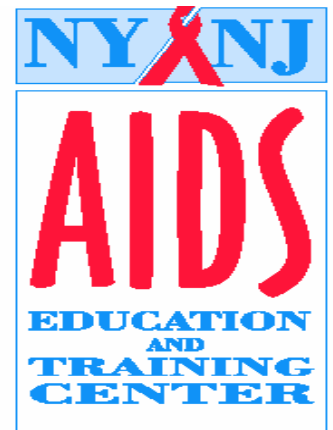


Topics in the Nursing Care of People Living with HIV/AIDS

Module I



Human Immunodeficiency Virus and Antiretroviral Therapy

Lucille Sanzero Eller PhD RN

Acknowledgements

This publication is supported by the New York/New Jersey AIDS Education and Training Center. The AIDS Education and Training Center (AETC) Program of the Ryan White CARE Act currently supports a network of 11 regional centers (and more than 130 local performance sites) that conduct targeted, multi-disciplinary education and training programs for healthcare providers treating persons with HIV/AIDS. The AETCs serve all 50 States, the District of Columbia, the Virgin Islands, Puerto Rico, and the six U.S.-affiliated Pacific Jurisdictions. The AETC Program is administered by the HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (DHHS).

The NY/NJ AETC's mission is to assist health care professionals, through education and training, to provide optimal quality services and sensitive care to HIV positive persons, and to provide access to current research and treatment of HIV/AIDS. We serve the New York and New Jersey healthcare communities by providing AIDS and HIV education and training to those who treat, manage, diagnose, or counsel individuals with HIV infection and AIDS, and to help prevent high risk behaviors that lead to HIV transmission.

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The National AETC Program also includes the following clinician services:

Warmline

National HIV Telephone Consultation Service: 1-800-933-3413

PEPline

National Clinicians' Post-Exposure Prophylaxis Hotline: 1-888-HIV-4911

Perinatal HIV Hotline

National Perinatal HIV Consultation and Referral Service: 1-888-448-8765

HIV/AIDS National Resource Center: www.aidsetc.org

Providing resources (including curricula and lecture slide sets) on HIV disease, treatment, education and data

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MISSION: These modules will equip nurses with the basic knowledge needed to provide safe, comprehensive care to clients with HIV/AIDS.

INTENDED AUDIENCE: These five modules are intended for all nurses who work with clients with HIV/AIDS in doctor's offices, hospitals, ambulatory care and correctional settings.

LEARNING OBJECTIVES:

After completing Module I of V the nurse should be able to:

Module I

1. accurately discuss the human immunodeficiency virus and recommended antiretroviral therapies.

OUTLINE:

Module I

Human Immunodeficiency Virus And Antiretroviral Therapy

- a. Basic Treatment Overview
- b. Drug Regimens
- c. ART Initiation
- d. SMART Trial
- e. Patient Monitoring
- f. Patient Education

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Additional thanks to Debbie M. Winters, APRN-BC AACRN and Maryann Andrews BSN RN for their thoughtful comments.

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Module I

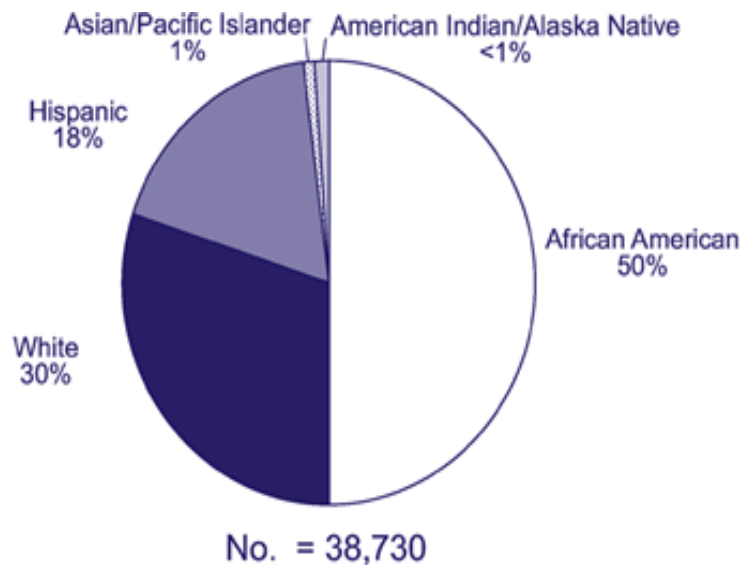
Human Immunodeficiency Virus and Antiretroviral Therapy

Epidemiology of HIV

An estimated 1,039,000 to 1,185,000 people in the United States were living with HIV/AIDS by the end of 2003 (Glynn and Rhodes, 2005). In 2004, 38,730 cases of HIV/AIDS were diagnosed and the Centers for Disease Control and Prevention (CDC) estimates that approximately 40,000 individuals become infected with HIV each year. These statistics are based on the 35 areas (33 states, Guam, and the U.S. Virgin Islands) with long-term, confidential name-based HIV reporting (CDC, 2005).

People of color are disproportionately represented in the HIV epidemic (See Figure I.1). For example, African Americans make up 12.9% of the U.S. population, but accounted for 50% of those diagnosed in 2004. Similarly, Hispanics make up 12.5% of the population and accounted for 18% of those diagnosed (CDC, 2006; U.S. Census Bureau, 2003). The incidence and prevalence of HIV also vary by geographic region, with Eastern states affected most (See Tables I.1 and I.2).

Figure I.1. Race/Ethnicity of Persons (including children) with HIV/AIDS diagnosed during 2004



Source: Centers for Disease Control and Prevention (CDC). (2006).

Table I.1. Top 10 AIDS Cases in 2004 by State/Territory

| State/Territory | # of new AIDS Cases in 2004 |
|-----------------|-----------------------------|
| New York | 7,641 |
| Florida | 5,822 |
| California | 4,679 |
| Texas | 3,298 |
| New Jersey | 1,848 |
| Illinois | 1,679 |
| Georgia | 1,640 |
| Pennsylvania | 1,629 |
| Maryland | 1,451 |
| North Carolina | 1,137 |

Source: Centers for Disease Control and Prevention (CDC). (2006, January 26). Basic statistics. Retrieved May 24, 2006, from <http://www.cdc.gov/hiv/topics/surveillance/basic.htm#hivest>

Table I.2. Top 10 Cumulative AIDS Cases through 2004 by State/Territory

| State/Territory | # of Cumulative AIDS Cases Through 2004 |
|-----------------|---|
| New York | 166,814 |
| California | 135,221 |
| Florida | 96,712 |
| Texas | 64,479 |
| New Jersey | 47,224 |
| Illinois | 31,020 |
| Pennsylvania | 30,526 |
| Georgia | 28,248 |
| Puerto Rico | 28,202 |
| Maryland | 27,550 |

Source: Centers for Disease Control and Prevention (CDC). (2006, January 26). Basic statistics. Retrieved May 24, 2006, from <http://www.cdc.gov/hiv/topics/surveillance/basic.htm#hivest>

Adequate management of HIV disease requires an understanding of patient characteristics, the virus itself, and antiretroviral (ARV) medications.

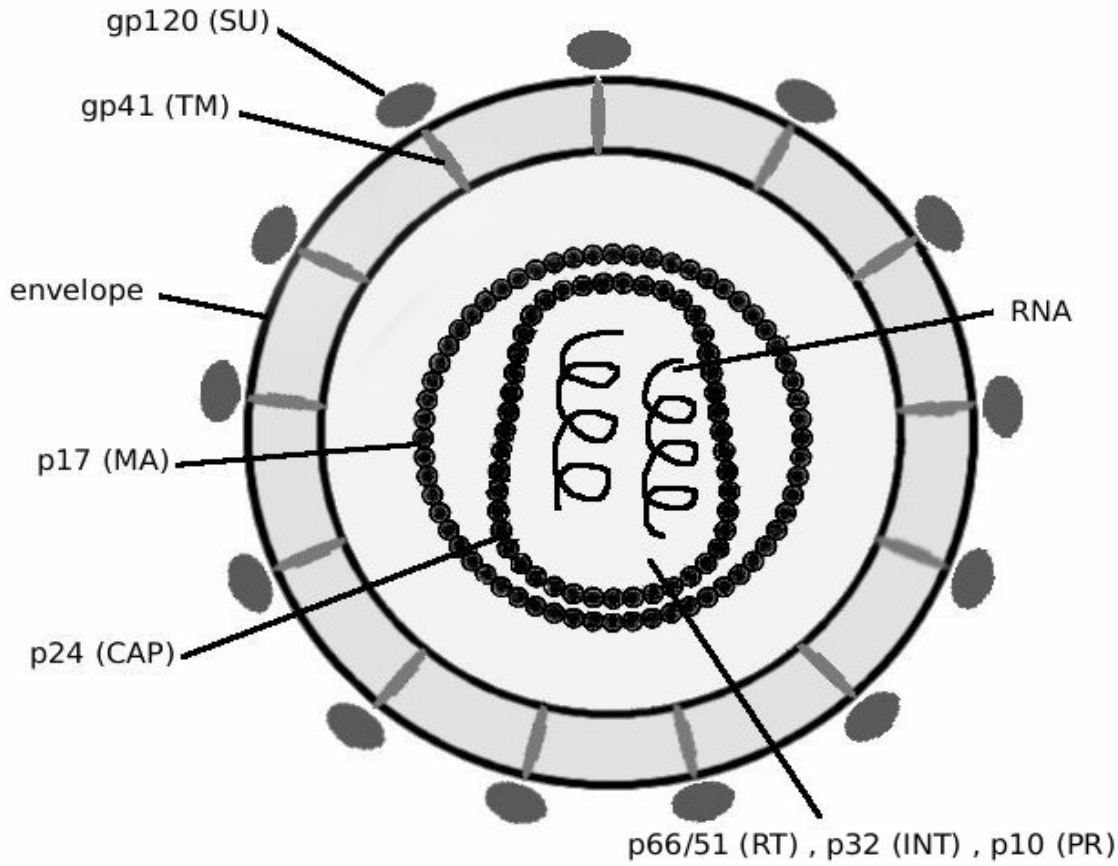
Human Immunodeficiency Virus (HIV)

HIV¹ is a retrovirus in the class lentivirus. The genes of HIV and other retroviruses are contained in RNA. Like other viruses, HIV cannot replicate unless it has infected a living cell. The virus replicates inside the living cell and, in the process, destroys the cell.

The HIV virion is a spherical particle approximately 0.1 micron in size, or 1/70 the diameter of a CD4+ T lymphocyte. The viral membrane is covered with 72 “spikes” made up of gp120 and gp41 proteins. The next layer, the matrix, consists of the p17 protein. The HIV inner core is made of p24 protein, and contains two identical strands of viral RNA. The core also contains reverse transcriptase, integrase, and protease; these enzymes are required for reverse transcription and HIV replication (see Figure I.2).

¹ HIV, as used in these modules, refers to HIV-1 unless otherwise noted. HIV-1 is the most common source of infection in the U.S.

Figure I.2. Diagram of HIV Virion



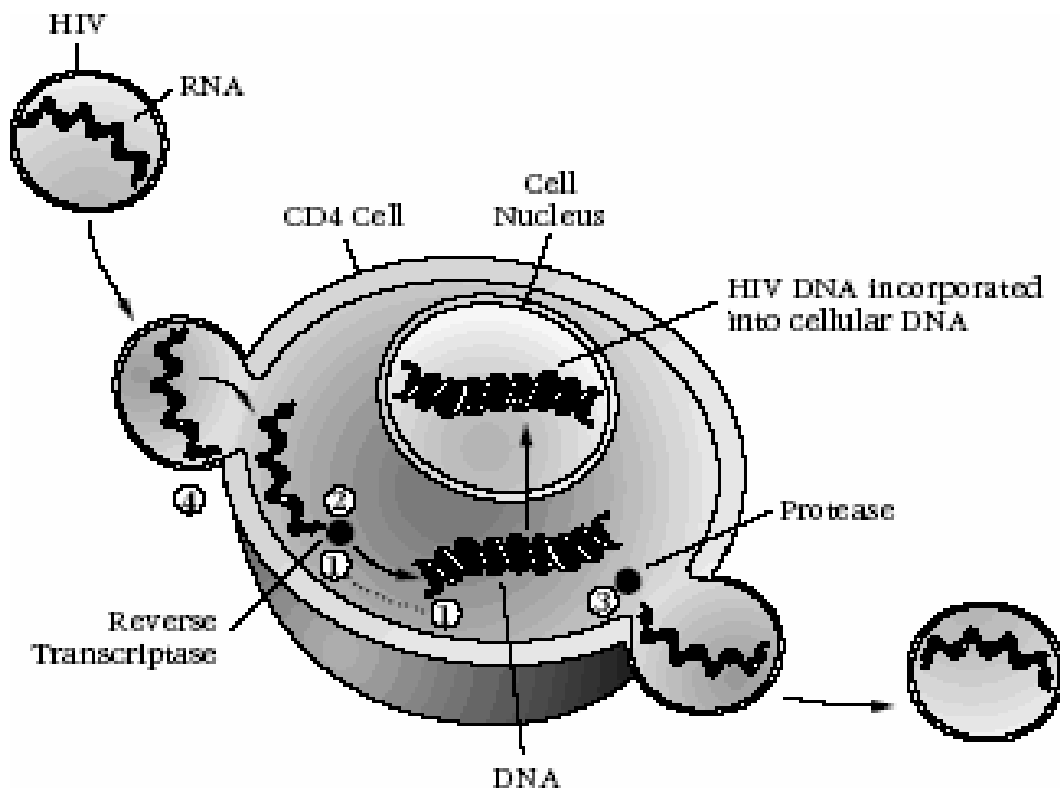
Mature HIV virion. MA = matrix, CAP = capsid, RT = reverse transcriptase (heterodimer), INT = integrase, PR = protease

Source: Nuyttens, J. (2006).

The steps in the HIV replication cycle include binding and fusion, reverse transcription of RNA, integration of HIV DNA into the cell's genome, and transcription and translation of the virus with release of virions from the infected cell (Figure I.3). When the virus replicates, it kills the infected cell, which, in most cases, is a CD4+ T lymphocyte. The steps in the HIV replication cycle are as follows:

1. **Binding and Fusion:** The virion's gp120 and gp41 proteins bind to a cell's CD4+ receptor molecule and then to one of two co-receptors (CCR5 or CXCR4) on the cell's surface. The viral membrane then fuses with the cell membrane and the contents of the virion are released into the cell.
2. **Reverse Transcription and Integration:** Inside the cell, the HIV enzyme reverse transcriptase is used to copy viral RNA into viral DNA. Viral DNA is then transported to the cell's nucleus, where it is spliced into the cell's DNA with the assistance of the HIV enzyme integrase.
3. **Transcription and Translation:** When the infected cell becomes activated, viral DNA is transcribed into messenger RNA (mRNA), which is then translated into viral proteins and enzymes.
4. **Assembly, Budding, and Maturation:** HIV proteins and enzymes assemble into new viral particles: following assembly, the virus buds from the cell. At this stage, the protease enzyme cleaves the long strands of protein into smaller functional HIV proteins, and enzymes and maturation occurs. Mature HIV particles are ready to infect new cells and repeat the replication process. ARV (antiretroviral) drugs are based on the HIV replication cycle. Figure I.3 describes the sites of action of ARV agents.

Figure I.3. Sites of Action of Antiretroviral Agents



1. Site of Action of Nucleoside Reverse Transcriptase Inhibitors (NRTI): Incorporate into DNA and block reverse transcriptase
2. Site of Action of Non- Nucleoside Reverse Transcriptase Inhibitors (NNRTI): Bind to reverse transcriptase
3. Site of Action of Protease Inhibitors (PI): Bind to protease to inhibit viral protein cleavage and therefore release of virus from cell
4. Site of Action of Fusion Inhibitors (FI): Interact with virus to inhibit virus-cell fusion

Source: Feinberg, J., and Maenza J. (2005).

Antiretroviral Therapy (ART)

Antiretroviral Therapy (ART) is the use of antiretroviral (ARV) drugs to treat HIV disease. Highly active antiretroviral therapy (HAART)² consists of regimens that combine several ARV drugs. Guidelines for ART were developed and are regularly updated by the Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents (Panel on Antiretroviral Guidelines, 2006). The full text of all HIV Guidelines can be retrieved at <http://www.hivatis.org/Guidelines/Default.aspx?Menuitem=Guidelines>.

The Food and Drug Administration (FDA) has approved a number of drugs for treating HIV infection. These drugs can be grouped into four classes, each having a different mechanism of action that interrupts HIV at different stages in the replication cycle (see Table I.3).

² Current guidelines recommend the use of combination (or highly active) therapy in all HIV treatment protocols. When antiretroviral therapy (ART) is used in this document, it refers to combination therapy with 3 or more drugs and is considered to be highly active.

Table I.3. Antiretroviral Drug Class and Mechanism of Action

| ARV Drug Class | Mechanism of Action |
|--|--|
| Nucleoside Reverse Transcriptase Inhibitors (NRTI) | Block reverse transcriptase enzyme that changes RNA to DNA before HIV's genetic code combines with infected cell's own genetic codes. NRTIs mimic the building blocks used by reverse transcriptase to copy HIV genetic material and thus disrupt the copying process. |
| Nonnucleoside Reverse Transcriptase Inhibitors (NNRTI) | Block reverse transcriptase enzyme that changes RNA to DNA before HIV's genetic code combines with infected cell's own genetic codes. NNRTIs physically prevent the reverse transcriptase enzyme from working. |
| Protease Inhibitors (PI) | Block the protease enzyme needed to cut long protein strands into the parts needed to assemble a mature virus. When protease is blocked, new viral particles cannot mature. |
| Fusion Inhibitors (FI) | Interfere with HIV's ability to enter into cells by blocking the merging of the virus with the cell membrane. This inhibition blocks HIV's ability to enter and infect the human cells. |

Several new classes of drugs are in various stages of clinical trials. These include gene therapies that block viral genes; integrase inhibitors that prevent integration of viral DNA into the nucleus of the infected cell; maturation inhibitors that inhibit the development of HIV's internal structures in newly formed virions; zinc finger inhibitors that break apart structures (zinc fingers) that hold the inner core together, thus preventing it from functioning; attachment and fusion inhibitors (e.g. CD4, CCR5, and CXCR4 receptor blockers) that prevent the virus from attaching to and entering a cell; and antisense drugs that mirror HIV's genetic code and lock on to the virus to block replication. Characteristics of all FDA approved ARVs, by class, can be found at <http://www.hivatis.org/Guidelines/Default.aspx?Menuitem=Guidelines>. This information includes dosing, food effects, storage, and adverse events. ART is not a cure for HIV disease, but can have specific and positive effects (see Table I.4). Since its advent in 1996, the use of combination therapy has reduced morbidity and mortality and improved the quality and quantity of life for people in all stages of HIV disease (Mannheimer, et al., 2005.)

Table I.4. Primary Goals of ART

| |
|---|
| <ul style="list-style-type: none"> • Maximal and durable suppression of HIV viral load • Restoration and preservation of immune function (improved CD4+ T lymphocyte count) • Improved quality of life • Reduced HIV-related opportunistic infections (OI) • Reduced morbidity and mortality |
|---|

Adapted from Panel on Antiretroviral Guidelines for Adults and Adolescents. (2006). Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Retrieved August 18, 2006, from <http://www.hivatis.org/Guidelines/Default.aspx?Menuitem=Guidelines>.

Initiation of Antiretroviral Therapy

The decision about when to initiate ART is based on a combination of factors, including the patient's ARV history, resistance profile, CD4+ T cell count, viral load, symptoms, co-morbidities, other medications, and ability and readiness to adhere to treatment and follow-up care. In addition, known barriers to adherence such as economic factors, substance use, mental health disorders, and lack of social support should be addressed through referral and treatment prior to the initiation of ART. The ultimate decision of whether or not to begin ART lies with the patient. Current recommendations for the initiation or deferral of ART appear in Table I.5.

Table I.5. Indications for Antiretroviral Therapy (ART)

1. ART is recommended for all patients with a history of an AIDS-defining illness or severe symptoms of HIV infection, regardless of CD4+ T cell count.
2. ART is recommended for asymptomatic patients with <200 CD4+ T cells/mm³.
3. Asymptomatic patients with CD4+ T cell counts of 201-350 cells/mm³ should be offered treatment.
4. For asymptomatic patients with CD4+ T cell counts >350 cells/mm³ and plasma HIV RNA (viral load) >100,000 copies/μL most experienced clinicians defer therapy but some may consider initiating treatment.
5. Therapy should be deferred for patients with CD4+ T cell counts >350 cells/mm³ and plasma HIV RNA <100,000 copies/μL

Adapted from: Panel on Antiretroviral Guidelines for Adults and Adolescents (2006). Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Retrieved August 18, 2006, from <http://www.hivatis.org/Guidelines/Default.aspx?Menuitem=Guidelines>

ART regimens recommended in the guidelines are shown in Table I.6. In selecting an ART regimen, the Panel also recommends that clinicians consider several strategies to help achieve the goals of therapy. These are:

- Maximization of adherence to the ARV regimen
- Rational sequencing of drugs
- Preservation of future treatment options
- Use of resistance testing in selected clinical settings

Advantages and disadvantages for each regimen are discussed in the guidelines, available at <http://www.hivatis.org/Guidelines/Default.aspx?Menuitem=Guidelines>.

Table I.6. Antiretroviral Regimens Recommended for Treatment of HIV-1 Infection in Antiretroviral Naïve Patients³

| | Regimens | Number of pills/day |
|-----------------------------------|---|---------------------|
| Preferred Regimens NNRTI-Based | efavirenz + (lamivudine or emtricitabine) + (zidovudine or tenofovir DF) [Note: efavirenz is not recommended for use in the first trimester of pregnancy or in women with high pregnancy potential*] | 1-3 |
| PI-based | lopinavir/ritonavir (coformulation) + (lamivudine or emtricitabine) + zidovudine | 6-7 |
| Alternate Regimens NNRTI-Based | efavirenz + (lamivudine or emtricitabine) + (abacavir or didanosine or stavudine) [Note: efavirenz is not recommended for use in the first trimester of pregnancy or in women with high pregnancy potential*] | 2-4 |
| | nevirapine + (lamivudine or emtricitabine) + (zidovudine or stavudine or didanosine or abacavir or tenofovir) [Note: high incidence of symptomatic hepatic events were observed in | 3-6 |

³ Adapted from: Panel on Antiretroviral Guidelines for Adults and Adolescents. (2006). Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Retrieved August 18, 2006, from <http://www.hivatis.org/Guidelines/Default.aspx?Menuitem=Guidelines>.

| | | |
|--------------|--|------|
| | women with pre-nevirapine CD4+ T cell counts >250 cells/μL and men with CD4+ T cell counts >400 cells/μL. Nevirapine should not be initiated in these patients unless the potential benefit clearly outweighs the risk] | |
| PI-based | atazanavir + (lamivudine or emtricitabine) + (zidovudine or stavudine or abacavir or didanosine) or (tenofovir + ritonavir 100 mg/day) | 3-6 |
| | fosamprenavir + (lamivudine or emtricitabine) + (zidovudine or stavudine or abacavir or tenofovir or didanosine) | 5-8 |
| | fosamprenavir/ritonavir [‡] + (lamivudine or emtricitabine) + (zidovudine or stavudine or abacavir or tenofovir or didanosine) | 5-8 |
| | indinavir/ritonavir [‡] + (lamivudine or emtricitabine) + (zidovudine or stavudine or abacavir or tenofovir or didanosine) | 7-12 |
| | lopinavir/ritonavir + (lamivudine or emtricitabine) + (stavudine or abacavir or tenofovir or didanosine) | 5-8 |
| | nelfinavir + (lamivudine or emtricitabine) + (zidovudine or stavudine or abacavir or tenofovir or didanosine) saquinavir (soft-gel capsules, hard-gel capsules, or tablets)/ritonavir (100-400 mg/day) + (lamivudine or emtricitabine) + (zidovudine or stavudine or abacavir or tenofovir or didanosine) | 5-8 |
| | saquinavir (sgc, hgc, or tablets) [#] /ritonavir [‡] + (lamivudine or emtricitabine) + (zidovudine or stavudine or abacavir or tenofovir or didanosine) | 7-15 |
| 3 NRTI-Based | abacavir + zidovudine + lamivudine (only when a preferred or an alternative NNRTI- or a PI-based regimen cannot or should not be used) | 2 |

* Women with high pregnancy potential includes women who want to conceive or who are not using effective contraception; [‡] Low-dose (100-400 mg) ritonavir per day; [#] sgc = soft gel capsule; hgc = hard gel capsule
The following information is based on the recent Guidelines for the use of ARV agents in HIV-infected adults and adolescents (Panel on Antiretroviral Guidelines, 2006).

Protease Inhibitors (PI)-based regimens, consisting of one or two PIs and two NRTIs, were the first ARV combinations used. PIs are associated with durable viral suppression, improved immunologic response, and longer survival. Problems with PIs include the potential for drug interactions, gastrointestinal intolerance, rash, paresthesias, dyslipidemia, fat maldistribution, and insulin resistance.

NNRTI regimens are sometimes preferred over PIs for initial therapy because they preserve PIs for later treatment options, have a lower pill burden than PI-based regimens, and avoid the side effects associated with PIs. However, resistance to NNRTIs develops more easily, with only a single mutation needed for

resistance. This resistance also typically extends to the entire class of drugs (cross-resistance). Potential adverse events for NNRTIs include rash, central nervous system symptoms, increased transaminase levels, and headaches.

The advantages of a triple NRTI regimen include a lower pill burden (Trizivir[®] is a single combination of abacavir, zidovudine, and lamivudine), fewer drug-drug interactions, and fewer side effects than those seen with PIs and NNRTIs. However, this regimen has been shown to have lower virologic activity and greater rates of virologic failure than other regimens.

The FDA granted accelerated approval on June 23, 2006 for the drug darunavir (formerly known as TMC-114). Darunavir (Prezista[™]) is a PI designed to treat resistant HIV strains. It is co-administered with a low-dose of ritonavir, in combination with other ARVs. Ritonavir slows the metabolism of darunavir, resulting in increased plasma concentrations. The recommended oral dose of darunavir tablets is 600 mg (two 300 mg tablets) taken twice daily taken with ritonavir 100 mg and food. The most frequently reported side effects of the darunavir-ritonavir regimen include diarrhea, nausea, and headache.

Evaluation

Ongoing evaluation of viral load and CD4+ T cell counts provides critical information for decisions regarding the initiation and ongoing management of ART.

Viral Load

Quantification of HIV RNA through plasma viral load (PVL) testing can detect the presence of HIV a few days after infection. It should be noted that PVL testing should be deferred for 2 to 4 weeks following acute illness or vaccination, as these may cause increases in plasma HIV RNA levels. Plasma HIV RNA results should be verified with a second PVL test before initiating or changing therapy. Over time, the same type of test should be used to measure viral load because different test methods can give different results for the same sample.

Techniques for assessing viral load include:

- The PCR (polymerase chain reaction) test uses an enzyme to amplify HIV DNA in the sample. This is labeled with chemical markers and these markers are measured to calculate the amount of virus.
- The branched DNA (bDNA) test works by binding fluorescent probes to HIV RNA following lysis of virions. Viral RNA is quantified by measuring fluorescence, which is converted to indicate the amount of HIV RNA in the sample.
- The nucleic acid sequence based amplification (NASBA) test first amplifies HIV RNA. A fluorescently labeled DNA probe then binds to RNA, producing a fluorescent signal that is measured to indicate the amount of HIV RNA in the sample.

A significant change in plasma viral load is indicated by a threefold increase or decrease. That is, a decrease of 1/3 or an increase of 3 times the previous test result would indicate a significant change (Panel on Antiretroviral Guidelines, 2005). Changes in PVL are often expressed as "log" changes. A meaningful change would be a change of 0.5- \log_{10} copies/ μ L. The goal of ART is an undetectable plasma viral load. Undetectable viral load refers to a viral load below the limits of assay detection. This should be achieved within 16-24 weeks of ART initiation or change.

PVL should be evaluated in the following situations (Panel on Antiretroviral Guidelines, 2006):

- Symptoms consistent with acute HIV infection to establish diagnosis when HIV antibody test is negative or indeterminate. Diagnosis of HIV infection by HIV RNA testing should be confirmed by ELISA and Western Blot performed 2-4 months after the initial negative or indeterminate test.
- Baseline evaluation of newly diagnosed HIV infection, use in conjunction with CD4+ T cell count to determine whether to initiate or defer therapy.
- For patients not on ART, every 3-4 months to assess changes in viral load; use in conjunction with CD4+ T cell count to help determine when to initiate ART.
- After initiation or change in ART, every 2-8 weeks for initial assessment of ART efficacy and to decide whether to continue or change therapy.
- After start of therapy, every 3-4 months to assess virologic effect of therapy and to decide whether to continue or change therapy.
- For patients on therapy, every 3-4 months to assess durability of ARV effect and to decide whether to continue or change therapy.
- In the case of a clinical event or a significant decline in CD4+ T cells, to determine association with a changing or stable viral load and decide whether to continue, initiate, or change therapy.

CD4+ T Cell Count

CD4+ T cells (also called T-4 cells, CD4+ T lymphocytes, and T helper cells) are a type of lymphocyte with CD4+ protein molecules on the cell surface. They are the cells most often infected by HIV.

The CD4+ T cell count is an indicator of the degree of immune system compromise. CD4+ T cell tests are reported as cells per cubic millimeter of blood (mm^3). Normal CD4+ T cell counts range from 500-1600/ mm^3 . A CD4+ T cell count below 200/ mm^3 meets the surveillance case definition for AIDS (CDC, 1992). Adequate viral suppression is reflected by an average increase in CD4+ T cells by 100 to 150 cells/ mm^3 per year, with an accelerated response in the first three months of treatment. With continued viral suppression, CD4+ T cells increase by approximately 100 cells/ mm^3 per year until a threshold is reached. It should be noted that because of fluctuations in CD4+ T cell values, blood should be drawn at the same time of day for each test and the same laboratory should be used in order to minimize variability. Other sources of variability are stress, fatigue, infections, and vaccinations. Because of the multiple sources of variation in the absolute CD4+ T cell count, treatment decisions should usually be based on two or more similar values. The CD4+ T cell percentage, which is more stable than CD4+ T cell count, can be also be evaluated. This is the percentage of total lymphocytes comprised of CD4+ T cells. The normal range is between 20% and 40%. A CD4+ T cell percentage below 14% is an indicator of AIDS (CDC, 1992).

The guidelines state that CD4+ T cell counts should be assessed when an individual first tests positive for HIV, and every 3-6 months thereafter to (1) determine when to initiate ART; (2) assess immunologic responses to ART; and (3) assess the need for initiating chemoprophylaxis for OIs. Treatment decisions usually should be based on two or more similar values (Panel on Antiretroviral Guidelines, 2006).

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SELF ASSESSMENT TEST

MODULE I: HUMAN IMMUNODEFICIENCY VIRUS AND ANTIRETROVIRAL THERAPY

DIRECTIONS: Please select the one best answer and circle your response directly on the self assessment test. To obtain Continuing Nursing Education credit, a minimum of 70% of the questions must be answered correctly. To assure your receipt of Continuing Nursing Education credit, please complete the self assessment test, program evaluation (reader information form) and HRSA participant information form (3 pages total).

This activity is eligible for nursing credit thorough June 30, 2007. Individuals who mail the required documentation noted above after this date will be ineligible for credit. The estimated time for completion of this activity is 1 hour. There is no fee for the nursing continuing education credit for this module.

Rutgers University mailing information is on the reverse side of this document.

- The proportion of those with HIV/AIDS in the United States diagnosed during 2004, in order of frequency from high to low is:
 - African American, White, Hispanic and Asian/Pacific Islander.
 - White, African American, Asian/Pacific Islander, Hispanic.
 - Hispanic, African American, White, Asian/Pacific Islander.
 - White, Hispanic, African American, Asian/Pacific Islander.
- Which of the statements is true about the human immunodeficiency virus (HIV)?
 - It is a retrovirus in the class rotavirus.
 - It has genes composed of deoxyribonucleic acid (DNA.)
 - It can reproduce on wet surfaces.
 - It destroys the infected cell when it replicates.
- The stages of the HIV replication cycle are:
 - binding and fusion; assembly, budding and maturation; reverse transcription and integration; and transcription and translation.
 - binding and fusion; reverse transcription and integration; transcription and translation; and assembly, budding and maturation.
 - assembly, budding and maturation; binding and fusion; reverse transcription and integration; and binding and fusion.
 - binding and fusion; assembly, budding and maturation; reverse transcription and integration; and transcription and translation.
- Protease inhibitors act by:
 - incorporating into cellular deoxyribonucleic acid (DNA).
 - inhibiting virus-cell fusion.
 - binding to reverse transcriptase.
 - blocking protease to inhibit viral protein cleavage.
- Nucleoside reverse transcriptase inhibitors (NRTIs) act by:
 - incorporating into cellular Deoxyribonucleic acid (DNA).
 - inhibiting virus-cell fusion.
 - blocking reverse transcriptase.
 - binding to protease to inhibit viral protein cleavage.
- New classes of antiretroviral drugs currently in clinical trials include:
 - gene therapies that inhibit development of HIV internal structures.
 - integrase inhibitors that prevent integration of viral DNA into the nucleus of the infected cell.
 - zinc finger inhibitors that prevent the virus from attaching to a cell.
 - attachment inhibitors that block viral genes.
- Antiretroviral therapy (ART) is recommended for:
 - all patients with CD4+ T cell counts >350 cells/mm³.
 - patients with CD4+ T cell counts >350 cells/mm³ and plasma HIV RNA $<100,000$ copies/ml.
 - all patients who are HIV positive.
 - asymptomatic patients with <200 CD4+ T cell counts.
- Which of these statements is accurate about viral load testing?
 - It can detect the presence of HIV a few days after infection.
 - It cannot detect the presence of HIV for the first 6 weeks after infection.
 - It is not affected by acute or chronic illness.
 - It should be started 12 months after initiation of ART.
- Which of these statements about CD4+ cells is true?
 - They can be used to test for the presence of HIV infection.
 - They are also called CD4+ T cells, T-4 cells, CD4+ lymphocytes or helper cells.
 - They normally range from 200-500 cells /mm³.
 - They decrease when viral suppression results from antiretroviral treatment.
- When an individual first tests positive for HIV the CD4+ counts should be assessed to determine:
 - if treatment for ART should be discontinued.
 - the need for ELISA or Western Blot testing.
 - the need to initiate chemoprophylaxis for opportunistic infections.
 - if the treatment needs to be changed.

PROGRAM EVALUATION & READER INFORMATION FORM

MODULE I: HUMAN IMMUNODEFICIENCY VIRUS AND ANTIRETROVIRAL THERAPY

To assure your receipt of Continuing Nursing Education credit, please mail your completed self assessment test, program evaluation/reader information form and HRSA participant information form (3 pages total) to: Dr Gayle A Pearson, Assistant Dean, Rutgers, The State University, College of Nursing, Center for Professional Development, 175 University Avenue, Conklin Hall 244, Newark, New Jersey 07102 or scan and email to: cpdn@rutgers.edu. Please allow 6 to 8 weeks for education credit processing. An attendance certificate will be emailed to you at that time. If you have any questions, contact 973-353-5895 or cpdn@rutgers.edu.

| PLEASE COMPLETE THIS FORM BY COMPLETELY FILLING IN THE CIRCLES WITH BLACK PEN OR PENCIL. | STRONGLY DISAGREE | DISAGREE | AGREE | STRONGLY AGREE | NOT APPLICABLE |
|--|----------------------|----------|-------|-------------------|-------------------|
| 1. As a result of completing the program, I am able to meet the following program goal: to equip the correctional nurse to arrange the necessary care and services to optimize the health of the HIV-infected patient. | ① | ② | ③ | ④ | ⑤ |
| 2. As a result of reading this module, I am able to accurately discuss the human immunodeficiency virus and recommended antiretroviral therapies. | ① | ② | ③ | ④ | ⑤ |
| 3. The objective of this program was relevant to the overall goals of the program. | ① | ② | ③ | ④ | ⑤ |
| 4. The module was an effective learning tool for me. | ① | ② | ③ | ④ | ⑤ |
| 5. The author of this module was an effective teacher. | ① | ② | ③ | ④ | ⑤ |
| 6. The slides that accompany the module are helpful. | ① | ② | ③ | ④ | ⑤ |

Time required to complete this learning activity: _____ minutes

Comments: _____

READER INFORMATION FORM

(Please print legibly as all information is needed for education credit processing.)

Name: (first and last): _____

Degree: _____ (NP, RN, LPN) Other: _____

Facility Name: _____

Facility Address: _____ Street _____

City _____ State _____ Zip Code _____

Email Address: _____

Please proceed to the next page and complete the HRSA participant information form.

Please completely fill in the circles (●) when answering the questions.

1. To create your unique ID number, use the month of your birth, the day of your birth, and the last four digits of your social security number. For example, May 29, 123-45-6789 has the ID number 05296789. Unique ID Number

Today's Date

2. Your Profession/Discipline (Select one)
Advanced Practice Nurse
Dentist
Mental Health Professional
Nurse
Nurse Practitioner
Other Dental Professional
Pharmacist
Physician
Physician Assistant
Social Worker
Substance Abuse Professional
Other (specify)

3. Your Primary Functional Role (Select one)
Administrator/Supervisor
Care Provider/Clinician
Case Manager
Intern/Resident
Researcher
Student/Graduate Student
Teacher/Faculty
Other (specify)
Not Working

4. Your Principal Employment Setting (Select one)
Community/Migrant Health Center
Community Mental Health Center
Correctional Facility
HMO/Managed Care Organization
Hospital or Hospital-Based Clinic
Rural Health Center
Solo/Group Private Practice
State/Local Health Department
Substance Abuse Treatment Prog.
STD/Family Planning Clinic
Tribal/Indian Health Service
Other Community-Based Service Organization (CBO)
Other Public Health Agency
Other Health Care
Non-health
Not Working

Questions 5-7 are about your principal employment setting

5. Is it a faith-based organization? Yes No Don't Know

6. Zip Code/Setting Rural Urban

7. Does the agency receive Ryan White CARE Act funding? Yes No Don't Know

7a. If you don't know, write the full name of your employer:

8. Are you of Hispanic, Latino, or Spanish origin? Yes No

8a. Your Racial Background (Select all that apply)
White
Black or African American
Asian
Native Hawaiian/Other Pacific Islander
American Indian/Alaska Native

9. Your Gender Female Male Transgender

10. Which of the following statements describes the way in which you most often provide services for HIV/AIDS patients (Select one)
Not applicable/Do not see patients
Refer/transfer HIV+ patients for all medical care
Provide primary care and refer/transfer HIV+ patients for HIV treatment only
Provide all HIV treatment and refer/transfer for primary care
Provide all medical care and refer/transfer when antiretroviral treatment fails
Provide all medical care throughout the course of the disease

11. Estimate the NUMBER of HIV+ clients/patients you have personally treated/managed in practice in the past month. Don't Know

For questions 12-18, estimate the PERCENTAGE of your HIV+ clients/patients in the past YEAR who were:

12. Racial or Ethnic Minorities
None 1-24% 25-49% 50-74% ≥75% Don't Know

13. On Antiretroviral Therapy
None 1-24% 25-49% 50-74% ≥75% Don't Know

14. Severely/Persistently Mentally Ill
None 1-24% 25-49% 50-74% ≥75% Don't Know

15. Substance Users
None 1-24% 25-49% 50-74% ≥75% Don't Know

16. Uninsured
None 1-24% 25-49% 50-74% ≥75% Don't Know

17. Women
None 1-24% 25-49% 50-74% ≥75% Don't Know

18. Incarcerated/Parolees
None 1-24% 25-49% 50-74% ≥75% Don't Know

PUBLIC BURDEN STATEMENT: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number. The OMB control number for this project is 0915-0281. Public reporting burden for this collection of information is estimated to be 10 minutes per form. These estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

For Office Use Only May 2004 AETC Subsite Program Number Agency RWCA Yes No Don't Know 22971