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Topics in Antiviral Medicine™

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On completion of this activity, the learner will be able to:

- Describe the important new data presented at the 2020 Conference on Retroviruses and Opportunistic Infections and the potential clinical implications for patients in the areas of epidemiology of HIV and HIV prevention efforts
- Describe the important new data presented at the 2020 Conference on Retroviruses and Opportunistic Infections and the potential clinical implications for patients in the area of tuberculosis coinfection, cryptococcosis, and talaromycosis
- Identify the comprehensive, culturally sensitive, and developmentally sensitive care practices for youth and adolescents infected or at-risk for infection with HIV and sexually transmitted infections

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This enduring material is designed for physicians who are actively involved in the medical care of people with HIV and other viral infections.

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**Perspective**

**Vaccination and Immunoprotection in People with HIV**

Vaccines play an important role in HIV primary care and are available for several sexually transmitted infections, including those caused by hepatitis A virus (HAV), hepatitis B virus (HBV), and human papillomavirus (HPV). HAV vaccination is increasingly important, given recent hepatitis A outbreaks and lack of immunity in many adults. A novel formulation of the hepatitis B vaccine shows promise in increasing rates of seroprotection. The Advisory Committee on Immunization Practices recommends the meningococcal conjugate vaccine for all individuals with HIV and has expanded the age range for administration of the HPV vaccine, recommending shared decision making about its administration in adults aged 27 to 45 years. This article summarizes a presentation by Steven C. Johnson, MD, at the International Antiviral Society–USA (IAS-USA) annual continuing education program held in New York, New York, in September 2019.

**Keywords:** HIV, STI, sexually transmitted infection, vaccine, hepatitis, immunoprotection, HBV, HPV, HAV

Currently, vaccines for 28 infectious diseases are available in the United States. For individuals with HIV, the Centers for Disease Control and Prevention (CDC) provide guidance on which vaccines are appropriate, based on CD4+ cell count, and how often they should be administered (see Table).

Hepatitis A virus (HAV), hepatitis B virus (HBV), and human papillomavirus (HPV) can all be transmitted sexually. Transmission of meningococcal disease is linked to close intimate or nonintimate contact, such as coughing or kissing. Therefore, discussions of these vaccines should be included in sexual health discussions between practitioners and patients.

**Hepatitis A Virus**

Historically, hepatitis A was common in the United States because of conditions such as crowding, poor sanitation, and lack of food safety, and it was a common infection in childhood. As society developed, housing became more separate and food safety measures increased, and rates of HAV infection began to decline. From 1995 to 2011, the incidence of HAV infection decreased by more than 95%. In 2016, the most effective way to prevent HAV infection is through vaccination.

Outbreaks of HAV infection began to occur in the United States, likely spread via person-to-person contact, and from 2011 to 2017, the incidence of HAV infection increased by 140%. This increasing incidence of HAV infection in the United States is illustrated in Figure 1. Currently, the most effective way to prevent HAV infection is through vaccination. The CDC recommends the HAV vaccine for all susceptible men who have sex with men (MSM) and for individuals who use drugs (injection or noninjection); have clotting factor disorders; are homeless or unstably housed; have been incarcerated; are researchers who work with HAV; will travel to countries with high or intermediate endemic HAV; or have close contact with an international adoptee. The CDC also notes that HAV vaccination can be considered for all nonimmune individuals.

**Hepatitis A Virus Postexposure Prophylaxis**

In some cases, the HAV vaccine or immunoglobulin may be given as HAV postexposure prophylaxis (PEP). Individuals recently exposed to HAV who have not previously received the hepatitis A vaccine may be given a single dose of the monovalent HAV vaccine or immunoglobulin (0.02 mL/kg) as soon as possible after exposure, ideally within 2 weeks because the efficacy of vaccine or immunoglobulin when administered more than 2 weeks after exposure has not been established. If hepatitis A immunoglobulin is administered to individuals for whom the vaccine is recommended, a dose of vaccine should be provided simultaneously with immunoglobulin, and the second vaccine dose should be administered according to the licensed schedule to complete the series. The combined HAV/HBV vaccine should be considered for individuals for whom both vaccines are recommended.

**Hepatitis B Virus**

HBV and HIV are transmitted via the same routes, and individuals with HIV often have HBV. There has been a gradual decline in the number of cases of HBV infection in the United States (see Figure 2), at least partly due to the rollout of vaccines, including in adolescents.
Hepatitis B vaccines include the standard recombinant vaccine, a newer novel adjuvant vaccine, and the combination HAV/HBV vaccine. The US Department of Health and Human Services (DHHS) Opportunistic Infection Guidelines recommend that HBV vaccination not be deferred based on CD4+ cell count, because some individuals with HIV and low CD4+ cell counts (<200/μL) respond to vaccination. Of individuals with HIV who did not respond to a 3-dose recombinant HBV vaccine, 25% to 50% responded to an additional vaccine dose, and 44% to 100% responded to revaccination with a 3-dose series. Therefore, the DHHS Opportunistic Infection Guidelines recommend that persons who do not respond to a complete hepatitis B vaccination series with one of the recombinant vaccines should receive a 3-dose revaccination series. However, some experts suggest delaying revaccination until antiretroviral therapy results in a sustained increase in CD4+ cell count. In 2 randomized trials, 4 doses of a double-dose recombinant HBV vaccine produced higher titers of hepatitis B surface antibody (anti-HBs) than 3 doses of the standard-dose vaccine. The newest HBV vaccine contains a novel adjuvant toll-like receptor agonist, and was approved by the US Food and Drug Administration (FDA) in November 2017. It is administered as 2 doses separated by 1 month. In clinical trials, seroprotection (anti-HBs ≥10 mIU) was achieved in 90% to 95% of participants who received the 2-dose HBV vaccine and in 65% to 81% of those who received a 3-dose standard recombinant HBV vaccine. However, the safety and efficacy of the novel adjuvant HBV vaccine in individuals with HIV have not been studied.

Similar to HAV, there is a potential role of passive immunization in HBV. Passive-active PEP (the simultaneous administration of Hepatitis B Immune Globulin (HBIG) and vaccine at separate sites) and active PEP (the administration of HBV vaccine alone) are highly effective in preventing HBV infection. Passive-active PEP is indicated for all individuals with HIV who have been exposed to HBV, regardless of CD4+ cell count or immune status to varicella. Active PEP is indicated for individuals with CD4+ cell counts ≥200/μL and no immunity to varicella. In clinical trials, seroprotection (anti-HBs ≥10 mIU) was achieved in 90% to 95% of participants who received the 2-dose HBV vaccine and in 65% to 81% of those who received a 3-dose standard recombinant HBV vaccine. However, the safety and efficacy of the novel adjuvant HBV vaccine in individuals with HIV have not been studied.
Sixty-two cases of meningococcal disease were reported in HIV-seropositive individuals from 1995 to 2014.

Infection was 1.1 per 1000 person-years overall, 2.85 per 100-person-years in those not taking active HBV treatment, 1.36 per 100-person-years in those taking lamivudine as the only HBV active drug, and 0.014 per 100-person-years in those taking tenofovir. These data suggest that tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) used to treat HBV can also act as a form of preexposure prophylaxis for HBV. Given the prevalence of tenofovir-based regimens, this may account for the lack of acute HBV infection in many individuals with HIV who are taking antiretroviral therapy.

Human Papillomavirus

The estimated prevalence of HPV infection (all serotypes) in the United States is 79 million, with an estimated incidence of 14 million new cases each year. There were more than 40,000 cases of HPV-associated cancer in 2015, including cervical, vulvar, vaginal, penile, anal, and oropharyngeal cancers.

The 4-valent HPV vaccine was FDA approved in 2006, followed by a 2-valent vaccine in 2009, and then a 9-valent vaccine in 2014, which became the only available HPV vaccine in the United States in 2017. In 2018, the FDA expanded the use of the 9-valent vaccine to include individuals aged 27 to 45 years. Subsequently, in 2019, the Advisory Committee on Immunization Practices (ACIP) adopted this age range in their recommendations.

According to the ACIP recommendations, clinicians can consider HPV vaccination for adults aged 27 to 45 years who have not been adequately vaccinated and may benefit. They note that having a new sex partner carries risk for acquiring a new HPV infection, regardless of age, and that most sexually active individuals have been exposed to some type of HPV. Additionally, adolescents aged 11 or 12 years remain the best target group for the HPV vaccine.

Current HPV vaccines do not prevent progression of HPV disease and are therefore preventative rather than therapeutic. Researchers are examining the possibility of a therapeutic HPV vaccine to perhaps change the natural history of established dysplasia.

Meningococcal Disease

In a surveillance system in the United States that included approximately 43 million people, 62 cases of meningococcal disease were reported in individuals with HIV from 1995 to 2014. The estimated incidence of meningococcal disease for individuals with HIV ranges from 3.4 to 6.6 cases per 100,000, with a relative risk approximately 5- to 13-fold higher among individuals with HIV than the general population. In 2016, the ACIP recommended the meningococcal conjugate vaccine for all individuals with HIV. The meningococcal conjugate vaccine is generally administered as 2 doses given 8 to 12 weeks apart, followed by a boosting dose at 5 years.

Vaccines and Travel

In addition to vaccines for sexual health, a number of other vaccines are recommended for people with HIV (see Table).

Vaccines are also important for travel, as individuals with HIV may acquire new sexually transmitted infections (STIs) while traveling. Certain vaccines may be indicated based on the travel destination (see Box).

Box. Indicated Vaccinations Based on Travel Destination for Individuals With HIV

- **Cholera:** Selected destinations with outbreaks and anticipated contact.
- **Hepatitis A virus:** Many parts of Central and South America, Mexico, Africa, and Asia.
- **Hepatitis B virus:** If not immune, most destinations where sexual activity is planned.
- **Influenza:** All destinations.
- **Japanese encephalitis:** Parts of Asia.
- **Meningitis:** Parts of Africa.
- **Polio:** Rarely given, although polio is still present in Nigeria, Afghanistan, and Pakistan.
- **Rabies:** Many destinations where the trip is prolonged or animal exposure is likely.
- **Typhoid:** Many parts of Central and South America, Mexico, Africa, and Asia.
- **Yellow Fever:** Parts of Africa and South America.

Summary

Vaccines play an important role in HIV primary care and are available for several STIs, including HAV, HBV, and HPV infections. HAV vaccination is increasingly important, given recent HAV outbreaks and a large group of nonimmune adults. A novel formulation of the HBV vaccine shows promise in providing higher rates of seroprotection but has not yet been studied in the context of HIV. The ACIP recommends the meningococcal conjugate vaccine for all individuals with HIV and has expanded the age range for administration of the HPV vaccine, recommending shared decision making about its administration in adults aged 27 to 45 years.

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References


Physical Function and Frailty in HIV

Aging is associated with declines in physical function that can be influenced by many factors, including HIV. These limitations may manifest as increased vulnerability to stressors, or frailty. Functional limitations and frailty can be used to guide clinical decisions, protect people from harm, and avoid strategies that are not likely to provide benefits. Such limitations could also serve as clinically relevant endpoints for some clinical trials. Interventions should ideally focus on early impairments that begin to occur in midlife, well before an individual becomes frail or experiences disabilities. Overall, physical activity is safe and effective in improving physical function, and counseling about physical activity should be a routine component of HIV care to increase the lifespan and healthspan of individuals with HIV. There are some promising pharmaceutical options, but more research is needed to determine the safety and long-term efficacy. This article summarizes an International Antiviral Society–USA (IAS-USA) webinar presented by Kristine M. Erlandson, MD, MS, on July 24, 2020. This webinar is available on demand at https://www.iasusa.org/courses/on-demand-webinar-2020-erlandson/.

Keywords: HIV, aging, disability, frailty, physical function

Disability

Much of the model for characterizing the changes in physical function associated with aging stems from the classic disablement model, first conceptualized in the 1960s, that later formed the basis of the World Health Organization International Classification of Functioning, Disability, and Health.\(^1\) This model assumes that there is an underlying pathology leading to 1) physical impairment that progresses to a 2) functional limitation that, ultimately, could lead to 3) disability (see Figure 1). Using this framework, impairment refers to a change in body function at the organ level. This impairment can be diagnosed during a physical examination or through imaging or laboratory tests (eg, vision or hearing impairment, osteopenia or osteoporosis, or loss of muscle mass). Limitations refer to decreased ability to do something because of the underlying impairment, and this can be assessed through performance-based measures (eg, performance of a 6-min walk), which may be more appropriate in research settings, or through individual self-report of daily functions, which may be preferred in the clinic setting.

The Centers for Disease Control and Prevention defines disability as “any condition of the body or mind (impairment) that makes it more difficult for the person with the condition to do certain activities (activity limitation) and interact with the world around them (participation restrictions).”\(^2\) Importantly, disability is a social phenomenon and is highly dependent on what is expected of the individual

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Dr Erlandson is Associate Professor of Medicine at the University of Colorado in Aurora, Colorado.
Within their culture, what the individual expects of themselves, what resources are available to help them function in their community, and how their physical environment is set up for accessibility.

Frailty Assessments

Frailty is a separate but closely-related concept to disability, describing the vulnerability of an individual to stressors. When a health-related stressor, such as hospitalization, illness, or injury, occurs in individuals who are frail, they may not be able to “bounce back” to their baseline level of function, which is a pattern that may be repeated each time there is a new stressor.

One of the most common ways to describe frailty is with the frailty phenotype. The frailty phenotype measures frailty by the presence or absence of 5 criteria: 1) slow gait or slowness, often measured via a 4-m walk; 2) weak grip, usually measured by a dynamometer; 3) low levels of physical activity, usually self-reported; 4) fatigue, usually self-reported; and 5) unintentional weight loss. For the frailty phenotype, which generally takes 5 to 10 minutes to assess, an individual is considered robust if they meet none of the above criteria, prefrail if they meet 1 or 2 of the criteria, and frail if they meet 3 or more of the criteria. Notably, some of these criteria can be attributable to factors or conditions other than frailty, such as fatigue caused by depression. The assessment occurs prospectively and may not be captured in a routine HIV clinic visit without prior planning.

The frailty phenotype attempts to define the components of the complex cycle of frailty (see Figure 2). Initially, factors such as senescent muscle changes, disease, and underlying comorbidities contribute to a loss of muscle mass. Loss of muscle mass affects exercise endurance (measured by maximum oxygen uptake [VO2 max]), strength and power, and resting metabolic rate. Over time, decreased exercise endurance can lead to slow walking speed, which can lead to lower levels of physical activity, resulting in fewer calories burned. These decreases in energy expenditure can also suppress appetite, leading to chronic undernourishment, feeding back into loss of muscle mass and continuing the cycle.

Decreased strength and power and slow walking speed are also associated with increased mortality and poor outcomes in the general population. Of note, although frailty is related to and often overlaps with comorbidity and disability, it is not equivalent to these. Frailty can exist outside of comorbidity, and disability can exist without frailty.

Another way to define frailty is through the deficit accumulation model, also called the Frailty Index. This model considers variables that increase with age, but are not ubiquitous with age, and that are associated with health status. For example, most people will need corrective lens as they get older, and wearing eyeglasses is not associated with health status, so needing eyeglasses would not be a useful variable for the Frailty Index.

The Frailty Index measures frailty as the number of contributing variables an individual has, divided by the total number of variables assessed. The Frailty Index can be adapted for specific populations and can be measured retrospectively via chart review. The initial Frailty Index included 70 variables ranging across activities of daily living, physical function, mood, cognition, neurologic function, and cardiovascular, endocrine, and respiratory health.

Similar to the Frailty Index, the VACS (Veterans Aging Cohort Study) Index uses routinely assessed laboratory-derived variables to predict mortality and morbidity in veterans with or without HIV. The VACS Index has been successfully applied to many populations within and outside of the Department of Veterans Affairs, nationally and internationally.

The Clinical Frailty Scale (Table 1) is a simplified version of the Frailty Index. It employs a visual diagnosis of frailty using a 9-point scale, with 1 being “Very Fit” and 9 being “Terminally Ill.” The Clinical Frailty Scale has been utilized in many clinical settings as it is useful for quick assessment and appears to perform quite well in predicting frailty. Each of the tools that can be used to assess frailty, including those discussed above, has its own advantages and disadvantage (Table 2).
The Short Physical Performance Battery (SPPB) has been well validated in the geriatric literature, and there is growing evidence of its applications for individuals with HIV. The SPPB measures objective functional outcomes and requires only a chair, stopwatch, and enough space to complete a 4-m walk, which can easily be done in a clinic. It is a prospective assessment that takes approximately 5 to 10 minutes to complete. Of note, it does have a ceiling effect, meaning that categorical scoring is such that many participants have perfect scores, even in the presence of other mild impairments.

Crane and colleagues examined the feasibility of the SPPB by administering it across 3 HIV clinics. In the study, 2 of the clinics administered the SPPB before or after a routine clinic visit, and one clinic required participants to return for a separate visit to complete the SPPB. Staff training to administer the SPPB took approximately 1 hour, and completion of the SPPB itself took approximately 7 minutes. The investigators concluded that it is feasible to implement the test without serious disruptions or injuries.

Another prospective assessment is the chair rise, which can be measured in a variety of ways, such as the time to complete 5 or 10 rises, or the number of chair rises an individual can complete in 30 seconds. This continuous scale produces less of a ceiling effect and can detect a range of values over a larger population; however, individuals with specific limitations, such as arthritis in the knees, may be unable to complete this assessment.

Weaker grip strength is associated with increased mortality, and grip strength is a component of frailty. Measuring grip strength requires a dynamometer, which must be regularly calibrated for accuracy, and individuals with specific limitations, such as arthritis in the hands, may have difficulty completing this assessment.

Completion of a 400-m or 6-min walk can be used to identify a higher level of physical endurance than shorter distances such as a 4-m walk. The 400-m walk or 6-min walk provide a continuous outcome (time or distance covered) and can help identify more subtle impairments in endurance or coordination. However, it requires more time and space than other assessment tools and may not always be a feasible option.

Questionnaires may also be used. These assessments are easy to standardize, can be completed in a variety of locations (eg, in a waiting room, by mail, or by telephone), and may be most appropriate as a brief screening to identify individuals with impairments. Of note, questionnaires are subjective and may not be as informative as an outcome for individuals in clinical intervention studies.

### Frailty in Individuals With HIV

Many factors thought to contribute to the development of frailty in the general population are observed in people with HIV, including inflammation, changes in body composition markers, and neurocognitive impairment. Other factors that may contribute to frailty include socioeconomic factors, such as education level and health insurance, and modifiable risk factors, such as obesity, low level of physical activity, and smoking.

Some data have suggested that frailty occurs more commonly in people with HIV. In the AGEhIV Cohort Study (Cross-sectional Comparison of the Prevalence of Age-Associated Comorbidities and Their Risk Factors Between HIV-Infected and Un-infected Individuals), frailty was more common in people with HIV than in those without across nearly every age range. In the MACS (Multicenter AIDS Cohort Study), which included men who have sex with men with and without HIV, prevalence of frailty was greater starting at age 50 years, and greater among older men with HIV than older uninfected controls. The prevalence of frailty in other
Interventions
The most effective intervention for frailty is physical activity or exercise, which when done consistently can improve physical function and reverse frailty over time. However, questions remain about the appropriate level of exercise for individuals with underlying inflammation, or whose neuropathy or other pain could potentially be exacerbated.

In a study of 69 sedentary people with and without HIV aged 50 to 75 years, who had no contraindications to exercise, participants engaged in a supervised exercise program 3 days per week for 24 weeks. Exercise started as 15 minutes on a treadmill and increased to 50 minutes over the course of the 24 weeks, and participants also completed 4 different resistance exercises. All participants completed 12 weeks of moderate-intensity exercise, and half the group was randomly assigned to increase to high-intensity exercise (high intensity based on their baseline measurements, VO2 max, and strength) or continue moderate-intensity exercise for the next 12 weeks. All participants had improvements in their physical function after 24 weeks, and improvements were similar among individuals with and without HIV. Furthermore, individuals with HIV had statistically significantly greater improvements in 400-meter walk time, time to climb a flight of stairs, and VO2 max. Overall, participants assigned to high-intensity exercise tended to have greater improvements in measures of strength, particularly among those with HIV. Improvements were also observed in components of frailty, and with an increase in lean mass and decrease in fat mass.

In addition to exercise, diet interventions may also help improve physical function. In a landmark study comparing the impact of a diet intervention in addition to an exercise intervention in older adults with obesity (without HIV), participants who had both diet and exercise interventions had the greatest improvement in their physical performance scores, followed by those who had exercise intervention only, and those who had diet intervention only, and those who had neither intervention.

Beyond diet and exercise, some data suggests that a comprehensive geriatric assessment may have some benefit in reducing frailty. The comprehensive geriatric assessment ensures comprehensive, individualized care, rather than system-focused or guideline-driven care. A comprehensive assessment can

<table>
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<tr>
<th>Test</th>
<th>Advantages</th>
<th>Disadvantages</th>
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<tr>
<td>Frailty phenotype</td>
<td>Well-validated in geriatric literature and HIV literature</td>
<td>Requires dynamometer&lt;br&gt;Overlaps with cognition/depression in HIV&lt;br&gt;Categorical&lt;br&gt;Subjective components&lt;br&gt;Prospective only</td>
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<tr>
<td>Frailty or Veterans Aging Cohort Index</td>
<td>Easy to derive from labs&lt;br&gt;Can collect retrospectively</td>
<td>No measure of physical function&lt;br&gt;More difficult to intervene (yes/no for each component)</td>
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<tr>
<td>Short Physical Performance Battery</td>
<td>Well-validated in geriatric literature&lt;br&gt;Objective outcomes&lt;br&gt;Only requires chair and 4 meters of space&lt;br&gt;Less of a ceiling effect&lt;br&gt;Greatest impairment in HIV&lt;br&gt;Changes with intervention</td>
<td>Takes 5-10 min&lt;br&gt;Ceiling effects as the standard 12-scale exam&lt;br&gt;Prospective</td>
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<td>4-meter walk</td>
<td>Well-validated in older populations&lt;br&gt;Quick&lt;br&gt;Does not require equipment&lt;br&gt;Continuous outcome</td>
<td>Requires some training to standardize across sites; space&lt;br&gt;Prospective</td>
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<td>Chair rise time</td>
<td>Easy/fast&lt;br&gt;Only requires chair&lt;br&gt;Continuous outcome&lt;br&gt;Less of a ceiling effect&lt;br&gt;Greatest impairment in HIV&lt;br&gt;Changes with intervention</td>
<td>Patients with severe knee problems may be unable to complete&lt;br&gt;Prospective</td>
</tr>
<tr>
<td>Grip strength</td>
<td>Associated with increased mortality</td>
<td>Requires dynamometer with calibration&lt;br&gt;Impacted by arthritis</td>
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<td>400-meter or 6-minute walk</td>
<td>Higher level&lt;br&gt;Less of a ceiling effect&lt;br&gt;Continuous outcome&lt;br&gt;Identifies more subtle impairments</td>
<td>Takes more time&lt;br&gt;Requires more space</td>
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<tr>
<td>Questionnaires</td>
<td>Easy to standardize&lt;br&gt;Can be done in waiting room or by mail&lt;br&gt;Might be more appropriate as a brief screen</td>
<td>Subjective&lt;br&gt;May not be amenable to interventions</td>
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Functional limitations and frailty can provide a window into patient vulnerability and can be used to guide clinical decisions. Interventions for frailty should ideally focus on early impairments before an individual becomes frail. Overall, physical activity is safe and effective in improving physical function, and counseling about physical activity should be a routine component of HIV care. There are some promising pharmaceutical options, but more research is needed to determine the safety and long-term efficacy.

Presented by Dr Erlandson in July 2020. First draft prepared from transcripts by Rachel Lastra. Reviewed and updated by Dr Erlandson in January 2021.

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Summary

Functional limitations and frailty can provide a window into patient vulnerability and can be used to guide clinical decisions. Interventions for frailty should ideally focus on early impairments before an individual becomes frail. Overall, physical activity is safe and effective in improving physical function, and counseling about physical activity should be a routine component of HIV care. There are some promising pharmaceutical options, but more research is needed to determine the safety and long-term efficacy.

References


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Perspective

Management and Prevention of HIV Among Transgender Adults

Transgender individuals face discrimination, violence, social exclusion, and other social, political, and economic factors that result in increased vulnerability to HIV. Rates of viral suppression and uptake of preexposure prophylaxis are lower among transgender individuals than the general population. HIV clinics can help improve these rates by promoting inclusivity and tailoring care to the specific needs of transgender patients. This article summarizes an International Antiviral Society–USA (IAS-USA) webinar presented by Asa E. Radix, MD, PhD, MPH, on August 18, 2020. This webinar is available on demand at https://www.iasusa.org/courses/on-demand-webinar-2020-radix/.

Keywords: hormones, gender-affirming hormone therapy, transgender healthcare, preexposure prophylaxis, PrEP, antiretroviral therapy, ART, HIV, transgender, gender diverse

When discussing health-related issues in the transgender population, it is important to be aware of the difference between the terms sex and gender. Sex refers to the biologic and physiologic characteristics that differentiate between males and females and is assigned at birth based on anatomy. Gender refers to an individual’s sense of identity as male, female, or something else on the spectrum (eg, nonbinary, genderqueer, gender diverse, gender nonconforming).

Language around gender identity is evolving, and it is crucial that health care practitioners stay educated about current terminology, which may differ culturally and geographically. Herein, the term transgender refers to individuals whose gender identity is different from their sex assigned at birth. Transgender women are those assigned male at birth but have a female or feminine gender identity, and transgender men are those assigned female at birth but have a male or masculine gender identity. The term cisgender is used to describe individuals who are not transgender (ie, whose gender identities are aligned with the sex they were assigned at birth).

An estimated 25 million adults worldwide identify as transgender. In the United States, between 1 and 1.4 million adults identify as transgender (35% of those as nonbinary), 1-3 and nearly 2% of high school students identify as transgender or nonbinary. 4,5

Discrimination and Violence

Many transgender people face discrimination. In a 2015 survey of transgender individuals in the United States, 58% reported experiencing discrimination; 46% reported experiencing sexual or physical assault; 33% reported experiencing discrimination in health care settings; 23% reported that they avoided health care because of discrimination; 15% reported being unemployed; 29% reported living in poverty; 50% reported ever being unhoused; and 50% reported experiencing rejection from their family. 6 In addition, a majority of those surveyed reported being bullied or harassed at school (K–12) because they were transgender: 54% were verbally harassed; 24% were physically attacked; 13% were sexually assaulted; and 17% dropped out of school as a result of severe mistreatment. 6

In 2019, 27 transgender women were reported murdered in the United States. 7 In 2020, as of August, 28 transgender women had been reported murdered in the United States. 8

Vulnerability to HIV

Transgender-specific vulnerabilities to HIV are often rooted in transphobia or in negative attitudes and beliefs about transgender people that lead to discrimination. Some of the structural, interpersonal, biologic, and individual factors that increase vulnerability to HIV for transgender individuals are shown in the Table. These factors include high rates of violence and victimization, as well as high prevalence of depression, suicidality, and substance use. Transgender individuals have high rates of sex work, which is often a result of exclusion from the workforce. Mistreatment and discrimination in health care settings can lead transgender individuals to avoid medical care, resulting in missed opportunities for HIV testing, lack of access to HIV prevention services, reduced diagnosis of and treatment for sexually transmitted infections.

Table. Factors That Increase Vulnerability to HIV for Transgender Individuals

<table>
<thead>
<tr>
<th>Structural and Interpersonal</th>
<th>Biologic</th>
<th>Individual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social exclusion (eg, housing, employment)</td>
<td>Effects of testosterone (eg, atrophic vaginitis)</td>
<td>Inconsistent condom use</td>
</tr>
<tr>
<td>Legal status</td>
<td>Effects of estrogen on tissue receptors</td>
<td>Substance use</td>
</tr>
<tr>
<td>Mistreated or denied care in health care settings</td>
<td>Sexually transmitted infections</td>
<td>Low self-efficacy</td>
</tr>
<tr>
<td>Poor access to prevention information</td>
<td></td>
<td>Sex work</td>
</tr>
<tr>
<td>Economic vulnerability</td>
<td></td>
<td>HIV prevention is a low priority</td>
</tr>
<tr>
<td>Violence and victimization</td>
<td></td>
<td>Mood disorders</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suicidality</td>
</tr>
</tbody>
</table>

Dr Radix is Clinical Associate Professor of Medicine at New York University School of Medicine in New York, New York.
infections (STIs), lack of engagement in care, and poor medication adherence.

Data on global HIV prevalence among transgender individuals are limited, largely because transgender women are often placed in the same category as men who have sex with men, especially in low- and middle-income countries. In a 2013 meta-analysis that examined 15 countries, the estimated global prevalence of HIV among transgender women was 19%, and transgender adults were 49 times more likely to have HIV than all adults of reproductive age. In the United States, HIV prevalence is estimated to be 0.39%. HIV prevalence is several times higher among transgender women (14.1%) and transgender men (3.2%).

According to the Centers for Disease Control and Prevention 2018 HIV Surveillance Report, 9,959 transgender women and 403 transgender men are living with HIV in the United States, with more than two-thirds being African American or Latinx (Figures 1 and 2). Overall, new diagnoses of HIV in transgender people increased between 2014 and 2018.

**Antiretroviral Therapy and Viral Suppression**

When people are diagnosed with HIV, it is crucial that they are engaged in care and initiated on antiretroviral therapy (ART) as early as possible. Rates of viral suppression are lower among transgender individuals than the general population for a variety of reasons: prioritization of transition-related medical care over HIV care, fears about drug interactions between hormones and HIV, low adherence to antiretroviral medications, negative experiences with care practitioners and health systems, fear of discrimination, stigma, mental health issues, substance use, and unstable housing. Data from the Ryan White HIV/AIDS Program from 2018 show an overall rate of viral suppression among transgender individuals of 81.8%, approximately 5% lower than all individuals living with HIV. Rates are lower in younger transgender individuals; 67.8% among those aged 20 to 24 years and 72.7% among those aged 25 to 29 years. Rates are also lower among those in temporary or unstable housing (74.1% and 68%, respectively).

Studies from the Program Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color, funded by Health Resources and Services Administration (HRSA) between 2012 and 2017, investigated ways to improve the HIV care continuum for transgender women. Interventions found to improve HIV outcomes included integrating HIV care with hormone therapy, peer health navigation, and contingency management (eg, a cash incentive for keeping appointments or achieving viral suppression). Additional studies of such interventions are underway.

**Interactions Between ART and Gender-Affirming Hormone Therapies**

A concern often raised is the possibility of drug-drug interactions between ART and gender-affirming hormone therapy, especially regimens containing estrogen. The first step in the metabolism of estrogen is hydroxylation in the liver by cytochrome P450 enzymes. Some hormone levels may be elevated or lowered, depending on the components of the ART regimen.

Although there are no data that specifically examine interactions between hormones used by transgender people and ART, recommendations regarding

![Figure 1. Transgender women diagnosed with HIV in the United States, by age, in 2018. Adapted from Dailey et al.](image1)

![Figure 2. Transgender people living with HIV in the United States, by race and ethnicity, in 2018. Adapted from Dailey et al.](image2)
potential interactions have been extrapolated from research on oral contraceptive medications containing ethinylestradiol. The antiretroviral drug classes with the least potential for interactions with gender-affirming hormone therapy are unboosted integrase strand transfer inhibitors and nonnucleoside reverse transcriptase inhibitors. ART regimens containing cobicistat-boosted elvitegravir or cobicistat- or ritonavir-boosted protease inhibitors may increase levels of testosterone and estradiol. ART regimens containing ritonavir-boosted protease inhibitors, efavirenz, etravirine or nevirapine, may decrease levels of estradiol, testosterone, and finasteride.

**PrEP Efficacy in Transgender Individuals**

HIV preexposure prophylaxis (PrEP) was first approved by US Food and Drug Administration for use based on results of the iPrEx (Preexposure Prophylaxis Initiative) study, which reported 29 transgender women in the study population (approximately 1% of participants). A later subanalysis identified additional transgender women in the study population, including people who did not identify as transgender but were taking estrogen, which increased the number of transgender women included to approximately 359 (14% of participants). Among transgender women in the study, PrEP initially appeared to be ineffective as the number of seroconversions was the same among people who were or were not taking PrEP (hazard ratio, 1.1). However, further examination of the data revealed that transgender women had extremely low adherence to PrEP. Among those assigned to PrEP who seroconverted, most had no detectable levels of PrEP drugs in their blood; among those who had levels consistent with taking more than 4 pills per week, no seroconversions were noted. Subsequent analyses have shown baseline characteristics that may explain differences in PrEP efficacy between transgender women and cisgender men who have sex with men.

The iFACT (Interaction between the use of feminizing hormone therapy and Antiretroviral agents Concomitantly among Transgender Women) Study, conducted in Thailand, examined interactions between PrEP and feminizing hormones among 20 transgender women. The investigators found that estrogen levels were not affected by PrEP but that tenofovir exposure was reduced by approximately 12% in the presence of feminizing hormones. In a small study of PrEP in North Carolina, in 4 transgender women taking feminizing hormones, 4 cisgender men, and 4 cisgender women, concentrations of tenofovir in blood and in rectal tissue were similar, although there were lower ratios of tenofovir diphosphate and deoxyadenosine-triphosphate in rectal tissue of transgender participants. The clinical significance of these data are unclear, considering the small sample sizes; however, they did show that estrogen levels do not change with PrEP use.

The iBrEATHe (Interactions Between Truvada and Hormone Therapy) study, a pharmacokinetic substudy of the Triumph Project (a PrEP demonstration project in transgender populations), investigated drug-drug interactions between PrEP and estradiol in transgender women and testosterone in transgender men. The study included 24 transgender men and 24 transgender women who were taking testosterone and estradiol, respectively. Participants received daily PrEP for 4 weeks, directly observed by video or in person. Investigators measured the participants’ serum hormone levels and tenofovir diphosphate levels weekly for 4 weeks and found that serum hormone levels were not affected by oral PrEP.

**The PrEP Care Continuum**

Data on the PrEP care continuum for transgender people are limited. The multisite LITE (Leading Innovation for Transgender Women’s Health and Empowerment) study, examined PrEP uptake among 1,100 transgender women without HIV across 6 US cities. Participants received baseline HIV and STI tests and then ongoing testing every 3 months. Of participants who were sexually active, 82% had heard of PrEP but only 22% had ever taken it, only 13% had taken PrEP in the last month, and only 9% had been adherent to PrEP in the last week. In a US study that enrolled 1,808 transgender men 24.3% met 1 or more criterion for PrEP eligibility, but only 34% of those had received information on PrEP from their care practitioner and only 11% were taking PrEP.

Many transgender individuals meet criteria for PrEP use, but only approximately 9% to 10% of those individuals take it. Several studies have examined key barriers to PrEP uptake in this population, including lack of knowledge about PrEP, mistrust of medical practitioners and researchers, concerns about interactions between PrEP medications and hormone therapy, low perceived HIV risk, HIV stigma, and lack of transgender-inclusive marketing. Facilitating PrEP uptake among transgender individuals requires implementing transgender-competent services, such as prescribing hormones in the HIV clinic, providing educational and promotional materials about PrEP, and ensuring that clinicians are recommending PrEP whenever appropriate and advising about the lack of interactions between PrEP and gender-affirming hormones. Because many transgender individuals are underinsured or uninsured, linking them to insurance or to medication assistance programs is also important.

**Inclusivity in the HIV Clinic**

To help engage and retain transgender individuals in care, the clinic environment should be made as inclusive as possible. Having a 2-step question on clinic intake forms that asks 1) current gender identity and 2) sex assigned at birth ensures that a patient’s gender identity is known and provides the physician with information to provide appropriate preventive care. Clinic staff should take special care to use an individual’s chosen name and pronouns consistently. Staff should also avoid using gendered titles (eg, Mr, ma’am) until they have verified a pa-
Gender affirmation refers to the process of being recognized and supported in one’s gender identity and expression, and may include social, legal, and psychological components, as well as medical interventions such as hormones and surgeries. Some individuals may change their name and pronouns and nothing else, or they may take hormones and decide against surgery, or vice versa. Medical care for a transgender individual should be individualized based on their goals, which may or may not include medical intervention.

Individualized Care

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Features of Quality Care for Transgender Individuals

- Gender identity determined by the patient and not via laboratory or psychometric tests
- Primary care practitioners and HIV specialists able to prescribe and monitor hormones
- Care provider and clinic staff knowledgeable about:
  - Diverse gender identities
  - Hormone regimens and guidelines
  - Preventive care after medical or surgical interventions
  - Surgeries and postoperative management

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of color living with HIV. *AIDS Behav*. 2019; [published online ahead of print, 2019 May 29]


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CDC Bio: cdc.gov/about/leadership/director.htm

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