Welcome to the HIV Clinic rotation. We would like to thank you for signing up for the rotation and your willingness to come for an evening session on Wednesdays. It is our intention that you learn about HIV infection, an approach to patients with the disease and an understanding of both the principles of antiretroviral therapy. You will also learn about treatment and prevention of opportunistic infections in these patients, immunizations and how to counsel patients regarding lifestyle recommendations to maximize patient health and prevent transmission. Much of what you learn will deal with taking care of HIV infected patients but some of the information is applicable to your own clinics.
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Learning Objectives:

1. Perform an HIV focused History and Physical examination.
2. Review the recommendations for HIV testing current recom-
   mended testing algorithms.
3. Understand the baseline testing procedures done on new pa-
   tients: CD4 count, HIV quantitative RNA level, HIV genotype, CMP,
   CBC, RPR, GC/chlamydia, Quantiferon gold, Hepatitis A, B and C
   marker testing, Toxoplasmosis IgG titer.
4. Review the immunizations given to HIV positive persons, why
   and how often they are given
5. Perform counseling regarding prevention of transmission of HIV
   with HIV positive patient
6. Know the principles of antiretroviral therapy
7. Review interpretation of genotype results and understand how
   information is used in formulating treatment regimen
8. Review the classes of antiretroviral medications and the mecha-
   nisms of action
9. Know the preferred starting regimens in treatment naïve pa-
   tients with no mutations
**HIV Testing:**

The current recommendation is that all persons between ages 13-64 should undergo HIV testing as a part of routine health care. Persons at higher risk of HIV (gay men with multiple partners since last test, heterosexual persons with multiple partners since last test, injection drug users and their sex partners, six partners of HIV-infected persons and persons who exchange sex for money or drugs) should be screened annually.

The current 4th generation HIV test measures both P-24 antigen and antibody to HIV. In brief, testing begins with a combination immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen. All specimens reactive on this initial assay undergo supplemental testing with an immunoassay that differentiates HIV-1 from HIV-2 antibodies. Specimens that are reactive on the initial immunoassay and nonreactive or indeterminate on the antibody differentiation assay would then be tested with HIV-1 nucleic acid testing to determine the presence of HIV infection.

**Background HIV Information:**

After infection there a burst of prolific viral replication resulting in very high levels of HIV in the blood which is maintained until the immune response develops. With the immune response the viral load drops to a “set point” which ranges from undetectable (elite nonprogressors) to high levels. During the acute phase, many patients develop symptoms of the acute retroviral syndrome, a mononucleosis-like illness which may be associated with neurologic manifestations including aseptic meningitis or radiculitis. The acute retroviral syndrome typically resolves over weeks. The acute period is followed by a long period of clinical latency during which most patients are asymptomatic. However, during that time viral replication is proceeding which is associated with systemic inflammation and potentially deleterious effects including accelerated vascular disease and possibly development of non HIV-associated malignancies. During the period of clinical latency the CD4+ lymphocyte population gradually declines. When it reaches a certain point, around 200 cells per mm$^3$, the immune system is inadequate and opportunistic infections develop.

**Background HIV Information Continued:**

Drugs which target HIV receptors or enzymes important for viral replication have been developed and are now used to control viral replication. HIV replication is error-prone with mutations occurring at a rate of 1 in $10^3$ replications. Thus therapy with one drug invariably leads to the emergence of resistant clones which can be prevented by the use of multiple drugs.

**Approach to Patient newly diagnosed with HIV:**

At the initial encounter with a newly diagnosed person, it is critical to educate the patient about what HIV is and what it does, review how it is transmitted and how to alter a person’s lifestyle to prevent transmission. Since it is sexually transmitted, ideally patients should refrain from sex. Short of that monogamous relationships are strongly encouraged. Barrier contraception with condoms must be used with all encounters. Certain practices, particularly anal receptive intercourse, have been shown to carry the highest risk of transmission, so patients should be informed about that as well. Use of enhancers, particularly crystal meth but also Doctor Poppers may increase the likelihood of multiple partner or anonymous sex and should also be discouraged. Patients should be informed about other sexually transmitted infections and that many of them including gonorrhea, chlamydia, syphilis, herpes, and vaginitis have
Approach to Patient Newly Diagnosed with HIV (Continued:)

been shown to increase the likelihood that HIV will be transmitted. Finally, injection drug users should be cautioned never to share needles and to use clean needles and take advantage of needle exchange programs. Heterosexual couples or women can be counseled that it is possible to have children with very low risk of infection, but we at Loyola might refer couples to specialized centers where special practices reducing risk even further are available. Baseline testing is performed on all patients at the initial encounter and includes the following:

- CD4+ cell count (order CD4a in epic)
- HIV viral load (HIVRT)
- HIV genotype (HIV genotyping) – a resistance test identifying mutations in the RT and protease genes
- RPR
- Toxoplasmosis IgG titer (identifies patients at risk for toxoplasmosis if they develop AIDS and present with neurological findings)
- GC/chlamydia nucleic acid test. Urine if urethral or cervical exposure but must sample pharynx or anus if exposed.
- Quantiferon gold
- Either anti HBs or anti HBC – identifies either persons with chronic hepatitis B, resolved hepatitis B or candidates for Hepatitis B vaccine
- Anti HBC
- CBC and diff
- CMP
- Urinalysis

Vaccines Routinely Provided to all HIV Positive Patients:

Pneumococcal vaccine both Prevnar 13 and Pneumococcal polysaccharide vaccine. Start with ...

Hepatitis B vaccine. 3 dose series using the 40 mcg dialysis product in patients who are anti HBs and HBsAg negative

Influenza vaccine seasonally

Hepatitis A vaccine at least in all patients with chronic hepatitis B or chronic Hepatitis C.

Meningococcal Vaccine (to gay men with multiple partners during the current outbreak)

OI Prevention

Antimicrobials are used to prevent as well as treat opportunistic infections. Prevention is secondary in order to prevent relapse, if the patient has had the infection and primary for patients at high risk for developing the infection. Risk is determined by the CD4 count.

<table>
<thead>
<tr>
<th>Opportunistic Infection Prophylaxis in HIV infected Patients</th>
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</thead>
<tbody>
<tr>
<td>Opportunistic Infection</td>
</tr>
<tr>
<td>--------------------------</td>
</tr>
<tr>
<td>Pneumocystis carinii pneumonia</td>
</tr>
<tr>
<td>Toxoplasma gondii</td>
</tr>
<tr>
<td>Mycobacterium avium coples</td>
</tr>
</tbody>
</table>

Antiretroviral Therapy

All patients with HIV should be on antiretroviral therapy. The goal of antiretroviral therapy is to reduce viral levels in the plasma (viral load) to undetectable levels and to restore immune function. HIV transcription is error-prone and mutations occur at a rate of $1 \times 10^3$ replications. Therefore the population of HIV virus in a given patient will include virions that have mutations rendering them resistance to HIV medications. Therapy with one antiretroviral drug will select for the resistant virus which will then replace the wild type virus and emerge as the dominant population. However, the likelihood that a virus with multiple mutations to three drugs is extremely low explaining why multidrug therapy is effective. Advances in antiretroviral therapy have been remarkable and rapid. Initially the drugs targeted the viral polymerase (reverse transcriptase) and were closely related to drugs currently in use for cancer chemotherapy. (See Figure on the HIV life cycle)
Antiretroviral Therapy Continued

The first were analogues of nucleoside bases which were used singly and invariably resulted in selection of resistant virus and failures. With the ability to clone the genes and model the folded enzymes, scientists were able to design drugs that would fit into the target site of the enzyme target. All the protease inhibitors were developed using that technology. There is one fusion inhibitor, T-20 or Env which was designed to mimic the structure of the GP-41 receptor for HIV. The currently available entry inhibitors block the CCR5 co-receptor and are thus effective in patients who are infected with virus that uses the CCR5 co-receptor but not CXCR4 (Before using that drug called maraviroc we test the patient’s virus to determine which coreceptor is used). The most recently available drugs target the viral integrase enzyme that promotes integration of proviral DNA into the host chromosome.

Nucleos(t)ide Reverse Transcriptase Inhibitors:

The initially used agents, zidovudine, stavudine (thymidine analogues [TAMs]) and didanosine are used much less frequently due to having more side effects (lipodystrophy, lactic acidosis, pancreatitis, neuropathy) than the newer agents tenofovir and abacavir. Nephrotoxicity from tenofovir is increasingly appreciated such that renal function is routinely monitored. Abacavir is associated with a potentially fatal hypersensitivity syndrome characterized by fever, rash, sometimes respiratory and GI symptoms. Risk if hypersensitivity syndrome is much greater in persons who are HLA-B5701 positive, hence we screen all patients for this gene before prescribing abacavir. The other commonly used nucleosides, lamivudine (3TC) and emtricitabine (FTC) have almost no side effects and are widely used in combination with other nucleosid(t)es.

Resistance to the NRTIs commonly occurs. A single mutation M184V is frequently selected and confers resistance to both 3TC and FTC, but its presence renders the virus more susceptible to AZT or tenofovir so we may continue the drugs to maintain the hypersusceptible phenotype. Resistance to the thymidine analogues usually requires more than one mutation; these mutations are called thymidine analogue mutations (TAMs). Resistance to abacavir and tenofovir is not as easily selected but one mutation may confer resistance.

Protease inhibitors when used alone have unforgiving pharmacodynamics. Initially they were dose multiple times daily and had to be taken on the clock. When it was determined that blood levels of most of the drugs could be increased and prolonged by adding ritonavir, a drug that blocks CYP 3A4 preventing the metabolism of the companion drug, all protease inhibitors are “boosted” with a low dose of ritonavir. Recently another CYP 3A4 blocker with no antiretroviral activity, cobicistat, has been available and is marked co-formulated with either atazanavir or darunavir. In general the protease inhibitors have a high barrier to resistance and multiple mutations are required.
Nucleoside Reverse Transcriptase Inhibitors
- Zidovudine (Retrovir®) or AZT
- Didanosine (Videx®) or DDI
- Stavudine (Zerit®) or D4T
- Abacavir (Ziagen)
- Tenofovir (Viread)

Nonnucleoside Reverse Transcriptase Inhibitors
- Nevirapine (Viramune)
- Efavirenz (Sustiva)
- Etravirine (Intellence)
- Rilpivirine (Edurant)

Protease Inhibitors (all but nelfinavir are used with a boosting agent – ritonavir or cobicistat)
- Atazanavir
- Darunavir
- Lopinavir/ritonavir
- Fosamprenavir
- Tipranavir
- Nelfinavir

Fusion Inhibitors
- Enfuvertide (injectable only)

Entry Inhibitors
- Maraviroc

Integrase Inhibitors
- Raltegravir
- Elvitegravir
- Dolutegravir

Coformulated Antiretroviral Agents
- Combivir – AZT and 3TC
- Truvada – Tenofovir and FTC
- Epzicom – Abacavir and 3TC
- Atripla – Tenofovir, FTC and efavirenz (one pill, once daily)
- Complera – Tenofovir, FTC and rilpivirine (one pill, once daily)
- Stribild – Tenofovir, FTC, elvitegravir and cobicistat (one pill, once daily)
- Triumeq – Abacavir, 3TC and dolutegravir (one pill, once daily)
- Kaletra – lopinavir, ritonavir
- Evotaz – Atazanavir, cobicistat
- Prezcomix – Darunavir, cobicistat

Entry Inhibitors:
Maraviroc is the only drug in this class. It blocks the CCR5 co-receptor and can only be used in patients whose HIV uses the CCR5 co-receptor only. Thus a co-receptor assay must be done on patients before the drug is prescribed. The drug is well tolerated and little is known about resistance.

Integrase Inhibitors:
These are very potent drugs that are well tolerated and very effective. Raltegravir was the first released. It is dosed twice daily and has a low barrier to resistance. Elvitegravir is available only coformulated with tenofovir, FTC and cobicistat. The latter extends the duration of effective levels of elvitegravir such that once daily dosing is possible. Dolutegravir is the most recently released of the group. It is dosed once daily and has a higher barrier to resistance. It is effective against virus that is resistant to raltegravir.
The following regimens are recommended for initiating therapy. The tables are copied from the most recent addition of Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents.

**Recommended Regimen Options**
(Drug classes and regimens within each class are arranged in alphabetical order.)

**INSTI-Based Regimens:**
- D70/ABC/3TC*—only for patients who are HLA-B*5701 negative (AI)
- D70 plus TDF/FTC* (AI)
- EVG/TDF/FTC—only for patients with pre-treatment estimated CCl 470 mL/min (AI)
- RAL plus TDF/FTC* (AI)

**PI-Based Regimens:**
- DRV/r plus TDF/FTC* (AI)

**Alternative Regimen Options**
(Drug classes and regimens within each class are arranged in alphabetical order.)

Regimens that are effective and tolerable, but that have potential disadvantages when compared with the recommended regimens listed above, have limitations for use in certain patient populations, or have less supporting data from randomized clinical trials. An alternative regimen may be the preferred regimen for some patients.

**NNRTI-Based Regimens:**
- EFV/TDF/FTC* (BI)
- RPV/TDF/FTC—only for patients with pre-treatment HIV RNA <100,000 copies/mL and CD4 cell count >200 cells/mm3 (BI)

**PI-Based Regimens:**
- ATV/r plus TDF/FTC*—only for patients with pre-treatment estimated CCl 470 mL/min (BI)
- ATV/r plus TDF (BI)
- DRV/r or DRV plus ABC/3TC*—only for patients who are HLA-B*5701 negative (Bill for DRV/r and Bill for DRV/r)
- DRV/r plus TDF/FTC—only for patients with pre-treatment estimated CCl 470 mL/min (BI)

Table 6. Recommended, Alternative, and Other Antiretroviral Regimen Options for Treatment-Naive Patients (page 2 of 2)

**Factors to Consider When Selecting an Initial Regimen**
When selecting a regimen for an individual patient, a number of patient and regimen specific characteristics should be considered, with the goal of providing a potent, safe, tolerable, and easy to adhere to regimen for the patient in order to achieve sustained virologic control. Some of the factors can be grouped into the following categories:

**Initial Characteristics of the Patient:**
- Pre-treatment HIV RNA level (viral load)
- Pre-treatment CD4 cell count
- HIV genotypic drug resistance testing results
- HLA-B*5701 status
- Patient preferences
- Patient’s anticipated adherence

**Specific Comorbidities or Other Conditions:**
- Cardiovascular disease, hyperlipidemia, renal disease, osteoporosis, psychiatric illness, neurologic disease, drug abuse or dependency requiring narcotic replacement therapy
- Pregnancy or pregnancy potential. Clinicians should refer to the latest Perinatal Guidelines for more detailed recommendations on the safety and effectiveness of ARV drugs during pregnancy.
- Coinfections: hepatitis C (HCV), hepatitis B (HBV), tuberculosis (TB)

**Regimen-Specific Considerations:**
- Regimen’s genetic barrier to resistance
- Potential adverse drug effects
- Known or potential drug interactions with other medications
- Convenience (e.g., pill burden, dosing frequency, availability of fixed-dose combination products, food requirements)
- Cost (see Cost Consideration and Antiretroviral Therapy section)
Follow up of Patients:

Frequency of follow up for patients with HIV infection is dependent on a number of factors including how long the patient has been in care, how adherent they are to lifestyle and treatment regimens and whether or not the infection is controlled. Patients who are not on therapy (presumably because they have chosen not to start) should be seen every three months. After initiation of therapy or a change in the antiretroviral regimen, patients should be seen four weeks after starting or initiating the change. Once the viral load testing indicates the patient is responding, three month follow up is recommended and that schedule should be continued for the first two years. After two years of ART with consistently suppressed viral load and CD4 count consistently above 300, frequency can be extended to every six months. However if the viral load remains detectable (above 200) patients should be seen every three months or more often as clinically necessary. Any change in clinical status, e.g., new HIV symptom, initiation of IFN or systemic corticosteroid therapy or antineoplastic therapy) should prompt return to the every three months schedule.

At each follow up visit, patients are queried about new symptoms or new health events, sexual, alcohol and drug use activity, adherence to ART, signs of depression. Physical examination is repeated. There may be opportunity for consultation with the dietician or the Clinical Pharmacist. Patients on ADAP should be reminded of the need to reapply every six months. In addition laboratory follow up according to the following schedule is done.

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4</td>
<td>Every 3-6 months during first 2 years of ART of if viremic or CD4 &lt;300. Every 12 months if consistently over 300 for 2 years. Optional if consistently over 500 and VL controlled</td>
</tr>
<tr>
<td>HIV Viral Load</td>
<td>Every 3 months. Extend to every 6 months if VL consistently suppressed and stable immunologic status for more than 2 years.</td>
</tr>
<tr>
<td>Resistance Test</td>
<td>At time of treatment failure</td>
</tr>
<tr>
<td>CMP</td>
<td>Every 3-6 months (for renal and hepatic toxicity). Consider phosphorous in patients on tenofovir</td>
</tr>
<tr>
<td>Lipid Profile</td>
<td>Annually if normal. 4-8 weeks after starting ART that affects lipids. Every six months if abnormal.</td>
</tr>
<tr>
<td>Glucose or A1C</td>
<td>Annually if normal, every 306 months if abnormal</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>Annually if normal, every six months if abnormal at last measurement.</td>
</tr>
<tr>
<td>Pregnancy test</td>
<td>Woman with childbearing potential</td>
</tr>
<tr>
<td>RPR</td>
<td>Annually or every 3-6 months if positive or following treatment</td>
</tr>
<tr>
<td>Quantiferon gold</td>
<td>Annually</td>
</tr>
<tr>
<td>GC/chlamydia</td>
<td>Annually or more often if exposed to multiple partners. Must sample pharynx or anus if exposed; if only genital exposure, urine adequate.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevnar-13</td>
<td>First visit</td>
</tr>
<tr>
<td>Pneumococcal polysaccharide vaccine</td>
<td>At least one month after Prevnar-13. Repeat in five years.</td>
</tr>
<tr>
<td>Influenza Vaccine</td>
<td>Annually</td>
</tr>
<tr>
<td>Hepatitis B Vaccine</td>
<td>If anti HBs negative and no evidence of chronic Hepatitis B. Use three dose regimen of 40 mcg preparation</td>
</tr>
<tr>
<td>Hepatitis A Vaccine</td>
<td>Anyone with chronic hepatitis B or C or other chronic liver disease including NASH</td>
</tr>
<tr>
<td>Meningococcal Vaccine</td>
<td>In event of ongoing outbreak as recommended by Public Health</td>
</tr>
</tbody>
</table>

We are currently not using Zoster vaccine.
Table 16. Monthly Average Wholesale Price* of Antiretroviral Drugs (Last updated April 8, 2015; last reviewed April 8, 2015) (page 3 of 4)

<table>
<thead>
<tr>
<th>ARV Drug (Generic and Brand Names)</th>
<th>Strength</th>
<th>Dosing</th>
<th>Tablets/Capsules/mLs per Month</th>
<th>AWP (Monthly)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease Inhibitors (PIs), continued</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fosamprenavir</td>
<td>700 mg tab</td>
<td>2 tabs twice daily</td>
<td>120 tabs</td>
<td>$2,408.86</td>
</tr>
<tr>
<td>Lexiva</td>
<td>700 mg tab</td>
<td>1 tab twice daily or 2 tabs once daily</td>
<td>60 tabs</td>
<td>$1,204.43</td>
</tr>
<tr>
<td>Lopinavir/Ritonavir</td>
<td>200 mg/50 mg tab</td>
<td>2 tabs twice daily or 4 tabs once daily</td>
<td>120 tabs</td>
<td>$977.22</td>
</tr>
<tr>
<td>Kaletra</td>
<td>80 mg/200 mg per mL soln</td>
<td>5 mL twice daily</td>
<td>300 mL</td>
<td>$918.13</td>
</tr>
<tr>
<td>Nelfinavir</td>
<td>625 mg tab</td>
<td>2 tabs twice daily</td>
<td>120 tabs</td>
<td>$1,169.22</td>
</tr>
<tr>
<td>Saquinavir</td>
<td>500 mg tab³</td>
<td>2 tabs twice daily</td>
<td>120 tabs</td>
<td>$1,260.01</td>
</tr>
<tr>
<td>Tipranavir</td>
<td>250 mg cap³</td>
<td>2 caps twice daily</td>
<td>120 caps</td>
<td>$1,596.18</td>
</tr>
<tr>
<td>Integrase Strand Transfer Inhibitors (INSTIs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dolutegravir</td>
<td>50 mg tab</td>
<td>1 tab once daily</td>
<td>30 tabs</td>
<td>$1,581.68</td>
</tr>
<tr>
<td>Evitegravir</td>
<td>85 mg tab</td>
<td>1 tab twice daily</td>
<td>60 tabs</td>
<td>$3,163.36</td>
</tr>
<tr>
<td>Raltitgravir</td>
<td>150 mg tab</td>
<td>1 tab daily</td>
<td>30 tabs</td>
<td>$1,352.05</td>
</tr>
<tr>
<td>Fusidin</td>
<td>400 mg tab</td>
<td>1 tab twice daily</td>
<td>60 tabs</td>
<td>$1,445.34</td>
</tr>
<tr>
<td>Fusion Inhibitor</td>
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<tr>
<td>Emtricitabine</td>
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<tr>
<td>Tenofovir</td>
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<tr>
<td>TDF</td>
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<td></td>
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<tr>
<td>Tenofovir</td>
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<tr>
<td>TDF</td>
<td></td>
<td></td>
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<tr>
<td>Co-Formulated Combination Products as Single Tablet Regimens</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Dolutegravir/Abacavir, Lamivudine</td>
<td>250/300/300 mg tab</td>
<td>1 tab daily</td>
<td>30 tabs</td>
<td>$2,648.84</td>
</tr>
<tr>
<td>Darunavir/Tenofovir/Fosamprenavir</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atazanavir</td>
<td>600/300/300 mg tab</td>
<td>1 tab daily</td>
<td>30 tabs</td>
<td>$2,551.99</td>
</tr>
<tr>
<td>Elvitegravir/Cobicistat/Tenofovir</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dolutegravir/Abacavir, Lamivudine</td>
<td>250/300/300 mg tab</td>
<td>1 tab daily</td>
<td>30 tabs</td>
<td>$2,948.70</td>
</tr>
</tbody>
</table>

Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

K-21
Reading List

**Essential:**
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents

**Suggested:**
*Excellent review article:*
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60164-1/abstract

*Review of resistance mechanisms:

*Online resistance mutation database with tool to plan therapy based on pattern of mutations:
Stanford University HIV Drug Resistance Database
http://hivdb.stanford.edu/

*Handbook serves as quick reference for HIV infection and HIV-associated opportunistic infections:*

*Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection:*