



EYE ON HIV

JESSICA STEEN OD, FAAO, DIPL.ABO

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FINANCIAL DISCLOSURES

- Speakers Bureau-Carl Zeiss Meditec, Bausch and Lomb, Viatris, Thea Pharma, Alcon, Allergan, Astellas, Dompé
- Consultant-Bausch and Lomb, Balance Ophthalmics, Carl Zeiss Meditec, Opus Genetics, Viatris, Allergan, Astellas, Alcon, Radius XR, iCare, Glaukos, Eyenovia, Tarsus, Orasis, Topcon, Envision Health Technologies, LKC
- Shareholder-Clearside Biomedical, Annexon Bio (<0.01% ownership)
- All relevant relationships have been mitigated

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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 in the United States and Florida
- HIV transmission
 - Occupational transmission
- Testing and reporting requirements
- Treatment

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HUMAN IMMUNODEFICIENCYVIRUS (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* (chimpanzees)
- Lentiviridae family of viruses
 - Bind to CD4T lymphocytes, macrophages, and monocytes
 - Has been in the United States since at least the mid-1970s...

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MMWR
Morbidity and Mortality Weekly Report
June 5, 1981 / 30(21):1-3

Pneumocystis Pneumonia --- Los Angeles

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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FULL LENGTH ARTICLE • Volume 95, Issue 4, P393-402, April 1982

**AMERICAN JOURNAL
OF OPHTHALMOLOGY**

Ocular Disorders Associated with a new Severe Acquired Cellular Immunodeficiency Syndrome

Gary N. Holland, M.D.¹ • Michael S. Gottlieb, M.D.² • Robert D. Yee, M.D.¹ • Howard M. Schanker, M.D.² • Thomas H. Pettit, M.D.¹

Among the prominent features of a newly described acquired cellular immunodeficiency syndrome that affects previously healthy male homosexuals are multiple opportunistic infections and Kaposi's sarcoma. Immunosuppression induced by cytomegalovirus infection may play a major role in the pathogenesis of this disorder. We have performed ophthalmic examinations on seven such patients and found ocular abnormalities in all cases. Six patients were examined during the course of their illness and one patient at autopsy only. Each patient had several cotton-wool spots in the affected eye. Other ocular findings included cytomegalovirus retinitis, severe retinal periphlebitis, and conjunctival Kaposi's sarcoma (one case each).


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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

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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
- Large amounts of circulating virus in the bloodstream = **highly contagious**

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HIV PATHOGENESIS

- 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 cells/mm³ and/or development of opportunistic infections
 - Risk of CMV retinopathy

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Retiring the term AIDS for more descriptive language

Isaac Níñez*, Alicia Piñeira-Moréndez, Sergio Iván Valdés-Ferrer* Lancet HIV 2024; 11: e195-98

After the discovery of HIV, the term AIDS became redundant, but its use has persisted and has come to embody negative connotations in the current landscape of the HIV epidemic. People commonly associate AIDS with a terminal illness. This misconception promotes stigma by others, including health-care workers, but also self-stigma, which can prevent individuals from accessing health care.

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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 600-1500cells/mm³ in healthy individuals

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HIV in the United States

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

HIV diagnoses in 2023 (13 years of age+): 39,201

81% male
56% 13-34 years of age
38% Black or African American

Peak rate of new dx in 1996;
588 new HIV diagnoses in 2023

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 66% of new HIV diagnoses in the United States (2023)
- 22% through heterosexual contact

Human Immunodeficiency Virus (HIV) Diagnoses, Rate Per 100,000 Population, 2024

Legend: 0 to 5.7, 5.8 to 9.7, 9.8 to 14.9, 15.0 to 20.7, 20.8 to 25.7

Broward: 28.2

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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). 4438 new HIV diagnoses in 2023, 252 new cases in Broward County.

Along the HIV Care Continuum, Year-End 2022

Category	Count	Percentage
PWVH	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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EHE Jurisdiction Bar Chart

Estimated rate per 100,000 of new HIV infections (including diagnosed and undiagnosed infections), 2022

County	Estimated rate per 100,000
Miami-Dade County, FL	~30
Orange County, FL	~28
Broward County, FL	~25
Volusia County, FL	~22
Alachua County, FL	~20
Polk County, FL	~18
DeKalb County, FL	~15
Pinellas County, FL	~12

Rate per 100,000

<https://ahead.hiv.gov/florida/>

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Stage 3 (AIDS), 2023 and cumulative, and persons living with diagnosed HIV ever classified as stage 3 (AIDS) (prevalence), year-end 2023 by metropolitan statistical area of residence—United States and Puerto Rico (Slide 5 of 10)

MSA of residence	Classification, 2023			Classification, cumulative			Prevalence of stage 3 (AIDS) year-end 2023		
	Rate	Rank	Persons aged ≥15 years	Rate	Rank	Total	Rate	Rank	Rate (per 100,000)
	(per 100,000)	(based on rate)		(per 100,000)	(based on rate)		(per 100,000)	(based on rate)	
Albuquerque, NM	45	2.6	99	1,513	8	1,513	67.7	71.5	
Lakeland-Winter Haven, FL	95	11.6	3	2,939	23	2,962	3,827	198.8	
Lancaster, PA	11	2.0	—	961	22	983	432	77.3	
Las Vegas-Henderson-North Las Vegas, NV	183	7.8	17	2,793	30	2,823	6,479	191.7	
Lexington-Fayette, KY	37	7.3	25	1,171	1	1,172	660	126.9	
Little Rock-North Little Rock-Conway, AR	48	6.3	31	2,244	18	2,258	355	46.5	
Los Angeles-Long Beach-Anaheim, CA	785	6.1	33	72,105	309	72,414	28,376	220.1	
→ Anaheim-Santa Ana-Irvine, CA	120	3.8	—	9,232	47	9,299	3,513	112.0	
→ Los Angeles-Long Beach-Glendale, CA	665	6.9	—	62,873	262	68,135	24,863	255.2	
Louisville/Jefferson County, KY-IN	106	7.8	18	3,640	30	3,870	1,809	136.1	
Madison, WI	9	1.3	—	749	5	754	376	54.2	
McAllen-Edinburg-Mission, TX	44	4.9	52	1,381	13	1,394	898	99.9	
Memphis, TN-MS-AR	179	13.4	1	8,497	25	8,522	1,518	261.4	
Miami-Fort Lauderdale-West Palm Beach, FL	294	12.8	2	24,681	1,019	25,700	22,255	440.8	
→ Fort Lauderdale-Pompano Beach-Sunrise, FL	269	13.7	—	23,050	269	23,319	10,155	517.4	
→ Miami-Miami Beach-Doral, FL	327	14.0	—	38,917	517	39,414	12,412	652.2	

Note. Data are presented for persons of all ages.



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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)

Disqualified 1558-3217 corneal donations in the US and Canada in 2018

Current testing: detectable within 4-8 days of exposure

Puente JAMA Ophthalmol. 2020

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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 syringes 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, Shanaa 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
 - Goldmann 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:

Volk Optical

Product Type OK to Use	Alkaline Aqueous	Bleach Solutions (Sodium Hypochlorite)	Bleach Resin	Centrifuge	Citric Acid	Glutaraldehyde	Peroxide	Hydrogen Peroxide (H ₂ O ₂)	Total Time
SO Lenses (Black & All Colors)	✓	✓	✓	✓	✓	✓	✓	✓	✓
SO Lenses (ACB)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Classic Series Lenses (Black & All Colors)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Super & Double Series Lenses (Black & All Colors)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Binocular Lenses (S-Mirror Lenses, Mini & Super Lenses, & S.T.)	✓	✓	✓	✓	✓	✓	✓	✓	✓
G-Series Gonio Lenses	✓	✓	✓	✓	✓	✓	✓	✓	✓
Contact Lenses	✓	✓	✓	✓	✓	✓	✓	✓	✓
Research Lenses	✓	✓	✓	✓	✓	✓	✓	✓	✓
Vitreous Surgical Lenses - Traditional	✓	✓	✓	✓	✓	✓	✓	✓	✓
Vitreous Surgical Lenses - ACB	✓	✓	✓	✓	✓	✓	✓	✓	✓

Solution Type

Example Dilution

Minimum Soak Time

Maximum Soak Time

0.525% (1000ppm) Sodium Hypochlorite Solution (NaClO) (Household Bleach)

1 Part 0.525% NaClO : 9 Parts Water
Antiseptic Soap Temp 40° - 77° F
(100° - 200° F)

10 Minutes

20 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
 - HIV testing must be *informed*, voluntary, and confidential
 - Florida Department of Health has a network of voluntary HIV testing programs in every county
 - 1. Anonymous and confidential**
 - Informed consent must precede an HIV test
 - 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
 - Test results may only be released to the individual patient or to the patient's legally authorized representative

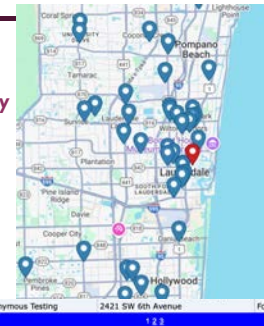
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INFORMED CONSENT FOR HIV TESTING IN FLORIDA

- 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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43 locations in Broward County



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FLORIDA STATUTES AND HIV TESTING (381.004 AND 384.25)

- Testing requirements (4)
 - Supplemental corroborative testing on all positive test results before the results of any positive test are provided to the patient
 - Social, medical, and economic consequences of a positive test result
- Penalties (5)
 - Any person who violates the confidentiality provisions...commits a misdemeanor of the first degree
 - 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
- Testing as a condition of treatment or admission (10)
 - 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/cdc-hiv-adult-confidential-case-report-form-Nov2019.pdf>

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

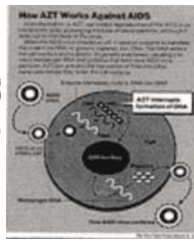
CURE STILL NOT ACHIEVED

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



Dr. David Ho-1996

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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)



F/TDF (emtricitabine/tenofovir disoproxil fumarate)-Truvada-oral medication
T/TAF (emtricitabine/tenofovir alafenamide)-Descovy-newer form
Cabotegravir-injectable-Apretude (every 2 months)
****Lenacapavir-Yeztugo-2 injections per year**



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; twice yearly injection

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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
(Hematopoietic stem cell transplant)
Delta 32 mutation

7 people are considered to be cured of HIV (Berlin, London, Dusseldorf, New York, City of Hope, Geneva, "next" Berlin)

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The case for CRISPR/Cas9

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

Open-label, Phase 1/2 trial

5 people have received treatment (IV)

Did NOT maintain HIV viral suppression when used alone; may have delayed rebound in 1. Of 5, 3 stopped taking ART-needed to restart

Maybe did not reach all cells?

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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!

- jessica.steen@gmail.com
- 480.289.0613