## Comprehensive Primary Care for Adults With HIV

### Updates, Authorship, and Related Guidelines

Date of current publication

December 15, 2022 edition

Highlights of changes, additions, and updates in the

December 15, 2022

In Table 4: Routine Screening for Adults With HIV, the following changes were made:
 Screening recommendations for cervical and anal cancers were updated to align with
 recommendations in the NYSDOH AI guidelines Screening for Cervical Dysplasia and
 Cancer in Adults With HIV and Screening for Anal Dysplasia and Cancer in Patients With
 HIV.

Recommendations for routine vision screening were removed.

Intended users New York State clinicians who provide primary care for adults with HIV

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Developer and funder New York State Department of Health AIDS Institute (NYSDOH AI)

Development process See Supplement: Guideline Development and Recommendation Ratings

Related NYSDOH AI guidelines

• Hepatitis C Virus Screening, Testing, and Diagnosis in Adults

- HIV Testing
- Immunizations for Adults With HIV
- <u>Laboratory Monitoring for Adverse</u>
   <u>Effects of ART</u>
- PEP to Prevent HIV Infection
- PrEP to Prevent HIV and Promote Sexual Health
- Prevention and Management of Hepatitis A Virus Infection in Adults With HIV
- <u>Prevention and Management of</u>
   <u>Hepatitis B Virus Infection in Adults With</u>
- Rapid ART Initiation
- <u>Screening for Anal Dysplasia and Cancer</u> <u>in Patients With HIV</u>
- Screening for Cervical Dysplasia and Cancer in Adults With HIV

- Selecting an Initial ART Regimen
- Substance Use Screening and Risk Assessment in Adults
- <u>Treatment of Chronic Hepatitis C Virus</u> <u>Infection in Adults</u>
- Virologic and Immunologic Monitoring in HIV Care

### Related NYSDOH AI Guidance

- Guidance: Addressing the Needs of Older Patients in HIV Care
- <u>Guidance: Adopting a Patient-Centered</u> <u>Approach to Sexual Health</u>
- GOALS Framework for Sexual History Taking in Primary Care
- <u>U=U Guidance for Implementation in</u> <u>Clinical Settings</u>



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### Purpose of This Guideline

This guideline on primary care for adults with HIV was developed by the New York State Department of Health AIDS Institute (NYSDOH AI) to guide clinicians in New York State who provide primary medical care for adults (≥18 years old) with HIV.

The purpose of this guideline is to provide New York State clinicians with evidence-based clinical recommendations for provision of comprehensive primary care to patients with HIV, whether care is provided in an HIV specialty or primary care setting. The goal is to ensure that individuals with HIV in New York State can access optimal primary care in multiple outpatient clinical settings.

**Note on "experienced" and "expert" HIV care providers:** Throughout this guideline, when reference is made to "experienced HIV care provider" or "expert HIV care provider," those terms are referring to the following 2017 NYSDOH AI definitions:

- Experienced HIV care provider: Practitioners who have been accorded HIV Experienced Provider status by the American
  Academy of HIV Medicine or have met the HIV Medicine Association's definition of an experienced provider are eligible
  for designation as an HIV Experienced Provider in New York State. Nurse practitioners and licensed midwives who
  provide clinical care to individuals with HIV in collaboration with a physician may be considered HIV Experienced
  Providers as long as all other practice agreements are met (8 NYCRR 79-5:1; 10 NYCRR 85.36; 8 NYCRR 139-6900).
  Physician assistants who provide clinical care to individuals with HIV under the supervision of an HIV Specialist
  physician may also be considered HIV Experienced Providers (10 NYCRR 94.2)
- Expert HIV care provider: A provider with extensive experience in the management of complex patients with HIV.

At the end of 2018, there were an estimated 1,173,900 individuals ≥13 years old with HIV in the United States [CDC 2020] and an estimated 108,683 in New York State [NYSDOH 2019]. Advances in antiretroviral therapy (ART) over the past 2 decades have significantly improved life span [Gueler, et al. 2017; Samji, et al. 2013; Zwahlen, et al. 2009]: life expectancy for a patient newly diagnosed with HIV now approaches that of an individual without a diagnosis of HIV. ART lowers rates of opportunistic infections and mortality [Lundgren, et al. 2015; El-Sadr, et al. 2006], and the immune system



reconstitution observed with use of ART is associated with significantly improved health outcomes in patients with HIV [Marin, et al. 2009; Emery, et al. 2008]. Clinicians should start and maintain ART in all patients with HIV.

Regardless of HIV treatment, however, when compared with individuals without HIV, those with HIV continue to have a higher risk of many comorbidities (see Box 1, below), including metabolic and infectious diseases and cancers. In one study, patients with HIV had significantly fewer morbidity-free years than patients without HIV [Marcus, et al. 2020].

#### Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations

#### Metabolic diseases

- Cardiovascular disease [Shah, et al. 2018; Drozd, et al. 2017]
- Osteoporosis [Compston 2016]
- Thromboembolic events [Malek, et al. 2011]
- Type 2 diabetes [McMahon, et al. 2018; Nansseu, et al. 2018; Monroe, et al. 2015]
- Renal disease [Swanepoel, et al. 2018; Althoff, et al. 2015]
- Liver disease [Soti, et al. 2018]

#### Malignancies

- AIDS-defining malignancies (e.g., Kaposi sarcoma, non-Hodgkin Lymphoma) [Guiguet, et al. 2009]
- Hepatocellular carcinoma [Pinato, et al. 2019]
- HIV-associated cancers (e.g., lung cancer, Epstein-Barr virus-associated lymphoma) [Yarchoan and Uldrick 2018]
- Human papillomavirus-related malignancies (e.g., anal cancer, cervical cancer, head and neck cancer) [Clifford, et al. 2017; Brickman and Palefsky 2015; Machalek, et al. 2012]
- Non-AIDS-defining malignancies [Park, et al. 2016; Althoff, et al. 2015; Deeken, et al. 2012]

#### Infectious diseases

- Hepatitis A virus [Bosh, et al. 2018; Penot, et al. 2018]
- Hepatitis B virus [Bosh, et al. 2018; Singh, et al. 2017]
- Hepatitis C virus [Bosh, et al. 2018; Graham, et al. 2001]
- Systemic viral illnesses (cytomegalovirus, Epstein-Barr virus, human herpesvirus-8, varicella zoster virus, herpes simplex virus) [Gilbert, et al. 2019; Basso, et al. 2018]
- Fungal illness (candidiasis, aspergillosis, *pneumocystis jiroveci* pneumonia, coccidiomycosis, cryptococcosis) [Limper, et al. 2017]
- Syphilis [Fujimoto, et al. 2018]
- Tuberculosis [Bruchfeld, et al. 2015]

### Other

- Chronic obstructive pulmonary disease [Bigna, et al. 2018; Risso, et al. 2017]
- Neurocognitive impairment [Cysique and Brew 2019; Tozzi, et al. 2007]
- Depression [Nanni, et al. 2015]
- Frailty [Greene, et al. 2015]

The increased incidence of comorbid conditions is associated with several factors, some of which are disease-specific, such as increased risks associated with ongoing immune activation [Deeks, et al. 2015; Deeks 2011]; presumed medication-associated toxicities, such as accelerated bone density loss; length of time of HIV viremia [Lang, et al. 2012]; and others, such as increased rates of malignancy and hepatitis C virus (HCV) (see Box 1, above). Many of these conditions are seen regardless of immune reconstitution and HIV disease stage, and long-term HIV survivors face additional burdens from concomitant disease, medication-associated toxicity (particularly for those on or with prolonged exposure to, early antiretroviral medications), and advanced aging [Maggi, et al. 2019].

Management of HIV disease in the primary care setting is similar to management of other chronic diseases, and screening for and managing comorbidities is standard for any primary care practice. This guideline offers practical recommendations and guidance for the ongoing clinical care of individuals with HIV, links to other NYSDOH AI guidelines for detailed recommendations on specific topics, and links to other helpful resources.

**All patients with HIV:** Regardless of viral suppression or CD4 count, HIV infection is associated with an increased risk of comorbidities related to persistent inflammation associated with the virus itself. ART clearly reduces morbidity and



mortality but can also contribute to comorbidities, such as weight gain [Bourgi(a), et al. 2020; Bourgi(b), et al. 2020] and osteoporosis [Komatsu, et al. 2018; Grigsby, et al. 2010].

Patients with CD4 count <200 cells/mm<sup>3</sup>: Morbidity and mortality are increased in individuals with low CD4 cell counts [Castilho, et al. 2022; Althoff, et al. 2019; May, et al. 2016]. Patients are at increased risk for morbidity and mortality if they experience unintentional weight loss or have poor functional status [Siika, et al. 2018; Serrano-Villar, et al. 2014]. Some conditions, such as AIDS-defining malignancies, are more common in individuals with low CD4 cell counts and may be associated with markedly poor outcomes [Borges, et al. 2014]. See the U.S. Department of Health and Human Services Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV.

Conditions related to low nadir CD4 cell count: A low nadir CD4 cell count (lowest lifetime CD4 cell count) reflects severe pretreatment immune dysfunction. Immune recovery in patients with low nadir CD4 cell counts may take longer or be less complete than in those with higher nadir CD4 cell counts [Stirrup, et al. 2018; Collazos, et al. 2016]. Studies have found increased morbidity and mortality for 5 years after ART is initiated [May, et al. 2016], and nadir CD4 cell count is a predictor of cognitive impairment and disorders [Ellis, et al. 2011]. Some patients may have persistently low CD4 cell counts despite achieving viral load suppression and will be at increased risk of clinical progression to AIDS-related and non-AIDS-related illnesses and death [Baker, et al. 2008].

**Structure and use of this guideline:** This guideline assumes that clinicians are familiar with performing a comprehensive patient history and examination and focuses on aspects of primary care that require additional attention in patients with HIV. The recommendations and supporting material in this guideline are structured as 6 sections with detailed tables (listed below) that provide specific recommendations, information, and resources on key issues to be addressed in primary care for individuals with HIV. Where appropriate, links are provided to other NYSDOH AI guidance and guidelines for more information.

- Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV
- Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV
- Table 3: Recommended Laboratory Testing for Adults With HIV
- Table 4: Routine Screening for Adults With HIV
- Table 5: Primary Prevention for Adults With HIV
- Table 6: Prophylaxis for Opportunistic Infections in Adults With HIV

For additional information on aging and HIV, see the NYSDOH AI <u>Guidance: Addressing the Needs of Older Patients in HIV</u> <u>Care</u>.

### Goals of Primary Care for Adults With HIV

Patients with HIV receive care in diverse settings [Cheng, et al. 2014]. A patient may receive primary care from an HIV or infectious diseases specialist with a strong, disease-specific focus or may seek HIV care from a primary care provider who does not specialize in HIV care. Some studies have suggested better outcomes when patients are followed by specialists, and other studies have demonstrated contradictory findings, in that patients who are followed only by specialists may experience gaps in care, particularly with regard to identification and management of comorbidities [Morales Rodriguez, et al. 2018; Rhodes, et al. 2017; Kerr, et al. 2012; Landon, et al. 2005]. Optimal care for people with HIV requires experience with both HIV and primary care.

This guideline seeks to ensure that individuals with HIV receive high-quality, comprehensive primary care in their setting of choice and provides recommendations for adult primary care for patients with HIV. The guideline is designed to support specialists in HIV care who may need additional information to provide comprehensive primary care and primary care providers who may need additional information to manage HIV-associated care.

The standard approach to primary care is the same for patients with and without HIV, whether care is delivered by a specialist or internist. An approach that is patient-centered and holistic will address the following:

- · Routine cancer screening
- Other essential primary and secondary prevention screening (e.g., osteoporosis, heart disease)
- Routine and HIV-specific immunizations
- Substance use



- Mental health disorders
- Sexual health
- Trauma assessment
- Geriatric care
- Patient education and encouragement regarding healthy lifestyle
- · Preconception counseling for those of childbearing potential

In addition to mainstays of primary care, there are unique considerations for patients with HIV, including treatment of HIV itself. Clinicians should inform patients of the benefits of antiretroviral therapy (ART) and strongly encourage patients to initiate ART as soon as possible.

Additional essential components of primary care for patients with HIV are:

- · Patient education and encouragement regarding adherence to ART to maintain viral suppression
- Monitoring for potential long-term effects of HIV and ART, such as bone density changes, dyslipidemia, weight gain, and renal dysfunction
- Opportunistic infection prophylaxis
- Identification and management of comorbidities that occur more often and at younger ages in people with HIV, including atherosclerotic heart disease, non-HIV-related malignancies, renal disease, liver disease, chronic obstructive pulmonary disease, neurocognitive dysfunction, depression, and frailty (see <a href="Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations">Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations</a>). Recent studies have found that smoking and hypertension contribute significantly to morbidity, regardless of HIV-related risk factors, such as CD4 cell count or viral load [Althoff, et al. 2019]
- Ongoing surveillance for diseases transmitted through the same routes as HIV, including hepatitis C virus, hepatitis B virus, human papillomavirus, and other sexually transmitted infections
- · Screening and treatment for substance use, including tobacco use
- Ongoing discussion and patient education regarding disclosure of HIV status, principles of <u>undetectable = untransmittable (U=U)</u>, <u>pre-exposure prophylaxis (PrEP)</u> and <u>post-exposure prophylaxis (PEP)</u> for sex partners, and harm reduction strategies

Consent and confidentiality: A patient's past medical records should be obtained whenever possible. Sharing of patient medical records among care providers who participate in health information exchanges such as the Statewide Health Information Network for New York (SHIN-NY), can facilitate information exchange (see <a href="New York eHealth Collaborative">New York eHealth Collaborative</a> What is the SHIN-NY?). Patients must sign a standard medical record request form (see the New York State <a href="standard consent form">standard consent form</a>). Information related to HIV care can be exchanged among care providers only if a patient consents specifically to release of HIV/AIDS-related information on the standard form.

Any HIV-related patient information is confidential, and by law, care providers must maintain this confidentiality (see New York Codes, Rules, and Regulations: <a href="Part 63">Part 63</a> - HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information).

Stigma and medical mistrust: Among people with HIV, stigma and medical mistrust remain significant barriers to healthcare utilization, HIV diagnosis, and medication adherence and can affect disease outcomes [Turan, et al. 2017; Chambers, et al. 2015]. Studies have found that both internalized stigma (manifested in feelings about self) and externalized stigma (enacted by others) can influence how often a patient seeks care, their engagement in care, and whether they maintain viral load suppression. Successful interventions to reduce stigma and medical mistrust include education of healthcare providers [Geter, et al. 2018], peer support [Flórez, et al. 2017], and social support [Rao, et al. 2018].

**Case management:** The goal of comprehensive case management is to improve patient outcomes and retention in care by providing the support and resources of a healthcare team that includes the clinical care provider. Comprehensive case management connects patients to community resources and can improve engagement with medical care, including screening and management of comorbid conditions, and HIV-specific outcomes, such as immune reconstitution [Brennan-Ing, et al. 2016].

Case management has been shown to dramatically improve viral load suppression among individuals who inject drugs or smoke crack cocaine, 2 groups who are difficult to retain in care. One study showed an increase in viral load suppression from 32% to 74% and another showed a mortality benefit from case management intervention [Kral, et al. 2018; Miller, et al. 2018].



**Peer support:** Peer support can provide an individual with emotional and practical guidance from someone with shared life experience and can be a tool to reduce stigma. Peer support has been found to improve retention in care [Cabral, et al. 2018] and improved viral suppression in a group of individuals with HIV who were recently incarcerated [Cunningham, et al. 2018]. However, data for the general population are inconclusive regarding the effects of peer interventions on viral load suppression or other outcomes, and more research is needed [Giordano, et al. 2016; Metsch, et al. 2016].

# History, Assessment, and Evaluation: Initial, Ongoing, and Annual

### **☑** RECOMMENDATIONS

### History, Assessment, and Evaluation

- For all adults with HIV who present for primary care, clinicians should perform the baseline assessments detailed in the following tables (A3):
  - Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV
  - Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV
  - Table 3: Recommended Laboratory Testing for Adults With HIV
  - Clinicians should repeat these assessments as indicated in Tables 1, 2, and 3. (A3)

History-taking for patients with HIV requires attention to all of the elements standard in primary care while including several additional elements, which are detailed in Table 1, below. It is essential to identify, assess, and monitor HIV- and antiretroviral therapy (ART)-related complications and other HIV-specific comorbidities (see <a href="Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations">Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations</a>).

A comprehensive baseline history includes sexual health, mental health, substance use (including illicit use of prescription drugs), and social history. Patients may choose not to disclose all pertinent personal information during the first visit, but a sympathetic and nonjudgmental attitude can help establish trust and facilitate further discussion and disclosure during subsequent visits.

**Anatomical inventory:** In addition to all elements of a standard patient history and physical examination, it is important for clinicians to perform an anatomical inventory and determine primary care needs based on which organs are present rather than on the gender expression of the patient. A matter-of-fact anatomical inventory will identify present and absent organs: penis, testes, prostate, breasts, vagina, cervix, uterus, and ovaries.

### **HIV-Specific Medical History**

Essential components of an HIV-specific medical history are detailed in this section and in Table 1, below. Confirmation of a patient's HIV infection should include documented laboratory testing results. If results are not available, <u>baseline testing</u> should be performed as noted in Table 1, below. If a patient was recently diagnosed with HIV, discussion of the reasons for testing and the route of exposure will assist the clinician in identifying appropriate goals for risk reduction education, counseling, and intervention, which may include ongoing screening for sexually transmitted infections (STIs).

Essential components of an HIV-specific medical history:

- Viral load and CD4 cell count at diagnosis, if known
- Patient circumstances at time of diagnosis (housing, employment, food security, relationship status, etc.)
- ART history, including previous regimens, reasons for any changes in prior regimens, and any adverse effects
- · Pauses in ART and lapses in adherence
- · Previous resistance testing results
- · History of opportunistic infections
- History of HIV-related hospitalization(s)
- Disclosure status (whether partners, family, or friends are aware of HIV status) and partner notification



- History of other STIs with shared risk factors, including hepatitis B virus (HBV) and hepatitis C virus (HCV)
- Ongoing high-risk behaviors for transmission of HIV and acquisition of STIs or infections associated with injection drug
  use
- Experience of stigma and social support

**ART history:** Essential elements of an ART history include all previous medications, why they were stopped, and reasons for stopping (e.g., allergies, adverse effects, pill-taking fatigue or discomfort, and drug resistance). Understanding these reasons and seeking ways to simplify ART regimens or reduce pill burden will support a therapeutic alliance around adherence going forward.

**ART initiation:** If a patient with HIV <u>has not yet started ART</u>, it should be initiated as soon as appropriate and possible, and any barriers to ART initiation should be assessed so support can be provided.

**Trauma-informed care:** A trauma-informed approach to care is important to mitigate any medical trauma, such as frightening experiences or stigma associated with the initial HIV diagnosis [Tang, et al. 2020; Sherr, et al. 2011]. See the following for more information:

- New York State Office of Mental Health: Recovery from Trauma
- New York State Trauma-Informed Network
- Trauma Informed Care in Medicine: Current Knowledge and Future Research Directions (article) [Raja, et al. 2015]

**Adherence:** For patients already taking ART, assessing adherence and providing support for optimal adherence are crucial and should include careful assessment of adverse medication effects, which often lead to adherence problems or medication cessation. Other factors to discuss that may pose barriers to adherence include insurance coverage, housing instability, disclosure status, substance use, and mental health.

**Viral hepatitis status:** Many of the risk factors for acquisition of viral hepatitis are the same as those for HIV. Assessment of a patient's viral hepatitis status, including a history of viral hepatitis infection and treatment, helps clinicians determine optimal treatment options. In individuals with HIV, progression of HBV- or HCV-associated liver fibrosis, cirrhosis, cancer, portal hypertension, and encephalopathy is more rapid than in those without HIV [Weber, et al. 2006; Thio, et al. 2002; Graham, et al. 2001; Benhamou, et al. 1999].

**HCV:** Because the risk of severe liver disease is increased in patients with HIV [Soti, et al. 2018], all patients with HCV and HIV should be <u>treated for HCV infection</u> as soon as possible. Potential interactions between ART and HCV medications should be identified and addressed. Treatment of chronic HCV is the same for individuals with and without HIV.

**HBV:** A history of HBV infection will influence HIV medication choice and requires attention to drug-drug interactions. Because tenofovir, emtricitabine, and lamivudine are effective against both HBV and HIV, it is important to assess baseline HBV status and choose combination HIV therapy to appropriately treat the HBV infection as well as HIV. It is also important to appropriately monitor for progression of fibrosis or hepatocellular carcinoma; however, ART initiation should not be delayed pending evaluation of HBV status and liver damage. See the NYSDOH AI guideline <a href="Pervention and Management of Hepatitis B Virus Infection in Adults With HIV">Pervention and Management of Hepatitis B Virus Infection in Adults With HIV</a>.

### General Medical Status, History, and Physical Examination

This guideline assumes that care providers are familiar with performing a comprehensive physical examination. Several areas may require additional attention because the incidence, associated complications, or severity may be increased in individuals with HIV or low CD4 cell counts.

**Medications:** Ideally, a complete medication history should be acquired at baseline and updated as needed during future visits. A detailed medication history (with emphasis on ART) allows the clinician to identify possible adverse drug-drug interactions between ART and medications the patient is taking to treat comorbidities (see <a href="Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations">Description Incidence in People With HIV and Selected Citations</a>). Patients with HIV may have multiple comorbidities due to infection and related inflammatory processes or the effects of medications. Examination of a patient's current medical status and medication regimen may identify the need for changes in the ART regimen, changes in medications prescribed for other medical conditions, options for simplification of medication regimens, and medications that may be discontinued (see the NYSDOH AI guideline <a href="Selecting an Initial ART Regimen">Selecting an Initial ART Regimen</a> Special Considerations for Comorbid Conditions).



### **ORDITION : OF THE PROPERTY OF**

- NYSDOH AI Resource: ART Drug-Drug Interactions
- Northeast/Caribbean AETC: HIV and HCV Drug Interactions: Quick Guides for Clinicians
- University of Liverpool: <u>HIV Drug Interaction Checker</u>

Metabolic changes: There are significant metabolic concerns for people with HIV and AIDS [Mankal and Kotler 2014]. Weight gain often occurs after initiation of ART. Assessing weight loss or gain at every visit will assist with early identification of metabolic changes [Bourgi(b), et al. 2020]. Female gender, Black race, pre-ART CD4 cell count depletion, and lower pre-ART body mass index have been associated with >10% weight gain at 2 years after ART initiation [Bourgi(b), et al. 2020]. Integrase strand transfer inhibitors (dolutegravir, bictegravir, raltegravir, elvitegravir, and cabotegravir) have been associated with greater weight gain than non-nucleoside reverse transcriptase inhibitors or protease inhibitors, particularly when used in combination with tenofovir alafenamide [Sax, et al. 2020]. Weight loss is more common in individuals with low CD4 cell counts and may prompt investigation of malignancy, infection, and psychosocial instability.

Head, eyes, ears, nose, and throat: An ophthalmologic examination at baseline and at least annually thereafter is indicated for patients with a CD4 count <50 cells/mm³. Cytomegalovirus (CMV) infection can lead to retinitis, vision loss, and death. Varicella zoster virus and herpesvirus infections can lead to retinitis and retinal necrosis [Nakamoto, et al. 2004]. After the introduction of highly active ART, the 10-year cumulative incidence for CMV retinitis was 33.6% for individuals with CD4 counts <50 cells/mm³ and 4.2% for those with CD4 counts <200 cells/mm³ [Sugar, et al. 2012]. Icterus may be present in individuals who are taking atazanavir as part of their ART regimen by causing a benign hyperbilirubinemia [Bertz, et al. 2013]. HIV viremia can also lead to a direct retinopathy at high viral loads and low CD4 cell counts [Jabs 1995].

Although HIV infection itself does not increase the likelihood of viral upper respiratory infections, symptoms such as cough, sinusitis, and otitis are common in patients with HIV [Brown, et al. 2017; Chiarella and Grammer 2017; Small and Rosenstreich 1997]. Because sinusitis and otitis can present without significant facial pain or discomfort in patients with CD4 counts <50 cells/mm³, it is reasonable to perform imaging and evaluate for infection with atypical organisms, such as fungal sinusitis, more readily in these patients.

People with HIV also have a higher risk of oral malignancies than those without HIV, and those with low CD4 cell counts may have diverse oropharyngeal findings, including oral Kaposi sarcoma, oral candidiasis, human papillomavirus (HPV)-and HIV-related parotitis, and necrotizing gingivitis, requiring evaluation during in-person examinations [Trevillyan, et al. 2018; Sorensen 2011; Epstein 2007]. Clinicians should encourage patients to have annual dental examinations (see National Institute of Dental and Craniofacial Research > HIV/AIDS & Oral Health).

**Heme/lymph:** Lymphadenopathy may occur at any stage of HIV disease, does not always correlate with disease progression or prognosis, and may be less pronounced in older patients. However, widespread, firm, or asymmetrical lymphadenopathy requires prompt consideration of lymphoma, syphilis, tuberculosis (TB), mycobacterium avium-intracellulare infection, and lymphogranuloma venereum, all of which can occur regardless of CD4 cell count but are more likely at lower CD4 cell counts. Nonadherence to ART may also be considered.

Diffuse large B-cell lymphoma, Burkitt lymphoma, and primary central nervous system lymphoma are AIDS-defining conditions; lymphoproliferative diseases, such as Castleman disease, should be considered as well. Any evidence of lymph nodes larger than 1 cm or evidence of fixed, matted, or hard nodes should prompt consideration for biopsy, particularly if a patient has a low CD4 cell count.

**Dermatologic:** An annual comprehensive skin examination ensures that concerns are identified early. Regardless of CD4 cell count, findings such as shingles and psoriasis are more frequent in people with HIV than in those without HIV [Alpalhão, et al. 2019; Erdmann, et al. 2018]. For more information, see <a href="National HIV Curriculum">National HIV Curriculum</a> Cutaneous <a href="Manifestations">Manifestations</a>.

Attention should be paid to any dermatologic history, such as a history of skin cancers and recurrent rash, which could be consistent with psoriasis, seborrheic dermatitis, atopic dermatitis, eosinophilic folliculitis, or secondary syphilis [Alpalhão, et al. 2019; Green, et al. 1996]. Symptoms can overlap and coexist.

Less common diseases, such as Kaposi sarcoma, eosinophilic folliculitis, disseminated zoster, molluscum contagiosum, and cutaneous HPV, may occur in patients with low CD4 cell counts. Familiarity with these diseases is important.

**Neurologic:** As noted in Table 1, below, clinicians should examine patients' neurologic and cognitive function at baseline, at least annually for those at risk (due to low CD4 cell count, age, or comorbidities) and more often if there are patient or



family concerns. Several standardized tests are available, including the <u>MoCA Test</u> (requires an account), <u>Mini-Cog</u>, and <u>Mini-Mental State Examination (MMSE)</u>.

Compared with patients who have higher CD4 cell counts, patients with low CD4 cell counts may be at increased risk for neurologic conditions, which can include rare diseases, such as progressive multifocal leukoencephalopathy, HIV-associated neurologic disease, toxoplasmosis, and cryptococcal meningitis, and common diseases with atypical presentation, such as syphilis and TB.

Imaging and diagnostic work-up are warranted for new or persistent neurologic symptoms (e.g., seizure, changes in mental status, or persistent headache) regardless of CD4 cell count, but especially in patients with a low CD4 cell count.

**Respiratory:** Clinicians should perform a lung examination at baseline and at least annually, or more often if indicated. Community-acquired pneumonia is more common in people with HIV, regardless of CD4 cell count, than in those without HIV [Almeida and Boattini 2017], as is chronic obstructive pulmonary disease [Bigna, et al. 2018]. Chronic lung disease is increasingly common among older people with HIV, among smokers, and among those who have had *Pneumocystis jiroveci* pneumonia (PJP; formerly known as *Pneumocystis carinii* pneumonia or PCP), who may have residual blebs that can lead to pneumothorax [Risso, et al. 2017].

In patients with low CD4 cell counts who have respiratory examination findings or symptoms, clinicians should perform a chest radiographic or computerized tomography to evaluate for infection or neoplasm [Yee, et al. 2020]. Clinicians should also maintain a low threshold for suspicion of TB and pursue appropriate diagnostic and public health measures if TB is suspected.

Comorbidities: For patients with comorbidities, such as cardiovascular disease, lung disease, renal disease, diabetes mellitus, and malignancies, personal and family history should be collected, and individual risk factors should be discussed. Because HIV has been associated with increased risk and accelerated disease process for these comorbidities, care providers should be sure to discuss appropriate screening and have a low threshold for diagnostic testing referral if symptoms develop [Kaspar and Sterling 2017; Triant 2013; Islam, et al. 2012; Shiels, et al. 2011; Bower, et al. 2009; Crothers, et al. 2006]. In individuals taking ART, risk factors such as smoking and hypertension cause more morbidity and mortality than HIV-specific risk factors, such as low CD4 cell count [Althoff, et al. 2019; Trickey, et al. 2016; Helleberg, et al. 2015].

History of particular comorbidities may also influence medication choice for those <u>starting ART</u>. For example, patients with a history of metabolic disease may wish to avoid protease inhibitors because of the association with central obesity, and patients with risk factors for significant renal disease may wish to avoid tenofovir disoproxil fumarate. If patients do have significant risk for and are taking ART or other medications that can affect these conditions, more frequent monitoring may be warranted [Crum-Cianflone, et al. 2010]. Nonalcoholic steatohepatitis is observed in 30% to 40% of people with HIV [Kaspar and Sterling 2017] and may affect both monitoring and medication choice.

Endocrine conditions, such as metabolic syndrome, insulin resistance, dyslipidemia, lipodystrophy, and osteoporosis, may be worsened by certain antiretroviral medications. A full medication history will help clinicians identify the possibility of ART-associated contribution to these conditions [Noubissi, et al. 2018; Gazzaruso, et al. 2003]. Because thyroid disease and hypogonadism occur more often in people with HIV than in those without, a low threshold for screening for these conditions is appropriate.

**Aging:** As the <u>population living with HIV ages</u>, frailty, functional, and cognitive assessments are essential. Baseline discussion of memory loss, neuropathic symptoms, and chronic pain can help identify conditions that may affect ART adherence. Nadir CD4 cell count is a predictor of cognitive impairment and disorders [Ellis, et al. 2011]. Collecting structured data through use of standardized assessments will help clinicians to determine illness course; standardized assessment tools include the <u>MoCA Cognitive Assessment</u>, <u>Mini-Cog</u>, and <u>MMSE</u>, as noted above. An annual assessment of functional status is also indicated.

**Psychosocial status:** Baseline and annual psychosocial assessments, as described in Table 2, below, include a detailed sexual, trauma, substance use, and psychiatric history; more frequent assessment may be required for patients who require follow-up in any area. Care providers, particularly those new to HIV care, may initially feel uncomfortable conducting these assessments. Resources are provided below for structured assessments; a team approach when possible may be helpful and allow for incorporation of multidisciplinary assessments, including those of a case manager and clinical social worker.

**Sexual health:** Discussion of <u>sexual health</u>, including a patient's history of STIs, is an important component of the baseline and annual assessments and is an opportunity to discuss a patient's concerns and questions. The frequency of the <u>sexual health assessment</u> is based on risk factors. It is particularly important to use nonjudgmental, sex-positive language in this



discussion to establish a strong connection and facilitate open discussion. Discussion of <u>U=U (undetectable = untransmittable)</u> in the clinical setting can facilitate reduction of stigma and discussion of important considerations in sexual health.

Reproductive status: Clinicians should ascertain reproductive history and goals with all patients and address contraception and plans for conception with patients of childbearing potential. Patients wishing to have children should be supported and provided with information on current strategies to eliminate perinatal HIV transmission. Risk of perinatal transmission is less than 1% when patients are virally suppressed and with informed management of the perinatal period [loannidis, et al. 2001]. For patients who are pregnant or planning pregnancy, care providers should discuss appropriate preconception planning, including folate use, medication safety, and plans for breastfeeding, as well as the risk to a partner without HIV if the patient has a detectable viral load. Education about HIV <u>pre-exposure</u> prophylaxis should be provided when indicated.

Menopause, whether natural or surgical, has been associated with increased fatigue and muscle aches or pains in people with HIV [Schnall, et al. 2018].

**Guide to the tables below:** Although the tables below are comprehensive in scope, this committee supports a flexible approach in using this guide to determine elements that should be included in a comprehensive initial history and physical examination. All aspects of the patient history and physical examination do not have to be covered in a single visit or by the primary care clinician. For some care providers and patients, the best approach may be to spend 2 or more visits completing the initial assessment and address some aspects of the history and physical examination during follow-up visits.

		Fre	equen	cy*
Assessment	To Include	1	Α	Е
Current HIV-Specifi	c Status and History			
HIV	History of HIV testing     Date and source of diagnosis     Route of exposure, if known     HIV type; if unknown, see NYSDOH AI guideline <u>Diagnosis and Management of HIV-2 in Adults</u>	I		
Antiretroviral therapy	<ul> <li>Date of ART initiation</li> <li>Current ART regimen</li> <li>Previous ART regimens and reasons for any changes in regimens</li> <li>History of drug resistance, if known</li> <li>Adverse effects</li> <li>Current adherence status and challenges</li> <li>Knowledge of <u>U=U</u></li> <li>If ART has not been initiated, see NYSDOH AI guideline <u>Rapid ART Initiation</u>.</li> </ul>	I	A	
Viral load	Most recent viral load     Peak viral load	I	Α	
CD4 cell count	Most recent CD4 cell count     Nadir CD4 cell count	I	А	
AIDS-defining conditions	<ul> <li>Previous diagnoses and treatments</li> <li>History of malignancies and treatments</li> <li>Investigation of symptoms such as weight loss, night sweats, or chronic cough</li> </ul>	I		
Opportunistic infections	<ul> <li>Previous OI prophylaxis</li> <li>Previous diagnoses and treatment, including latent TB infection</li> <li>Adverse reactions to medications for OI prophylaxis or treatment</li> </ul>	I		



#### Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV \*Frequency Key: I = initial (baseline) visit; A = annual visit; E = every visit Frequency\* **Assessment** To Include Ε **Current Medications** Complete medication • All medications: prescribed, over-the-counter, herbal preparations; Ε list include nonpharmacologic agents Potential drug-drug interactions Adverse effects · Challenges with adherence to prescribed medications Current General Medical Status and History **Immunizations** · History of immunizations Status of HIV- and age-related preventive immunizations Age-related disease Results of previous age-related disease screening tests Τ Α screening Cardiovascular • History of cardiac events, stroke, and treatment ı Α History of hypertension • History of diabetes or insulin resistance • Risk factors for CVD · Family history of CVD Respiratory History of COPD and treatment Ī Α Current tobacco/vape use and smoking history • History of prior malignancies and treatment Ī Cancer Α Previous age-appropriate screening and results · Family history of malignancies · History of renal disease and treatment ı Renal • Consider ART history • Consider associated comorbidities • History of and treatment for viral hepatitis (HAV, HBV, or HCV) Ī Hepatic Adverse reactions to medications • Risk factors for nonalcoholic steatohepatitis · Past alcohol use Current alcohol use • Symptoms of thyroid dysfunction or hypogonadism Endocrine ı Α · Sexual dysfunction · Weight loss or weight gain • Family history of metabolic syndrome and thyroid disease History of osteoporosis and treatment, fractures, and previous screening History of lipodystrophy and treatment • Use of hormonal therapy (including treatments obtained without • Current and previous ART use, which may contribute to metabolic syndrome, lipodystrophy, and insulin resistance Gastrointestinal · History of GI disease and treatment ı Α • GI-related adverse effects of medications and effect (if any) on adherence to prescribed medications Family history of GI disease Changes in vision, including blurry vision, double vision, flashes of light, Ī Vision Α loss of vision, use of glasses, and blindness or legal blindness Changes in hearing Ī Hearing Α Recent audiology testing or new hearing aid use



### Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV

\*Frequency Key: I = initial (baseline) visit; A = annual visit; E = every visit

		Fre	equen	су*
Assessment	To Include	ı	Α	E
Neurologic	<ul> <li>History of neurocognitive assessment and results</li> <li>Assessment of current neurocognitive status, preferably using standardized tools such as the MoCA Test (requires an account), MiniCog, or MMSE</li> <li>History of neuropathy and treatment</li> <li>Assessment of symmetric distal polyneuropathy, which is common,</li> </ul>	I	А	
Dermatologic	<ul> <li>particularly in patients exposed to earlier generations of ART</li> <li>History of psoriasis and treatment</li> <li>History of seborrheic dermatitis and treatment</li> <li>History of atopic dermatitis and xerosis and treatment</li> <li>History of skin cancer and treatment</li> <li>Note: Dermatitis can worsen with degree and duration of immunosuppression.</li> </ul>	I	A	
Surgery	<ul> <li>History of surgical procedures, including adverse reactions to anesthesia</li> <li>History of or planned gender-affirming surgery (see <u>WPATH Standards of Care Version 8</u>)</li> </ul>	I	Α	
Pain	<ul> <li>History of evaluation and treatment for chronic pain (initial visit)</li> <li>Current treatment for chronic pain (every visit)</li> <li>See CDC <u>Clinical Practice Guideline for Prescribing Opioids for Pain —</u>         United States, 2022</li> </ul>	I		E
Sleep	History of chronic obstructive sleep apnea and treatment     History of sleep disturbances and treatment	ı		
Nutrition	History of Steep disturbances and treatment     History of wasting     Dietary habits, including appetite     Food insecurity     Note: If indicated, see <u>USDA Food Security Survey Tools</u>			E
Frailty	<ul> <li>Functional status</li> <li>History of gait instability or other problems associated with frailty</li> <li>Assessment of current status using standardized tools, such as those available through the Comprehensive Geriatric Assessment Toolkit Plus</li> </ul>	I	A	
Travel	<ul> <li>Recent travel; assess for potential exposure to infectious disease</li> <li>Frequency and location of international travel (work or leisure)</li> <li>Status of travel-related immunizations</li> <li>Lifetime travel history, if indicated</li> </ul>	I	A	
Pets	<ul> <li>Current and past pet ownership, including exotic animals</li> <li>History of zoonotic diseases and treatment</li> </ul>	I	Α	

**Abbreviations:** ART, antiretroviral therapy; CDC, Centers for Disease Control and Prevention; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; GI, gastrointestinal; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; MMSE, Mini-Mental State Examination; NYSDOH AI, New York State Department of Health AIDS Institute; OI, opportunistic infection; TB, tuberculosis; U=U, undetectable = untransmittable; USDA, United States Department of Agriculture; WPATH, World Professional Association for Transgender Health.



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#### Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV \*Frequency Key: I = initial (baseline) visit; A = annual visit; N = as needed Frequency\* **Assessment** To Include Ν Gender and Sexual Identity Gender identity · Current gender identity and sex assigned at birth Τ Ν **Pronouns** History of sexual identity Current sexual I Α Ν identity Gender transition • Gender transition goals; successes and challenges 1 • History of, planned, or desired gender-affirming surgery • Current, past, or planned use of gender-affirming hormones • Source of gender-affirming hormones • Adverse effects of gender-affirming treatments Inventory of sexual • Presence or absence of penis, testes, prostate, breasts, vagina, cervix, 1 Α Ν uterus, and ovaries; determination of patient's preferred terms for body organs parts Current Psychosocial Status and History • Housing stability or connection to resources if housing is unstable Ν Housing ١ Relocation plans Monitor for signs of housing instability. Immediate and extended family members as defined by the patient Family and other Ī Α significant • Significant relationships relationships and · HIV disclosure status responsibilities • Financial and care-giving dependents, including children, spouse or life partner, aging parents, and extended or chosen family members • Community support, including functional needs and agency or family assistance Transportation · Pets in home · Monitor for signs of instability. Interpersonal and • Members of the patient's primary interpersonal and social support ı Α Ν social support network People to whom the patient has disclosed their HIV status network • Discussion of experienced and perceived stigma • Monitor for signs of instability. • Current employment status or employment goals Ī **Employment** Α Access to financial support if unemployed or under-employed • Employment-associated risks to health or well-being, including stigma and discrimination • Access to private medical insurance, Medicaid, ADAP, or Medicare Medical insurance ı Ν Prescription coverage Hospitalization coverage Access to resources for coverage if uninsured (see NYSDOH Uninsured Care Programs) Incarceration History of incarceration Ī Probation, parole, and other legal status End-of-life planning · Documented healthcare proxy Ī Α • Documented preferences for end-of-life care and living will • Long-term care plans



#### Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV \*Frequency Key: I = initial (baseline) visit; A = annual visit; N = as needed Frequency\* To Include Assessment Current Mental Health Status and History Mental illness • History of mental illness and treatment Adverse reactions to medications • History of psychiatric hospitalization • Suicide risk assessment and past history of suicide attempts Family history • See USPSTF: Screening for Depression in Adults (2016); assess mental health using standardized tools, such as the PHQ-2, PHQ-9, and C-SSRS. History of trauma, including domestic violence; physical, verbal, sexual, or Ī Trauma Α Ν emotional abuse; or witnessed trauma History or current experience of elder abuse Any effects on current function and coping strategies Stress • Current major stressors Ī Α Ν Stress management and coping skills • Current experience or history of HIV-associated or other stigmas Current Substance Use and History Alcohol • History of use, including use disorder diagnosis and treatment Ν Adverse reactions to medications Screening for current use, and if indicated, risk assessment using standardized tools If indicated, implementation of a harm reduction treatment plan • Current level of tobacco use and type; smoking prevalence is high in Tobacco use and Τ Ν vaping people with HIV [Pacek and Cioe 2015] History of use and prior treatment • Adverse reactions to medications • All types of drug use, including misused prescription medications ī Use of Α Ν • History of use, including use disorder diagnosis and treatment nonprescription drugs and misuse of · Route of use prescribed drugs • History of overdose Screening for current use, and if indicated, risk assessment using standardized tools • If indicated, implementation of a harm reduction treatment plan Sexual and Reproductive Health and History Sex partner(s) and Current sex partner(s) 1 Α Ν • HIV, ART, and viral load status of partner(s), if known; PrEP and other activity measures to prevent STIs used by partner(s) • Frequency of and preferred sexual activities; challenges History of sexual dysfunction · History of or current engagement in transactional sex • NYSDOH AI resources: GOALS Framework for Sexual History Taking in Primary Care, U=U Guidance for Implementation in Clinical Settings Sexually transmitted • History of and treatment for syphilis, gonorrhea, chlamydia, human Ī Α Ν infections papillomavirus, and other STIs • Source of prior treatment for any STI • Assessment of ongoing risk factors, and if indicated, implementation of harm or risk reduction plan; use of condoms or other barrier protection • Screening of all potentially exposed sites (see CDC Sexually Transmitted Infections Treatment Guidelines, 2021 > Screening Recommendations for evidence-based recommendations)



# Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV \*Frequency Key: I = initial (baseline) visit; A = annual visit; N = as needed

		Fre	quen	cy*
Assessment	To Include	ı	Α	N
Reproductive history	Offspring	I		
	Previous failed attempts at reproduction			
	Previous treatment for reproductive issues and source			
	Adverse effects			
	Contraceptive history			
	Previous abortion(s)			
Reproductive goals	Family planning goals	ı		N
	Contraception use and options			
	Possible drug-drug interactions for individuals taking ART			

**Abbreviations:** ADAP, AIDS Drug Assistance Program; ART, antiretroviral therapy; CDC, Centers for Disease Control and Prevention; C-SSRS, Columbia-Suicide Severity Rating Scale; NYSDOH AI, New York State Department of Health AIDS Institute; PHQ, Patient Health Questionnaire; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; U=U, undetectable = untransmittable; USPSTF, U.S. Preventive Services Task Force.

### **Laboratory and Diagnostic Testing**

Table 3, below, outlines recommended laboratory testing for adults with HIV.

		Fre	equen	су*
Laboratory Test	Comments	ı	Α	N
HIV-1 RNA quantitative viral load	uantitative viral effective ART.		A	N
CD4 lymphocyte count	<ul> <li>Check every 3 to 6 months if CD4 count &lt;200 cells/mm³; not indicated if viral load is consistently undetectable (CD4 count ≥200 cells/mm³).</li> <li>Monitor every 3 months if diagnosis is recent (&lt;2 years), viral load suppression is inconsistent, or CD4 count is close to or below 200 cells/mm³.</li> <li>See NYSDOH AI guideline Virologic and Immunologic Monitoring in HIV Care.</li> </ul>		A	N
HIV-1 resistance testing (genotypic)	<ul> <li>Perform at treatment initiation.</li> <li>Perform if HIV RNA (viral load) is ≥500 copies/mL; archive genotype may be considered if viral load is &lt;500 copies/mL.</li> <li>Consult with an expert in HIV care in the event of treatment failure.</li> </ul>			N
G6PD	<ul> <li>Consult with an expert in HIV care in the event of treatment failure.</li> <li>Screen for deficiency to avoid use of oxidant drugs, including dapsone, primaquine, sulfonamides.</li> <li>Prevalence of G6PD deficiency is highest among people of African, Asian, or Mediterranean descent, but consider in all patients given diversity of backgrounds.</li> </ul>			
Complete blood count	<ul> <li>For patients not taking zidovudine, check at initiation of ART and repeat as clinically indicated.</li> <li>For patients taking zidovudine, check at initiation and 4 weeks after initiation; follow every 3 months for the first year, then every 6 months.</li> <li>Consider with any change in medication.</li> </ul>	1	A	



### **Table 3: Recommended Laboratory Testing for Adults With HIV**

		Fre	equen	су*
Laboratory Test	Comments	ı	Α	N
Estimated glomerular filtration rate	<ul> <li>For patients taking TDF, check at initiation, then repeat at 4 weeks, 3 months, 6 months, and 12 months for the first year, then every 6 months thereafter.</li> <li>For patients not taking TDF, check at initiation, at 6 months during the first year, then annually thereafter.</li> <li>Check after initiation of medication with risk for renal disease (e.g., use of nonsteroidal anti-inflammatory agents, angiotensin-converting enzyme inhibitors).</li> <li>Check if patient has history of diabetes or other renal diseases.</li> </ul>	I	A	N
<ul> <li>Hepatic panel:</li> <li>Aspartate aminotransferase</li> <li>Alanine aminotransferase</li> <li>Alkaline phosphatase</li> <li>Total bilirubin</li> </ul>	<ul> <li>Check 3 months after initiation of ART, after initiating medication with risk for liver disease (e.g., statins, azoles), or if there is a history of viral hepatitis, and then at 12 months.</li> <li>Check every year if patient is stable and without above risks.</li> </ul>	ı	A	N
Random blood glucose (fasting or hemoglobin A1C if high)	<ul> <li>Check every 6 to 12 months if a patient has risk factors for diabetes (family history, obesity, use of protease inhibitors or integrase strand transfer inhibitors).</li> <li>If abnormal, repeat random glucose as a fasting glucose or A1C.</li> <li>Results are used to diagnose diabetes. See <u>Standards of Medical Care in Diabetes—2019 Abridged for Primary Care Providers</u>.</li> </ul>	I	A	N
Tuberculosis screening	<ul> <li>Obtain IGRA TB test (such as T-SPOT or QuantiFERON-TB) or tuberculin skin test (commonly known as PPD) at baseline for diagnosis of latent TB infection, unless the patient has previously tested positive for or has documented TB.</li> <li>Repeat annually for patients at risk (e.g., unstable housing, incarceration, travel, or immigration).</li> <li>Consider preventive therapy for patients with ≥5 mm reaction to PPD. See CDC TB Treatment for Persons with HIV and DHHS Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV &gt; Mycobacterium tuberculosis Infection and Disease.</li> </ul>	ı	А	
<ul><li>Hepatitis A</li><li>Anti-hepatitis A</li><li>immunoglobulin</li></ul>	Repeat after vaccination to ensure immunity.     See NYSDOH AI guideline Prevention and Management of Hepatitis A <u>Virus Infection in Adults With HIV &gt; Transmission and Prevention</u> for testing and vaccination recommendations.	I		N
<ul><li>Hepatitis B</li><li>Surface antibody</li><li>Surface antigen</li><li>Core antibody</li></ul>	<ul> <li>If HBsAg-positive, perform an HBV DNA viral load test.</li> <li>Repeat anti-HBs test after vaccination to ensure immunity.</li> <li>See NYSDOH AI guideline Prevention and Management of Hepatitis B         <u>Virus Infection in Adults With HIV &gt; HBV Screening and Diagnosis</u> and &gt;         <u>HBV Vaccination</u> for testing and vaccination recommendations.</li> </ul>	I		N
<ul><li>Hepatitis C</li><li>HCV antibody</li><li>HCV RNA quantitative viral load</li></ul>	<ul> <li>If patient was previously treated for HCV or is antibody-positive, perform HCV viral load test.</li> <li>Check at entry to care; repeat as clinically indicated for patients with exposure risk.</li> <li>See NYSDOH Al guideline Hepatitis C Virus Screening, Testing, and Diagnosis in Adults &gt; HCV Testing Sequence and Diagnosis.</li> </ul>	I		N



### **Table 3: Recommended Laboratory Testing for Adults With HIV**

*Frequency Key: I = ini	tial (baseline) visit; A = annual visit; N = as needed			
		Fre	equen	cy*
Laboratory Test	Comments	ı	Α	N
Varicella titer	<ul> <li>For patients with no evidence of immunity and CD4 count &gt;200 cells/mm³, consider vaccination for chicken pox (Varivax; 2 doses, 3 months apart); engage patients in shared decision-making, taking into consideration the potential risks of a live vaccine.</li> <li>Live vaccines are contraindicated for patients with CD4 counts &lt;200 cells/mm³.</li> <li>For patients ≥50 years old, regardless of varicella titer status or CD4 cell count, consider vaccination for herpes zoster with recombinant zoster virus (Shingrix; 2 doses, 2 to 6 months apart).</li> </ul>	I		
Urinalysis	<ul> <li>Evaluate for proteinuria.</li> <li>Check for symptoms of UTI or change in creatinine or other urinary symptoms (including glucosuria for patients on tenofovir).</li> <li>See NYSDOH AI guideline <u>Laboratory Monitoring for Adverse Effects of ART</u>.</li> </ul>	1	A	N
Urine pregnancy test	<ul> <li>Perform for all individuals of childbearing potential who are sexually active.</li> <li>Repeat at patient request.</li> </ul>	ı		N
Lipid panel	<ul> <li>Perform at least every 3 years if patient has increased risk for CVD.</li> <li>Consider annual screening if patient is taking protease inhibitors.</li> <li>For adults &gt;75 years old, initiate discussion of possible benefits of ageappropriate preventive therapies in the context of comorbidities and life expectancy.</li> <li>HIV is considered a risk-enhancing factor for CVD; clinicians may opt to perform more frequent lipid testing in patients with cardiovascular comorbidities.</li> </ul>		+/-	N
Serum thyroid- stimulating hormone	<ul> <li>Insufficient evidence exists for routine screening of nonpregnant adults.</li> <li>Adults with HIV have higher incidence of thyroid dysfunction than those without HIV. Discuss annual screening. See USPSTF <a href="Thyroid Dysfunction: Screening">Thyroid Dysfunction: Screening</a>.</li> </ul>		+/-	
Gonorrhea and chlamydia	<ul> <li>Perform baseline testing at oral, anal, urethral, and cervical sites for MSM and TGW and others as indicated by individual exposure.</li> <li>Repeat based on risk factors and sites of exposure.</li> <li>Repeat every 3 months for MSM and TGW. See NYSDOH STI self-collection outside of a clinic setting in New York State (NYS) Question &amp; Answer.</li> <li>See Update to the CDC's Treatment Guidelines for Gonococcal Infection, 2020.</li> </ul>		A	N
Syphilis	<ul> <li>Use same laboratory test consistently.</li> <li>Repeat at least annually</li> <li>Repeat every 3 months for patients with risk of exposure (e.g., MSM). See NYSDOH STI self-collection outside of a clinic setting in New York State (NYS) Question &amp; Answer.</li> </ul>	ı	A	N
Trichomonas	Perform screening test if the patient has a vagina and is sexually active.	ı	Α	N
HLA-B*5701	Must be performed before initiation of abacavir, otherwise not routine.			N

Abbreviations: anti-HBs, hepatitis B surface antibody; ART, antiretroviral therapy; CDC, Centers for Disease Control and Prevention; MSM, men who have sex with men; CVD, cardiovascular disease; DHHS, U.S. Department of Health and Human Services; FDA, U.S. Food and Drug Administration; G6PD, glucose-6-phosphate dehydrogenase; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; IGRA, interferon-gamma release assay; MSM, men who have sex with men; NYSDOH AI, New York State Department of Health AIDS Institute; PPD, purified protein derivative; TB, tuberculosis; TDF, tenofovir disoproxil fumarate; TGW, transgender women; USPSTF, U.S. Preventive Services Task Force; UTI, urinary tract infection.



### Routine Screening and Primary Prevention

### **☑** RECOMMENDATIONS

### **Routine Screening and Primary Prevention**

- For adults with HIV who are seen for primary care, clinicians should provide:
  - Risk-, age-, and sex-based screening as indicated and recommended in <u>Table 4: Routine Screening for Adults</u>
     With HIV (A3)
  - Primary preventive care as recommended in Table 5: Primary Prevention for Adults With HIV (A3)
- Clinicians and patients should engage in shared decision-making regarding routine health screening tests, weighing the risks and benefits of screening based on such factors as life expectancy, cost, potential harms, and HIV-compounded risk. (A3)

Prevention is the cornerstone of primary care and is mostly the same for patients with and without HIV. Tables 4 and 5, below, provide links to standard screening guidelines, some of which are specific to HIV.

Table 4: Routine Scree	ning for Adults With HIV	
Type of Screening [a]	Recommended Guideline(s) [b]	Age of Screening Initiation, Frequency, and Comments
Breast cancer [c]	USPSTF: Breast Cancer: Screening (2016) USPSTF: BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing (2019)	<ul> <li>Discuss screening with patients who are 50 to 75 years old every 2 years.</li> <li>Evidence of benefit is insufficient for patients who are &gt;75 years old.</li> <li>Begin screening as early as age 40 years for patients with family history of breast cancer (parent, sibling, or child).</li> </ul>
Colon cancer [c]	USPSTF: Colorectal Cancer: Screening (2021)	<ul> <li>Screen patients who are 45 to 75 years old: frequency depends on screening method. Confirm annually that appropriate testing has been completed.</li> <li>In patients who are &gt;75 years old, the decision to perform screening should be individualized.</li> </ul>
Cervical cancer [c]	NYSDOH AI: Screening for Cervical Dysplasia and Cancer in Adults With HIV (2022)	<ul> <li>Begin screening at 21 years old or within 2 years of onset of sexual activity.</li> <li>Continue screening for patients ≥65 years old; however, consider life expectancy and risk in shared decision-making with patient regarding continued screening.</li> <li>Recommendations for cervical cancer screening in patients with HIV are not the same as those for people who do not have HIV.</li> </ul>
Anal dysplasia and cancer	NYSDOH AI: Screening for Anal Dysplasia and Cancer in Patients With HIV (2022)	<ul> <li>Screen MSM, cisgender women, transgender women, and transgender men who are ≥35 years old.</li> <li>Engage younger patients in shared decision-making regarding screening or deferral until age 35 years.</li> <li>Recommendations for anal cancer screening in patients with HIV are not the same as those for people who do not have HIV.</li> </ul>
Lung cancer [c]	USPSTF: <u>Lung Cancer: Screening</u> (2021)	• Screen patients who are 55 to 80 years old who have a 20 pack-year history and currently smoke or have quit within the past 15 years.
Prostate cancer [c]	USPSTF: Prostate Cancer: Screening (2018)	<ul> <li>In patients who are 55 to 69 years old, the decision to perform screening should be individualized.</li> <li>Engage in shared decision-making for patients who are ≥70 years old.</li> </ul>



Table 4: Routine Scree	ning for Adults With HIV	
Type of Screening [a]	Recommended Guideline(s) [b]	Age of Screening Initiation, Frequency, and Comments
Bone density	USPSTF: Osteoporosis to Prevent Fractures: Screening (2018)	Some experts recommend baseline bone densitometry screening for osteoporosis in postmenopausal cisgender women and in cisgender men and transgender women ≥50 years old who have HIV [Thompson, et al. 2021; Aberg, et al. 2014].      See NYSDOH AI guideline Selecting an Initial ART Regimen > Special Considerations for Comorbid Conditions.
Abdominal aortic aneurysm	USPSTF: Abdominal Aortic Aneurysm: Screening (2019)	<ul> <li>Screen cisgender men and transgender women who are 65 to 75 years old who have ever smoked.</li> <li>There is insufficient evidence for or against screening in cisgender women and transgender men who have ever smoked.</li> </ul>

**Abbreviations:** CDC, Centers for Disease Control and Prevention; MSM, men who have sex with men; NYSDOH AI, New York State Department of Health AIDS Institute; USPSTF, U.S. Preventive Services Task Force.

#### Notes:

- a. An anatomical inventory is necessary to identify appropriate sex-based screening.
- b. If no NYSDOH Al guideline is available, the relevant USPSTF guideline is included; the USPSTF guidelines are comprehensive and evidence-based.
- c. Screening recommendations are the same for individuals with HIV and without HIV.

Туре	Recommended Guideline(s)	Comments
Tobacco smoking	USPSTF: Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions (2021)	USPSTF:  - Screen all adults for tobacco use.  - Recommend cessation.  - Provide behavioral interventions and FDA-approved pharmacologic therapy.  Resources: Millionhearts.hhs.gov:  - Protocol for Identifying and Treating Patients Who Use Tobacco  - Identifying and Treating Patients Who Use Tobacco: Action Steps for Clinicians  - Tobacco Cessation Change Package
Unhealthy alcohol and drug use	NYSDOH Al: Substance Use Screening and Risk Assessment in Adults (2020)	NYSDOH AI: Screen all adults for alcohol, tobacco, and drug use. Assess level of use and treat as indicated. Laboratory screening is not recommended. Resources: USPSTF: Unhealthy Alcohol Use in Adolescents and Adults: Screening and Behavioral Counseling Interventions (2018) NYSDOH AI: Substance Use Harm Reduction in Medical Care, Treatment of Alcohol Use Disorder, and Treatment of Opioid Use Disorder



Table 5. Primary Previ	ention for Adults With HIV	
Туре	Recommended Guideline(s)	Comments
Cardiovascular disease	USPSTF:  • Aspirin Use to Prevent Cardiovascular Disease: Preventive Medication (2022)  • Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication (2022)  • Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults	Resources:  • American College of Cardiology ASCVD Risk Estimator Plus  • Characteristics, Prevention, and Management of Cardiovascular Disease in People Living With HIV: A Scientific Statement From the American Heart Association
Depression	With Cardiovascular Risk Factors: Behavioral Counseling Interventions (2022)  USPSTF: Screening for Depression in Adults (2016)	USPSTF: Screen for depression, with adequate systems in place to ensure accurate diagnosis, effective
	. ,	treatment, and appropriate follow-up.  Resources:  - PHQ-2  - PHQ-9  - C-SSRS
Domestic violence	USPSTF: Intimate Partner Violence, Elder Abuse, and Abuse of Vulnerable Adults: Screening (2018)	Screen for domestic violence, including intimate partner violence, child abuse, and elder abuse.
Sexually transmitted infections	USPSTF: <u>Sexually Transmitted</u> <u>Infections: Behavioral Counseling</u> (2020)	<ul> <li>USPSTF: Provide behavioral counseling for all sexually active adults and adolescents.</li> <li>Include discussion of appropriate vaccinations.</li> </ul>
Neural tube defects in pregnancy	USPSTF: Folic Acid for the Prevention of Neural Tube Defects: Preventive Medication (2017)	USPSTF: Folic acid supplementation is recommended for individuals who are planning or capable of pregnancy.
Breast cancer	USPSTF: Breast Cancer: Medication Use to Reduce Risk (2019)	<ul> <li>USPSTF:         <ul> <li>Risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors are recommended for women who are at increased risk of breast cancer and at low risk of medication-related adverse events.</li> <li>Routine preventive medication is not recommended for women who are not at increased risk.</li> </ul> </li> <li>Note: This committee advises clinicians to screen for breast cancer in transgender and transfeminine men and cisgender females.</li> </ul>
Skin cancer	USPSTF: Skin Cancer Prevention: Behavioral Counseling (2018)	USPSTF: Counsel patients to minimize ultraviolet radiation.
Falls	USPSTF: Falls Prevention in Community-Dwelling Older Adults: Interventions (2018)	<ul> <li>USPSTF: Exercise interventions are recommended for adults ≥65 years old who are at increased risk for falls.</li> <li>Note: This committee advises clinicians to include osteoporosis screening.</li> </ul>

**Abbreviations:** ASCVD, atherosclerotic cardiovascular disease; C-SSRS, Columbia-Suicide Severity Rating Scale; FDA, U.S. Food and Drug Administration; NYSDOH AI, New York State Department of Health AIDS Institute; PHQ, Patient Health Questionnaire; USPSTF, U.S. Preventive Services Task Force.



## **Prevention of Opportunistic Infections**

### **☑** RECOMMENDATIONS

### **Prevention of Opportunistic Infections**

- Clinicians should initiate prophylaxis for specific OIs and discontinue prophylaxis as indicated in <u>Table 6: Prophylaxis</u> for Opportunistic Infections in Adults With HIV. (A\*)
  - Before initiating dapsone, clinicians should test patients for G6PD deficiency. (A\*)
- Clinicians may discontinue primary OI prophylaxis in patients who are taking effective ART and have evidence of immune recovery. (A\*)

Abbreviations: ART, antiretroviral therapy; G6PD, glucose-6-phosphate dehydrogenase; OI, opportunistic infection.

The incidence of and mortality related to OIs have decreased since the early days of the HIV epidemic, but OIs remain a concern [Masur 2015]. Although the median initial CD4 cell count in individuals newly diagnosed with HIV has risen through the years [NYSDOH 2019], a significant number of people have low CD4 cell counts at HIV diagnosis and are at risk for OIs [Tominski, et al. 2017; Ransome, et al. 2015]. It is essential that clinicians who care for patients with HIV can identify common OIs and know when to provide and discontinue appropriate prophylaxis (see Table 6, below).

Table 6: Prophylaxis for Opportunistic Infections in Adults With HIV				
Opportunistic Infection	Indications for Initiation and Discontinuation of Primary Prophylaxis	Preferred and Alternative Agent(s)	Indications for Discontinuation of Secondary Prophylaxis	
Cryptococcosis	Primary prophylaxis is not routinely recommended.	N/A	<ul> <li>CD4 count &gt;100 to 200 cells/mm³ for ≥6 months</li> <li>Completed initial therapy, maintenance therapy for 1 year, and is asymptomatic for cryptococcosis</li> </ul>	
Cytomegalovirus	Primary prophylaxis is not routinely recommended.	N/A	<ul> <li>CD4 count &gt;100 to         150 cells/mm³ for             ≥6 months     </li> <li>No evidence of active disease</li> <li>Engaged in routine ophthalmologic examination</li> </ul>	
Mycobacterium avium complex	<ul> <li>Initiation: Not recommended for individuals who are rapidly initiating ART or who are on ART and have an undetectable viral load</li> <li>Discontinuation: Taking ART and CD4 count &gt;100 cells/mm³ for ≥3 months</li> </ul>	Preferred: Azithromycin; clarithromycin     Alternative: Rifabutin; azithromycin plus rifabutin	<ul> <li>Taking ART and CD4         count &gt;100 cells/mm³         for ≥6 months</li> <li>At least 12 months of         MAC treatment         completed [a]</li> <li>Asymptomatic for MAC</li> </ul>	



Opportunistic Infection	Indications for Initiation and Discontinuation of Primary Prophylaxis	Preferred and Alternative Agent(s)	Indications for Discontinuation of Secondary Prophylaxis
Pneumocystis jiroveci pneumonia (formerly Pneumocystis carinii pneumonia)	<ul> <li>Initiation: CD4 count         &lt;200 cells/mm³ (or         &lt;14%) or history of         oropharyngeal         candidiasis</li> <li>Discontinuation: Taking         ART and CD4 count         &gt;200 cells/mm³ for         ≥3 months</li> </ul>	Preferred: TMP/SMX single strength once daily     Alternatives:	<ul> <li>Taking ART and CD4         count &gt;200 cells/mm³         for ≥3 months</li> <li>Adequate viral         suppression</li> <li>Continue prophylaxis if         PJP occurs with CD4         count &gt;200 cells/mm³         (or &lt;14%)</li> <li>Consider stopping         prophylaxis if viral load is         suppressed for         ≥3 months and CD4         count &gt;100 cells/mm³</li> </ul>
Toxoplasma gondii encephalitis [a,c]	<ul> <li>Initiation: CD4 count     &lt;100 cells/mm³ and     positive serology for         <i>Toxoplasma gondii</i>         (lgG+)</li> <li>Discontinuation: Taking         ART and CD4 count         &gt;100 cells/mm³ for         ≥3 months</li> </ul>	Preferred: TMP/SMX single strength once daily     Alternatives:     Dapsone [b] plus pyrimethamine plus leucovorin     Atovaquone with or without pyrimethamine plus leucovorin	<ul> <li>Taking ART and CD4         count &gt;200 cells/mm³         for ≥6 months</li> <li>Initial therapy         completed</li> <li>Asymptomatic for TE</li> </ul>

**Abbreviations:** ART, antiretroviral therapy; G6PD, glucose-6-phosphate dehydrogenase; lgG, immunoglobulin G; MAC, *Mycobacterium avium* complex; PJP, *Pneumocystis jiroveci* pneumonia; TE, *Toxoplasma* encephalitis; TMP/SMX, trimethoprim/sulfamethoxazole.

#### Notes:

- a. Obtaining blood cultures or bone marrow cultures may be advisable to ascertain disease activity.
- b. Screen for G6PD deficiency before initiating dapsone.
- c. Lifelong prophylaxis to prevent recurrence is indicated in adults or adolescents with a childhood history of toxoplasmosis.

### **Oral Health Complications**

Dental Standards of Care Committee, May 2016

Oral health care is a critical component of comprehensive HIV medical management. Development of oral pathology is frequently associated with an underlying progression of HIV-disease status. A thorough soft-tissue examination may reveal pathology associated with dysphagia or odynophagia. Dental problems can result in or exacerbate nutritional problems. In addition, psychosocial and quality-of-life issues frequently are associated with the condition of the oral cavity and the dentition.

**Medications and oral health:** Many of the medications taken by patients with HIV have side effects that may manifest in the oral cavity. Potential side effects include the following:

- Candidal growth: Antibiotics may cause or exacerbate
- · Xerostomia: Antihistamines, antidepressants, antipsychotics, antihypertensives, and anticholinergic agents
- Increased risk of dental caries: Clotrimazole troches and nystatin suspension pastilles (contain sugar)
- Gingival hyperplasia: Phenytoin
- Oral ulcers: Zalcitabine (DDC)



### **Good practice reminders:**

- **Dental care referral:** Include as part of every primary health care initial visit; semiannual oral healthcare visits are essential to dental prophylaxis and other appropriate preventive care. In the later stages of HIV disease, greater numbers of oral lesions and aggressive periodontal breakdown are more likely and may necessitate oral healthcare visits more frequently than twice per year.
- Oral examination: Include a visual examination and palpation of the patient's lips, labial and buccal mucosa, all surfaces of the tongue and palate, and the floor of the mouth in the overall physical examination performed during a primary care visit. The gingiva should be examined for signs of erythema, ulceration, or recession. Refer patients found to have oral mucosal, gingival, or dental lesions for a visit to an oral healthcare provider as soon as possible for appropriate diagnostic evaluation and treatment.
- **Oral care education:** Include preventive oral health care in primary care patient education to stress the importance of regular dental visits, brushing, flossing, and the use of fluorides and antimicrobial rinses.



### All Recommendations

### ☑ ALL RECOMMENDATIONS: COMPREHENSIVE PRIMARY CARE FOR ADULTS WITH HIV

### History, Assessment, and Evaluation

- For all adults with HIV who present for primary care, clinicians should perform the baseline assessments detailed in the following tables (A3):
  - Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV
  - Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV
  - Table 3: Recommended Laboratory Testing for Adults With HIV
- Clinicians should repeat these assessments as indicated in Tables 1, 2, and 3. (A3)

### **Routine Screening and Primary Prevention**

- For adults with HIV who are seen for primary care, clinicians should provide:
  - Risk-, age-, and sex-based screening as indicated and recommended in <u>Table 4: Routine Screening for Adults</u>
     With HIV (A3)
  - Primary preventive care as recommended in Table 5: Primary Prevention for Adults With HIV (A3)
- Clinicians and patients should engage in shared decision-making regarding routine health screening tests, weighing the risks and benefits of screening based on such factors as life expectancy, cost, potential harms, and HIV-compounded risk. (A3)

### **Prevention of Opportunistic Infections**

- Clinicians should initiate prophylaxis for specific OIs and discontinue prophylaxis as indicated in <u>Table 6: Prophylaxis</u> for Opportunistic Infections in Adults With HIV. (A\*)
  - Before initiating dapsone, clinicians should test patients for G6PD deficiency. (A\*)
- Clinicians may discontinue primary OI prophylaxis in patients who are taking effective ART and have evidence of immune recovery. (A\*)

Abbreviations: ART, antiretroviral therapy; G6PD, glucose-6-phosphate dehydrogenase; OI, opportunistic infection.

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# Supplement: Guideline Development and Recommendation Ratings

Table S1: Guideline Deve	Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program		
Developer	New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program		
Funding source	NYSDOH AI		
Program manager	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See <a href="Program Leadership">Program Leadership</a> and Staff.		
Mission	To produce and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for practitioners who provide prevention or treatment of HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders for adults throughout New York State in the wide array of settings in which those services are delivered.		
Expert committees	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout New York State to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of New York State, all relevant clinical practice settings, key New York State agencies, and community service organizations.		
Committee structure	<ul> <li>Leadership: Al-appointed chair, vice chair(s), chair emeritus, clinical specialist(s), JHU Guidelines Program Director, Al Medical Director, Al Clinical Consultant, AVAC community advisor</li> </ul>		
	Contributing members		
	Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders		
Disclosure and management of conflicts of interest	<ul> <li>Annual disclosure of financial relationships with commercial entities for the 12 months prior and upcoming is required of all individuals who work with the guidelines program, and includes disclosure for partners or spouses and primary professional affiliation.</li> <li>The NYSDOH AI assesses all reported financial relationships to determine the potential for undue influence on guideline recommendations and, when indicated, denies participation in the program or formulates a plan to manage potential conflicts. Disclosures are listed for each committee member.</li> </ul>		
Evidence collection and review	<ul> <li>Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update.</li> <li>A comprehensive literature search and review is conducted for a new guideline or an extensive update using PubMed, other pertinent databases of peer-reviewed literature, and relevant conference abstracts to establish the evidence base for guideline recommendations.</li> <li>A targeted search and review to identify recently published evidence is conducted for</li> </ul>		
	<ul> <li>guidelines published within the previous 3 years.</li> <li>Title, abstract, and article reviews are performed by the lead author. The JHU editorial team collates evidence and creates and maintains an evidence table for each guideline.</li> </ul>		



### Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program

# Recommendation development

- The lead author drafts recommendations to address the defined scope of the guideline based on available published data.
- Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations.
- When published data are not available, support for a recommendation may be based on the committee's expert opinion.
- The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.

# Review and approval process

- Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the Al Community Advisory Committee.
- Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations.
- Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.

#### **External reviews**

- External review of each guideline is invited at the developer's discretion.
- External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.

### **Update process**

- JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations.
- If changes in the standard of care, newly published studies, new drug approval, new drugrelated warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates and will invite full committee review as indicated.

Table S2: Recommendation Ratings and Definitions		
Strength	Quality of Evidence	
A: Strong B. Moderate	Based on published results of at least 1 randomized clinical trial with clinical outcomes or validated laboratory endpoints.	
C: Optional	* Based on either a self-evident conclusion; conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.	
	Based on published results of at least 1 well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.	
	2 <sup>†</sup> Extrapolated from published results of well-designed studies (including nonrandomized clinical trials) conducted in populations other than those specifically addressed by a recommendation. The source(s) of the extrapolated evidence and the rationale for the extrapolation are provided in the guideline text. One example would be results of studies conducted predominantly in a subpopulation (e.g., one gender) that the committee determines to be generalizable to the population under consideration in the guideline.	
	3 Based on committee expert opinion, with rationale provided in the guideline text.	