Guidance for COVID-19 and People with HIV

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Reviewed

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This guidance reviews special considerations regarding COVID-19 for people with HIV and their health care providers in the United States. Information and data on COVID-19 are rapidly evolving. Clinicians should refer to updated sources for more specific recommendations regarding prevention, diagnosis, and treatment of COVID-19, including the NIH COVID-19 Treatment Guidelines, which has a section on Special Considerations in People with HIV.

Whether people with HIV are at greater risk of acquiring SARS-CoV-2 infection is currently unknown. Data on the clinical course of COVID-19 in people with HIV are emerging. In the initial case series from Europe and the United States, no significant differences in clinical outcomes were found between people with HIV who developed COVID-19 and individuals without HIV.[1-10] For example, data from the Veterans Aging Cohort Study compared outcomes in 253 mostly male participants with HIV and COVID-19 who were matched with 504 participants with only COVID-19.[10] In this comparison, no difference emerged in COVID 19 related hospitalization, intensive care unit (ICU) admission, intubation, or death between patients with or without HIV. In contrast, worse outcomes, including increased COVID 19 mortality rates, in people with HIV have been reported in other cohort studies from the United States, the United Kingdom, and South Africa.[11-16] In a multicenter cohort study of 286 patients with HIV and COVID-19 in the United States, lower CD4 count (i.e., <200 cells/mm^3), despite virologic suppression, was associated with a higher risk for the composite endpoint of ICU admission, mechanical ventilation, or death.[14] In another study of 175 patients with HIV and COVID-19,

a low CD4 count or CD4 nadir was associated with poor outcomes.[15] In a cohort study in New York, people with HIV had higher rates of hospitalization and mortality with COVID-19 compared with people without HIV.[16]

In the general population, individuals who are at highest risk of severe COVID-19 include those older than 60; those who are pregnant; and those with comorbidities, such as obesity, diabetes mellitus, cardiovascular disease, pulmonary disease, smoking history, sickle cell disease—as well as solid organ transplant recipients.[17] Many people with HIV have one or more comorbidities that may put them at increased risk for a more severe course of COVID-19. Both COVID-19 and HIV disproportionately affect communities of color. Based on the available literature, close monitoring is warranted for all people with HIV and SARS-CoV-2 infection, especially those with advanced HIV or with comorbidities.

Guidance for all Persons with HIV

- People with HIV should follow all applicable recommendations of the U.S. Centers for Disease Control and Prevention (CDC) to prevent acquisition of SARS-CoV-2, such as practicing social or physical distancing, wearing masks consistently, avoiding crowded areas, and using proper hand hygiene **(AIII)**.
- People with HIV should receive SARS-CoV-2 vaccines, regardless of CD4 or viral load, because the potential benefits outweigh potential risks **(AIII)**.
    - Based on recent literature to date, people with HIV appear to be at increased risk for severe outcomes with COVID-19 compared with people without HIV and should be included in the category of high-risk medical conditions when developing vaccine priority **(AIII).**
    - People with HIV were included in clinical trials of the two mRNA vaccines; at this time, the safety and efficacy in this specific subgroup have not been fully reported.[18,19] People with HIV who are well controlled on antiretroviral therapy (ART) typically respond well to licensed vaccines. Guidance for these vaccines, including for people with HIV, is available through the Advisory Committee on Immunization Practices (ACIP) and from the Infectious Diseases Society of America. Confidentiality about

their underlying condition should be preserved when administering vaccines to people with HIV.

- Current recommendations of the ACIP, the American College of Obstetricians and Gynecologists (ACOG), and the Society of Maternal Fetal Medicine (SMFM) state that pregnant and lactating people who otherwise meet criteria for vaccination should not be restricted from vaccine access. The CDC also provides information about vaccine considerations for people who are pregnant or breastfeeding.
- Influenza and pneumococcal vaccinations should be kept up-to-date, with attention to timing because receipt of other vaccines is not recommended within 2 weeks of COVID-19 vaccination **(AIII)**.
- People with HIV who have COVID-19 should be clinically managed in the same way as people in the general population with COVID-19, including when making medical care triage determinations **(AIII)**.

Antiretroviral Therapy

- Health care providers should make every effort to ensure that people with HIV maintain an adequate supply of ART and all other concomitant medications **(AIII)**.
- People with HIV should talk to their pharmacists and/or health care providers about exploring options for alternative delivery, such as changing to mail-order delivery of medications, when possible.
- People with HIV for whom a regimen switch is planned for reasons other than toxicities or virologic failure should consider delaying the switch until close follow-up and monitoring are possible **(AIII)**.
- Many drugs, including some antiretroviral (ARV) agents (e.g., lopinavir/ritonavir, boosted darunavir, tenofovir disoproxil fumarate/emtricitabine), have been or are being evaluated in clinical trials or are being prescribed for off-label use to treat or prevent COVID-19. At this time, no ARV agents have been shown to be effective in these settings.[17–19] People with HIV should not switch their ARV regimens or add ARV drugs to their regimens for the purpose of preventing or treating SARS-CoV-2 infection **(AIII)**.

Clinic or Laboratory Monitoring Visits Related to HIV Care

- Together with their health care providers, people with HIV should weigh the risks and benefits of attending versus not attending in-person HIV-related clinic appointments at this time. Factors to consider include the extent of local COVID-19 transmission, the health needs that will be addressed during the appointment, their HIV status (e.g., CD4 cell count, HIV viral load), the interval since their last laboratory testing, the need for vaccinations, and their overall health.
- Telephone or virtual visits for routine or non-urgent care and adherence counseling may replace face-to-face encounters.
- For people who have a suppressed HIV viral load and are in stable health, routine medical and laboratory visits should be postponed to the extent possible.

People with HIV and in Opioid Treatment Programs

- Clinicians caring for persons with HIV who are enrolled in opioid treatment programs (OTPs) should refer to the Substance Abuse and Mental Health Service Administration (SAMHSA) website for updated guidance on avoiding treatment interruptions during the COVID-19 pandemic. State methadone agencies are also responsible for regulating OTPs in their jurisdictions and may provide additional guidance.

Guidance for People with HIV in Self-Isolation or Quarantine Due to SARS-CoV-2 Exposure

Health care workers should—

- Verify that patients have adequate supplies of all medications and expedite additional drug refills as needed.
- Devise a plan to evaluate patients if they develop COVID-19 related symptoms, including for possible transfer to a health care facility for COVID-19 related care.

People with HIV should—

- Contact their health care providers to report that they are self-isolating or in quarantine.
- Inform their health care providers about the specific amount of ARV medications and other essential medications they have on hand and arrange for delivery of refills, if needed.

Guidance for People with HIV Who Have Fever and/or Respiratory or Other Symptoms and are Seeking Evaluation and Care

Guidance for Health Care Workers

- Follow CDC recommendations, as well as state and local health department guidance on infection control, triage, diagnosis, and management.

Guidance for People with HIV

- Follow CDC recommendations regarding symptoms.
- Call their health care providers for medical advice if they develop a fever and symptoms (e.g., cough, dyspnea). New onset or worsening dyspnea warrants in-person evaluation.
- Call the clinic in advance before presenting to the care providers.
- Always use respiratory and hand hygiene and cough etiquette when presenting to the health care facility and wear a face mask.
- Alert registration staff immediately upon arrival of their symptoms, if they present to a clinic or an emergency facility without calling in advance, so that measures can be taken to prevent COVID-19 transmission in the health care setting. Specific clinic actions include placing a mask on the patient and rapidly putting the patient in a room (if available, negative-pressure) or other space separated from other people.

Guidance for Managing People with HIV Who Develop COVID-19

Guidance When Hospitalization Is Not Necessary

The person with HIV should do the following:

- Manage symptoms at home with supportive care for symptomatic relief.
- Maintain close communication with their health care provider and report if symptoms progress (e.g., sustained fever for >2 days, new shortness of breath). Patients and/or caregivers should be aware of warning signs and symptoms that warrant in-person evaluation, such as new dyspnea, chest pain/tightness, confusion, or other mental status changes.
- Continue their ARV therapy and other medications as prescribed.
- Be aware that people with HIV with additional comorbidities may be eligible for one of the anti-SARS-CoV-2 monoclonal antibodies available through Emergency Use Authorization from the FDA.[20-22]

Guidance When the Person with HIV Is Hospitalized

- ART should be continued. If the ARV drugs are not on the hospital's formulary, administer medications from the patient's home supplies.
- ARV drug substitutions **should be avoided**. If necessary, clinicians may refer to recommendations on ARV drugs that can be switched in the U.S. Department of Health and Human Services (HHS) guidelines for caring for persons with HIV in disaster areas.
- If patients receive ibalizumab (IBA) intravenous (IV) infusion every 2 weeks as part of their ARV regimen, clinicians should arrange with the patient's hospital provider to continue administration of this medication without interruption.
- If patients are taking an investigational ARV medication as part of their regimen, arrangements should be made with the investigational study team to continue the medication if possible.
- For critically ill patients who require tube feeding, some ARV medications are available in liquid formulations, and some—but not all—pills may be crushed. Clinicians should consult an HIV specialist

and/or pharmacist to assess the best way for a patient with a feeding tube to continue an effective ARV regimen. Information may be available in the drug product label or from this document from the Toronto General Hospital Immunodeficiency Clinic.

Guidance Regarding Approved, Investigational, or Off-Label Treatment for COVID-19

- Remdesivir is currently the only FDA-approved antiviral treatment for COVID-19. Dexamethasone is commonly used in the management of patients with COVID-19 who require supplemental oxygen. People with HIV who are hospitalized with COVID-19 should generally receive these drugs for the same indications as people with COVID-19 who do not have HIV coinfection.
- Several other medications are available through Emergency Use Authorizations from the FDA, such as baricitinib, convalescent plasma, bamlanivamab, bamlanivimab plus etesvimab, and casirivimab plus imdevimab. Clinicians should refer to the latest COVID-19 Treatment Guidelines for methods of managing COVID-19 based on disease severity.
- For patients with HIV receiving COVID-19 treatment, clinicians must assess the potential for drug interactions between the COVID-19 treatment and the patient's ARV therapy and other medications. Information on potential drug interactions may be found in product labels, drug interaction resources, clinical trial protocols, or investigator brochures.
- When available and if indicated, clinicians may consider enrolling patients with HIV in a clinical trial evaluating the safety and efficacy of an experimental treatment for COVID-19. Persons with HIV should not be excluded from consideration for these trials. *Clinicaltrials.gov* is a useful resource for finding studies investigating potential treatments for COVID-19.

Additional Guidance for HIV Clinicians

- Some Medicaid and Medicare programs, commercial health insurers, and AIDS Drug Assistance Programs (ADAPs) have restrictions that

prevent patients from obtaining a 90 day supply of ARV drugs and other medications. During the COVID-19 pandemic, clinicians should ask insurers/programs to waive drug-supply quantity restrictions. ADAPs also should provide patients with a 90-day supply of medications.

- People with HIV may need additional assistance with food, housing, transportation, and childcare during times of crisis and economic fragility. To enhance care engagement and continuity of ARV therapy, clinicians should make every attempt to assess their patients' need for additional social assistance and connect them with resources, including navigator services when possible.
- During this pandemic, social distancing and isolation may exacerbate mental health and substance use issues for some persons with HIV. Clinicians should assess and address these patient concerns and arrange for additional consultations, preferably virtually, as needed.
- Telehealth options, including telephone or video calls, should be considered for routine visits and to triage visits for patients who are ill.
- Reports indicate that some measures designed to control the spread of COVID-19 may increase the risk of intimate partner violence and/or child abuse, as well as limit the ability of people to distance themselves from abusers or to access external support. Providers should assess patient safety at each clinical encounter, either in-person or via telemedicine, being cognizant of the patient's ability to speak privately.
- During the COVID-19 pandemic, reproductive desires and pregnancy planning should be discussed with all people of childbearing potential. This discussion should include information on what is known and not known about COVID-19 during pregnancy. Pre-pregnancy discussions should be patient centered and should include the option to defer efforts to conceive until after the peak of the pandemic and/or more is known about the effect of COVID-19 during pregnancy. Individuals may be at increased risk of unintended pregnancy when stay-at-home measures are in effect, and continuation or initiation of appropriate contraception should be addressed, including emergency contraception. Based on clinical trial data, use of intrauterine devices and contraceptive implants beyond the expiration date specified on a

package insert may be considered.[23] Depot-medroxyprogesterone acetate also may be considered for subcutaneous self-injection.

Special Considerations for Pregnancy, HIV, and COVID-19

COVID-19 and Pregnancy

- Although data are limited, no evidence to date suggests that pregnant individuals are more susceptible to SARS-CoV-2 infection than non-pregnant individuals.
- Overall, the risk of severe COVID-19 disease or death remains relatively low in pregnant individuals when compared with non-pregnant women of reproductive age. However, studies from the United States, United Kingdom, and Sweden, as well as a meta-analysis of 77 studies, demonstrate that pregnant women with COVID-19 have an increased risk of hospitalization, intensive care admission, and mechanical ventilation compared to age-matched non-pregnant women with COVID-19. Some but not all of these studies found an increased risk of death among pregnant women with COVID-19.[24-28]
- As in the overall population, a disproportionately high rate of COVID-19 exists among pregnant women of color compared with white women and possibly an increased rate of COVID-19 severity among pregnant women of color compared to white women.[24, 27, 29, 30]
- Cohort studies have not shown an increase in fetal loss in pregnant women with COVID-19 compared to those without COVID-19.[25, 31, 32]
- Emergency cesarean delivery and preterm delivery (28–36 weeks gestation) appear to be increased in pregnant women with COVID-19 compared with those without COVID-19. Although some increase in neonatal intensive care unit admission in neonates exposed to SARS-CoV-2 has been seen, this trend is primarily due to complications of prematurity or known exposure, and most neonates do well.[25, 28, 32]
- Vertical transmission of SARS-CoV-2 from mother to infant appears to be very uncommon; neonatal infection appears in most cases to occur postnatally.[32, 33]

COVID-19, Pregnancy, and HIV

- Currently, limited data are available on pregnancy and maternal outcomes in individuals who have COVID-19 and none specific to pregnancy outcomes in individuals with COVID-19 and HIV.
- Pregnant individuals with HIV who have COVID-19 should be clinically managed in the same way as pregnant individuals without HIV who have COVID-19, including when making medical care triage determinations and decisions about vaccination and treatment. COVID-19 treatment and vaccination should not be withheld for pregnant individuals with HIV; see the joint statement by the American College of Obstetricians and Gynecologists and the Society of Maternal Fetal Medicine.
- Pregnant individuals with HIV admitted for COVID-19 should continue their ARV regimen. Clinicians should consult with an HIV expert if any changes in regimens are needed for individuals not virally suppressed.

Children with HIV

Knowledge to date about COVID-19 in children and in children with HIV can be summarized as follows:

- Minimal data exist on COVID-19 among children with HIV infection. One report from South Africa of 159 children with COVID-19 included two children with HIV.[34] Although both children with HIV were hospitalized, only one was symptomatic, and neither died. HIV infection did not seem to contribute to more severe COVID-19 illness.[35] Like the adult population, children and adolescents of color have disproportionately higher rates of COVID-19 disease and hospitalization.[36]
- Children appear less likely to become severely ill with COVID-19 than older adults.[37-39]
- Some subpopulations of children at increased risk of more severe COVID-19 illness may exist: Younger age (younger than 1), obesity, underlying pulmonary or cardiac pathology, and immunocompromising conditions are associated with more severe outcomes.[40]
- A multisystem inflammatory syndrome in children (MIS-C) presenting with hyperinflammatory shock with features of Kawasaki disease and

toxic shock syndrome has been described to be temporally associated with SARS-CoV-2 infection in the United States, United Kingdom, Europe, and South Africa, with the syndrome occurring 2 to 4 weeks or more following infection. The children have serologic evidence of infection but may not have positive nasopharyngeal RT-PCR testing.[41-43] Children can present with diverse signs and symptoms, including fever and gastrointestinal symptoms; significantly elevated markers of inflammation; and, in severe cases, myocarditis and cardiogenic shock. Children with MIS C tend to be older (mean age 8 years) than in classic Kawasaki disease (peak incidence at age 10 months).[44, 45]

- Infants and children with HIV should be current on all immunizations, including influenza and pneumococcal vaccines. Refer to the Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children information on immunizations, including a vaccine schedule for children with HIV.
- Guidance for ART management and clinic or laboratory monitoring visits related to HIV care in children with HIV during the pandemic should follow the guidance outlined above (See "Antiretroviral Therapy" and "Clinic or Laboratory Monitoring Visits Related to HIV Care" sections).

More information regarding ARV management in adult, pregnant, and pediatric patients, as well as recommendations for prophylaxis and treatment of specific opportunistic infections, can be found in the medical practice guidelines for HIV/AIDS.

The CDC website provides information about COVID-19 for people with HIV.

This interim guidance was prepared by the following working groups of the Office of AIDS Research Advisory Council:

- HHS Panel on Antiretroviral Guidelines for Adults and Adolescents
- HHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV
- HHS Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission

- HHS Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV
- HHS Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children

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