

**HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED
IMMUNODEFICIENCY SYNDROME (AIDS)
INFECTION AMONG PERSONS ≥18 MONTHS OF AGE
INFECTION AMONG CHILDREN <18 MONTHS OF AGE
HIV EXPOSURE AMONG CHILDREN <18 MONTHS OF AGE**

REPORTING INFORMATION

In accordance with Ohio Administrative Rule (OAC) 3701-3-12 and divisions (B) and (C) of section 3701.24 of the Ohio Revised Code (ORC), reporting requirements are as follows:

Persons Required to Report

Health care providers

Health care providers shall report every case of HIV infection, including AIDS, for persons under their treatment and care. In an institutional or health care facility setting, a designated agent, including, but not limited to, an infection preventionist may make the report for the diagnosing or treating health care provider.

Every health care provider attending a newborn infant or child born to an HIV infected mother shall report every instance of perinatal exposure to HIV and any subsequent test results on every such exposed newborn infant or child until such time that either an HIV infection or a serostatus that is negative is confirmed. In an institutional or health care facility setting, a designated agent, including, but not limited to, an infection preventionist, may make the report for the diagnosing or treating health care provider.

Health care providers should become familiar with the U.S. Centers for Disease Control and Prevention (CDC) HIV infection laboratory testing guidance and recommendations [1] if unfamiliar with testing used to aid in the diagnosis of an HIV infection, and/or consult with the reference laboratory they use when sending specimens for HIV diagnostic testing.

Laboratories

The individual in charge of the laboratory shall report all positive or repeatedly reactive results from antigen detection, nucleic acid detection, detection of antibody confirmed with a supplemental test, or positive cultures used in the diagnosis of HIV infection, CD4 count and percentage when performed to monitor the progression of HIV disease, and detectable and undetectable viral load results when performed to monitor the efficacy of HIV treatment. If a second laboratory is used for additional or supplemental HIV testing, the person in charge of the laboratory first receiving the specimen shall report the results of the supplemental testing.

Laboratories performing HIV diagnostic testing should become familiar with the criteria established by the Clinical and Laboratory Standards Institute (CLSI) [2], the aforementioned U.S. Centers for Disease Control and Prevention's (CDC) HIV infection laboratory testing guidance and recommendations, and the Association Public Health Laboratories (APHL) HIV testing algorithm reporting guidance [3]. Laboratories are to report all of the following HIV diagnostic and prognostic test results or combinations of results (see following page):

- The initial positive/reactive HIV antibody or combination HIV antibody/antigen test result **and** the corresponding supplemental test results used as part of a multi-test algorithm to verify (i.e. confirm) HIV infection, unless the final result interpretation of the multi-test algorithm resolves to negative/nonreactive;
- A positive/reactive result on an HIV antigen test (e.g. p24 antigen);
- A positive/reactive qualitative HIV nucleic acid (RNA or DNA) amplification test (NAAT or NAT) (e.g. polymerase chain reaction [PCR]), including undetectable results;
- A quantitative HIV nucleic acid amplification test (i.e. viral load), including undetectable results, reported as copies/ML and log value;
- A positive/reactive result on an HIV isolation test (e.g. HIV-1 viral culture, HIV-2 viral culture);
- A nucleotide sequence from an HIV genotype test; and
- CD4+ T-lymphocyte counts and percentages of all values unless the patient is not known to have HIV infection.

Laboratories performing HIV diagnostic testing should refer to “*Reporting Lab Results in Ohio from a Multistep HIV Diagnostic Testing Algorithm*” table included at the end of the HIV section of this manual for guidance on reporting HIV diagnostic test results performed as part of a multi-step testing algorithm to public health.

Reporting Time Frames

Health care providers (e.g. physicians, in- and outpatient facilities, medical clinics): are to report no later than five days from the date of diagnosis or specimen collection date, whichever is later. For instances of perinatal exposure to HIV, reports are to be made no later than five days from the date of the infant’s birth.

Laboratories (including inpatient hospital labs): are to report no later than five days from the test result date.

Reporting Forms and Electronic Reporting Methods

Health Care Providers (e.g. physicians, in- and outpatient facilities, medical clinics): are to report on the [Adult HIV/AIDS Confidential Case Report Form](#) (CDC 50.42A, Rev. 06/2016) for patients 13 years of age and older; and [Pediatric HIV/AIDS Confidential Case Report Form](#) (CDC 50.42B, Rev. 06/2016) for patients less than 13 years of age, including reports of perinatal exposure to HIV.

Health care providers should refer to the *Key HIV Reporting Elements* on the following pages for assistance in completing required fields on the case report form. A document is offered at the end of the HIV section of this manual as a tool to assist those interviewing patients in “*Talking with Patients about Behavioral Risk Factors for Acquiring HIV.*” Documenting and reporting a patient’s mode(s) of HIV transmission to public health remains crucial to describing the trends in the epidemiology of HIV infection as well as targeting comprehensive prevention interventions at high risk populations.

In addition, the aforementioned “*Reporting Lab Results in Ohio from a Multistep HIV Diagnostic Testing Algorithm*” table included at the end of the HIV section of this manual may also be of use to physicians and other health/medical facility staff who are less familiar with new HIV testing technology used by laboratories to confirm/verify an HIV diagnosis and what should be reported

to the public health authority in Ohio.

Laboratories (including inpatient hospital labs): are to report the aforementioned HIV test results. Electronic Laboratory Reporting (ELR) is the preferred method of reporting; however, traditional paper copy lab reports are accepted. DO NOT fax HIV-related test results to ODH. Laboratories performing HIV testing, including hospital labs, with the capability or interest in ELR should visit the ODH ELR website at <http://www.odh.ohio.gov/healthstats/elr/elr1.aspx> for further information. Otherwise, laboratories are permitted to use their own reporting form and are to include all of the following information as specified in Ohio administrative rule 3701-3-12:

Case/patient information: name, diagnosis, date of birth, sex, ethnicity, race, and street address including city, state, and zip code.

Health care provider information: name, telephone number, and street address including city, state, and zip code.

Laboratory information: name, telephone number, and street address including city, state, and zip code.

Laboratory test information: specimen collection date, specimen type, test name, test result, and reference range, where applicable.

Where to Report

Health care providers (e.g. physicians, in- and outpatient facilities, medical clinics):

HIV confidential case report forms should be completed for all newly diagnosed persons and those HIV infected persons new to your facility. Forms should be mailed in an envelope marked "**Confidential**" and submitted to the designated local public health department in each county listed below:

<u>County</u>	<u>Designated Local Health Department</u>
Cuyahoga	Cleveland Department of Public Health
Franklin	Franklin County Public Health (includes Columbus)
Hamilton	Hamilton County Public Health (includes Cincinnati)
Jefferson	City of Steubenville Health Department
Lucas	Toledo-Lucas County Health Department
Mahoning	Youngstown City Health District
Montgomery	Public Health Dayton and Montgomery County
Stark	Canton City Health Department
Summit	Summit County Health District (includes Akron)
<i>All other Ohio Counties</i>	County Health Department

***Ohio Department of Health
Attention: HIV Surveillance Program
246 North High Street
Columbus, Ohio 43216-0118***

Laboratories (including inpatient hospital labs):

Laboratories are to submit paper copy HIV-related lab results to the designated local public health department listed above based upon the patients' county of residence. In the absence of patient residence, lab reports should be sent to the local public health department where the physician

and/or health care facility is located. If this is unknown, laboratories should send HIV lab reports in an envelope marked "**Confidential**" to the Ohio Department of Health using the ODH address listed above. Please DO NOT fax HIV-related test results to ODH.

Local health departments (LHDs)

Local health departments may make a copy of the HIV case report forms they receive from health care providers/facilities for their own records but should forward the original HIV case report form within five business days to the Ohio Department of Health (ODH) in an envelope marked "**Confidential**" to the ODH address listed previously. Please do NOT fax HIV case report forms to ODH.

LHDs receiving separate HIV lab reports from laboratories that confirm an HIV diagnosis [e.g. HIV antibody/antigen; qualitative HIV nucleic acid (RNA or DNA) amplification test (NAAT or NAT, PCR)] should ensure the regional LHD responsible for performing HIV/STD disease intervention activities receives the lab results so that the local disease intervention specialists (DIS) can perform partner services. The regional LHDs performing HIV partner services are encouraged to enter the results into the Ohio Disease Reporting System (ODRS), but the lab results must be entered in their entirety and not only those fields used for partner services. Otherwise all HIV diagnostic lab results, including those received for "previous positives" should be forwarded to ODH following the same procedures for sending HIV case report forms. Please do NOT fax HIV-related test results to ODH.

LHDs should also send all CD4 and viral load laboratory results to ODH following the reporting procedures outlined for sending in HIV case report forms. LHDs may make a copy of any lab reports they receive for their own use.

Key HIV Reporting Elements

The following information is to be reported by health care providers on the HIV confidential case report forms previously described:

Patient Identification

- Patient First, Last and Middle Name(s)
- Alternate/Alias Name(s) used (if applicable)
- Current Street Address –include city, county, state/country, zip code
- Address Type – residential, corrections, foster home, shelter, temporary, postal, homeless

Health Care Facility Completing Form

- Facility Name
- Facility Phone Number (include area code)
- Facility Street Address
- Facility City, County, State and Zip Code
- Facility Type (i.e. inpatient, outpatient, screening/diagnostic agency, other)
- Name of Person Completing Form
- Date Form Completed (mm/dd/yyyy)

Patient Demographics

- Sex at Birth – male, female, unknown
- Country of Birth – U.S., if not U.S.-borne, specify country of birth by name
- Date of Birth (mm/dd/yyyy)

- Alias/Alternate Birth Date (if applicable)
- Vital Status – alive, dead
- Death of Death (if applicable)
- State of Death (if applicable)
- Current Gender Identity – male, female, transgender male-to-female (MTF), transgender female-to-male (FTM), unknown, additional gender identity
- Ethnicity – Hispanic/Latino, Not Hispanic/Latino, unknown
- Race (check all that apply)

Patient Residence at Diagnosis – *only if different from current address*

- Address Type – residence at HIV diagnosis, residence at AIDS diagnosis
- City, County, State and Zip Code – if different than current address
- Country of Residence at Diagnosis of HIV/AIDS – if outside of U.S., specify country by name

Facility of Diagnosis

- Diagnosis Type – HIV, AIDS
- Facility Name – if other than facility completing form
- Facility Address – if other than facility completing form
- Health Care Provider Name
- Health Care Provider Phone Number (include area code)
- Health Care Provider Specialty (e.g. internal medicine, infectious diseases, pathology)

Patient History – Answer “Yes”, “No” or “Unknown” to each of the following regardless of the patient’s birth sex and/or current gender identity:

- Sex with Male
- Sex with Female
- Injection of Non-Prescription Drugs
- Received Clotting Factor for Hemophilia/Coagulation Disorder and the Date Received (mm/dd/yyyy)
- Heterosexual contact with any of the following: intravenous/injection drug user, bisexual male (for females only), person with hemophilia/coagulation disorder with documented HIV infection, transfusion recipient with documented HIV infection, transplant recipient with documented HIV infection, person with documented HIV infection with risk not specified
- Received Blood Transfusion/Blood Components (other than clotting factor) and Date Received (mm/dd/yyyy)
- Received Transplant of Tissue/Organs or Artificial Insemination and Date Received (mm/dd/yyyy)
- Worked in Healthcare or Clinical Laboratory Setting - if occupational exposure is being investigated or suspected, specify occupation and setting

Special Note on Patient History: *reports documenting or suggesting an occupational exposure to HIV (e.g. needle stick injury from documented HIV infected patient) as the source of HIV transmission may involve contacting the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Association (OSHA) as this is considered a rare occurrence of documented HIV transmission. In addition, any newly diagnosed patient who when interviewed indicates recent receipt of clotting factor, a blood transfusion, or tissue/organ transplant as the source of their HIV infection, and denies all other known modes of HIV transmission/exposures, is considered a Case of Public Health Interest (COPHI). COPHI investigations will be performed in coordination with CDC to determine if local and/or national sources of blood and associated blood*

products/components have been contaminated and place other patients and their health care providers at risk for HIV or other blood borne pathogen exposure.

Laboratory Results

- Test Name(s) – HIV antibody (IA/EIA, Western Blot, IFA), HIV qualitative detection (viral load, HIV culture), HIV quantitative detection (viral load), and immunologic tests (CD4 count and percentage)
- Specimen Collection Date(s) (mm/dd/yyyy)
- Test Result(s) – positive, reactive, detectable, undetectable (viral load only)
- Test Parameter (for quantitative results) – for viral load: detectable/undetectable, copies/mL, log value; for CD4 count: cells/uL and CD4 percentage
- For Antibody Testing Only – test manufacturer (e.g. BioRad, Abbott, Alere)

Clinical Diagnosis and Treatment of Patient

- Opportunistic Infections, if applicable
- Date of Diagnosis (mm/dd/yyyy)
- Treatment/Referral Services Information, if available

Maternal and Birth History

- For female patients – pregnancy status, previous live births
- For children of patient – child’s name, date of birth, hospital of birth, hospital city and state, country of birth

Note: Pediatric HIV infections, including pediatric AIDS cases, and perinatal HIV exposure are separately reportable conditions and should be reported using the aforementioned pediatric HIV confidential case report form

Comments Field

The comments section of the case report form should be used to document any other key or pertinent information to assist in further investigation of the case (e.g. country of birth and country of diagnosis for HIV-2 infections if outside the U.S.; if initially diagnosed outside of Ohio, name of city/state recently moved to/from Ohio; names and contact information of other/previous treating physicians/facilities; name of spouse/partner(s) and their HIV diagnostic status.

AGENT

Human immunodeficiency virus (HIV) is a retrovirus. Two strains are known, HIV-1 and HIV-2.

CASE DEFINITIONS (CDC, revised April 2014)

1. CRITERIA FOR A CONFIRMED CASE

Criteria for a confirmed case can be met by either laboratory evidence or clinical evidence, as described below. Health care providers/facilities should follow-up directly with the reference laboratory they use/contract with to perform verification or confirmation of HIV diagnostic testing for questions surrounding the interpretation of HIV test results based upon the test manufacturer (e.g. Abbott, BioRad, Alere) the laboratory uses for HIV diagnostics and/or if the test results and interpretation provided by the laboratory appear to be conflicting. *This is particularly important if there is a possibility or suspicion by the health care provider that a patient has an acute HIV infection (i.e. was recently infected but is not showing antibodies for HIV) as this may require additional testing and/or an additional serum sample for the patient.*

All Persons ≥18 Months of Age and Children <18 Months of Age whose Mothers are Not Infected

Laboratory Evidence

Laboratory criteria requires reporting the date of the specimen collection (MM/DD/YYYY) for positive test results in multi-test algorithms or stand-alone virologic tests, and enough information about the tests used to determine that they meet any of the following criteria:

- A multi-test algorithm consisting of
 - A positive (reactive) result from an initial HIV antibody or HIV combination antigen/antibody test, **AND**
 - An accompanying or subsequent positive result from a supplemental HIV test different from the initial test, **OR**
- A positive (reactive) result of a multi-test HIV antibody algorithm from which only the final result was reported, including a single positive (reactive) result on a test used only as a supplemental test (e.g. HIV Western blot, immunofluorescence assay [IFA]) or on a test that might be used as either an initial test or a supplemental test (e.g. HIV-1/2 type-differentiating rapid antibody immunoassay) when it might reasonably be assumed to have been used as a supplemental test (i.e. because the algorithm customarily used by the reporting laboratory is known), **OR**
- A positive (reactive) result or report of a detectable quantity (i.e. within the established limits of the laboratory test) from any of the following HIV virologic (i.e. non-antibody) tests:
 - Qualitative HIV NAAT (DNA or RNA),
 - Quantitative HIV NAAT (viral load assay),
 - HIV-1 p24 antigen test,
 - HIV isolation (viral culture), **OR**

- HIV nucleotide sequence (genotype).

The initial HIV antibody or HIV combination antigen/antibody test and the supplemental HIV test that is used to verify (i.e. confirm) the result from the initial test can be of any type used as an aid to diagnose HIV infection.

The initial and supplemental tests must be "orthogonal" (i.e. have different antigenic constituents or use different principles) to minimize the possibility of concurrent nonspecific reactivity. Tests will be assumed to be orthogonal if they are of different types.

For example:

- One test is a combination antigen/antibody test and the other an antibody-only test.
- One test is an antibody test and the other a nucleic acid amplification test (NAAT).
- One test is a rapid immunoassay (a single-use analytical device that produces results in <30 minutes) and the other a conventional immunoassay (EIA).
- One test is able to differentiate between HIV-1 and HIV-2 antibodies and the other is not.

Tests also will be assumed to be orthogonal if they are of the same type (e.g. two conventional immunoassays) but made by different manufacturers. The type of HIV antibody test that verifies the initial test might be one formerly used only as an initial test (e.g. conventional or rapid immunoassay, HIV-1/2 type-differentiating immunoassay), or it might be one traditionally used as a supplemental test for confirmation (e.g. Western blot, immunofluorescence assay [IFA]).

Clinical Evidence

Clinical criteria for a confirmed case (i.e. a "physician-documented" diagnosis) are met by the combination of:

- A note in a medical record by a physician or other qualified medical-care provider that states that the patient has HIV infection, **AND**
- One or both of the following:
 - The laboratory criteria for a case were met based on tests done after the physician's note was written (validating the note retrospectively), **OR**
 - Presumptive evidence of HIV infection (e.g. receipt of HIV antiretroviral therapy or prophylaxis for an opportunistic infection), an otherwise unexplained low CD4+ T-lymphocyte count, or an otherwise unexplained diagnosis of an opportunistic illness [See page 10 for a list of opportunistic illnesses].

Children <18 Months of Age Born to Mothers who were either Known to be Infected or the Mother's Infection Status was Unknown at Birth

Laboratory Evidence

A child aged <18 months is categorized for surveillance purposes as HIV infected if all of the following criteria are met:

- Positive (reactive) results on at least one specimen (not including cord blood) from any of following HIV virologic tests:
 - HIV-1 NAAT (DNA or RNA),
 - HIV-1 p24 antigen test, including neutralization assay for a child aged >1 month,
 - HIV isolation (viral culture), **OR**
 - HIV nucleotide sequence (genotype), **AND**
- The specimen collection date (MM/DD/YYYY) is known, **AND**
- One or both of the following:
 - Confirmation of the first positive (reactive) result by another positive (reactive) result on one of the above virologic tests from a specimen obtained on a different date, **OR**
 - No subsequent negative (nonreactive) result on an HIV antibody test and no subsequent negative (nonreactive) result on an HIV NAAT before age 18 months.

Clinical Evidence

The clinical evidence criteria for a confirmed case can be the same as the clinical criteria previously specified for “persons ≥18 months of age and children <18 months of age whose mothers were not infected”, **OR**

- All three of the following alternative criteria:
 - Evidence of perinatal exposure to HIV infection before age 18 months,
 - A mother with documented HIV infection,
 - A confirmed positive test for HIV antibody (e.g., a positive initial antibody test or antigen/antibody test, confirmed by a supplemental antibody test) and a mother whose infection status is unknown or undocumented, **AND**
- Diagnosis of an opportunistic illness indicative of AIDS (stage 3 HIV infection) [See page 10 for a list of opportunistic illnesses], **AND**
- No subsequent negative (nonreactive) result on an HIV antibody test.

2. CRITERIA FOR CLASSIFYING PERINATAL EXPOSURE TO HIV AND UNINFECTED CHILDREN <18 MONTHS OF AGE

Exposed

A child <18 months of age who is born to an HIV-infected mother is classified for surveillance purposes as perinatally exposed to HIV.

Uninfected

A child <18 months of age who is born to an HIV-infected mother is classified for surveillance purposes as not infected with HIV if all three of the following criteria are met:

- The aforementioned laboratory criteria for HIV infection among children <18 months of age are not met,
- No diagnosis of an AIDS (stage-3)-defining opportunistic illness attributed to HIV infection [See page 10 for a list of opportunistic illnesses], **AND**

- Either laboratory or clinical evidence of absence of HIV infection as described below:

For example:

- No positive (reactive) HIV NAAT (RNA or DNA) and at least one of the following:
 - Two negative (nonreactive) HIV NAATs from specimens obtained on different dates, both of which were at age ≥ 1 month and one of which was at age ≥ 4 months
 - At least two negative (nonreactive) HIV antibody tests from specimens obtained on different dates at age ≥ 6 months, **OR**
- A note in a medical record by a physician or other qualified medical-care provider states that the patient is not infected with HIV.

Special Note: The U.S. Department of Health and Human Services Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children: A Working Group of the Office of AIDS Research Advisory Council (OARAC) has issued recommendations on diagnosing and monitoring HIV infection in infants and children, including perinatal exposure to HIV infection [11].

3. SPECIAL CONSIDERATION ON CLASSIFYING HIV-2 INFECTIONS

All HIV infections in the United States should be assumed to be type 1 (HIV-1) unless laboratory test results are sufficient to classify the infection as type 2 (HIV-2), dual HIV-1 and HIV-2 infections, or undifferentiated HIV infection, as described below. Clinical or epidemiologic evidence might lead to laboratory testing for HIV-2 but is insufficient for classifying the HIV type as HIV-2. CDC considers any HIV-2 infection diagnosed within the U.S. a case of public health interest (COPHI). State HIV surveillance programs are required to notify CDC of all newly diagnosed HIV-2 infections reported to ascertain a special investigation worksheet that must be returned to CDC with patient identifiers removed upon completion.

Persons ≥ 18 Months of Age and Children < 18 Months Age Not Perinatally Exposed

HIV-2 infection

For HIV-2 infection, one or more of the following laboratory criteria are necessary:

- FDA-approved HIV 1/2 type-differentiating antibody test (e.g. HIV Multispot) result is positive (reactive) for HIV-2 and negative (nonreactive) for HIV-1,
- Positive (reactive) HIV-2 Western blot (WB) (or immunoblot or line assay) result and negative (nonreactive) or indeterminate HIV-1 WB result,
- Positive (reactive) qualitative HIV-2 NAAT result,
- Detectable quantitative HIV-2 NAAT (viral load), **OR**
- Laboratory results are interpreted as consistent with HIV-2 infection by a laboratory expert experienced in differentiating HIV-2 from HIV-1 if laboratory evidence for HIV-2 is ambiguous.

Dual infection with HIV-1 and HIV-2

The HIV type is classified as "dual" infection (both HIV-1 and HIV-2) if both an HIV-1 NAAT and an HIV-2 NAAT are positive (reactive).

Undifferentiated HIV type

The HIV type is classified as “undifferentiated” if there is no positive (reactive) or detectable result from an HIV-1 NAAT and a laboratory expert cannot resolve ambiguous evidence for HIV-2, such as:

- HIV-2 WB is positive (reactive) and HIV-1 WB is HIV positive (reactive), **OR**
- HIV-1/HIV-2 type-differentiating antibody test result interpretation is “undifferentiated” (positive for both HIV-1 and HIV-2).

HIV STAGE 3 (AIDS)-DEFINING OPPORTUNISTIC ILLNESSES

Bacterial infections, multiple or recurrent*

Candidiasis of bronchi, trachea, or lungs

Candidiasis of esophagus

Cervical cancer, invasive†

Coccidioidomycosis, disseminated or extrapulmonary

Cryptococcosis, extrapulmonary

Cryptosporidiosis, chronic intestinal (>1 month’s duration)

Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month

Cytomegalovirus retinitis (with loss of vision)

Encephalopathy attributed to HIV§

Herpes simplex: chronic ulcers (>1 month’s duration) or bronchitis, pneumonitis, or esophagitis (onset at age >1 month)

Histoplasmosis, disseminated or extrapulmonary

Isosporiasis, chronic intestinal (>1 month’s duration)

Kaposi sarcoma

Lymphoma, Burkitt (or equivalent term)

Lymphoma, immunoblastic (or equivalent term)

Lymphoma, primary, of brain

Mycobacterium avium complex or *Mycobacterium kansasii*, disseminated or extrapulmonary

Mycobacterium tuberculosis of any site, pulmonary†, disseminated, or extrapulmonary

Mycobacterium, other species or unidentified species, disseminated or extrapulmonary

Pneumocystis jirovecii (previously known as “*Pneumocystis carinii*”) pneumonia

Pneumonia, recurrent†

Progressive multifocal leukoencephalopathy

Salmonella septicemia, recurrent

Toxoplasmosis of brain, onset at age >1 month

Wasting syndrome attributed to HIV§

* Only among children aged <6 years.

† Only among adults, adolescents, and children aged ≥6 years.

§ Suggested diagnostic criteria for these illnesses, which might be particularly important for HIV encephalopathy and HIV wasting syndrome, are described in the following references: CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994; 43 (No. RR-12). CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992; 41 (No. RR-17).

Note

The U.S. Centers for Disease Control and Prevention (CDC) revised surveillance case definition for HIV infection (United States, 2014) takes into account advances in HIV testing technology, newer multi-test algorithms used in the diagnosis of HIV infection, including criteria to differentiate HIV-

1 and HIV-2 infections, and recognizes the importance of identifying new HIV infections at the earliest stage to assist in linking infected persons to medical and public health interventions. For public health surveillance analytical purposes only, a case of HIV infection is classified by increasing severity/progression using a staging system: stages 0 through 3 and stage unknown [4].

The surveillance case definition is intended for monitoring HIV infection burden, and assisting in planning for prevention and care, on a population level. ***It is not intended as a basis for clinical decision-making.*** The 2014 revised surveillance case definition for HIV infection replaces the previous HIV infection and AIDS surveillance case definitions [5-10].

SIGNS AND SYMPTOMS

In 50-80% of new cases of HIV, the patient will develop "acute retroviral syndrome." This can occur 1-3 weeks after exposure and is characterized by a mononucleosis-like syndrome consisting of fever, lymphadenopathy, pharyngitis, rash, myalgias, and sometimes diarrhea, headache, nausea and vomiting. During this phase HIV infection can often only be suspected because antibody tests for the HIV virus may sometimes be negative at this very early infection stage. In some instances, the acute retroviral syndrome is misinterpreted as a simple cold or flu for which the patient does not seek medical attention or in which a health care provider fails to consider HIV in the diagnosis. The acute retroviral syndrome usually resolves without treatment, so many people with HIV may be asymptomatic for up to ten years. Patients with known or suspected acute retroviral syndrome with risk factors for HIV infection should be immediately referred to an infectious disease, preferably an HIV/AIDS, specialist. In patients presenting with symptoms, they are often nonspecific, such as lymphadenopathy, anorexia, unexplained weight loss, chronic diarrhea, night sweats, fever and fatigue. Alternatively, patients can present with neurologic problems. Progression of immunosuppression is indicated by decreasing CD4 levels. Severe immunosuppression or certain opportunistic infections result in a diagnosis of AIDS.

DIAGNOSIS

Diagnosis is based upon laboratory evidence of HIV infection. HIV tests are available for use on blood, oral fluid and urine. Antibody (Ab), antigen (Ag), combination Ab/Ag, and nucleic acid amplification tests are widely available and used in the diagnosis of HIV infection.

EPIDEMIOLOGY

Source

HIV has been found in blood and blood products, semen, vaginal secretions, breast milk, saliva and tears. Evidence suggests that saliva and tears are not implicated in transmission of the virus.

Occurrence

Human disease caused by HIV was first recognized in the United States in 1981; however HIV, the causative agent, was not identified until 1983. All 50 U.S. states and territories have reported HIV and AIDS cases. In Ohio, each of Ohio's 88 counties has reported cases. Persons at risk for HIV infection include men who have sex with men, intravenous drug users, hemophiliacs who have received non-heat-treated blood products, persons who have had sexual contact with persons with HIV, recipients of blood transfusions or transplanted organs not tested for HIV antibody, and unborn and newborn children of mothers with HIV infection. HIV incidence disproportionately affects racial and ethnic minorities in Ohio as well as throughout the U.S.

Mode of Transmission

HIV has been isolated from blood and blood products, semen, vaginal secretions, breast milk, saliva and tears. Epidemiologic evidence indicates that HIV can be transmitted from person-to-person through sexual contact; by percutaneous exposure to contaminated blood, including the sharing of contaminated intravenous needles; by transfusion of contaminated blood or blood products; and from an infected pregnant woman to her unborn child. Although HIV has been isolated from saliva and tears, there is no evidence to support transmission of HIV through casual contact such as sharing of food or sharing eating utensils. Transmission has occurred in unusual circumstances of blood-to-blood contact. These situations include an intentional self-inoculation of contaminated blood, a blood-to-blood exposure after a bite resulting in severe tissue damage, and suspected transmission through a blood-contaminated toothbrush and razor. No animal or vector borne transmission has been documented.

Period of Communicability

Current evidence indicates that once a person is infected with HIV, infection and communicability persists for life. Communicability may vary as the body's viral load fluctuates with the stage of disease. Higher levels of circulating virus in the body are associated with increased likelihood of virus transmission from infected persons to non-infected persons, however; asymptomatic infected persons can transmit infection to others. Persons in any stage of HIV infection must be presumed infectious.

Incubation Period

Information from transfusion-associated cases of AIDS suggests an incubation period from infection to symptomatic AIDS ranging from six months to eight years or longer without HIV related treatment. With available treatments, onset of disease may be delayed beyond 10 years.

PUBLIC HEALTH MANAGEMENT

Cases

Investigation

Persons newly diagnosed with HIV infection should be interviewed to identify individuals who have had sexual or needle-sharing contact so that these individuals may be encouraged to seek HIV testing. The Ohio Department of Health's (ODH's) HIV Partner Counseling and Referral Services (PCRS) works with local public health agencies to provide this interviewing, contact notification, and initial linkage to care for cases reported to ODH. Call the ODH HIV/STD Prevention Program for details and referrals: 614-644-1838.

Treatment

Anti-retroviral treatment may significantly slow progression of HIV infection. Prophylactic treatment is available to prevent or decrease the severity of opportunistic infections. An ongoing relationship with a physician is essential for management of HIV infection, and an HIV/AIDS specialist should be consulted for current treatment options. CD4 and viral load tests are routinely performed to monitor the patient's immune status and efficacy of treatment, respectively. Assistance in locating and accessing medical and social services is provided for persons with HIV infection and is available from HIV case managers and linkage coordinators throughout Ohio. Call ODH HIV Care Services Program at 614-466-6374 to locate a case manager near the patient.

Isolation

Isolation is inappropriate, except for protection of patients with severe immunosuppression. However, cases should be counseled about avoiding behaviors that may result in blood or body fluid exposures that could infect others.

Contacts

Sexual/needle-sharing contacts

These individuals should be contacted, informed that they have been named as a contact of someone infected with HIV, encouraged to be tested for HIV, and counseled about avoiding HIV risk behaviors. ODH's Counseling, Testing and Referral Services (CTRS) works with local health and community organization to offer HIV testing services, and provide contact notification for cases reported to ODH. Call the ODH HIV/STD Prevention Program for details and referrals: 614-644-1838.

Occupational exposures

According to CDC, there have been less than 60 documented cases of occupational transmission of HIV to health care workers in the United States. Proper use of gloves and goggles, along with safety devices to prevent injuries from sharp medical devices, can help minimize the risk of exposure to HIV in the course of caring for patients with HIV. When workers are exposed, CDC recommends immediate treatment with a short course of antiretroviral drugs to prevent infection [13]. The Occupational Safety and Health Administration (OSHA) have established guidelines on occupational exposure to bloodborne pathogens and needle stick prevention [14].

Non-Occupational exposures

Non-occupational exposure is a general term for exposure to HIV outside an occupational or health care setting. Post-exposure prophylaxis (PEP) is treatment for a possible exposure to HIV. CDC has released guidelines that recommend providing antiretroviral medication following non-occupational exposure to HIV [15].

Post-exposure prophylaxis (PEP)

CDC has published PEP guidelines [15]. PEP involves taking antiretroviral medicines as soon as possible, but no later than 72 hours (i.e. 3 days) after a person is exposed to HIV to reduce the chance of becoming HIV infected. Two to three drugs are usually prescribed for a course of 28 days. PEP is not always effective and does not guarantee a person exposed to HIV will not become infected with HIV. Physician referral is necessary.

Pre-exposure prophylaxis (PrEP)

CDC has published interim PrEP guidelines targeting various high risk groups [16-18]. PrEP is a new HIV prevention method in which a person that does not have HIV infection takes a daily antiretroviral medicine to reduce their risk of becoming infected. The goal of PrEP is to prevent HIV infection for persons exposed to the virus. According to CDC, when used consistently, "PrEP has been shown to reduce the risk of HIV infection among adult men and women at very high risk for HIV infection through sex or injecting drug use. PrEP will not be right for everyone and is not intended to be used in isolation, but rather in combination with other methods to reduce the risk of transmitting HIV."

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Reporting Lab Results in Ohio from a Multistep HIV Diagnostic Testing Algorithm

Only applies to confidential (i.e. named) and not anonymous HIV testing results
 Laboratories should follow the test manufacturers' guidance in interpreting results

Tests performed	Test results	Report results?
Step 1. HIV 1/2 Ag/Ab combination immunoassay	Nonreactive	No. Do not report result
Step 1. HIV 1/2 Ag/Ab combination immunoassay Step 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 reactive and HIV-2 nonreactive	Yes. Report results of both tests
Step 1. HIV 1/2 Ag/Ab combination immunoassay Step 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 nonreactive and HIV-2 reactive	Yes. Report results of both tests (this is an HIV-2 infection)
Step 1. HIV 1/2 Ag/Ab combination immunoassay Step 2. HIV-1/HIV-2 antibody differentiation immunoassay Step 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive or indeterminate 3. RNA not detected	No. Do not report results
Step 1. HIV 1/2 Ag/Ab combination immunoassay Step 2. HIV-1/HIV-2 antibody differentiation immunoassay Step 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive 3. RNA detected	Yes. Report all results
Step 1. HIV 1/2 Ag/Ab combination immunoassay Step 2. HIV-1/HIV-2 antibody differentiation immunoassay Step 3. HIV-1 RNA assay	1. Reactive 2. Indeterminate 3. RNA detected	Yes. Report all results
Step 1. HIV 1/2 Ag/Ab combination immunoassay Step 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 reactive and HIV-2 reactive	Yes. Report results of both tests
Step 1. HIV 1/2 Ag/Ab combination immunoassay Step 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. Nonreactive or indeterminate	Testing is inconclusive. <i>CDC recommends follow-up testing for HIV Ab and HIV-1 RNA as soon as possible as this may be an acute HIV infection.</i>

- Adapted from *Laboratory Testing for Diagnosis of HIV Infection*. Centers for Disease Control and Prevention. Available at: <http://www.cdc.gov/hiv/pdf/HIVtestingAlgorithmRecommendation-Final.pdf> Accessed February 26, 2016.
 Ag=antigen; Ab=antibody

Tips When Talking with Patients about Behavioral Risk Factors for Acquiring HIV Infection

Although some patients may be uncomfortable disclosing personal risk factors such as sexual behaviors and illicit drug use, many patients want to have these discussions but may not initiate the discussion on their own. Some patients have greater confidence in their clinician's ability to provide high-quality care when asked about sexual and sexually transmitted infection (STI) history during the initial visits.

Why is it important for providers to ask about risk factors for HIV?

- To get an accurate history
- To screen appropriately for STIs
- To assess risk and provide information and support for risk reduction
- To prevent secondary transmission of HIV

How can I put my patients at ease?

- Reassure your patients that their responses will remain confidential.
 - Foster a relationship of trust, allowing open communication.
 - Acknowledge that this topic may be difficult to talk about.
 - Let them know that you ask all of your patients these types of questions.
 - Tell them that the information they provide about their sexual and drug-use behaviors will help you provide the best possible care.
 - Describe behaviors instead of assigning labels to the behavior. Use terms "drug user", "men who have sex with men", "women who have sex with women", or "sex worker".
 - Word questions in such a way to de-stigmatize behaviors
- Examples:
- "Some people inject drugs. Have you ever done that?"
 - "Some people have anal intercourse. Have you ever done that?"
 - "Some people exchange sex for drugs or money. Have you ever done that?"
- Respect a patient's choice to not answer a question. This increases the chance that she/he will provide the information at a later date when the subject is reintroduced.

How can I collect all the HIV risk information I need without overwhelming patients with a lot of questions?

Use open-ended questions when possible to avoid simple "yes" or "no" responses. This also helps you gather enough detail to understand potential transmission risks and make more meaningful recommendations for prevention of secondary transmission.

Examples:

- What do you know about HIV and the ways people can get/transmit it?
- Can you tell me about your current sexual activities?
- Are your sex partners' male, female, or both?
- Do your partners have any HIV risk factors that you are aware of (e.g. man who has sex with other men, injection drug user)?
- What kind of sexual contact do you have/have you had (vaginal, anal, oral, use of objects)?

At the end of the session

- Summarize the patient's responses to make certain that both you and your patient understand what was said.
- Encourage the patient to ask questions about any issues he or she might not have understood, and, if needed, schedule a follow-up appointment.

What is HIV?

Human immunodeficiency virus (HIV) is the virus that can lead to acquired immunodeficiency syndrome, or AIDS. Unlike some other viruses, the human body cannot get rid of HIV. That means that once you have HIV, you have it for life.

Who is at risk?

In the United States, HIV is spread mainly through anal or vaginal sex or by sharing drug-use equipment with an infected person. Substance use can contribute to these risks indirectly because alcohol and other drugs can lower people's inhibitions and make them less likely to use condoms.

- Gay and bisexual men are more severely affected by HIV than any other group in the United States.
- Among men with HIV, black/African American men who have sex with other men have the highest rates of HIV.
- One in four people living with HIV infection in the United States are women.
- Most new HIV infections in women are from heterosexual contact (84%). Only about half of women who are diagnosed with HIV are in care.
- Substance use and abuse are important factors in the spread of HIV.
- Vulnerable populations (e.g., people living in poverty, those with mental illness, and those with a history of abuse) are more likely to have high rates of alcohol and substance use.

How do you get HIV?

Only certain body fluids—blood, semen, vaginal fluids, and breast milk—from an HIV-infected person can transmit HIV. These fluids must come in contact with a mucous membrane or damaged tissue or be directly injected into the bloodstream (from a needle or syringe) for transmission to possibly occur. Mucous membranes can be found inside the rectum, the vagina, the opening of the penis, and the mouth.

HIV is not spread through food or water or by casual contact.

Can you get HIV from receiving medical care?

Although HIV transmission is possible in health care settings, it is extremely rare. Careful practice of infection control, including universal precautions (i.e., using protective practices and masks and gloves to prevent HIV and other blood-borne infections) protects patients and health care providers from possible HIV transmission in medical and dental offices and hospitals.

The risk of getting HIV from receiving blood transfusions, blood products, or organ/tissue transplants that are contaminated with HIV is extremely small because of rigorous testing of the US blood supply and donated organs and tissues.

How do you know if you have HIV?

You cannot rely on symptoms to know whether you have HIV. The only way to know for sure if you are infected with HIV is to get tested.

Is there a cure for HIV?

Although there is no cure for HIV infection, there are treatment options that can help people living with HIV experience long and productive lives.

If you are pregnant, should you worry about HIV?

Perinatal transmission occurs when HIV is transmitted from a woman to a fetus or child during pregnancy, labor, delivery, or breastfeeding. Unprotected sexual activity is common throughout pregnancy, especially when condoms are no longer used for contraception. Early prenatal care provides opportunities for treatment that can reduce the risk of mother-to-child transmission. All pregnant women should be screened for HIV as early as possible during each pregnancy. Women with HIV who take antiretroviral medication during pregnancy can reduce the risk of transmitting HIV to their babies to less than 1%.

Should I get an HIV Test?

The following are behaviors that increase your chances of getting HIV. If you answer yes to any of them, you should definitely get an HIV test. If you continue with any of these behaviors, you should be tested every year. Talk to a health care provider about an HIV testing schedule that is right for you.

- Have you injected drugs, including steroids or shared equipment (such as needles, syringes, works) with others?
- Have you had unprotected vaginal, anal or oral sex with men who have sex with men, multiple partners, or anonymous partners?
- Have you exchanged sex for drugs or money?
- Have you been diagnosed with or treated for hepatitis, tuberculosis (TB), or a sexually transmitted disease (STD), like syphilis?
- Have you had unprotected sex with someone who could answer yes to any of the above questions?
- All pregnant women should be screened for HIV as early as possible during each pregnancy.

If I do not want to go to my doctor, where can I go to get tested for HIV?

The Ohio Department of Health (ODH) provides free and confidential HIV testing. The HIV test used provides results within 20 minutes and does not involve needles. Patients learn their status in a single visit and newly diagnosed HIV-positive patients are linked to medical care immediately. To find an HIV test site in your area, visit www.preventhivstdohio.net or call 1-800-332-AIDS.