

# Primary Care Guidelines for the Management of Persons Infected With HIV: 2013 Update by the HIV Medicine Association of the Infectious Diseases Society of America

Judith A. Aberg,<sup>1</sup> Joel E. Gallant,<sup>2,3</sup> Khalil G. Ghanem,<sup>3</sup> Patricia Emmanuel,<sup>4</sup> Barry S. Zingman,<sup>5</sup> and Michael A. Horberg<sup>6</sup>

<sup>1</sup>Division of Infectious Diseases and Immunology, New York University School of Medicine, Bellevue Hospital Center, New York; <sup>2</sup>Southwest CARE Center, Santa Fe, New Mexico; <sup>3</sup>Johns Hopkins University School of Medicine, Baltimore, Maryland; <sup>4</sup>Department of Pediatrics, University of South Florida Health, Tampa; <sup>5</sup>Albert Einstein College of Medicine, Montefiore Medical Center, Bronx, New York and <sup>6</sup>Mid-Atlantic Permanente Research Institute, Rockville, Maryland

Evidence-based guidelines for the management of persons infected with human immunodeficiency virus (HIV) were prepared by an expert panel of the HIV Medicine Association of the Infectious Diseases Society of America. These updated guidelines replace those published in 2009. The guidelines are intended for use by healthcare providers who care for HIV-infected patients. Since 2009, new antiretroviral drugs and classes have become available, and the prognosis of persons with HIV infection continues to improve. However, with fewer complications and increased survival, HIV-infected persons are increasingly developing common health problems that also affect the general population. Some of these conditions may be related to HIV infection itself or its treatment. HIV-infected persons should be managed and monitored for all relevant age- and sex-specific health problems. New information based on publications from the period 2009–2013 has been incorporated into this document.

**Keywords.** HIV; primary care; guidelines; HIV monitoring; HIV metabolic; HIV vaccines; sexually transmitted diseases.

## EXECUTIVE SUMMARY

### Summary of Changes

These updated guidelines replace those published in 2009 [1]. The following general changes have been made to the document since the previous publication:

- The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was used in the updating of this guideline. Recommendations are graded as either being strong or weak and the quality of the evidence is graded as high, moderate, low, or very low.

- Recommendations on the optimal way to diagnose HIV have given way to expanded recommendations on the initial evaluation and immediate follow-up for HIV-infected patients. Easy-to-use tables have also been added.
- Recommendations for long-term complications have been removed.
- A new section was added on metabolic comorbidities, replacing the need for separate guidelines on dyslipidemia, which had been previously published [2].
- A more robust section and table on sexually transmitted diseases has been added.

Formatting changes have also been incorporated to help readers easily identify the recommendations.

Summarized below are the recommendations made in the updated guidelines for the management of persons infected with HIV. Each section of the guideline begins with a specific clinical question and is followed by numbered recommendations and a summary

Received 25 September 2013; accepted 26 September 2013.

Correspondence: Judith A. Aberg, MD, New York University School of Medicine, 550 First Ave, BCD 5 (Rm 558), New York, NY 10016 (judith.berg@nyumc.org).

**Clinical Infectious Diseases** 2014;58(1):1–10

© The Author 2013. Published by Oxford University Press on behalf of the Infectious Diseases Society of America. All rights reserved. For Permissions, please e-mail: journals.permissions@oup.com.

DOI: 10.1093/cid/cit757

of the most relevant evidence in support of the recommendations. The Panel followed a process used in the development of other IDSA guidelines, which included a systematic weighting of the strength of recommendation and quality of evidence using the GRADE system [3–8] (Table 1). A detailed description of the methods, background, and evidence summaries that support each of the recommendations can be found in the full text of the guidelines.

## RECOMMENDATIONS FOR THE MANAGEMENT OF PERSONS INFECTED WITH HIV

### I. What initial evaluation and immediate follow-up should be performed for HIV-infected patients?

#### Recommendations

1. A comprehensive present and past medical history, physical examination, medication/social/family history, and review of systems, including HIV-related information, should be obtained for all patients upon initiation of care (*strong recommendation, moderate quality evidence*).

#### HIV Disease Tests

##### Serological Assays for HIV

#### Recommendation

2. Patients who have no documentation of their HIV serostatus or who were tested anonymously should have an HIV serologic test performed upon initiation of care (*strong recommendation, low quality evidence*).

##### CD4 Cell Counts and Percentages

#### Recommendations

3. A CD4 cell count with percentage should be obtained upon initiation of care (*strong recommendation, high quality evidence*).
4. Measurement of the CD8 cell count and the ratio of CD4 cells to CD8 cells is unnecessary as the results are not used in clinical decision making (*strong recommendation, high quality evidence*).

##### Plasma HIV RNA Levels

#### Recommendation

5. A quantitative HIV RNA (viral load) level should be obtained upon initiation of care (*strong recommendation, high quality evidence*).

##### HIV Resistance Testing

#### Recommendations

6. Because drug-resistant virus can be transmitted from one person to another, all patients should be assessed for transmitted drug resistance with an HIV genotype test upon

initiation of care (*strong recommendation, high quality evidence*). If therapy is deferred, repeat testing at the time of antiretroviral therapy (ART) initiation should be considered because of the potential for superinfection (*weak recommendation, low quality evidence*).

7. Resistance testing is also indicated for patients who are experiencing virologic failure to guide modification of ART (*strong recommendation, high quality evidence*).
8. In persons failing integrase strand transfer inhibitor (INSTI)-based regimens, genotypic testing for INSTI resistance should be ordered (*strong recommendation, high quality evidence*).

##### Coreceptor Tropism Assay

#### Recommendation

9. Tropism testing should be performed if the use of a CCR5 antagonist is being considered (*strong recommendation, high quality evidence*).

##### Laboratory Tests

##### Complete Blood Count and Chemistry Panel

#### Recommendation

10. A complete blood count with differential white blood cell count and chemistry panel should be obtained upon initiation of care (*strong recommendation, high quality evidence*).

##### Glucose-6-Phosphate Dehydrogenase

#### Recommendation

11. Screening for glucose-6-phosphate dehydrogenase (G6PD) deficiency is recommended upon entry into care or before starting therapy with an oxidant drug in patients with a predisposing racial or ethnic background (*strong recommendation, moderate quality evidence*).

##### Fasting Lipid Profile

#### Recommendation

12. Because many antiretroviral drugs, HIV infection itself, and host factors are associated with increased cholesterol and triglyceride levels, a fasting lipid profile should be obtained upon initiation of care (*strong recommendation, high quality evidence*).

##### HLA B\*5701 Screening

#### Recommendations

13. HLA-B\*5701 testing should be performed before initiating abacavir therapy (*strong recommendation, high quality evidence*).
14. Patients who are positive for the HLA B\*5701 haplotype are at high risk for hypersensitivity reaction and should not

**Table 1. Guidelines From Various Sources Regarding Aspects of Care of HIV-Infected Persons**

Topic	Title	URL	Issuing Agency	Reference
Adolescent transition	Adolescent Transition Workbook	<a href="http://www.aids-ed.org/aidsetc?page=etres-display&amp;resource=etres-269&amp;">http://www.aids-ed.org/aidsetc?page=etres-display&amp;resource=etres-269&amp;</a>	AETC National Resource Center	[73]
Adolescent transition	Transitioning HIV-Infected Adolescents Into Adult Care, 2011	<a href="http://www.hivguidelines.org/clinical-guidelines/adolescents/transitioning-hiv-infected-adolescents-into-adult-care/">http://www.hivguidelines.org/clinical-guidelines/adolescents/transitioning-hiv-infected-adolescents-into-adult-care/</a>	New York State Department of Health AIDS Institute	[74]
ART for adults and adolescents	Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents	<a href="http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf">http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf</a>	US Department of Health and Human Services	[20]
ART for adults and adolescents	Antiretroviral treatment of adult HIV infection: 2012 recommendations of the International Antiviral Society–USA panel	<a href="http://jama.jamanetwork.com/article.aspx?articleid=1221704">http://jama.jamanetwork.com/article.aspx?articleid=1221704</a>	International Antiviral Society–USA	[21]
ART and management guidelines for adults, adolescents, infants, and children	There are >30 guidelines covering a broad range of topics in the prevention, diagnosis, and management of HIV and its associated coinfections and comorbidities	<a href="http://www.hivguidelines.org/clinical-guidelines/">http://www.hivguidelines.org/clinical-guidelines/</a>	New York State Department of Health AIDS Institute	[105]
ART for pediatric patients	Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection	<a href="http://aidsinfo.nih.gov/guidelines">http://aidsinfo.nih.gov/guidelines</a>	NIH	[19]
ART for pregnant women	Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1-Infected women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the US	<a href="http://aidsinfo.nih.gov/guidelines">http://aidsinfo.nih.gov/guidelines</a>	US Public Health Service Task Force	[58]
Chronic kidney disease	Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients	<a href="http://www.journals.uchicago.edu/doi/abs/10.1086/430257">http://www.journals.uchicago.edu/doi/abs/10.1086/430257</a>	HIV Medicine Association of IDSA	[26]
Diabetes	Standards of Medical Care in Diabetes–2013	<a href="http://care.diabetesjournals.org/content/36/Supplement_1/S4.full">http://care.diabetesjournals.org/content/36/Supplement_1/S4.full</a>	American Diabetes Association	[78]
Hepatitis	EASL Clinical Practice Guidelines: Management of chronic hepatitis B virus infection–2012	<a href="http://www.easl.eu/assets/application/files/4a7bd873f9cccbf_file.pdf">http://www.easl.eu/assets/application/files/4a7bd873f9cccbf_file.pdf</a>	EASL	[32]
Hepatitis	EASL Clinical Practice Guidelines: Management of hepatitis C virus infection–2011	<a href="http://www.easl.eu/assets/application/files/4a7bd873f9cccbf_file.pdf">http://www.easl.eu/assets/application/files/4a7bd873f9cccbf_file.pdf</a>	EASL	[106]
HIV testing and counseling	Revised Guidelines for HIV Testing	<a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm</a>	CDC	[107]
HIV testing in adolescents	Testing for Adolescents	<a href="http://pediatrics.aappublications.org/content/128/5/1023.full?linkType=FULL&amp;resid=128/5/1023&amp;journalCode=pediatrics">http://pediatrics.aappublications.org/content/128/5/1023.full?linkType=FULL&amp;resid=128/5/1023&amp;journalCode=pediatrics</a>	American Academy of Pediatrics	[108]
Immunization schedules	Child and Adolescent Immunization Schedule	<a href="http://www.cdc.gov/vaccines/schedules/index.html">http://www.cdc.gov/vaccines/schedules/index.html</a>	CDC	[109]
Immunizations	ACIP Recommendations	<a href="http://www.cdc.gov/vaccines/pubs/ACIP-list.htm">http://www.cdc.gov/vaccines/pubs/ACIP-list.htm</a>	ACIP	[33]
Mental health	Mental Health Care for People With HIV Infection: Clinical Guidelines for the Primary Care Practitioner	<a href="http://www.hivguidelines.org/clinical-guidelines/">http://www.hivguidelines.org/clinical-guidelines/</a>	New York State Department of Health AIDS Institute	[14]
Occupational exposures	Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis	<a href="http://www.jstor.org/stable/10.1086/672271">http://www.jstor.org/stable/10.1086/672271</a>	US Public Health Service	[110]
Occupational exposures	HIV Prophylaxis Following Occupational Exposure	<a href="http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/">http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/</a>	New York State Department of Health AIDS Institute	[111]

Table 1 continued.

Topic	Title	URL	Issuing Agency	Reference
Opportunistic infections	Guidelines for Treating Opportunistic Infections Among HIV-Infected Adults and Adolescents	<a href="http://aidsinfo.nih.gov/guidelines">http://aidsinfo.nih.gov/guidelines</a>	DHHS, HIVMA/IDSA; CDC	[10]
Opportunistic infections in children	Guidelines for Prevention and Treatment of Opportunistic Infections among HIV-Exposed and HIV-Infected Children	<a href="http://aidsinfo.nih.gov/guidelines">http://aidsinfo.nih.gov/guidelines</a>	DHHS, HIVMA/IDSA, CDC, PIDS	[31]
Pediatric HIV	Red Book: 2012 Report of the Committee of Infectious Diseases	<a href="http://aapredbook.aappublications.org/">http://aapredbook.aappublications.org/</a>	American Academy of Pediatrics	[64, 112]
Perioperative management of HIV-infected patients	Perioperative Management of HIV-Infected Patients	<a href="http://www.hivguidelines.org/clinical-guidelines/adults/perioperative-management-of-hiv-infected-patients/">http://www.hivguidelines.org/clinical-guidelines/adults/perioperative-management-of-hiv-infected-patients/</a>	New York State Department of Health AIDS Institute	[113]
Resistance testing	European Recommendations for the Clinical Use of HIV Drug Resistance Testing: 2011 Update	<a href="http://www.europeanaidscinicalsociety.org/images/stories/EACS-Pdf/2011-european-hiv-drug-resistance-guidelines.pdf">http://www.europeanaidscinicalsociety.org/images/stories/EACS-Pdf/2011-european-hiv-drug-resistance-guidelines.pdf</a>	European AIDS Clinical Society	[114]
Risk assessment	Incorporating HIV Prevention Into the Medical Care of Persons Living With HIV	<a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5212a1.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5212a1.htm</a>	CDC, Health Resources and Services Administration, NIH, HIV Medicine Association of IDSA	[36]
Sexually transmitted diseases	Sexually Transmitted Diseases Treatment Guidelines 2010	<a href="http://www.cdc.gov/std/treatment/2010/STD-Treatment-2010-RR5912.pdf">http://www.cdc.gov/std/treatment/2010/STD-Treatment-2010-RR5912.pdf</a>	CDC	[42]
Transgender	Care of the HIV-Infected Transgender Patient	<a href="http://www.hivguidelines.org/clinical-guidelines/transgender/care-of-the-hiv-infected-transgender-patient/">http://www.hivguidelines.org/clinical-guidelines/transgender/care-of-the-hiv-infected-transgender-patient/</a>	New York State Department of Health AIDS Institute	[13]
Travel medicine	CDC Health Information for International Travel 2014 (commonly called the Yellow Book), Chapter 8—Advising Travelers With Specific Needs, Immunocompromised Travelers.	<a href="http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-8-advising-travelers-with-specific-needs/immunocompromised-travelers">http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-8-advising-travelers-with-specific-needs/immunocompromised-travelers</a>	CDC	[52]

Abbreviations: ACIP, Advisory Committee on Immunization Practices; AETC, AIDS Education and Training Centers; ART, antiretroviral therapy; CDC, Centers for Disease Control and Prevention; DHHS, US Department of Health and Human Services; EASL, European Association for the Study of the Liver; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV-1, human immunodeficiency virus type 1; HIVMA, HIV Medicine Association; IDSA, Infectious Diseases Society of America; NIH, National Institutes of Health; PIDS, Pediatric Infectious Diseases Society.

be treated with abacavir (*strong recommendation, high quality evidence*).

### Urinalysis and Calculated Creatinine Clearance

#### Recommendations

15. A baseline urinalysis and calculated creatinine clearance or estimated glomerular filtration rate should be obtained, especially in black HIV-infected patients and those with advanced disease or comorbid conditions, because of an increased risk of nephropathy (*strong recommendation, high quality evidence*).
16. Urinalysis and calculated creatinine clearance assay should also be performed prior to initiating drugs such as tenofovir or indinavir that have the potential for nephrotoxicity (*strong recommendation, moderate quality evidence*).

### Coinfection and Comorbidity Laboratory

#### Tests Tuberculosis Screening

#### Recommendations

17. Upon initiation of care, HIV-infected patients without a history of tuberculosis or a prior positive tuberculosis screening test should be tested for *Mycobacterium tuberculosis* infection by either a tuberculin skin test (TST) or by an interferon- $\gamma$  release assay (IGRA) (*strong recommendation, high quality evidence*). Those with positive test results should be treated for latent *M. tuberculosis* infection after active tuberculosis has been excluded [9, 10] (*strong recommendation, high quality evidence*).
18. Repeat testing is recommended in patients with advanced HIV disease who initially had negative TST or IGRA results but subsequently experienced an increase in the CD4

cell count to >200 cells/ $\mu$ L on ART and who may thus have developed sufficient immunocompetence to mount a positive reaction (*strong recommendation, high quality evidence*).

19. HIV-infected patients who are close contacts of persons with infectious tuberculosis should be treated for latent *M. tuberculosis* infection regardless of their TST or IGRA results, age, or prior courses of tuberculosis treatment; active tuberculosis should be excluded first (*strong recommendation, high quality evidence*).

### Serologic Testing for *Toxoplasma gondii*

#### Recommendations

20. All HIV-infected patients should be tested for prior exposure to *T. gondii* by measuring anti-*Toxoplasma* IgG upon initiation of care (*strong recommendation, moderate quality evidence*).

21. *Toxoplasma*-seronegative adults, representing 70%–90% of the US population, should be counseled on how to avoid new infection (*weak recommendation, moderate quality evidence*).

### Viral Hepatitis Screening and Vaccination Recommendations

#### Recommendations

22. HIV-infected patients should be screened for evidence of hepatitis B virus (HBV) infection upon initiation of care by detection of hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), and antibody to hepatitis B total core antigen (anti-HBc or HBcAb) (*strong recommendation, high quality evidence*), and those who are susceptible to infection should be vaccinated against HBV (*strong recommendation, high quality evidence*). HBsAb should be repeated 1–2 months or at the next scheduled visit after the third vaccine was given to assess for immunogenicity. A second series of vaccine is recommended for those whose HBsAb levels are negative or <10 IU/mL after primary vaccine series (*strong recommendation, high quality evidence*).

23. Vaccination should be recommended for nonimmune sexual partners of patients who are positive for HBsAg (*strong recommendation, high quality evidence*).

24. Patients who are negative for HBsAg and HBsAb but positive for anti-HBc should be screened for chronic HBV infection by determination of HBV DNA; those without evidence of chronic infection should consider vaccination (*strong recommendation, low quality evidence*).

25. HIV-infected patients should be screened for hepatitis C virus (HCV) infection upon initiation of care by a test for HCV antibody and annually thereafter for those at risk (*strong recommendation, high quality evidence*).

26. HCV RNA should be ordered on all those with a positive HCV antibody test to assess for active HCV disease (*strong recommendation, high quality evidence*).

27. Infants born to HBV- and /or HCV-infected women should be tested for HBV and HCV transmission, respectively (*strong recommendation, high quality evidence*).

28. Hepatitis A vaccination is recommended for all susceptible men who have sex with men (MSM), as well as other susceptible individuals with indications for hepatitis A vaccine (eg, injection drug users, persons with chronic liver disease, travelers to countries with high endemicity, or patients who are infected with hepatitis B and/or C) (*strong recommendation, high quality evidence*). Hepatitis A total or IgG antibody should be repeated 1–2 months or at the next scheduled visit after the second vaccine to assess for immunogenicity. A repeat vaccine series is recommended in those who remain seronegative (*strong recommendation, high quality evidence*).

29. Hepatitis A vaccine may be considered for all other non-immune patients (negative anti-HAV total or IgG antibody) (*weak recommendation, low quality evidence*).

### Screening and Vaccination Recommendations for Herpes Viruses

#### Recommendations

30. Patients at lower risk of cytomegalovirus (CMV) infection (eg, populations other than MSM or injection drug users, both of which may be assumed to be seropositive) should be tested for latent CMV infection with an anti-CMV IgG upon initiation of care (*strong recommendation, moderate quality evidence*).

31. Patients who are susceptible to varicella zoster virus (VZV) (those who have not been vaccinated, have no history of varicella or herpes zoster, or are seronegative for VZV) should receive postexposure prophylaxis with varicella zoster immune globulin (VariZIG) as soon as possible (but within 10 days) after exposure to a person with varicella or shingles (*strong recommendation, moderate quality evidence*).

32. Varicella primary vaccination may be considered in HIV-infected, VZV-seronegative persons aged >8 years with CD4 cell counts >200 cells/ $\mu$ L (*moderate recommendation, low quality evidence*) and in HIV-infected children aged 1–8 years with CD4 cell percentages >15% (*strong recommendation, moderate quality evidence*).

### Screening for Syphilis

#### Recommendations

33. All patients should be screened for syphilis upon initiation of care and periodically thereafter, depending on risk (*strong recommendation, high quality evidence*).

34. A lumbar puncture should always be performed for patients with a reactive syphilis serology who have neurologic or ocular symptoms or signs, irrespective of past syphilis treatment history (*strong recommendation, high quality evidence*).

35. A lumbar puncture should be performed in patients who experience serologic treatment failure (ie, whose nontreponemal titers fail to decline 4-fold after stage-appropriate therapy, or whose titers increase 4-fold if reinfection is ruled out) (*weak recommendation, low quality evidence*).

### **Screening for Other Sexually Transmitted Diseases (Refer to Section II for Information on Routine Sexually Transmitted Disease Screening)**

#### **Recommendation**

36. All women should be screened for trichomoniasis, and all women aged  $\leq 25$  years should be screened for *Chlamydia trachomatis* infection (*strong recommendation, high quality evidence*).
37. Men and women should be screened for gonorrhea and chlamydia infection at initial presentation and then annually if at risk for infection (*strong recommendation, high quality evidence*).
38. Retesting in 3 months is indicated in men and women found to be positive for gonorrhea and chlamydial infections and women found to be positive for trichomoniasis on initial screening, because of high reinfection rates (*strong recommendation, moderate quality evidence*).
39. All of these conditions should be screened for periodically thereafter, depending on the population, reported behaviors, the presence of other sexually transmitted diseases (STDs) in the patient or his/her partner(s), and the prevalence of STDs in the community (*strong recommendation, low quality evidence*).

### **Cervical Cancer Screening and Prevention**

#### **Recommendations**

40. HIV-infected women should have a cervical Pap test performed upon initiation of care, and this test should be repeated at 6 months and annually thereafter if results are normal (*strong recommendation, moderate quality evidence*).
41. Women with atypical squamous cells (both ASC-US [atypical squamous cells of unknown significance] and ASC-H [ASC, cannot rule out high-grade squamous intraepithelial lesion]), atypical glandular cells, low-grade or high-grade squamous intraepithelial lesion, or squamous carcinoma noted by Pap testing should undergo colposcopy and directed biopsy, with further treatment as indicated by results of evaluation (*strong recommendation, high quality evidence*).

### **Screening for Anal Human Papillomavirus**

#### **Recommendation**

42. HIV-infected men and women with human papillomavirus (HPV) infection are at increased risk for anal dysplasia and cancer. MSM, women with a history of receptive anal

intercourse or abnormal cervical Pap test results, and all HIV-infected persons with genital warts should have anal Pap tests (*weak recommendation, moderate quality evidence*).

43. HPV vaccination is recommended for all females aged 9–26 years and all males aged 9–21 years. Males aged 22–26 years should also be vaccinated if not vaccinated at younger ages (*strong recommendation, high quality evidence*).

### **Serum Testosterone Level**

#### **Recommendation**

44. Morning serum testosterone levels are recommended in adult men with decreased libido, erectile dysfunction, reduced bone mass or low trauma fractures, hot flashes, or sweats, and should be considered in the setting of less specific symptoms such as fatigue and depression (*strong recommendation, moderate quality evidence*).
45. Obtaining testosterone levels in women in nonresearch settings is not recommended (*strong recommendation, low quality evidence*).

### **Chest Radiography**

#### **Recommendation**

46. A baseline chest radiograph should be obtained in all HIV-infected patients with a positive tuberculosis screening test result to rule out active tuberculosis; it may also be useful in other patients who are likely to have preexisting lung abnormalities (*strong recommendation, moderate quality evidence*).

### **Other Laboratory Tests**

#### **Recommendation**

47. Routine testing for cryptococcal infection with serum cryptococcal antigen or for disseminated *Mycobacterium avium* complex infection by culture of blood for acid-fast bacilli are not recommended, but may be considered in selected patients with CD4 cell counts  $< 50$  cells/ $\mu$ L (*strong recommendation, moderate quality evidence*).

### **Behavioral Intervention**

#### **Recommendations**

48. General messages regarding risk reduction should be provided at all healthcare encounters, regardless of risk behaviors reported by the patient or perceived risk on the part of the healthcare provider. Such messages can be delivered by the provider, by others in the healthcare setting, or by educational materials (eg, pamphlets, posters, and videos) in the healthcare setting (*strong recommendation, low quality evidence*).
49. Tailored messages are critical for patients who report persistent high-risk behavior or who have symptoms or signs of STDs. In nearly all situations, the provider should

offer brief counseling; in general, persons exhibiting risk behavior should also be referred to programs capable of offering more extensive intervention programs (*strong recommendation, moderate quality evidence*).

## Schedule-of-Care Evaluation for HIV-Infected Patients

### Adults

#### Recommendations

50. Viral load is generally monitored every 3–4 months in untreated patients and patients on stable ART. This interval may be prolonged to 6 months for adherent patients whose viral load has been suppressed for more than 2–3 years and whose clinical and immunologic status is stable. Viral load should be monitored more frequently after initiation or change in ART: preferably within 2–4 weeks, and not more than 8 weeks, after initiation or modification, with repeat testing every 4–8 weeks until viral load becomes undetectable (*strong recommendation, moderate quality evidence*).
51. CD4 cell counts should be monitored both to assess the urgency for initiation of ART or the efficacy of ART and to determine the need for prophylaxis against opportunistic infections (*strong recommendation, high quality evidence*). CD4 cell counts should generally be monitored every 3–4 months. For patients on suppressive ART regimens whose CD4 counts have increased well above the threshold for opportunistic infection risk, the CD4 count can be monitored every 6–12 months unless there are changes in the patient's clinical status [11] (*strong recommendation, moderate quality evidence*).
52. STD screening and tuberculosis screening tests should be repeated periodically depending on symptoms and signs, behavioral risk, and possible exposures (*strong recommendation, moderate quality evidence*).
53. Vaccinations for pneumococcal infection (*strong recommendation, high quality evidence*), influenza (*strong recommendation, high quality evidence*), varicella (*strong recommendation, moderate quality evidence*), and hepatitis A (*strong recommendation, high quality evidence*) and B (*strong recommendation, high quality evidence*) should be offered as indicated (Table 2). The likelihood of a response to any vaccine is greatest in patients with higher CD4 cell counts and in patients receiving suppressive ART.

## II. What are the special considerations for women and the prevention of mother-to-child transmission?

### Contraception and Preconception Care

#### Recommendation

54. All HIV-infected women of childbearing age should be asked about their plans and desires regarding pregnancy upon initiation of care and routinely thereafter (*strong recommendation, low quality evidence*).

## Breast Cancer Screening

### Recommendations

55. Mammography should be performed annually in women aged >50 years (*strong recommendation, high quality evidence*).
56. In women aged 40–49 years, providers should perform individualized assessment of risk for breast cancer and inform them of the potential benefits and risks of screening mammography (*strong recommendation, high quality evidence*).

## Menopause

### Recommendations

57. Hormone replacement therapy, particularly if prolonged, has been associated with a small increased risk of breast cancer and cardiovascular and thromboembolic morbidity, and its routine use is not currently recommended (*strong recommendation, high quality evidence*).
58. Hormone replacement therapy may be considered in women who experience severe menopausal symptoms (eg, vasomotor symptoms and vaginal dryness) but should generally be used only for a limited period of time and at the lowest effective doses (*weak recommendation, low quality evidence*).

## Mother-to-Child Transmission

### Recommendations

59. To prevent infection of their fetus, pregnant women should be treated for HIV infection, regardless of their immunologic or virologic status (*strong recommendation, high quality evidence*).
60. Infants exposed to HIV in utero should receive antiretroviral postexposure prophylaxis and undergo HIV virologic diagnostic testing at 14–21 days of life, at 1–2 months of age, and at 4–6 months of age (*strong recommendation, high quality evidence*).
61. High-risk exposed infants should have virologic testing at birth (*strong recommendation, moderate quality evidence*).

## III. What are the special considerations for children?

### Recommendations

62. HIV-infected infants should undergo HIV resistance testing (*strong recommendation, high quality evidence*) and, because of the rapid progression of disease, should initiate therapy in the first year of life regardless of CD4 cell count, RNA level, or clinical status (*strong recommendation, high quality evidence*).
63. After the first year of life, initiation of therapy in HIV-infected children is based on age, CD4 count/percentage, viral load, and symptoms. ART should be initiated in all

**Table 2. Routine Immunizations for HIV-Infected Adults**

Vaccine	Status	Dose/Regimen	Comments
<i>Haemophilus influenzae</i> type B vaccine	Consider in selected settings; see comments	0.5 mL IM	Administer to asplenic patients
Hepatitis A vaccine	Recommended in selected settings; see comments	1 mL IM with revaccination in 6–12 mo for Havrix or 6–18 mo for Vagta; also available in combination with hepatitis B vaccine as Twinrix administered as 3 or 4 doses	HAV vaccination is recommended for all susceptible men who have sex with men, as well as others with indications for HAV vaccine (eg, injection drug users, travelers to countries of high endemicity, persons with chronic liver disease, or who are infected with hepatitis B and/or C). Vaccination can be considered for all nonimmune patients
Hepatitis B vaccine	Recommended in selected settings; see comments	1 dose of 40 µg/mL (Recombivax HB) administered on a 3-dose schedule or 2 doses of 20 µg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 mo	Administer to patients without evidence of past or present hepatitis B infection. Vaccinated patients should be tested for HBsAb response 1–2 months or at the next scheduled clinic visit after the third dose
HPV vaccine	Ideally given prior to sexual activity. Indicated for females age 9–26 and males age 9–26	Gardasil 0.5 mL IM for 3 dose series given at 0, 2, and 6 mo	
Influenza vaccine	Inactivated influenza vaccine recommended; do not use live attenuated intranasal vaccine (FluMist)	0.5 mL IM annually	All patients. Especially important in patients at high risk for exposure to or morbidity from influenza.
Pneumococcal vaccine	Recommended	Should receive a dose of PCV13 (Prevnar 13), followed by a dose of PPV23 (Pneumovax) at least 8 wk later. If previously vaccinated with PPV23, give PCV13 at least 1 y after PPV23.	Administer to patients with CD4 cell count $\geq 200/\mu\text{L}$ . A second PPV23 dose is recommended 5 y after the first PPV23 dose
Polio vaccine	OPV contraindicated; IPV should be given if indicated	0.5 mL SC; 3 doses over 6–12 mo for primary immunization	For travelers to an area endemic for polio
Tetanus toxoid	Same as for patient without HIV infection	Td 0.5 mL IM Tdap 0.5–0.75 mL IM as per package insert	Substitute 1-time dose of Tdap vaccine at time of next booster, then Td every 10 y. Precautions with pregnancy. Td may be administered after 20 wk gestation or immediately postpartum
Varicella vaccine (primary)	Consider in selected settings; see comments	0.5 mL IM as 2 doses administered 3 mo apart	Administer to HIV-infected persons with a CD4 count $\geq 200$ cells/ $\mu\text{L}$ who do not have evidence of immunity to varicella.
Zoster vaccine			Safety and efficacy in HIV-infected persons unknown; consider in patients >60 y of age with CD4 counts $\geq 200$ cells/ $\mu\text{L}$ .

Source: Adapted from the Advisory Committee on Immunization Practices [33].

Abbreviations: HAV, hepatitis A virus; HBsAg, hepatitis B surface antigen; HIV, human immunodeficiency virus; HPV, human papillomavirus; IM, intramuscular; IPV, inactivated polio vaccine; OPV, oral polio vaccine; PCV13, 13-valent pneumococcal conjugate vaccine; PPV23, 23-valent pneumococcal polysaccharide vaccine; SC, subcutaneous; Td, tetanus-diphtheria; Tdap, tetanus-diphtheria-pertussis.

symptomatic children (*strong recommendation, high quality evidence*).

(a) CD4 cell counts and viral loads should be monitored no less than every 3–4 months (*strong recommendation, moderate quality evidence*).

(b) Childhood vaccinations should be administered according to Advisory Committee on Immunization Practices schedules for HIV-infected infants and children (*strong recommendation, high quality evidence*).

64. HIV-infected infants and children should be managed by a specialist with knowledge of the unique therapeutic, pharmacologic, behavioral, and developmental issues associated with this disease (*strong recommendation, low quality evidence*).

#### IV. What are the special considerations for adolescents?

65. HIV-infected adolescents require an individual and developmental approach to therapy and care given by an HIV



specialist with expertise in this population (*strong recommendation, low quality evidence*).

66. Adolescents infected with HIV should have a coordinated, deliberate transition to adult care (*strong recommendation, low quality evidence*).

## V. What are the metabolic comorbidities associated with HIV and antiretroviral therapy?

### Recommendations

67. Fasting blood glucose and/or hemoglobin A1c should be obtained prior to and within 1–3 months after starting ART. Patients with diabetes mellitus should have a hemoglobin A1c level monitored every 6 months with a goal of <7%, in accordance with the American Diabetes Association Guidelines (*strong recommendation, moderate quality evidence*).
68. Fasting lipid levels should be obtained prior to and within 1–3 months after starting ART. Patients with abnormal lipid levels should be managed according to the National Cholesterol Education Program Guidelines (*strong recommendation, moderate quality evidence*).
69. Baseline bone densitometry (DXA) screening for osteoporosis in HIV-infected patients should be performed in postmenopausal women and men aged  $\geq 50$  years (*strong recommendation, moderate quality evidence*).

## VI. How can patient adherence to HIV care be optimized?

### Recommendations

70. All HIV-infected patients should be provided timely access to routine and urgent primary medical care (*strong recommendation, moderate quality evidence*).
71. HIV care sites should make every effort to provide care in a way that is linguistically and culturally appropriate and competent (*strong recommendation, moderate quality evidence*).
72. HIV care sites should utilize a multidisciplinary model but identify a primary provider for each patient and support the development of trusting long-term patient–provider relationships (*strong recommendation, moderate quality evidence*).
73. All patients should be evaluated for depression and substance abuse, and if present, a management plan that addresses these problems should be developed and implemented in collaboration with appropriate providers (*strong recommendation, high quality evidence*).

## Notes

**Acknowledgments.** The Panel wishes to express its gratitude to Drs John T. Brooks, Diane Havlir, and Alice Pau for their thoughtful reviews of an earlier version of the guideline. We also thank Jennifer Padberg for her kind editorial assistance and tireless efforts for without which this guideline would not have been completed.

**Financial support.** Support for this IDSA guideline was provided by the Infectious Diseases Society of America.

**Disclaimer.** Guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations. The Infectious Diseases Society of America considers adherence to this guideline to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances.

**Potential conflicts of interest.** The following list is a reflection of what has been reported to IDSA. To provide thorough transparency, IDSA requires full disclosure of all relationships, regardless of relevancy to the guideline topic. Evaluation of such relationships as potential conflicts of interest (COI) is determined by a review process that includes assessment by the Standards and Practice Guidelines Committee (SPGC) Chair, the SPGC liaison to the development panel, and the Board of Directors liaison to the SPGC and, if necessary, the COI Task Force of the Board. This assessment of disclosed relationships for possible COI will be based on the relative weight of the financial relationship (ie, monetary amount) and the relevance of the relationship (ie, the degree to which an association might reasonably be interpreted by an independent observer as related to the topic or recommendation of consideration). The reader of these guidelines should be mindful of this when the list of disclosures is reviewed. For activities outside of the submitted work, J. A. A. served on the advisory board for Abbvie, Janssen (Tibotec), Merck, and ViiV, and received research grants from the National Institutes of Health, Kowa, Gilead, and Wyeth/Pfizer. For activities outside of the submitted work, J. E. G. has received grants from Gilead, Bristol-Myers Squibb, Vertex Pharmaceuticals, and ViiV. Also outside of the submitted work, he has received personal fees from Gilead, Bristol-Myers Squibb, Janssen, Merck, ViiV, and GlaxoSmithKline. He is also a member of the Department of Health and Human Services panel for adult and adolescent antiretroviral therapy guidelines. For activities outside of the submitted work, B. S. Z. received grants from Gilead, ViiV, GlaxoSmithKline, and Siemens. All other authors report no potential conflicts.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

## References

- Aberg JA, Kaplan JE, Libman H, et al. Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV Medicine Association of the Infectious Diseases Society of America. *Clin Infect Dis* **2009**; 49:651–81.
- Dube MP, Stein JH, Aberg JA, et al. Guidelines for the evaluation and management of dyslipidemia in human immunodeficiency virus (HIV)-infected adults receiving antiretroviral therapy: recommendations of the HIV Medical Association of the Infectious Diseases Society of America and the Adult AIDS Clinical Trials Group. *Clin Infect Dis* **2003**; 37:613–27.
- Guyatt GH, Oxman AD, Kunz R, et al. Going from evidence to recommendations. *BMJ* **2008**; 336:1049–51.
- Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* **2008**; 336:924–6.
- Jaeschke R, Guyatt GH, Dellinger P, et al. Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive. *BMJ* **2008**; 337:a744.
- Guyatt GH, Oxman AD, Kunz R, et al. Incorporating considerations of resources use into grading recommendations. *BMJ* **2008**; 336:1170–3.
- Schunemann HJ, Oxman AD, Brozek J, et al. Grading quality of evidence and strength of recommendations for diagnostic tests and strategies. *BMJ* **2008**; 336:1106–10.
- Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schunemann HJ. What is “quality of evidence” and why is it important to clinicians? *BMJ* **2008**; 336:995–8.
- Mazurek GH, Jereb J, Vernon A, LoBue P, Goldberg S, Castro K. Updated guidelines for using interferon gamma release assays to detect

- Mycobacterium tuberculosis* infection—United States, 2010. MMWR Recomm Rep **2010**; 59:1–25.
10. AIDSinfo. Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents, **2013**. Available at: <http://aidsinfo.nih.gov/guidelines/>. Accessed 15 September 2013.
  11. Gale HB, Gitterman SR, Hoffman HJ, et al. Is frequent CD4+ T-lymphocyte count monitoring necessary for persons with counts  $\geq 300$  cells/ $\mu$ L and HIV-1 viral suppression? Clin Infect Dis **2013**; 56:1340–43.
  13. New York State Department of Health AIDS Institute. Care of the HIV-infected transgender patient, **2013**. Available at: <http://www.hivguidelines.org/clinical-guidelines/transgender/care-of-the-hiv-infected-transgender-patient/>. Accessed 15 September 2013.
  14. New York State Department of Health AIDS Institute. Mental health care for people with HIV infection: clinical guidelines for the primary care practitioner. Available at: <http://www.hivguidelines.org/Content.aspx?PageID=261>. Accessed 6 February 2009.
  19. Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the use of antiretroviral agents in pediatric HIV infection, **2012**. Available at: <http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf>. Accessed 15 September 2013.
  20. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services, **2013**. Available at: <http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf>. Accessed 15 September 2013.
  21. Thompson MA, Aberg JA, Hoy JF, et al. Antiretroviral treatment of adult HIV infection: 2012 recommendations of the International Antiviral Society—USA panel. JAMA **2012**; 308:387–402.
  26. Gupta SK, Eustace JA, Winston JA, et al. Guidelines for the management of chronic kidney disease in HIV-infected patients: recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis **2005**; 40:1559–85.
  31. AIDSinfo. Guidelines for the prevention and treatment of opportunistic infections among HIV-exposed and HIV-infected children, **2013**. Available at: <http://aidsinfo.nih.gov/guidelines/>. Accessed 15 September 2013.
  32. European Association for the Study of the Liver. EASL clinical practice guidelines: management of chronic hepatitis B virus infection. J Hepatol **2012**; 57:167–85.
  33. Advisory Committee for Immunization Practices (ACIP). Recommended adult immunization schedule: United States, 2013. Ann Intern Med **2014**; 158:191–9.
  36. Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration, National Institutes of Health, HIV Medicine Association of the Infectious Diseases Society of America. Incorporating HIV prevention into the medical care of persons living with HIV. Recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR Recomm Rep **2003**; 52(RR-12):1–24.
  42. Workowski KA, Berman S. Sexually transmitted diseases treatment guidelines, 2010. MMWR Recomm Rep **2010**; 59:1–110.
  52. Kotton CN, Freedman DO. CDC health information for international travel (Yellow Book). Chapter 8: advising travelers with specific needs, immunocompromised travelers, **2014**. Available at: <http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-8-advising-travelers-with-specific-needs/immunocompromised-travelers>. Accessed 15 September 2013.
  58. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States, **2013**. Available at: <http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf>. Accessed 15 September 2013.
  64. American Academy of Pediatrics. Human immunodeficiency virus infection. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. Red book: 2009 report of the committee on infectious diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics, **2009**.
  73. Robinson P, Cavalier Y, Davison C, Donovan M, Fox D. Adolescent transition workbook, **2006**. Available at: <http://www.aids-ed.org/aidsetc?page=etres-display&resource=etres-269&>. Accessed 15 September 2013.
  74. New York State Department of Health AIDS Institute. Transitioning HIV-infected adolescents into adult care, **2011**. Available at: <http://www.hivguidelines.org/clinical-guidelines/adolescents/transitioning-hiv-infected-adolescents-into-adult-care/>. Accessed 15 September 2013.
  78. No authors listed. Executive summary: standards of medical care in diabetes—2013. Diabetes Care **2013**; 36:(suppl 1):4–10.
  105. New York State Department of Health AIDS Institute. Clinical guidelines, **2013**. Available at: <http://www.hivguidelines.org/clinical-guidelines/>. Accessed 15 September 2013.
  106. European Association for the Study of the Liver. EASL clinical practice guidelines: management of hepatitis C virus infection. J Hepatol **2011**; 55:245–64.
  107. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm Rep **2006**; 55(RR-14):1–17.
  108. Committee on Pediatric AIDS. Adolescents and HIV infection: the pediatrician's role in promoting routine testing. Pediatrics **2011**; 128:1023–29.
  109. Centers for Disease Control and Prevention. Immunization schedules, **2012**. Available at: <http://www.cdc.gov/vaccines/schedules/index.html>. Accessed 15 September 2013.
  110. Kuhar DT, Henderson DK, Struble KA, et al. Updated US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis. Infect Control Hosp Epidemiol **2013**; 34:875–92.
  111. New York State Department of Health AIDS Institute. Post-exposure prophylaxis, **2012**. Available at: <http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/>. Accessed 15 September 2013.
  112. No authors listed. Human immunodeficiency virus infection. In: Larry KP, ed. Red book: American Academy of Pediatrics, **2012**: 418–39.
  113. New York State Department of Health AIDS Institute. Perioperative management of HIV-infected patients, **2012**. Available at: <http://www.hivguidelines.org/clinical-guidelines/adults/perioperative-management-of-hiv-infected-patients/>. Accessed 15 September 2013.
  114. Vandamme AM, Camacho RJ, Ceccherini-Silberstein F, et al. European recommendations for the clinical use of HIV drug resistance testing: 2011 update. AIDS Rev **2011**; 13:77–108.