

HIV & AIDS: AN OVERVIEW AND UPDATE

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FINANCIAL DISCLOSURES

- Speaker-Carl Zeiss Meditec, Bausch and Lomb, Oyster Point Pharma, Thea Pharma, Alcon
- Advisory Board-Bausch and Lomb, Santen, Peripherex, Ocuphire, OcuTerra, Oyster Point Pharma, Allergan, Iveric Bio
- Shareholder-Clearside Biomedical (<0.01% ownership)
- All relevant relationships have been mitigated

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FLORIDA Board of Optometry

First Biennium Renewal: Optometrist initially licensed within the biennium are exempt from the continuing education (CE) requirements for renewal with the exception of one (1) hour of HIV / AIDS. Any live classroom course approved by any MQA Board is acceptable.

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QUICK OVERVIEW

- Background
- HIV and AIDS in the United States, Florida
- HIV Transmission
 - Occupational transmission
- Testing and reporting requirements
- Treatment


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HUMAN IMMUNODEFICIENCY VIRUS (HIV)

- Humans are not natural hosts of HIV
- Zoonotic virus
 - Simian immunodeficiency virus
 - Between 1884 and 1924 in Central West Africa, chimpanzee blood entered a hunter's body
 - *Pan troglodytes*
- Lentiviridae family of viruses
 - Bind to CD4 T lymphocytes, macrophages, and monocytes
 - Has been in the United States since at least the mid-1970s...



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Epidemiologic Notes and Reports

Pneumocystis Pneumonia --- Los Angeles

June 5, 1981 / 90(21):1-3

In the period October 1980-May 1981, 5 young men, all active homosexuals, were treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had laboratory-confirmed previous or current cytomegalovirus (CMV) infection and candidal mucosal infection. Case reports of these patients follow.

All the above observations suggest the possibility of a cellular-immune dysfunction related to a common exposure that predisposes individuals to opportunistic infections such as pneumocystosis and candidiasis. Although the role of CMV infection in the pathogenesis of pneumocystosis remains unknown, the possibility of *P. carinii* infection must be carefully considered in a differential diagnosis for previously healthy homosexual males with dyspnea and pneumonia.

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STAGES OF HIV

- Stage 1: Acute infection
 - Asymptomatic or flu-like symptoms following infection (2-4 weeks)
 - Viral replication must first occur
 - Large amounts of circulating virus in the bloodstream = **highly contagious**

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HIV PATHOGENESIS

- Virus binds to CD4 cell (host cell) and **coreceptor (CCR5)**, release viral RNA into the host cell nucleus, viral RNA infects T lymphocytes, viral RNA incorporated into cell
- Reverse transcriptase forms viral DNA, viral DNA is integrated into host cell's genetic material, viral RNA is formed and released to infect other cells
- An immune response (innate and adaptive) develops and partially clears the virus

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STAGES OF HIV

- Stage 2: Chronic infection
 - Asymptomatic HIV infection or clinical latency
 - Active virus replicating ultimately overwhelms the immune system and leads to stage 3
- Stage 3: Acquired immunodeficiency syndrome (AIDS)
 - High viral load, at risk of opportunistic infection
 - Without treatment survival is approximately 3 years
 - CD4+ T lymphocytes below 200/mm³ and/or development of opportunistic infections
 - Risk of CMV retinopathy

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"WHAT ARE MY NUMBERS, DOC?"

- Viral load
 - "Undetectable" (less than 20 copies/mL of blood)
 - High is considered above 100,000 copies/mL of blood
 - Low is below 10,000 copies/mL of blood
 - Viral suppression is 200 copies/mL of blood
- CD4 count ranges from 600-1500 cells/mm³ in healthy individuals

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HIV and AIDS in the United States

New HIV Diagnoses and People with Diagnosed HIV in the US and Dependent Areas by Area of Residence.

HIV diagnosis in 2021 (13 years of age+): 36,136

- 81% male
- 56% 13-34 years of age
- 40% Black or African American
- Peak rate of new dx in 1996

State: Florida
 Number of Diagnoses: 4072
 Rate per 100,000 people: 21.7

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PREVALENCE OF HIV

- 1.2 million people living with diagnosed HIV at the end of 2021 in the United States (and 6 dependent areas); of those, 87% knew they had HIV
 - Florida: #5
 - DC, New York, Maryland, Georgia
- Male to male sexual contact accounted for 67% of new HIV diagnoses in the United States
 - 22% through heterosexual contact
 - Union County

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TRENDS OF HIV PREVALENCE

- Persons who inject drugs account for 7% new HIV diagnosis
 - Continues to increase
 - 49% white
- More than 5,000 women were diagnosed with HIV in 2020 (Florida #4)
 - 1/9 women with HIV are unaware that they have it
 - Testing rates were low in women with behaviors that increase risk of acquiring HIV
- Black and African American individuals 13 years of age and older account for 40% of new HIV diagnoses, Hispanic and Latino individuals account for 29% of new diagnosis in 2021

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New HIV diagnoses in Florida has been relatively stable since 2012

At the end of 2022, 124,577 people are living with an HIV diagnosis in Florida
80% are receiving care, 73% are retained in care, and 70% have a suppressed viral load (<200 copies/mL)

Category	Count	Percentage
PWH	124,577	100%
In Care	99,000	80%
Retained in Care	90,604	73%
Suppressed Viral Load	86,839	70%

Florida Department of Health, 2023

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HIV AND AIDS IN THE UNITED STATES

- Overall death rate in those with HIV was 1.5/100,000 people across the United States (2021)
- Peak deaths due to AIDS in the United States was 2004 (2.2 million)
 - Caveat—reported deaths may or may not be related to AIDS

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In 2022, 99 people died of HIV/AIDS in Broward County

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ISOLATION OF HIV

- HIV can be **isolated** from:
 - Blood, semen, vaginal secretions, CSF fluid, amniotic fluid, pericardial fluid, breast milk, tears
 - Breastfeeding is not recommended for mothers with HIV
 - Transmission occurs with exposure of mucous membranes to visible blood or body fluids

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WAYS IN WHICH HIV IS NOT TRANSMITTED

- Saliva, tears, sweat
- Mosquitoes, ticks, other insects

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Occupational HIV Transmission

- 58 confirmed cases in the United States; 150 possible cases
 - 1 case since 1999 in the United States—*lab tech, needle puncture, live HIV culture in 2008*
 - CDC 2015
- Eye Bank Association of American (EBAA)
 - Excludes tissue from donors affected by: HIV type 1 and 2, hepatitis B, hepatitis C, HSV, rabies, West Nile, Zika, Ebola
 - **BUT** no known transmissibility through corneal donation!
 - Known **lack** of transmissibility through ocular tissues and tears!

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Corneal donation

Men who have sex with men & injection drug use: 5 year ban on donation in the United States (based on a 1994 recommendation)

Current testing: detectable within 8 days of exposure

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1. Donors should be determined ineligible who in the 10 days prior to death:
 - a) were diagnosed with acute COVID-19; OR
 - b) tested positive for COVID-19 by direct viral testing methods (e.g., NAAT and/or antigen); OR
 - c) had close contact[†] with a person diagnosed with or suspected to have COVID-19 AND developed signs and symptoms of COVID-19, regardless of a plausible alternative etiology or vaccination history
2. Donors should be evaluated for eligibility by a Medical Director who:
 - a) in the 10 days prior to death, without a known close contact with a person diagnosed with or suspected to have COVID-19, developed new signs and/or symptoms consistent with acute COVID-19 not explained by a plausible alternative etiology; OR
 - b) in the 10 days prior to death, had a known close contact with a person diagnosed with or suspected to have COVID-19 AND was asymptomatic; OR
 - c) in the 11 to 20 days prior to death had a positive or reactive test for SARS-CoV-2[‡] AND had ongoing signs and/or symptoms of COVID-19, regardless of a plausible alternative etiology.

March 22, 2022

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Occupational HIV transmission

Splashes with body fluids-net zero-even if fluids have blood in them

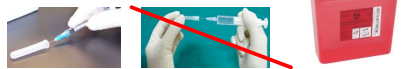
Fluid splashes to mucous membranes-extremely low risk-even if blood is involved

Needle-stick injury-less than 1%

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REDUCING RISK OF OCCUPATIONAL HIV TRANSMISSION

- Barriers when anticipating contact with blood or bodily fluids
 - Not necessary for routine examination, but gloves should be worn for routine examination if open wounds or dermatitis is present
 - Must discard gloves after each patient
 - Wash hands with soap and water immediately after contact with body fluids; dry hands completely with a fresh towel
 - Dispose used syring in a sharps container
 - Do not recap needles



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Double Glove?

Cochrane Database of Systematic Reviews | Review - Intervention

Gloves, extra gloves or special types of gloves for preventing percutaneous exposure injuries in healthcare personnel

Christina Mischke, Jos H Verbeek, Annika Saarto, Marie-Claude Lavoie, Manisha Pahwa, Sharee Ijaz
Authors' declarations of interest
Version published: 07 March 2014 | Version history

36 RCTs

Authors' conclusions

There is moderate-quality evidence that double gloving compared to single gloving during surgery reduces perforations and blood stains on the skin, indicating a decrease in percutaneous exposure incidents. There is low-quality evidence that triple gloving and the use of special gloves can further reduce the risk of glove perforations compared to double gloving with normal material gloves. The preventive effect of double gloves on percutaneous exposure incidents in surgery does not need further research. Further studies are needed to evaluate the effectiveness and cost-effectiveness of special material gloves and triple gloves, and of gloves in other occupational groups.

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REDUCING RISK OF OCCUPATIONAL HIV TRANSMISSION

- Clinical disinfectant procedures
 - Trial contact lenses-commercially available peroxide system
 - Goldman tonometer probe, gonioscopy lens-bleach solution (0.525% NaClO for 10-26 minutes), CaviWipes
 - Alcohol, peroxide, and acetone are not recommended due to the potential of damaging the lens surface
 - Check recommendations according to manufacturer

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DISINFECTION

1. Clean lens & surgical products first by following Cleaning Method A (See CLEANING METHODS TABLE)

2. Disinfect by selecting one of the solution types from the Table below:

Product Type OK to Use	Alkaline Alkaline	9% Bleach Solutions (Sodium Hypochlorite)	Bole Alcohol Tissues	CaviWipes	Clorox DPA	Chloroxatrinyl Peroxide	Phenol-GL Phenol-GL HLD	Isopar Dip
BIO Lenses (Black & All Colors)	✓	✓	✓	✓	✓	✓	✓	✓
BIO Lenses (ACS)	✓	✓	✓	✓	✓	✓	✓	✓
Classic Series Lenses (Black & All Colors)	✓	✓	✓	✓	✓	✓	✓	✓
Super & Digital Series Lenses (Black & All Colors)	✓	✓	✓	✓	✓	✓	✓	✓
Mirror Lenses (S-Mirror Lenses, Mini-4-Mirror Lens & B&T)	✓	✓	✓	✓	✓	✓	✓	✓
G-Series Contact Lenses	✓	✓	✓	✓	✓	✓	✓	✓
Research Lenses	✓	✓	✓	✓	✓	✓	✓	✓
Research Lenses	✓	✓	✓	✓	✓	✓	✓	✓
Wettable Surgical Lenses - Traditional	✓	✓	✓	✓	✓	✓	✓	✓
Wettable Surgical Lenses - ACS	✓	✓	✓	✓	✓	✓	✓	✓

Solution Type	Example Dilution	Minimum Soak Time	Maximum Soak Time
0.525% (500ppm) Sodium Hypochlorite Solution (NaClO) (Domestrol Bleach)	1 Part 5.25% NaClO : 9 Parts Water Ambient Room Temp 60° - 72° (16.67° - 22.22°)	10 Minutes	26 Minutes

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IF EXPOSURE OCCURS AT WORK

- Report the exposure to the appropriate person and see a doctor immediately
 - Post-exposure prophylaxis can reduce the risk of developing infection
 - Must be started within 72 hours after exposure
 - PEPLine: 1-888-448-4911

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FLORIDA STATUTES AND HIV TESTING (381.004 AND 384.25)

- 381.004
 - i. HIV testing must be informed, voluntary, and confidential
 - ii. Florida Department of Health has a network of voluntary HIV testing programs in every county
 1. **Anonymous and confidential**
 - iii. Informed consent must precede an HIV test
 1. If the test is positive, information on the availability of appropriate medical and support services, importance of notifying partner who may have been exposed, and on preventing transmission of HIV must be provided
 2. Test results may only be released to the individual patient or to the patient's legally authorized representative

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INFORMED CONSENT FOR HIV TESTING IN FLORIDA

- Disclose that the provider is required by law to report the test subject's name to the local county health department if the HIV test results are positive;
- Alert the patient that as an alternative, the patient may secure the HIV test at a site that tests anonymously, the locations of which the provider must make available; and
- Relate the extent of the confidentiality rights that adhere to the test results in the provider's patient records.

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FLORIDA STATUTES AND HIV TESTING (381.004 AND 384.25)

- a. Testing requirements (4)
 - i. Supplemental corroborative testing on all positive test results before the results of any positive test are provided to the patient
 1. Social, medical, and economic consequences of a positive test result
- b. Penalties (5)
 - i. Any person who violates the confidentiality provisions... commits a misdemeanor of the first degree
 - ii. Any person who obtains information that identifies an individual who has an STI (including HIV or AIDS), who knew or should have known the nature of the information and maliciously, or for monetary gain, disseminates the information, commits a felony of the third degree
- c. Testing as a condition of treatment or admission (10)
 - i. Unlawful to require an HIV related test for admission to a medical facility or prior to providing treatment

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- a. 384.25
- i. Reporting requirements for sexually transmissible diseases
 1. Each person who makes a diagnosis or treats a person with a sexually transmissible disease and each positive laboratory test for a sexually transmissible disease with a positive test result must be reported to the Department of Health within 2 weeks

https://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/_documents/dc-hiv-adult-confidential-case-report-form-Nov2019.pdf

U.S. Department of Health and Human Services		Adult HIV Confidential Case Report Form		Centers for Disease Control and Prevention (CDC)	
Health Department Use Only (insert all dates as month/year)					
Date Reported to Health Department		CDC Reporting Date		Form Approved 09/01/07 Exp. 11/30/2012	
Reporting Health Dept.—City/County		City/County Number		State Number	
Document Source		Surveillance Method		Report Medium	
Did this report initiate a new case investigation?		If "Yes",		If "No",	
Facility Providing Information (insert all dates as month/year)					
Facility Name		Street Address		Phone	
City		County		State	
Facility Type		Specialty		Other Facility	
Date Form Completed		Person Completing Form		Phone	

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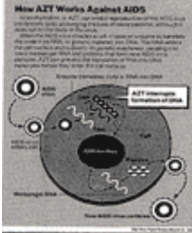

U.S. APPROVES DRUG TO PROLONG LIVES OF AIDS PATIENTS

CURE STILL NOT ACHIEVED

Distribution Will Be Limited Because of Short Supply and Fear of Side Effect

By IRVIN MOLOTSKY
Special to The New York Times

New York Times, March 21, 1987


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PREEXPOSURE PROPHYLAXIS (PrEP)

- PrEP prescribing is well within the scope of primary care physicians
- CDC estimates 1.2 million people have some indication for PrEP
 - Sexual partner with HIV
 - If the viral load is not known, or the person has been diagnosed with an STI within the past 6 months
 - One or more sexual partners whose HIV status is unknown

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Pre-Exposure Prophylaxis (PrEP)



FITDF (emtricitabine/tenofovir disoproxil fumarate)-Truvada-oral medication

T/TAF (emtricitabine/tenofovir alafenamide)-Descovy-newer form

Cabotegravir-newest-injectable-Apretude (every 2 months)

Reduces risk for sexual transmission of HIV as high as 99% and about 75% for reducing HIV transmission through injection drug use
May be continued during pregnancy and while breastfeeding

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ANTIRETROVIRAL THERAPY (ART)

- Tenofovir with either lamivudine or emtricitabine plus dolutegravir, raltegravir, bictegravir, or doravirine; abacavir/lamivudine plus dolutegravir; or dual therapy with emtricitabine plus dolutegravir
 - Recommended in single tablet form
- Injectable cabotegravir and rilpivirine (Cabenuva)
- December 22, 2022-approval of Sunlenca (lenacapavir)
 - Capsid inhibitor-for those resistant to multiple classes of medication



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Patient with HIV achieves remission following stem cell transplant at City of Hope

The individual, who was treated for leukemia, is the fourth in the world and the oldest to go into long-term remission of HIV after receiving stem cells from a donor with a rare genetic mutation

July 27, 2022

Not an option for most people with HIV
Delta 32 mutation

3 people are considered to be cured of HIV, with a fourth in ART-remission since 2018

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The case for CRISPR/Cas9

EBT 101: In lab based studies: 40% functional cure

Open-label, Phase 1/2 trial

3 people have received IV therapy so far

Data to be released 2024

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Treatment as Prevention

Undetectable viral load

Reachable in about 6 months after beginning treatment

Undetectable = untransmissible

U=U



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Looking Ahead (or Behind?)

90-90-90 target to end the HIV pandemic

90% of all people with HIV will know their status

90% of all diagnosed people with HIV will be on sustained ARV treatment

90% of all people with HIV will be virally suppressed by 2020

90-90-90: good progress, but the world is off-track for hitting the 2020 targets

21 SEPTEMBER 2020



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THANK YOU!

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