Initial Evaluation

This is a PDF version of the following document:
Section 2: Basic HIV Primary Care
Topic 1: Initial Evaluation

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Introduction

Background

Untreated HIV infection causes significant disease, beginning with an acute, self-limited viral syndrome and ultimately progressing to acquired immunodeficiency syndrome (AIDS), with the time between initial HIV infection and AIDS varying widely from a few months to longer than 10 years (Figure 1). Early diagnosis, linkage to care, antiretroviral therapy, and retention in care all play an important role in preserving the health of individuals with HIV as well as preventing forward transmission of HIV to others. The initial medical visit for a person newly diagnosed with HIV infection provides an important opportunity for a positive interaction and reinforcement for engagement in care. A similar evaluation can also occur at the time of transfer of care or with reengagement into care after a prolonged absence. At any of these initial encounters, the interaction between the individual with HIV and the medical provider may influence the patient’s likelihood of returning for further medical care.

Goals of Initial Evaluation

The multiple goals of the initial evaluation as outlined in the Adult and Adolescent ARV Guidelines Baseline Evaluation section are to confirm the presence of HIV infection, obtain a complete medical history and perform a comprehensive physical examination, obtain appropriate baseline and historical laboratory data, assess the patient’s understanding about HIV infection and transmission of HIV to others, and initiate medical care as recommended in the HIVMA Primary Care Guidelines.[3,4] In addition, it is important to establish a positive relationship with the patient at this initial encounter. Furthermore, HIV can have a significant psychosocial impact on the individual with HIV, as well as on his or her partner, family, and community. Thus, from the first medical encounter onward, the clinical care for persons with HIV must be culturally sensitive and nonjudgmental, patient-centered, and multidisciplinary. This review will explore the initial evaluation and monitoring of persons who are newly diagnosed with HIV infection.
Overview of HIV Surveillance Case Definition

The Centers for Disease Control and Prevention (CDC) HIV/AIDS case definition and classification systems were developed for surveillance purposes and are not intended for clinical purposes. Nevertheless, clinicians frequently refer to these classification systems when describing persons with HIV as a quick reference to the individual's clinical and immune status. In addition, these classification systems are often referred to for the purposes of social security and disability applications, programs for medication benefits, and eligibility for housing benefits. The CDC established the first HIV surveillance case definition in 1982, with major revisions in 1987, 1993, 2008, and most recently in 2014. The previously used letters (A, B, C) in the 1993 classification, which represented clinical criteria, were replaced in the 2008 case definition by a 4-stage system based on CD4 count (or percentage) and the presence or absence of AIDS-defining conditions. The staging system was again updated in the 2014 surveillance case definition and consists of a 5-stage system (0, 1, 2, 3, or unknown).

Laboratory Criteria for HIV Diagnosis

Laboratory criteria to meet the 2014 case definition for HIV include (1) a positive HIV antibody or combination antibody/antigen test, and an accompanying or subsequent positive result from a supplemental HIV test different from the initial test, or (2) a positive result of a multitest HIV antibody algorithm from which only the final result was reported, or (3) a positive result or report of a detectable quantity from any of the following HIV virologic (i.e. non-antibody) tests: qualitative HIV nucleic acid amplification testing (DNA or RNA), quantitative HIV RNA level (viral load assay), HIV-1 p24 antigen test, HIV isolation (viral culture), or HIV nucleotide sequence (genotype) (Figure 2). Obtaining a CD4 cell count as a surrogate marker to indicate HIV infection and the degree of immunosuppression is not recommended since CD4 counts can markedly decline without HIV infection in the setting of acute illness, bone marrow suppression, or chronic hepatitis C infection.

Staging

The initial evaluation of a person diagnosed with HIV is an important time to determine the stage, or status, of the HIV disease. In the most recent 2014 case definition, a 5-stage system (0, 1, 2, 3, or unknown) is used (Figure 3). Stage 0 indicates early HIV infection, inferred from a negative or indeterminate HIV test result within 6 months of a confirmed positive result. Stage 1 is defined by CD4 count equal to or greater than 500 cells/mm³, or percentage equal to or greater than 26%, without the presence of an AIDS-defining clinical condition. Stage 2 is defined by CD4 count equal to or greater than 200 cells/mm³ and less than 500 cells/mm³, or a percentage between 14 and 25%, without an AIDS-defining clinical condition. Stage 3 is defined by a CD4 count less than 200 cells/mm³, or a percentage less than 14%, or the presence of an AIDS-defining illness. The absolute CD4 count takes precedence over the CD4 percentage, and the percentage is only considered if the corresponding CD4 count is unknown; this change was made because clinical evidence suggests the CD4 percentage has little effect on the prognosis and may actually overestimate the clinical stage. Stage unknown refers to a person with laboratory confirmation of HIV infection, but no information about CD4 cell count or percentage (and no information about the presence of AIDS-defining clinical conditions).

Changes in Stage

In previous case definitions, a patient’s stage of HIV infection was based on the most advanced stage ever experienced, or the “life-time stage”. Once a patient progressed to a more advanced stage, a patient’s stage would not revert to any earlier stage. The updated 2014 staging system is more flexible, allowing for a patient’s status to change in either direction after diagnosis; this is helpful in describing a patient’s “real-time stage”, or the status of HIV disease in the present moment. Admittedly, this new staging system is somewhat
vague and it remains unclear how clinicians will utilize this more flexible component of staging for surveillance purposes.

**Clinical Criteria for HIV Diagnosis**

According to the 2014 case definition, clinical criteria for a confirmed case is met when there is a note in a medical record by a physician or other qualified medical provider that states that the person has HIV infection, followed by either laboratory criteria meeting the case definition, presumptive evidence of HIV infection (i.e. receipt of HIV antiretroviral therapy or prophylaxis for an opportunistic infection), an otherwise unexplained low CD4 count, or an otherwise unexplained diagnosis of an opportunistic illness.

**AIDS-Defining Clinical Conditions**

In persons with laboratory-confirmed HIV infection, stage 3 (AIDS) is defined based on laboratory criteria (CD4 cell count) or clinical conditions. The list of AIDS-defining clinical conditions is extensive (Figure 4).[6]
Initial Assessment: History Taking

The initial evaluation and the focus of the first visit should take into account whether the client is newly diagnosed with HIV or has established HIV and is new to the clinic. Further, in some instances, the client may have active HIV-related issues that need to be immediately addressed and these issues may take priority and dominate the first visit. In general, while obtaining the initial history, the clinician should obtain information from the client in an open, nonjudgmental manner. The initial encounter forms the basis of the client-provider relationship and should be informed by a patient-centered, multidisciplinary approach. Risk reduction counseling can often be introduced during the discussion of sexual history, the patient’s support network can be assessed, and the patient’s readiness for antiretroviral therapy (or adherence to antiretroviral therapy if already initiated) can be evaluated. The HIVMA Primary Care Guidelines provide detailed guidance for the elements to include in a comprehensive patient history at the initial visit, and the key points are summarized below:[3]

- Date of diagnosis of HIV infection and, if known, the approximate date of initial HIV infection
- Identified risk factors related to HIV acquisition
- Prior HIV-associated complications and comorbidities, including opportunistic infections, malignancies, and other HIV-related conditions
- Past medical history, including chronic medical conditions
- Past surgical history
- Psychiatric history, especially any history of depression, bipolar disorder, posttraumatic stress disorder, and domestic violence
- Residence and travel history (to determine if patient has lived in or traveled to regions endemic for certain diseases, such as histoplasmosis or coccidioidomycosis)
- Medication history (including historical antiretroviral therapy past to present, over-the-counter drugs, pain medications, and dietary or herbal supplements)
- Allergies and intolerances to medications, including hypersensitivity reactions to antibiotics and antiretroviral medications
- Social history (assess for high-risk behaviors, tobacco, alcohol and illicit drug use), sexual history, including sexual practices (including all exposure sites, condom and contraceptive use), HIV status of their partners, and whether they have disclosed their HIV infection to their partners
- Social support, coping strategies (including how a patient is dealing with a new HIV diagnosis or established HIV infection), employment status and history, financial status, housing, marital status, and desires related to family planning/reproduction
- Family history
- Comprehensive medical review of symptoms
Initial Evaluation: Physical Examination

A complete physical examination should be performed at the initial encounter, with particular attention given to the oral, integumentary, and lymph node examinations. The key components of the physical examination as outlined in the HIVMA Primary Care Guidelines include:[3]

- **Vital signs and General Appearance:** including height and weight, evidence of obesity, wasting, or lipodystrophy
- **Skin:** rashes, bruising, inflammatory dermatoses, cutaneous lesions, and cutaneous manifestations of systemic disease (e.g. spider angiomata, caput medusa suggestive of liver disease)
- **Lymph nodes:** generalized or localized lymphadenopathy (cervical, axillary, inguinal)
- **Eye:** retinal exudates or cotton wool spots, hemorrhages, pallor, icterus
- **Oropharynx:** abnormalities of dentition, gingiva, or mucosa including ulcers, candidiasis, and oral hairy leukoplakia
- **Cardiovascular:** peripheral pulses, auscultation, and presence/absence of edema
- **Chest:** auscultation for breath sounds, airway movement, and wheezing
- **Breast:** nodules, nipple discharge
- **Abdomen:** masses, tenderness, hepatosplenomegaly
- **Genitourinary:** ulcers, warts, discharge, and appearance of cervix on gynecologic examination
- **Anorectal:** ulcers, warts, fissures, hemorrhoids, masses
- **Neuropsychiatric:** speech problems, gait abnormalities, focal deficits (motor or sensory), headaches, seizures, signs of dementia or memory impairments, depression and anxiety inventory, signs of drug or alcohol intoxication
Baseline Laboratory Studies

As part of the initial evaluation for persons with HIV infection, a number of routine laboratory analyses are recommended in addition to infection-related tests.[3,4,7] Recommendations from the Adult and Adolescent ARV Guidelines and the HIVMA Primary Care Guidelines are outlined below.[3,4,7] Where noted, recommendations are also included from the 2015 STD Treatment Guidelines.[8]

HIV Disease Tests

- **Laboratory Confirmation of HIV Infection**: Most individuals seen for an initial HIV evaluation have laboratory documentation of their HIV infection. If, however, documentation of the HIV diagnosis is not available, appropriate confirmatory HIV diagnostic testing should be performed, with the logic that individuals may have undergone referral based only on a preliminary positive HIV test, or, in rare cases, individuals have factitiously claimed to have HIV infection.[9]

- **CD4 Cell Count with Percentage**: This test helps to establish the risk of specific HIV-associated complications and the need for prophylaxis against opportunistic infections. For persons with HIV infection, measurement of CD4 cell count serves as the best laboratory indicator of immune function. Of note, CD4 counts can vary, especially during an acute illness, and may be impacted by certain medications and intercurrent illnesses. The absolute cell count is the number most often used in clinical practice, but the percentage can also be used to assess immune function and is somewhat less variable than the absolute count. A significant change between two CD4 count readings is an approximate 30% change in the absolute count, or an increase or decrease of 3 percentage points.[10] Falsely elevated CD4 counts may occur in patients with anatomical or functional asplenia.[11]

- **Quantitative Plasma HIV RNA Level (viral load)**: The plasma HIV RNA level defines a baseline viral load, which can predict rapidity of disease, with higher HIV RNA levels clearly correlating with more rapid progression of disease and greater risk of developing AIDS (Figure 5).[12,13] In addition, HIV RNA levels, particularly when greater than 100,000 copies/mL can impact the efficacy of some regimens and thus impact the initial choice of antiretroviral therapy. The U.S. Food and Drug Administration (FDA) has approved several HIV RNA assays and the lower limits of detection threshold for the most commonly used assays range from 20 to 80 copies/mL.

- **HIV Drug-Resistance Testing**: Two types of HIV drug-resistance tests are widely available: genotypic and phenotypic tests. Baseline HIV drug-resistance testing assesses transmitted drug resistance. In the United States, transmission of HIV that is resistant to at least one antiretroviral medication occurs in approximately 10 to 15% of persons; these resistance mutations usually are to a nucleoside reverse transcriptase inhibitor (NRTI), a nonnucleoside reverse transcriptase inhibitor (NNRTI), or a protease inhibitor (PI).[14] A baseline genotypic resistance test is recommended to look for mutations in the reverse transcriptase and protease gene as part of the initial evaluation for all individuals diagnosed with HIV.[14] In contrast, baseline resistance testing of the integrase gene is not routinely recommended in antiretroviral-naive individuals, unless there is concern for transmitted INSTI drug resistance.[14,15,16] Considering all preferred recommended first-line antiretroviral regimens for adults and adolescents consist of an INSTI anchor combined with a 2-NRTI backbone, the clinical benefit and cost-effectiveness of baseline resistance testing has diminished compared to earlier time periods when NNRTIs and PIs were used as a preferred anchor medication.[17] If antiretroviral therapy is deferred, repeat HIV drug-resistance testing at the time of initiation of antiretroviral therapy should be considered due to potential for superinfection during the interval since previous testing.

- **HLA-B*5701**: Routine baseline screening for this haplotype is not recommended at the initial visit, unless the patient is being considered for an antiretroviral regimen that contains abacavir. The HLA-B*5701 is used to identify individuals at high risk for abacavir hypersensitivity reaction.[18] A negative test does not rule out the possibility of a hypersensitivity reaction but makes it extremely unlikely.

- **Coreceptor Tropism Testing**: Tropism testing is not recommended as a routine test for the initial
visit; this test is recommended at the time the use of the CCR5 antagonist maraviroc is being considered. Maraviroc is not recommended as a preferred agent in treatment-naïve patients.[19,20]

- **Pregnancy Test:** Pregnancy testing should be performed in women at initiation or modification of antiretroviral therapy, since certain medications may be teratogenic, such as efavirenz and possibly dolutegravir.
- **Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency Screening:** Screening is recommended at entry to care or before use of oxidant drugs, such as dapsone, nitrofurantoin, and primaquine, or sulfamethoxazole, in patients with a predisposing racial or ethnic background; with exposure to oxidant drugs, persons with G6PD deficiency have increased risk of acute hemolysis. Persons at higher genetic predisposition for G6PD include black men and women, as well as men from the Mediterranean, Middle East, India, and Southeast Asia.[21]

**Routine Laboratory Tests**

- **Complete Blood Count (CBC) with Differential:** Obtaining a baseline CBC is important since anemia, leukopenia, and thrombocytopenia are common among persons with HIV infection. Also, the CBC is used to calculate the total CD4 count.
- **Basic Chemistry Panel and Calculated Creatinine Clearance:** This panel should include serum sodium, potassium, bicarbonate, chloride, blood urea nitrogen, glucose (preferably fasting), creatinine. As part of the basic chemistry panel, the test should determine creatinine-based estimated glomerular filtration rate.
- **Hepatic Aminotransferase Levels:** This should include alanine aminotransferase (ALT) and aspartate aminotransferase (ALT) levels.
- **Urinalysis:** Individuals with HIV have an increased risk of developing HIV-associated nephropathy and chronic kidney disease. This risk is disproportionately higher among African-Americans. The presence of proteinuria may be an early marker of disease in patients with normal renal function.
- **Fasting Lipid Panel (Total cholesterol, HDL, LDL, Triglycerides):** Antiretroviral drugs, HIV infection itself, and host factors are all associated with increased risk of cardiovascular disease and dyslipidemia. Fasting lipids should be checked at baseline.
- **Fasting Plasma Glucose or Hemoglobin A1c:** These tests screen for glucose intolerance and diabetes, which are more prevalent in the population of people living with HIV.
- **Serum Testosterone:** Men with HIV infection, particularly those with advanced immunosuppression, have increased risk of developing hypogonadism. Serum testosterone testing should be considered in males with fatigue, weight loss, loss of libido, erectile dysfunction, depression, or with evidence of reduced bone mineral density. An early-morning (fasting) free testosterone test is preferred.

**Coinfection and Comorbidity Screening**

- **Bartonella Screening:** Routine serologic screening for *Bartonella* infection in persons with HIV infection is not recommended. In addition, routine screening of pets for *Bartonella* infection is not recommended.[22]
- **Cryptococcal Screening:** The Adult and Adolescent Opportunistic Infection Guidelines state that some experts recommend routine screening for cryptococcal antigen in individuals newly diagnosed with HIV infection and a CD4 count less than 100 cells/mm$^3$ (and particularly when the CD4 count is less than 50 cells/mm$^3$).[23]
- **Cytomegalovirus (CMV):** Routine serologic testing (anti-CMV antibody) for evidence of established CMV infection is recommended only for persons with HIV infection who have a lower risk of acquiring CMV infection; routine CMV antibody screening is not recommended for men who have sex with men or persons who inject drugs, since these individuals can be assumed to be CMV seropositive. Patients with CD4 count less than 50 cells/mm$^3$ should receive education to report symptoms that may indicate CMV retinitis, particularly floaters, flashing lights, or change in visual acuity.[24] In addition, some specialists recommend routine referral of patients with a CD4 count less than 50 cells/mm$^3$ to an ophthalmologist for a dilated ophthalmologic examination to screen for CMV retinitis.
• **Hepatitis A Virus (HAV):** Screen for evidence of prior infection or immunity with hepatitis A antibody.

• **Hepatitis B Virus (HBV):** All persons diagnosed with HIV should undergo testing for hepatitis B infection with hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), and hepatitis B core antibody (anti-HBc total).[25] Individuals who test negative for HBsAg and HBsAb but positive for anti-HBc (“isolated core antibody”) should be screened for occult chronic hepatitis B infection with HBV DNA.

• **Hepatitis C Virus (HCV):** At entry into care, all persons with HIV infection should undergo routine testing for HCV infection with HCV antibody; confirmatory testing of all positive HCV antibody tests with HCV RNA testing is recommended.[26] Repeat annual testing is recommended for those individuals who test negative and have ongoing risk of HCV acquisition.[26] Due to possible seronegative HCV infection among individuals with HIV infection, HCV RNA testing should be considered in some patients with a negative HCV antibody, especially those with a history of injection drug use and either a CD4 less than 200 cells/mm$^3$ or an abnormal ALT.[27]

• **Mycobacterium avium Complex (MAC) Screening:** The Adult and Adolescent Opportunistic Infection Guidelines states that obtaining culture of blood for acid-fast bacilli (AFB) to screen for disseminated MAC infection may be considered in patients with CD4 counts less than 50 cells/mm$^3$ if initiating MAC prophylaxis.[28] Screening is particularly important in patients with symptoms that suggest disseminated MAC infection (fever, weight loss, night sweats, fatigue, diarrhea, and anemia). In contrast, routine screening for MAC in patients with a CD4 count greater than 50 cells/mm$^3$ is not recommended.

• **Mycobacterium tuberculosis:** All individuals with HIV entering care should undergo screening for tuberculosis with tuberculin skin testing (TST) or interferon-gamma release assay (IGRA).[29] Individuals with a positive tuberculosis test result should receive treatment for latent *M. tuberculosis* infection after active tuberculosis has been excluded by a thorough history and chest radiographic imaging. Repeat TST or IGRA testing is recommended in persons with advanced HIV disease who initially had negative results but subsequently experienced an increase in the CD4 cell count to greater than 200 cells/mm$^3$ on antiretroviral therapy; in this situation, these individuals may have developed sufficient immunocompetence to mount a positive TST or IGRA reaction.

• **Toxoplasma gondii:** Screen for toxoplasmosis with anti-*Toxoplasma* IgG. If *Toxoplasma* serology is negative, patients should be counseled about methods to avoid exposure.[30] To minimize exposure risk, individuals with HIV who are *Toxoplasma*-seronegative should avoid eating raw or undercooked meat and shellfish; they should wash their hands after handling raw meat or after gardening or contact with soil; and if they own cats, they should not change the litter box and should be encouraged to keep their cats inside.[30] If a person with HIV has a negative *Toxoplasma* serology at baseline, but then has a CD4 count decline to less than 100 cells/mm$^3$ (or they have high risk for *Toxoplasma* exposure), the *Toxoplasma* serology should be repeated.

### Screening for Sexually Transmitted Diseases

• **Syphilis:** All persons with HIV should undergo screening for syphilis at the initial visit and periodically thereafter if ongoing risk factors exist. In recent years, there have been high rates of syphilis in persons with HIV, especially among men with HIV who have sex with men; this phenomenon may be linked to methamphetamine abuse, changing patterns of sexual networks (e.g. internet venues for meeting sex partners), and serosorting (preferential selection of sex partners of same HIV serostatus, which may lead to higher rates of unprotected sexual encounters) among other factors.[8] A lumbar puncture should always be performed for individuals with a reactive syphilis serology who have neurologic, ocular, or otic symptoms or signs, irrespective of past syphilis treatment history. The CDC recommends screening for syphilis with a nontreponemal test (RPR or VDRL) though many laboratories have transitioned to a reverse screening sequence using a treponemal test first; the reverse sequence screening has led to cases of discordant results.[31]

• **Herpes Simplex Virus (HSV):** HSV-1 and HSV-2 type-specific antibody tests are available but not routinely recommended by the HIVMA Primary Care Guidelines. The Adult and Adolescent Opportunistic Infection Guidelines recommend consideration of screening for HSV-2 due to the
extensive interactions between HIV and HSV-2, and the availability of effective therapy for HSV-2.[32]

- **Routine STD Screening in Women:** All women should be screened for *Neisseria gonorrhoeae, Chlamydia trachomatis,* and *Trichomonas vaginalis* at baseline and periodically thereafter, depending on risk and the prevalence of sexually transmitted diseases in the community. Retesting in 3 months is indicated for women found to be positive for any of these infections on initial screening because of high reinfection rates. Nucleic acid amplification testing (NAAT) or PCR of urine is the preferred method of screening, but for clinics that do not have urine PCR testing for trichomoniasis, screening should utilize a wet mount or culture for *T. vaginalis.*

- **Routine STD Screening in Men:** All men should be screened for gonorrhea and chlamydia at baseline and at least annually thereafter, depending on risk and the prevalence of sexually transmitted infections in the community. Retesting in 3 months is indicated for men found to be positive for gonorrhea and chlamydial infections because of high reinfection rates. The 2015 STD Treatment Guidelines and the Adult and Adolescent Opportunistic Infection Guidelines further clarify that all men who have sex with men should have testing for urethral and rectal gonorrhea and chlamydia, as well as testing for oral gonorrhea—if they report receptive sex at these sites.[8] The nucleic acid amplification test (NAAT) is the preferred approach for these screening tests at urethral, rectal, and pharyngeal sites.[8,33] Screening for oropharyngeal chlamydia is not recommended. When testing for urethral infection, testing of a urine sample (not a urethral swab) with a NAAT is the preferred approach and is FDA-approved. There are no guidelines for screening men for *T. vaginalis.*

- **Cervical Cancer Screening:** Sexually active women with HIV infection should undergo cervical cancer screening at initial entry to HIV care and again 12 months later if the initial test was normal; some experts repeat cervical cancer screening after 6 months, consistent with previous guidelines.

- **Anal Cancer Screening:** No clear recommendations exist regarding screening for anal cancer in persons with HIV; this topic remains highly controversial. The HIVMA Primary Care Guidelines recommend anal Pap screening in men who have sex with men, women with a history of receptive anal intercourse (or abnormal cervical Pap test results), and all persons with HIV infection who also have genital warts.[3] This recommendation is considered a weak recommendation based on limited, moderate quality evidence. Stronger evidence-based guidelines are likely in the future since studies are ongoing.
Immunizations

Providing appropriate immunizations is an important component of comprehensive HIV clinical care and should be addressed at the first visit. In general, response to any vaccine will be greatest in patients with higher CD4 cell counts and in those receiving suppressive antiretroviral therapy.[3] Some routine immunizations, such as hepatitis A and hepatitis B, require baseline serologic testing first to determine whether the patient has immunity. The Advisory Committee on Immunization Practices (ACIP) provides annual recommendations for routine immunizations of adults, including specific recommendations for adults with HIV infection.[34] For a full discussion of the topic of immunizations in persons with HIV infection, please refer to the review of Immunizations in Module 2, Lesson 4.
Summary Points

- The goals of the initial evaluation are to confirm the presence of HIV infection, obtain a complete medical history and physical examination, obtain appropriate baseline and historical laboratory data, ensure patient understanding about HIV infection and its transmission, and to initiate primary care as recommended in the HIVMA Primary Care Guidelines.
- Medical care for persons with HIV infection should be culturally sensitive and nonjudgmental, patient-centered, and multidisciplinary.
- The 2014 CDC case definition for HIV is divided into 5 stages based on CD4 count (or percentage) and the presence or absence of AIDS-defining conditions. The previously used letters (A, B, C) in the 1993 classification are not used in the new HIV case definition, and absolute CD4 count takes precedence over CD4 percentage.
- Acceptable diagnostic tests to meet the HIV case definition include HIV antibody tests, combination antibody/antigen tests, and HIV virologic tests.
- The initial patient history should be comprehensive and cover past medical, surgical, and psychiatric history, as well as address sexual behaviors, substance use, financial issues, interpersonal/family issues, and cultural influences that may impact care.
- A complete physical examination should be performed at the first visit, with special attention given to the oral, skin, and lymph node examinations.
- Baseline laboratory evaluation includes HIV disease tests, antiretroviral-specific tests, basic blood counts and chemistry panels, and comorbidity and coinfection tests.
- Providing appropriate immunizations is an important component of comprehensive HIV clinical care and should be addressed at the first visit. In general, response to any vaccine will be greatest in patients with higher CD4 cell counts and in those receiving suppressive antiretroviral therapy.


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[U.S. FDA] -

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[ACIP] -

References

[PubMed Abstract] -

[PubMed Abstract] -
Figures

Figure 1 Natural of History of Untreated HIV Infection

Following acute HIV infection, persons with untreated HIV infection typically develop a steady decline in CD4 cell count, usually progressing to AIDS within 10 years of the initial infection.

Illustration: David H. Spach, MD
Figure 2 Laboratory Criteria for HIV Diagnosis


<table>
<thead>
<tr>
<th>Laboratory Criteria: 2014 CDC Case Definition for HIV Infection</th>
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<tbody>
<tr>
<td><strong>Multitest Algorithm consisting of:</strong></td>
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<tr>
<td>• Positive (reactive) result from initial HIV antibody or combination antigen/antibody test, and</td>
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<tr>
<td>• Accompanying or subsequent positive result from a supplemental HIV test different from initial test</td>
</tr>
<tr>
<td><strong>Positive Result of a Multitest Antibody Algorithm from which only final result reported</strong> (including a single positive result on a test used only as a supplemental test) or on a test that might be used as either an initial test or a supplemental test (e.g., HIV-1/2 type-differentiating rapid antibody immunoassay) when it might reasonably be assumed to have been used as a supplemental test (e.g., because the algorithm customarily used by the reporting laboratory is known)</td>
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<tr>
<td><strong>Positive HIV Virologic (non-antibody) Test:</strong> Positive result or report of a detectable quantity (i.e., within the established limits of the laboratory test) from any of the following HIV virologic (i.e., non-antibody) tests:</td>
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<tr>
<td>• Qualitative HIV NAT (DNA or RNA)</td>
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<td>• Quantitative HIV NAT (viral load assay)</td>
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<td>• HIV p24 antigen test</td>
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<td>• HIV isolation (viral culture)</td>
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<td>• HIV nucleotide sequence (genotype)</td>
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### Figure 3 2014 CDC Case Definition for HIV Infection for Adolescents and Adults


<table>
<thead>
<tr>
<th>Stage</th>
<th>CD4 Count</th>
<th>CD4 %*</th>
<th>Clinical Evidence</th>
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<tbody>
<tr>
<td>Stage 0</td>
<td>Early HIV Infection</td>
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<tr>
<td>Stage 1</td>
<td>≥500 cells/mm³</td>
<td>≥26</td>
<td>No AIDS-defining condition</td>
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<tr>
<td>Stage 2</td>
<td>200-499 cells/mm³</td>
<td>14-25</td>
<td>No AIDS-defining condition</td>
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<tr>
<td>Stage 3</td>
<td>&lt;200 cells/mm³</td>
<td>&lt;14</td>
<td>or Documentation of AIDS-defining condition</td>
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<tr>
<td>Stage unknown</td>
<td>No data</td>
<td>No data</td>
<td>and No information on presence of AIDS-defining conditions</td>
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*Use CD4 percentage only if no data available for CD4 count
Figure 4 Stage 3-Defining Opportunistic Illnesses in HIV Infection


<table>
<thead>
<tr>
<th>2014 CDC Revised Classification System: Stage 3-Defining Opportunistic Illnesses in HIV Infection</th>
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<tbody>
<tr>
<td>• Bacterial infections, multiple or recurrent*</td>
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<tr>
<td>• Candidiasis of bronchia, trachea, or lungs</td>
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<td>• Candidiasis of esophagus</td>
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<td>• Cervical cancer, invasive*</td>
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<td>• Coccidioidomycosis, disseminated or extrapulmonary</td>
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<td>• Cryptococcosis, extrapulmonary</td>
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<td>• Cryptosporidiosis, chronic intestinal (&gt;1 month)</td>
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<td>• Cytomegalovirus disease (other than liver, spleen, or nodes), onset age &gt; 1 month</td>
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<tr>
<td>• Cytomegalovirus retinitis (with loss of vision)</td>
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<td>• Encephalopathy attributed to HIV</td>
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<td>• Herpes simplex: chronic ulcers (present for &gt;1 month) or bronchitis, pneumonitis, or esophagitis (onset at age &gt; 1 month)</td>
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<tr>
<td>• Histoplasmosis, disseminated or extrapulmonary</td>
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<td>• Isosporiasis, chronic intestinal (&gt; 1 month’s duration)</td>
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<td>• Kaposi’s sarcoma</td>
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<td>• Lymphoma, Burkitt’s (or equivalent term)</td>
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<td>• Lymphoma, immunoblastic (or equivalent term)</td>
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<td>• Lymphoma, primary of brain</td>
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<tr>
<td>• Mycobacterium avium complex or Mycobacterium kansasii, disseminated or extrapulmonary</td>
</tr>
<tr>
<td>• Mycobacterium tuberculosis of any site, pulmonary*, disseminated, or extrapulmonary</td>
</tr>
<tr>
<td>• Mycobacterium, other species or unidentified species, disseminated or extrapulmonary</td>
</tr>
<tr>
<td>• Pneumocystis jirovecii (previously known as “Pneumocystis carinii”) pneumonia</td>
</tr>
<tr>
<td>• Pneumonia, recurrent*</td>
</tr>
<tr>
<td>• Progressive multifocal leukoencephalopathy</td>
</tr>
<tr>
<td>• Salmonella septicemia, recurrent</td>
</tr>
<tr>
<td>• Toxoplasmosis of brain, onset at age &gt; 1 month</td>
</tr>
<tr>
<td>• Wasting syndrome attributed to HIV</td>
</tr>
</tbody>
</table>

*Only among children aged < 6 years
*Only among adults, adolescents, and children aged ≥ 6 years
*Suggested diagnostic criteria for these illnesses are defined in prior surveillance case definitions
Figure 5 HIV RNA Levels and CD4 Cell Counts and Risk of Developing AIDS