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IDSA GUIDELINES

Primary Care Guidance for Providers Who Care for Persons With Human Immunodeficiency Virus: 2024 Update by the HIV Medicine Association of the Infectious Diseases Society of America

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Advances in antiretroviral therapy (ART) have made it possible for persons with human immunodeficiency virus (HIV) to have a lifespan that approaches that of people without HIV without progressing to AIDS or transmitting HIV to sexual partners or infants. There is, therefore, increasing emphasis on maintaining health throughout the lifespan. To receive optimal medical care and achieve desired outcomes, persons with HIV must be consistently engaged in care and able to access uninterrupted treatment, including ART. Comprehensive, evidence-based HIV primary care guidance is, therefore, more important than ever. Creating a patient-centered, stigma-free care environment is essential for care engagement. Barriers to care must be decreased at the societal, health system, clinic, and individual levels. As the population ages and noncommunicable diseases arise, providing comprehensive healthcare for persons with HIV becomes increasingly complex, including management of multiple comorbidities and the associated challenges of polypharmacy while also attending to HIV-specific health concerns. Clinicians must address issues specific to preventive health, including cancer screening, providing recommended vaccinations, and promoting sexual health, including sexually transmitted infection diagnosis, treatment, and prevention. Clinicians also must address issues for specific populations, including persons of childbearing potential during preconception and pregnancy, children, adolescents, and transgender and gender-diverse individuals. This guidance from an expert panel of the HIV Medicine Association of the Infectious Diseases Society of America updates the previous 2020 HIV Primary Care Guidance.

Keywords. HIV; primary care; immunizations; comorbidities; STIs.

Continuous access to antiretroviral therapy (ART) and engagement in a patient-centered, stigma-free, high-quality care environment are essential to assist people with human immunodeficiency virus (HIV) to achieve their health goals, improve their quality and length of life, and eliminate HIV transmission to sexual partners and infants through viral suppression. As effective ART has become simpler over time, HIV care and the care environment have become increasingly complex, and updated HIV primary care guidance is needed. As people with HIV live longer, clinicians must attend to preventing and managing comorbidities and coinfections that often occur earlier and more frequently in people with HIV than in people without HIV. This becomes increasingly important as individuals age. Likewise, screening for and addressing substance use and mental health conditions throughout the lifespan is essential to effective HIV care. At the same time, a strained HIV workforce struggles to provide care to an ever-increasing population of people with HIV and to do so with diminishing resources. Many people with HIV, including those at increased likelihood of acquiring HIV, disproportionately experience barriers to accessing care and treatment, including income inequality, unstable housing, food insecurity, joblessness, and poor access to transportation.

Received 30 August 2024; editorial decision 08 September 2024; published online 12 October 2024

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Clinical Infectious Diseases®

https://doi.org/10.1093/cid/ciae479

These barriers are embedded in a social framework interwoven with racism, sexism, and discrimination against those whose race, ethnicity, sexual orientation, or gender identity is in the minority. Increasingly, HIV care must acknowledge and address these issues to end the HIV epidemic in all populations. Ensuring that clinical settings are free of stigma and discrimination is a first and essential step. Unfortunately, the United States is still far below its goals for ending the epidemic. The most recent available data show that among all people estimated to be living with HIV (diagnosed or undiagnosed), only 57% had suppressed virus, with lower levels among Black, Hispanic/Latino, and Indigenous populations; people who inject drugs; and heterosexual cisgender men. Only 47% of all people with HIV met the definition for care retention, with even lower rates in many populations [1]. Such disparities highlight the fact that HIV care, as well as HIV prevention, must be person-centered, inclusive of attention to social determinants of health, and based on equity.

While this Guidance primarily addresses care for people with HIV, a patient-centered and individualized approach to HIV prevention and care is required to end the HIV epidemic. Substantial health disparities that are driven by societal inequities continue to be seen among those with new HIV diagnoses. Although pre-exposure prophylaxis (PrEP) is a highly effective tool for HIV prevention, its implementation is not yet equity-based or centered in the populations who would most benefit [2–4]. Some HIV care providers also provide PrEP, but expansion of both HIV testing and PrEP access is needed using novel service-delivery approaches that are beyond the traditional clinic visit to improve access. Similarly, the ongoing sexually transmitted infection (STI) epidemic disproportionately affects people with and vulnerable to HIV. STI screening, treatment, and prevention should be included in a syndemic approach to HIV prevention and care.

All of these factors contribute to the need for evolving HIV care recommendations in order to meet new and intensified challenges. This version of the Primary Care Guidance for Providers Who Care for Persons With Human Immunodeficiency Virus contains an expanded section devoted to patient-centered optimization of HIV care, including use of tools such as multidisciplinary care teams, telehealth, and street medicine. The Guidance has new sections devoted to immunizations, cancer screening, and STIs, including a focus on mpox (formerly monkeypox) and STI prevention using doxycycline postexposure prophylaxis (doxyPEP). An updated discussion of metabolic diseases addresses statin use in people with HIV as well as approaches to comorbidity screening and management. A section on children with HIV has been added, along with updated sections on care for adolescents, persons of childbearing potential, and transgender and gender-diverse populations, and on coronavirus disease 2019 (COVID-19) and people with HIV.

METHODS

Panel Composition

Participants on the panel are HIV Medicine Association (HIVMA) members who are experts in the care of persons with HIV and who volunteered to participate. Two co-chairs (M. A. H. and M. A. T.) with experience in developing guidelines led the expert panel.

Literature Review, Analysis, and Consensus Development of Evidence-based Recommendations

The expert panel, with the assistance from a consultant experienced in medical literature reviews, conducted a literature review to identify new contributions to the field from the date of the last guideline publication in 2020 to December 2023, except when noted in the literature cited. In particular, changes to key guidelines and recommendations and late-breaking data deemed to be practice-changing were included up to the time of manuscript submission. Panel members responsible for each section evaluated the evidence and developed recommendations accordingly. The entire panel reviewed all recommendations, and decisions on the final recommendations were made by consensus based on the evidence. The full panel participated in reviewing and editing the final document. A medical writer contributed to copy editing and formatting prior to submission.

Disclosure and Management of Potential Conflicts of Interest

All panel members complied with the Infectious Diseases Society of America (IDSA) policy on conflicts of interest, which requires disclosure of any financial or other interest that might be construed as constituting an actual, potential, or apparent conflict. Panel members were provided with IDSA's conflict of interest disclosure statement and asked to identify ties to companies that develop products that might be affected by promulgation of the guidance or any other potential conflicts. Information for panel members and spouses was requested regarding employment, consultancies, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory committees. Disclosure of new conflicts of interest was solicited at the beginning of each panel meeting. The panel made decisions on a case-by-case basis as to whether an individual's role should be limited as a result of a conflict or potential conflict. No limiting conflicts were identified.

RECOMMENDATIONS FOR THE PRIMARY CARE OF PERSONS WITH HIV

The following recommendations are based on evidence available to the panel at the time of publication. Many of the recommendations refer to other guidelines and recommendations, including, but not limited to, those from the Department of Health and Human Services (HHS), Centers for Disease

Control and Prevention (CDC), and the CDC Advisory Committee on Immunization Practices (ACIP), with the recognition that these sources evolve over time and that no single primary care guidance publication can fully anticipate these changes. In general, recommendations from the most current versions of guidelines and ACIP recommendations should be followed.

SECTION 1: OPTIMIZING CARE ENGAGEMENT, MEDICATION ADHERENCE, AND VIRAL SUPPRESSION

Recommendations

- All persons with HIV should be provided timely access to routine and urgent medical care via a patient-centered approach, beginning with Rapid ART at entry, if feasible.
- Longitudinal low-barrier models, such as extended or nontraditional business hours, walk-in acute or primary care, telehealth, and alternate care venues, including street medicine, should be incorporated as feasible.
- HIV care sites should provide linguistically and culturally appropriate care.
- HIV care sites should maximize diversity of the workforce to represent the patient population served in terms of gender identity, sexual orientation, race, ethnicity, primary language, and meaningful representation of persons with HIV.
- HIV care sites should implement programs that incorporate evidence-based and evidence-informed interventions shown to improve HIV care engagement and viral suppression, including providing gender-affirming and trauma-informed care, addressing structural and social determinants of health, and integrating mental health and substance use treatment with harm reduction and cultural humility at the core.
- HIV care sites should use a multidisciplinary team model but identify a primary clinician with experience and expertise in HIV for each patient and support the development of trusting long-term patient–clinician relationships.
- Because HIV-related stigma and misinformation remain highly prevalent within healthcare systems, HIV care site employees and clinicians should advocate for patients' rights throughout the healthcare system to ensure that people with HIV are appropriately considered for medical and surgical procedures.
- Surgical and dental decisions for people with HIV should be based on shared decision-making among the HIV specialist, surgeon, and patient while weighing all relevant factors and should not depend on the CD4 cell count or HIV RNA level alone.
- People with HIV should be considered as both solid organ recipients (regardless of donor HIV status) and solid organ donors to people with HIV.

Evidence Summary

Initiating ART on the day of or within 7 days of diagnosis is considered Rapid ART [5]. Rapid ART is a pillar of Ending the HIV Epidemic: A Plan for America and the National HIV/AIDS Strategy, while also being endorsed in each of the major clinical HIV treatment guidelines [6–9]. ART should be offered unless a clinical concern exists that warrants delaying ART initiation, such as cryptococcal or tuberculous meningitis, or if the patient expresses a desire to delay therapy. Structural, systemic, or programmatic barriers that would impede Rapid ART should be removed [10]. Elimination of barriers to the initial linkage to care leads to shorter times to viral suppression. Delay from diagnosis to the initial appointment for HIV care has been shown to be a predictor of failure to engage in care, which Rapid ART mitigates [11]. Persons engaged in Rapid ART programs may need enhanced support to achieve continuous care engagement and viral suppression [12].

The long-term effectiveness of ART is dependent on durable suppression of viral replication. Clinicians should emphasize that viral suppression not only improves the patient's health but prevents HIV transmission to others [13]. "Undetectable = Untransmittable" (U = U) messaging is welcomed and encouraged by communities with HIV and should be part of routine messaging in the clinic to mitigate stigma and encourage ART adherence. Pursuit of viral suppression should ensure that those individuals whose virus is not suppressed do not feel further stigmatized. Conversations should be conducted in a nonjudgmental fashion and should seek reasons and potential solutions for the adherence challenges that result in viremia. Stigma mitigation is important to optimizing adherence and viral suppression as stigma is a significant driver of care disengagement and adherence challenges [14].

Wherever persons with HIV are cared for, people-first language (such as "people with HIV" instead of "HIV-infected people") and gender-affirming language should be used, and appropriate pronouns and names should be used in electronic health records and when addressing patients directly [15]. Knowledge dissemination is critical to combating stigma in healthcare settings, while many myths about HIV remain [16, 17]. Clinicians should disseminate knowledge regarding scientific advances, including that HIV is a chronic illness in the setting of effective ART; that risk of transmission in healthcare settings is <1% with no reports of healthcare transmission in the modern ART and post-exposure prophylaxis (PEP) era; and that surgical and dental decisions should be based on shared decision-making among the HIV specialist, surgeon, and patient while weighing all relevant clinical factors. Decisions related to surgical and dental procedures should not depend on the CD4 cell count or HIV RNA level alone [18, 19]. Furthermore, people with HIV can be considered as both recipients and donors in solid organ transplantation, and HIV alone should not be an exclusionary factor [20–23]. People with HIV can receive

organs from all donors, while people with HIV can only donate organs to other people with HIV. The HIV Organ Policy Equity Act, enacted in 2013, reversed a federal ban on use of organs from people with HIV in recipients with HIV and set standards for research and clinical care in solid organ transplantation among people with HIV. It is important for clinicians to consider referrals for transplantation; updated lists of approved transplantation centers for people with HIV are accessible through the Health Resources and Services Administration Organ Transplantation and Procurement Network webpage [24].

The primary reason for treatment failure, particularly among patients on their first ART regimen, is suboptimal adherence to care or treatment regimens [25, 26]. Medication adherence is essential to achieving and maintaining viral suppression with modern ART, although 100% adherence may not always be necessary for optimal viral suppression outcomes [27]. Discussions and education around adherence to ART should use an empathetic lens with the goal of identifying barriers to adhering to regular medication use and brainstorming feasible solutions. Counseling about the importance of medication adherence should be provided carefully and thoughtfully so as not to perpetuate (or lead to) a sense of self-guilt or anxiety about missed doses. Further, inconsistent adherence may be linked to other important health outcomes, for example, cardiovascular disease and increased mortality, even in the setting of viral suppression [28].

There are many drivers of poor treatment adherence including inconsistent access to medications (including inability to afford medications, limited pharmacy hours, requirements to pick up prescription refills monthly); structural and societal-level barriers (including inadequate transportation; health system barriers to engagement; food or housing insecurity; stigma and discrimination based on HIV status, race, ethnicity, gender identity, sexual orientation, disability, or immigration status); clinic-level barriers (including stigmatizing/discriminatory language or practice by office staff or clinicians, restrictive hours, inaccessible location, lack of a mutually trusting and respectful, collaborative patient–clinician relationship); and patient-level barriers (mental health and substance use issues, pill fear, pill fatigue) [29–34]. Additionally, periods of transition (eg, postpartum, relocation, employment/insurance changes, incarceration) may lead to disengagement in care. Some populations may warrant dedicated programs and support to assist with care reengagement [35]. All of these factors must be considered when designing systems to improve care engagement.

Adherence to care means not only medication adherence but also medical visit attendance and continual engagement in care [36]. Low adherence to visits and poor engagement in care have been found to predict approximately 50% higher mortality among persons with HIV [37]. Thus, it is critically important that HIV care providers and clinics have evidence-based and evidence-informed strategies to effectively engage and assist patients in staying in care [38]. Interventions that improve care engagement or viral suppression generally achieve 1 of 3 things: care coordination through a multidisciplinary team of providers (both physical and behavioral health) and social supports, provision of an essential need such as housing or food assistance, or creation of an environment that elicits and acknowledges patients' goals, motivations, and care needs. Specific considerations may include physical location, clinic environment, and the individual's biopsychosocial situation. Inherent in each of these is a strengths-based approach that leverages a patient's strengths as a part of the solutions [39]. While many interventions have demonstrated some impact on care engagement and adherence to medication, none have a very large effect size [38]. Barriers to care are heterogeneous; therefore, programs to overcome these barriers will need to be similarly heterogeneous. Differentiated service delivery, whereby the location, intensity, frequency of the service, and who delivers that service are tailored to individual needs, is a model that factors in heterogeneous needs at a large scale [40].

Components that could provide a foundation for individual care engagement include social engagement programs, reminders around the clinic about the importance of attending appointments, patient navigation (including enhanced personal contacts), financial incentives, nutrition assistance, and mobile health platforms that leverage mobile devices to better engage patients [41–46]. Intake assessments and ongoing assessments of barriers to care should include social and economic factors such as stigma, violence, social support, food insecurity, unstable housing, and transportation challenges. Lack of adequate food or safe housing can impact the ability to remain adherent to a treatment regimen and even be associated with increased risk of death [47]. Early assessment by a qualified social worker or case manager is essential, and ongoing access to effective case management teams is necessary to overcome barriers to care [48].

At times, how and where care is delivered needs to shift entirely. Accordingly, there are several promising new care models that can help advance access and thus improve health outcomes. Telehealth is a technological innovation that was widely implemented during the COVID-19 public health emergency that allows clinicians to interface with patients via synchronous audio or video to overcome barriers and improve continuity of care [49]. Telehealth consultations can be leveraged to bring HIV care to a primary care clinic or resource-limited and rural settings or to address the shortage of HIV clinicians via peer mentoring [50–54]. The Centers for Medicare & Medicaid Services guidance issued in June 2023 requires audio-video technology for most nonbehavioral telehealth consultations and permits audio-only for mental health encounters [55]. A systematic review showed improved physician-defined outcomes with videoconferencing as opposed to audio-only.

However, because patient outcomes were comparable between videoconference and audio-only, lack of videoconferencing capability should not be a barrier to telehealth encounters [56]. The benefits of a telehealthcare model include enhanced access to a multidisciplinary care team, on-demand care, and flexibility [57]. Despite these benefits, telehealth has the potential to introduce privacy and confidentiality concerns and potentially worsen disparities via the digital divide [58–60]. Telehealth also operates under ambiguous state-by-state piecemeal regulations that change in a dynamic environment. Laboratory and vaccination coordination are additional challenges. Telehealth can, however, bring evidence-based care to resource-limited populations such as incarcerated individuals and people who inject drugs. The Drug Enforcement Agency and Substance Abuse and Mental Health Services Administration rules have approved telehealth as an acceptable modality for medications for opioid use disorder and other co-occurring mental health disorders [61–63]. Further, telehealth provides an opportunity to optimize HIV care through low-barrier models such as harm reduction, an approach to healthcare that is guided by the philosophy of "meeting people where they are," both mentally and physically, and treating them with dignity and respect [64]. Syringe services programs and potential alternative care venues are the cornerstone of harm reduction, aimed at mitigating the harms associated with injection drug use [65]. Another low-barrier model is street medicine, a rapidly evolving form of harm reduction that sets the traditional healthcare system aside and enables providers to physically meet people from vulnerable communities (including persons who are unhoused) at sites accessible to them, such as walk-in clinics and other alternative care venues [66–71]. The incorporation of these innovative modalities into the practice of HIV medicine offers an opportunity to optimize care engagement in diverse and need-to-reach communities.

The quality of the patient–provider relationship is often cited as one of the most important factors in care engagement. Having a provider with whom the patient feels comfortable and can communicate effectively and honestly is key to developing this type of relationship [32, 72, 73]. The multidisciplinary care model for care coordination often helps patients remain in care, identifies unmet care needs, and improves adherence to medications [74–76]. Having an HIV team that includes a case manager, social worker, or staff with similar responsibilities and skills has been shown to enhance adherence to care and engagement [39]. Other team members may include physicians, HIV clinical pharmacists, nurses, nurse practitioners, physician assistants, mental health professionals, peers, health educators, patient navigators, and nutritionists. Culturally and linguistically competent care is critical to successful care engagement. Stigma mitigation is facilitated by diversifying the workforce to represent the patient population served in terms of gender identity, sexual orientation, race, ethnicity, and primary language and by ensuring meaningful representation of persons with HIV. A broad range of components, from having staff of the same race, culture, or lifestyle to having art and reading material in the clinic that reflects the culture of the local community, may be useful in facilitating this goal [77]. Tailored programs that facilitate care engagement are an essential component of effectively caring for persons with HIV. Ensuring the meaningful involvement of people with HIV in program design and implementation is critical to shaping clinical programs that prioritize access and care engagement.

Ongoing monitoring of care engagement and viral suppression is one element in a comprehensive package of quality and performance measures that can enhance care outcomes for persons with HIV. A national expert panel with participants from HIVMA and IDSA has developed HIV quality-of-care performance metrics [78]. These metrics are endorsed by the National Quality Forum and the CMS and have been adopted by many care organizations. Importantly, mortality decreases when performance measures are met [79].

SECTION 2: INITIAL EVALUATION AND IMMEDIATE FOLLOW-UP FOR PERSONS WITH HIV

Recommendations

- A comprehensive present and past medical history that includes HIV-related information, medication/social/family history (Tables 1 and 2), review of systems, and physical examination (Table 3) should be obtained for all patients upon initiation of care, ideally at the first visit or, if not feasible, as soon as possible after the first visit. In particular, in settings of Rapid ART initiation, clinicians may initially truncate parts of the comprehensive history and physical and provide a more targeted exam but with close follow-up to complete the essential and more comprehensive assessment.
- As many patients will not be able to recall details of prior treatments and laboratory results, medical records should be requested and reviewed, and the current medical record should be updated accordingly. Baseline laboratory assessments should be obtained at the initial visit (Table 4).

Evidence Summary

History of the Present Illness and HIV-Related and Other Medical and Surgical Histories

Table 1 outlines pertinent elements of the history of present illness (the reason that the patient presents to the clinic) and HIV-related information that should be obtained at the initial assessment. Table 2 outlines pertinent elements of current and past medical conditions, as well as other pertinent history to be addressed at the initial visit. Because of the high incidence of coinfections and comorbidities in people with HIV, special

Table 1. Initial Assessment: History of the Present Illness and Human Immunodeficiency Virus–Specific History

History of the present illness
• Questions should focus on establishing rapport, putting the patient at ease, and determining the patient's primary reason for the visit, if not simply to establish the patient in HIV care • Assess the patient's level of knowledge about HIV treatment and prevention, evaluate educational needs, and determine what ancillary and social support might be necessary (ideally in collaboration with effective case management) • If not previously treated with ART, assess the patient's readiness to begin ART immediately, including on the day of the first visit if feasible • If previously but not currently on ART, assess the patient's readiness to reinitiate ART immediately, including on the day of the first visit if feasible and if adequate information is available to choose an appropriate regimen • Assess the need for assistance with social services such as housing, transportation, and food access, and involve support staff early if appropriate
HIV-specific history
• Approximate date of HIV diagnosis • Approximate date of HIV acquisition and likely cause for HIV acquisition (including sexual trauma if appropriate), which can sometimes be determined on the basis of prior negative test results, occurrence of symptoms suggestive of acute retroviral infection, or timing of activities that may have resulted in exposure • Prior HIV care • Nadir CD4 cell count and highest viral load • Current and past exposure to antiretroviral drugs o Use of pre- or postexposure prophylaxis (including medications and date of last use) o Use of antiretrovirals for prevention of perinatal transmission o Prior antiretroviral treatment • Drug regimens taken and HIV RNA level while on those regimens • Duration of therapy • Reasons for changing regimens (eg, virologic failure, tolerability, simplification) and adherence challenges • Past medical record review (request records if not available) o Results of all prior resistance testing • Prior HIV-associated conditions o Opportunistic infections and/or malignancies according to the Centers for Disease Control and Prevention stage 3 definition o Other HIV-related conditions (eg, thrush)
History for people who currently inject drugs
• Current drug-use practices • Source of needles and needle-sharing practices • Access to naloxone

Abbreviations: ART, antiretroviral therapy; HIV, human immunodeficiency virus.

attention should be paid to this aspect of the history as well as any risk factors that may contribute to the development of comorbidities.

Family Medical History

A family medical history has become more important now that persons with HIV are living longer and are at increased risk for age- and sex-specific conditions in addition to HIV- and treatment-related complications. Clinicians should ask about any family history of conditions that might predispose the patient to malignancies, neurologic diseases, osteoporosis, and atherosclerotic disease and whether there is a family history of early coronary artery disease.

Social History

Clinicians should ask how the patient is adjusting to the diagnosis of HIV, who they have informed of their HIV status, and what support they receive from family and friends. If needed, patients should be offered assistance with the disclosure process. Work and educational histories should be discussed, including whether these have been affected by the diagnosis of HIV. Assessment of access to housing, food, transportation, and other primary social needs is essential. Other pertinent information includes insurance issues, financial status, relationship and family status, and plans for having children.

It is critical to obtain a sexual history in an open, nonjudgmental manner by using a sexual health framework and asking about the 5 "P's": past and current partners, practices, protection from STIs (including past PrEP use), past history of STIs, and pregnancy intention. Although targeted toward the general population, the CDC publishes an excellent step-by-step guide to taking a sexual history [80]. Important considerations for counseling and education are discussed in Section I of that document (Optimizing Care). Very few states require healthcare providers to notify sex partners of patients, but clinicians should be aware of laws in their own jurisdiction and advocate for repeal of laws that criminalize HIV status [81]. All clinicians should familiarize themselves with basic discussions about gender identity, including communication about appropriate pronouns, and fundamentals of care for transgender and gender-diverse individuals. See Section 11 for additional discussion of gender-affirming care.

As part of the initial evaluation and at periodic intervals thereafter, clinicians should assess for the presence of depression, anxiety, post-traumatic stress disorder (PTSD), and sexual or physical abuse, including domestic violence, using direct questions or validated screening tools (Patient Health Questionnaire-9 [PHQ-9] and Generalized Anxiety Disorder 2-item [GAD-2]) [82, 83]. Persons with HIV have high rates of adult sexual and physical abuse and childhood sexual abuse. A history of current and past psychoactive drug use, including

Table 2. Other Medical and Surgical History

Comorbidities

Current or past chronic medical conditions that might affect the choice of therapy or response to therapy

- Prior and present gastrointestinal disease
- Liver disease including viral hepatitis A, B, and C; past treatment for hepatitis B and/or C
- Cardiovascular disease and risk factors, including hyperlipidemia, hypertension, diabetes mellitus, and smoking
- Osteopenia or osteoporosis
- Kidney disease
- History of receipt of blood products, organ transplant, or tattoos

Other past medical conditions that may have implications for persons with HIV

- Chickenpox or shingles, measles
- *Mycobacterium tuberculosis* illness, exposure, treatment; prior testing or treatment for latent tuberculosis
- STIs including syphilis, chlamydia, gonorrhea, herpes simplex, trichomoniasis, chancroid, HPV
- Abnormal anal cytology; past anorectal disease including warts, fissures

Gynecologic and obstetric history

- Past pregnancies and plans for future pregnancy, history of artificial insemination by an unidentified donor
- Birth control practices
- Last cervical Pap test, abnormal Pap test ever, colposcopy, loop electrosurgical excision procedure, biopsy (cone/knife)
- Menstrual history
- Other gynecologic conditions including pelvic inflammatory disease

Mental health history, current and past

- Previous or current psychotherapy and medication treatment
- Anxiety disorders, bipolar disorder, depression, violent behavior
- Suicidal, homicidal ideation; history of hospitalization due to mental health issues
- History of trauma, including sexual and physical abuse, intimate partner and other violence; post-traumatic stress disorder (with appreciation for the sensitive nature of these inquiries and the emotional responses they may elicit)
- History of substance use and treatments for substance use (if any, note which substances used)

Current or past use of psychoactive substances

- Tobacco including e-cigarettes; years of use and estimate of cumulative exposure
- Cannabis and cannabinoids (including vaping)
- Vaping (regardless of substance)
- Alcohol use: quantify daily/weekly/monthly use
- Stimulants, including methamphetamine, cocaine, crack cocaine
- Opioids
- Other nonprescription drugs
- Misuse or overuse of prescription drugs
- Other substances primarily used with sex (amyl nitrate [poppers], erectile dysfunction drugs)
- Past injection drug use (regardless of substance used); history of needle sharing; hospitalizations related to injection drug use

Past hospitalizations, surgical procedures, transfusions, or blood product receipt, especially during 1975–1985 or outside the United States and Canada

Immunization status (obtain from past medical records if possible)

- Childhood vaccination including for measles, mumps, rubella, rotavirus
- Coronavirus disease 2019
- Hepatitis A and B
- HPV
- Influenza
- Meningococcus
- Mpox
- Pneumococcus: with type of vaccine
- Varicella zoster
- Tetanus/diphtheria or tetanus/diphtheria/acellular pertussis
- Respiratory syncytial virus
- Travel vaccinations

Travel and residential history pertinent to endemic infectious diseases that may be reactivated, including histoplasmosis (Ohio and Mississippi River valleys), coccidioidomycosis (southwestern deserts), or tuberculosis

Pediatric medical history

- Maternal HIV, obstetric, and birth history
- Exposure to antiretroviral drugs perinatally
- Growth and development milestones
- Childhood vaccination history
- Caregiver environment and support
- Education history

Family medical history

- Diabetes
- Early heart disease: myocardial infarction in a first-degree relative before age 55 years in male relatives and before age 65 years in female relatives
- Hypertension

Table 2. Continued

- Hyperlipidemia
- Cancer
- Any other significant medical condition

Social history

- Race and ethnicity
- Gender identity and sexual orientation; pronouns
- Patient birthplace, residence, and travel history
- Employment history
- Incarceration history
- Education history
- Financial support
- Children: ages, plans for having children in the future, HIV status of children
- Pets
- Diet and exercise
- Sexual history: nonjudgmental inquiry about types of activity including partners (number, gender, whether met online) and practices (genital, anal, oral; use of drugs with partners; exchange of sex to meet needs such as money, housing, drugs; assessment of satisfaction with sexual performance); STI prevention including use of barrier protection such as condoms or dental dams, frequency of barrier use, and prior HIV preexposure prophylaxis or doxycycline postexposure prophylaxis use; past STIs and treatment (including mpox); sexual trauma, violence, and abuse also should be explored, recognizing the sensitivity of these issues
- Marital/relationship status
  - Partner(s) health and HIV status
  - Partner(s) access to healthcare, including HIV testing (if appropriate)
  - Disclosure of HIV status to partner(s)
- Social support and participation in support groups
- Disclosure history: friends, family, work colleagues
- Access to stable housing, food, transportation
- For minors, review legal guardianship and consent/assent

Medications

- Current medications, including over-the-counter medications, supplements
- Use of complementary or alternative therapy or treatment

Allergies and intolerance

- Dates and types of reactions, including hypersensitivity reactions to antiretroviral therapy

Healthcare maintenance and preventative health screenings (as appropriate)

Dates of last:

- Cervical or anal Pap (and results, if known)
- Mammogram
- Bone density
- Colonoscopy and/or anoscopy (and results, if known)
- Abnormal aortic aneurysm screening
- Dental visit
- Dilated eye exam
- Lung cancer screening (if applicable and results, if known)

Abbreviations: HIV, human immunodeficiency virus; HPV, human papillomavirus; STI, sexually transmitted infection.

alcohol and tobacco, and injection drug use should be taken. See Section 3 for more on screening and treatment for mental health and substance use issues.

Allergies and Medications

A discussion of allergies and intolerances should include questions about hypersensitivity reactions to antibiotics and ART. Clinicians should ask about all current medications, including dietary or herbal supplements, some of which have been shown to interact with ART. All prior ART regimens, including years of use, prior side effects, and reasons for switching, should be recorded. It is also important to assess prior adherence to medications and document viral loads while on each regimen.

Review of Systems

The review of systems should be comprehensive and include questioning about common HIV-related symptoms (see Table 3). Patients should be questioned about how their current weight compares with their past weights, and a dietary assessment should be performed. Given the high incidence of comorbidities in people with HIV, eliciting a history of comorbidities and their risk factors is essential. Depression, anxiety, and PTSD are common among people with HIV, especially cisgender women and lesbian, gay, bisexual, transgender, queer plus (LGBTQ+) populations, and the review of systems should include questions that focus on changes in mood, libido, sleeping patterns, appetite, concentration, and memory.

Physical Examination

A complete physical examination should be performed at the initial encounter or as soon afterward as possible. In addition to recording all vital signs (including height and weight), persons aged >50 years should be assessed for frailty. For all patients, the overall body habitus should be assessed, looking

Table 3. Initial Assessment—Review of Systems and Physical Examination

Review of Systems	Physical Examination
A complete review of systems with special attention to the areas listed below: • Unexplained weight loss or gain, night sweats, fever, changes in body habitus • Skin: skin discoloration, rash, ulcers, or lesions • Lymph nodes: localized or generalized enlargement of lymph nodes • Eyes: vision change or loss • Mouth: gum disease, ulcers, oral lesions or pain, dental health and dentition for children • Cardiopulmonary: chest pain, palpitations, wheezing, dyspnea, orthopnea • Gastrointestinal: odynophagia, dysphagia, diarrhea, nausea, pain • Endocrinology: symptoms of hyperglycemia, thyroid disease, hypogonadism • Neurologic and psychiatric: persistent and severe headaches, memory loss, loss of concentration, depression, apathy, anxiety, mania, mood swings, lower-extremity paresthesias, pain or numbness, paralysis or weakness, cognitive difficulties, dizziness, seizures, sleep disorders • Genitourinary: dysuria, urethral or vaginal discharge or lesions, hematuria • Orthopedic: hip pain, joint pain, fractures, diagnosis of or risk factors for osteopenia/osteoporosis • Anorectal: anal discharge, rectal bleeding, rectal itching, pain or fullness in anal area • Developmental milestones: for infants and young children, assess for motor or speech delays • Growth delay and failure to thrive for infants and children	A complete physical examination should be performed, with special attention to the following areas: • Vital signs: including height and weight • General: including body habitus, evidence of obesity, wasting, lipodystrophy, assessment of frailty, ambulatory ability • Skin: seborrheic dermatitis, ecchymoses, purpura, petechiae, Kaposi sarcoma, herpes simplex or zoster, psoriasis, molluscum contagiosum, onychomycosis, folliculitis, condylomata, cutaneous fungal infections, acanthosis • Lymph nodes: generalized or localized lymphadenopathy • Eye: retinal exudates or cotton wool spots, hemorrhages, pallor, icterus • Oropharynx: oral hairy leukoplakia, candidiasis (thrush, palatal erythema, angular cheilitis), aphthous ulcers, gingivitis, periodontal disease, Kaposi sarcoma, tonsillar or parotid gland enlargement • Cardiovascular: heart exam, peripheral pulses, presence/absence of edema or bruits • Chest: lung exam • Breast: nodules, nipple discharge • Abdomen: hepatomegaly, splenomegaly, masses, tenderness • Genitourinary: ulcers, warts, chancres, rashes; gynecologic exam including bimanual exam, discharge (if male: testicular exam; evaluation for hernia) • Anorectal: ulcers, warts, fissures, internal or external hemorrhoids, masses, Kaposi sarcoma; prostate exam when appropriate • Neuropsychiatric: depression; mania; anxiety; signs of personality disorder; difficulties in concentration, attention, and memory; signs of dementia; speech problems; gait abnormalities; focal deficits (motor or sensory); lower-extremity vibratory sensation; deep tendon reflexes

for evidence of wasting, obesity, or, particularly in patients who have received older ART regimens, evidence of drug-related lipohypertrophy (including dorsocervical fat pad, gynecomastia, or visceral abdominal fat accumulation) and/or lipoatrophy (including loss of subcutaneous fat in the face, extremities, or buttocks). All adult patients with CD4 count <50 cells/μL, as well as infants and young children with profound immunodeficiency, should be referred to an ophthalmologist for a dilated funduscopic examination. Though persistent generalized lymphadenopathy is common among untreated persons with HIV, it does not correlate with prognosis or disease progression. However, focal or rapidly progressive lymphadenopathy may require further evaluation, including biopsy. Additionally, if lymphadenopathy does not quickly resolve with initiation of ART, diagnostic studies should be pursued. Neurology and/or neuropsychology referral for assessment of neurocognitive disorders, dementia, and focal neuropathies may be indicated [84, 85]. Cervical motion and uterine or adnexal tenderness on bimanual pelvic examination suggest pelvic inflammatory disease and should prompt STI testing. An anorectal examination is important to evaluate for anal warts, other STIs, and anal cancer, with age-appropriate screening for prostate abnormalities if assigned male at birth.

Baseline Laboratory Evaluation

A number of initial laboratory studies are indicated for persons who present with a new HIV diagnosis or for persons who reengage in care (see Table 4). Other tests may be indicated depending on the age and sex of the patient and/or symptoms. When rapid initiation of ART is possible, it is important to obtain baseline laboratory tests, including HIV RNA level, CD4 cell count, resistance testing, and viral hepatitis serology, and to assess for safety and general medical condition; however, ART initiation need not be delayed until results are received. The absence of results for HIV RNA level, HIV genotype, and hepatitis B surface antigen (HBsAg) will influence the choice of antiretrovirals (ARVs) for rapid initiation. If results of HIV screening are not available for review, an HIV diagnosis should be confirmed, preferably using a fourth-generation antigen/antibody test with rapid turnaround time.

Recommendations

HIV-Specific Tests for All Persons With HIV

- Patients who have no documentation of their HIV status or who were tested anonymously should have an HIV antigen/antibody screening test performed upon initiation of care. When HIV RNA is obtained, in addition to antigen/antibody for HIV screening, an isolated positive HIV RNA should be verified by repeat testing if HIV antibody is negative, especially in the setting of prior use of long-acting cabotegravir as PrEP.
- A CD4 cell count with percentage should be obtained upon initiation of care.
- Measurement of the CD8 cell count and the ratio of CD4 to CD8 cells is not considered necessary, as the results are not used in clinical decision-making.

Table 4. Recommended Initial Laboratory Screening and Other Studies in Persons With Human Immunodeficiency Virus

Test	Comment(s)
HIV-specific tests for all persons with HIV	In infants and children aged <18 years with perinatal HIV exposure, maternal antibodies can persist up to 24 months; therefore, HIV RNA nucleic acid tests are considered diagnostic; infants, children, and adolescents with HIV and history of initiating early ART may have negative antigen/antibody test
• HIV antigen/antibody testing	If written evidence of diagnosis not available or if viral load low or undetectable (an isolated positive HIV RNA with negative HIV antibody should be verified by repeat testing, especially in the setting of prior CAB-LA exposure as PrEP)
• CD4 cell count and percentage	CD4 cell count and percentage access are necessary to assess for immunosuppression and support decisions on OI prophylaxis and vaccinations
• Plasma HIV RNA polymerase chain reaction (HIV viral load)	Establish baseline and monitor viral suppression
• HIV resistance testing	• Baseline genotype for protease inhibitor, nonnucleoside reverse transcriptase inhibitor, nucleoside/nucleotide reverse transcriptase inhibitor, mutations for persons who have never initiated therapy or who are reengaging in care and not on therapy or with inconsistent access to therapy; INSTI genotype is recommended if clinical concern for transmitted INSTI resistance and/or acquired INSTI resistance, as in the setting of prior CAB-LA (as PrEP) exposure
HIV-related tests in selected patients	
• Coreceptor tropism assay	If use of C-C motif chemokine receptor 5 antagonist is being considered
• Human leukocyte antigen (HLA) B*5701	If use of abacavir is being considered
Other laboratory tests	
• Complete blood cell count with differential	Assess for anemia, neutropenia, thrombocytopenia
• Alanine aminotransferase, aspartate aminotransferase, total bilirubin, alkaline phosphatase	Assess for evidence of liver damage, hepatitis, or systemic infection (eg, elevated alkaline phosphatase with some OIs)
• Total protein and albumin	High total protein common with untreated HIV infection due to increased immunoglobulin fraction secondary to B-cell hyperplasia; low albumin may indicate nutritional deficiency or nephrotic syndrome
• Electrolytes, blood urea nitrogen, creatinine	Assess kidney function; use creatinine to calculate estimated glomerular filtration rate
• Lipid profile and blood glucose; hemoglobin A1c	Fasting not needed for initial lipid and glucose assessment; if abnormal, repeat fasting (hemoglobin A1c should be measured prior to ART initiation but is not used for diagnosis of diabetes in those on ART)
• Urinalysis	Assess for evidence of proteinuria, hematuria
Screening for coinfections	
• Gonorrhea, chlamydia	Nucleic acid amplification test (NAAT) with sites based on exposure history (eg, urine, vaginal, rectal, oropharyngeal; 3-site testing preferred for all patients)
• Trichomoniasis	In all persons who have vaginal sex
• Syphilis	Using local protocol (either rapid plasma reagin or treponemal-specific antibody tests)
• Latent *Mycobacterium tuberculosis*	Tuberculin skin test or IGRA; IGRA preferred if history of Bacillus Calmette-Guérin vaccination
• Varicella virus	Anti-varicella IgG if no known history of chickenpox or shingles
• Viral hepatitis A, B, C	Measure HBsAg, HBsAb, HBcAb, HCV Ab, HAV IgG antibody. If HBsAg-positive or HBcAb-positive, order HBV DNA level. If HCVAb-positive, known past HCV, or considering acute HCV, order HCV RNA level. HCV genotype should be collected unless a pan-genotypic treatment regimen will be used. Screen for hepatocellular carcinoma for all adult patients with cirrhosis and noncirrhotic patients with chronic HBV for an extended period
• Measles titer	Adequate evidence of immunity includes being born in the United States before 1957, written documentation of adequate vaccination, or serologic evidence of immunity [104]. Persons born in the 1960s may have been vaccinated with a vaccine other than MMR and may have waning immunity. Patients may opt to receive a booster MMR vaccine rather than check serology
• Cryptococcal antigen	Indicated for patients with CD4 count <100 cells/μL or symptoms consistent with infection
• Toxoplasma antibody	Indicated for patients with CD4 count <200 cells/μL or symptoms consistent with infection
Tests that may be performed under certain circumstances	
• Chest radiography	For patients with evidence of latent *Mycobacterium tuberculosis* infection; consider in patients with underlying lung disease for use as comparison in evaluation of future respiratory illness
• Cytology: cervical and/or anal Pap test	Cervical; anal if indicated. Abnormal results require follow-up with colposcopy or high-resolution anoscopy, respectively
• Glucose-6-phosphate dehydrogenase	Screen for deficiency in persons, especially those assigned male at birth, who are of African, Mediterranean, or Asian descent before prescribing oxidant drugs such as dapsone and primaquine in those with glucose-6-phosphate dehydrogenase deficiency. Sulfonamides should be used with caution without prior screening
• Pregnancy test in persons of childbearing potential	Pregnancy status is required to inform choice of ART and discussions about conception in persons of childbearing potential

Table 4. Continued

Test	Comment(s)
• Serum testosterone level	In cisgender males with fatigue, weight loss, loss of libido, erectile dysfunction, or depression or who have evidence of reduced bone mineral density. Morning free testosterone is preferred. See Section 7 for management of hypogonadism
Tests that are not recommended for general screening purposes	
• HSV IgG, CMV IgG, biomarkers of inflammation	In asymptomatic persons, routine testing for all persons is not recommended for HSV, CMV. Biomarkers of inflammation are not recommended. CMV IgG may be considered if blood transfusion is contemplated in a person at low risk for CMV exposure. A negative CMV IgG may support use of CMV-free blood products

Abbreviations: ART, antiretroviral therapy; CAB-LA, long-acting cabotegravir, CMV, cytomegalovirus; HAV, hepatitis A virus; HBV, hepatitis B virus; HBcAb, hepatitis B core antibody; HBsAb, hepatitis B surface antibody; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HSV, herpes simplex virus; IgG, immunoglobulin G; IGRA, interferon-γ release assay; INSTI, integrase strand transfer inhibitor; MMR, measles, mumps, rubella; OI, opportunistic infection; PrEP, preexposure prophylaxis.

- A quantitative HIV RNA level (HIV viral load) should be obtained upon initiation of care.
- Patients should be assessed for transmitted drug resistance with a genotype assay for protease and reverse transcriptase mutations upon initiation of care.
- If baseline integrase strand transfer inhibitor [INSTI] resistance is suspected (eg. transmitted mutations) or if HIV was acquired after receipt of long-acting cabotegravir for PrEP, regardless of the time since drug discontinuation due to the long half-life of injectable drug, genotypic testing for integrase resistance should be obtained.
- Resistance testing should be obtained for patients who reengage in care and who are currently not on ART or who have not had consistent ART access, recognizing that the absence of resistance mutations does not guarantee the absence of resistance when no selective pressure is present.
- Resistance testing, including for integrase mutations if appropriate, is indicated for patients who are experiencing virologic failure to guide modification of ART and should be performed while the patient is on the failing ART regimen or within 4 weeks of discontinuing the ART regimen.

Evidence Summary

Clinicians should be familiar with the current CDC HIV testing algorithms and interpretation of results based on the algorithms and assays used [86]. Confirming an HIV diagnosis is especially important in patients who are asymptomatic and have a normal CD4 cell count and an undetectable or very low viral load. In addition, patients may present to care with misinformation regarding previous test results. Delayed seroconversion may occur in persons who acquire HIV while taking oral PrEP or, especially, after exposure to cabotegravir as PrEP. If HIV infection is suspected within 3 months of taking oral PrEP or within 12 months following exposure to injectable long-acting cabotegravir (CAB-LA), HIV antibody testing and an HIV RNA level should be obtained. A positive HIV RNA result in the absence of a positive antibody should be verified by repeat testing because of the high rate of false-positive HIV RNA results reported in HIV Prevention Trials Network (HPTN) 083, especially if the last dose of CAB-LA was less than 6 months prior to screening [87, 88]. As new data emerge, CDC guidelines should be consulted for recommendations on screening for HIV in the setting of PrEP use [89].

The initial CD4 cell count is used to stage HIV infection, establish the risk of specific HIV-associated complications, and determine the need for prophylaxis against opportunistic infections (OIs). It is important that the clinician and patient be aware of the substantial variation in CD4 cell counts, especially during acute illness. Because CD4 cell counts may be affected by a variety of medications and intercurrent illnesses, caution should be taken when interpreting CD4 cell counts in these situations. Although the absolute CD4 cell count is the measure that is most often used in clinical practice, the CD4 cell percentage can also be used to assess immune function and is somewhat less variable than the absolute count. Total CD4 counts of 200 and 500 cells/μL generally correspond to CD4 cell percentages of 14% and 29%, respectively. In children aged <5 years, there is more variability in the absolute CD4 cell count; therefore, CD4 percentage is generally preferred for monitoring immune status [86, 90, 91].

The initial HIV RNA level defines the patient's baseline so that response to therapy can be measured. Clinicians should be aware of changes in the type of HIV RNA assay used, the associated variability, and differences in interpretation of results between assays. Thresholds for lower limits of detection for the most commonly used assays range from 20 to 50 copies/mL. Viral load should be measured during the initial evaluation of the untreated patient when establishing care or when a patient reengages in care. Viral suppression is defined as a viral load that is persistently below the level of quantification of the assay; however, the threshold for prevention of HIV sexual transmission is considered to be <200 copies/mL [7].

Drug-resistant HIV can be transmitted from one person to another. The purpose of baseline genotypic resistance testing is to assess for resistance (transmitted or acquired) that would

influence ART selection. Baseline genotypic resistance testing for protease and reverse transcriptase mutations should be performed for all persons beginning treatment [7]. Resources are available and frequently updated to assist clinicians in the interpretation of drug-resistance mutations [92, 93]. Because transmission of integrase mutations is currently uncommon, baseline integrase genotyping is recommended only when transmission of integrase resistance is suspected, such as when HIV is suspected to have been acquired from an individual known to have been taking a regimen that contains an integrase inhibitor [94]. All persons who acquired HIV after using cabotegravir for HIV PrEP should have integrase resistance testing performed due to the long half-life of this drug and the risk of selecting integrase resistance when fully inhibitory drug levels are no longer present. These individuals should not receive INSTI therapy until an integrase genotype test is performed and sensitivity is demonstrated [7]. Lack of genotypic testing limits the regimens that may be prescribed, including 2-drug regimens such as dolutegravir/lamivudine fixed-dose combination, and other combinations in which resistance to one drug would result in functional monotherapy [7]. In persons who reengage in care and who have been off therapy for 4 or more weeks, resistance mutations may be absent due to lack of selective pressure rather than absence of resistance, and results should be interpreted with this in mind.

Patients who are taking a failing ARV regimen (HIV RNA level >200 copies/mL) should undergo resistance testing to guide interventions and improve viral control. In those with HIV RNA levels between 201 and 500 copies/mL, testing may not be successful but should be considered.

HIV-Related Tests in Select Patients

Recommendations

- Co-receptor tropism testing should be performed if the use of a chemokine receptor 5 (CCR5) antagonist is being considered.
- Human leucocyte antigen (HLA) B*5701 testing should be performed before initiation of abacavir therapy.
- Patients who are positive for the HLA B*5701 haplotype are at high risk for abacavir hypersensitivity reaction and should never be treated with abacavir (this should be noted appropriately in the medical record).

Evidence Summary

Co-receptor tropism testing is needed to determine which patients are appropriate candidates for initiation or continuation of a CCR5 antagonist [7]. CCR5 antagonists are not effective for patients with X4 or dual/mixed-tropic (D/M) virus. The use of a CCR5 antagonist under these circumstances could increase the risk of virologic failure and the development of resistance to the other drugs in the regimen. Tropism screening may fail to detect X4 or D/M virus if it is present at very low levels, and patients may experience treatment failure with CCR5 antagonists because of the presence of pre-existing X4 or D/M virus not detected by the tropism assay. Patients who exhibit virologic failure while taking a CCR5 antagonist may also be considered for tropism testing. Routine tropism testing is not recommended prior to initiation of regimens that do not contain a CCR5 antagonist. Repeat tropism testing is recommended when considering the use of a CCR5 antagonist as part of the ART regimen, even if previously done in the past, unless the previous tropism was X4 or D/M. Tropism may shift from R5 to X4 or D/M during the course of infection, especially with more advanced immunodeficiency (CD4 count <100 cells/μL). A proviral DNA tropism assay can be used in patients with undetectable HIV RNA when considering the use of a CCR5 antagonist in a new regimen [7].

Screening for the HLA B*5701 haplotype is essential in patients being considered for abacavir therapy in order to identify those who are at high risk for the abacavir hypersensitivity reaction [7]. A negative test result does not rule out the possibility of a hypersensitivity reaction but indicates that it is extremely unlikely. Patients who have negative test results should still be counseled about a hypersensitivity reaction before being treated with abacavir [7].

Laboratory Tests to Assess Safety and General Health

Recommendations

- A complete blood count with differential white blood cell count and chemistry panel with electrolytes, glucose, creatinine, calculated creatinine clearance (or estimated glomerular filtration rate [eGFR]), blood urea nitrogen, total protein, albumin, total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and urinalysis should be obtained upon initiation of care.
- Because many ARV drugs, the HIV infection, and host factors are associated with abnormal cholesterol and triglyceride levels, a lipid profile should be obtained upon initiation of care and repeated fasting, if appropriate.

Evidence Summary

Anemia, leukopenia, and thrombocytopenia are common among persons with untreated HIV. The complete blood count is also used to calculate the absolute CD4 cell count. A chemistry panel (including electrolytes, glucose, creatinine, eGFR, blood urea nitrogen, total protein, albumin, total bilirubin, AST, and ALT) is an important tool to assess renal and hepatic function and to look for evidence of pre-existing liver injury or hepatitis.

Kidney function is abnormal in up to 30% of persons with untreated HIV, and HIV-associated nephropathy is a relatively

common cause of end-stage renal disease, especially in Black persons with HIV, although both rates and mortality have declined with more effective ART [95, 96]. A calculated creatinine clearance or eGFR should be obtained to further assess baseline renal function. The eGFR assists in prescribing ARV agents and other commonly used medications that require renal dosing. Clinicians should be aware that some medications such as cobicistat, dolutegravir, bictegravir (BIC), and trimethoprim may affect creatinine secretion and elevate serum creatinine without affecting renal function [97]. A screening urinalysis for proteinuria should be considered at initiation of care and annually thereafter, especially in patients who are at increased risk for developing kidney disease (including those with CD4 counts <200 cells/μL or HIV RNA >4000 copies/mL and those with diabetes mellitus, hypertension, or hepatitis C virus [HCV] coinfection) [7]. Patients with proteinuria of grade ≥1 by dipstick analysis or reduced kidney function can be referred to a nephrologist for consultation and should undergo additional studies, including quantification of proteinuria, renal ultrasound, and possible renal biopsy. As discussed in Section 7, screening for glucose intolerance and diabetes mellitus is recommended because of the increased prevalence in this population. Among adults and children with HIV, fasting blood studies are more problematic because of feeding schedules in children and work schedules in adults, and clinicians should obtain fasting levels when nonfasting levels are abnormal [7]. The lipid profile is important because of high rates of cardiovascular disease in this population and the importance of managing risk factors. Additionally, several ARVs affect lipid levels or have drug interactions with statins (see Section 7).

Screening for Coinfections

Recommendations

- Upon initiation of care, persons with HIV without a history of tuberculosis or a prior positive tuberculosis screening test should be screened for *Mycobacterium tuberculosis* infection using either a tuberculin skin test (TST) or an interferon-gamma release assay (IGRA). Those with positive test results should be treated for latent *M. tuberculosis* infection after active tuberculosis has been excluded.
- Persons with HIV who have close contact with 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.
- Persons with HIV should be screened for evidence of hepatitis B virus (HBV) infection upon initiation of care by detection of HBsAg, hepatitis B surface antibody (HBsAb), and antibody to hepatitis B total core antigen (anti-HBc or HBcAb). If HBsAg is positive, HBV viral load should be ordered.
- Persons with HIV should be screened for evidence of immunity to hepatitis A virus (HAV) with HAV immunoglobulin G (IgG).
- Persons with HIV should be screened for HCV antibody upon initiation of care. If positive, HCV RNA should be ordered to assess for active HCV infection. Curative therapy should be offered to all who are diagnosed with active HCV. HCV RNA testing is indicated ≥12 weeks post-completion of anti-HCV treatment to check for successful and sustained treatment. HCV RNA should be used for screening if HCV infection within the last 6 months is suspected or there is a history of prior HCV infection that has cleared due to spontaneous resolution or curative treatment. HCV RNA testing should be considered in persons with advanced immunosuppression (CD4 cell count <200 cells/μL).
- Infants born to persons with HBV and/or HCV should be tested for HBV and HCV transmission.
- Persons who are not immune to HAV and HBV should be immunized according to current national guidelines.
- All persons with HIV born in 1957 or after should be tested for immunity to measles, mumps, and rubella (MMR) by measuring antibodies.
- MMR vaccine should be given to protect against measles, mumps, and rubella if persons were born in 1957 or after and have not received this vaccine or do not have immunity to these infections.
- Serologic screening for varicella zoster virus (VZV) may be considered for persons who have not had chickenpox or shingles and who have not been previously vaccinated (see Section 4).
- Screening for toxoplasma IgG is recommended for asymptomatic persons with CD4 count <200 cells/μL and for those with symptoms suggestive of toxoplasmosis.
- Testing for serum cryptococcal antigen is indicated in persons with CD4 count <100 cells/μL and in symptomatic patients but is not routinely recommended in asymptomatic persons if CD4 count is ≥100 cells/μL.
- Screening for syphilis, chlamydia, gonorrhea, and, for persons having vaginal sex, trichomonas should be performed at entry to care (Please refer to Section 6).

Evidence Summary

All persons with HIV should be tested for *M. tuberculosis* infection using TST or IGRA upon initiation of care [7, 98, 99]. A TST or IGRA should be performed any time there is concern about a recent exposure. For those with CD4 count ≤200 cells/μL, testing should be repeated after the CD4 count increases to >200 cells/μL following initiation of ART. For a person with HIV, induration of >5 mm by TST is considered a positive result and should prompt chest radiography and other evaluation, as warranted, to rule out active tuberculosis [100]. Annual testing should be considered for those who have

negative results by TST or IGRA but are at ongoing risk for exposure [7, 101]. Routine cutaneous anergy testing is not recommended because of lack of standardization of reagents and poor predictive value and because prophylaxis provided to anergic persons has been shown to prevent few cases of tuberculosis [102]. The QuantiFERON-TB Gold in-tube test (Cellestis Limited) and the T-SPOT TB test (Oxford Immunotech) are approved by the US Food and Drug Administration (FDA) as aids for detecting latent *M. tuberculosis* infection.

A large meta-analysis suggests that IGRAs perform similarly to TSTs when identifying persons with HIV with latent tuberculosis infection [103]. However, prior vaccination with Bacillus Calmette-Guérin (BCG) vaccine may result in a positive TST result, whereas there is less cross-reactivity with the IGRA. IGRAs that are reported as indeterminant should be repeated, as follow-up testing may be negative. The CDC states that use of an IGRA is preferred over the TST in patients with a history of BCG vaccination and in patients with a low likelihood of returning to have their skin test read. Advanced immunosuppression may be associated with false-negative results in all types of immunologically based tests used for detection of *M. tuberculosis* infection. The routine use of the IGRA in children, especially those aged <5 years, is currently not recommended due to limited data and some evidence of lower sensitivity.

Screening for and prevention of HAV, HBV, and HCV are critical in the management of people with HIV. Those who have HBV and/or HCV coinfection should be managed according to the most current published guidelines [98, 104–106]. Hepatitis A vaccination is especially important for persons with unstable housing, for persons who inject drugs (PWID), and for those with chronic liver disease due to recent outbreaks in certain communities [107]. Prevaccination screening for HAV infection is cost-effective when there is a seroprevalence of >30% in the patient population [108]. Because of worse outcomes for persons with HIV and HBV coinfection, persons with HIV who also have HBV should be adequately treated for HBV [7]. Because many persons with HIV may be treated with tenofovir-based ART that also suppresses HBV, stopping tenofovir-based ART may result in a flare of HBV, especially when changing ART to a 2-drug regimen that does not contain tenofovir. Persons with HBV are at higher risk for hepatocellular carcinoma (HCC) even in the absence of cirrhosis. Screening for HCC in persons with HBV should be conducted according to the American Association for the Study of Liver Diseases guidelines [104]. Persons not immune to HAV and HBV should be immunized according to applicable guidelines (see Section 4).

Persons with HIV should be screened for HCV antibody upon initiation of care. If positive, HCV RNA should be ordered to assess for active HCV infection. HCV RNA should be used in persons with a negative HCV antibody if infection within the last 6 months is expected and in persons with a history of prior HCV infection that has cleared due to spontaneous resolution or curative treatment. HCV RNA should be considered in persons with advanced immunosuppression (CD4 count <200 cells/μL), especially in persons who are HCV-seronegative with a history of injection drug use or with unexplained increased serum transaminases because approximately 2%–4% of persons with HIV–HCV coinfection have false-negative HCV antibody results; this occurs primarily among those with advanced immunosuppression [98]. According to multiple studies, the rate of mother-to-infant HCV transmission is up to 3-fold higher among women with HIV, and pregnant people with HIV should be tested for HCV with each pregnancy [106, 109]. Infants can be tested for HCV RNA after age 2 months or for HCV antibody after age 18 months [110]. All persons diagnosed with chronic HCV should be offered curative treatment. Eradication of HCV reduces, but does not eliminate, the risk of HCC in persons with cirrhosis; therefore, ongoing HCC screening in this group is warranted. Screening for HCC is recommended in all patients with cirrhosis due to hepatitis B or C or other nonviral etiologies (including alcohol use and fatty liver disease) [111].

Acceptable evidence of immunity against measles includes at least 1 of the following: written documentation of adequate vaccination, laboratory evidence of immunity, laboratory confirmation of measles, or birth in the United States before 1957 [112, 113]. It is advisable to determine anti-varicella IgG levels for patients who are unable to verify a history of chickenpox or shingles [114, 115]. STI screening should be obtained as part of the initial assessment. See Section 6.

In spite of a high prevalence of toxoplasma IgG in the population, toxoplasma encephalitis occurs among those with advanced immune deficiency. Screening for toxoplasma IgG, therefore, is indicated for asymptomatic persons with CD4 count <200 cells/μL and for those with a clinical presentation suggestive of toxoplasmosis. Testing for serum cryptococcal antigen is indicated in persons with CD4 count <200 cells/μL or in symptomatic individuals [98].

Tests That May Be Performed Under Certain Circumstances

Recommendations

- A baseline chest radiograph should be obtained in all persons with HIV who have a positive tuberculosis screening test result in order to rule out active tuberculosis. It may also be useful in other patients who are likely to have pre-existing lung abnormalities, including those who smoke or have a history of injecting drugs.
- Before starting therapy with oxidant drugs such as dapsone and primaquine, screening for glucose-6-phosphate dehydrogenase (G6PD) deficiency is recommended, particularly

for individuals assigned male at birth of African, Mediterranean, or Asian descent. Sulfonamides should be used with caution without prior screening.
- Persons of childbearing potential should have a pregnancy test upon initiation of care or reengagement in care.
- In general, routine testosterone testing is not recommended among cisgender males with HIV. However, morning serum testosterone levels are recommended in adult cisgender men with decreased libido, erectile dysfunction, reduced bone mineral density (BMD) or low trauma fractures, hot flashes, or sweats.
- Obtaining testosterone levels in cisgender women at baseline in non-research settings is not recommended.

Evidence Summary

In general, all persons with HIV do not require a baseline chest X ray. However, persons with HIV are susceptible to a variety of pulmonary complications. A radiograph obtained at baseline in these individuals, as well as in persons with a history of pulmonary disease or smoking, may be useful for comparison in the evaluation of future respiratory complaints. Because people who inject drugs are especially likely to have radiographic abnormalities that may be mistaken for infiltrates, careful clinical history and physical assessment are warranted to guide subsequent medical decision-making. For discussion of cancer screening in persons who smoke, see Section 5. G6PD deficiency is a genetic condition that may result in hemolysis after exposure to oxidant drugs. Persons assigned male at birth and individuals of African, Mediterranean, and Asian descent have higher likelihood of these genetic variants. Dapsone and primaquine are often used to treat persons with HIV and can lead to hemolysis in the presence of G6PD deficiency. Sulfonamides should be used with caution without prior screening [116, 117].

The pregnancy status of all persons of childbearing potential should be assessed at the initial visit. In addition, the intent to have children, intent or ability to use consistent birth control, and timing of potential conception should be discussed. Although preliminary data suggested that neural tube defects were associated with dolutegravir use during conception, updated data showed no statistical significance, and dolutegravir is now a recommended drug for treatment during conception as well as pregnancy [118, 119]. The HHS perinatal guidelines provide ART recommendations for pregnant individuals [120]. The HHS ART guidelines provide recommendations for individuals who are planning to conceive and those unable to use reliable contraception [7] (see Sections 8 and 9).

Cisgender men with HIV, especially those with advanced disease, are at risk for hypogonadism. Interpretation of testosterone values must be made in clinical context, as all currently available assays (including measures of total, free, and bioavailable testosterone) are associated with technical issues that may result in significant variability. Testing should be performed on a specimen obtained in the morning (ideally before 10 AM) and confirmed with repeat testing if the result is below the lower limit of normal. Recommendations differ regarding the optimal assay to use for initial testing in the setting of HIV. Testosterone circulates primarily bound to plasma proteins (including sex hormone–binding globulin and albumin). If total testosterone is used for initial testing, a determination of sex hormone–binding globulin and/or free testosterone is strongly recommended when alterations of binding proteins are suspected (including patients with cirrhosis and hepatitis, hyper- or hypothyroidism, or nephrotic syndrome). Free testosterone may be determined by equilibrium dialysis (most reliable but most expensive) or using the free online testosterone calculator developed by the Hormonology Department, University Hospital of Ghent, Belgium [121]. So-called direct free testosterone (analogue) assays are unreliable and should not be used. If a diagnosis of hypogonadism is established, measurement of luteinizing hormone and follicle-stimulating hormone is recommended to determine whether the source of dysfunction is primary (testicular) or central (pituitary or hypothalamic) in origin. Hypogonadism should be treated by clinicians who are familiar with monitoring patients on androgen replacement therapy (see Section 4). For recommendations pertaining to age-appropriate cancer screening, see Section 5.

Tests Not Recommended for General Screening Purposes

Recommendations

- Routine testing for herpes simplex virus (HSV) IgG, cytomegalovirus (CMV) IgG, and biomarkers of inflammation is not recommended.

Evidence Summary

Routine screening for HSV is not recommended [122]. Routine screening for CMV IgG is not generally useful because CMV seroprevalence is extremely high and generally not actionable [98]. Testing for CMV IgG may be considered, however, if blood transfusion is contemplated in a person at low risk for CMV exposure. The identification of seronegativity would prompt the use of CMV-negative or leukocyte-reduced blood products when transfusions are needed, thus reducing the risk of iatrogenic infection. There are no data supporting the use of inflammatory biomarkers for risk assessment of comorbidities [123].

SECTION 3: ROUTINE HEALTHCARE MAINTENANCE CONSIDERATIONS FOR PEOPLE WITH HIV

Effective HIV primary care requires regular health maintenance, including HIV-related lab monitoring, mental health and substance use screenings, oral health examination, and patient education and counseling. Health assessments that are

recommended for the general population (age- and gender-guided) as well as those specific for people with HIV should be reviewed and addressed at least annually with patients with HIV, whether performed at 1 or more visits (Table 5).

HIV-Specific Monitoring Following the Initial Assessment

Recommendations

- After initiation of ART, HIV RNA should be rechecked after 2–4 weeks but no later than 8 weeks and then every 4–8 weeks until suppression is achieved. Afterward, viral load should be monitored every 3–4 months to confirm maintenance of suppression below the limit of assay detection. This interval may be prolonged to every 6 months for patients whose viral load has been suppressed for more than 1 year and whose clinical and immunologic status is stable. Viral load should be monitored more frequently after reinitiating or changing ART, preferably within 2–4 weeks, with repeat testing every 4–8 weeks until viral load becomes undetectable. More frequent testing may be considered in other clinical scenarios, such as pregnancy and/or breastfeeding.
- If HIV RNA results are above the limit of assay detection but <200 copies/mL, referred to as "blips," assessing and addressing medication adherence, tolerability, and drug–drug interactions are warranted with an earlier repeat of HIV RNA testing.
- CD4 cell count should be monitored to determine the need for prophylaxis against OIs and to aid in generating appropriate differential diagnoses. CD4 cell counts should generally be monitored every 3–6 months for the first 2 years or if the virus is not suppressed. After 2 years, for patients on suppressive ART regimens with CD4 counts of 300–500 cells/μL, CD4 cell count can be monitored every 12 months unless there are changes in the patient's clinical or virologic status. If the CD4 count rises above 500 cells/μL, CD4 monitoring is optional.
- Repeat HIV genotypic resistance testing for mutations in the reverse transcriptase and protease genes, including in the integrase genes, when there is history of INSTI use, should be performed if virologic failure occurs and when clinically indicated. If ART initiation has been delayed, repeat genotype testing prior to ART initiation should be considered.

Evidence Summary

Frequency of HIV RNA monitoring depends on the response to therapy and duration and consistency of viral suppression. Once ART has been initiated, HIV RNA is monitored to confirm response to therapy and attainment and maintenance of viral suppression. After HIV RNA becomes undetectable, monitoring is approximately quarterly but can be every 6 months for persons with at least 1 year of continuous suppression and stable clinical and immune status [7]. More frequent testing may be warranted during pregnancy and/or breastfeeding, and the HHS Perinatal Antiretroviral Guidelines should be followed [120].

After virologic suppression has been achieved, if a viral load blip (isolated increase in HIV RNA above the limit of assay detection but <200 copies/mL that is followed by spontaneous suppression) or persistent low-level viremia with HIV RNA <200 copies/mL occurs, medication adherence should be assessed, and any identified barriers should be addressed. Medication tolerability should be reviewed, and side effects should be managed. Potential drug–drug interactions, including with over-the-counter medications and supplements, should also be reviewed. Earlier HIV RNA testing, for example, after 2–4 weeks, to ensure that no virologic failure (2 consecutive HIV RNA levels >200 copies/mL) has occurred is recommended [6]. If low-level viremia occurs, HIV viral load should be checked at least every 3 months to ensure that virologic failure has not occurred. As discussed in Section 1, assessing adherence regularly, ideally through a multidisciplinary team approach, is essential for identifying and addressing barriers, with a goal of preventing loss of virologic suppression and promoting improved adherence after such loss. Once ART is initiated and sustained virologic suppression is achieved, CD4 cell count can be monitored less frequently. Once the virus is suppressed for at least 2 years and CD4 cell count rises above the level associated with risk for opportunistic diseases, monitoring can occur annually or not at all if the CD4 count is >500 cells/μL [7].

The recommended frequency of HIV RNA and CD4 monitoring is not the only determinant of how frequently patients should be seen for overall healthcare needs. Patients with concurrent medical conditions may need to be seen more frequently, as well as patients who need ancillary services, such as treatment adherence counseling, mental health and substance use treatment services, STI screening, HIV education, case management services, or harm-reduction counseling.

If virologic failure occurs, genotypic resistance testing for mutations in reverse transcriptase, protease, and integrase (if indicated) genes should be performed to guide the choice of the next treatment regimen. If ART initiation has been substantially delayed, repeat resistance testing may be considered prior to initiating ART [7].

Other Lab Monitoring

Recommendations

- Complete blood count should be monitored every 12 months or when clinically indicated.
- A chemistry panel including glucose, creatinine, eGFR, electrolytes, AST/ALT, and total bilirubin should be done 1–2 months after ART initiation or change. Otherwise, it should be done every 6 months and when clinically indicated. If the

Table 5. Routine Health Care Maintenance for People With Human Immunodeficiency Virus After Initial Assessment

Type of Intervention	Intervention	Recommendation	Comments
-specific monitoring	HIV RNA	Assess every 4–8 weeks after initiation of ART until undetectable and then every 3–4 months. In patients with consistent viral suppression and stable CD4 cell count for more than 1 year, measure every 6 months. If viral blip occurs (HIV RNA detectable but <200 copies/mL), assess adherence and barriers and repeat after 2–4 weeks.	
	CD4 cell count	Assess every 3–6 months for the first 2 years after starting ART or if viremia is present or if CD4 <300 cells/μL. If CD4 300–500 cells/μL and HIV RNA suppressed for 2 years, measure every 12 months. If CD4 >500 cells/μL and HIV RNA suppressed for 2 years, measurement is optional.	
	HIV genotype	Repeat if virologic failure occurs and when clinically indicated. Genotypic testing should include mutations in protease PR/reverse transcriptase genes as well as integrase genes when there is a history of integrase strand transfer inhibitor use, including use of cabotegravir PrEP.	
	Human leucocyte antigen B*5701 testing	No need to repeat this test if done in past. A negative test result is required prior to use of abacavir.	
	Tropism testing	Should be done prior to use of CCR5 antagonist regardless if tropism was done in past. If result is ever X4 or dual-mixed, no need to repeat again as CCR5 antagonist can never be used.	
Other labs	Complete blood count	Perform once a year or when clinically indicated.	
	Chemistry panel	Perform 1–2 months after antiretroviral start or change. Then, every 6 months and when clinically indicated. If not on ART, every 6–12 months.	Including creatinine, estimated glomerular filtration rate, electrolytes, and aspartate aminotransferase/ alanine aminotransferase/total bilirubin.
	Urinalysis	Perform annually if at risk of kidney disease and when clinically indicated. Perform before and during use of tenofovir disoproxil fumarate/tenofovir alafenamide.	
	Pregnancy test	Perform in persons of childbearing potential prior to ART start or change and when clinically indicated.	
Screening for mental health and substance use issues	Depression screening	Perform using a validated tool such as Patient Health Questionnaire (PHQ)-2 or -9 at least annually if resources available and when clinically appropriate.	
	Anxiety screening	Perform using a validated tool such as General Anxiety Disorder -2 or -7 in patients aged <65 years at least annually, if resources available and when clinically indicated.	
	Tobacco use screening	Perform for every adolescent and adult at every visit and offer smoking cessation options if current smokers.	
	Substance and alcohol use screening	Perform using validated tools such as alcohol use disorders identification test and drug abuse screening test at least annually when clinically indicated. Refer to treatment if substance or alcohol use disorder is diagnosed.	

Table 5. Continued

Type of Intervention	Intervention	Recommendation	Comments
Screening for and monitoring of metabolic disorders	Blood pressure screening	Perform at every visit.	
	Weight measurement	Perform at every visit.	
	Screening for hyperlipidemia	Lipid profile: perform every 5 years if normal; more frequently if abnormal or other cardiovascular risk factors present (every 6–12 months); if abnormal, repeat fasting.	Follow atherosclerotic cardiovascular disease risk calculator. Consider testing 1–3 months after starting or changing ART. See Section 7 for further discussion.
	Screening for diabetes mellitus and glucose intolerance	Serum glucose: perform annually; if abnormal, obtain fasting glucose. Hemoglobin A1C should be obtained prior to initiation of ART, if possible. In persons with diabetes, repeat at least every 6 months (more frequently if clinically indicated). Urine microalbumin or urine protein/creatinine ratio: in patients with diabetes, repeat at least every 6 months (more frequently if clinically indicated).	Consider testing 1–3 months after starting or changing antiretroviral medications. Hemoglobin A1c is not used to diagnose diabetes in persons on ART. It may be used for screening and monitoring. Consider threshold cutoff of 5.8%. See Section 7 for further discussion.
	Screening for bone mineral density	Baseline bone densitometry by dual-energy X-ray absorptiometry should be performed in all postmenopausal women and men aged ≥50 years.	See Section 7 for further discussion.
Screening for infectious diseases	Syphilis screening	Perform at least annually in asymptomatic persons; repeat every 3–6 months in asymptomatic persons if risk of acquisition is high, regardless of doxyPEP use.	Acquisition risk depends on sexual activities, use of barrier protection, and local prevalence.
	Gonorrhea and chlamydia screening	Perform at least annually in asymptomatic persons; can repeat every 3–6 months in asymptomatic persons if risk of acquisition is high, regardless of doxyPEP use.	Screening by NAAT at all sites of sexual contact (rectal, oropharyngeal, vaginal, urine/urethral) is recommended for all sexually active persons with HIV. Acquisition risk depends on sexual activities, use of barrier protection, and local prevalence.
	Trichomoniasis screening	Perform annually for persons having vaginal sex.	Screen using NAAT testing.
	Hepatitis A, B, and C screening	Hepatitis C: in sexually active cisgender men and transgender women who have sex with cisgender men and people who inject drugs, screen annually. Hepatitis B: repeat HBV serology (HBsAg, HBsAb, and HBcAb total) in persons without known HBV infection or immunity prior to switching to ART without tenofovir and when clinically indicated, including prior to HCV treatment with direct-acting antivirals.	In those with new abnormal liver function tests, check for acute HAV, HBV, and HCV. Use HCV RNA and HBV DNA testing when clinically appropriate, including for HCV screening in persons with past HCV or those suspected of recent infection within the past 6 months.
	Tuberculosis screening	Perform annually in patients at risk for tuberculosis.	Perform either tuberculin skin test or interferon-γ release assay.
Screening for and prevention of cancer	Smoking	Screen at every visit and for smokers, advise about benefits of cessation and offer pharmacotherapy and referral to behavioral interventions.	Provide resources per local guidelines, including classes, agents that facilitate smoking cessation.
	Low-dose chest computed tomography scan	Those aged between ages 50 and 80 years who have ≥20 pack-years of smoking and are current or former smokers should have an annual low-dose computed tomography scan of the lungs.	
	Prostate cancer screening	Digital rectal exam: considered primary evaluation before PSA screening; consider for patients aged 55–69 years. PSA screening: Age 50–69 years: discuss risks and potential benefits with patient. Age ≥70 years: PSA screening is not recommended.	The impact of HIV on prostate cancer risk is not yet known. African Americans and people with a relative with prostate cancer have a higher burden of prostate cancer. Clinicians should follow US Preventative Services Task Force or American Cancer Society guidelines and consider patient wishes.

Table 5. Continued

Type of Intervention	Intervention	Recommendation	Comments
	Colon cancer screening	Perform for those aged 45–75 years if average risk (including personal and family history). Age 76–85 years: individualize screening based on overall health and prior screening. Consider screening earlier if first-degree relatives diagnosed with colon cancer prior to age 50 years.	Screening tests include: stool-based screening (guaiac fecal occult blood test, FIT, FIT-DNA) every year (or up to 3 years for FIT-DNA) or colonoscopy every 10 years if normal, or more frequently if polyps are identified.
	Breast cancer screening	Age 50–75 years: mammography performed at least every 2 years.	Age 40–49 years: inform of the potential risks and benefits of screening and offer screening every 2 years.
	Cervical cancer screening	Age <21 years: Pap test within 1 year of sexual activity, no later than age 21 years. Age 21–29 years: Pap test at diagnosis of HIV, repeat yearly ×3, then if all normal, Pap test every 3 years. Age <30 years: no HPV testing unless abnormalities are found on Pap test. Age ≥30 years: Pap test only, same as age 21–29 years. Or Pap test with HPV testing, if both negative, then Pap test with HPV every 3 years.	Abnormal Pap test and/or HPV follow-up similar to general population. Note: In general, continue screening past age 65 years.
	Anal cancer screening	Digital anorectal exam: perform at least annually if asymptomatic. Anal Pap: screen transgender women and men aged >35 years who have sex with men and all other people with HIV aged >45 years, with anal Pap smears if there is access to or ability to refer for high-resolution anoscopy and treatment.	Abnormal anal Pap tests should prompt referral for high-resolution anoscopy.
	Hepatocellular carcinoma screening	Perform alpha-fetoprotein and liver ultrasound every 6 months.	For patients with cirrhosis from any cause or chronic hepatitis B, as well as fibrosis levels F3 or F4 among patients with hepatitis C.
Other healthcare maintenance	Reproductive desires	All persons with HIV regardless of sexual orientation and gender identity should be asked about their reproductive desires. Persons of childbearing potential should be routinely asked about their plans and desires regarding pregnancy.	ART, hormone therapy, and other treatments may affect pregnancy and pregnancy plans.
	Oral health examination	All persons with HIV should have oral health examinations biannually.	
	Patient education	Tailor education at every visit to patient's current needs. Regularly address with all patients the importance of medication adherence and viral suppression for personal health and preventing sexual transmission (undetectable equals untransmittable) and provide information on sexual health and harm-reduction practices including PrEP, PEP, safer injection practices, syringe services programs, and naloxone.	Brief counseling and tailored interventions should be offered to patients who may benefit from them to reduce risk. Refer patients to programs that offer interventions not accessible locally, such as medication for opioid use disorder, mental health services, sexually transmitted infection testing, viral hepatitis treatment, PrEP, PEP.

Abbreviations: ART, antiretroviral therapy; CCR5, C-C motif chemokine receptor 5; doxyPEP, doxycycline postexposure prophylaxis; FIT, fecal immunochemical test; HAV, hepatitis A virus; HBcAb, hepatitis B core antibody; HBsAb, hepatitis B surface antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HPV, human papillomavirus; NAAT, nucleic acid amplification test; PEP, postexposure prophylaxis; PrEP, preexposure prophylaxis; PSA, prostate-specific antigen.

patient is not on ART, a chemistry panel should be done every 6–12 months.

- Urinalysis should be monitored annually for those at risk for kidney disease and when clinically indicated. Urinalysis should be monitored before and during treatment with tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF).
- Tuberculosis screening should be performed annually for persons at risk for infection. Repeat testing is recommended in patients with advanced HIV disease who initially had negative TST or IGRA results but subsequently experienced an increase in CD4 cell count to >200 cells/μL on ART and who may thus have developed sufficient immune competence to mount a positive reaction.
- HCV screening with HCV antibody should be repeated every 12 months for persons at increased likelihood of exposure or when clinically indicated. Screening with HCV RNA rather than HCV antibody is indicated for persons with suspected HCV infection within the past 6 months and previous HCV infection that has cleared due to spontaneous resolution or curative treatment. Screening with HCV RNA instead of HCV antibody should be considered for persons with severe immunodeficiency (CD4 count <200 cells/μL).
- Consider repeating hepatitis B serology, including HBsAb, HBsAg, and HBcAb, in persons not infected with or immune to HBV who are switching to an ART regimen that does not contain tenofovir and when clinically indicated, including before starting HCV treatment with direct-acting antiviral (DAA) medication.
- Pregnancy testing in people with HIV of childbearing potential should be performed prior to ART initiation or modification and when clinically indicated.
- Screening for sexually transmitted infections should be performed periodically, as discussed in Section 6.

Evidence Summary

Complete blood count and chemistry panels should be monitored regularly to assess medication toxicity and to monitor potential for existing comorbid conditions (eg, chronic kidney disease, hepatitis). Monitoring frequency depends on the presence of underlying medical conditions and the need to monitor for ART toxicities, depending on the regimens chosen [6, 7, 124]. Persons with co-occurring diabetes, hypertension, HCV, nephrotoxic medication such as tenofovir, genetic predisposition, or advanced HIV disease are at increased likelihood of kidney disease and should be monitored for renal function at least every 6 months, and urinalysis should be performed at least annually. Urinalysis should be monitored before and during treatment with tenofovir-containing compounds [6, 7, 124].

Annual tuberculosis screening should be considered for those who have negative results for latent tuberculosis but are at ongoing risk for exposure, such as through incarceration, congregate settings, homelessness, and travel to countries with high tuberculosis incidence [98, 101]. A TST or IGRA should be performed any time there is concern of a recent exposure or after a CD4 count increase to >200 cells/μL following initiation of ART. Routine cutaneous anergy testing is not recommended.

HCV screening should be repeated at least annually in persons who are at increased likelihood of exposure, such as persons who inject drugs, cisgender men who have sex with cisgender men, and transgender women [98, 125–128]. HCV RNA testing is indicated for screening when HCV infection within the past 6 months is suspected and in people who had previous HCV infection that cleared spontaneously or through treatment. HCV RNA testing should be considered when a person has severe immunodeficiency with CD4 count <200 cells/μL, especially if the person has a history of injection drug use or an ALT level above the upper limits of normal [7, 129]. Repeating HCV RNA after confirmed curative therapy (undetectable HCV RNA at least 12 weeks post-completion of treatment) is not necessary unless there is a clinical indication, such as evidence of unexplained liver injury or ongoing exposure [106].

Persons who have negative hepatitis B serology should be vaccinated (see Section 4). Persons who test positive for HBV infection (with the presence of HBsAg or HBV DNA) should have TDF or TAF and emtricitabine (FTC) or lamuvidine (3TC) included in the ART regimen. People who test positive only with HBcAb may have resolved HBV infection with loss of HBsAb, and HBV DNA testing can be performed to confirm. If the HBV DNA test is negative, the person should then be vaccinated. HBV reactivation can occur in patients during and after treatment with HCV DAA medication, and repeat hepatitis B screening (including with HBV DNA testing if indicated) should be considered in patients not infected with or immune to HBV, especially those with isolated HBcAb, prior to treatment with HCV DAAs [7, 130–132].

A pregnancy test should be performed in persons of childbearing potential prior to initiating or modifying ART. Clinicians should discuss the benefits of ART with the patient as well as regimens that are recommended during pregnancy and their potential toxicities. Shared decision-making with the patient should occur regarding the choice of ART for initiation, continuation, or modification.

Screening and Treatment for Mental Health and Substance Use Issues

Recommendations

- Screening for depression using a validated screening tool should be conducted on every adult patient at least once, with screening frequency based on risk. Annual screening is reasonable, given the elevated risk of depression in people with HIV.

- Screening for anxiety using a validated screening tool should be conducted on every adult patient aged <65 years, with screening frequency based on risk. Annual screening is reasonable, given the elevated risk of anxiety in people with HIV.
- Screening for tobacco use should be conducted for every person with HIV at every visit. Current smokers should be advised of the benefits of quitting and offered options to assist with smoking cessation, including pharmacotherapy and connection to behavioral interventions.
- Screening for unhealthy alcohol use and substance use using validated screening tools should be conducted on every adult patient at least once, with screening frequency based on need. Annual screening is reasonable given the elevated risk of unhealthy alcohol and substance use in people with HIV. Individuals diagnosed with an alcohol or substance use disorder should be offered treatment, including pharmacotherapy (such as methadone or buprenorphine for opiate use disorder) and connection to behavioral health interventions.
- Individuals who inject drugs should be counseled on safer injection and substance use practices to prevent viral hepatitis and other infectious diseases and injection-related conditions such as endocarditis, osteomyelitis, cellulitis, and abscesses. They should be educated on PrEP and PEP for injection partners and provided information on syringe services programs, where available.
- All individuals with substance misuse or use disorders should be provided with life-saving medications such as naloxone for overdose prevention.

Evidence Summary

People with HIV have high rates of depression; anxiety; and tobacco, alcohol, and substance use disorders. After initial screening, optimal screening intervals for mental health and substance use disorders are not known. Repeat screening on a regular basis, such as annually, is reasonable because of the high prevalence of these conditions among people with HIV [133–136]. Screening for depression and anxiety should include the use of validated screening tools such as Patient Health Questionnaire-2 (PHQ-2), PHQ-9, and GAD-2 [82, 83, 137, 138]. People with HIV should be screened for drug and alcohol use with validated screening tools such as the Alcohol Use Disorders Identification Test and the Drug Abuse Screening Test [134, 136, 139]. Self-reported substance use screening tools can be incorporated into electronic health records [140]. Patients who are found to have alcohol or substance misuse or use disorders should be offered or referred for pharmacotherapy, such as buprenorphine or methadone for opioid use disorder and naltrexone for alcohol or opioid use disorder, and/or behavioral health treatment provided within a harm-reduction model of care. Education on safer injecting practices and drug use, syringe services programs, and overdose prevention provides people with choices on how to minimize health risks such as injection-related infections and where to access services if and when they are ready. Naloxone should be provided for overdose prevention. Co-location of substance use treatment with HIV care is ideal [141]. Brief interventions that include use of motivational interviewing can be provided by trained healthcare personnel [142].

Tobacco use is a major cause of decreased life expectancy and poor health outcomes, including cardiovascular disease and lung cancer, in people with HIV [143–146]. People with HIV should be asked about tobacco use at every visit [147–149]. This can be accomplished when taking the patient's vital signs. People who smoke tobacco should be counseled on the benefits of quitting, offered pharmacotherapy, especially varenicline, and connected to behavioral health interventions [150, 151]. See Section 5 for cancer screening in smokers.

Other Health Maintenance Considerations

Recommendations

- All persons with HIV, regardless of sexual orientation and gender identity, should be asked about their pregnancy intentions. Persons of childbearing potential should be routinely asked about their pregnancy intentions, especially prior to treatments that may affect the ability to have children or the outcome of pregnancy.
- Patient education should be tailored at every visit based on the patient's current needs. In particular, the clinician should evaluate the need for education on the following:
  - The importance of medication adherence in achieving viral load suppression to maximize personal health and eliminate HIV transmission to sexual partners (U = U);
  - Optimizing sexual health of the patient and their sexual partners by informing patients about PrEP, PEP, barrier methods, and other strategies for HIV and STI prevention; and
  - Safer use of recreational drugs and their potential side effects and known drug interactions.
- All persons with HIV should have regular oral health examinations at least every 6–12 months.

Evidence Summary

It is important to discuss pregnancy intention and family planning with every patient, especially prior to prescribing medication or treatments that may affect pregnancy or fertility, such as ART or hormone therapy for gender-affirming care. Education should include U = U and the ability to become pregnant without risk of HIV transmission, as well as available options for preserving sperm/ova for future family planning prior to certain treatments. Every patient should also be informed of the possibility of becoming or getting their partner pregnant; if

desired, options for birth control should be reviewed and offered (see Section 8).

Barriers to adherence and care engagement should be repeatedly assessed. Clinicians should engage in effective patient education in a respectful and nonjudgmental manner for maintenance of physical, emotional, spiritual, and sexual health. Providing information on medication adherence, sexual health, and recreational drug use is critical for engaging and retaining patients in care (see Section 1).

People with HIV have frequent oral health complications, especially if the CD4 cell count is low [152]. Any identified oral health complication should be addressed immediately. In addition, every patient should have regular oral health exams. Given the risks for oral complications, a biannual oral health examination for people with HIV is reasonable.

SECTION 4: IMMUNIZATIONS FOR PERSONS WITH HIV

Vaccinations are routinely provided as part of primary care visits, and HIV primary care providers play a unique and trusted role in providing counseling and guidance on recommended immunization strategies. However, due to the time required for counseling, it is advisable to use standing orders and delegate routine vaccinations, which do not require shared decision-making, to other members of the healthcare team, such as qualified nursing or pharmacy staff. Shared decision-making is a collaborative process often used when there is uncertainty regarding the benefits of a specific treatment for a particular population [153, 154]. The healthcare provider shares clear and understandable information about a health condition, explains the necessary decisions and available options, and allows the patient to express their preferences and values. Together, the patient and provider discuss the pros and cons, including risks, which results in a collaborative decision that respects the patient's autonomy. Studies have shown that when shared decision-making is not required, computerized standing orders are more effective than computerized reminders, especially for offering influenza and pneumococcal vaccinations [153, 155]. Vaccination receipt is increasingly regarded as a measure of healthcare quality, and all members of the healthcare team can collectively contribute to achieving these quality metrics. Current immunization recommendations are included in Table 6. However, recommendations change frequently, and HHS OI guidelines and ACIP recommendations should be checked frequently [98, 110, 156].

Pneumococcus, Influenza, Meningococcus, Tetanus-Diphtheria-Pertussis

Recommendation

- Vaccination against infection with pneumococcus, influenza, meningococcus, and tetanus-diphtheria-pertussis should be offered to all people with HIV.

Evidence Summary

Evidence of increased invasive disease due to 7 serotypes not covered in the pneumococcal conjugate vaccine (PCV) 13 (Prevnar13) and the approval of new vaccines with broader coverage have led to revised recommendations for pneumococcal vaccination. The use of PCV20 (Prevnar 20; Vaxneuvance) alone or a combination with PCV15 plus 23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax23) given at least 8 weeks later is now recommended for all individuals aged ≥65 years and for those aged between 19 and 64 years with underlying conditions (such as HIV) who are unvaccinated or whose vaccination status is unknown (see Figure 1). Although there are no clinical outcome data for people with HIV, no additional PPSV23 doses are needed when PCV20 is used, making this a simple and preferred regimen [157, 158]. For those who have received both PCV13 and PPSV23 and are aged <65 years, 1 dose of PCV20 can be administered at least 5 years after the last dose of PPSV23 to complete the series or a second dose of PPSV23 can be administered at least 5 years after the prior dose, with a third and final dose administered at age 65 years or later but at least 5 years after the last PPSV23 dose. For persons aged at least 65 years at the time of a PPSV23 dose, no additional doses are needed. Those who have received only PPSV23 can be given PCV20 with no additional vaccinations or they can be given PCV15 followed by PPSV23 after 8 weeks. Those who have received only PCV13 can be given PCV20 at least 1 year later to complete the series or be given PPSV23 at least 8 weeks later with subsequent PPSV23 doses to complete the series. When there is no access to PCV15, PPSV23, or PCV20, patients should receive whatever is available to receive protection. For those who are aged <65 years and have received PCV20 or PCV15 with PPSV23 at least 8 weeks later, no additional pneumococcal vaccine is needed at age 65. Shared decision-making is recommended when considering PCV20 for adults aged ≥65 years who completed their series with other vaccines. If the decision to administer is made, it should be administered at least 5 years after the last PPSV23 dose. PCV21 (Capvaxive) has also been approved by the FDA and could be substituted for PCV20 in adults for whom a dose of PCV20 is currently recommended [159]. At the time of publication of this guidance, no specific data are available for PCV21 in people with HIV.

All people with HIV should receive an annual influenza vaccination, but they should not receive live vaccination via nasal spray (LAIV4 Flumist). Patients aged >65 years should receive 1 of 3 high-dose, adjuvanted, or recombinant influenza vaccines: HD-IIV4 (Fluzone), aIIV4 (Fluad), or RIV4 (Flublok) [160, 161]. Recommendations for tetanus toxoid, reduced diphtheria toxoid, and reduced acellular pertussis (Tdap; Adacel, Boostrix) are the same as for the general population. Pregnant individuals should receive Tdap during each pregnancy between 26 and 37 weeks' gestation [162]. Adults with

Table 6. Immunizations for People With Human Immunodeficiency Virus

Vaccination	Dose	Revaccination	Comment
Influenza, standard dose: IIV4 (Afluria, Fluarix, FluLaval, Fluzone), ccIV4 (Flucelvax), aIIV4 (Fluad), RIV4 (Flublok); high dose: HD-IIV4 (Fluzone)	1	Yearly	Age >65 years high dose (HD-IIV4, aIIV4, RIV4). LAIV4 (FluMist) is contraindicated for people with HIV; for people with egg allergy, use IIV or RIV.
Tetanus, diphtheria, and acellular pertussis: TdaP (Adacel, Boostrix); tetanus, diphtheria (Tenivac, Tdvax);	1	10 years	Td can be given every 10 years; give TdaP with each pregnancy, give Td if contaminated wound and none received in 5 years.
Meningococcus (MenACWY-TT vaccine; MenQuadfi or Menveo)	2 doses, 2 months apart	5 years	MenACWY-TT: every 5 years after primary series. MenACWY-D is no longer available. Vaccination against meningococcus B not routinely recommended for all individuals. Two MenB vaccines are available, MenB-4C (Bexsero) and MenB-FhBp (Trumenba). A pentavalent meningococcal is available from serogroups ACWY and B (Penvrava) if both vaccines are indicated.
Measles, mumps, rubella	2 doses, 1 month apart	…	CD4 >200 cells/μL and no immunity; if pregnant and not immune, administer after delivery if CD4 >200 cells/μL.
Hepatitis A (Havrix, Vaqta)	2 doses, 6 months apart	…	Check for evidence of immunity post-vaccination, 1–2 months post-vaccination series complete.
Hepatitis B	…	Nonresponders to primary series: repeat full primary series of recombinant, adjuvanted vaccine 0, 1 months (can give third dose at 6 months if HBsAb not seroprotective). Alternatives for revaccination due to nonresponse: double dose recombinant vaccines (Engerix-B, Recombivax HB) at 0, 1, 6 months.	Vaccinate those who do *not* have chronic hepatitis B virus. Check for evidence of immunity postvaccination (HBsAb titer >10 mIU/mL).
• Hepatitis B–naive to vaccination, primary series: recombinant, adjuvanted vaccine (HepB- CpG, Heplisav-B)	2 doses, 0, 1 month	…	Primary series: HepB-CpG (Heplisav-B): after 2 doses, check antibody levels at 1–2 months (and if not immune [titer is not >10 mIU/mL] may consider third dose).
• Alternatives to HepB-CpG: recombinant vaccine double dose (Engerix-B, Recombivax-HB)	3 doses, 0, 1, and 6 months (double dose)	…	Alternatives to HepB-CpG: Engerix-B (20 μg; double dose = 40 μg); Recombivax HB (10 μg; double dose = 20 mcg); check HBsAb titer 1–2 months after complete series.
• Alternatives to HepB-CpG and needing hepatitis A vaccination: combined hepatitis A and recombinant hepatitis B vaccine (Twinrix)	0, 1, and 6 months	…	…
Human papillomavirus (Gardisil)	3 doses (0, 1–2, 6 months)	…	Recombinant 9-valent can be offered to people with HIV up to age 45 years with shared decision-making; vaccination should not be given during pregnancy.
Mpox (Jynneos)	2 doses, 4 weeks apart (subcutaneous or intradermal)	…	Jynneos live nonreplicating vaccinia vaccine requires both doses for maximal immunity (subcutaneous preferred); ACAM 2000 vaccine contraindicated with HIV.
RSV (Arexvy, Abrysvo)	1 dose	…	Those aged ≥75 years should receive a dose; those aged 60–74 years with likelihood of severe RSV should receive a dose (2 different vaccines available); limited data in people with HIV.
VZV (Varivax)	2 doses, 3 months apart		Contraindicated if CD4 <200 cells/μL.
Recombinant zoster vaccine (Shingrix for prevention of recurrence)	2 doses, 0, 2–6 months apart		Can be given to those aged ≥18 years to prevent recurrence of herpes zoster (if prior VZV).
Severe acute respiratory syndrome coronavirus 2 (COVID-19); primary series in persons who are moderately to severely immunocompromised	Because of the changing nature of COVID-19 vaccine policy, see the Centers for Disease Control and Prevention COVID-19 vaccine recommendations for details (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html)		
• Unvaccinated	3 doses (mRNA; Pfizer-BioNTech or Moderna); 2 doses Novavax	…	Pfizer-BioNTech: second dose 3 weeks from first dose, third dose 4 weeks from second dose. Moderna: each dose 4 weeks apart; Novavax: 3 weeks apart.

Table 6. Continued

Vaccination	Dose	Revaccination	Comment
• Received 1 dose prior mRNA	2 doses		Moderna: each dose at least 4 weeks apart. Pfizer-BioNTech: 3 weeks from last dose; 4 weeks from first and second updated.
• Received 2 doses prior mRNA	1 dose	…	Moderna or Pfizer-BioNTech at least 4 weeks after last dose.
• Received 1 or more Novavax or Janssen	1 dose	…	Moderna, Pfizer-BioNTech, or Novavax: at least 8 weeks after last dose.
Vaccination following primary series completion: Please check ACIP recommendations for updates			
• Received complete series not including 2023–2024 vaccine	1 dose 2023–2024 vaccine	…	…
• Received complete series including 2023–2024 vaccine	Age ≥65 years: 1 additional dose 2023–2024 vaccine; age 19–64 years: may give 1 additional 2023–2024 vaccine based on risk		
• Subsequent revaccination	Please check ACIP recommendations.		
Pneumococcus (please see Figure 1 for illustration)			
• PCV20 (Prevnar20) • PCV21 (Capvaxive may be substituted for PCV20)	1 dose	No further doses of PCV20 or PCV21 are needed after first dose. At any time, if PCV20 or PCV21 is substituted for PPSV23, the pneumococcal vaccination series is complete. …	• If no pneumococcal vaccine given or unknown, 1 dose of PCV20 completes pneumococcal vaccination (preferred due to simplicity). PCV21 could be substituted for PCV20 in adults in whom a dose of PCV20 is currently recommended. • If previous PPSV23 or PCV13 alone, can give 1 dose of PCV20 at least 1 year later to complete the series. • If previous PCV13 and PPSV23 received before age 65 years, may give 1 dose PCV20 at least 5 years later to complete series. • If previous PCV13 and 1 dose of PPSV23 received at age ≥65 years, no further vaccine needed, but may receive 1 dose PCV20 at least 5 years later with shared decision-making.
• PCV15 (Vaxneuvance)	1 dose	Give PPSV23 8 weeks after PCV15 to complete the series.	• If no pneumonia vaccine given or unknown, may give 1 dose, followed by PPSV23 8 weeks later (alternative). • If previous PPSV23 alone, give 1 dose PCV15 at least 1 year later to complete series. • If previous PCV13 alone, no PCV15 needed; give PPSV23 at least 8 weeks later or PCV20 at least 1 year later.
• PPSV23 (Pneumovax23)	Do not give as initial vaccine	If only received PPSV23, give PCV20 or PCV15 at least 1 year later to complete series.	If received PCV13 and PPSV23: • If received PPSV23 at age <65 years, may give third and final PPSV23 dose at least 5 years after second PPSV23 dose; OR may receive 1 dose PCV20 at least 5 years after last PPSV23. • If received PPSV23 at age ≥65 years, no further PPSV23 needed (may receive 1 dose of PCV20 with shared decision-making).
Travel Vaccines			
• Vibrio cholera (CVD103-HGR; Vaxchora)	1 dose, oral	…	CVD103-HgR live attenuated; give 10 days prior to exposure; lasts for 3 months; do not give if CD4 <200 cells/μL.
• Polio (Ipol)	3 doses (0, 1–2, 6–12 months)	…	IM, inactivated vaccine for those at high risk for exposure to poliovirus.
• Typhoid (Thyphim Vi)	1 dose	…	Thyphim Vi polysaccharide vaccine (IM), administer 1 week prior to exposure; note: do not give oral vaccine; avoid in pregnancy.

Abbreviations: ACIP, Advisory Committee on Immunization Practices; COVID-19, coronavirus disease 2019; CpG, cytidine monophosphate guanosine; HBsAb, hepatitis B surface antibody; HIV, human immunodeficiency virus; IM, intramuscular; mRNA, messenger ribonucleic acid; PCV. pneumococcal conjugate vaccine; PPSV, pneumococcal polysaccharide vaccine; RSV, respiratory syncytial virus; VZV, varicella zoster virus.

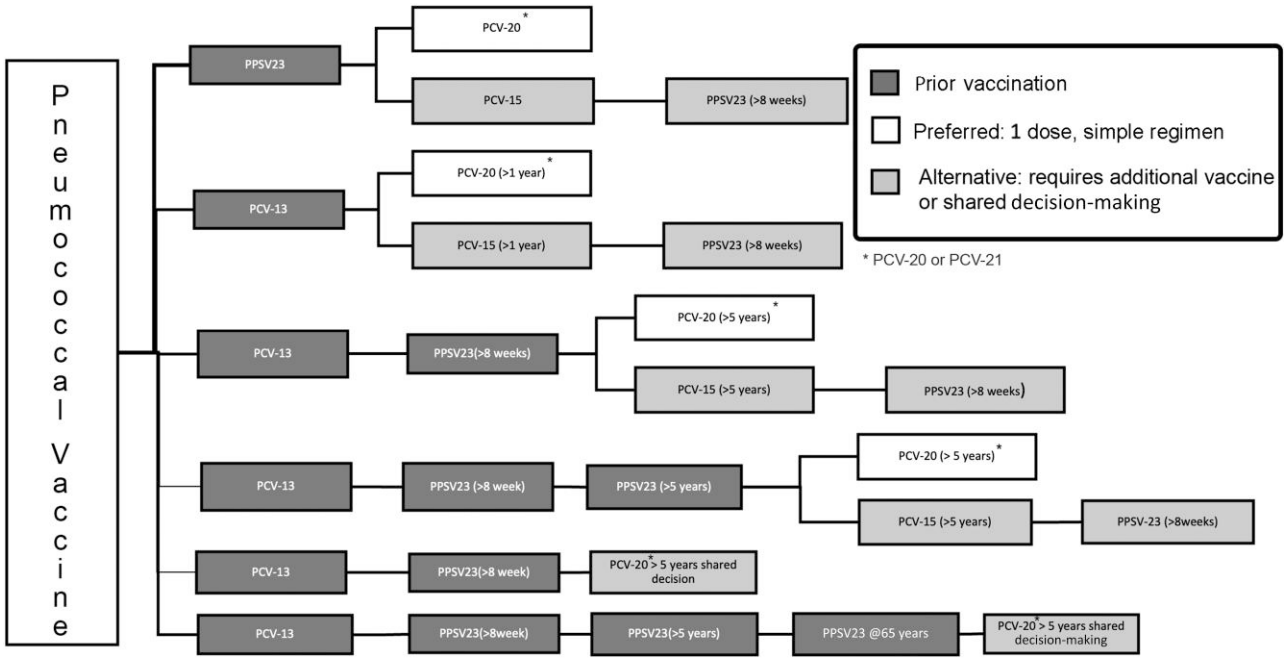

Figure 1. Vaccinations to prevent pneumococcus infection. Abbreviations: PCV, pneumococcal conjugate vaccine; PPSV, pneumococcal polysaccharide vaccine.

HIV should receive a 2-dose quadrivalent meningococcal conjugate vaccine primary series of serogroup A, C, W, and Y (Menveo, MenQuadfi) at least 2 months apart if not previously vaccinated. After the primary series, revaccination should occur every 5 years. Serogroup B meningococcal vaccine (Bexsero, Trumenba) is not routinely recommended but may be given to persons aged 16–23 years and under certain circumstances [163]. Although there are no specific data for people with HIV, a new pentavalent meningococcal vaccine that contains antigens from serogroups ACWY and B (Penbraya) may be given when both vaccines are indicated at the same time [156].

HAV and HBV

Recommendations

- Vaccination for HAV is recommended for all nonimmune individuals with HIV, especially those with indications for hepatitis A vaccine (including PWID, those unstably housed, those with current or prior incarceration, gay and bisexual men or transgender persons with chronic liver disease, travelers to countries with high endemicity, and persons who have hepatitis B and/or C).
- HAV IgG antibody testing 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.
- Individuals susceptible to infection should be vaccinated against HBV.
  - The adjuvant recombinant vaccine (HepB-CpG; Heplisav-B) 2 doses at 0, 1 month is preferred.
  - Alternative regimens can be used if HepB-CpG is not available, including double doses of the recombinant hepatitis B vaccines Engerix-B 40 μg (two 20-μg doses) or Recombivax-HB 20 μg (two 10-μg doses) or standard doses of the combined hepatitis A and recombinant hepatitis B vaccine (Twinrix) given at 0, 1, and 6 months.
- HBsAb levels should be checked 1–2 months after completion of the primary immunization series. If HBsAb is <10 mIU/mL, revaccination with a full vaccine series is necessary. Three doses of HepB-CpG may be considered.
- Vaccination should be recommended for nonimmune sexual partners of persons who are positive for HBsAg.
- Persons who are negative for HBsAg and HBsAb but positive for HBcAb should receive vaccination.

Evidence Summary

Responses to both HAV and HBV vaccines are reduced in patients with a CD4 count <200 cells/μL and those with quantifiable HIV RNA levels. An interim analysis of AIDS Clinical Trial Group (ACTG) study A5379 of adjuvanted recombinant HepB-CpG (Heplisav-B) given at 0, 1, and 6 months to unvaccinated people with HIV who had viral suppression and a median CD4 count of 625 cells/μL (range, 149–1562) showed that 100% developed seroprotective titers of HBsAb >10 mIU/mL

at 28 weeks (4 weeks after a 3-dose vaccine series). At 24 weeks (after 2 doses and prior to the third dose), 98.5% had seroprotective titers. In addition, at 28 weeks (4 weeks after the third dose), 83.8% had titers >1000 mIU/mL [164]. These data are promising, but durability of such high titers is unknown and will be assessed in the ongoing A5379 study [164]. In a person with a high CD4 cell count, a 2-dose HepB-CpG series is seroprotective, but the high titers achieved after a third dose in persons with high CD4 cell counts and suppressed virus, as well as improved responses after a third dose in persons without HIV but who had chronic kidney disease, suggest that those with low CD4 cell counts might achieve a more robust response with 3 doses. Until additional data are available, if a titer >10 mIU/mL is not achieved, consider the patient to be a nonresponder, and a full revaccination series is recommended [98].

Vaccines that can be used if HepB-CpG is not available include 2 recombinant hepatitis B vaccines (Engerix-B or Recombivax-HB) using a double dose at 0, 1, and 6 months or combined hepatitis A and hepatitis B recombinant vaccine at 0, 1, and 6 months. PreHevbrio® is a third recombinant vaccine for which insufficient data exist for people with HIV. Patients who fail to respond to an initial series can be revaccinated with a full series of double-dose Engerix-B or Recombivax-HB (at 0, 1, and 6 months) or a complete 2-dose series of HepB-CpG. Initial data from ACTG 5379 look promising for 2 or 3 doses of HepB-CpG for people with HIV who did not achieve seroprotection from an initial vaccination series. In these individuals, either 2 or 3 doses of HepB-CpG was superior to 3 single-strength doses of Engerix-B, with seroprotective responses of 93.1%, 99.4%, and 80.6%, respectively [165]. Although few people with low CD4 counts were included in the study, these preliminary data suggest that 3 doses of HepB-CpG might be an effective strategy for revaccination in these individuals. A 2-dose strategy is likely to achieve seroprotection for many, and checking HBsAb levels 2 months after the second dose can inform if a third dose should be given at 6 months, as both strategies were superior to 3-dose single-strength recombinant vaccine. However, ACTG 5379 is ongoing, and the durability of seroprotection is still unknown. No safety data on HepB-CpG are available in pregnancy; therefore, HepB-CpG should be avoided in this population. For those initially vaccinated when the CD4 count was <200 cells/μL, an improved response may be observed after virologic suppression on ART and a CD4 count >200 cells/μL are achieved. One dose of vaccine should be administered to patients who have a positive anti-HBc with a negative HBsAg and HBsAb. If the HBsAb titer is not >100 mIU/mL, a full series should be administered [166]. Prior to administration of any HBV vaccine, it is necessary to confirm that the patient does not have chronic HBV.

Those who have been incompletely vaccinated should receive 1 dose of hepatitis B vaccine following exposure to HBV. Those who have not been vaccinated should receive hepatitis B immune globulin (IG) within 24 hours to 7 days for percutaneous exposure to HBV and up to 14 days for sexual exposure to HBV. All infants born to HBsAg-positive persons should receive hepatitis B IG and hepatitis B immunization, preferably in the first 12 hours of life. Routine vaccination for HAV and HBV is recommended for all infants [120, 167]. Serologic testing for viral hepatitis should be repeated if suspected exposure occurs or if there are newly elevated transaminase levels.

MMR, Papillomavirus, and VZV

Recommendations

- MMR vaccine should be administered to people with CD4 count ≥200 cells/μL to protect against measles, mumps, and rubella if they were born in the United States in 1957 or after and have not received this vaccine or do not have immunity to these infections.
- Persons aged between 9 and 26 years should be vaccinated against human papillomavirus (HPV), and those aged 27–45 years who are unvaccinated or inadequately vaccinated should be offered the vaccination series, if appropriate, through shared decision-making.
- Persons who are susceptible to VZV (those who have not been vaccinated, have no history of varicella or herpes zoster, or are seronegative for VZV) should receive PEP with varicella zoster IG as soon as possible (but within 10 days) after exposure to a person with varicella or shingles.
- Varicella primary vaccination should be considered in VZV-seronegative persons aged >8 years with CD4 count >200 cells/μL and in children with HIV aged 1–8 years with CD4 cell percentages >15%. Primary varicella vaccination is contraindicated for persons with CD4 count <200 cells/μL.
- Recombinant zoster vaccine (RZV), 2-dose series, should be given to those aged ≥18 years to prevent reactivation. Response may be better if suppressed on ART and the CD4 count is >200 cells/μL.

Evidence Summary

In 2019, there were 1274 individual cases of measles in 31 states, the highest number reported in the United States since 1992 [168]. The majority of cases occurred in individuals who had not received measles vaccination. The MMR vaccine is administered in a 2-dose series with at least 1 month between doses. MMR should not be given if CD4 is <200 cells/μL. Acceptable evidence of immunity against measles includes written documentation of adequate vaccination, laboratory evidence of immunity, laboratory confirmation of measles, or birth in the United States before 1957 [113].

A preventive 9-valent HPV vaccine (9vHPV; Gardisil) is routinely recommended in a 3-dose schedule for all persons with HIV aged 9–26 years. Catch-up vaccination can be offered to those aged 27–45 years based on shared decision-making [156, 169]. The vaccine is safe and highly effective in preventing infection with the HPV subtypes associated with genital warts and those responsible for approximately 70% of cervical cancers and most anal cancers. Evidence shows a vaccine-associated decrease in the prevalence of HPV infections, anogenital lesions, and precancerous cervical neoplasia [169]. Studies show the safety of HPV vaccine in women, men, and children [170]; however, the efficacy data for people with HIV are limited, with mixed results [171–174]. Furthermore, little is known about the efficacy of HPV vaccination in older age groups. One study reported that when HPV vaccination was given to those with HIV at an older age but <45 years anal dysplasia was reduced [175]. The vaccine is not expected to impact the development of cancer in those who already harbor oncogenic subtypes. All persons with HIV should receive 3, rather than 2, doses of vaccine, regardless of age [176].

Varicella vaccination (Varivax) should be considered (2 doses of single-antigen varicella vaccine, not measles/mumps/rubella/varicella, administered 3 months apart) for adults and adolescents with HIV with a CD4 count >200 cells/μL on suppressive ART who do not have prior evidence of immunity to varicella (including documented prior infection) [177, 178]. Children should also receive the vaccine if aged >8 years and with a CD4 cell percentage ≥15%. Persons without evidence of immunity who have no history of varicella or shingles and no history of vaccination against VZV and who are at risk of developing severe disease or complications should receive varicella zoster IG within 10 days after exposure to persons with varicella or shingles [110, 177, 178]. Varicella zoster IG is not indicated for persons who received 2 doses of varicella vaccine and became immunocompromised later in life [110, 177]. RZV (Shingrix) should be administered to adults aged ≥18 years using 2 doses 2–6 months apart for the prevention of herpes zoster [98]. Those whose virus is suppressed on ART with CD4 count >200 cells/μL may respond better, but the vaccine can be safely given regardless of CD4 cell count. Those who have not had varicella exposure (either infection or vaccination) should not be offered this vaccine. Data indicate that 99% of those born prior to 1980 have had varicella, even if they do not recall receiving the vaccination [179]. Studies in HIV have found the vaccine to be safe and immunogenic after 2 doses.

COVID-19, Mpox, and Respiratory Syncytial Virus

Recommendations

- All people with HIV should receive updated COVID-19 vaccines as recommended by the CDC. Due to rapid changes in recommendations, the CDC guidance should be checked for the most current information.
- The following should be counseled about transmission of mpox and offered vaccination with the live-nonreplicating modified vaccinia Ankara-Bavarian Nordic (MVA-BN) vaccine. The full 2-dose series is required for optimum protection.
  - Persons without mpox lesions who have known or suspected exposure to someone with mpox or with a sex partner in the past 2 weeks who was diagnosed with mpox;
  - Cisgender men who have sex with cisgender men or transgender, nonbinary, or gender-diverse persons who, in the last 6 months, have had a new diagnosis of an STI or more than 1 sexual partner;
  - Persons who, in the last 6 months, have had sex at a commercial sex venue or sex related to a large commercial event or in a geographic area where mpox transmission is occurring;
  - Persons who have a sex partner with any of the above risks or persons who anticipate experiencing any of the above scenarios.
- Persons aged ≥75 years should receive 1 dose of a respiratory syncytial virus (RSV) vaccine. Those aged 60–74 years who are at increased likelihood of severe RSV should receive 1 dose of an RSV vaccine.

Evidence Summary

Vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has had a dramatic impact in reducing severe illness, hospitalization, and mortality. People with HIV are at increased likelihood of reinfection with SARS-CoV-2 [180] and for post-COVID-19 conditions (PCCs, formerly postacute symptoms of COVID-19 or PASC); vaccination protects against development of PCCs [181]. Those who are previously unvaccinated or who received a monovalent COVID-19 vaccine in the past should receive an updated COVID-19 vaccine at least 2 months after the last dose [182]. Note that these recommendations continue to change, and all clinicians should check the CDC website for the most current information [183].

The CDC recommends vaccination against mpox for cisgender gay, bisexual, and other men who have sex with cisgender men and those who are transgender, gender-diverse, or nonbinary and who, in the past 6 months, have had a new diagnosis of at least 1 STI or more than 1 sex partner. Additionally, persons who, in the last 6 months, have had sex at a commercial sex venue or sex in association with a large public event or in a geographic area where mpox transmission is occurring should be offered vaccination. Vaccination is recommended for sexual partners of persons described above and persons who anticipate experiencing any of the above [156]. A live nonreplicating vaccinia virus vaccine for smallpox and mpox (MVA-BN; Jynneos) is safe to administer to those with

immunocompromising conditions, including HIV, although the immune response may be diminished in this population, particularly those with low CD4 cell counts or unsuppressed virus. There are insufficient data during pregnancy and breastfeeding. The peak antibody response is achieved 2 weeks after the second dose [184]. Data from an electronic record review suggest that the Jynneos vaccine was effective in preventing mpox disease [185]. It is crucial that both doses are received for optimal immunity. Those who are unvaccinated and have had exposure should receive the complete series with the first dose within 4–14 days of exposure [98]. The duration of protection remains uncertain, but there is evidence that suggests that severity of disease is reduced in individuals who develop mpox after vaccination, including those with HIV [186–188]. The live attenuated ACAM 2000 smallpox vaccine should not be given to people with HIV (see Section 6).

RSV is a highly contagious virus that can cause severe lower respiratory infections in young children and older adults. Recently, the FDA approved 2 vaccines for those aged ≥60 years, based on risk for severe RSV disease. The RSVPreF3 is a single-dose adjuvanted recombinant prefusion F protein (preF) vaccine, and the RSVPreF is a single-dose recombinant stabilized preF vaccine (Arexvy, Abrysvo). In clinical trials, the efficacy of preventing RSV-associated lower respiratory infection varied from 77% to 81% [189]. Of 38 177 participants who received the vaccines, 6 cases of inflammatory neurologic events after RSV vaccination occurred [189]. Persons aged 60–74 years who have heart or lung disease or weakened immune systems, who are frail, or who live in a group setting are at increased likelihood of severe RSV and should receive 1 dose of an RSV vaccine. Persons aged ≥75 years should receive 1 dose of an RSV vaccine. Data regarding RSV vaccine in people with HIV are limited. Risks and benefits should be assessed based on shared decision-making [190].

Travel Vaccination

Recommendation

- Individuals who travel should be advised to follow CDC guidelines, with particular attention to CD4 cell count, based on their travel activities and destinations.

Evidence Summary

Cholera is a toxin-mediated bacterial infection that results from ingestion of contaminated food or water, leading to severe watery diarrhea. Cholera is likely to occur in areas with inadequate sanitation. CVD103-HgR (Vaxchora) is a single-dose live attenuated oral cholera vaccine recommended for travel to high-risk areas in which *Vibrio cholera* transmission can occur. The duration of protection is approximately 3 months, and vaccine efficacy may be lower in people with HIV. CVD103-HgR should be given at least 10 days prior to potential exposure among those aged 18–64 years [191]. Before 2022, poliovirus cases had not been seen in the United States for more than 30 years, and only a limited number of cases had been reported in Afghanistan and Pakistan. In 2022, there was a 23% increase globally in polio cases caused by circulating vaccine-derived poliovirus and decreased polio vaccination rates, including a paralytic case in New York City, accompanied by local wastewater surveillance for poliovirus [192]. The risk of acquiring vaccine-derived polio is low and can be mitigated by vaccination. Those who may have high-risk exposure can receive a 3-dose vaccine (Ipol) if CD4 is >200 cells/μL and if the benefits outweigh the risks [193]. Typhoid fever can cause life-threatening illness due to *Salmonella* Typhi. Individuals who travel to high-incidence areas should consider vaccination to reduce the risk for typhoid fever. Typhoid vaccine Thyphim Vi covers *Salmonella enterica* serotype paratype A, B, and C. The intramuscular vaccine should be administered 1 week prior to travel. People with HIV should avoid the live-attenuated oral vaccine (Vivotif) [194].

SECTION 5: SCREENING FOR AND PREVENTING CANCER

Because of an increased likelihood of both first and second primary cancers among people with HIV, enhanced cancer prevention, screening, and treatment efforts are needed for people with HIV both before and after an initial cancer diagnosis. It is recommended that clinicians who are treating patients with cancer inquire and screen for HIV if serostatus is not established [195, 196]. Clinicians treating HIV should regularly inquire about cancer risks and ensure recommended screenings [195]. Although persons with HIV have increased rates of certain cancers, recommendations for screening (prostate, breast, colon, lung) are not different from those for the general population, and providers should follow US Preventive Services Task Force (USPSTF) and American Cancer Society guidelines. However, AIDS-defining cancers and non–AIDS-defining cancers, especially virally based cancers, occur more frequently in people with HIV and merit increased attention [197–199]. Higher CD4 count (≥350 cells/μL) and maximal viral suppression are associated with lower 5-year mortality among patients with HIV and any cancer diagnosis [200]. While most cancers are not diagnosed at younger ages in people with HIV, lung cancer, anal cancer, and myelomas may occur at younger ages among people with HIV compared with those without HIV. People with HIV are at greater risk for oral/pharyngeal and kidney cancers [198, 201]. Viral suppression is especially associated with lower risk of virally associated and non–AIDS-defining cancers among those on ART [201]. As such, as with most comorbidities, viral suppression is urged for people with HIV who have cancer. Because people with HIV have

higher mortality rates after they develop cancer, increased observation, vigilance, and screening are required [202].

Recommendations

Prevention

- All patients should be asked about tobacco use at every healthcare encounter, and those who smoke should be strongly encouraged to stop smoking and offered smoking cessation assistance, including pharmacotherapy and behavioral interventions.
- Because alcohol increases risk of certain cancers, moderation in alcohol consumption should be recommended.
- Vaccinations against HPV and HBV are essential to reduce the risk of cervical, anal, head, and neck cancers and hepatocellular carcinoma.

Screening and Detection

- Providers should be vigilant for cancer, especially human oncogenic viral-based cancers, associated with Epstein-Barr virus (EBV), HPV, HCV, and HBV, even if no specific screening is recommended.
- Screening for prostate, breast, lung, and colon cancer should be conducted according to USPSTF and American Cancer Society guidelines for the general population.
- Biennial mammogram screening is recommended for persons aged 40–74 years, per USPSTF guidelines.
- A digital anal rectal exam should be performed annually, whether or not high-resolution anoscopy (HRA) is available.
- Transgender women, cisgender men aged >35 years who have sex with cisgender men, and all other people with HIV aged >45 years should be screened with an anal Papanicolaou (Pap) test if there is access to or ability to refer for HRA (preferred) and treatment. The IDSA recommends HPV testing with cytology only and not just HPV testing alone.
  - For low-grade squamous intraepithelial lesions or worse, the patient should be referred for HRA and HPV testing if aged <45 years. Patients aged at least 45 years should be referred for HRA and HPV testing.
  - All high-grade squamous intraepithelial lesions (HSILs) should be treated, ideally with hyfrecation, and monitored routinely among people with HIV and aged >35 years.
  - All patients with anal cancers should be referred to surgical oncology for treatment.
- Persons with HIV aged between 21 and 29 years should have a cervical Pap test annually. If the results of 3 consecutive cervical Pap tests are normal, follow-up Pap screening should be in 3 years.
  - Abnormal Pap test results require either follow-up colposcopy by a qualified practitioner or repeat Pap test in 6–12 months.
  - For persons aged ≥30 years, cervical Pap tests should be done annually. If the results of 3 consecutive Pap tests without an HPV test are normal, a follow-up Pap should be performed in 3 years. If the Pap test is done with HPV testing and both the cytology and HPV testing are negative, follow-up cervical cancer screening can be done in 3 years after a single Pap smear.
  - Unlike for people without HIV, there is no age limit for Pap screening.
  - If HPV testing reveals HPV16 or HPV16/18, referral for colposcopy is recommended.
- Providers should follow USPSTF screening recommendations for prostate cancer.
  - Shared decision-making for prostate-specific antigen (PSA) testing is recommended for patients aged 50–69 years with at least a 10-year life expectancy.
  - PSA-based prostate cancer screening should be considered for persons of Black or African descent, people with prostates aged 45–49 years with at least a 10-year life expectancy, and persons who have at least 1 first-degree relative with prostate cancer.
- Screening for hepatocellular carcinoma every 6 months by ultrasound with or without alpha-fetoprotein is recommended for those with cirrhosis from any cause, those with chronic hepatitis B, and those with a history of chronic hepatitis C (treated or untreated) and stage F3 or F4 fibrosis.

Special Populations

- After vaginoplasty, patients should be reminded that screening for conditions related to remaining organs, such as prostate cancer, is still necessary.
- Cancer screening for transgender and gender-diverse persons should be conducted based on guidelines for the organs and tissues present in the individual.
- Among transgender people with prostates, PSA is unreliable for those on androgen blockers and those who have undergone orchiectomy. For those with a neovagina, a neovaginal and rectal exam should be used to examine the prostate.

Evidence Summary

Acquired immunodeficiency, as encountered among people with HIV, is associated with an increased risk for cancer [203]. As such, interventions that may prevent cancer are essential to HIV care. Healthcare systems should maintain a record of patients' current smoking status. All clinicians should advise patients to stop smoking and document this message at least yearly in the health record. Pharmacotherapy such as varenicline should be offered, as well as referrals for behavioral

interventions to assist with smoking cessation [146, 150, 204]. The CMS, American Cancer Society, and USPSTF recommend that adults aged between 50 and 80 years with a ≥ 20 pack-year smoking history and who currently smoke or have quit within the past 15 years receive screening noncontrast low-dose computed tomography (LDCT) scan of the chest to detect lung cancer [205]. Persons with HIV may receive the same mortality benefit from LDCT screening as those not living with HIV if the CD4 count is >500 cells/μL and the patient is ART-adherent [206].

Heavy alcohol use can negatively impact most cancer treatments and may put people at greater risk for esophageal, stomach, and liver cancers [207]. As such, reduced alcohol use is advised. Further, vaccination against HBV and HPV is also strongly recommended to prevent liver cancer and HPV-associated cancers, including anal, cervical, and head and neck cancers. Although persons with HIV have increased rates of certain cancers, recommendations for screening (prostate, breast, colon, lung) are not different from those for the general population. Because people with HIV are at increased risk of both primary and additional cancers, screening for cancer is needed, and enhanced secondary cancer prevention is essential [196].

While screening for most cancers in adults with HIV is not different from that of the general population, including breast cancer screening, providers who treat adults with HIV should have high suspicion for cancers, even if no regular screening is recommended. Providers should be especially vigilant for human oncogenic virally based cancers, including cancers that are due to EBV, HPV, HBV, and HCV [203]. Higher CD4 count (≥350 cells/μL) and maximal viral suppression are associated with lower 5-year mortality among patients with HIV and any cancer diagnosis. Maximal viral suppression should be encouraged, especially if people with HIV and cancer are undergoing chemotherapy or radiation therapy [200]. Genital, oral, cervical, and anal warts should be treated to prevent development of cancer [208].

Screening for hepatocellular carcinoma every 6 months by ultrasound with or without alpha-fetoprotein is recommended for those with cirrhosis from any cause [209]. This recommendation applies to people with HIV and chronic HBV and those with treated or untreated HCV and fibrosis stage F3 or F4. Breast cancer is the second leading cause of cancer-related deaths in women in the United States after lung cancer [210]. It does not appear to be increased in prevalence among people with HIV, although unusual clinical presentations and rapid progression have been reported, suggesting that breast cancer may behave more aggressively in this setting (bilateral disease, poorly differentiated carcinoma, and early metastasis) [210]. At present, screening mammography in persons with HIV should follow USPSTF and American Cancer Society guidelines for the general population, which are not always concordant [211, 212].

Anal cancer incidence (as well as oral cancers that are of HPV origin) is greatly elevated among people with HIV, especially among cisgender men who have sex with cisgender men, older people with HIV, people with CD4 count <200 cells/μL, and African Americans [208, 213]. There are national screening guidelines for the use of anal Pap tests in healthcare maintenance, especially among people with HIV [214]. For all people with HIV who have a prostate, a digital rectal exam is recommended to detect masses, blood, or prostate size and smoothness. Data published in 2022 demonstrate the benefit of anal cancer screening and treatment among cisgender men with HIV aged >35 years who have sex with cisgender men and all other people with HIV aged >45 years if there is access to or ability to refer to HRA (preferred) and treatment. If an anal Pap test or HRA is done, all HSILs should be treated, preferably using hyfrecation, and monitored regularly for clearance or recurrence. The exact timing of follow-up monitoring is still undetermined [215, 216]. Additional data are needed to determine whether persons with a history of receptive anal intercourse and all persons with genital warts should have periodic anal Pap tests if access to appropriate referral for follow-up, including HRA, is available [217]. If anal cancer is diagnosed, referral should be made to oncology or surgical oncology for appropriate treatment [208]. Data are needed to generate recommendations for anal cancer screening and prevention in cisgender women.

Prostate cancer screening that follows USPSTF guidelines is generally recommended. There is increasing evidence, however, that prostate cancers among people with prostates aged 50–69 years who have a 10-year life expectancy should have shared decision-making about PSA testing. Among Black adults with a prostate, the lower age limit for PSA screening is 45 years. PSA screening is not recommended at this time for adults with a prostate aged ≥70 years [218–220].

For persons aged between 21 and 29 years, cervical cancer screening should be performed within 1 year of sexual debut but not later than age 21 years or at the diagnosis of HIV. If the initial Pap test is negative, some experts recommend that a repeat Pap test be performed within 6–12 months. If the results of 3 consecutive Pap tests are normal, a follow-up Pap test should be performed at 3 years. The use of HPV co-testing in this age group is not recommended. For persons aged >30 years, cervical cancer screening should commence at diagnosis and be continued throughout a patient's lifetime and not stopped at age 65 years as recommended for the general population. In this age group, Pap testing can be done with cytology alone or with the addition of HPV co-testing. Some experts recommend that a repeat Pap test be done 6 months after the initial Pap test. If the results of 3 consecutive Pap tests are normal, a follow-up Pap test should be done in 3 years. If testing is done with Pap and HPV co-testing and if the results of both tests are normal, the next screening can occur in 3 years [221, 222].

Special considerations are needed for transgender adults with HIV in regard to cancer. While likely multifactorial, transgender persons have a greater risk of being diagnosed with cancer later than the general population, lower odds of receiving appropriate oncologic treatment, and worse odds of survival than other people with cancer. Thus, greater vigilance is needed for transgender individuals at risk of cancer [223]. Further, even after vaginoplasty, there needs to be lifelong follow-up for prostate cancer and other cancers found among people born with male sex organs that are not removed. It also should be noted that among transgender individuals with prostates, PSA testing may be unreliable if they are taking androgen blockers or are status post-orchiectomy. For those with a neovagina, a neovaginal exam of the prostate should be performed [224].

SECTION 6: STI SCREENING, TREATMENT, AND PREVENTION

In 2022, the United States experienced extremely high rates of chlamydia, gonorrhea, and syphilis, with continuing and striking disparities by race/ethnicity, gender, sexual orientation, age, and geography. People with HIV accounted for 36.4% of cases of primary and secondary syphilis among gay and bisexual men [225]. Trichomonas is common among persons who have vaginal sex, although most cases are asymptomatic. Beginning in 2022, global outbreaks of mpox disproportionately affected people with HIV and have been particularly frequent and more severe among those with advanced immune suppression [226]. Evidence is evolving to support prevention of some STIs using doxyPEP, although the risk of antimicrobial resistance is an ongoing concern. It is essential that STI screening, treatment, and prevention efforts be centered on equity-based strategies.

Screening and Treatment for STIs

Chlamydia, Gonorrhea, Syphilis, and Trichomonas

Recommendations

- Services for STI (including mpox) screening, treatment, and prevention should be convenient and affordable, delivered in a stigma-free environment, and made accessible to populations with the highest prevalence of infection using equity-based strategies.
- All patients should be screened for gonorrhea, chlamydia, and syphilis upon entry into care. Persons who have receptive vaginal sex should be screened for trichomonas using the vaginal or cervical nucleic acid amplification test (NAAT). Screening for gonorrhea and chlamydia should be by NAAT at all sites of sexual contact (oral, anal, urethral/urine, vaginal/neovaginal). Done correctly, self-collected NAAT swabs may be used to enhance acceptability.
- In asymptomatic sexually active persons, screening for gonorrhea, chlamydia, and syphilis should be repeated at least annually. Persons who have receptive vaginal sex should be screened for trichomonas at least annually.
- In persons with multiple or anonymous sex partners, screening should be conducted every 3–6 months depending on sexual activities, presence of recent STIs in the patient or their partner(s), and local community STI prevalence. Those found to have gonorrhea, chlamydia, syphilis, or trichomonas on initial screening should be treated and rescreened in 3 months because of high reinfection rates.
- For those diagnosed with pharyngeal gonorrhea, a test of cure should be performed at 7–14 days with an NAAT or culture, although testing at 7 days is associated with a higher rate of false-positive results. If an NAAT obtained for test of cure is positive, a culture should be obtained, and positive cultures should undergo antimicrobial susceptibility testing.
- For gonorrhea that is unresponsive to treatment, regardless of site, culture should be obtained, and positive cultures should undergo antimicrobial susceptibility testing.
- All persons with syphilis should be screened for ocular and otic involvement as well as neurologic symptoms and signs. However, a lumbar puncture is not indicated in individuals with isolated ocular or otic symptoms. A lumbar puncture should be performed in those with neurologic findings.
- Retreatment after treatment failure should be implemented according to CDC STI guidelines. Following a diagnosis of syphilis, nontreponemal titers should be followed and a lumbar puncture performed if titers increase by 4-fold (sustained by at least 2 weeks) without evidence of reinfection after treatment. Cerebrospinal fluid (CSF) examination and retreatment may be considered if titers do not decrease 4-fold by 24 months.
- Pregnant individuals should be screened for chlamydia, gonorrhea, and syphilis at the first prenatal visit, 28 weeks, and also, for syphilis, at delivery. Screening for trichomonas should be offered at the first prenatal visit. Screening should be more frequent depending on past STI incidence in the patient or partner(s) and community STI prevalence. Partners of pregnant persons with STIs should be offered screening and treatment.
- Because of increasing antibiotic resistance, especially with gonorrhea, CDC STI treatment guidelines should be consulted frequently, and treatment should follow these recommendations.
- In cisgender women, trichomonas should be treated using metronidazole 500 mg twice daily for 7 days, while a single 2-g dose may be used in cisgender men.

Evidence Summary

Between 2018 and 2022, gonorrhea diagnoses increased by 11% overall but were lower than in 2021, with 40% occurring among

gay, bisexual, and other cisgender men who have sex with men. Syphilis diagnoses increased a striking 78.9%; this includes 3755 cases of congenital syphilis, a 183% increase since 2018. Cases of chlamydia were level compared with 2018 but at a high incidence of 1 649 716 cases. Chlamydia, gonorrhea, and syphilis continued to disproportionately affect racial and ethnic minorities, with 31% of these cases occurring in non-Hispanic African Americans and half of diagnosed STIs occurring among persons aged 15–24 years [225].

Screening

Nucleic acid amplification testing is the most sensitive screening method for chlamydia and gonorrhea and should be obtained from all sites of sexual exposure. For persons with a vagina/neovagina, swabs from that area are more sensitive than urine, while urine is acceptable for persons with a penis. Self-collected vaginal/neovaginal and anal swabs are as sensitive as those collected by care providers and may be more acceptable and adaptable to at-home testing. The COVID-19 pandemic accelerated interest in home-testing for STIs, sometimes paired with telemedicine or online ordering of test kits, particularly for gonorrhea and chlamydia [227]. In a pilot study in Washington, DC, in which self-tests for HIV, chlamydia, and gonorrhea were sent to users by mail, positivity rates for chlamydia and gonorrhea (especially in extragenital areas) were high in returned samples [228]. Clinicians should be familiar with CDC's updated laboratory testing guidelines for syphilis [229]. Diagnosis of syphilis generally relies on serologic testing that consists of a nontreponemal test (with positives expressed in titers) and a treponemal test. However, self-testing has relied on treponemal antibody testing, which may be falsely negative in early infection or positive long after an initial infection has been treated. Clinicians should be familiar with considerations regarding point-of-care testing for syphilis from the National Syphilis and Congenital Syphilis Syndemic Federal Task Force [230]. The development of nontreponemal tests suitable for self-testing remains a research gap of high interest.

All persons with syphilis should be screened for ocular and otic syphilis and for neurologic signs and symptoms. Persons with syphilis and ocular or otic symptoms should receive treatment immediately to preserve vision and hearing. However, a lumbar puncture is not required unless neurologic signs or symptoms are present. A lumbar puncture is indicated in those with neurologic findings and those whose nontreponemal titer has increased 4-fold (sustained for more than 2 weeks) without evidence of reinfection. Persons whose nontreponemal titers have not decreased 4-fold by 24 months should be examined clinically; a CSF examination and retreatment may be considered. CDC STI guidelines should be consulted when treatment fails [213]. Pregnant persons are at high risk for STIs and should be screened for gonorrhea, chlamydia, syphilis, and trichomonas at the first prenatal visit, 28 weeks, and also at delivery for syphilis [120, 225]. Congenital syphilis is preventable and can be eliminated by diligent screening and treatment during pregnancy, including at delivery. Note that treponemal antibody tests (such as fluorescent treponemal antibody absorption (FTA-ABS) or microhemagglutination assay for *Treponema pallidum* (MHA-TP)) often remain positive for life despite effective treatment [231].

Trichomoniasis is the most common STI among those who have vaginal sex, with disproportionately high rates among Blacks and cisgender women with HIV [231]. It is associated with increased HIV shedding in those without viral suppression, with pelvic inflammatory disease, and with adverse pregnancy outcomes. Screening should be conducted using an NAAT or an FDA-approved rapid test and repeated in 3 months for those who test positive, as reinfection rates are high. During pregnancy, screening should occur at the first prenatal visit and during the third trimester, at minimum, with treatment delivered as needed.

Treatment

Antibiotic resistance is of high concern, especially for gonorrhea, although most strains have remained sensitive to ceftriaxone to date. In 2020, CDC recommended gonorrhea treatment with a single dose of intramuscular ceftriaxone 500 mg (or 1000 mg for those who weigh ≥150 kg) without concurrent azithromycin [232]. Test of cure with an NAAT or culture is recommended for pharyngeal gonorrhea at 7–14 days after treatment, although testing at 7 days is associated with a higher rate of false-positive results. Culture should be obtained for all gonorrhea treatment failures so that antimicrobial susceptibility testing can be performed [231]. The preferred treatment for early, secondary, latent, and late-latent syphilis continues to be benzathine penicillin G. However, doxycycline can be used for 14–28 days, depending on the stage of the disease in the event of true penicillin allergy or penicillin shortage. If neurosyphilis is present or the patient is pregnant, intravenous aqueous crystalline penicillin G should be used, even if desensitization is required. The high price of commercially obtained benzathine penicillin and intermittent shortages of this drug are barriers to ending the syphilis epidemic, particularly among pregnant women for whom no other viable regimens are recommended. In cisgender women with HIV, treatment of trichomonas using metronidazole 500 mg twice daily for 7 days was more effective than a single 2-g dose of metronidazole; cisgender men can be treated using the single-dose regimen [231]. In most cases, chlamydia is treated with doxycycline 100 mg twice daily for 7 days. However, rectal chlamydia associated with inguinal lymphadenopathy or symptoms of proctocolitis (such as bloody discharge, tenesmus, ulcers) raises suspicion of lymphogranuloma venereum (LGV). Although LGV and non-LGV chlamydia can be distinguished by molecular testing, LGV is usually diagnosed clinically and treated with 21 days of doxycycline 100 mg twice daily. Close monitoring of and referral

to the CDC STI treatment guidelines are essential, as susceptibilities and recommendations change over time [231].

Mycoplasma Genitalium

Recommendations

- Persons with recurrent urethritis or cervicitis should be screened with an NAAT for *Mycoplasma genitalium* (Mgen). Screening should be considered for those with pelvic inflammatory disease.
- Screening for Mgen in asymptomatic persons or screening of extragenital sites is not recommended.

Evidence Summary

Mgen is a cause of nongonococcal/nonchlamydial penile urethritis and can cause persistent or recurrent urethritis. It has been associated with cervicitis, endometritis, and pelvic inflammatory disease in cross-sectional studies. Case-control and cross-sectional studies suggest that urogenital Mgen is more common among people with HIV and may be associated with HIV shedding among people not taking ART [231]. Resistance to azithromycin is widespread, and fluoroquinolone resistance is increasing. Multidrug resistance to azithromycin, fluoroquinolones, and doxycycline has been identified [233]. Resistance testing for refractory or recurrent infections should be performed where available, but molecular tests are not yet widely available outside of research settings. There are insufficient data on clinical outcomes associated with asymptomatic Mgen, and antibiotic use in this setting could increase the prevalence of resistant organisms. Therefore, screening of asymptomatic persons for Mgen is not recommended. The efficacy of doxyPEP for prevention of symptomatic Mgen is an area of active investigation, as is the risk of Mgen resistance in this setting [234].

Mpox

Screening and Treatment

Recommendations

- Persons exposed to mpox through sexual activity or close contact should be advised to monitor for symptoms for 21 days, consider vaccination if asymptomatic and within 14 days of exposure, and seek medical care immediately if symptoms develop.
- Persons with cutaneous, oropharyngeal, or anorectal lesions suspected to be due to mpox should receive polymerase chain reaction (PCR) testing of lesions for orthopoxvirus (mpox) and should isolate as recommended in the CDC guidelines.
- Persons with suspected mpox should be offered screening for HIV (if not known to have HIV) and STIs, especially chlamydia, gonorrhea, and syphilis.
- ART initiation should not be delayed when HIV is diagnosed concurrent with mpox, and therapy should be adjusted as soon as possible for those on ART with virologic failure in the setting of mpox.
- Treatment with tecovirimat should be offered to people with HIV whose virus is not suppressed or whose CD4 count is <350 cells/μL, those who are pregnant, and those who have other immunocompromising conditions; severe disease; oropharyngeal, anorectal, genital lesions; bacterial superinfection, especially requiring debridement; or other conditions that put them at high risk of poor outcomes, as designated by the CDC.

Evidence Summary

Compared with previous mpox outbreaks, the global outbreak that began in 2022 occurred predominantly among cisgender men and transgender women who have sex with cisgender men and has been associated with more mucosal and anorectal disease and delayed prodromal symptoms compared with previous outbreaks in endemic countries. A global systematic review of 52 studies that included 6345 persons with mpox found that 40% of persons also had HIV [235]. A global series of mpox among 382 people with HIV and CD4 count <350 cells/μL found high prevalence of serious outcomes, including necrotizing skin lesions, lung involvement, secondary infections, and sepsis, particularly in those with CD4 count <100 cells/μL. In the group as a whole, 28% were hospitalized and 7% died. Among those who died, all had CD4 count <200 cells/μL, and mortality was especially high (57%) among 21 persons who developed mpox immune-related inflammatory syndrome (IRIS) after initiation or reinitiation of ART. In this series, only 16% received tecovirimat (TPOXX) [226]. Initiation of ART, however, should not be delayed because of concern about IRIS, as viral suppression can be lifesaving in this population. As of March 2023, the CDC reported that 94% of deaths associated with mpox in the United States were among people with HIV. In those with CD4 count data available, 96% of deaths were among people with CD4 counts <50 cells/μL. Among those with treatment data available, only 9.1% were receiving ART prior to their mpox diagnosis. Of all mpox deaths, 90% occurred among Black men [236]. An equity-based approach to mpox screening, treatment, and prevention is essential, prioritizing people with HIV, especially those with low CD4 counts or uncontrolled virus and racial and ethnic groups that bear a disproportionate burden of severe mpox.

PCR testing of mpox lesions is associated with the highest diagnostic yield [237], although virus can often be recovered from the anorectal and oropharyngeal regions. Other STIs often occur concurrently with mpox, and STI (and HIV if status is unknown) screening is imperative in persons who present with suspicion of mpox. People with suspected or confirmed mpox who are at risk of serious outcomes should receive TPOXX under an expanded access investigational new drug submission administered by the CDC [238]. This includes people with unsuppressed virus or CD4 count <350 cells/μL; other immunocompromising conditions; severe disease;

oropharyngeal, anorectal, or genital lesions; or bacterial superinfection, especially requiring debridement. People without severe disease may consider enrolling remotely in the Study of Tecovirimat for Human Mpox Virus (STOMP) trial, a National Institutes of Health–sponsored study to determine the effectiveness of TPOXX [239].

Although the 2022 mpox outbreak peaked in the summer of 2022 and was curtailed by vaccination, education, and behavior change among persons at highest likelihood of acquisition, clusters of resurgence continued to occur in 2023 and increased in early 2024 [188, 240]. A health alert from the CDC in December 2023 notified health professionals of the human-to-human transmission of clade I mpox within the Democratic Republic of Congo (DRC), with concern for international spread. Mpox infections in the United States have been with the clade II virus, while clade I is associated with increased transmissibility and more severe outcomes than with clade II. Clinicians should be aware of the possibility of clade I infection in persons returning from the DRC and other affected nations who develop symptoms within 21 days of travel. Both Jynneos vaccination and TPOXX treatment are thought to be effective against the clade I virus [241]. Vaccination efforts are of ongoing importance, including ensuring that both doses of vaccine are received. As of November 2023, only 61% of people who received an initial MVA-BN smallpox vaccine (Jynneos) received the full series [242]. A global case series of 37 persons with mpox reinfection or mpox that occurred after adequate vaccination found that cases were mild, with few lesions and little mucosal involvement, no deaths, and only 1 hospitalization in spite of only 2 individuals receiving TPOXX [187]. Therefore, while a 2-dose vaccination series may not prevent infection, it likely will prevent severe disease (see Section 4: Immunizations).

Prevention of STIs

Recommendations

- Individuals with recurrent STIs and ongoing sexual activities that place them at high likelihood of STI acquisition should receive tailored HIV and STI prevention messages that are appropriate to the individual's sexual health goals. If available, persons with recurrent STIs may benefit from counseling or more structured programs that offer interventions to reduce acquisition.
- Clinicians should discuss the potential benefits and harms of doxyPEP with individuals who may benefit from it. DoxyPEP should be discussed with and offered to cisgender gay, bisexual, and other men who have sex with cisgender men; transgender women; and people with HIV who have had syphilis, chlamydia, or gonorrhea in the last 12 months or who anticipate engaging in sexual activities associated with the increased likelihood of acquiring an STI. The dose of doxycycline is 200 mg as a single dose (maximum 200 mg in 24 hours), ideally taken as soon as possible after sex but no later than 72 hours afterward.
- At present, data are inadequate to support the efficacy of doxyPEP in cisgender women, cisgender heterosexual men, transgender men, and gender-diverse persons assigned female at birth. Shared decision-making should be used in these populations.
- Persons who actively use doxyPEP should be screened for syphilis, chlamydia, and gonorrhea at 3- to 6-month intervals, depending on sexual practices.

Evidence Summary

Persons with frequent recurrent STIs may benefit from counseling and other structured interventions to decrease STI acquisition. Condoms can be effective in decreasing STI acquisition and should be offered. Some individuals with recurrent STIs may benefit from prevention of bacterial STIs using doxyPEP, defined as a single dose of doxycycline 200 mg taken as soon as possible after sex but no later than 72 hours afterward. The maximum dose of doxycycline is 200 mg within 24 hours.

Preliminary data that support the activity of doxycycline in preventing chlamydia and syphilis came from a substudy of the French National Agency for Reserch on AIDS (ANRS) Ipergay trial of intermittent HIV PrEP, in which participants took doxycycline 200 mg within 72 hours of sexual exposure. Doxycycline use was associated with a 70% decrease in chlamydia and syphilis but no decrease in gonorrhea [234]. Two randomized trials subsequently demonstrated the efficacy of doxyPEP in preventing chlamydia, gonorrhea, and syphilis among cisgender gay and bisexual men and transgender women. The DoxyPEP trial, a randomized, open-label trial in Seattle, Washington, and San Francisco, California, included 630 cisgender gay and bisexual men and transgender women. In May 2022, the study was stopped by its data and safety monitoring board after a planned interim analysis showed statistically significant reductions in syphilis (relative risk [RR], 0.23; 95% confidence interval [CI], .04–1.29), chlamydia (RR, 0.26; 95% CI, .12–.57), and gonorrhea (RR, 0.43; 95% CI, .26–.71) and no safety concerns, including among people with HIV [243]. In the PrEP cohort, the RRs were 0.45 (95% CI, .32–.65) for gonorrhea, 0.12 (95% CI, .05–.25) for chlamydia, and 0.13 (95% CI, .03–.59) for syphilis. In the cohort of people with HIV, the RRs were 0.43 (95% CI, .26–.71) for gonorrhea, 0.26 (95% CI, .12–.57) for chlamydia, and 0.23 (95% CI, .04–1.29) for syphilis [244]. The limited antimicrobial resistance data from this study are inconclusive, although 6 of 20 incident gonorrhea isolates in the doxycycline arm displayed tetracycline resistance [245]. ANRS 174 (DOXYVAC) was a French randomized, open-label, factorial-design trial that evaluated doxyPEP and meningococcal B vaccine (4CMenB) in gay and bisexual men on PrEP. The study was stopped by its data

and safety monitoring board after an unplanned interim analysis found statistically significant reductions in first cases of syphilis, chlamydia, gonorrhea, and Mgen in those on doxyPEP compared with no doxyPEP [246]. Although the interim analysis suggested that 4CMenB vaccination was protective against gonorrhea, this finding was not confirmed after missing study data were included. The final analysis confirmed statistically significant preventative effects of doxyPEP against first episodes of chlamydia (adjusted hazard ratio [aHR], 0.14; 95% CI, .09–.23; $P < .0001$), syphilis (aHR, 0.21; 95% CI, .11–.41; $P < .001$), and gonorrhea (aHR, 0.67; 95% CI, .52–.87; $P = .003$), although the effect against gonorrhea was modest and less than in the interim analysis. The effect of 4CMenB vaccination on incident gonorrhea was not statistically significant. Consistent with local epidemiology, tetracycline resistance was seen in all available gonorrhea samples from baseline and follow-up, and high-level tetracycline resistance (minimum inhibitory concentration > 8 mg/L) was more common in incident samples from the doxyPEP arm than the control arm (36% vs 13%; $P < .043$). No chlamydia resistance was detected, and there was no statistically significant difference between the arms in detection of pharyngeal methicillin-resistant *Staphylococcus aureus* or rectal extended-spectrum β-lactamase–producing *Escherichia coli* [247]. A randomized, open-label trial compared doxyPEP to standard of care among 449 nonpregnant cisgender Kenyan women aged 18–30 years who were taking HIV PrEP. The study (dPEP Kenya) showed no difference between the doxyPEP arm and the standard-of-care arm in the incidence of chlamydia or gonorrhea. In a subset of participants in the doxyPEP arm, doxycycline was present in only 29% of hair samples. Low uptake of the intervention limited the ability to understand the true efficacy of doxycycline for bacterial STI prevention in cisgender women under more ideal adherence conditions. In addition, high-level tetracycline resistance, previously described in Kenya, was seen in 100% of gonorrhea samples identified at baseline and at study visits in both study arms [248]. DoxyPEP, therefore, is recommended for cisgender gay, bisexual, and other men who have sex with cisgender men and for transgender women who have a history of at least 1 diagnosis of syphilis, chlamydia, or gonorrhea within the last 12 months or who anticipate sexual activities associated with increased likelihood of STI acquisition. No recommendations can be made at this time for the use of doxyPEP in cisgender women, cisgender heterosexual men, transgender men, and other gender-diverse persons; additional research is needed. Use of doxyPEP in these populations should be based on shared decision-making.

The main concern for doxyPEP implementation is the risk of antimicrobial resistance, particularly for gonorrhea, but also for the microbiome, including common organisms such as *Staphylococcus*. Additional data are needed to fully assess the public health impact of doxyPEP. Until more data are available, it will be important to judiciously target its use. Modeling based on a cohort at Fenway Clinic (Boston, Massachusetts) found that targeting doxyPEP to cisgender gay and bisexual men, transgender women, and nonbinary persons assigned male at birth who had been diagnosed with a bacterial STI within the last 12 months or with repeated STIs was the most efficient use of doxyPEP. Providing doxyPEP to all PrEP users or people with HIV prevented more STIs but was less efficient and exposed more people to doxycycline (higher number needed to treat to prevent 1 STI) [249]. As data evolve, the CDC recommendations for use of doxyPEP will be updated [250]. People who receive doxyPEP should continue to receive routine screening for asymptomatic STIs and ongoing evaluation of the need for continuing doxyPEP.

SECTION 7: METABOLIC AND OTHER NONCOMMUNICABLE COMORBIDITIES ASSOCIATED WITH HIV, ANTIRETROVIRAL THERAPY, AND AGING

Now that approximately 50% of the global population of people with HIV is aged >50 years, concern has heightened about increased rates of common comorbidities associated with age [251, 252], including long-term cardiovascular morbidity, especially in those with traditional risk factors such as dyslipidemia, glucose intolerance or diabetes mellitus, hypertension, and smoking. The benefits of ART used in accordance with published guidelines outweigh the risks of cardiovascular disease and other comorbidities associated with long-term exposure [253]. Multiple guidelines are available to assist providers in the identification and management of lipid abnormalities, diabetes mellitus, excess weight, liver steatosis, and other comorbidities [254–258]. People with HIV also are at higher risk for weight gain, loss of BMD, hypogonadism, frailty, and neurocognitive disorders.

Recommendations

- Fasting (optimal) or random lipid levels should be obtained prior to and within 1–3 months after starting ART. Abnormal random lipid levels should be repeated when fasting. Patients with abnormal lipid levels should be managed according to the National Lipid Association Part 2 and 2018 Multispecialty Blood Cholesterol Guidelines. All patients should be assessed for 10-year atherosclerotic cardiovascular disease (ASCVD) risk. Those at high risk should be further evaluated and managed according to established guidelines that recognize HIV risk-enhancing factors.
- Statin therapy is recommended for primary prevention of cardiovascular disease in people with HIV aged 40–75 years, regardless of lipid levels and ASCVD risk. The recommendation is strongest for those with a 10-year ASCVD risk of 5% or higher. For people with HIV aged <40 years, evidence is

insufficient to recommend for or against statin therapy for primary prevention of cardiovascular disease. Decisions in this age group should be individualized, taking into consideration risk-enhancing factors for the general population and for people with HIV.
    - High-intensity statins (atorvastatin 40–80 mg daily or rosuvastatin 20–40 mg daily) are recommended for persons with a 10-year ASCVD risk above 20%.
    - At least moderate-intensity statins (specifically, pitavastatin 4 mg daily, atorvastatin 20 mg daily, and rosuvastatin 10 mg daily) are recommended for persons with HIV and at lower risk.
- Prior to starting ART, random or fasting blood glucose and hemoglobin A1c (HbA1c) should be obtained. If random glucose is abnormal, fasting glucose should be obtained. After initiation of ART, HbA1C is insensitive and may significantly underestimate the risk of diabetes. However, an HbA1C that is >6.5% remains a reliable criterion for diagnosis of diabetes in people with HIV. If HbA1C is <6.5%, fasting plasma glucose is the best screening test for people with HIV receiving ART. Those with a diagnosis of diabetes mellitus should have their HbA1c level monitored at least every 6 months, with an HbA1c goal of <7% in accordance with the American Diabetes Association (ADA) guidelines.
- Weight should be obtained at every visit. In addition, waist circumference (an indirect marker of visceral fat) should be measured annually. Monitoring and counseling on diet, exercise, and alcohol intake should start at the time of ART initiation and be done at every visit.
- Current data do not support switching an ART regimen solely because of weight gain.
- If liver transaminases are increased, workup for nonalcoholic fatty liver disease (NAFLD) should include ultrasound, magnetic resonance imaging (MRI), or CT scan. Presence of steatosis should lead to a fibrosis workup that includes FIB-4, Fibroscan, or MRI elastography, although biopsy remains the standard. Weight reduction is the cornerstone of treatment of NAFLD. Persons with nonalcoholic steatohepatitis (NASH) or fibrosis should be referred to a hepatologist.
- Baseline bone densitometry (DXA) screening for osteoporosis should be performed in post-menopausal cisgender women and men aged ≥50 years. Screening for transgender people should follow national recommendations based on their individualized risk for osteoporosis.
- Testosterone replacement therapy for cisgender men should be prescribed with caution and only in those with symptomatic hypogonadism, given the long-term side effects. See Section 11 for discussion of hormone therapy for transgender men.
- Annual screening for frailty should be considered in people with HIV aged >50 years; the frailty phenotype screen is the most commonly used tool.

Evidence Summary

Lipid Abnormalities and Cardiovascular Risk

HIV infection is associated with dyslipidemia. In the absence of ART, HIV infection results in lower total cholesterol, high-density lipoprotein (HDL-C), and low-density lipoprotein (LDL-C) levels. Initiation of ART, specifically with boosted protease inhibitors (PIs), increases LDL-C and improves HDL-C, but the latter does not normalize to pre-HIV levels [259]. Among nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), TDF has been associated with lipid-lowering effect [260]; however, TDF is less commonly used currently due to its effect on kidney function and bone mineral density. Other NRTIs, such as TAF and abacavir, appear to have a similar and minimal effect on lipids [261].

HIV is a recognized independent atherosclerotic cardiovascular disease (ASCVD) risk enhancer in the 2018 American College of Cardiology/American Heart Association (ACC/AHA) multispecialty cholesterol management guidelines [255]. At this time, there are no validated cardiovascular risk assessment tools for use in people with HIV, and the default is to use the pooled cohort equations from the 2013 ACC/AHA guidelines and to adjust for the presence of HIV risk enhancers, understanding the limitations of such [255]. The frequency of follow-up testing and response to therapy should be based on the current National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 2 and the 2018 Multispecialty Blood Cholesterol guidelines [255, 262]. All patients should be assessed for ASCVD risk. Those with elevated risk should be further evaluated and managed according to established guidelines.

Statin drugs are known to exert a multifactorial effect to prevent cardiovascular disease in the general population. The randomized controlled the Stopping Atherosclerosis and Treating Unhealthy Bone With Rosuvastatin in HIV (SATURN)-HIV trial showed that in individuals with HIV and virologic suppression, LDL-C <130 mg/dL, and evidence of heightened inflammation, rosuvastatin decreased carotid intima-media thickness, improved kidney function, and attenuated systemic and vascular inflammation, including decreasing T-cell and monocyte activation [263–267], but worsened insulin resistance [268]. Recently, the Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE) study, a multinational placebo-controlled study that enrolled 7769 participants with HIV aged 40–75 years who had low to intermediate ASCVD risk, found that pitavastatin 4 mg daily reduced the risk of major cardiovascular events by 36%, including for those with LDL-C levels below current guideline thresholds for statin initiation [269, 270]. Overall, the protective effect was seen across demographics, CD4 cell count ranges, and viral load levels. REPRIEVE is a practice-changing study, and statin use is now recommended in people with HIV aged ≥40 years, assuming no known allergy to statins or other contraindications,

Table 7. Effect of Protease Inhibitors and Nonnucleoside Reverse Transcriptase Inhibitors on Statins

Statin	Protease Inhibitors	Nonnucleoside Reverse Transcriptase Inhibitor
Atorvastatin	Use lowest atorvastatin starting dose and titrate, monitor for safety, as risk for myopathy/rhabdomyolysis can be increased with some protease inhibitors Do not coadminister with atazanavir/cobicistat Maximum dose of atorvastatin is 20 mg with darunavir/cobicistat or darunavir + ritonavir	Acceptable with appropriate dosing and monitoring Efavirenz and etravirine decrease atorvastatin's AUC No data for nevirapine; may need higher atorvastatin starting dose Doravirine does not affect levels of atorvastatin
Fluvastatin	Use lowest fluvastatin starting dose and titrate, monitor for safety, as risk for myopathy/rhabdomyolysis can be increased with some protease inhibitors	Acceptable with appropriate dosing and monitoring Etravirine may increase fluvastatin's AUC May need lower fluvastatin starting dose with etravirine No data on doravirine
Lovastatin	Contraindicated (greatly increases lovastatin's AUC)	Acceptable with appropriate dosing and monitoring Decrease in simvastatin AUC, so may need higher lovastatin starting dose No data on doravirine
Pitavastatin	Acceptable with appropriate dosing and monitoring No significant change in pitavastatin's AUC with lopinavir/ritonavir Pitavastatin's mean AUC decreased 26% with darunavir	No data for NNRTIs
Pravastatin	Acceptable with appropriate dosing and monitoring, except with darunavir Decrease in pravastatin's AUC, except with darunavir, which increases pravastatin's AUC by 81%	Acceptable with appropriate dosing and monitoring Efavirenz decreases pravastatin's AUC, but no change with etravirine No data for nevirapine, rilpivirine, doravirine May need higher pravastatin starting dose with efavirenz
Rosuvastatin	Use lowest rosuvastatin starting dose and titrate, monitor for safety, as risk for myopathy/rhabdomyolysis can be increased with some protease inhibitors Maximum dose of rosuvastatin is 10 mg with atazanavir, atazanavir/cobicistat, or atazanavir + ritonavir and 20 mg with darunavir/cobicistat Lopinavir/ritonavir and tipranavir + ritonavir increases rosuvastatin's AUC No dose adjustments with cobicistat; cobicistat increases Cmax 89% and AUC by 38%	Acceptable with appropriate dosing and monitoring No data on doravirine
Simvastatin	Contraindicated (greatly increase simvastatin's AUC)	Acceptable with appropriate dosing and monitoring Efavirenz and etravirine decrease simvastatin's AUC No data for nevirapine, doravirine May need higher simvastatin starting dose

Abbreviations: AUC, area under the curve; NNRTI, nonnucleoside reverse transcriptase inhibitor.

regardless of CVD risk or lipid levels. The strength of the benefit rises as the ACC/AHA pooled cohort equation score predicting 10-year risk of ASCVD events increases, with the number needed to treat to prevent a major event within 5 years decreasing from 130 and above for those with scores below 5% to 53 or lower for scores of 5% and above. Therefore, the recommendation for statin use is stronger for those with a 10-year ASCVD risk of 5% and higher. For those with lower scores, the benefit is still present but less pronounced. To decide on statin use in this population, additional risk factors, as described for the general population as well as risk-enhancing factors for people with HIV, should be considered. High-intensity statin therapy is recommended for those with risk greater than 20%, as for the general population, while at least moderate-intensity statin therapy is now recommended for those with lower risk. Additionally, statins may be considered in people with HIV who are younger than the REPRIEVE population (aged <40 years) with additional risk factors, including those with neonatal or pediatric acquired infection who are now adults with long-standing HIV, a population not included in the risk calculators. It is important to note that a slightly higher risk of diabetes was seen in REPRIEVE with pitavastatin than placebo (6.0% vs 4.7%, respectively), although at this time, it is unclear whether participants who developed incident diabetes in the study had pre-diabetes or were at high risk of diabetes at the time of enrollment in REPRIEVE. Treatment-limiting or grade 3 or higher muscle symptoms were seen in 2.3% of the pitavastatin group and 1.5% of the placebo group. Based on data from REPRIEVE, recommendations regarding statin therapy in people with HIV have been published by the HHS Adult and Adolescent Antiretroviral Guidelines Panel and a multisociety team that includes the ACC, AHA, and HIVMA [271].

Despite the fact that pitavastatin was used in REPRIEVE, it is likely that this preventive effect is generalizable across statins and that other statins can be used. High-intensity statins include atorvastatin 40–80 mg and rosuvastatin 20–40 mg, while moderate-intensity statins include pitavastatin 4 mg, atorvastatin 10–20 mg, and rosuvastatin 10 mg (all taken daily). Caution should be used, however, when prescribing statins with PIs (especially ritonavir), cobicistat, and some nonnucleoside reverse transcriptase inhibitors (NNRTIs) due to

potentially serious drug–drug interactions (Table 7). Most PIs and cobicistat inhibit the metabolism of statins, thereby increasing the potential for statin toxicity, with the strongest interactions seen with simvastatin and lovastatin, which are contraindicated with ritonavir or cobicistat. However, pitavastatin and pravastatin are metabolized by glucuronidation, thereby having little effect when coadministered with a boosted PI or cobicistat. However, pravastatin may adversely interact with darunavir, and dose modification may be needed. In addition, atorvastatin and rosuvastatin may be used in patients who take a boosted PI or boosted elvitegravir but should be initiated at low doses and titrated carefully according to tolerability and effect. Efavirenz induces statin metabolism, resulting in lowering of statin levels. Nevirapine, etravirine, and rilpivirine have not been extensively studied. Doravirine does not affect levels of atorvastatin [272]. Cobicistat is expected to have interactions that are similar to those for ritonavir with statins; however, these interactions have not been fully studied. There may be other pathways that affect drug metabolism and lead to unexpected interactions, and it is advisable to refer to the package insert of the ARV or drug–drug interaction tables from the HHS ART guidelines before prescribing lipid-lowering agents.

Glucose Metabolism and Diabetes

Among people with HIV, HbA1c is insensitive, although highly specific for diagnosing diabetes. As such, HbA1c is no longer the preferred method for diagnosing diabetes among persons with HIV [273–276]. The ADA established the diagnostic criteria of diabetes mellitus as a fasting plasma glucose level of ≥126 mg/dL (7.0 mmol/L), a 2-hour plasma glucose level of ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test conducted with a standard loading dose of 75 g, or an HbA1c ≥ 6.5% [273]. However, recognizing the potential underestimation of the risk of diabetes by using HbA1C in HIV, the National Health and Nutrition Examination Survey and others endorse an HbA1C cutoff of ≥5.8% to improve the sensitivity for diagnosis in the population with HIV [274]. Although data are lacking on the effects of integrase inhibitors on HbA1c, some studies, but not all, suggest that NNRTIs, PIs, and the NRTIs zidovudine and abacavir may affect HbA1c and result in misleading results [274, 275, 277]. The ADA 2019 Standards recommend against the use of HbA1c to diagnose diabetes in persons with HIV on ART and states that in cases of HbA1c and fasting glucose discordance, the abnormal laboratory test should be repeated, and the diagnosis of diabetes should be made only if repeat testing is again above the diagnostic cut point [273].

Random or fasting serum glucose and HbA1c should be obtained prior to starting ART. If random blood glucose is abnormal, fasting blood glucose should be obtained. After initiation of ART, only plasma glucose criteria should be used to diagnose diabetes. A random glucose >200 mg/dL should prompt further testing with a fasting blood glucose. Therefore, either a random or fasting glucose should be obtained at entry to care and annually thereafter for screening of diabetes. Patients with diabetes mellitus should have their HbA1c level monitored at least every 6 months, with a HbA1c goal of <7% in accordance with the ADA guidelines. Though controversial, the American College of Physicians recommends less stringent control, with an aim to achieve an HbA1c between 7% and 8% [278]. Given the potential for over- or underestimation of HbA1c in patients on ART, it is prudent to assess the correlation of blood glucose levels with HbA1c values on an individual basis in order to determine the appropriate HbA1c target.

Lifestyle interventions such as weight loss, increased physical activity, and dietary modification remain the cornerstone of diabetes prevention and management. However, if treatment is needed, insulin-sensitizing agents are preferred. Patients should be managed according to the ADA guidelines [273, 279]. No data suggest that switching ARVs is beneficial in patients with impaired glucose tolerance associated with HIV infection itself or traditional risk factors.

Weight and Fat Gain

Weight gain is a well-recognized consequence of ART initiation and is more common in non-White and female individuals [280]. Some regimens, namely integrase inhibitors and TAF, have been associated with larger gains in weight. However, it is presently unclear whether the regimens used as comparators suppress weight gain with ART initiation. For instance, TDF use has been associated with weight suppression in PrEP studies and in HIV treatment initiation studies. Also, when TDF is switched to TAF, an increase in weight of about 1 kg on average is seen in the initial 6–12 months after switch [281, 282]. Similarly, the ADVANCE study showed that efavirenz (EFV) led to smaller gains in weight when compared with dolutegravir, both given with TAF/FTC [283]. A substudy that assessed the genetic mutations that control EFV metabolism revealed that only slow metabolizers (high EFV blood level) had blunted weight gain, whereas fast metabolizers gained an amount of weight that was similar compared with those on dolutegravir [284]. These data suggest that the weight-suppressive effect of EFV may not be desirable and may signal toxic effects. TDF has been associated with mitochondrial dysfunction in subcutaneous adipose tissue, signaling the potential for adipose dysfunction with TDF [285]. As such, the weight-suppressive effect of TDF should not necessarily be viewed as desirable.

The weight gain seen with ART is concerning for patients and providers as studies have linked it to a higher incidence of diabetes [286] and hypertension [287]. There is also evidence of ectopic fat depositions in people with HIV, for example, in the liver and pericardium, which may be detrimental. The HIV provider who is treating a patient with large gains in weight after ART may contemplate switching ART. It is important to know that switches have not been successful at reversing

weight gain [288, 289], including switches off of INSTIs, unless the switch is from INSTI to EFV. However, the EFV-linked weight suppressive effect is likely a toxic effect and should not be seen as desirable. A randomized, placebo-controlled switch study in virologically [290] suppressed individuals on BIC/TAF/FTC showed similar weight gain at 48 weeks after switching to islatravir/doravirine compared with continuing on BIC/TAF/FTC [291]. Discontinuation of TAF did not improve weight in the TANGO study, questioning the independent effect of TAF on weight [289]. The TAF-to-TDF switch effect, for the purpose of suppressing weight gain, is modest at best, could lead to adipose tissue dysfunction and mitochondrial toxicity, and thus is not recommended as a strategy to decrease weight [292]. The benefit of the modest effect on weight of TAF-to-TDF switch also needs to be weighed against the bone and renal toxicities of TDF. Switch studies from daily oral BIC/FTC/TAF to injectable cabotegravir/rilpivirine given every 2 months did not lead to a significant change in weight compared with continuation of the oral regimen, further evidence that TAF is not likely a culprit in weight gain [293]. Glucagon-like peptide (GLP)-1 receptor agonists for obesity should be reserved for select situations while awaiting results of ongoing trials among people with HIV.

All patients on ART should be routinely counseled on lifestyle modifications, including alcohol reduction/cessation, increased physical activity, healthier diet with reduction in saturated fat and added sugars, and increase in dietary fiber. Patients with large gains in weight may benefit from some of the new agents recommended for obesity in the general population, such as GLP-1 receptor agonists. Although there are few data on their use in people with HIV, a randomized controlled trial in people with lipohypertrophy (abdominal obesity) showed excellent safety and efficacy with decrease in weight and visceral and trunk fat [294].

Liver Steatosis

More data show that NAFLD is common in HIV, with prevalence ranging from 20% to 63%, even in people with HIV without HCV. Liver steatosis is linked to obesity and happens at lower body mass index (BMI) in the HIV population. NAFLD represents the most common cause of increased transaminases in people with HIV without excess alcohol or infectious hepatitis. NAFLD has been associated with older toxic ART such as didanosine or stavudine but not clearly with newer regimens. NAFLD can progress to NASH, liver cirrhosis, fibrosis, and ultimately cancer. NAFLD is also an independent risk factor for cardiovascular disease, diabetes mellitus, and all-cause mortality [295, 296]. Although NAFLD is known to be associated with obesity, HIV-associated NAFLD occurs at lower BMI than in the general population. Diagnosis of NAFLD may involve histology (liver biopsy) or imaging (ultrasound, CT scan, or MRI). Once NAFLD is identified, further workup should be performed to assess for fibrosis. Although biopsy remains the standard, newer modalities, including Fibroscan and MRI elastography, are increasingly used. In addition, clinicians have used soluble markers to estimate fibrosis, such as FIB-4, with low FIB-4 (<1.3) conferring a low likelihood of advanced fibrosis. Lifestyle modification and weight reduction are the cornerstone of treatment. Pharmacotherapy should be reserved for individuals with NASH, particularly for those with significant fibrosis ≥ F2 or individuals with less severe disease but at high risk of faster disease progression, such as persons with diabetes. Promising investigational therapies for HIV-associated NAFLD include tesamorelin [297] and GLP-1 receptor agonists [298].

Bone Metabolism

Baseline bone densitometry by DEXA should be performed in all post-menopausal cisgender women and men aged ≥50 years, based on expert opinion with limited supporting evidence [299–304]. If DEXA scan reveals osteopenia or osteoporosis, a workup for secondary causes of osteopenia should be performed. The most common secondary causes of osteopenia are vitamin D deficiency, hypogonadism, excess alcohol (>3 drinks/day), smoking, and hyperthyroidism or hyperparathyroidism. The initiation of any ART regimen leads to a decrease in BMD of 2%–6%, and the decrease is more prominent in the first 24–48 weeks of ART. Among all ART, TDF has been shown to lead to a 1%–2% larger decrease in BMD when compared with any other non-TDF regimen, including TAF [305, 306]. When TDF is combined with ritonavir-boosted PI, bone loss is even more accentuated than when combined with unboosted integrase inhibitors [307, 308]. If the DEXA demonstrates osteoporosis or there is a history of fragility fracture, intervention with vitamin D, calcium, and a bisphosphonate or other medical therapy may be warranted. Bisphosphonates appear to be safe and effective in improving BMD [309] and in blunting the initial drop in BMD after ART initiation [310]. It is important to exclude osteomalacia prior to initiating a bisphosphonate, as this could lead to increased fragility and fracture. Common reasons for osteomalacia in this population are tenofovir-induced renal phosphate wasting and vitamin D deficiency, which have been reported in 40%–80% of people with HIV. The spectrum and severity of metabolic complications associated with vitamin D deficiency among adults with HIV remain to be better characterized. Patients with vitamin D deficiency and osteopenia by DEXA should be treated with vitamin D and calcium without bisphosphonates until the vitamin D deficiency has resolved. A follow-up DEXA should be repeated 1 year later to monitor the response to therapy. It is now clear that switching off of TDF to another NRTI or to an NRTI-sparing regimen is effective at increasing BMD and should be considered [311, 312].

Routine screening for vitamin D deficiency in patients with normal or unavailable DEXA is not recommended, given the

lack of data among people with HIV. The USPSTF concludes that the evidence on screening for vitamin D deficiency in asymptomatic adults to improve health outcomes is insufficient [313]. However, patients should be counseled about the health benefits of regular exercise, with resistance exercise being especially important to bone building, normal dietary calcium, and vitamin D intake and the harmful risks of cigarette smoking and excessive alcohol consumption.

In people with HIV, avascular necrosis (AVN) was reported to be associated with exposure to tenofovir for longer than 1 year in one study [314]. Other more common causes of AVN include moderate to high alcohol consumption, hyperlipidemia, and corticosteroid use [314, 315]. Routine radiographic monitoring for AVN in asymptomatic persons is not recommended. However, for patients who present with persistent hip pain who have normal standard radiologic studies, MRI is the preferred method of diagnosis, and both sides should be imaged regardless of whether pain is bilateral or not. Most patients with symptomatic AVN will ultimately require surgical intervention, including hip replacement [315, 316].

Hypogonadism

The prevalence of hypogonadism among cisgender men with HIV has been reported to be high prior to the introduction of ART. However, screening for hypogonadism is recommended only for men who have symptoms [317, 318]. In 2014, the FDA released safety alerts that warned of potential increased cardiac risk associated with testosterone replacement products [319–321]. Subsequently, a large systematic review and meta-analysis failed to demonstrate an increased risk of cardiac events in the general population; however, caution remains [322]. Although the Endocrine Society Guidelines [323] recommend short-term testosterone replacement therapy (TRT) for cisgender men with HIV and low testosterone, many patients have remained on TRT long term. It is unclear whether those who were diagnosed with hypogonadism at the time of their HIV diagnosis need to remain on TRT after immune recovery on ART. Since the FDA advisory, the overall percentage of cisgender men who use TRT has declined, but less so among those with HIV [324, 325]. As the population of men with HIV ages, clinicians should balance the benefits against the harms of continuing TRT that may no longer be indicated. TRT may result in testicular atrophy and permanent inability to produce the natural hormone. Men may experience "withdrawal" when TRT is stopped, given the steroidal effects of testosterone as well. Therefore, initial TRT should be prescribed with caution and only in cisgender men with symptomatic hypogonadism, given the long-term side effects.

Neurocognitive Impairment

Neurocognitive impairment is more common in older people with HIV than those not living with HIV [326]. HIV-associated neurocognitive disorder (HAND) encompasses multiple neurocognitive effects of HIV and associated inflammation on the central nervous system, resulting in deficits that range from asymptomatic neurocognitive impairment to dementia [327]. While there are no specific treatments for HAND at this time, clinicians should be aware that some persons with HIV may experience neurocognitive decline that is out of proportion to their age and should provide an appropriate workup when such symptoms present.

Frailty

People with HIV are disproportionately affected by frailty and at a younger age than those without HIV [328]. Prevalence of frailty and prefrailty in people with HIV aged >50 years is about 11% and 47%, respectively [329]. Frailty is a strong predictor of both mortality and incident comorbidity in people with HIV, independent of other risk factors [330]. Annual screening for frailty should be considered in people with HIV aged >50 years. The most commonly used screening tools include the frailty phenotype [331] and the frailty index [332], with the former being simpler and more commonly recommended, although it requires a dynamometer. HIV virologic suppression decreases the risk of frailty [333]. The most effective interventions to prevent and treat frailty are increasing physical activity and structured exercise [334]. Nutritional optimization is effective and increases the efficacy of an exercise intervention [334]. Diagnosing and treating concomitant depression is also paramount. There are no data yet to recommend pharmacologic interventions for HIV frailty.

SECTION 8: SPECIAL CONSIDERATIONS FOR INDIVIDUALS OF CHILDBEARING POTENTIAL AND FOR PREVENTION OF PERINATAL HIV TRANSMISSION

People with HIV who are of childbearing potential are living long, healthy lives, and the need for routine gynecological care has increased. They have the same reproductive health needs and concerns as those not living with HIV. As part of the initial assessment, a comprehensive gynecologic and obstetrical history should be obtained that consists of menstrual history, sexual practices, hormonal therapy history and current use, male or female condom use and consistency of use, previous STIs and other genital tract infections, prior abnormal Pap test results including subsequent evaluation and treatment, pregnancy history, history of gynecologic conditions (including uterine fibroids, endometriosis, and infertility) or surgery (including gender reassignment surgery), and current gynecologic symptoms (including abnormal vaginal discharge, abnormal vaginal bleeding, amenorrhea, and pelvic pain). Recommendations for care during menopause do not differ from those for persons not diagnosed with HIV.

Contraception and Prepregnancy Care

Recommendation

- All persons with HIV who are of childbearing potential should be asked about their plans and desires regarding pregnancy upon initiation of care and routinely thereafter. Clinicians should ensure that informed decisions are made about contraception to prevent unintended pregnancy and offer counseling if pregnancy is desired. Counseling should include considerations for the choices of ART and infant feeding methods.

Evidence Summary

Any encounter with a nonpregnant patient with reproductive potential is an opportunity to counsel about wellness and healthy habits that may improve reproductive and obstetrical outcomes if the patient decides to reproduce [335]. An in-depth discussion about childbearing is indicated if the patient expresses the desire for future pregnancy, is not trying to conceive but is not using appropriate contraception, or expresses uncertainty about reproductive plans. Regardless of the patient's sex, the goal is to ensure that informed decisions are made about contraception with prevention of an unintended pregnancy and to offer counseling if pregnancy is desired. Patients should explicitly be asked to communicate with their provider if their plans change, when they are ready to consider pregnancy, or when they have questions related to reproduction and parenthood. In persons who are at risk for pregnancy (trying to conceive or not using effective and consistent contraception), providers should carefully review all medications, including over-the-counter medications, and avoid drugs with potential reproductive toxicity. The time of greatest risk to the fetus is early in pregnancy, often before the pregnancy has been recognized. Ideally, a prenatal vitamin with folic acid should be prescribed prior to conception. Choice of ART for use during pregnancy and breast/chest feeding is discussed in detail in HHS perinatal guidelines [120].

Individuals who do not wish to become pregnant should be counseled on effective contraception. Combined estrogen–progestin hormonal contraceptives (birth control pill, transdermal patch, and vaginal ring) are one option; however, they may have interactions with several ARVs, resulting in decreased effectiveness or increased risk of adverse effects. Contraceptive implants, injectable contraception (depot medroxyprogesterone acetate), and intrauterine devices are other available options. Spermicides have been associated with an increased risk of HIV acquisition and are not recommended for use with partners who are not diagnosed with HIV [336].

Providers should be prepared to discuss conception among serodifferent couples. The partner with HIV should always be started/continued on ART and achieve/maintain sustained HIV RNA suppression to below the limits of detection prior to beginning efforts to conceive. With durable viral suppression, there is effectively no risk of sexual transmission. For couples that are using condoms and wish to limit their episodes of condomless sex, a discussion about sex during the time of peak fertility is appropriate. Prepregnancy administration of ARV PrEP for the partner not diagnosed with HIV offers an additional means to reduce the risk of sexual transmission [336].

Prevention of Perinatal Transmission

Recommendations

- To prevent perinatal transmission, all pregnant and breast-/chest-feeding persons with HIV should be treated with ART, regardless of their immunologic or virologic status. Therapy should be initiated as early as possible, preferably prior to conception.
- Infants exposed to HIV in utero should be managed according to HHS perinatal guidelines.

Evidence Summary

Perinatal transmission of HIV is preventable if pregnant persons are screened for HIV and, if diagnosed with HIV, receive immediate ART according to HHS perinatal guidelines [120, 337]. If HIV status is unknown, pregnant people should be tested for HIV at the first antenatal visit and again in the third trimester if there is ongoing risk of exposure to HIV. In those who start ART before conception and maintain viral load suppression <50 copies/mL, there is essentially zero risk of perinatal transmission [120, 337].

If an individual in labor presents for delivery without having antenatal HIV testing, an expedited HIV test (preferably fourth-generation HIV antigen/antibody testing) should be performed. If the test is positive, intravenous zidovudine should be initiated immediately without waiting for confirmatory tests [120]. Persons who are pregnant and who have an HIV viral load that is unknown or >1000 copies/mL at or near delivery (within 4 weeks), independent of antepartum ART, should be counseled regarding the potential benefit of cesarean delivery. If the patient consents, a scheduled cesarean delivery at 38 weeks' gestation should be offered to reduce the risk of perinatal transmission [120]. All newborns who were exposed perinatally to HIV should receive postpartum ARV drugs to reduce the risk of perinatal transmission of HIV. Post-exposure prophylaxis in the neonate should be initiated ideally within 6 hours [120]. A newborn's ARV regimen should be determined by maternal HIV transmission risk factors according to the perinatal guidelines. Providers with questions about ARV management of perinatal HIV exposure should consult an expert in pediatric HIV infection or the Perinatal HIV/AIDS National Clinician Consultation Center hotline [338].

Infant Feeding

Recommendations

- In the United States, persons with HIV should receive evidence-based, patient-centered counseling to support shared decision-making about infant feeding.
- Individuals with HIV who are on ART with a sustained undetectable viral load and who choose to breast/chest feed should be supported in their decision.
- Engaging Child Protective Services is not an appropriate response to the choice of infant feeding for individuals with HIV.

Evidence Summary

Counseling about infant feeding should begin prior to conception or as early as possible in pregnancy and should be repeated throughout pregnancy and again after delivery [120]. Choosing a method of feeding for a baby is one of the most important decisions a new parent makes. The decision can be compounded by mixed messages from providers who are uncomfortable talking about infant feeding for people with HIV. With current ART, rates of HIV transmission through breast/chest feeding are low but not zero. Currently, there is no consensus on a universal approach, and diverse strategies are used for HIV RNA monitoring for the breast-/chest-feeding parents, infant HIV testing, and ARV prophylaxis [120, 339]. Individuals with HIV who choose to formula feed should be supported in this decision. Providers should ask about potential barriers to formula feeding and explore ways to address them. Replacement feeding with formula or banked pasteurized donor human milk is recommended to eliminate the risk of HIV transmission through breast/chest feeding when people with HIV are not on ART and/or do not have a suppressed viral load during pregnancy (at a minimum throughout the third trimester), as well as at delivery. Engaging Child Protective Services or similar agencies is not an appropriate response to the infant feeding choices of an individual with HIV.

SECTION 9: SPECIAL CONSIDERATIONS FOR CHILDREN

Recommendations

- A plasma HIV NAAT (HIV RNA or HIV DNA) is equally recommended to diagnose HIV in infants and children aged <18 months with perinatal and post-natal HIV exposure.
- In infants with perinatal and post-natal HIV exposure, the results of a plasma HIV NAAT can be affected by maternal ART or by ARV drugs administered to the infant as prophylaxis or presumptive HIV therapy.
- For children aged 18 to ≤24 months with nonperinatal HIV exposure and for all children aged >24 months, HIV antibody or HIV antigen/antibody tests are recommended for diagnostic testing.
- Infants and children diagnosed with HIV should be started on ART immediately or within days of diagnosis. The urgency of Rapid ART initiation is especially critical for children aged <1 year who carry the highest risk of rapid disease progression and mortality.
- In children with disseminated *Mycobacterium avium* complex disease, *M. tuberculosis* disease, and cryptococcal meningitis, ART initiation may be delayed by 2–8 weeks with treatment for the OI prioritized. Appropriate timing of ART initiation in these cases should be discussed with a pediatric HIV specialist.
- If a child with HIV has not initiated ART, healthcare providers should closely monitor the virologic, immunologic, and clinical status at least every 3–4 months while continuing to educate and work with the family to overcome barriers to treatment.
- Absolute CD4 cell count (or CD4 percentage in children aged <5 years) and HIV RNA levels should be evaluated at the time of diagnosis and should be monitored at least every 3–4 months in infants and children. Close follow-up also allows for timely weight-based ART dose adjustment in infants and young children.
- Childhood vaccinations should be administered according to ACIP schedules for infants and children with HIV.
- Infants and children with HIV should be managed by a specialist with knowledge of the unique therapeutic, pharmacologic, behavioral, psychosocial, and developmental issues associated with pediatric HIV infection.

Evidence Summary

Most pediatric HIV infections are caused by perinatal transmission of the virus from the mother during pregnancy, delivery, or breastfeeding. The racial and ethnic disparities in the HIV epidemic among adults in the United States are, therefore, mirrored in pediatric populations. The rate of acquisition of HIV infection among infants has decreased significantly in the United States, primarily because of effective measures to prevent mother-to-child transmission of HIV. Between 2010 and 2019, annual perinatal HIV diagnosis rates declined from 1.9 to 0.9 per 100 000 live births, and perinatal HIV transmission rates declined from 1.6% to 0.9%. National elimination goals for diagnosis and transmission rate of perinatal HIV were first achieved in 2019. However, perinatal transmission of HIV still occurs, and racial and ethnic disparities persist, requiring ongoing public health investment and efforts [340]. Other routes of HIV transmission in children include feeding blood-tinged premasticated food, contact of nonintact skin with blood-containing body fluid, transfusion of contaminated blood products, and sexual abuse. These scenarios should prompt testing of the child for HIV infection. HIV testing should also

be conducted among all children in foster care and those who were adopted domestically (if unknown exposure or at risk for acquiring HIV) and internationally (since perinatal HIV screening is variable in global settings) [341]. Children with HIV are frequently born outside the United States, including adopted children and members of immigrant families. These children may have non-B subtypes of HIV, incomplete medical and treatment histories, and an increased risk of tuberculosis and other infections.

Neonates and infants (including breastfed infants) who are exposed to HIV perinatally or postpartum should be managed according to HHS perinatal and pediatric guidelines [91]. Plasma HIV RNA and HIV DNA NAATs are equally recommended for diagnosis of HIV in infants aged <18 months. However, both tests can be affected by maternal ART through transplacental transfer of ARV drugs from the mother to the fetus or by ARV drugs administered to the infant as prophylaxis or presumptive HIV therapy. Qualitative whole blood HIV proviral DNA PCR assays to detect cell-associated virus are less affected by ARV drugs [120]. For children aged 18 to ≤24 months with nonperinatal HIV exposure and for all children aged >24 months, HIV antibody or HIV antigen/antibody tests are used for diagnostic testing. For suspected acute HIV infection, an additional HIV NAAT may be necessary to diagnose HIV infection.

All infants and children diagnosed with HIV should be started on ART as soon after diagnosis as possible (immediately or within days) using regimens based on pediatric HHS guidelines [91]. Multiple studies have reported that early ART initiation in infants and children preserves immune function and is associated with improved growth and neurodevelopmental outcomes [342–344]. In infants with perinatally acquired infection, early ART initiation may limit the formation of the viral reservoir and control of viral replication before HIV can evolve into diverse and potentially more pathogenic and/or resistant quasi-species, preserve immune function, prevent clinical disease progression, and improve neurodevelopmental outcomes. Early initiation of suppressive ART in infants aged <6 months results in a considerable proportion of infants with HIV who fail to produce their own HIV-specific antibodies. These infants are HIV-seronegative when tested; however, viral reservoirs remain, and viral rebound occurs if ART is stopped [342–344]. It is, therefore, important to educate the caregiver on the importance of continuing consistent ART without treatment interruptions.

Genotypic resistance testing should be performed at the time of diagnosis; however, ART can be initiated before results are available. All infants should receive *Pneumocystis jirovecii* prophylaxis in the first year of life, irrespective of CD4 cell count or percentage [110]. In general, infants with untreated perinatally acquired HIV have higher viral loads than adults, and there are age-specific differences in CD4 cell counts, with infants having higher normal absolute lymphocyte counts than adults. In young children (aged <5 years), CD4 percentages are less variable than absolute counts [345]. Infants and children with undiagnosed HIV are likely to present with unexplained fevers, hepatosplenomegaly, generalized lymphadenopathy, parotitis, persistent oral and diaper candidiasis, recurrent invasive bacterial infections, recurrent diarrhea, failure to thrive, central nervous system diseases, and delays in growth and development [346].

While initiating and managing pediatric ART, it is essential to understand that achieving consistent adherence in children is often challenging. Intensive adherence counseling and follow-up during the first few weeks to months after ART initiation is recommended to support the child and caregiver, including detailed instructions on the administration of ARV drugs and caregiver treatment literacy [91]. After initiation of ART or after a change in ARV regimen, children should be followed up in 1–2 weeks to assess effectiveness, tolerability, and adverse events and to evaluate and support medication adherence. Head circumference should be measured in children aged <3 years and plotted against standard growth curves. Furthermore, developmental assessment is important in infants and children. Laboratory testing for toxicity and viral load response is recommended at 2–4 weeks after treatment initiation or change in ARV regimen. Clinicians and multidisciplinary teams should schedule frequent clinical in-person and/or telemedicine visits to monitor patients closely during the first few months after initiating a new ART regimen. For infants, more frequent clinical visits are required to ensure that growth and development are on schedule, that appropriate adjustments of dosage are made, and that the infant is tolerating ART. CD4 cell count can be monitored less frequently (every 6–12 months) in children who are adherent to therapy, who have sustained virologic suppression and CD4 cell count values that are well above the threshold for OI risk, and who have stable clinical status [91]. Viral load measurement every 3–4 months is recommended to monitor ART adherence.

Caregivers, families, and children with HIV face a wide array of socioeconomic, educational, legal, immigration, and structural challenges that affect adherence and retention in care and require ongoing case management support to achieve and sustain positive HIV disease, health, and developmental outcomes. Disclosure of HIV status to children with perinatally acquired HIV is an emotionally and socially complex process that requires caregiver and child support. Studies suggest that disclosure of perinatal HIV status can increase self-esteem and adherence to ART and improve access to psychosocial support [347–350].

All recommended childhood immunizations should be administered to infants exposed to HIV. If HIV infection is confirmed, immunologic status (CD4 cell count or percentage) should be assessed, and guidelines for the immunizations of

the child with HIV should be followed [156, 346]. Children with HIV should be immunized with all age-appropriate inactivated vaccines. Inactivated influenza vaccine should be administered annually according to the most current recommendations. In general, the administration of live vaccines, such as MMR and varicella, is guided by the CD4 cell count or percentage. Rotavirus vaccine, however, should be administered to infants with HIV or exposed to HIV irrespective of CD4 cell count or percentage [346].

In the era of ART, there has been a substantial decrease in frequency of OIs and malignancies in children [346]. Prevention and treatment of OIs in children should be managed according to the HHS pediatric OI guidelines [110]. Leiomyosarcomas and non-Hodgkin B-cell lymphomas of the Burkitt type (including those in the central nervous system) occur more frequently in children with HIV than in immunocompetent children. Kaposi sarcoma, caused by human herpesvirus 8, is rare in children in the United States but has been documented in children with HIV who have emigrated from sub-Saharan African countries.

SECTION 10: SPECIAL CONSIDERATIONS FOR ADOLESCENTS

Recommendations

- Adolescents with HIV require an individual and developmentally guided approach to therapy and care, ideally through an HIV specialist and team with expertise in this population.
- Adolescents with HIV should be counseled about preventative measures, including smoking cessation, alcohol and other substance use prevention, gender, and sexual health, including safer sex practices, to prevent development of comorbidities.
- Screening for early detection and management of comorbidities should be considered for adolescents with HIV.
- Vaccinations should be administered according to ACIP schedules for children with HIV, including ensuring catch-up vaccinations, if applicable, and administration of vaccines that prevent comorbidities, if applicable.
- Adolescents with HIV should have a coordinated, deliberate transition to adult care, with an emphasis on supporting their capacity for self-care including, but not limited to, retention, adherence to care, medical literacy, and engagement in mental health and substance use treatment.

Evidence Summary

The care of adolescents with HIV, whether perinatally or nonperinatally acquired, presents many challenges [347, 348, 351]. The median age of the US cohort of children who acquired HIV early in life, primarily via perinatal transmission, is now mid to late teens, and many have reached adulthood [352, 353] with varying degrees of health. Youth with HIV, in addition to the biological and psychosocial changes that normally occur in adolescence, often cope with stigma, disclosure, loss of family members, and negotiation of sexual activity. In many studies, rates of cognitive, psychiatric, and behavioral problems are higher in those with perinatally acquired infection [354, 355]. As a result of these challenges, many youths with perinatally acquired infection have poorer adherence to ART and may experience decreased engagement in care compared to with other populations [347]. Disclosure for this population is complicated as it includes becoming aware of one's own diagnosis and the subsequent self-disclosure of one's diagnosis to others (eg, sexual partners). While disclosure of diagnosis by the caregiver to the child or adolescent can be overwhelming to caregivers, it should occur by late childhood and prior to adolescence, as it has been correlated with better adjustment to illness, lower rates of depression, and improved adherence with care and ART [91, 348, 351]. Support should be provided for both types of disclosure. Screening for and addressing mental health challenges and concerns is an important part of caring for this population.

Puberty may affect drug metabolism, underscoring the importance of adolescent-specific studies. Decisions regarding dosing should take into consideration sexual maturity, with those with a sexual maturity rating ≥4 being dosed according to adult treatment guidelines. This is becoming less relevant because weight-based dosing is becoming the standard of care. Special attention should be paid to attaining and maintaining viral suppression, along with risk reduction counseling, STI and pregnancy prevention, and secondary HIV prevention in early or later adolescence [356, 357].

Long-term treatment, which may result in treatment fatigue, viral resistance due to suboptimal adherence or good adherence to suboptimal regimens, or potential end-organ toxicity, therefore, requires monitoring [358]. Early-acquired HIV, particularly in the setting of suboptimal viral suppression, can result in chronic immune activation and inflammation, which leads to noncommunicable disease comorbidities (eg, metabolic syndrome, dyslipidemia, chronic kidney disease, obesity, bone disease, atherosclerotic vascular disease, and cardiopulmonary abnormalities) [352, 358–361]. This risk is compounded by modifiable risk factors, particularly smoking/vaping and poor diet, which often begin during adolescence. Caring for youths with early-acquired HIV necessitates a life course approach with counseling regarding modifiable risk factors; prevention, including smoking cessation, dietary modification, and vaccination against preventable conditions; and screening for and early management of comorbidities [362, 363].

Youth who acquired HIV through sexual activity or injection drug use, in addition to the biological and psychosocial changes that normally occur in adolescence, have issues that are similar to those for adults, including high rates of substance use; STIs;

mental health comorbidities such as depression, anxiety, and PTSD [352]; and social determinants that may present barriers to care [7]. Sexual and gender identity and sexual behaviors should be discussed in a nonjudgmental manner in order to understand sexual risk and diminish stigma [364]. Multidisciplinary teams that simultaneously address biological and psychosocial issues are critical in optimizing outcomes, including early initiation of therapy and adherence support to maximize immune recovery and health and minimize transmission risk [365, 366]. ART should be prescribed according to established adult and adolescent treatment guidelines [7] (see also Section 1: Optimizing Care).

The transition of adolescents from pediatric to adult care usually occurs between the ages of 18 and 25 years and is impacted by variable factors, from patient preference to availability of providers and system/clinic rules. Youths are at high risk of falling out of care and experiencing poor clinical outcomes during this transition period [367, 368]. The transition of care from pediatric or adolescent providers to adult providers should be a deliberate, comprehensive, and coordinated multidisciplinary youth-friendly process that involves the healthcare team and the patient [369–371]. Care must be given to synergistically attend to the diverse needs of the adolescent that extend beyond medical care, including employment, independent living, and intimate relationships. Over time, youths must learn to negotiate the healthcare system and assume increasing responsibility for their healthcare. There are several resources on best practices for transitioning youths with HIV to adult care [7, 372–375].

SECTION 11: CONSIDERATIONS FOR TRANSGENDER AND GENDER-DIVERSE ADULTS

Recommendations

- Transgender and gender-diverse persons with HIV should have access to care that is gender-affirming, nondiscriminatory, nonstigmatizing, and culturally sensitive.
- Intake forms, medical records, and other documentation should include gender identity options in addition to sex assigned at birth, chosen name and pronouns, and legal name.
- Transgender persons should be offered medically necessary gender-affirming interventions in accordance with national guidelines.
- HIV care providers should be familiar with gender-affirming hormone treatment and necessary clinical and laboratory monitoring or provide referral to a clinician or endocrinologist experienced in transgender care.

Evidence Summary

Transgender people identify with a gender that differs from their sex assigned at birth. Recent data estimate that approximately 1.3 million adults in the United States identify as transgender or gender diverse [376]. It is important to use the appropriate terminology when talking with and about transgender persons. Many terms are used and often are confused with each other or used incorrectly (Table 8). Gender dysphoria refers to the discomfort that some transgender people may experience due to the discrepancy between their gender identity and sex assigned at birth. Some individuals opt for medical interventions, such as the use of gender-affirming hormones and surgeries, to align their physical characteristics with their gender identity.

Stigma and discrimination are serious issues that threaten the quality of care for transgender and gender-diverse persons, regardless of HIV status. Nearly half of transgender persons face family rejection, 40% report a history of attempted suicide, 29% live in poverty, 30% have experienced homelessness, 33% have experienced discrimination within the healthcare system, and 23% avoid the healthcare system due to fear of discrimination [377]. Global estimates show a pooled HIV prevalence of 19.9% (95% CI, 14.7%–25.1%) among transgender women, with 66-fold higher odds of HIV prevalence than the general population [378]. Data among transgender men are limited, but estimated HIV prevalence is 2.56% (95% CI, .0%–5.9%) [378]. Given the disproportionate impact of HIV on transgender individuals and the psychosocial barriers they face, health systems and healthcare providers should strive to create more

Table 8. Terminology Associated With Gender Identity and Hormonal Therapy

Gender identity: An individual's sense of being male, female, nonbinary, agender, etc.
Transgender, trans, nonbinary, gender diverse: Adjectives used to refer to persons whose gender identity does not align with their sex recorded at birth (the latter primarily based on visible physical anatomy)
Nonbinary: An adjective used to refer to persons whose gender identity is outside the gender binary, that is, do not identify exclusively as a man or a woman; some nonbinary persons may not identify with any gender (agender)
Cisgender: An adjective used to refer to people whose gender identity corresponds to the sex they were assigned at birth
Gender expression: How a person communicates their gender through appearance, dress, name, pronouns, mannerisms, and speech
Gender-affirming hormone treatment and surgeries: Broad categories of medical interventions that transgender persons might consider to align their appearance and their gender identity
Gender affirmation: An overall process of alignment of physical characteristics and/or gender expression with gender identity
Gender dysphoria: Discomfort felt by some persons due to lack of alignment between gender identity and the sex recorded at birth; not all transgender persons have dysphoria, but many US insurance companies require this diagnosis for payment for gender-affirming medical and surgical interventions
Feminizing hormone therapy: The use of estrogens and often androgen blockers with the objective of inducing changes in physical characteristics to better match patient gender identity
Masculinizing hormone therapy: The use of testosterone with the objective of inducing changes in physical characteristics to better match patient gender identity
Sex assigned at birth: Refers to a person's status as male, female, or intersex based on physical characteristics at birth

welcoming, affirming, and trauma-informed clinical environments. Clinic intake and registration forms should allow selection of gender identity in addition to assigned sex at birth [379]. Patients should be addressed using their chosen name (when different from legal name) and pronouns. Additionally, educational and health promotional materials designed for transgender individuals create a better sense of inclusion. Staff should undergo training on gender diversity and delivery of culturally competent and sensitive care. This comprehensive approach by all staff may facilitate patient empowerment, care engagement, and viral suppression [380, 381].

Gender-affirming hormone therapy (GAHT) is safe when provided under medical supervision. This care is often provided by primary care providers and HIV specialists who have received training, including informally, through mentorship or continuing medical education [224]. HIV care providers should be familiar with gender-affirming hormone treatment and necessary clinical and laboratory monitoring or provide referral to a medical provider or endocrinologist experienced in transgender care. Persons should be offered GAHT in accordance with established clinical practice guidelines, such as those published by the Endocrine Society [382] and the World Professional Association for Transgender Health [224]. Before initiating gender-affirming medical therapy for adult patients, the clinician should ascertain that the patient's gender identity is persistent and that they have the capacity to consent to treatment. The clinician should review expectations in terms of the timeline for changes and types of changes associated with hormone therapy, as well as a balanced risk assessment of those therapies. Prior to initiating hormone therapy or undergoing gonadectomy, clinicians should discuss parenthood goals, the impact of these interventions on fertility, and available options for sperm or oocyte preservation [224]. Some payers may require an assessment and referral letter from a mental health professional prior to gender-affirming medical interventions.

Feminizing hormone regimens typically use estrogen and antiandrogen medications, such as spironolactone. In 3–6 months, patients may start to experience breast growth, decreased muscle mass, softer skin, redistribution of body fat, and fewer spontaneous erections [224]. Transgender individuals who receive estrogen therapy may be at increased risk of hypertriglyceridemia, venous thromboembolism (VTE), and cardiovascular disease. Transdermal estrogen formulations may pose lower risk of thrombosis and are preferred for those aged >45 years, with a history of VTE, or with known risk factors for cardiovascular disease [224]. Oral conjugated estrogen formulations and ethinyl estradiol are not recommended due to an increased risk of thromboembolic events [224]. Smoking cessation should be encouraged. Clinical evaluations with laboratory monitoring of serum estradiol and testosterone should occur every 3 months for the first year and once to twice per year thereafter, with potassium monitoring at the same intervals for those on spironolactone. Target levels for individuals receiving feminizing GAHT are serum total testosterone <50 ng/dL and serum estradiol approximately 100–200 pg/mL [224].

For masculinizing hormone therapy, testosterone remains the mainstay treatment. Results, including cessation of menses, deepening of voice, increased muscle mass, and facial hair, typically start within 3–6 months [224]. Androgen therapy may result in erythrocytosis, increases in LDL cholesterol, and increases in serum creatinine [224, 383]. After initiating testosterone therapy, hemoglobin/hematocrit and serum testosterone should be measured every 3 months for the first year and 1–2 times per year thereafter. The serum total testosterone level should be maintained in the normal physiologic cisgender male range of 400 to 700 ng/dL [224].

Several ARV regimens, including NRTIs, unboosted INSTIs, rilpivirine, and doravirine, are not anticipated to impact GAHT and require no additional monitoring [384, 385]. Estradiol levels may be decreased by the NNRTIs efavirenz, etravirine, and nevirapine. Ritonavir-boosted PIs may increase or decrease estradiol levels, while cobicistat-boosted PIs may increase estradiol [386]. Testosterone levels are increased by boosted PIs and elvitegravir/cobicistat and decreased by efavirenz, etravirine, and nevirapine [386]. When pharmacokinetic interactions are anticipated, clinicians should monitor clinical effects as well as serum hormone concentrations and adjust hormone doses as needed. It is important to provide patients with accurate information on drug–drug interactions between their ART and hormone therapy, including the lack of deleterious effects on hormone therapy, and to make dose adjustments as appropriate. Lack of communication around this concern may contribute to fear of drug–drug interactions and poor adherence to one therapy or the other [387].

SECTION 12: COVID-19 AND HIV

People with HIV have been impacted by SARS-CoV-2 infection (COVID-19) since the early days of the pandemic. Early on, the presumption was that people with HIV would fare poorly due to damaged immune systems, but that has not necessarily proven to be the case. This section discusses the interaction of COVID-19 and HIV only. IDSA has excellent living guidelines for COVID-19 management and treatment for the general population [388]. The best protections against COVID-19 for people with HIV are up-to-date vaccinations and good health hygiene and safety. It is important for providers to remember that HIV care should not be disrupted simply due to COVID-19. In fact, aiming for viral suppression and maximization of CD4 count is recommended to prevent more severe COVID-19 infections [389, 390]. Early in the pandemic, and even 1 year after general quarantines ended, access to HIV care was limited, and many people with HIV had disruptions in HIV

care, including refills of ART, disease monitoring, provider visits, and laboratory testing [390, 391]. Providers who care for people who are more severely immunocompromised (CD4 <200 cells/μL) should ensure that their office is safe for people with HIV. The CDC guidelines should be consulted for the latest healthcare facility guidelines[392].

Recommendations

- CD4 count and viral suppression should be maximized to lower risk for COVID.
- Weight loss should be encouraged because obesity is a significant risk factor for severe COVID-19 infection.
- Pulmonary comorbidities should be treated to maximize protection against severe COVID-19 infection.
- It is important to ensure that patients with more advanced HIV are fully vaccinated, including vaccines targeted to newer SARS-CoV-2 variants, and to use mRNA vaccines when possible (see Section 4).
- There is no evidence that people with HIV and COVID-19 require a change to their ART simply due to presence of COVID-19 coinfection.
- HIV is not a contraindication to COVID-19 vaccination, and COVID-19 vaccination does not impact HIV viremia.
- Treatment recommendations for COVID-19 in people with HIV are the same as for people without HIV, and treatment recommendations do not change by HIV viral load or CD4 cell count.
- Treatment of COVID-19 is not changed by HIV infection, and ART is not changed due to treatment for COVID-19.
- Dexamethasone and other corticosteroids should not be used in the outpatient setting when caring for people with HIV who have COVID-19 in the absence of other indications.
- It is important to be cognizant of significant drug–drug interactions with ritonavir-boosted nirmatrelvir and all medications and supplements. Antiretroviral therapy does not require dose adjustments in this setting.
- Previously disproven COVID-19 treatment should not be used for people with HIV, including ivermectin and sotrovimab in the outpatient setting.
- Because people with HIV may be at increased risk of PCCs, ask about PCC-related symptoms among people with HIV who are post-30 days from COVID-19 diagnosis.

Evidence Summary

People with HIV are at increased risk of acquiring SARS-CoV-2 infection and possibly of becoming reinfected with SARS-CoV-2, with risk inversely proportional to CD4 cell count, especially if CD4 count is <200 cells/μL [180, 393–395]. In multiple studies, it was found that a CD4 count <200 cells/μL was associated with increased mortality, while CD4 <350 cells/μL was associated with an increased risk of hospitalization [393, 396]. People with HIV should be on ART and aim for CD4 count >200 cells/μL but ideally >350 cells/μL. This is especially important for decreasing the risk of hospitalization or more severe COVID-19 infection [393]. Additional evidence suggests that all persons (regardless of HIV status) would benefit from weight loss, as obesity is associated with more severe COVID-19 infection [397]. Data also suggest that a higher risk for more severe COVID-19 is associated with cirrhosis, alcoholic hepatitis, chronic kidney disease, diabetes mellitus, and smoking [395]. Further, chronic pulmonary disease, specifically bronchiectasis, chronic obstructive pulmonary disease, interstitial lung disease, pulmonary embolism, and pulmonary hypertension, have been associated with more severe COVID-19 infection, including greatly increased risk of hospitalization and death. All of these conditions should be maximally optimized prior to infection (including stopping smoking) to lower the risk of severe infection.

Early data (from 2020) showed an association between decreased access to testing among non-Latino Blacks and Latinos and late diagnoses with more severe COVID-19 infections [398]. While testing access improved during the pandemic and the public health emergency has ended, access to testing may remain key for certain subpopulations. Vaccination against COVID-19, including all recommended boosters, is key for COVID-19 prevention and lowering risk for severe COVID-19 infections in people with HIV (see Section 4). Consistent evidence indicates that people with HIV with CD4 count >200 cells/μL have robust immune response (approximating that of people without HIV infection), but mRNA vaccines perform superiorly to other vaccines [396, 399, 400]. Further, HIV is not a contraindication to COVID-19 vaccination, regardless of CD4 count or degree of HIV viral suppression, and COVID-19 vaccination does not impact HIV viremia [181, 401]. Even with effective vaccination, there is still some evidence that people with HIV are at increased risk for breakthrough infection; however, the need for hospitalization or risk of death is not increased relative to people without HIV [399, 402].

Controversy persists on the role of ARV agents in preventing COVID-19 infection or mitigating the severity of infection in people with HIV. Observational evidence from several studies has suggested that tenofovir may be associated with lower risk of severe COVID-19; however, no confirmatory data from randomized trials exist [403]. Similarly, evidence for PIs and prevention of COVID-19 remains inconclusive [404]. There is no evidence to suggest that people with HIV and COVID-19 require a change to their ART simply because of the COVID-19 infection. No change is required to ART while on anti–COVID-19 treatment, including remdesivir or ritonavir-boosted nirmatrelvir. Close monitoring for potential increased risk of side effects is recommended. However, dexamethasone and other corticosteroids used as anti–COVID-19

treatment should be avoided in the outpatient setting because side effects may increase due to drug–drug interactions [405].

As discussed in Section 4, PCCs are an ever-increasing phenomenon following SARS-CoV-2 infection. The exact incidence is unclear, and treatment is mainly symptomatic. There is some evidence that people with HIV may be at increased risk for PCCs, especially if not virally suppressed or with a lower CD4 count [406–408]. As such, providers should ask about PCC-related symptoms among people with HIV who are 30 days post–COVID-19 diagnosis. No treatment modifications for ART or comorbidities are indicated in the presence of PCCs.

Notes

Acknowledgments. The authors thank the following individuals for their contributions to this guidance: Andrea Weddle, MSW (HIV Medicine Association [HIVMA] executive director), Helaine Resnick, PhD, MPH (consultant, literature reviews), Kendra Porter, BS, and Lily Fathi, BA. The authors also thank the reviewers (Joseph Cherabie, MD, MSc, Carolyn Chu, MD, MSc, Michael Mugavero, MD, Tim Horn, MS, and members of the Infectious Disease Society of America [IDSA] Standards and Practice Guidelines Subcommittee) for their thoughtful comments that improved the manuscript.

Disclaimer. This guidance cannot account for individual variation among patients and is not intended to supplant clinician judgment with respect to particular patients or special clinical situations. The HIVMA and the IDSA consider adherence to this guidance to be voluntary, with the ultimate determination regarding its application to be made based on individual patient circumstances.

Financial support. The IDSA provided financial support for this guidance.

Potential conflicts of interest. The following list includes what has been reported to IDSA. To provide thorough transparency, IDSA requires full disclosure of all relationships, regardless of relevancy to the guideline or guidance topic. Evaluation of such relationships as potential conflicts of interest is determined by a review process that includes assessment by the Board of Directors liaison to the Standards and Practice Guidelines Committee and, if necessary, the Conflicts of Interest and Ethics Committee. The assessment of disclosed relationships for possible conflicts of interest is 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). IDSA requests panel members to disclose activities and financial relationships/investments related to consultant/advisory roles, promotional speakers bureau, stocks/bonds, honoraria, expert testimony, ownership interest, research grants, organizational benefits, intellectual property, other numeration, activities with other organizations, and relevant financial interest of family members. Readers of this guidance should be mindful of this when the list of disclosures is reviewed.

M. T. serves as chair of the Excision Biotherapeutics Independent Data Monitoring Committee. A. A. reports grant funding from the National Institutes of Health (NIH) and Gilead Sciences; consulting fees from ViiV Healthcare and Gilead Sciences; serving as chair of the HIVMA Board of Directors, chair of the Advocates for Youth Board, and Board member of the Well Project; and receipt of payment for expert testimony by Medicolegal for consulting unrelated to the manuscript. J. A. C. reports grant funding from the NIH, serving on the American Conference for the Treatment of HIV Advisory Board, and receipt of consulting fees from Prime Education and Integritas Communications. M. H. reports Ryan White Program Part C grant funding and serving as a past member of the HIVMA Board of Directors and past chair of HIVMA. M. K. J. reports grants from NIH, Gilead Sciences, Laurent, and the Cancer Prevention & Research Institute of Texas; payment or honoraria from HCPLIVE and ACTHIV; serving on the IDSA Coordinating Council; support for travel from the HIV Congress (India); and past service on the HIVMA Board of Directors. G. M. reports grants from Astellas, Redhill, Genentech, Cognivue, and Pfizer; consulting fees from Gilead, Merck, and ViiV/GSK; and consulting fees from Janssen. A. R. reports serving as a board member for the American Sexual Health Association and the World Professional Association of Transgender Health. N. R. reports serving as chair of the Committee on Pediatric and Adolescent HIV at the American Academy of Pediatrics. W. R. S. reports consulting fees from ViiV Healthcare and payment or honoraria for lectures from ViiV Healthcare. T. S. reports research funding from Gilead Sciences and ViiV Healthcare and funding for speaking and serving on an advisory board from ViiV/GSK. H. T. reports grants from the National Institute on Drug Abuse, Gilead Sciences, and ViiV Healthcare; consulting fees from RTI International Simon Fraser University, Westat; participation on the Multi-Center Safety-Study Examining the Use of the O'Neil Long-Acting Naltrexone Impact in Participants with Opioid Use Disorder Receiving Repeat Dosing; and serving on the HIVMA Board of Directors, Black Harm Reduction Network, and Florida Reduction Collective and Safety Project. The remaining author reports 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.

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