved health outcomes in studies of various illnesses, yet it is often overlooked during a patient assessment. Patients may be reluctant to participate in group activities or frequent organizations that support people with HIV/AIDS because of the real or perceived stigma attached. Fear of disclosure is still a very real concern for many patients. As one patient said, “Once you tell someone they know. You can never take back your words.” Strong social support provides a network of safety and encouragement that allows the patient to share their concerns and feelings while not feeling stigmatized for who they are or what they will become.

Conclusion

Twenty-five years after the first case of HIV/AIDS was reported we are still struggling with the disease. There is still no cure, and new cases are being reported daily. It would appear that the gravity of the situation will be causing changes in the way we have viewed the disease. No longer an affliction of gay men and addicts, HIV has touched each of us in some way. World leaders are beginning to respond, and the realization is apparent that without change generations of people will be lost.

Advancements in ART include combination pills to decrease pill burden while maintaining efficacy, the development of new drugs and new classes of drugs, and continued efforts toward vaccine development. The CDC has revised its testing recommendations to promote earlier identification of HIV/AIDS by destigmatizing the testing process and making HIV testing a routine part of healthcare. Research continues to help broaden our understanding of HIV and the way it impacts the human body.

Each of us can play a role in the fight against HIV/AIDS:

- Take the time to do a complete sexual history to identify risk factors;
- Treat people with HIV/AIDS with respect;
- Increase HIV/AIDS awareness at work and in the community;
- Volunteer at a local HIV community based organization;
- Participate in HIV fund raising activities;
- Keep up to date on HIV knowledge;
- Advocate for programs to benefit people living with HIV/AIDS.

It will make a difference.

References


HIV/AIDS: State Of Florida Mandatory Update Test

1. HIV and AIDS have gone from a chronic illness to an acute illness.
   A. True.
   B. False.

2. The annual incidence (new cases) of HIV infection in the US, as reported by the CDC in 2008:
   A. Was thought, for many years, to have remained relatively stable at 40,000 new cases per year.
   B. Has now been determined to be over 50,000 per year and was reported to be 56,300 in 2006.
   C. Reflects that among men the leading cause of infection is unprotected sex with men; for women it is unprotected heterosexual sex.
   D. All of the above.

3. HIV and AIDS are both political and medical diseases.
   A. True.
   B. False.

4. Prior to the development of highly active antiretroviral medications, care of those with HIV/AIDS was often synonymous with palliative care.
   A. True.
   B. False.

5. Factors influencing HIV infection in Sub-Saharan Africa include all the following EXCEPT:
   A. The high rate of condom use has helped to decrease the spread of HIV.
   B. The cost of antiretroviral medications.
   C. The stigma of HIV and AIDS.
   D. Children who are at risk because of loss of parents due HIV/AIDS.
6. The most recent category of antiretroviral medications discussed in this course, are:
   
   A. The protease Inhibitors and integrase inhibitors.
   B. The nucleoside reverse transcriptase inhibitors and fusion inhibitors.
   C. Integrase inhibitors and entry inhibitors.
   D. The non-nucleoside reverse transcriptase inhibitors and protease inhibitors.

7. The CDC’s 2006 revised recommendations for HIV testing make testing, in the healthcare setting, a routine part of healthcare without requiring a specific consent or specific pre-test counseling. These recommendations:

   A. Apply to all patients aged 13-64 in all healthcare settings after informing the patient that test will occur, unless the patient declines.
   B. Apply to all patients being treated for TB and STDs regardless of their risk factors for contracting HIV.
   C. Apply to patients with high risk behaviors who should be tested at least once per year.
   D. All of the above.

8. The optimal duration of postexposure prophylaxis for occupational exposure to HIV is unknown. Because 4 weeks of zidovudine appeared protective in occupational and animal studies, PEP should be administered for 4 weeks, if tolerated.

   A. True.
   B. False.

9. Non-occupational post-exposure prophylaxis (nPEP) is recommended:

   A. To be started within 72 hours of exposure.
   B. As a 28-day course of highly active antiretroviral medications.
   C. Clinicians should evaluate risks and benefits of nPEP on a case-by-case basis.
   D. All of the above.

10. Taking antiretroviral (ART) medications at the right dose and time has been shown to promote viral suppression and reduce AIDS related mortality.

   A. True.
   B. False.