

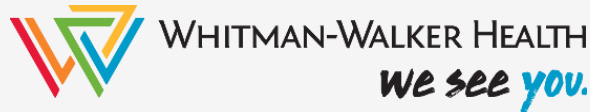
# HIV TREATMENT AS PREVENTION: BENEFITS AND RISKS OF U=U MESSAGING

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GLMA Annual Conference on LGBTQ Health  
Las Vegas, Nevada  
October 11, 2018



# Conflict of Interest Disclosures

- Sean Bland

The O'Neill Institute for National and Global Health has received funding from Gilead Sciences for its Ryan White Policy Project and for a separate HIV Prevention Project. Sean Bland received an honorarium from Gilead Sciences for participating in a community advisory board in April 2017.

- Daniel Bruner

Whitman-Walker Health has received funding from Gilead Sciences for a Mobile Outreach Retention and Engagement project, focusing on patients who have fallen out of care or who encounter significant barriers to engagement in care. Gilead Sciences is also a sponsor of a National LGBT Cultural Competency Summit, organized by Whitman-Walker and the National LGBT Cancer Network.

- Scott Schoettes

None.

# GOALS OF THIS PRESENTATION

We hope to assist participants to:

- Appreciate the advantages as well as the potential drawbacks of the U=U message.
- Communicate in a more nuanced and effective manner with patients, the public, and policymakers about Treatment as Prevention and the implications for people with HIV whose virus is not suppressed as well as those who are virally suppressed.
- Advocate more effectively for the rights and well-being of all people living with HIV.

# CURRENT EVIDENCE OF TREATMENT AS PREVENTION

**It is now established that when a person living with HIV has a sustained undetectable viral load, they do not pass HIV to their sexual partners.**

## Research Studies:

- HIV Prevention Trials Network (HPTN) 052 (2011) – early vs. delayed antiretroviral (ART) initiation reduced HIV transmission; follow-up study found no transmission when person with HIV was virally suppressed.
- PARTNER Study (2016) - followed 1166 serodiscordant, mostly heterosexual, couples (one partner was HIV positive and one was HIV negative) for nearly four years and found zero transmissions from the HIV positive partner when that partner was taking ART and virally suppressed.
- Opposites Attract Study (2017) - found no HIV transmission among more than 350 serodifferent gay male couples who engaged in 17,000+ instances of anal sex without a condom over four years, when partner with HIV was virally suppressed.
- PARTNER2 Study (2018) – found no HIV transmissions among 972 serodifferent gay male couples who had sex 77,000 times without condoms with undetectable viral load.
- Centers for Disease Control and Prevention. *Fact Sheet: Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV*. August 2018. <https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf>.
- National Institute of Allergy and Infectious Diseases. *10 Things to Know About HIV Suppression*. November 2017. [https://docs.wixstatic.com/ugd/de0404\\_07874daa25c84e2493c924332e0b9b40.pdf](https://docs.wixstatic.com/ugd/de0404_07874daa25c84e2493c924332e0b9b40.pdf).
- World Health Organization. *Viral suppression for HIV Treatment Success and Prevention of Sexual Transmission of HIV*. July 2018. <http://www.who.int/hiv/mediacentre/news/viral-suppression-hiv-transmission/en>.

# CURRENT EVIDENCE OF TREATMENT AS PREVENTION

The preventive benefits of treatment-mediated viral suppression were reported as early as 2008, but the medical and scientific communities were cautious to embrace the message until recently.

- Vernazza P et al. *HIV-positive individuals not suffering from any other STD and adhering to an effective antiretroviral treatment do not transmit HIV sexually*. Report of the Swiss National AIDS Commission 2008. <http://i-base.info/qa/wp-content/uploads/2008/02/Swiss-Commission-statement-May-2008-translation-EN.pdf>. Accessed Sept. 18, 2018.
- Averitt D et al. *The Liberating Message of “Undetectable = Untransmittable”*. Infectious Disease News July 2018. <https://www.healio.com/infectious-disease/hiv-aids/news/print/infectious-disease-news/%7B41e2b2a5-fa72-4bb1-be1d-a76e544ded93%7D/the-liberating-message-of-undetectable--untransmittable>. Accessed Sept. 18, 2018.

# SUSTAINED VIRAL SUPPRESSION IS ALSO BENEFICIAL FOR THE HEALTH OF THE INDIVIDUAL LIVING WITH HIV

Sustained viral suppression, particularly if antiretroviral therapy is initiated promptly after infection, is associated with reduced mortality and morbidity – generally a dramatic increase in life expectancy and quality of life.

- Lee JS et al. Incomplete viral suppression and mortality in HIV patients after antiretroviral therapy initiation. *AIDS* 2017. 31(14):1989-1997.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5695564>.
- Mugavero MJ et al. Viremia copy-years predicts mortality among treatment-naive HIV-infected patients initiating antiretroviral therapy. *Clin Infect Dis* 2011. 53(9):927-935.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3189165>.
- Zoufaly A et al. Cumulative HIV viremia during highly active antiretroviral therapy is a strong predictor of AIDS-related lymphoma. *J Infect Dis* 2009. 200(1):79-87.  
<https://academic.oup.com/jid/article/200/1/79/1746330>.

# GETTING THE NEWS OUT ABOUT TREATMENT AS PREVENTION: THE U = U CAMPAIGN

Initiated in 2016 by a coalition of people living with HIV and activists seeking to spread the message of undetectable = untransmittable (U=U). Endorsed by over 700 organizations from nearly 100 countries, and favorably referenced by the CDC, top NIH officials, and other authorities.

- Prevention Access Project. *Risk of Sexual Transmission of HIV from a Person Living With HIV Who Has an Undetectable Viral Load: Messaging Primer & Consensus Statement*. <https://www.preventionaccess.org/consensus>. Accessed Sept. 7, 2018.
- Averitt D et al. *The Liberating Message of “Undetectable = Untransmittable”*. *Infectious Disease News* July 2018. <https://www.healio.com/infectious-disease/hiv-aids/news/print/infectious-disease-news/%7B41e2b2a5-fa72-4bb1-be1d-a76e544ded93%7D/the-liberating-message-of-undetectable--untransmittable>. Accessed Sept. 18, 2018.
- Goodenow M D. *NIH Director’s Update: Why Is U=U a Game Changer?* <https://mailchi.mp/od.nih.gov/letter-from-the-oar-director?e=9841b11756>. Accessed Sept. 7, 2018.

# WHY PERCEPTIONS OF THE RISK OF HIV TRANSMISSION ARE SO IMPORTANT

**HIV remains a greatly stigmatized condition, by persons who have not been diagnosed with HIV and by many persons living with HIV themselves; much of the stigma is because of the fear of infecting others.**

- *National HIV/AIDS Strategy for the United States: Updated to 2020*. July 2015. <https://files.hiv.gov/s3fs-public/nhas-update.pdf>. Accessed Sept. 19, 2018.
- Mahajan AP et al. Stigma in the HIV/AIDS epidemic: A review of the literature and recommendations for the way forward. *AIDS* 2008; 22(Suppl 2): S67–S79. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2835402>.

**The news that viral suppression eliminates the risk of sexual transmission has enormous psychological benefits for people living with HIV themselves, and decreases the fear of people who are HIV-negative and increases their willingness to engage in romantic and sexual relationships with HIV-positive people.**

**Federal, state and local disability discrimination laws, which apply to people with an HIV diagnosis, generally permit discrimination to protect against a “direct threat” – a “significant risk” of transmitting HIV to others.**

- 42 USC §§ 12111(3), 12113 (a) & (b) (employment); 42 USC § 12182(b)(3) (public accommodations, including health care)
- Lisa Guerin, *The Direct Threat Defense Under the ADA*, <https://www.nolo.com/legal-encyclopedia/the-direct-threat-defense-under-the-ada.html>. Accessed Sept. 6, 2018.
- *School Bd. of Nassau County, Fla. v. Arline*, 460 U.S. 273 (1987)
- *Bragdon v. Abbott*, 524 U.S. 624 (1998)

**Current criminal laws and law enforcement actions in many states are based on the assumption that sexual contact with an HIV-positive person involves a significant risk of transmission.**



# IMPLICATIONS FOR HIV CRIMINAL LAWS

33 states have criminal laws that specifically penalize at least some consensual sexual activities by individuals with an HIV diagnosis – generally unless the sexual partner has had notice of HIV. Other laws provide for enhanced penalties for other sexual offenses (such as prostitution or sex with a minor) if the defendant is living with HIV. The laws vary widely in their definition of the sexual activities criminalized and defenses that are available. Many laws criminalize sexual activity that poses essentially no risk, or very low risk, of infection. In some states without HIV-specific criminal laws, HIV-positive people have been prosecuted for sexual activity under general criminal laws (such as assault, battery, or reckless endangerment).

Recently, statements issued by prominent scientists have argued that HIV criminalization is inconsistent with treatment as prevention and U=U.

- Barre-Sinoussi F et al. Expert consensus statement on the science of HIV in the context of criminal law. *J Intl AIDS Soc* 2018, 21:e25161. <https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25161>.
- Mayer KH et al. Addressing HIV criminalization: Science confronts ignorance and bias. *J Intl AIDS Soc* 2018, 21:e25163. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6058272>.
- McCall B. Scientific evidence against HIV criminalization. *Lancet* 2018; 392(10147): 543-544. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)31732-X/abstract](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31732-X/abstract).
- Editorial. HIV criminalization is bad policy based on bad science. *The Lancet HIV* 2018; 5(9): 473. [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(18\)30219-4/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(18)30219-4/fulltext).

# IMPLICATIONS FOR HIV CRIMINAL LAWS

Some have cautioned that criminal law reform should not simply exempt individuals with an undetectable viral load, or simply provide a defense against prosecution based on viral load. They argue that this would exacerbate the discriminatory impact of criminal laws and the criminal justice system on Blacks, other people of color, low-income persons, transgender and cisgender female sex workers, and other marginalized persons. Broader criminal law reform is needed in this area.

- *Consensus Statement on HIV “Treatment as Prevention” in Criminal Law Reform.* <https://www.hivtaspcrimlaw.org/the-consensus-statement>. Accessed Sept. 20, 2018.
- Center for HIV Law and Policy. *HIV Criminal Law Reform: A Call to Action.* Aug. 22, 2018. <https://www.hivlawandpolicy.org/news/news-release-hiv-criminal-law-reform-a-call-action>.
- Arpita Appannagari and Kate Boulton. *Science Alone is Not the Solution.* Center for HIV Law and Policy, Sept. 6, 2018. <https://www.hivlawandpolicy.org/fine-print-blog/science-alone-not-%C2%A0solution>.

# IMPLICATIONS FOR HIV CRIMINAL LAWS

The evidence of treatment as prevention supports the case that criminalizing any sex by an HIV+ person is counterproductive to public health efforts to control/eliminate the epidemic – for instance, because it may create a disincentive to learn one’s HIV status or to engage in HIV care (because law enforcement may have access to testing and treatment records).

Leaving that aside, what are the pros and cons of taking U = U into account:

- To mount a defense for an individual’s defense if charged with exposing another person to HIV sexually without their knowledge.
- Having a statute in which criminal liability hinges on a person’s viral load.

# IMPLICATIONS FOR HEALTH CARE WORKERS LIVING WITH HIV

There has not been a documented transmission from a health care provider to a patient in the U.S. in over 30 years, and significant questions exist as to whether the one transmission that purportedly occurred in [year] was due to improper sanitizing of dental equipment. Nevertheless, the federal courts have upheld adverse actions by hospitals, dental practices and dental schools against health care workers and medical students where there is any possibility of blood-to-blood contact and therefore a chance, however slight, of transmission through accident – including surgeons, surgical nurses and technicians, dentists, dental hygienists and dental students.

- The courts have relied on the “direct threat” defense under disability discrimination laws – ruling that even a very small risk of HIV transmission is a “significant risk” because of the life-long, life-altering nature of HIV.
- See, e.g., *Waddell v. Valley Forge Dental Assoc., Inc.*, 276 F.3d 1275 (11th Cir. 2001), cert. denied, 535 U.S. 1096 (2002); *Mauro v. Borgess Medical Center*, 137 F.3d 398 (6th Cir.), cert. denied, 525 U.S. 815 (1998); *Doe v. University of Md. Medical Health Sys. Corp.*, 50 F.3d 1261 (4th Cir. 1995); *Bradley v. University of Tex. M.D. Anderson Cancer Ctr.*, 3 F.3d 922 (5th Cir. 1993); *Leckelt v. Board of Commissioners of Hosp. Dist. No. 1*, 909 F.2d 820 (5th Cir. 1990).

The CDC has withdrawn its previous guidance on HIV-positive health care workers. The society of Hospital Epidemiology of America (SHEA) has proposed that the HIV-positive health care worker’s viral load can be taken into account in determining whether they should be restricted from performing or assisting with procedures that might pose a risk of blood transfer from provider/worker to patient.

- Henderson DK et al. *SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus*. *Infect Control & Hosp Epid* 2010; 31(3): 203-232. <https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/shea-guideline-for-management-of-healthcare-workers-who-are-infected-with-hepatitis-b-virus-hepatitis-c-virus-and-or-human-immunodeficiency-virus/99255FA2F4C8C236D4BB296590C3CD7E>. Also available at [https://www.shea-online.org/images/guidelines/BBPathogen\\_GL.pdf](https://www.shea-online.org/images/guidelines/BBPathogen_GL.pdf).

**Is this reasonable in light of the extremely small risk of accidental blood transfer and the racial, income and regional disparities in viral load?**

# IMPLICATIONS FOR INDIVIDUALS LIVING WITH HIV SEEKING SURGERY OR OTHER HEALTH CARE

Health care providers who have refused to treat patients with HIV because of an alleged risk of HIV transmission from the patient – primarily surgeons and dentists – have lost their cases because the courts have recognized that with universal precautions the risk of transmission is insignificant.

- [Abbott v. Bragdon, 163 F.3d 87 \(1<sup>st</sup> Cir. 1998\), cert. denied, 526 U.S. 1131 \(1999\)](#)
- [United States v. Morvant, 898 F. Supp. 1157 \(E.D. La. 1995\)](#)

What if a surgeon or other health care provider refuses a procedure requested by a patient because the patient's viral load is not suppressed, or uncontrolled?

# IMPLICATIONS EMPLOYMENT OF PERSONS LIVING WITH HIV IN SAFETY-SENSITIVE POSITIONS OR POSITIONS REQUIRING “GOOD HEALTH”

Individuals living with HIV who are otherwise qualified for law enforcement jobs or other jobs involving risk of injury generally have won discrimination cases against employer claims that the possibility of injury, and exposure to blood, constituted a “direct threat.”

- E.g., [Holiday v. City of Chattanooga, 206 F.3d 637 \(6<sup>th</sup> Cir. 2000\)](#) (HIV+ man seeking position as police officer). *But see*, [Montalvo v. Radcliffe, 167 F.3d 873 \(4<sup>th</sup> Cir.\), cert. denied, 528 U.S. 813 \(1999\)](#) (martial arts school justified in denying admission to 12-year-old boy with HIV). *See also*, [EEOC v. Prevo's Family Market, Inc., 135 F.3d 1089 \(6<sup>th</sup> Cir. 1998\)](#) (grocery store employee with HIV could be terminated because he worked with sharp knives in produce preparation and refused to provide his employer with medical evidence regarding the risk of transmission through accidents).

**Should an applicant's or employee's viral load be relevant?**

**Should an employer be legally permitted to condition employment on an employee's attaining and maintaining an undetectable viral load?**

# WHAT ABOUT THE MILITARY?

The U.S. military bans otherwise qualified individuals with an HIV diagnosis from the uniformed services. Currently serving individuals who receive an HIV diagnosis are barred from deployment overseas, among other restrictions. The Department of Defense recently announced a policy of discharging persons in the uniformed services who are not eligible for overseas deployment within a year. A lawsuit was recently filed challenging the military's HIV policies as outdated and unconstitutional.

- Army Regulation 600-110, *Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus*. April 22, 2014. [https://www.army.mil/e2/downloads/rv7/r2/policydocs/r600\\_110.pdf](https://www.army.mil/e2/downloads/rv7/r2/policydocs/r600_110.pdf).
- Dep't of Defense, *Interim Guidance: DoD Retention Policy for NonDeployable Service Members*. Feb. 14, 2018. <https://www.defense.gov/Portals/1/Documents/pubs/DoD-Universal-Retention-Policy.pdf>.
- Erik Larson, *Trump Administration Can't Dodge Suit Over Military HIV Policy*, Bloomberg Sept. 14, 2018. <https://www.bloomberg.com/news/articles/2018-09-14/trump-administration-can-t-dodge-suit-over-military-hiv-policy>
- Samantha Allen, *The Danger of "Deploy or Get Out" Facing HIV-Positive Troops*, Daily Beast Sept. 19, 2018. <https://www.thedailybeast.com/the-danger-of-deploy-or-get-out-facing-hiv-positive-troops?via=ios>

**Should the military be able to require service members to attain and maintain an undetectable viral load, and consent to regular monitoring?**

# WHAT ABOUT THE FOREIGN SERVICE AND THE PEACE CORPS?

For many years, the State Department barred persons with HIV from the Foreign Service on the grounds that their need for expert health care restricted them from ‘worldwide availability.’ In the wake of litigation challenging that policy as medically outdated and a violation of the Rehabilitation Act, the Government agreed to consider Foreign Service candidates on a case-by-case basis, based on their individual situation.

- [Taylor v. Rice, 451 F.3d 898 \(D.C. Cir. 2006\).](#)
- *U.S. State Department Changes Policy Disqualifying HIV-Positive People From Entering Foreign Service.* The Body Feb. 19, 2008. <http://www.thebody.com/content/art45158.html>.

Recently, Peace Corps volunteers stationed in foreign countries have been terminated when they were diagnosed with HIV. The agency allegedly based its actions on a concern that it would be unable to accommodate the volunteer’s medical needs. The HIV Medicine Association and NASTAD have written the Peace Corps, arguing that HIV treatment is well-tolerated and very effective in most if not virtually all individuals.

- Antigone Barton, *Peace Corps Discharge of Volunteers Diagnosed With HIV Raises Questions About Policy's Realities.* Science Speaks: Global ID News May 22, 2018. <https://sciencespeaksblog.org/2018/05/22/peace-corps-discharge-of-volunteers-diagnosed-with-hiv-raises-questions-about-policys-realities>.

**What relevance should viral load have for a Foreign Service Officer or a Peace Corps volunteer? Should the State Department or the Peace Corps be able to require an individual to attain and maintain an undetectable viral load, and to consent to regular monitoring?**



# IMPLICATIONS FOR THE PROVIDER-PATIENT RELATIONSHIP

## What is the provider's role in urging/persuading the patient to remain treatment adherent in order not to expose sex partners to HIV?

- Fuller SM et al. Patients' perceptions and experiences of shared decision-making in primary HIV care clinics. *J Assoc Nurses in AIDS Care* 2017; 28(1): 75-84. [https://www.nursesinaidscarejournal.org/article/S1055-3290\(16\)30117-0/fulltext](https://www.nursesinaidscarejournal.org/article/S1055-3290(16)30117-0/fulltext).
- Abholz H-H. Conflicts between personal and public health care: Can one GP serve two masters? *Br J Gen Pract* 2007; 57(542): 693–694. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2151782>.
- Bayer R. The continuing tensions between individual rights and public health. *EMBO Rep* 2007; 8(12): 1099–1103. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2267241>.

# Questions? Comments?