Guidelines for the Testing, Management, and Treatment of HIV/AIDS

MVP Health Care®, as part of a continuing Quality Improvement Program, has adopted the New York State Department of Health's (NYSDOH) AIDS Institute's recommendations for the prevention and management of HIV infection in adults, children, adolescents and the prevention of HIV transmission during the perinatal period. The guidelines were developed by NYSDOH in conjunction with the Johns Hopkins University School of Medicine, Division of Infectious Diseases. In addition, MVP reviews and utilizes guidelines from the Centers for Disease Control (CDC).

This document contains an overview of testing, management, and treatment of HIV from different professional and regulatory organizations such as the New York State Department of Health's (NYSDOH, and the American Congress of Obstetricians and Gynecologists (ACOG). There may be differences in recommendations regarding HIV testing among the organizations. **Providers in New York State must follow the New York State requirements at a minimum.**

Statistics – Morbidity & Mortality

- How many people receive an HIV diagnosis each year in the United States and 6 dependent areas?

  In 2020, 30,635 people received an HIV diagnosis in the United States and dependent areas.[a,b] The annual number of new diagnoses decreased 8% from 2016 to 2019.

- How many people have HIV in the United States?

  An estimated 1,189,700 people in the United States[c] had HIV at the end of 2019, the most recent year for which this information is available. Of those people, about 87% knew they had HIV.

- How does HIV affect different groups of people?

  There are different ways to answer this question.

  In 2020, male-to-male sexual contact[d] accounted for 68% of all new HIV diagnoses in the United States and dependent areas. In the same year, heterosexual contact accounted for 22% of all HIV diagnoses.

  There are also variations by age. Young people aged 13 to 24 are especially affected by HIV. In 2020, young people accounted for 20% (6,135) of all new HIV diagnoses. All young people are not equally affected by HIV, however. Young gay and bisexual men accounted for 84% (5,161) of all new HIV diagnoses in people aged 13 to 24 in 2020.[e] Young Black/African American gay and bisexual men are even more severely affected, as they represented 53% (2,740) of new HIV diagnoses among young gay and bisexual men.

CDC's fact sheets explain the impact of HIV on various populations in the United States.

How many deaths are there among people with HIV?

In 2020, there were 18,489 deaths among people with diagnosed HIV in the US and dependent areas.[a] These deaths could be from any cause.

- Are some regions of the United States more impacted by HIV than others?

  Yes. HIV is largely an urban disease, with most cases occurring in metropolitan areas with 500,000 or more people. The South has the highest *number* of people living with HIV, but if population size is taken into account, the Northeast has the highest *rate* of people living with HIV. (Rates are the number of cases of disease per 100,000 people. Rates allow number comparisons between groups of different sizes.)

[a] Unless otherwise noted, data in this web content are for adults and adolescents aged 13 and older.
[b] American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Republic of Palau, and the US Virgin Islands.
[c] In the 50 states and the District of Columbia.
[d] The term male-to-male sexual contact is used in CDC surveillance systems. It indicates a behavior that transmits HIV infection, not how individuals self-identify in terms of their sexuality.
[e] Includes infections attributed to male-to-male sexual contact *and* injection drug use (men who reported both risk factors).

1. New York State Public Health Law related to HIV testing

New York State Department of Health (NYS DOH)

Title: Part 63 - HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information | New York Codes, Rules and Regulations (ny.gov) HIV Testing

2. Guidelines for testing in pregnancy

Centers for Disease Control (CDC)

Pregnant Women, Infants, and Children | Gender | HIV by Group | HIV/AIDS | CDC

3. HIV Testing During Pregnancy and at Delivery

NYS DOH Aids Institute

PERINATAL HIV CARE - AIDS Institute Clinical Guidelines (hivhttps://www.hivguidelines.org/perinatal-hiv-care/guidelines.org)Prenatal and Perinatal Human Immunodeficiency Virus Testing: Expanded Recommendations

The American College of Obstetricians and Gynecologists

https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Prenatal-and-Perinatal-Human-Immunodeficiency-Virus-Testing

The New York State Department of Health HIV Testing Guideline:

The HIV Testing guideline addresses the screening and diagnostic methods for accurate diagnosis of HIV. There is a section devoted to HIV/AIDS Laws and Regulations regarding HIV Testing. This includes the most current information for Public Health Law and associated amendments.

The New York State HIV Testing Law requires health care providers, including but not limited to physicians, physician assistants, nurse practitioners and nurse midwives who are providing primary care services, to offer HIV testing to all persons age 13 and older (or younger with risk factors). This must be done at least once and must be done more often if there is evidence of risk activity. See the Frequently Asked Questions document on the DOH Web site: 2018 Guidelines for use of the HIV Diagnostic Testing Algorithm for Laboratories (ny.gov)

New York State Public Health Law related to HIV testing has evolved over the years to keep pace with changes in the epidemic and clinical practice. Key provisions were passed in 2010, 2014, 2015, 2016, 2017, and 2018. A Notice of Adoption of updated law and regulation pertaining ***to HIV/AIDS Testing, Reporting and Confidentiality of HIV Related Information*** was published in the State Register on May 17th, 2017.

Effective March 28, 2017, Chapter 461 of the Laws of 2016 allows disclosure of confidential HIV-related information to qualified researchers for medical research purposes upon the approval of a research protocol under applicable State or federal law.

Key provisions of these regulation amendments implementing the legislation include:

- Removing the requirement for informed consent prior to ordering an HIV-related test and removing references to consent forms.
- Adding a provision stating that performing an HIV test as part of routine medical care requires at a minimum advising that an HIV-related test is being performed, prior to ordering an HIV-related test.
- Removing the reference to expiration of an individual's informed consent.
- Adding a provision authorizing local and state health departments to share HIV surveillance information with health care providers, including entities engaged in care coordination, for purposes of patient linkage and retention in care.
- Clarifying language pertaining to reporting by blood and tissue banks.
- Inserting updates to the list of reportable HIV-related test results that need to be reported. These updates are consistent with CDC and Association of Public Health Laboratories guidance related to the diagnosis of HIV infection. Additionally, reporting of

results for NYS residents and NYS-located clinicians is explicitly required. This change was designed to address known gaps in reporting.

- Including language specifically stating that reports must include the requesting provider and facility. The requirement is expected to improve the quality of provider data and lead to more complete data. This should improve accuracy of the Department's surveillance data and, consequently, the National HIV/AIDS Strategy retention and care measures.
- Removing the requirement that the information on HIV provider reporting forms associated with newly diagnosed cases of HIV infection be reported within 60 days.
- Adding individuals who were previously diagnosed as HIV positive, and who are at elevated risk of transmitting HIV to others, to the contact notification prioritization process.
- Removing the requirement that data on the partners of HIV cases be destroyed after three years, and stating that the Department will establish a policy for "record retention and schedule for disposition."
- Eliminating the upper age limit of 64 for the offering of HIV testing.
- Allowing the disclosure of HIV related information to qualified researchers in compliance with State and federal law.

Guidelines and Training for Providers:

The New York State Department of Health (NYSDOH) has resources to support routine HIV testing for adults and minors. A toolkit was developed for primary care providers and contains all of the resources needed to implement HIV testing in a manner that is consistent with public health law and good clinical practice. The HIV Testing Toolkit has numerous NYSDOH documents related to HIV testing saved in PDF format available here:

HIV Testing Toolkit

Pregnancy and HIV (available: PERINATAL HIV CARE - AIDS Institute Clinical Guidelines (hivguidelines.org)

Timely diagnosis of HIV and rapid initiation of antiretroviral therapy are crucial to reducing the risk of perinatal HIV transmission and maintaining the health of pregnant patients and their infants. This guideline was developed by the New York State (NYS) Department of Health (DOH) AIDS Institute (AI) to provide evidence-based recommendations regarding HIV testing during pregnancy and at delivery and to promote universal HIV screening for all pregnant patients to achieve the following:

- Ensure universal HIV screening early in pregnancy, during the third trimester, and during labor for individuals who do not have a documented negative HIV status.
- Encourage third-trimester testing for syphilis and HIV testing.

- Encourage HIV testing for pregnant and postpartum patients who exhibit symptoms of acute HIV.
- Increase uptake of pre-exposure prophylaxis among pregnant patients who do not test positive for HIV but who are at high risk of HIV acquisition during pregnancy and postpartum.

Centers for Disease Control (CDC) Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings (available: https://www.cdc.gov/hiv/basics/testing.html)

The major revisions from previously published guidelines are as follows:

For patients in all health-care settings

- HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Persons at high risk for HIV infection should be screened for HIV at least annually.
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing. Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings. New York State Department of Health requires counseling about the testing to be done and documented. (Providers in New York State must follow the New York State requirements at a minimum.)

For pregnant women

- HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.
- HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Repeat screening in the third trimester is recommended in certain jurisdictions with elevated rates of HIV infection among pregnant women.

The American College of Obstetricians and Gynecologists. Committee Opinion: Prenatal and Perinatal Human Immunodeficiency Virus Testing: Expanded Recommendations (available: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Prenatal-and-Perinatal-Human-Immunodeficiency-Virus-Testing)*

- Human immunodeficiency virus testing is recommended for all sexually active women or women who use intravenous drugs and should be a routine component of pre-pregnancy and prenatal care.

- Human immunodeficiency virus testing using the opt-out approach, which is currently permitted in every jurisdiction in the United States, should be a routine component of care for women during pre-pregnancy and as early in pregnancy as possible.
- Repeat HIV testing in the third trimester, preferably before 36 weeks of gestation, is recommended for pregnant women with initial negative HIV antibody tests in areas with high HIV incidence or prevalence and women known to be at risk of acquiring HIV infection.
- Rapid screening during labor and delivery or during the immediate postpartum period using the opt-out approach should be done for women who were not tested earlier in pregnancy or whose HIV status is otherwise unknown. Results should be available 24 hours a day and within 1 hour.
- If a rapid HIV test result in labor is reactive, antiretroviral prophylaxis should be immediately initiated while waiting for supplemental test results.
- If the diagnosis of HIV infection is established, the woman should be linked into ongoing care with a specialist in HIV care for co-management.

CDC, NYS DOH and ACOG all agree on guidelines for testing in pregnancy. All pregnant women should be tested as early as possible during the pregnancy, preferably at the first visit. Testing should be routinely recommended during the third trimester (preferably between 34 and 36 weeks) and those with specific risk factors should be strongly encouraged to be tested at this time. Women presenting in labor without prior testing during the current pregnancy or known HIV positive status should have expedited testing with consent. If maternal testing is declined the newborn must have expedited testing performed. Maternal consent is not required for newborn testing.

Test Follow-up

For a patient who tests negative, the result must be provided to them and counseling regarding risk factors and pre- and post-exposure prophylaxis. This does not have to be done in person and the counseling may use written materials (see FAQ 10).

For a patient who tests positive, the ordering provider or their representative must provide or arrange for a follow up visit for HIV care, with the patient's consent, and should document that the visit was arranged in the medical record. Patient counseling should also be provided (see FAQ10).

This guideline is not intended to replace the role of the physician's clinical judgment in the management of medical services, it is an educational guideline provided to assist in the delivery of good medical care. All treatment decisions are ultimately based on the physician's clinical assessment and judgment. Where medication recommendations are made, please refer to each health plan's formulary for coverage considerations.

*Pending update

MVP updates the Guidelines for the Testing, Management, and Treatment of HIV/AIDS annually. The review process is also initiated when new scientific evidence or national standards are published. Practitioners are alerted via the web site, and by written notices from the plan via fax or newsletter. A print copy of the clinical guideline can be requested by calling the MVP Quality Improvement Department at **(800) 777-4793 extension 1-2247**.