CLINICAL GUIDELINES PROGRAM
NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

Diagnosis and Management of Acute HIV Infection

NOTE: This printable guideline includes the NYSDOH AI guideline *Rapid ART Initiation.*

Updates, Authorship, and Related Guidelines

Date of current publication	July 19, 2021
Highlights of changes, additions, and updates in the July 19, 2021 edition	• Recommendations on diagnosis of acute HIV infection have been updated in the Presentation and Diagnosis section: – Clinicians can presume the diagnosis of acute HIV when high levels (>10,000 copies/mL) of HIV RNA are detected in plasma with sensitive NAT, and the result of the HIV screening or type-differentiation test is negative or indeterminate. (A2) – Clinicians should seek expert consultation when an ambiguous HIV result is obtained for an individual taking PrEP because the diagnosis of acute HIV can be particularly challenging in patients taking PrEP. (A3) – When a low-level quantitative HIV RNA viral load result (<10,000 copies/mL) is obtained in the absence of serologic evidence of HIV infection, the clinician should repeat HIV RNA testing *and* perform an Ag/Ab combination immunoassay to exclude a false-positive result. (A2) ○ Note: A serologic test result that does not meet the criteria for HIV infection is a nonreactive screening result (Ab or Ag/Ab combination) or a reactive screening result with a nonreactive or indeterminate Ab differentiation confirmatory result. • Recommendations on HIV transmission and resistance have been updated in the Management, Including While on PEP or PrEP section: – Clinicians should inform patients about the increased risk of transmitting HIV during acute infection and for the 6 months following infection in patients who do not initiate ART. (A2) – Patients taking PrEP: Because the risk of drug-resistant mutations is higher in patients who acquire HIV while taking PrEP, clinicians should consult with an experienced HIV care provider and recommend a fully active ART regimen. (A3)
Intended users	Clinicians in New York State who provide ambulatory, inpatient, and emergency medical care for adults ≥18 years old who present with signs or symptoms of acute HIV infection or report an exposure within the past 4 weeks
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Purpose of This Guideline

This guideline on diagnosis and management of acute HIV infection was developed by the Medical Care Criteria Committee of New York State Department of Health AIDS Institute (NYSDOH AI) to guide clinicians in NYS who provide ambulatory, inpatient, and emergency medical care for adults ≥18 years old who present with signs or symptoms of acute HIV infection or report an exposure within the past 4 weeks.

This guideline provides evidence-based clinical recommendations for the diagnosis and treatment of acute HIV infection in adults, with the goals of ensuring that NYS clinicians are able to:

- Recognize the risks for and signs and symptoms of acute HIV, include HIV infection in the differential diagnosis, and consider HIV testing in any person who presents with signs and symptoms suggestive of influenza ("flu"), mononucleosis ("mono"), or other viral syndromes, including suspected COVID-19.
- Perform appropriate diagnostic and confirmatory testing when HIV infection is suspected and manage the treatment of acute HIV.
- Meet the NYS requirements for reporting and partner notification.
- Recommend or offer immediate initiation of antiretroviral therapy (ART) to improve the patient's health and reduce the risk of HIV transmission; refer and confirm that patients can access optimal HIV care.
- Initiate or refer the patient for prevention services.

TERMINOLOGY

- **Acute HIV infection:** Describes the period immediately after infection with HIV when an individual is viremic and has detectable p24 antigen or has HIV RNA without diagnostic HIV antibodies. In the medical literature, "primary HIV infection" may describe this same period.
- **Recent infection:** Generally used to describe the 6-month period after infection occurs.
- **Early infection:** May refer to acute or recent infection, after which infection is defined as chronic.

Early diagnosis for early treatment: Accumulating evidence supports a decision to begin HIV treatment at the time of diagnosis [Lundgren, et al. 2015]. Initiation of ART during acute infection may have several beneficial clinical outcomes, including improved preservation of immunologic function, significantly reduced time to viral suppression, and reduction of

the viral reservoir, which could be important for cure strategies [Pilcher, et al. 2017; Margolick, et al. 2015; Phanuphak, et al. 2015; Le, et al. 2013; Saez-Cirion, et al. 2013; Ananworanich, et al. 2012; Buzon, et al. 2012; Lafeuillade, et al. 2012; Hocqueloux, et al. 2010; Koegl, et al. 2009; Streeck, et al. 2006; Pires, et al. 2004]. The risk of sexual transmission of HIV during acute or recent infection is significantly higher than during chronic infection [Hollingsworth, et al. 2015; Hollingsworth, et al. 2008; Pinkerton 2008; Pilcher, et al. 2004]; this difference likely correlates with high levels of viremia and is consistent with other routes of transmission [Bellan, et al. 2015]. The public health benefit of early ART initiation is well documented, with a significant reduction of HIV transmission among virally suppressed individuals. Further, in September 2017, the NYSDOH endorsed the consensus from the Prevention Access Campaign that undetectable = untransmissable ("U = U"), which indicates that individuals with a durable (≥6 months) undetectable viral load will not sexually transmit HIV [Prevention Access Campaign 2018; NYSDOH 2017].

Recognizing and diagnosing acute HIV infection is crucial to linking patients to care early and presents an important opportunity to reduce HIV transmission. Factors that may contribute to the increased risk for transmission during acute infection include:

- Hyperinfectivity associated with both markedly high viral load levels (often much greater than 10 million viral copies/mm^3) and increased infectiousness of the virus [Ma, et al. 2009; Quinn, et al. 2000].
- Missed HIV diagnosis [Nakao, et al. 2014; Chin, et al. 2013]. Because the nonspecific flu- or mono-like symptoms are frequently unrecognized as symptoms of acute HIV infection or attributed to a nonspecific viral syndrome, the diagnosis is often missed. Missed diagnosis of acute HIV infection results in a lost opportunity to recommend treatment and risk-reduction counseling that could reduce both viral load levels and high-risk behavior [Kroon, et al. 2017; Rutstein, et al. 2017; Fonner, et al. 2012; Steward, et al. 2009; Colfax, et al. 2002].

For many reasons, detecting acute HIV infection is an essential link in the chain of prevention. Evidence demonstrates that patients with a recent diagnosis of HIV are more likely to reduce risk behaviors if they are given counseling at the time of testing [Fonner, et al. 2012; Steward, et al. 2009] and are linked to primary HIV care [Metsch, et al. 2008]. In addition, for those who elect to initiate ART, their risk of transmission is significantly diminished [Cohen, et al. 2016; Cohen, et al. 2011].

→ KEY POINTS

- HIV is highly transmissible during acute infection; rapid initiation of antiretroviral therapy (ART) reduces transmission, with significant public health benefits, and early viral suppression preserves immune function, with significant clinical benefits for the individual with HIV.
- Acute HIV often has nonspecific signs and symptoms and often goes unsuspected and undetected. This committee urges a high index of suspicion for acute infection and HIV testing for any individual who reports recent high-risk behavior or presents with signs or symptoms of influenza, mononucleosis, or other viral syndromes.
- When HIV infection is diagnosed, immediate linkage to care is essential; ART dramatically reduces HIV-related morbidity and mortality, and viral suppression prevents HIV transmission.
- The urgency of ART initiation is even greater if the newly diagnosed patient is pregnant, has acute HIV infection, is ≥50 years old, or has advanced disease. For these patients, every effort should be made to initiate ART immediately, ideally on the same day as diagnosis.
- All clinical care settings should be prepared, either on-site or with a confirmed referral, to support patients in initiating ART as rapidly as possible after diagnosis.
- When a diagnosis of acute HIV infection is made, clinicians should discuss the importance of notifying all recent contacts and refer patients to partner notification services, as mandated by New York State law. The NYSDOH can provide assistance if necessary.
  - See NYSDOH Provider Reporting and Partner Services for more information about required reporting.

☆ NEW YORK STATE LAW

- Clinicians must perform diagnostic HIV laboratory tests in full compliance with NYS HIV/AIDS Laws and Regulations.
- Clinicians must report confirmed cases of HIV according to NYS law (see NYSDOH Provider Reporting and Partner Services).
- Additional information regarding testing procedures and regulations is available from the NYSDOH Wadsworth Center (518-474-2163).
- **Consent:** In November 2016, amendments to NYS public health law removed the requirement for written or oral informed consent before an HIV test is ordered; see HIV Testing, Reporting and Confidentiality in New York State 2017-18 Update: Fact Sheet and Frequently Asked Questions.

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

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

Presentation and Diagnosis

☑ RECOMMENDATIONS

New York State HIV Testing Requirements

- According to New York State law, physicians must offer an HIV test to all patients aged 13 years and older (or younger with risk) if a previous test is not documented, even in the absence of symptoms consistent with acute HIV. Although written consent to HIV testing is no longer required in New York State, patients must be given the opportunity to decline, and verbal consent must be documented in the medical record.

Presentation

- Clinicians should include acute HIV infection in the differential diagnosis for *anyone* (regardless of reported risk) who presents with signs or symptoms of influenza ("flu"), mononucleosis ("mono"), or other viral syndromes (A3), especially when the patient:
  - Presents with a rash. (A2)
  - Requests HIV testing. (A3)
  - Reports recent sexual or parenteral exposure to a person with or at risk of HIV infection. (A2)
  - Presents with a newly diagnosed STI. (A2)
  - Presents with aseptic meningitis. (A2)
  - Is pregnant or breastfeeding. (A3)
  - Is currently taking antiretroviral medications for PrEP or PEP. (A3)
- Diagnostic HIV RNA testing should be considered for patients who present with compatible symptoms (see Box 1: Acute Retroviral Syndrome), particularly in the presence of an STI [Patel, et al. 2006] or a recent sexual or parenteral exposure with a partner known to have HIV or with unknown HIV serostatus. (A2)

When Acute HIV Infection Is Suspected

- Clinicians should always perform a plasma HIV RNA assay in conjunction with an Ag/Ab combination immunoassay screening test. (A2)
- Clinicians should use an Ag/Ab combination immunoassay (preferred) as the initial HIV screening test according to the standard HIV laboratory testing algorithm.
  - If the screening test is reactive, clinicians should perform an HIV-1/HIV-2 Ab differentiation immunoassay to confirm HIV infection. (A1)
  - **Note:** When rapid Ab screening is performed, even with a rapid Ag/Ab combination immunoassay, a laboratory-based Ag/Ab combination immunoassay is recommended for follow-up diagnostic HIV testing.

Diagnosis

- Clinicians can presume the diagnosis of acute HIV when high levels (>10,000 copies/mL) of HIV RNA are detected in plasma with sensitive NAT, and the result of the HIV screening or type-differentiation test is negative or indeterminate. (A2)
- When a low-level quantitative HIV RNA viral load result (<10,000 copies/mL) is obtained in the absence of serologic evidence of HIV infection, the clinician should repeat HIV RNA testing *and* perform an Ag/Ab combination immunoassay to exclude a false-positive result. (A2)

☑ RECOMMENDATIONS

- **Note:** A serologic test result that does not meet the criteria for HIV infection is a nonreactive screening result (Ab or Ag/Ab combination) or a reactive screening result with a nonreactive or indeterminate Ab differentiation confirmatory result.

- Clinicians should seek expert consultation when an ambiguous HIV result is obtained for an individual taking PrEP because the diagnosis of acute HIV can be particularly challenging in patients taking PrEP. (A3).

ART Initiation

- If a diagnosis of acute infection is made based on HIV RNA testing, clinicians should recommend ART initiation without waiting for serologic confirmation. (A2)
- When a pregnant individual is diagnosed with acute infection by HIV RNA testing, the clinician should *not* wait for the result of a confirmatory test to initiate ART; initiation of ART is strongly recommended for pregnant patients. (A2)

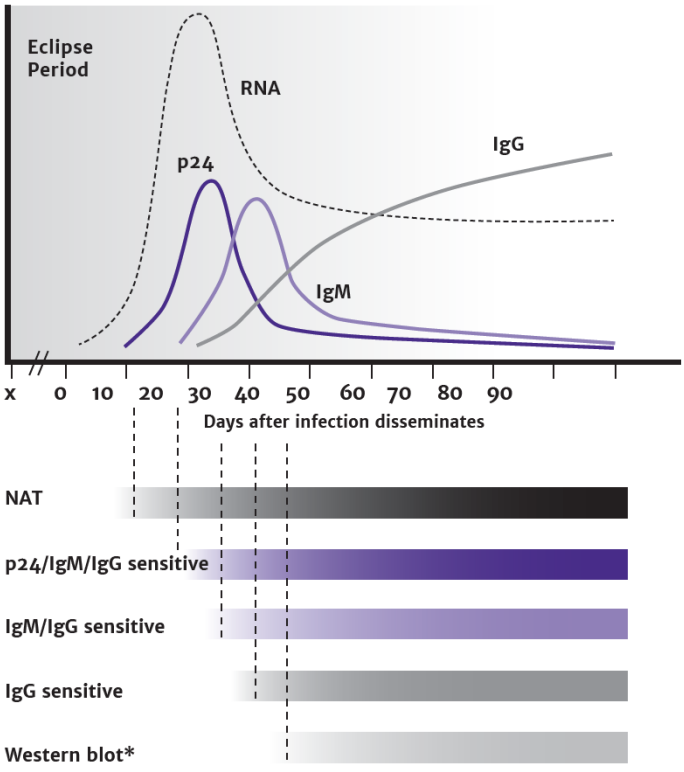
Partner Notification

- Clinicians should offer assistance with partner notification and refer patients to other sources for partner notification assistance (NYSDOH What Health Care Providers Need to Know about Partner Services or New York City Contact Notification Assistance Program). (A2)

Abbreviations: Ab, antibody; Ag, antigen; ART, antiretroviral therapy; NAT, nucleic acid test; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

The time from HIV infection to detection of the virus depends on the test that is used. Figure 1, below, illustrates the window of detection of HIV infection according to Ab, Ag/Ab combination, and HIV RNA tests.

Figure 1: HIV Test Window of Detection [a,b]



* Western blot is no longer used for HIV.

Abbreviations: IgG, immunoglobulin G; IgM, immunoglobulin M; NAT, nucleic acid test.

Notes:

a. Figure reproduced from CDC: HIV Diagnostic Tests.
b. Without PrEP or PEP exposure; PrEP or PEP exposure may delay seroconversion. Very early treatment of acute HIV infection may also alter the serologic response [Stekler, et al. 2023; Hare, et al. 2006; Kassutto, et al. 2005].

Presentation

Patients acutely infected with HIV will often experience at least some symptoms of acute retroviral syndrome (ARS). Fever and influenza- or mononucleosis-like symptoms are common in acute HIV infection but are nonspecific. Rash, mucocutaneous ulcers, oropharyngeal candidiasis, and meningismus are more specific and should raise the index of suspicion (see below for a more extensive list of signs and symptoms). The mean time from exposure to onset of symptoms is generally 2 to 4 weeks, with a range of 5 to 29 days; however, some cases have presented with symptoms up to 3 months after exposure [Apoola, et al. 2002]. Theoretically, this time course may be prolonged in patients who become infected while on PEP or PrEP.

Box 1: Acute Retroviral Syndrome

Signs and symptoms of ARS with the expected frequency among symptomatic patients are listed below [a]. The most specific symptoms in this study were oral ulcers and weight loss; the best predictors were fever and rash. The index of suspicion should be high when these symptoms are present.

- Fever (80%)
- Tired or fatigued (78%)
- Malaise (68%)
- Arthralgias (joint pain) (54%)
- Headache (54%)
- Loss of appetite (54%)
- Rash (51%)
- Night sweats (51%)
- Myalgias (pain in muscles) (49%)
- Nausea (49%)
- Diarrhea (46%)
- Fever and rash (46%)
- Pharyngitis (sore throat) (44%)
- Oral ulcers (mouth sores) (37%)
- Stiff neck (34%)
- Weight loss (>5 lb; 2.5 kg) (32%)
- Confusion (25%)
- Photophobia (24%)
- Vomiting (12%)
- Infected gums (10%)
- Sores on anus (5%)
- Sores on genitals (2%)

Note:

a. Data are from Hecht FM, Busch MP, Rawal B, et al. Use of laboratory tests and clinical symptoms for identification of primary HIV infection. *AIDS* 2002;16(8):1119-1129. [PMID: 12004270]

Diagnosis

Acute HIV infection is often not recognized in the primary care setting because the symptom profile is similar to that of influenza, mononucleosis, and other common illnesses. Furthermore, patients often do not recognize that they may have recently been exposed to HIV. Therefore, the clinician should have a high index of suspicion for acute HIV infection in a patient who may have recently engaged in behavior involving sexual or parenteral exposure to another individual's blood or body fluids and who is presenting with a febrile, influenza-, or mononucleosis-like illness. Identifying acute HIV infection during pregnancy is particularly important because effective intervention can prevent mother-to-child transmission [Patterson, et al. 2007].

High levels of HIV RNA detected in plasma through sensitive NAT, combined with a negative or indeterminate HIV screening or type-differentiation test, support the presumptive diagnosis of acute HIV infection [DHHS 2019; Robb, et al. 2016].

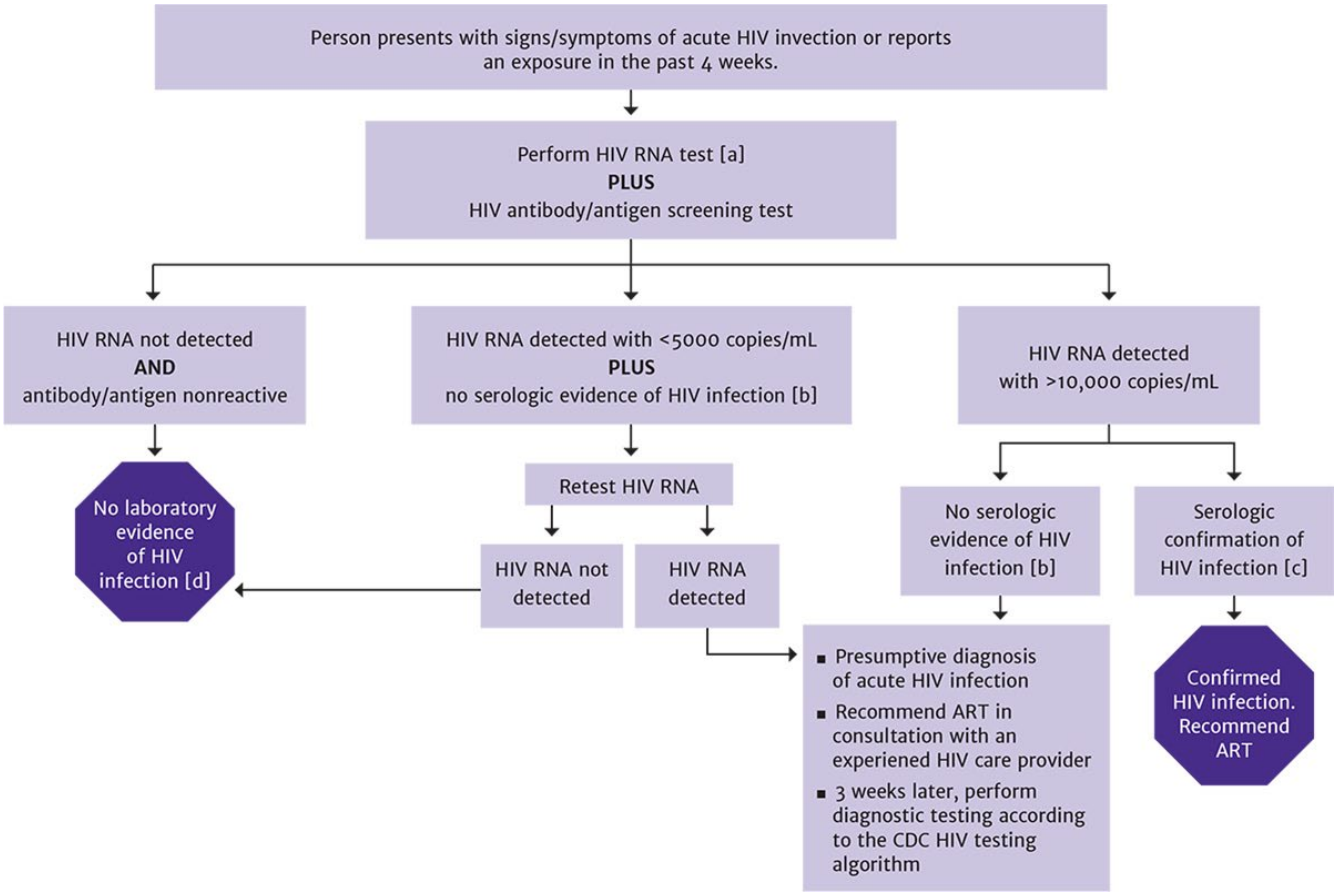
When low-level viremia is reported by HIV RNA testing (<5,000 copies/mL) in the absence of serologic confirmation of HIV infection, HIV RNA testing should be repeated to exclude a false-positive result [Hecht, et al. 2002]. Repeat HIV RNA testing with a result that indicates the presence of low-level viremia may represent true HIV infection, warranting appropriate counseling regarding transmission risk and initiation of ART.

HIV RNA levels tend to be very high in acute infection; however, a low value may represent any point on the upward or downward slope of the viremia associated with acute infection or could simply represent chronic infection. HIV RNA can also be suppressed during acute infection in patients who are taking PrEP. Plasma HIV RNA levels during acute infection do not appear significantly different in patients who are and are not symptomatic [Patterson, et al. 2007]. Viremia occurs approximately 1 to 2 weeks before the detection of a specific immune response. Patients diagnosed with acute infection by HIV RNA testing should always receive follow-up diagnostic testing 3 weeks later to confirm infection (see the standard HIV laboratory testing algorithm). Figure 2, below, illustrates diagnostic testing for acute HIV infection.

→ KEY POINTS

- The diagnosis of acute HIV infection requires a high degree of clinical awareness. The nonspecific signs and symptoms of acute HIV infection are often not recognized or attributed to another viral illness.
- Diagnostic HIV RNA testing should be considered for all patients who present with compatible symptoms (see signs and symptoms of ARS, above), particularly in the context of an STI [Patel, et al. 2006] or a recent sexual or parenteral exposure with a partner known to have HIV or a partner whose HIV serostatus is not known.
- Individual laboratories have internal protocols for reporting HIV tests with preliminary results. The terms used when preliminary results cannot be classified include *indeterminate*, *inconclusive*, *nondiagnostic*, and *pending validation*. Clinicians can contact the appropriate laboratory authority to determine the significance of nondefinitive results and the recommended supplemental testing, particularly when acute HIV infection is suspected. Clinicians are advised to become familiar with the internal test-reporting policies of their institutions.

Figure 2: Diagnostic Testing for Acute HIV Infection



Notes:

a. Viremia will be present several days before antibody detection.
b. The absence of serologic evidence of HIV infection is defined as nonreactive screening result (antibody or antibody/antigen combination) or a reactive screening result with a nonreactive or indeterminate antibody-differentiation confirmatory result.
c. Serologic confirmation as defined by the CDC HIV testing algorithm. Western blot is no longer recommended as the confirmatory test because it may yield an indeterminate result during the early stages of seroconversion and may delay confirmation of diagnosis.
d. No further testing is indicated.

Management, Including While on PEP or PrEP

☑ RECOMMENDATIONS

Managing Acute HIV

- Clinicians should recommend ART to all patients diagnosed with acute HIV infection. (A1)
- Clinicians should inform patients about the increased risk of transmitting HIV during acute infection and for the 6 months following infection in patients who do not initiate ART. (A2)
- As part of the initial management of patients diagnosed with acute HIV infection, clinicians should:
  - Consult with a care provider experienced in the treatment of acute HIV infection. (A3)
  - Obtain HIV genotypic resistance testing for the protease (A2), reverse transcriptase (A2), and integrase (B2) genes at the time of diagnosis.
- **Patients taking PEP:** When acute HIV infection is diagnosed in an individual receiving PEP, ART should be continued pending consultation with an experienced HIV care provider. (A3)
- **Patients taking PrEP:** Because the risk of drug-resistant mutations is higher in patients who acquire HIV while taking PrEP, clinicians should consult with an experienced HIV care provider and recommend a fully active ART regimen. (A3)
  - Clinicians who do not have access to experienced HIV care providers should call the Clinical Education Initiative (CEI) Line at 866-637-2342.

Initiating ART

- When a patient agrees with the clinician's recommendation to initiate ART during acute HIV infection:
  - The clinicians should implement treatment to suppress the patient's plasma HIV RNA to below detectable levels. (A1)
  - Clinicians should perform baseline laboratory testing listed in Box 2: Baseline Laboratory Testing Checklist for all patients initiating ART immediately; ART can be started while awaiting laboratory test results. (A3)

Abbreviations: ART, antiretroviral therapy; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis.

Patients are at greatest risk for transmitting HIV during periods of high viremia early in infection. Clinicians should counsel patients with acute HIV about the increased risk of transmission during the 6 months after infection. Partner notification [Golden, et al. 2004], counseling on safer sex, and screening for other sexually transmitted infections are all essential in the management of any new HIV diagnosis.

Consultation: When choosing an ART regimen for a patient with acute HIV infection, clinicians should consult a care provider experienced in treating acute HIV infection.

- Data are insufficient to support a specific ART regimen(s) for the treatment of acute HIV infection; instead, the choice of regimen should be made based on recommendations for selecting an initial ART regimen.
- The risks of transmitted resistance should be considered when prescribing ART while awaiting HIV resistance results.
- The risks of acquired mutations should be considered in those who acquire HIV while on PrEP.

Clinicians who do not have access to experienced HIV care providers should call the CEI Line at 866-637-2342.

All Recommendations

☑ ALL RECOMMENDATIONS: DIAGNOSIS AND MANAGEMENT OF ACUTE HIV INFECTION

New York State HIV Testing Requirements

- According to New York State law, physicians must offer an HIV test to all patients aged 13 years and older (or younger with risk) if a previous test is not documented, even in the absence of symptoms consistent with acute HIV. Although written consent to HIV testing is no longer required in New York State, patients must be given the opportunity to decline, and verbal consent must be documented in the medical record.

Presentation

- Clinicians should include acute HIV infection in the differential diagnosis for *anyone* (regardless of reported risk) who presents with signs or symptoms of influenza ("flu"), mononucleosis ("mono"), or other viral syndromes (A3), especially when the patient:
  - Presents with a rash. (A2)
  - Requests HIV testing. (A3)
  - Reports recent sexual or parenteral exposure to a person with or at risk of HIV infection. (A2)
  - Presents with a newly diagnosed STI. (A2)
  - Presents with aseptic meningitis. (A2)
  - Is pregnant or breastfeeding. (A3)
  - Is currently taking antiretroviral medications for PrEP or PEP. (A3)
- Diagnostic HIV RNA testing should be considered for patients who present with compatible symptoms (see Box 1: Acute Retroviral Syndrome), particularly in the presence of an STI [Patel, et al. 2006] or a recent sexual or parenteral exposure with a partner known to have HIV or with unknown HIV serostatus. (A2)

When Acute HIV Infection Is Suspected

- Clinicians should always perform a plasma HIV RNA assay in conjunction with an Ag/Ab combination immunoassay screening test. (A2)
- Clinicians should use an Ag/Ab combination immunoassay (preferred) as the initial HIV screening test according to the standard HIV laboratory testing algorithm.
  - If the screening test is reactive, clinicians should perform an HIV-1/HIV-2 Ab differentiation immunoassay to confirm HIV infection. (A1)
  - **Note:** When rapid Ab screening is performed, even with a rapid Ag/Ab combination immunoassay, a laboratory-based Ag/Ab combination immunoassay is recommended for follow-up diagnostic HIV testing.

Diagnosis

- Clinicians can presume the diagnosis of acute HIV when high levels (>10,000 copies/mL) of HIV RNA are detected in plasma with sensitive NAT, and the result of the HIV screening or type-differentiation test is negative or indeterminate. (A2)
- When a low-level quantitative HIV RNA viral load result (<10,000 copies/mL) is obtained in the absence of serologic evidence of HIV infection, the clinician should repeat HIV RNA testing *and* perform an Ag/Ab combination immunoassay to exclude a false-positive result. (A2)
  - **Note:** A serologic test result that does not meet the criteria for HIV infection is a nonreactive screening result (Ab or Ag/Ab combination) or a reactive screening result with a nonreactive or indeterminate Ab differentiation confirmatory result.
- Clinicians should seek expert consultation when an ambiguous HIV result is obtained for an individual taking PrEP because the diagnosis of acute HIV can be particularly challenging in patients taking PrEP. (A3)

ART Initiation

- If a diagnosis of acute infection is made based on HIV RNA testing, clinicians should recommend ART initiation without waiting for serologic confirmation. (A2)

☑ ALL RECOMMENDATIONS: DIAGNOSIS AND MANAGEMENT OF ACUTE HIV INFECTION

- When a pregnant individual is diagnosed with acute infection by HIV RNA testing, the clinician should *not* wait for the result of a confirmatory test to initiate ART; initiation of ART is strongly recommended for pregnant patients. (A2)

Partner Notification

- Clinicians should offer assistance with partner notification and refer patients to other sources for partner notification assistance (NYSDOH What Health Care Providers Need to Know about Partner Services or New York City Contact Notification Assistance Program). (A2)

Managing Acute HIV

- Clinicians should recommend ART to all patients diagnosed with acute HIV infection. (A1)
- Clinicians should inform patients about the increased risk of transmitting HIV during acute infection and for the 6 months following infection in patients who do not initiate ART. (A2)
- As part of the initial management of patients diagnosed with acute HIV infection, clinicians should:
  - Consult with a care provider experienced in the treatment of acute HIV infection. (A3)
  - Obtain HIV genotypic resistance testing for the protease (A2), reverse transcriptase (A2), and integrase (B2) genes at the time of diagnosis.
- **Patients taking PEP:** When acute HIV infection is diagnosed in an individual receiving PEP, ART should be continued pending consultation with an experienced HIV care provider. (A3)
- **Patients taking PrEP:** Because the risk of drug-resistant mutations is higher in patients who acquire HIV while taking PrEP, clinicians should consult with an experienced HIV care provider and recommend a fully active ART regimen. (A3)
  - See the NYSDOH AI guideline PrEP to Prevent HIV and Promote Sexual Health > Managing a Positive HIV Test Result.
  - Clinicians who do not have access to experienced HIV care providers should call the Clinical Education Initiative (CEI) Line at 866-637-2342.

Initiating ART

- When a patient agrees with the clinician's recommendation to initiate ART during acute HIV infection:
  - The clinicians should implement treatment to suppress the patient's plasma HIV RNA to below detectable levels. (A1)
  - Clinicians should perform baseline laboratory testing listed in Box 2: Baseline Laboratory Testing Checklist for all patients initiating ART immediately; ART can be started while awaiting laboratory test results. (A3)

Abbreviations: Ab, antibody; Ag, antigen; ART, antiretroviral therapy; NAT, nucleic acid test; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

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Supplement: Guideline Development and Recommendation Ratings

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

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Recommendation development	• The lead author drafts recommendations to address the defined scope of the guideline based on available published data. • Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations. • When published data are not available, support for a recommendation may be based on the committee's expert opinion. • The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.
Review and approval process	• Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the AI Community Advisory Committee. • Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations. • Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.
External reviews	• External review of each guideline is invited at the developer's discretion. • External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.
Update process	• JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations. • If changes in the standard of care, newly published studies, new drug approval, new drug-related warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates and will invite full committee review as indicated.

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