

HIV & AIDS Epidemiological Overview for Florida Providers

Faculty

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Purpose

The purpose of this CME activity is to provide an overview of key aspects of HIV/AIDS disease to fulfill the legislative requirements of: Florida Board of Medicine, Florida Board of Osteopathic Medicine, Florida Board of Podiatric Medicine and Florida Board of Nursing.

Objectives

- Discuss the epidemiology of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS).
- 2. Explain the etiology of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS).
- 3. Describe HIV modes of transmission including infection control strategies in preventing the transmission of HIV/AIDS.
- 4. Discuss the current Florida laws on HIV/AIDS, including impact on testing, offering of HIV testing to pregnant women, maintaining confidentiality of test results, reporting, and treatment including counseling of patients.

Disclaimer

- This information in this educational activity is provided for general medical education purposes only and is not meant to substitute for the independent medical judgment of a physician relative to diagnostic and treatment options of a specific patient's medical condition. The viewpoints expressed in this CME activity are those of the authors/faculty. They do not represent an endorsement by Flagler Hospital, Inc. In no event will Flagler Hospital, Inc. be liable for any decision made or action taken in reliance upon the information provided through this CME activity.
- It is the healthcare providers responsibility to understand and abide by the full text of specific Florida Statutes and Administrative Codes governing HIV/AIDS regarding testing, informed consent, reporting of results, counseling, and confidentiality as summarized in the following slides. Links to the complete content of Florida Statutes and Florida Administrative Codes are provided within the slides.

HIV/AIDS: Key Historical Markers

Pre-1980

1959: First case of HIV-1 infection detected in a blood sample from a man in Kinshasa, Democratic Republic of the Congo (mode of transmission unknown)

Avert (2020). *History of HIV and AIDS Overview*. Retrieved from https://www.avert.org/professionals/history-hiv-aids/overview

1980s

1982: CDC used the term 'AIDS' (acquired immune deficiency syndrome) for the first time, describing it as a disease at least moderately predictive of a defect in cell mediated immunity, occurring in a person with no known case for diminished resistance to that disease.

1983: CDC identified all major routes of HIV transmission, ruling out transmission by casual contact, food, water, air or surfaces

1984: National Cancer Institute announced they had found the cause of AIDS, the retrovirus HTLV-III/LAV. A blood test was created to screen for HIV.

1985: U.S Food and Drug Administration (FDA) licensed the first commercial blood test, ELISA, to detect HTLV-III/LAV antibodies. Blood banks began to screen the USA blood supply.

1986: International Committee on the Taxonomy of Viruses officially changed the name of the AIDS virus from HTLV-III/LAV to HIV (human immunodeficiency virus).

1987: FDA approved the first HIV antiretroviral treatment drug, zidovudine (AZT). FDA approved the western blot blood test kit, a more specific HIV antibody test. The World Health Organization confirmed HIV could be passed from mother to child during breastfeeding.

1988: Nationwide HIV and AIDS care system in the USA is funded by the Ryan White CARE Act (see https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program).

1990s

1990: USA enacted the Americans with Disabilities Act (ADA) which prohibits discrimination against those with disabilities including people living with HIV. FDA approved the use of zidovudine (AZT) to treat children with AIDS.

1992: FDA licensed a 10 minute testing kit for healthcare professionals to use in detecting HIV.

1993: CDC added pulmonary tuberculosis, recurrent pneumonia and invasive cervical cancer to the list of AIDS indicators.

1994: USA Public Health Service recommended use of AZT to prevent mother-to-child transmission of HIV. FDA approved an oral HIV test - the first non-blood HIV test.

1995: FDA approved the first protease inhibitor beginning a new era of highly active antiretroviral treatment (HAART).

1996: FDA approved the first home testing kit, a viral load test to measure the level of HIV in the blood, the first non-nucleoside transcriptase inhibitor (NNRTI) drug (nevirapine), and the first HIV urine test.

1997: FDA approved Combivir, a combination of two antiretroviral drugs taken as a single daily tablet.

1998: CDC published first national treatment guidelines for antiretroviral therapy in adults and adolescents with HIV.

1999: CDC released a new HIV case definition to help state health departments expand their HIV surveillance and tracking.

HIV/AIDS: Key Historical Markers continued

2000s

2000: U.S. Congress reauthorized the Ryan White CARE Act. ²

2001: U.S. Centers for Disease Control and Prevention (CDC) announced a new HIV Prevention Strategic Plan to cut annual HIV infections in the U.S. by half within five years. ²

2002: FDA approved the first rapid HIV test with 99.6% accuracy and a result in 20 minutes.¹

2004: U.S. Food and Drug Administration (FDA) approved use of oral fluid samples with a rapid HIV diagnostic test kit, which provided results in approximately 20 minutes.²

2006: Male circumcision was found to decrease the chance of female-to-male HIV transmission by 53-60%. It was emphasized male circumcision should be considered in areas with high HIV and low male circumcision prevalence.¹

2007: WHO and UNAIDS issued new guidance recommending "provider-initiated" HIV testing in healthcare settings. This aimed to widen knowledge of HIV status and greatly increase access to HIV treatment and prevention. ¹

2009: U.S. Food and Drug Administration (FDA) approves the 100th antiretroviral drug. ²

2010s

2011: FDA approved Complera, the second all-in-one fixed dose combination tablet, expanding treatment options available for people living with HIV. $^{\rm 1}$

2012: FDA approved PrEP for HIV-negative people to prevent sexual transmission of HIV. ¹

2014: UNAIDS "Fast Track" targets called for dramatic scaling-up of HIV prevention and treatment programs to avert 28 million new infections and end the epidemic as a public health issue by 2030.¹

2017: More than half of the global population living with HIV are receiving antiretroviral treatment, a record of 19.5 million people.¹

2018: National Institutes of Health (NIH) launches a large international study to compare the safety and efficacy of antiretroviral treatment regimens for both pregnant women and their infants who have HIV. ²

2018: An international research team found that early antiretroviral therapy (ART) is key to avoiding brain atrophy for people living with HIV. 2

2019: National Institutes of Health (NIH) funded scientists developed a new tool to measure success of HIV cure strategies. The tool accurately and easily counts cells that make up the HIV reservoir, the stubborn obstacle to an HIV cure. ²

1. Avert (2020). *History of HIV and AIDS Overview*. Retrieved from https://www.avert.org/professionals/history-hiv-aids/overview

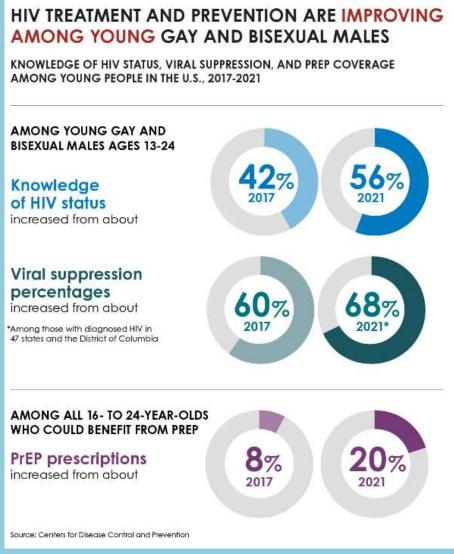
2. HIV.gov (n.d). A timeline of HIV and AIDS. Retrieved from https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline

World Health HIV/AIDS: 2023 Statistics

- HIV remains a major global public health issue, having claimed 40.4 million [32.9 - 51.3 million] lives so far with ongoing transmission in all countries globally
- There were an estimated 39.0 million [33.1-45.7 million] people living with HIV at the end of 2022, two thirds of whom (25.6 million) are in the WHO African Region.
- In 2022, 630,000 [480,000 880,000] people died from HIV-related causes and 1.3 million [1.0 1.7 million] people acquired HIV

Centers for Disease Control and Prevention: HIV/AIDS: 2023 Update HIV TREATMENT AND PREVENTION ARE IN AMONG YOUNG GAY AND RISEXUAL MANNEY TO THE PROPERTY OF THE PROPERTY OF

- Estimated annual new HIV infection rates have decreased by 12% in 2021 compared to 2017- decreasing from approximately 36,500 infections to approximately 32,100
- The decline was driven by a 34% decrease in new infections among 13 to 24-year-olds, mostly gay and bisexual males
- The CDC estimates annual HIV infections decreased from 9,300 in 2017 to 6,100 in 2021 among 13 to 24-year olds

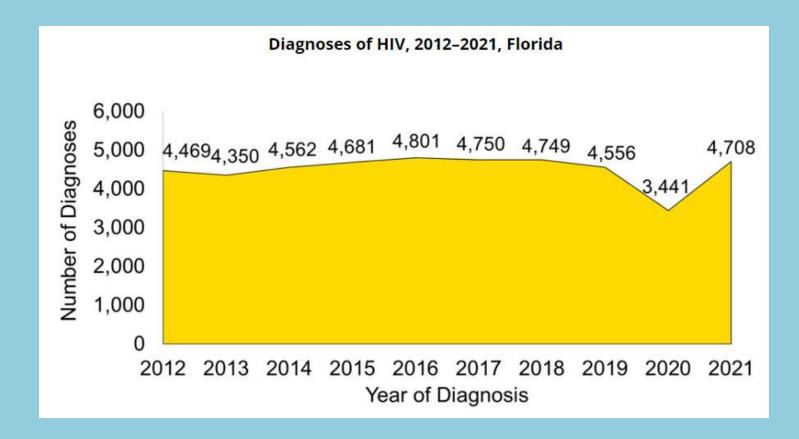


Florida HIV/AIDS Diagnosis by Year: 2012-2021

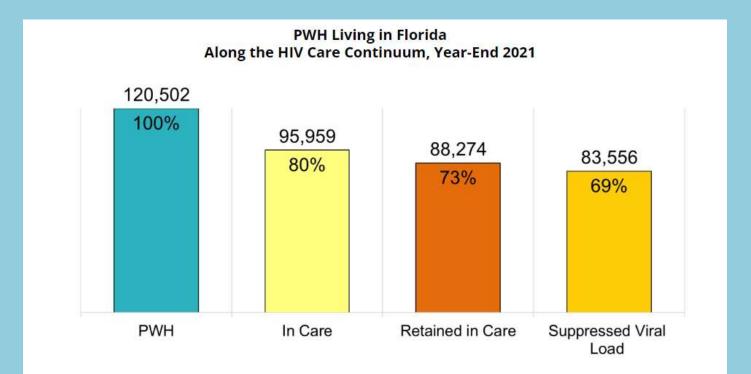
Florida tracks HIV/AIDS cases by the year they were diagnosed and by the year they are reported.

- Year of diagnosis: the year an individual is first diagnosed with HIV/AIDS.
- Year of report: reflects the year an individual's case is first reported to the Florida Department of Health

NOTE: The year of diagnosis and the year of report may be different for each case because there are specific requirements set by the CDC for when an HIV/AIDS case is considered reportable, even though the individual has been diagnosed. Data for 2020 and 2021 should be interpreted with caution due to the impact of COVID-19 on HIV testing, care-related services, and case surveillance activities.



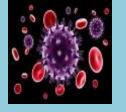
Florida Individuals Diagnosed and Living with HIV



Care Continuum Definitions

- PWH: The number of persons with an HIV diagnosis living in Florida at the end of 2021
- In Care: PWH with at least one documented viral load or CD4 lab, medical visit, or prescription from 1/1/2021 to 3/31/2022
- Retained in Care: PWH with two or more documented viral load or CD4 labs, medical visits, or prescriptions at least three months apart from 1/1/2021 to 6/30/2022
- Suppressed Viral Load: PWH with a suppressed viral load (<200 copies/mL) on the last viral load test from 1/1/2021 to 3/31/2022

HIV/AIDS: Etiology



- Formally called human T-cell lymphotropic virus-type III/lymphadenopathy-associated virus
 (HTLV-III/LAV), a member of the retrovirus group and as such carries a ribonucleic acid (RNA)
 genome and a reverse transcriptase enzyme (RNA-directed DNA polymerase) that enables
 virus to replicate within the host
- HIV attacks the human body's immune system, reducing the number of CD4 cells (T lymphocytes) in the body increasing an individual's risk of getting other infections
- The loss of CD4 cells makes it difficult for the body to fight off infections and certain cancers
- HIV does not live long outside the body and cannot reproduce outside the human body
- HIV causes AIDS if not treated
- Individuals diagnosed with HIV, viral load can become untraceable if antiretroviral therapy medication (ART) is taken properly (as prescribed)
- If the viral load remains undetectable, individuals can live long healthy lives and have no risk of transmitting HIV to an individuals who have not been diagnosed with HIV

HIV/AIDS: Etiology continued

- AIDS Acquired Immunodeficiency Syndrome
- Transferred via Human Immunodeficiency Virus (HIV) through blood, vaginal fluid, semen and breast milk
- Diagnosed when CD4 T cell count decreases below 200
- Diagnosed in conjunction with opportunistic infection
 - Pneumocystis pneumonia (PCP)- infection of the lungs
 - Kaposi's sarcoma (KS)- skin cancer
 - Cytomegalovirus (CMV)- infection typically affecting the eyes
 - Candida- fungal infection that can cause thrush or infections in the throat or vagina
- AIDS-related manifestations
 - Serious weight-loss
 - Extreme fatigue
 - Swelling of lymph nodes
 - Sores of mouth, anus, or genitals
 - Prolonged diarrhea
 - Brain tumors

Stages of HIV/AIDS: Etiology continued

Stage 1 Acute HIV infection

- Within 2-4 weeks, individuals diagnosed with HIV may have a flu-like illness that could last for a few weeks
- Acute HIV causes a large amount of virus in the blood and individuals highly contagious
- Symptoms: Fever, headache, muscle pain, rash, sore throat and painful mouth blisters, swollen lymph gland, night sweats

Stage 2

Clinical latency (HIV inactive or dormant)

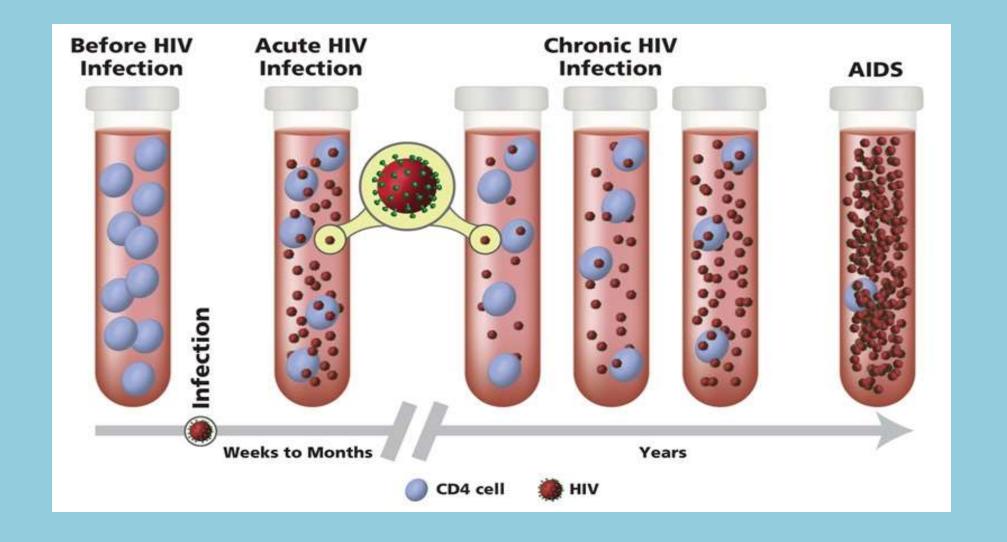
- HIV is active & transmissible, low virus reproduction
- Individuals who are taking their ART medication, may live at this stage for several decades
- Individuals can progress to stage 3 quickly if ART medication are not taken appropriately
- Symptoms: fever, body rash, sore throat, swollen glands, joint/muscle aches, GI issues

Stage 3

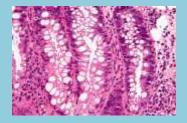
Acquired Immunodeficiency Syndrome (AIDS)

- Most severe stage of HIV
- Immune system is damaged, increased risk of opportunistic illnesses
- Symptoms: weight loss, chronic diarrhea, night sweats, fever, persistent cough, mouth & skin problems

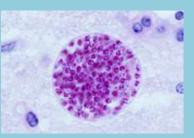
Stages of HIV/AIDS: Etiology continued



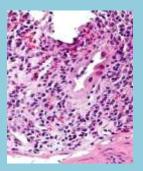
Common Infections Associated with HIV/AIDS



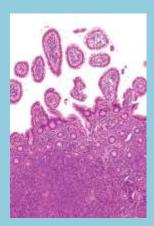
Cryptosporidiosis



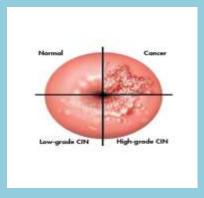
Toxoplasmosis



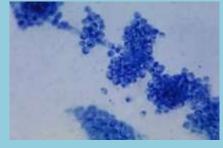
Cytomegalovirus



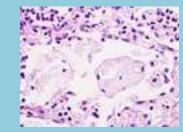
Lymphoma



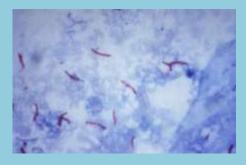
Cervical Cancer



Candidiasis



Cryptococcal Meningitis



Tuberculosis (TB)



Kaposi's Sarcoma

Independent Study: Read "Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV by Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents"

https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf

Transmission of HIV

HIV is Transmitted By:

- Blood (blood transfusions) & organ/tissue donations
- Semen
- Pre-seminal fluid
- Rectal fluids
- Vaginal fluids (birth)
- Breast milk
- Sharing needles or syringes
- Vaginal or anal sex
- Eating food previously chewed by HIV+ individual (i.e. mothers to babies)

HIV is **NOT** Transmitted By:

- Air or water
- Saliva, sweat, tears, or social kissing (closed-mouth kissing)
- Insects or pets
- Sharing toilets
- Sharing food/drinks
- Shaking hands
- Sharing utensils/dishes/other household items
- Hard surfaces

Testing for HIV: Recommendations

- U.S. Preventive Services Task Force (USPSTF) & Agency for Healthcare Research Quality (AHRQ) recommend that:
 - All persons 15 to 65 years of age should be tested regardless of risk status and all pregnant women should be screened/tested prior to childbirth
 - Persons younger than 15 and older than 65 years of age who are at increased risk (i.e. new sexual partner, risky sexual behaviors, sharing needles) should be screened/tested
- However, CDC recommends everyone between 13 and 64 years of age get tested for HIV at least once
- Florida has specific statutes and laws related to HIV/AIDS that provide guidance regarding testing, transmission, prevention, reporting, treatment, and partner notification. This activity provides an overview of HIV/AIDS related statutes and laws that are applicable for use by healthcare providers in counseling patients.

Testing for HIV: Florida Law - Consent

Fla. Admin. Code r. 64D-2.004

Testing Requirement

- (1) Prior to testing for HIV, the notification and consent requirements of sections 381.004(2)(a) and (b), F.S., must be met.
- (2) Informed consent to perform a test for HIV in a non-health care setting need not be in writing if there is documentation in the medical record that the test has been explained and consent has been obtained.
- (3) In health care and non-health care settings, informed consent to perform a test for HIV shall be in writing for the following:
- (a) Prior to the first donation of blood, blood components, organs, skin, semen, or other human tissue or body part in accordance with section 381.0041, F.S. The consent form must specify that the donor is consenting to repeated HIV testing of each donation for the subsequent year. The consent form must be signed annually prior to transfusion or other use;
- (b) Prior to testing for HIV for insurance purposes, in accordance with section 627.429, F.S., or
- (c) Prior to testing for HIV for contract purposes in a health maintenance organization, in accordance with section 641.3007, F.S.
- (4) The following minors can be tested for HIV without parental consent:
- (a) Any minor who requests examination, testing, consultation or treatment for a sexually transmissible disease, including HIV, in accordance with section 384.30, F.S.
- (b) Any minor who has reached the age of 17 years, in compliance with section 743.06, F.S.
- (c) Any married minor or unwed pregnant minor, in accordance with sections 743.01 and 743.065, F.S.
- (5) Pursuant to section 381.004(7), F.S., the Department of Health developed the Model Protocol for HIV Counseling and Testing In Health Care Settings, dated June 30, 2017, and the Model Protocol for HIV Counseling and Testing In Non-Health Care Settings, dated June 30, 2017, consistent with the provisions of this section and incorporates these documents by reference in this rule. The model protocols can be obtained at https://www.flrules.org/Gateway/reference.asp?No=Ref-09328, and https://www.flrules.org/Gateway/reference.asp?No=Ref-09328, and https://www.flrules.org/Gateway/reference.asp?No=Ref-09328.
- (6) Persons ordering an HIV test must ensure that all reasonable efforts are made to notify the test subject of the test result and relate certain information to the test subject in accordance with section 381.004(2)(c), F.S., and the applicable Model Protocol for HIV Counseling and Testing specified in subsection (5), above. Blood establishments and persons who collect blood, organs, skin, semen, or other human tissue or body parts shall comply with Rule 64D-2.005, F.A.C., and sections 381.0041(5), and (6), F.S. https://www.flrules.org/gateway/RuleNo.asp?ID=64D-2.004

Testing for HIV in Pregnancy: Florida Law

Fla. Stat. Ann. § 384.31 Testing of Pregnant Women; duty of the attendant

Every person, including every physician licensed under chapter 458 or chapter 459 or midwife licensed under part I of chapter 464 or chapter 467, attending a pregnant woman for conditions relating to pregnancy during the period of gestation and delivery shall cause the woman to be tested for sexually transmissible diseases, including HIV, as specified by department rule. Testing shall be performed by a laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder for such purposes. The woman shall be informed of the tests that will be conducted and of her right to refuse testing. If a woman objects to testing, a written statement of objection, signed by the woman, shall be placed in the woman's medical record and no testing shall occur.

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0384/Sections/0384.31.html

Testing for HIV in Pregnancy: Florida Law cont'd

Fla. Admin. Code r. 64D-3.042

STD Testing Related to Pregnancy

- (1) Practitioners attending a woman for prenatal care shall cause the woman to be tested for chlamydia, gonorrhea, hepatitis B, HIV and syphilis as follows:
- (a) At initial examination related to her current pregnancy; and again.
- (b) At 28 to 32 weeks gestation.
- (2) Exceptions to the testing outlined in subsection (1), above, are as follows:
- (a) A woman, who tested positive for hepatitis B surface antigen (HbsAg) during the initial examination related to her current pregnancy, need not be re-tested at 28-32 weeks gestation.
- (b) A woman, with documentation of HIV infection or AIDS need not be re-tested during the current pregnancy.
- (3) Women who appear at delivery or within 30 days postpartum with:
- (a) No record of prenatal care, or
- (b) Prenatal care with no record of testing;
- (c) Prenatal care with no record of testing after the 27th week of gestation shall be considered at a high risk for sexually transmissible diseases and shall be tested for hepatitis B surface antigen (HBsAg), HIV and syphilis prior to discharge.
- (4) Emergency Departments of hospitals licensed under Chapter 395, F.S., may satisfy the testing requirements under this rule by referring any woman identified as not receiving prenatal care after the 12th week of gestation, to the county health department.
- (a) The referral shall be in writing; and,
- (b) A copy shall be submitted to the county health department having jurisdiction over the area in which the emergency department is located.

https://www.flrules.org/gateway/ruleno.asp?id=64D-3.042&Section=0

Testing for HIV in Pregnancy: Florida Law cont'd

Fla. Admin. Code r. 64D-3.042 STD Testing Related to Pregnancy cont'd

- (5) Prior to any testing required by this rule, practitioners shall:
- (a) Notify the woman which tests will be conducted;
- (b) Inform the woman of her right to refuse any or all tests;
- (c) Place a written statement of objection signed by the woman each time she refuses required testing in her medical record specifying which tests were refused. If the woman refuses to sign the statement, the provider shall document the refusal in the medical record. No testing shall occur for the infections specified in the refusal statement of objection.
- (6) Women who had a serologic test for syphilis during pregnancy that was reactive, regardless of subsequent tests that were non-reactive shall be tested as soon as possible at or following delivery.
- (7)(a) Specimens shall be submitted to a laboratory certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder to perform tests for chlamydia, gonorrhea, hepatitis B surface antigen (HBsAg), HIV and syphilis.
- (b) The practitioner submitting the specimens for testing to a certified laboratory shall state that these specimens are from a pregnant or postpartum woman.
- (8) Practitioners required by law to prepare birth and stillbirth certificates shall document on the certificate if chlamydia, gonorrhea, hepatitis B, HIV, syphilis infections or genital herpes or genital human papilloma virus were present and/or treated during this pregnancy.
- (9) Nothing in this rule shall prohibit a practitioner from testing these women for other sexually transmissible diseases in accordance to prevailing national standards, community disease distribution or the professional judgment of the practitioner.

https://www.flrules.org/gateway/ruleno.asp?id=64D-3.042&Section=0

Reporting of HIV Test Results: Florida Law

Fla. Stat. Ann. §384.25 Reporting required.

- (1) Each person who makes a diagnosis of or treats a person with a sexually transmissible disease and each laboratory that performs a test that concludes with a positive result for a sexually transmissible disease or a result indicative of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) shall report such facts as may be required by the department by rule, within a time period as specified by rule of the department, but in no case to exceed 2 weeks.
- (2) The department shall adopt rules specifying the information required and the maximum time period for reporting a sexually transmissible disease. In adopting such rules, the department shall consider the need for information, protections for the privacy and confidentiality of the patient, and the practical ability of persons and laboratories to report in a reasonable fashion.
- (3) To ensure the confidentiality of persons infected with the human immunodeficiency virus (HIV), reporting of HIV infection and AIDS must be conducted using a system developed by the Centers for Disease Control and Prevention of the United States Public Health Service or an equivalent system.
- (a) The department shall adopt rules requiring each physician and laboratory to report any newborn or infant up to 18 months of age who has been exposed to HIV. Such rules may include the method and time period for reporting, which may not exceed 2 weeks, information to be included in the report, enforcement requirements, and follow up activities by the department.
- (b) The reporting may not affect or relate to anonymous HIV testing programs conducted pursuant to s. 381.004(3).
- (c) After notification of the test subject, the department may, with the consent of the test subject, notify school superintendents of students and school personnel whose HIV tests are positive.
- (4) Each person who violates the provisions of this section or the rules adopted hereunder may be fined by the department up to \$500 for each offense. The department shall report each violation of this section to the regulatory agency responsible for licensing each health care professional and each laboratory to which these provisions apply.

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0384/Sections/0384.25.html

Reporting of HIV Test Results: Florida Law

Fla. Stat. Ann. § 775.0877
Diseases or Conditions to be Reported

(1) Diseases or conditions listed in subsection (3), below, are identified by the Department as being of public health significance. These diseases or conditions must be reported by the practitioner, hospital, laboratory, or other individuals via telephone (with subsequent written report within 72 hours, see Rules 64D-3.030-.033, F.A.C.), facsimile, electronic data transfer, or other confidential means to the Department, which includes the County Health Departments. Reporters are not prohibited from reporting diseases or conditions not listed by rule. Reports should include all associated testing results performed (e.g. serogroup, serotype, and antimicrobial susceptibility results). Physicians and other healthcare providers using point of care tests for diagnosis of infectious diseases must report test results to the Department when they are indicative of an infectious disease reportable directly to the Department by laboratories unless such point of care testing is subject to routine reflex testing by a supplementary or confirmatory testing the results of which would be reportable.

Practitioner Reporting					Laboratory Reporting					
	Timeframes			mes	Evidence of current or recent	Timeframes				
Reportable Diseases or Conditions	Suspect Immediately	Immediately	Next Business Day	Other	infection with etiological agents and all associated testing results performed should be reported (e.g. species, serogroup, serotype, and antimicrobial susceptibility *2 results)	Submit isolates or specimens for confirmation *1	Suspect Immediately	Immediately	Next Business Day	Other
Acquired Immune				2	Acquired Immune	Laboratory Reporting Not				
Deficiency Syndrome (AIDS)				weeks	Deficiency Syndrome (AIDS)	Applicable				
Human immunodeficiency virus (HIV) infection				2 weeks	Repeatedly reactive enzyme immunoassay, followed by a positive confirmatory tests, (e.g. Western Blot, IFA): Positive result on any HIV virologic test (e.g. p24 AG, Nucleic Acid Test (NAT/NAAT) or viral culture). All viral load (detectable and undetectable) test results.*14,					3 days
Human immunodeficiency virus (HIV) Exposed Newborn – infant < 18 months of age born to a HIV infected woman			x		All HIV test results (e.g., positive or negative immunoassay, positive or negative virologic tests) for those < 18 months of age					3 days

Reporting HIV Test Results & Confidentiality: Florida Law

Fla. Stat. Ann. §381.004(2)(e)
Human Immunodeficiency Virus Testing; Informed consent; Results; Counseling; Confidentiality

- (e) Except as provided in this section, the identity of any person upon whom a test has been performed and test results are confidential and exempt from the provisions of s. 119.07(1). No person who has obtained or has knowledge of a test result pursuant to this section may disclose or be compelled to disclose the identity of any person upon whom a test is performed, or the results of such a test in a manner which permits identification of the subject of the test, except to the following persons:
- 1. The subject of the test or the subject's legally authorized representative.
- 2. Any person, including third-party payors, designated in a legally effective release of the test results executed prior to or after the test by the subject of the test or the subject's legally authorized representative. The test subject may in writing authorize the disclosure of the test subject's HIV test results to third party payors, who need not be specifically identified, and to other persons to whom the test subject subsequently issues a general release of medical information. A general release without such prior written authorization is not sufficient to release HIV test results.
- 3. An authorized agent or employee of a health facility or health care provider if the health facility or health care provider itself is authorized to obtain the test results, the agent or employee participates in the administration or provision of patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a need to know such information. The department shall adopt a rule defining which persons have a need to know pursuant to this subparagraph.
- 4. Health care providers consulting between themselves or with health care facilities to determine diagnosis and treatment. For purposes of this subparagraph, health care providers shall include licensed health care professionals employed by or associated with state, county, or municipal detention facilities when such health care professionals are acting exclusively for the purpose of providing diagnosis or treatment of persons in the custody of such facilities.
- 5. The department, in accordance with rules for reporting and controlling the spread of disease, as otherwise provided by state law.
- 6. A health facility or health care provider which procures, processes, distributes, or uses:
- a. A human body part from a deceased person, with respect to medical information regarding that person; or
- b. Semen provided prior to July 6, 1988, for the purpose of artificial insemination.
- 7. Health facility staff committees, for the purposes of conducting program monitoring, program evaluation, or service reviews pursuant to chapters 395 and 766.
- 8. Authorized medical or epidemiological researchers who may not further disclose any identifying characteristics or information.

Reporting HIV Test Results & Confidentiality: Florida Law

Fla. Stat. Ann. §381.004(2)(e) continued

- 9. A person allowed access by a court order which is issued in compliance with the following provisions:
- a. No court of this state shall issue such order unless the court finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for disclosure against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters blood, organ, and semen donation and future human immunodeficiency virus-related testing or which may lead to discrimination. This paragraph shall not apply to blood bank donor records.
- b. Pleadings pertaining to disclosure of test results shall substitute a pseudonym for the true name of the subject of the test. The disclosure to the parties of the subject's true name shall be communicated confidentially in documents not filed with the court.
- c. Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party.
- d. Court proceedings as to disclosure of test results shall be conducted in camera, unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.
- e. Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure which shall specify the persons who may have access to the information, the purposes for which the information shall be used, and appropriate prohibitions on future disclosure.
- 10. A person allowed access by order of a judge of compensation claims of the Division of Administrative Hearings. A judge of compensation claims shall not issue such order unless he or she finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means.
- 11. Those employees of the department or of child-placing or child-caring agencies or of family foster homes, licensed pursuant to s. 409.175, who are directly involved in the placement, care, control, or custody of such test subject and who have a need to know such information; adoptive parents of such test subject; or any adult custodian, any adult relative, or any person responsible for the child's welfare, if the test subject was not tested under subparagraph (b)2. and if a reasonable attempt has been made to locate and inform the legal guardian of a test result. The department shall adopt a rule to implement this subparagraph.
- 12. Those employees of residential facilities or of community-based care programs that care for developmentally disabled persons, pursuant to chapter 393, who are directly involved in the care, control, or custody of such test subject and who have a need to know such information.
- 13. A health care provider involved in the delivery of a child can note the mother's HIV test results in the child's medical record.
- 14. Medical personnel or nonmedical personnel who have been subject to a significant exposure during the course of medical practice or in the performance of professional duties, or individuals who are the subject of the significant exposure as provided in subparagraphs (h)10.-12.
- 15. The medical examiner shall disclose positive HIV test results to the department in accordance with rules for reporting and controlling the spread of disease.

Reporting HIV Test Results & Confidentiality: Florida Law

Fla. Stat. Ann. §381.004 (2)(f)

(f) Except as provided in this section, the identity of a person upon whom a test has been performed is confidential and exempt from the provisions of s. 119.07(1). No person to whom the results of a test have been disclosed may disclose the test results to another person except as authorized by this subsection and by ss. 951.27 and 960.003. Whenever disclosure is made pursuant to this subsection, it shall be accompanied by a statement in writing which includes the following or substantially similar language: "This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is NOT sufficient for this purpose." An oral disclosure shall be accompanied by oral notice and followed by a written notice within 10 days, except that this notice shall not be required for disclosures made pursuant to subparagraphs (e)3. and 4.

http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0300-0399/0381/Sections/0381.004.html

Florida Law: Criminal Transmission of HIV

Fla. Stat. Ann. § 381.0041(11)(b) Third Degree Felony

Any person who has human immunodeficiency virus infection, who knows he or she is infected with human immunodeficiency virus, and who has been informed that he or she may communicate this disease by donating blood, plasma, organs, skin, or other human tissue who donates blood, plasma, organs, skin, or other human tissue is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0381/Sections/0381.0041.html

Fla. Stat. Ann. §384.24(2) Third Degree Felony

It is unlawful for any person who has human immunodeficiency virus infection, when such person knows he or she is infected with this disease and when such person has been informed that he or she may communicate this disease to another person through sexual intercourse, to have sexual intercourse with any other person, unless such other person has been informed of the presence of the sexually transmissible disease and has consented to the sexual intercourse. http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0300-0399/0384/Sections/0384.24.html

Fla. Stat. Ann. § 384.34(5) Multiple Violations-first degree

Any person who violates s. 384.24(2) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Any person who commits multiple violations of s. 384.24(2) commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0384/Sections/0384.34.html

Florida Law: Criminal Transmission of HIV

Fla. Stat. Ann. § 775.0877 Third Degree Felony

A person who pleads guilty or nolo contendere to, or is convicted of, committing or attempting to commit one of the crimes that is listed in subsection (1) of this statute and involves the transmission of bodily fluids from one person to another, who subsequently tests positive for HIV and is informed of that test result, and who then again commits one of the crimes listed in subsection (1) is guilty of criminal transmission of HIV, a felony of the third degree. The offenses listed in subsection (1) include, among others, sexual assault, incest, child abuse, indecent assault upon a minor child, sexual performance by a minor, and donation of contaminated blood. It is an affirmative defense that the person exposed knew the infected person was infected with HIV, knew the action could result in infection, and consented with that knowledge.

http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0700-0799/0775/Sections/0775.0877.html

Fla. Stat. Ann. § 796.08(5) Third Degree Felony

A person who (a) Commits or offers to commit prostitution; or (b) Procures another for prostitution by engaging in sexual activity in a manner likely to transmit the human immunodeficiency virus, and who, prior to the commission of such crime, had tested positive for human immunodeficiency virus and knew or had been informed that he or she had tested positive for human immunodeficiency virus and could possibly communicate such disease to another person through sexual activity commits criminal transmission of HIV, a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. A person may be convicted and sentenced separately for a violation of this subsection and for the underlying crime of prostitution or procurement of prostitution.

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0700-0799/0796/Sections/0796.08.html

Treating: HIV/AIDS

- Antiretroviral therapy (ART) used only to control HIV disease; there is NO cure
 - Typically 2 medications from 1 class with a third medication from a dissimilar class are combined into a single pill for the purpose of treating HIV/AIDS to avoid producing drug-resistant strains of the disease. However, new ART involving different combinations of medications are becoming available.
 - Anti-HIV classes of medication
 - Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
 - Nucleoside or nucleotide reverse transcriptase inhibitors (NRTIs)
 - Protease inhibitors (PIs)
 - Entry or fusion inhibitors
 - Integrase inhibitors
- Each ART medication has specific, unique side effects that could contribute to comorbid conditions

Treating: HIV/AIDS in Pregnancy

- Early, consistent collaboration between Primary Care Physicians and Infectious
 Disease Specialists is key to treatment and counseling of HIV/AIDS infected women
 including prevention of perinatal HIV transmission
- Pregnant women diagnosed with HIV should be prescribed ART medication to reduce perinatal transmission
 - "Providers should consider multiple factors, including adverse effects, drug
 interactions, pharmacokinetics (PKs), convenience of the individual drugs and
 drug combinations in the regimen, available pregnancy safety and outcome
 data, and the patient's resistance test results and comorbidities"
 - Cesarean delivery is recommended during the 38th week to prevent mother-tochild transmission

<u>Independent Study</u>: Read the Guideline Overview "Recommendations for Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States" by the U.S. Department of Health and Human Services

https://clinicalinfo.hiv.gov/en/guidelines/perinatal/recommendations-arv-drugs-pregnancy-overview

Treating/Preventing: HIV/AIDS Transmission to Infants

- Infants born to HIV positive mothers should be:
 - Given HIV medicine after birth, preferably within 6 to 12 hours of delivery to protect infants from HIV transmission during childbirth.
 - Tested for 14 to 21 days of life, at 1 to 2 months, and again at 4 to 6 months.
- Infants with positive HIV test results should receive ART.
- HIV can be transmitted through breast milk. HIV has lower transmission risk if positive mother takes HIV medication and has an undetectable viral load.

HIV/AIDS Prevention Strategies: Teens and Adults

- HIV Testing
- Public Programs & Education
 - Syringe Services purchased or exchanged
 - Not sharing needles
 - Condom distribution
 - Using condoms correctly
- Drug Treatment Programs
 - Prevention of mother-to-child transmission
 - Pre-exposure Prophylaxis (PrEP)
 - Post exposure Prophylaxis (PEP)
 - Appropriate HIV Medication utilization
- Responsible Sexual Behaviors
 - Practice abstinence
 - Limit number of sexual partners
 - Select activities with little to no risk (i.e. oral sex)
 - Diagnose and treat sexually transmitted diseases
- Medical male circumcision

HIV/AIDS Prevention Strategies: Healthcare Providers

Follow *Infection Control Standard Precautions* to prevent HIV/AIDS transmission:

- 1. Use gloves, goggles, gowns/aprons, and other barriers as appropriate when anticipating contact with blood or body fluids
- 2. Immediately after contact with blood or body fluids, remove used gloves AND thoroughly wash hands and other skin surfaces with soap and water for minimum of 20 seconds
- 3. Use safe and careful handling and disposing of sharp instruments during and after use as follows:
 - Use safety devices to prevent needle-stick injuries
 - Dispose syringes or other sharp instruments in a sharps container





Florida's Plan to Reduce HIV Transmission & Deaths

The Florida Department of Health has adopted the reduction of HIV transmission as a top priority goal. The comprehensive plan to achieve this goal is outlined in the *Four Key Components* below.

- Implement routine HIV and Sexually Transmitted Infections (STIs) screening in health care settings and priority testing in nonhealth care stings
- 2. Provide rapid access to treatment and ensure retention in care (Test and Treat)
- 3. Improve and promote access to pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and non-occupational post-exposure prophylaxis (nPEP) biomedical medications
- 4. Increase HIV awareness and community response through outreach, engagement, and messaging



Reducing HIV Transmission & Deaths Using PrEP

- Pre-Exposure Prophylaxis (PrEP) biomedicals have been FDA approved since 2012 for high risk HIV
 negative individuals for the purpose of reducing HIV transmission
- PrEP, taken consistently as prescribed is highly effective at reducing HIV transmission from sex approximately 99% in HIV negative individuals and reducing HIV transmission by at least 74% in HIV negative individuals who use illicit injectable drugs ¹
 - Examples²:
 - HIV negative individual engaged in a continuous sexual relationship with a HIV positive partner
 - Gay or bisexual male who has had anal sex without using a condom or has been diagnosed with an STD in the past 6 months
 - Heterosexual male or female who does not use condoms regularly during sex with partners of unknown HIV status who are at risk of HIV infection
 - Individuals who have injected illicit drugs within the past 6 months
- PrEP medications are currently covered by most health insurance plans or through many medication assistance programs

1. CDC. (2019). PrEP. Retrieved from https://www.cdc.gov/hiv/basics/prep.html

^{2.} Effectiveness of prevention strategies to reduce the risk of acquiring or transmitting HIV. (2022, June 17). CDC. Retrieved from https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html#anchor_1562942347

^{3.} Preexposure prophylaxis for the prevention of HIV Infection in the United States – 2021 Update. CDC. Retrieved from https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Reducing HIV Transmission & Deaths Using PEP and nPEP

- Post-exposure prophylaxis (PEP) are biomedicals used for an individual exposed to HIV through work-related incidence(s). Post-exposure prophylaxis biomedicals are also used in an individual's exposure to HIV not related to his/her occupation and defined as Non-occupational prophylaxis (nPEP).
 - Examples:
 - PEP: Needlesticks, or other work-related exposure
 - nPEP: exposed to HIV during sex, sexual assault, sharing needles

Prep vs. Pep PrEP and PEP are methods for preventing HIV that involve taking HIV medicines. When you take steps to protect yourself against a disease, like HIV, it's called prophylaxis. PrEP and PEP are for people who don't have HIV, but are at risk of getting it. PEP stands for PrEP stands for What's it called? post-exposure pre-exposure prophylaxis. prophylaxis. After HIV exposure. Before HIV exposure. When is it taken? In emergency situations, PEP PrEP is taken every day. is taken within 72 hours (3 before possible exposure. days) after possible exposure. PEP is for people who don't have PrEP is for people who don't HIV but may have been exposed: have HIV and: Who's it for? · are at risk of getting HIV from sex · by sharing injection drug equipment are at risk of getting HIV from · during a sexual assault injection drug use · at work through a needlestick PEP can prevent HIV when Consistent use of PrEP can taken correctly, but it is not reduce the risk of getting **How effective** always effective. HIV from sex by about 99% is it? Start PEP as soon as possible and from injection drug use to give it the best chance of by at least 74%. working. Ask your health care provider Within 72 hours of a potential about a prescription for PrEP. exposure to HIV, talk to your How do you or use PrEPLocator.org to health care provider or an find a health care provider emergency room doctor get it? in your area who can prescribe about a prescription for PEP. PrEP. For more information, visit NIH.cov

CDC. (2019). PEP. Retrieved from https://www.cdc.gov/hiv/basics/pep.html
 U.S. Department of Health and Human Services. (2020). PrEP vs. PEP. Retrieved from https://hivinfo.nih.gov/understanding-hiv/infographics/prep-vs-pep

Reducing HIV Transmission & Deaths Through Counseling/Patient Resources

- Agencies/Programs that provide case management to assist individuals with accessing available resources in their communities include:
 - AIDS Drug Assistance Program (Florida)
 - 1-850-245-4422
 - Centers for Disease Control and Prevention National AIDS Hotline
 - 1-800-352-AIDS (Florida hotline)
 - Florida AIDS Hotline
 - 1-800-FLA-AIDS (English)
 - 1-800-545-SIDA (Espanol)
 - 1-800-AIDS-101 (Creole)
 - KnowYourHIVStatus.com
 - 1.800-FLA-AIDS (1-800-352-2437)



Summary

This CME activity has provided an overview of the HIV/AIDS disease specific to Florida. It is recommended that healthcare providers use the incorporated independent study readings and cited references to further study the clinical management of HIV/AIDS. It is also recommended that healthcare providers keep updated by reviewing the latest evidence-based articles, guidelines, protocols, and laws related to the evolving clinical management of HIV/AIDS in order to provide optimal patient care.