

COVID-19 vaccination in adults living with HIV

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ABSTRACT

The Centers for Disease Control and Prevention has recommended use of vaccines manufactured by Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen to prevent COVID-19 infection in the United States. Although these vaccines are safe and have been administered to millions of persons nationwide, special populations warrant closer focus. Adults living with HIV may have specific clinical considerations that should be acknowledged when making COVID-19 vaccination prescribing decisions. This article discusses these practice considerations and provides clinical and additional guidance for nurse practitioners and other clinicians responsible for prescribing COVID-19 vaccines in adults living with HIV.

Keywords: AIDS; COVID-19; HIV; infectious diseases; vaccine; vaccine-preventable diseases.

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Introduction

By mid-June of 2021, 312 million COVID-19 vaccinations were administered within the United States. In addition, approximately 44% of the entire U.S. population had been fully vaccinated (Global Change Data Lab, 2021). Globally, nearly 21% of the world's population had received at least one dose of a COVID-19 vaccination, with 33.2 million doses of COVID-19 vaccine administered daily (Global Change Data Lab, 2021).

Although newer vaccines are under development and entering global markets rapidly, in late May 2021, the Centers for Disease Control and Prevention (CDC) recommended use of vaccines manufactured by Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen to prevent COVID-19 infection in the United States (CDC 2021b, 2021d, 2021f, 2021g). These vaccines were initially endorsed by the US Food and Drug Administration (FDA) (2021) under emergency use authorization (EUA). However, the Pfizer-BioNTech vaccine received full approval

by the FDA in late August of 2021 (American Association of Nurse Practitioners, 2021). Administration schedules and number of injections required to achieve full immunity vary among these vaccines; the Pfizer-BioNTech vaccine is also indicated for use in those aged 12 years and older (**Table 1**). The CDC recommends administration of a third dose of an messenger RNA (mRNA) vaccine 28 days after administration of the second dose of an mRNA vaccine for immunocompromised persons, including those with advanced/untreated HIV/AIDS (Mayo Clinic, 2021).

Although mRNA technology is used to invoke immunity with the Pfizer-BioNTech and Moderna vaccines, viral vector technology is used in the Johnson & Johnson/Janssen vaccine (CDC, 2021a). The three vaccines are deemed safe and highly efficacious at preventing COVID-19 infection. In addition, the recommendation for selecting either one of the available vaccines in clinical practice is the same (CDC, 2021b). The most common adverse events reported from all COVID-19 vaccines include pain, erythema, and edema at the injection site in addition to fatigue, headache, myalgias, chills, fever, and nausea (CDC, 2021h).

The CDC has provided additional data underscoring the importance of vaccination against COVID-19 in persons with underlying medical conditions (**Table 2**), including weakened immune systems, autoimmune conditions, Guillain-Barré syndrome, idiopathic facial paralysis (Bell palsy), and infection with the HIV (cf. CDC, 2021a). This article will examine safety and efficacy, and illustrate other clinical considerations related to COVID-19 vaccination specifically in adults living with HIV (ALWH).

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Table 1. COVID-19 vaccines: age indications, dosing, and immunity considerations (CDC, 2021a)

Manufacturer	Vaccine Platform	Age Indication (years)	Dose(s) and Interval	Time to Achieve Full Immunity
Johnson & Johnson/ Janssen	Viral vector	≥18	1 injection	14 d after injection
Moderna	mRNA	≥18	2 injections, 28 d apart	14 d after second injection ^a
Pfizer-BioNTech	mRNA	≥12	2 injections, 21 d apart	14 d after second injection ^a

^aCDC recommends administration of a third dose of an mRNA vaccine 28 days after administration of the second dose of an mRNA vaccine for immunocompromised persons, including those with advanced/untreated HIV/AIDS (Mayo Clinic, 2021).
d, days; mRNA, messenger RNA.

COVID-19 infection in adults living with HIV

Because COVID-19 is a novel coronavirus disease, there are limited data examining specific risk factors and determining those at higher risk for developing COVID-19 (CDC, 2021a). It is unknown as to whether ALWH are at higher risk for developing COVID-19 compared with adults not infected with HIV (National Institutes of Health [NIH], Office of AIDS Research, 2021a). However, some data have shown poorer outcomes for ALWH acutely coinfecting with SARS-CoV-2 (Geretti et al., 2020; Bhaskaran, et al., 2020; Boule, et al, 2020; Dandachi et al., 2020; Hoffman et al., 2020; Boerner, 2021; Tesoriero, et al., 2021).

Low CD4 cell counts (<200 cells/mm³), regardless of virologic suppression of HIV, have been associated with greater likelihood of developing the severe forms of COVID-19, characterized by intensive care unit (ICU) admission, need for mechanical ventilation, and death (CDC, 2021f; Hoffman et al., 2020). Many ALWH have comorbidities that contribute to their risk for severe COVID-19 illness (National Institutes of Health [NIH], Office of AIDS Research, 2021a). This emphasizes the importance of COVID-19 vaccination in ALWH.

Clinical vignettes

Case 1

Apolinar (all pronouns) is a 32-year-old, bisexual, unmarried, Hispanic, cisgender man who was diagnosed with HIV infection in December 2019. Within the first hours of diagnosis, he was linked to counseling and treatment with daily oral bicitegravir 50 mg, emtricitabine 200 mg, and tenofovir alafenamide 25 mg after confirming he was negative for hepatitis B. Follow-up appointments showed he achieved viral suppression within the first 3 months of treatment, and his liver function tests remained within expected laboratory parameters. In March 2020, when COVID-19 started, his blood pressure was 132/89 mmHg and he was prescribed lifestyle changes and non-pharmacological interventions focusing on weight loss and limiting sodium intake. In June 2020, when the COVID-

19 outbreak in his city warranted curfew orders, his employer deemed him an essential worker and kept him in person for 75% of his time until vaccines were available. During his July 2021 follow-up, his blood pressure was found at 137/83 mmHg and he was prescribed daily oral captopril 25 mg. He qualifies for early vaccination as an essential worker and his employer is encouraging him to get vaccinated. He comes for his antiretroviral yearly prescription and to check his blood pressure and brings up his doubts about getting vaccinated. How should the nurse practitioner (NP) approach Apolinar's case?

Nurse practitioner's approach to the clinical vignette

Case 1

Key elements in Apolinar's clinical history are risk factors (HIV infection and hypertension) and protective factors (employed, undetectable viral load, normal liver function, and documented compliance with pharmacological and nonpharmacological therapies). Per the CDC recommendations above, he is eligible for any of the three vaccines. It is fundamental for his NP to discuss the increased risk for severe COVID-19 disease and death without vaccination, especially given that he belongs to two risk categories (HIV infection and hypertension).

Case 2

Brittany (she, her) is a 19-year-old, heterosexual, unmarried, White, cisgender female community-college student diagnosed with HIV infection at age 15 years, when she faced sexual abuse at home and was placed in foster care. She has a personal history of heroin use disorder, currently in remission, and has engaged in transactional sex during the past year when she was furloughed from her full-time job during the first wave of COVID-19. Brittany now works 10 hours per week at her community college, which she finds stressful and copes by smoking two packs of cigarettes per week. She takes daily oral dolutegravir 50 mg and lamivudine 300 mg, with

Table 2. Medical conditions associated with severe illness^a from COVID-19 infection (CDC, 2021e)

Cancer
Chronic kidney disease
Chronic lung disease
Asthma
Cystic fibrosis
Chronic obstructive pulmonary disease (COPD)
Interstitial lung disease
Pulmonary hypertension
Dementia/neurological conditions
Diabetes (type 1 or type 2)
Down syndrome (trisomy 21)
Heart conditions
Heart failure
Cardiomyopathies
Coronary artery disease
Hypertension
HIV infection
Increased body mass index (BMI)
Overweight (BMI >25 kg/m ² but <30 kg/m ²)
Obesity (BMI >30 kg/m ² but <40 kg/m ²)
Severe obesity (BMI >40 kg/m ²)
Immunocompromised states
Acquired immunodeficiency
Adverse event from medications
Primary immunodeficiency
Prolonged corticosteroid use
Liver disease
Alcohol-related liver disease
Chronic liver disease
Cirrhosis
Nonalcoholic fatty liver disease
Pregnancy
Sickle cell disease or thalassemia
Smoking, current or former
Solid organ or blood stem cell transplant
Stroke or cerebrovascular disease
Substance use disorders

Table 2. Medical conditions associated with severe illness^a from COVID-19 infection (CDC, 2021e), continued

Alcohol abuse
Cocaine abuse
Opioid abuse
^a Requiring hospitalization, intensive care services, mechanical ventilation, or leading to death.

moderate compliance. Today's laboratory parameters show a CD4 count of 575 cells/mL (down from 1,302 cells/mL 3 months ago) and a viral load of 475 copies/mL (up from undetectable 3 months ago). Although she is eligible for vaccination at several federal, state, and local vaccination sites, she is concerned receiving the vaccine may affect her reproductive capacity and her response to antiretroviral treatment and wants to discuss her choices with you. What should be the NP's key talking points for Brittany?

Nurse practitioner's approach to the clinical vignette

Case 2

Elements worth stressing in Brittany's clinical history are various risk factors (current smoker, sexual abuse, sex work, heroin use disorder, HIV infection, moderate anti-retroviral therapy compliance, and worsening CD4 and viral load) and very few protective factors (young, employed, attends community college). Per the CDC recommendations discussed, she is eligible for any of the three vaccines currently being used in the United States. It is important to dispel myths about vaccines with her and address her hesitancy, given that there is no evidence that any of the vaccines on the market can compromise fertility. Although vaccines seem to be more effective in ALWH who have achieved undetectable viral loads with normal CD4 levels, the immune response in Brittany's case may be decreased, as evidenced by her most recent laboratory results. Thus, besides recommending the vaccine, her NP should emphasize adherence to antiretroviral therapy and the use of barrier methods if she engages in sex work again. Her barriers to health care must also be addressed, given her new employment status.

COVID-19 vaccination considerations in adults living with HIV

Although ALWH were included in the clinical trials of the COVID-19 vaccines, safety and efficacy in these persons have yet to be fully reported (CDC, 2021i; NIH Office of AIDS Research, 2021b). Current recommendations indicate that

all ALWH should receive the COVID-19 vaccination, regardless of CD4 count or viral load (CDC, 2021i; NIH Office of AIDS Research, 2021b). This clinical guidance comes with a strong evidence-based AIII recommendation (NIH Office of AIDS Research, 2021a) and was derived from clinical trial data suggesting that the benefits afforded by COVID-19 vaccination in ALWH outweigh the risks associated with receiving a vaccine (NIH Office of AIDS Research, 2021b).

NPs and other prescribers should refrain from prescribing COVID-19 vaccination in ALWH with a history of severe allergic reaction to the vaccines' ingredients (CDC, 2021i). None of the COVID-19 vaccines contain eggs, latex, gelatin, or preservatives (CDC, 2021c). They also do not contain metals (CDC, 2021c). Because the Pfizer-BioNTech and Moderna vaccines contain polyethylene glycol, hypersensitivity with polysorbates (found in some vaccines and other pharmacologic agents) is possible (CDC, 2021c). A complete list of the active and inactive ingredients found in the current three vaccines can be found in Appendix C of the CDC's *Interim Clinical Considerations for use of COVID-19 Vaccines Currently Authorized in the United States* (2021c).

Adults living with HIV who are well-controlled on antiretroviral regimens respond well to COVID-19 vaccines (NIH Office of AIDS Research, 2021b). In addition, administration of antiviral drugs at any time before or after administration of any of the current vaccines does not inhibit development of a protective antibody response (CDC, 2021c). Also, no pharmacological interactions have been reported between COVID-19 vaccines and antiretroviral medications (World Health Organization [WHO], 2021).

Data do suggest, however, that CD4 count could be an important principle regarding COVID-19 vaccine efficacy in ALWH. Ruddy et al found anti-SARS-CoV-2 receptor-binding domain antibodies were detectable in all participants in their small sample ($n = 12$) of ALWH administered the first dose of an mRNA vaccine (2021). However, those who had lower CD4 counts (<200 cells/ mm^3) had fewer antibodies (Ruddy et al, 2021). Although more research data are needed (WHO, 2021), this could suggest the need for continued emphasis on handwashing, social distancing, and appropriate use of face coverings for these persons, even after full COVID-19 vaccination. Clinicians should also be mindful of the unique vaccine schedules for ALWH, which vary depending on CD4 counts ≥ 200 or <200 cells/ mm^3 (Blackwell, 2016). This is because administration of any other vaccine within 2 weeks of COVID-19 vaccination is not recommended (NIH Office of AIDS Research, 2021a). Pregnant or lactating individuals with HIV who otherwise meet eligibility for COVID-19 vaccination should not be restricted from their access (NIH Office of AIDS Research, 2021a).

Ruddy et al. (2021) found ALWH vaccinated with an mRNA COVID-19 vaccine had a similar incidence of adverse events compared with vaccinated adults not infected with HIV. These included mild or moderate pain at the injection site ($n = 12$; 100%), mild or moderate fatigue ($n = 6$; 50%), and myalgia ($n = 5$; 42%). Post-vaccination, none of the participants became infected with SARS-CoV-2 or developed any other acute infections, experienced anaphylaxis or severe reactions affecting activities of daily living, or developed neurological sequelae (Ruddy et al., 2021).

Vaccines against COVID-19 are recently developed agents, and data regarding adverse events from their administration in ALWH are needed. Consequently, nurse practitioners, physicians, and physician associates prescribing, administering, or monitoring COVID-19 vaccinations in ALWH should be familiar with the mechanisms in place for reporting adverse events through the Vaccine Adverse Events Reporting System (VAERS). Administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death are mandated reporting events (CDC, 2021c, CDC, 2021j, and <https://vaers.hhs.gov>).

The role of the nurse practitioner

ALWH make up a vulnerable population possessing multiple psychosocial factors that affect their health outcomes (Triant & Ghandi, 2021). Societal inequalities, including poverty and access to timely and equitable care, are vital considerations for nurse practitioners and other clinicians to contemplate when navigating ALWH through the health care system (Triant & Ghandi, 2021; WHO, 2021). Advocacy for inclusion of ALWH in future COVID-19 vaccination trials is important, and those trials must include adequate sampling of those with advanced HIV disease as well (WHO, 2021).

Another substantial hurdle that must be confronted is vaccine hesitancy. Although vaccine hesitancy in the general U.S. population has declined over the course of the pandemic (Dreisbach, 2021), ALWH who are cognizant of the history of the AIDS epidemic may present with unique historical contexts that may affect their choice to receive COVID-19 vaccination (Eyal & Halkitis, 2020). Vaccine hesitancy may be of particular concern among African American ALWH (Bogart et al., 2021). Systemic racism has contributed to engrained community mistrust in medical treatment by many African American ALWH; this may have a bearing on their willingness to receive COVID-19 vaccination (Bogart et al., 2021).

Bogart and partners found at least one COVID-19 mistrust belief among their sample of African American men living with HIV ($n = 101$); half of these men expressed at least one COVID-19 vaccine or treatment hesitancy belief (Bogart et al., 2021). In addition, as their COVID-19 mistrust beliefs increased, so did their vaccine and

Table 3. Clinical considerations of COVID-19 vaccination in ALWH

<ul style="list-style-type: none"> • ALWH could be at higher risk for morbidity and mortality from COVID-19 infection.
<ul style="list-style-type: none"> • All three vaccines currently in use in the United States are clinically appropriate in ALWH.
<ul style="list-style-type: none"> • Administration of the COVID-19 vaccines in ALWH is recommended regardless of current CD4 count. However, immunocompromised persons, including those with advanced/untreated HIV/AIDS who received an mRNA vaccine, should receive a third dose of the mRNA vaccine 28 days after administration of the second dose.
<ul style="list-style-type: none"> • Clinicians should consider the unique vaccine schedules for ALWH, including those with CD4 counts ≥ 200 cells/mm³ and those with count < 200 cells/mm³ (see) and space administration of other vaccines at least 2 weeks pre- or post-COVID-19 vaccination administration.
<ul style="list-style-type: none"> • COVID-19 vaccines do not interact with antiretroviral therapeutic (ART) medications and should be administered without consideration of ART regimens.
<ul style="list-style-type: none"> • Common adverse events (pain, erythema, and edema at the injection site in addition to fatigue, headache, myalgias, chills, fever, and nausea) are statistically similar in ALWH and non-HIV-infected samples (see).
<ul style="list-style-type: none"> • Reporting of major adverse events post-COVID-19 vaccine administration is essential.
Administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death are mandated reporting events.
See CDC, 2021c, CDC, 2021j, and https://vaers.hhs.gov for guidance on reporting of mandated reporting events.
<ul style="list-style-type: none"> • NPs and other clinicians should serve as advocates for ALWH by working to ensure their inclusion in ongoing COVID-19 clinical trials and by addressing vaccine hesitancy in ALWH through education.

treatment hesitancy. However, this study also revealed that social service and health care providers were identified as the men's most trusted sources (Bogart et al., 2021). This highlights the potentially sacred role NPs, social workers, and other health care professionals can have when working with this vulnerable population.

As trusted health care collaborators, NPs and other clinicians can educate African American ALWH about COVID-19 disease processes, potential ways in which their HIV infection can affect an acute infection with SARS-CoV-2 (and vice versa), and the importance of vaccination as a means of COVID-19 prevention. Although these strategies are borne from research on African American men living with HIV, they can perhaps be extrapolated across the spectrum of ALWH of all ethnicities and backgrounds.

Conclusion

Widespread uptake of vaccination is seen as the most important mechanism in ending the COVID-19 pandemic. Although the current vaccines being used in the United States for COVID-19 are safe and highly efficacious at preventing COVID-19 infection, their use in ALWH warrants particular attention (**Table 3**). Because data exist that strongly suggest ALWH are at higher risk for severe COVID-19 illness, emphasis on safe utilization of COVID-19 vaccines in this population is paramount.

NPs and other health care providers must be familiar with the limited research regarding COVID-19 vaccination in ALWH. They should also be aware of the clinical guidance regarding safe COVID-19 vaccination in this population, the incidence of common adverse events, and how to report adverse events to help contribute to a greater knowledge about the potential unique interplays between HIV infection and COVID-19 vaccination. Samples recruited for future clinical trials evaluating safety and efficacy of COVID-19 vaccines must continue to include ALWH. They should also be expanded to include children and adolescents living with HIV and those with advanced disease.

Finally, NPs and other health care providers must acknowledge their responsibility of serving as advocates for this vulnerable population. Through education and work toward the elimination of social inequities, NPs and other clinicians can help eliminate the disparities in ALWH that disproportionately affect their access to care and influence their overall health outcomes.

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