

ClusterF*#k

Molecular HIV Surveillance

Criminalization

**And the Real
Risks to PLHIV**

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TCA webinar TODAY

The Center for HIV Law and Policy



HIV prevention research - a new forum
for advocacy on the latest

avac.org/choice-agenda

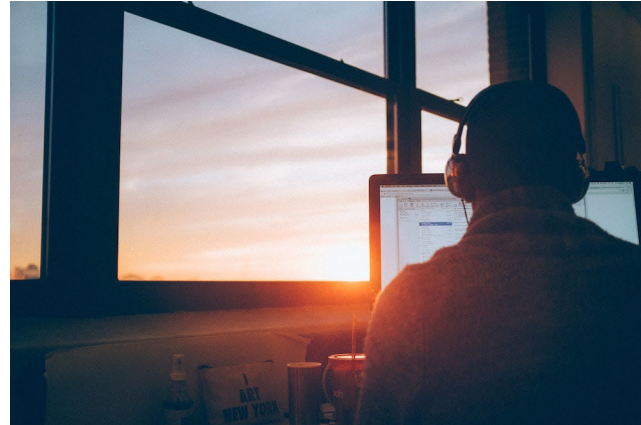
Playlist

A close-up, artistic photograph of a DJ mixer. Two large, white, over-ear headphones are resting on the mixer's surface. The scene is bathed in vibrant purple and blue light, creating a moody, club-like atmosphere. The background is blurred, showing more of the DJ equipment and some colorful bokeh lights.

DJ Jimberly

- **Xanadu**
Unmet Ozcan
- **Rush**
Troye Sivan
- **Ain't No Stopping Us Now**
Risco Connection
- **Corazon Sin Cara**
Prince Royce
- **I'll Be There**
Chic (feat. Nile Rodgers)

Please
join us in
August



THE CHOICE AGENDA

HIV prevention research - a new forum
for advocacy on the latest

The Choice Agenda presents

Tales from Two Cities

HIV and STI research highlights from Brisbane and Chicago

Speakers:

Dr. Aniruddha Hazra – University of Chicago

Nyaradzo M Mgodhi – University of Zimbabwe

Roger Pebody – NAM, Aidsmap.com

Charlie Peterson – University of Illinois - Chicago

August 3 9 AM eastern

Register & more info
tinyurl.com/talesfromtwocities



Cluster F*#k

Speakers

- **Amir Sadeghi**
Policy/Advocacy Manager The Center for HIV Law and Policy
- **Brian Minalga**
Deputy Director Office of HIV/AIDS Network Coordination
- **Andy Spieldenner**
Executive Director MPact Global Action

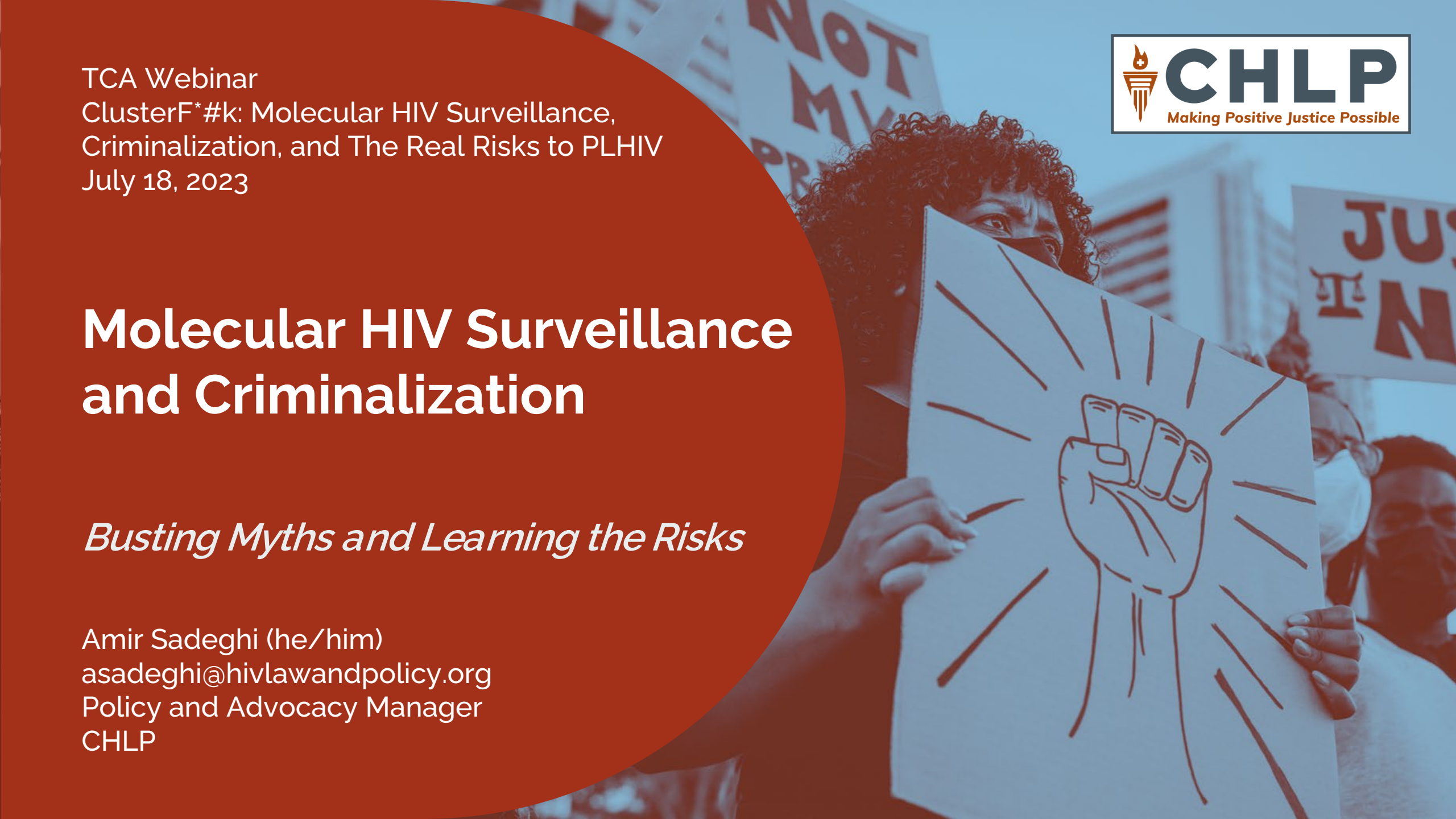
TCA Webinar
ClusterF*#k: Molecular HIV Surveillance,
Criminalization, and The Real Risks to PLHIV
July 18, 2023



Molecular HIV Surveillance and Criminalization

Busting Myths and Learning the Risks

Amir Sadeghi (he/him)
asadeghi@hivlawandpolicy.org
Policy and Advocacy Manager
CHLP



The Center for HIV Law & Policy (CHLP)

- Positive Justice Project
 - New national HIV criminalization organizing body in the works
- Legal and policy analysis, bill drafting assists, and state-specific advocacy resources in 20 U.S. states to date
- Worked with defense attorneys representing PLHIV in dozens of cases over the past several years (e.g., Michael Johnson)
- National Prosecutors Roundtable on HIV Criminal Law: led to dismissal, reduction of charges in at least 4 jurisdictions, now working on guiding principles (with Association of Prosecuting Attorneys)

What is molecular HIV surveillance (MHS)?

MHS became a requirement for HIV prevention funding, has overflowed with controversy ever since

HIV drug resistance test ordered

Genetic data reported to state, local HDs and CDC

Analysis of genetic data

This additional blood sample test creates a genetic sequence of the HIV virus, which doctors use to best prescribe you drugs to effectively manage your HIV.

Genetic data created by drug resistance test is shared, without PLHIV's knowledge or consent, for uses outside of their own individual medical treatment.

Public health officials analyze HIV genetic data and make inferences about the similarity in strains, mapping PLHIV into sexual and social (i.e., needle-sharing) networks, without PLHIV's knowledge or consent.

What is molecular HIV surveillance (MHS)?

MHS became a requirement for HIV prevention funding, has overflowed with controversy ever since

- In short, it's the **public health use of individual's HIV drug resistance data to map the sexual and social networks** of PLHIV
- CDC, state health departments collect, store, analyze, and report HIV drug resistance data to **track “clusters” of HIV transmission**
- They call it “cluster and outbreak detection and response” or CDR
- There are other kinds of “cluster analysis” for public health purposes that don't rely on analyzing molecular data shared without consent

Is MHS like other types of molecular surveillance?

No

- Molecular analysis for foodborne illnesses ≠ MHS
- HIV transmissions are distinct from other infectious diseases
- History of policies that dehumanize PLHIV are foundational to public health in the US

Do they need my consent to share my health data?

No

Health departments and the CDC argue that they don't need your consent to share your HIV genetic data by claiming your general "consent to care" gives them the authority to do what they want with that data.

Most PLHIV don't even know that their HIV genetic data is being used to map the social and sexual networks of other PLHIV, people in their own communities, neighborhoods, and counties.

But my data is kept safe, right?

That's not so clear

The CDC claims they're working to address issues about the privacy of your health data, but data breaches happen all the time.

Victim Count in Alaska Health Department Breach Soars

2018 Breach Report Said 501 Affected, But Now Up to 700,000 Being Notified

Marianne Kolbasuk McGee (HealthInfoSec) · January 23, 2019

Twitter Facebook LinkedIn Credit Eligible Get Permission



2 major Asheville health care providers grapple with significant data breaches

by Charles Perez | Mon, July 10th 2023, 8:28 PM EDT

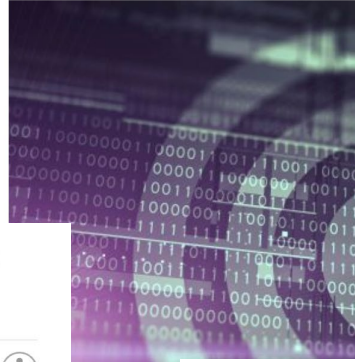


Alaska state breach that people.

JULY 10, 2023 - According to a statement from Nashville-based HCA Healthcare, Mission Hospital's parent company, patient information was "made available by an unknown and unauthorized party on an online forum." (Photo credit: WLOS staff)

Houston Health Department Suffers Healthcare Data Breach

The Houston Health Department, EPIC Pharmacy Network, and Alliance Physical Therapy Group suffered from healthcare data breaches recently.



Hackers breached Florida health care system, potentially exposing data on 1.3 million people

By Sean Lyngaas, CNN
Updated 2:07 PM EST, Tue January 4, 2022



Troubling trends in health data privacy

According to a report from cybersecurity firm Critical Insight, *Healthcare Breach Report*.

- Roughly 20 million people affected by health data breaches in first half of 2022 alone
- Health care providers account for 73% of breaches
- Hackers are shifting from hacking large hospital systems, focusing more on “specialty clinics” that likely have more security vulnerabilities, fewer staff to handle attacks
 - “Specialty clinics” were top source at 31%, up from 23% in 2021, 20% in 2019
- Newer report on 2H shows downtread in number of breaches, but larger number of people affected



Can my health data be used against me?

Yes

HIV criminalization is a real risk for PLHIV because anything from your HIV test results to the genetic data shared for MHS can be used by police and prosecutors against you.

Many states have various types of codes protecting the confidentiality of your health data ... **except** when sharing with law enforcement and with other “authorized” entities.

HIV CRIMINALIZATION IN THE UNITED STATES

AN OVERVIEW OF THE VARIETY AND PREVALENCE OF LAWS USED TO PROSECUTE AND PUNISH PLHIV IN THE US.

LEARN MORE AT HIVLAWANDPOLICY.ORG



6 STATES MAY REQUIRE REGISTRATION AS A SEX OFFENDER as part of the punishment under HIV-specific laws



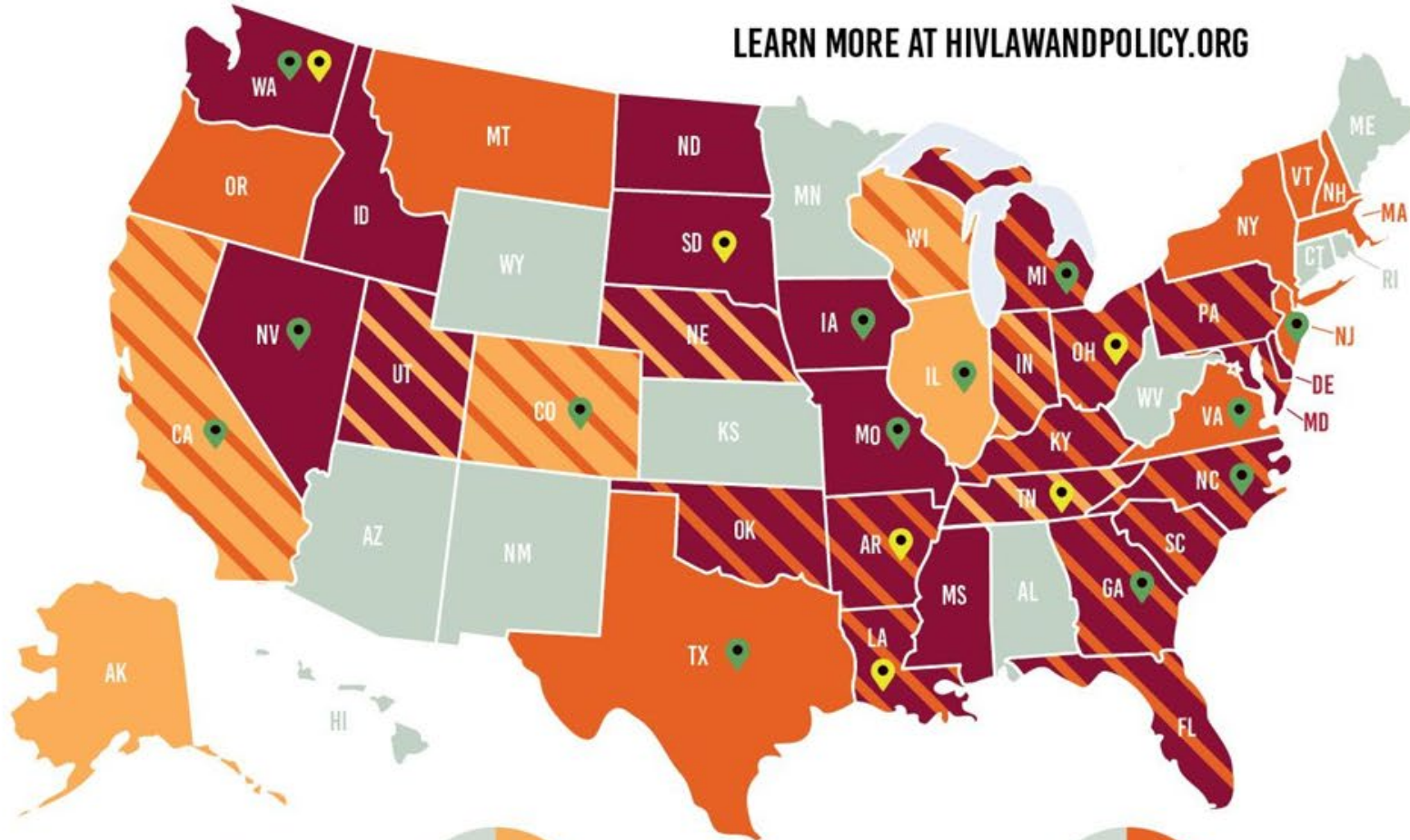
13 STATES HAVE REFORMED OR REPEALED one or more parts of their HIV-specific criminal laws



30

STATES HAVE HIV-SPECIFIC CRIMINAL LAWS AND/OR SENTENCE ENHANCEMENTS APPLICABLE TO PLHIV

(Note: Total reflects overlap among the 25 states with HIV-specific laws and the 9 with sentence enhancements.)



STATES WITH HIV-SPECIFIC CRIMINAL LAWS

including laws targeting sex/non-disclosure, exposure to bodily fluids, needle-sharing, sex work, and blood/organ/semen donation



STATES WITH SENTENCING ENHANCEMENTS

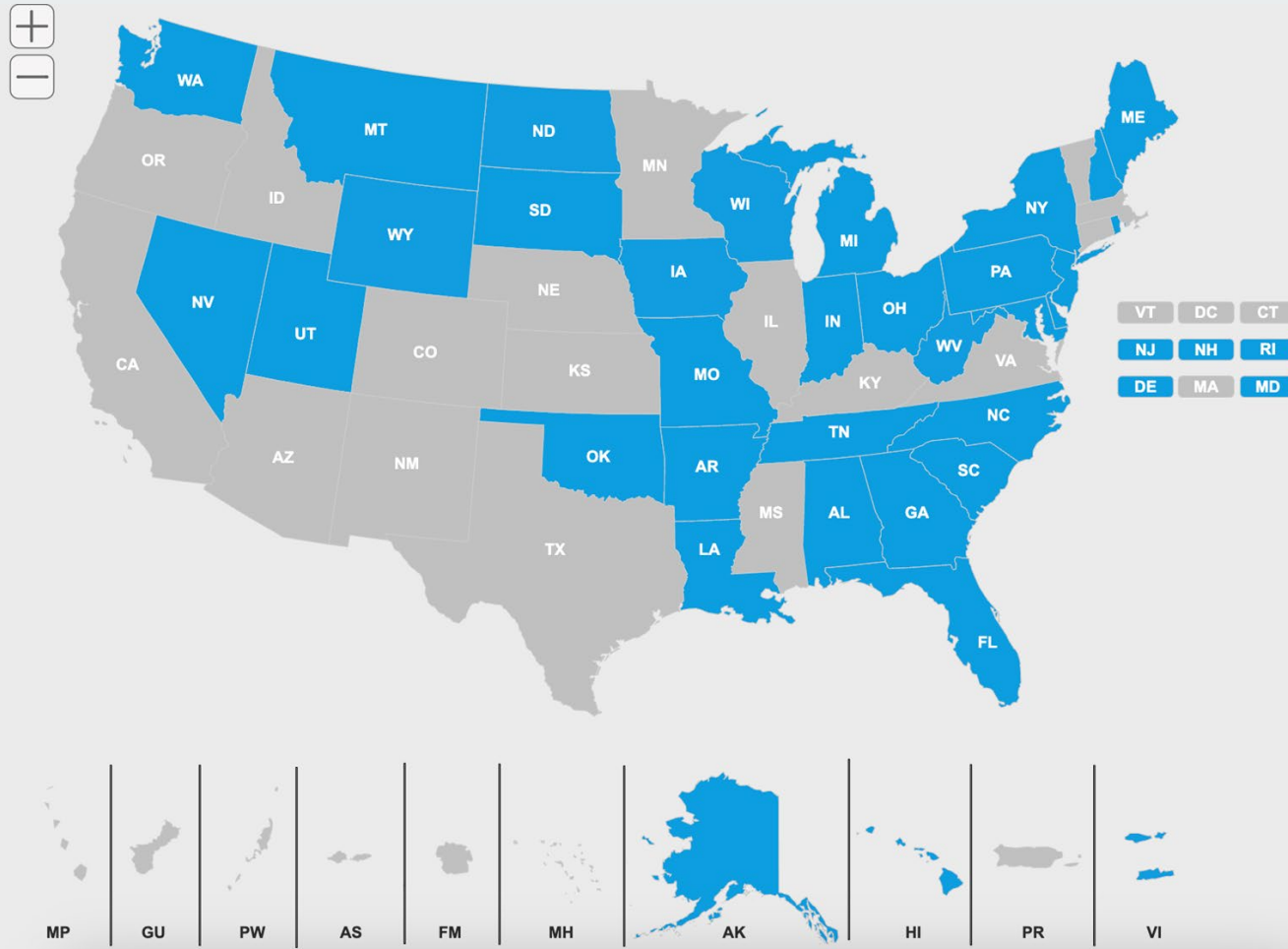
applicable to PLHIV who commit an underlying sexual assault crime.



STATES THAT HAVE PROSECUTED PLHIV UNDER NON-HIV-SPECIFIC, GENERAL CRIMINAL LAWS

This number represents states with reported charges and/or convictions for non-HIV-specific offenses, where positive HIV status was relevant in establishing a (non-HIV-specific) element of the offense.

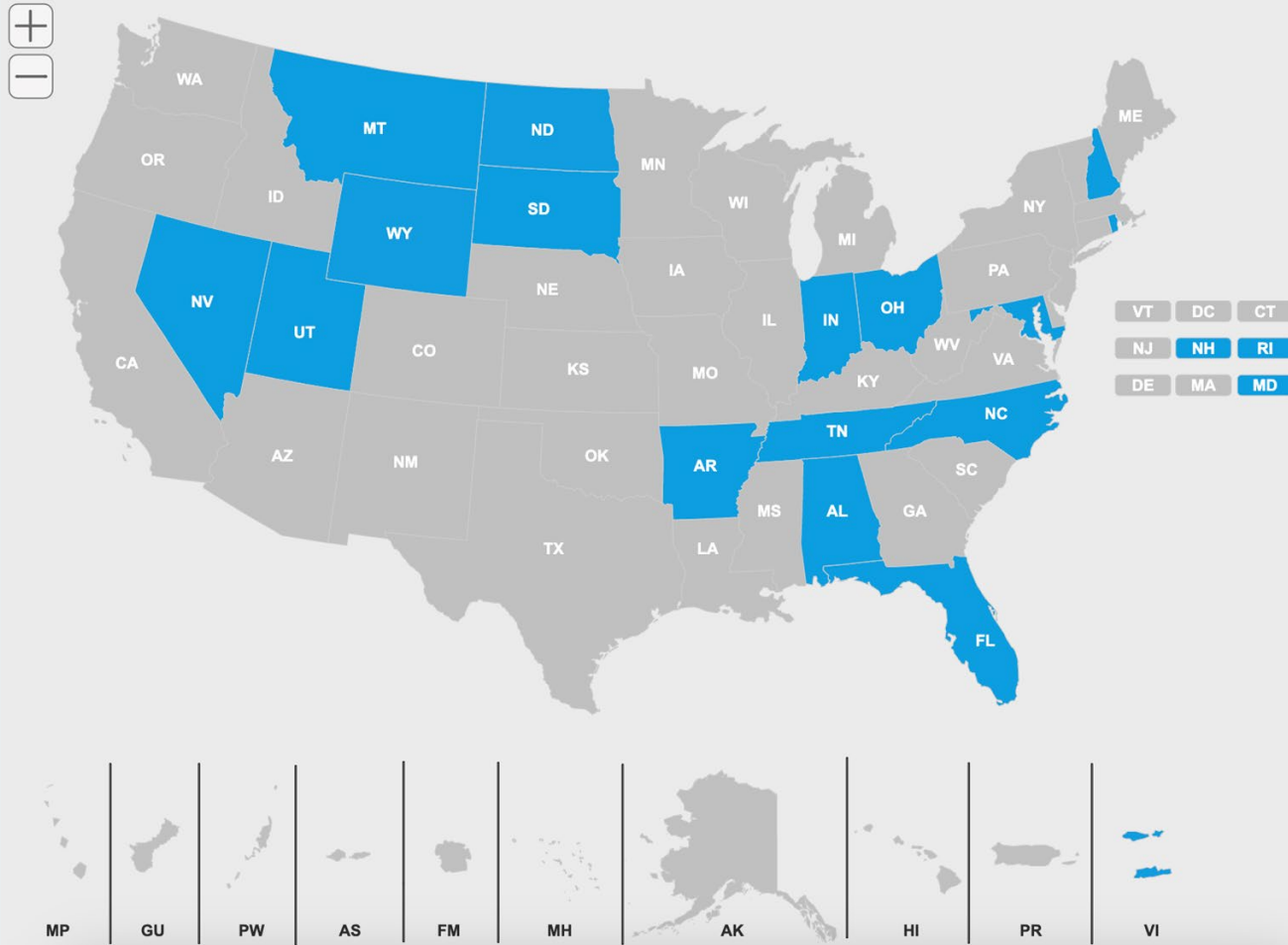
Risk isn't a “hypothetical”—it's the reality right now



States that allow HDs to release HIV data to law enforcement, courts, prosecutors.

Source: NASTAD “US HIV Data Protection Landscape”
<https://nastad.org/resources/hiv-data-protection-landscape>

Risk isn't a "hypothetical"—it's the reality right now



Of those states, these don't even require a court order for data to be released.

Source: NASTAD "US HIV Data Protection Landscape"
<https://nastad.org/resources/hiv-data-protection-landscape>

Public health officials, HDs assist in criminal prosecutions

- Ohio: Ohio Rev. Code Ann. § 3701.243 (B)(1)(h)(2016) allows for HIV test results to be disclosed “to law enforcement authorities pursuant to a search warrant or a subpoena...”
- Tennessee: Tenn. Code Ann. § 68-10-113 (3)(2016) allows for “medical or epidemiological information” to be released to “appropriate state agencies, or county and district courts to enforce ... regulations governing the control and treatment of STDs ...”
- Arkansas: Ark. Code Ann. 20-15-904 (a)(2016) describes PLHIV as “ a danger to the public” and 20-15-904 (c)(2) (2016) states that “any prosecuting attorney of this state may subpoena” medical files to prosecute their HIV criminal laws.

Public health officials, HDs assist in criminal prosecutions

- Maryland: MD. Code Regs. 10.18.04.02(C)(3)(d)(2016) states a health officer may be required to consult with the State's attorney about prosecutions related to disease exposure; MD. Code. Ann., Health-Gen. §§ 18-207(a)(4)(III), (b)(4) (2016) leaves the door open for health "records or files" to be used in criminal proceedings
- South Carolina: S.C. Code Ann. § 44-29-135(c) (2016); S.C. Code Ann. Regs. 61-21(G) (2015) allows for state Department of Health and Environmental Control records and files to be released to law enforcement and used in criminal proceedings

Public health officials, HDs assist in criminal prosecutions

- **Indiana: IND. Code § 16-41-8-4 (2016)** also permits medical records, upon a petition from a prosecuting attorney, to be used in prosecutions
- **Louisiana: LA. Admin. Code Title 48 § 13505(G)(4) (2018)** allows medical information to be released upon court order or other discovery device. The person whose medical records are requested is entitled to adequate notice to allow them to prepare a written or personal response, “unless there is a clear and imminent danger to an individual” (LA. Admin. Code Title 48 §§ 509(F), 13505(B) (2018)).

Communicable disease privacy protections

State confidentiality statutes (*generally*) prohibit release of personally identifiable data without consent

EXCEPT

- To carry out the public health functions of the health department/ public health “emergencies” (e.g., Nushawn Williams)
- To enforce control measures
- In response to a court order or subpoena
- For first responders
- For law enforcement
- Most protect state/local officials against “mistakes”

Lane crossing: public health & law enforcement

Public Health (city and state health departments)

- State laws that require testimony concerning health records, counseling
- Health department officials who offer services as “experts” testifying against PLHIV
- Perceived “duty to warn”

Law Enforcement

- Called on to enforce quarantine, masking orders
- Arrests, enforcement/prosecution of HIV/VH exposure laws and policies occur in a vacuum of information or pushback from public health professionals

MHS data can't prove “directionality” ... yet

Don't let that reassure you just yet

CDC was so concerned about raw “next-generation sequencing data” in 2021 they released a statement cautioning its use (“risks ... outweigh any potential benefits”)

Expanded Guidance on Collection, Use and Release of HIV Sequence Data October 2021

Summary

- State and local HIV surveillance programs funded by CDC should collect HIV sequence data only in the form of Sanger sequences or, when next generation sequencing (NGS) has been conducted, consensus sequences. Currently, there is no documented public health benefit to collecting raw NGS data through HIV surveillance, and therefore, the risks of collecting these data outweigh any potential benefits.
- Analyses of HIV sequence data reported to HIV surveillance programs should not be interpreted as determining transmission direction or proving direct transmission between individuals, nor should analyses attempt to do so.
- CDC does not release HIV sequence data reported from HIV surveillance programs to GenBank or other publicly available sequence data repositories. State and local HIV surveillance programs funded by CDC and their academic partners should not release sequence data to GenBank or other publicly available sequence repositories without individual consent.

Justification

Collecting HIV sequence data is important for detecting and responding to HIV clusters and outbreaks. The sequences typically used for cluster detection by CDC and state and local health departments are either generated through Sanger sequencing or are consensus sequences generated after next generation sequencing (NGS). These sequences provide the most common nucleotide at each location in the sequenced gene(s) and do not provide the ability to identify direction of transmission. These data provide the necessary information to detect HIV clusters and outbreaks and respond with prevention and care interventions, which is the intended purpose for the collection of these data. Raw NGS HIV sequence data (i.e., the granular information about the sequence of each of the thousands of viruses in a person) may offer additional potential to infer direction of transmission between individuals, which is not the intended purpose of collecting these data. The collection of raw NGS data by HIV public health surveillance systems carries implications for the ethical balance of risks and harms of molecular sequence collection.

Currently, the risks of collecting raw NGS HIV data outweigh any potential benefits, as there is no documented public health benefit to collecting these data and these data may offer additional potential to infer direction of transmission. Perceived or actual ability to infer the direction of transmission could be associated with additional risks, such as release of data for non-public health purposes (i.e., for use in criminal or civil cases) or use of data to prompt public health actions that stigmatize people with HIV or people experiencing marginalizing circumstances. These factors could undermine community trust in this work.

Therefore, when laboratories conduct NGS, only HIV consensus sequences (and not raw NGS sequence data) should be reported to or collected by CDC-funded HIV surveillance programs.

Modernization of public health surveillance systems is important and should allow for flexibility in future needs, but raw NGS HIV data should not be collected in public health data systems at the current time. Continued reassessment of the relative benefits and risks of collecting these data, with guidance and input from key partners, including health departments, people with HIV, and laboratories, is essential to understand changing conditions that might shift the balance of benefit and risk. Conditions that might warrant reconsideration of the collection of NGS sequence data by public health agencies include: evidence demonstrating an established public health benefit to the collection and use of these data; people with HIV no longer experiencing disproportionate stigma or harms from criminal justice systems; community consultations to meaningfully involve people with HIV in this decision; and adequate protections in all jurisdictions that collect these data that ensure the data are used only for public health purposes by prohibiting data from being released or used as evidence in criminal or civil litigation.



MHS data can't prove “directionality” ... yet

Don't let that reassure you just yet

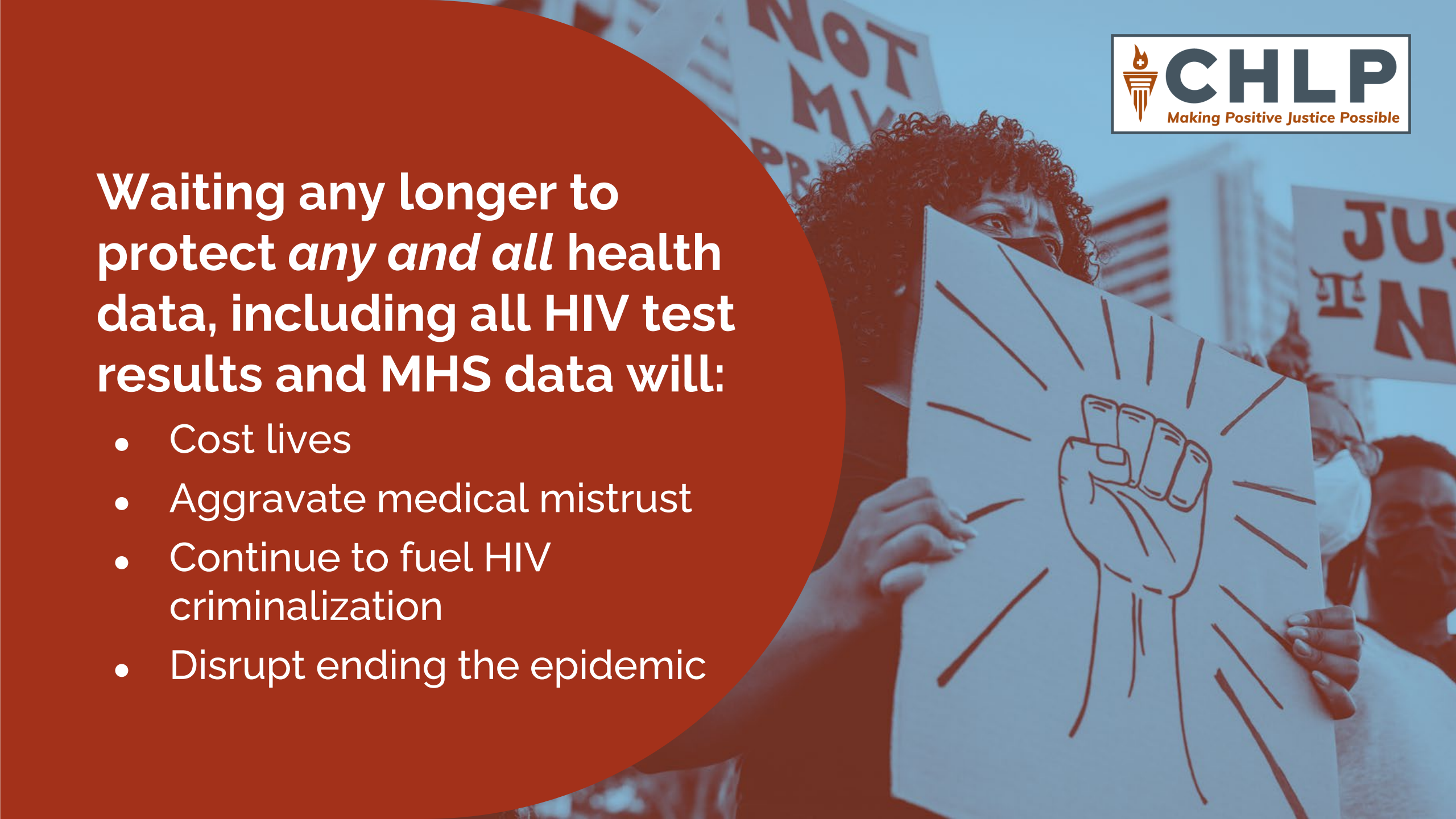
Science doesn't rule in criminal legal courts: prosecutors can use MHS-related data as circumstantial evidence, and judges and juries might misunderstand the limitations (e.g., directionality).

Assumptions about direction of transmission already have produced convictions (e.g., Michael Johnson—also a prosecution in which the state HD cooperated...).

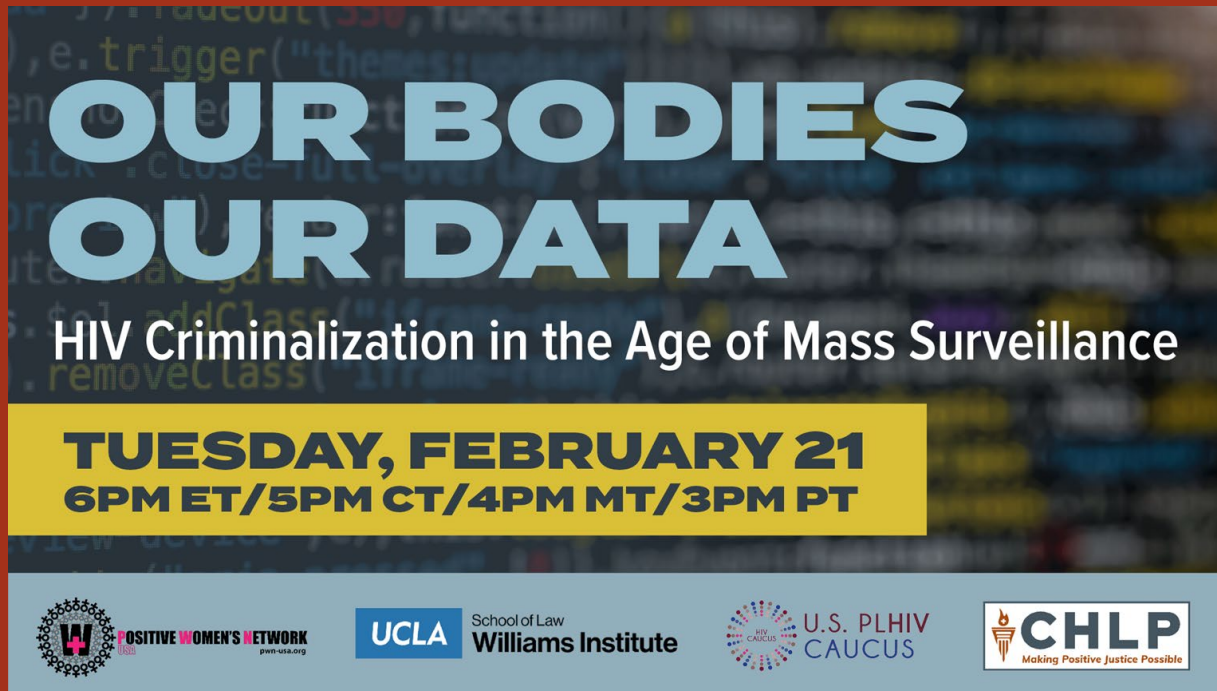
Permitting MHS without the informed consent of patients deepens medical mistrust: building trust in our public health system means respecting the bodily autonomy of PLHIV.

Waiting any longer to protect *any and all* health data, including all HIV test results and MHS data will:

- Cost lives
- Aggravate medical mistrust
- Continue to fuel HIV criminalization
- Disrupt ending the epidemic




Want more about MHS and Criminalization?


The poster features a dark background with faint, colorful code snippets. The main title "OUR BODIES OUR DATA" is in large, bold, light blue letters. Below it, the subtitle "HIV Criminalization in the Age of Mass Surveillance" is in white. A yellow banner contains the date and time: "TUESDAY, FEBRUARY 21 6PM ET/5PM CT/4PM MT/3PM PT". At the bottom, logos for the Positive Women's Network, UCLA School of Law Williams Institute, U.S. PLHIV Caucus, and CHLP are displayed.


**OUR BODIES
OUR DATA**


HIV Criminalization in the Age of Mass Surveillance

TUESDAY, FEBRUARY 21
6PM ET/5PM CT/4PM MT/3PM PT

 **POSITIVE WOMEN'S NETWORK**
pnw-usa.org

 **UCLA** School of Law
Williams Institute

 **U.S. PLHIV
CAUCUS**

 **CHLP**
Making Positive Justice Possible

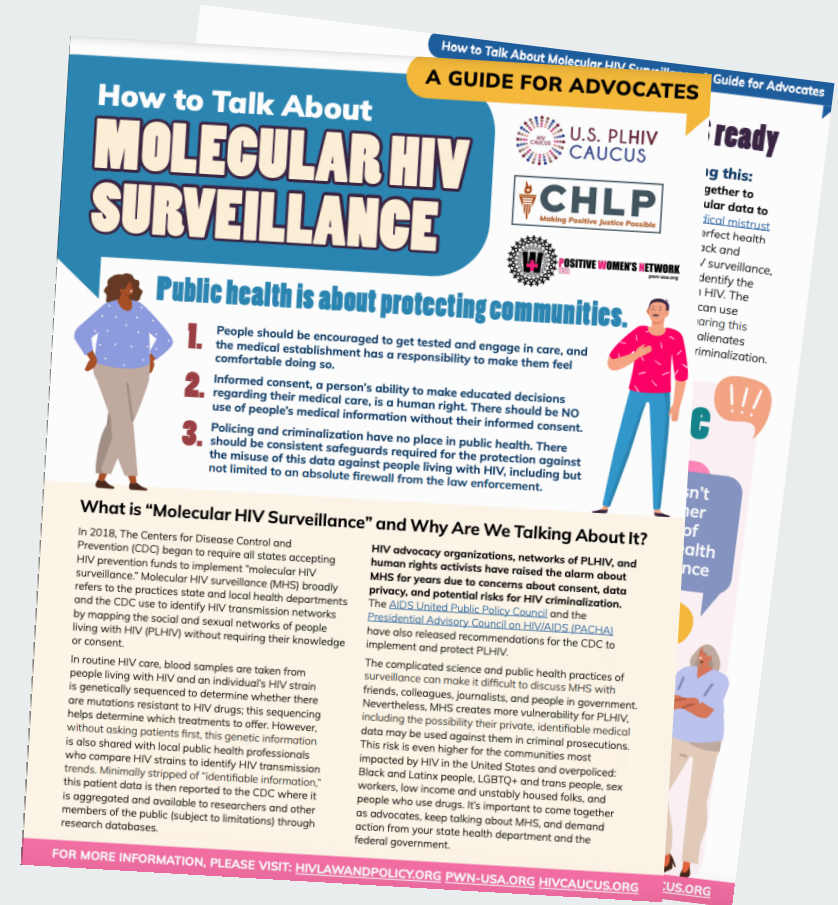
HIV Is Not a Crime
Awareness Day Event
“Our Bodies, Our Data: HIV
Criminalization in the Age of
Mass Surveillance”

[hivlawandpolicy.org/events
/our-bodies-our-data](https://hivlawandpolicy.org/events/our-bodies-our-data)

Want more about MHS and Criminalization?

How To Talk About Molecular HIV Surveillance: A Guide For Advocates

hivlawandpolicy.org/resources/how-talk-about-molecular-hiv-surveillance-chlp-pwn-us-plhiv-caucus-2023





Thank you!

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[@hivlawandpolicy](https://twitter.com/hivlawandpolicy)



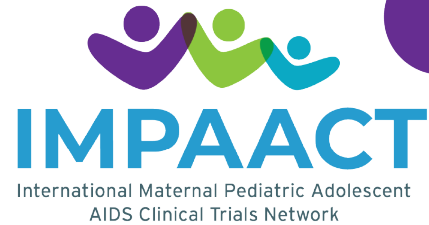


ClusterF*#k

Brian Minalga, MSW

Deputy Director, HANC

Fred Hutch



HIV VACCINE
TRIALS NETWORK

Agenda

Phylogenetics: What and Why

Research vs. Public Health

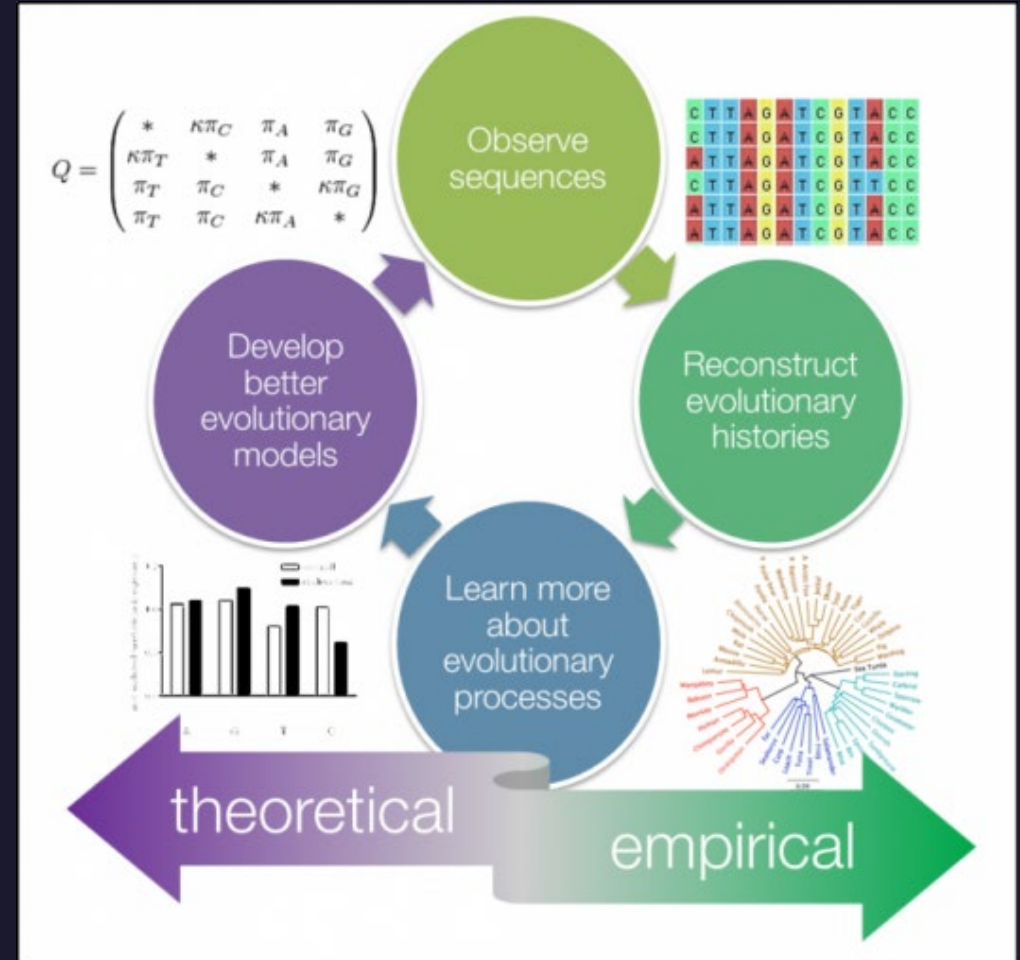
Specific Examples

Working Together



Talk Nerdy To Me

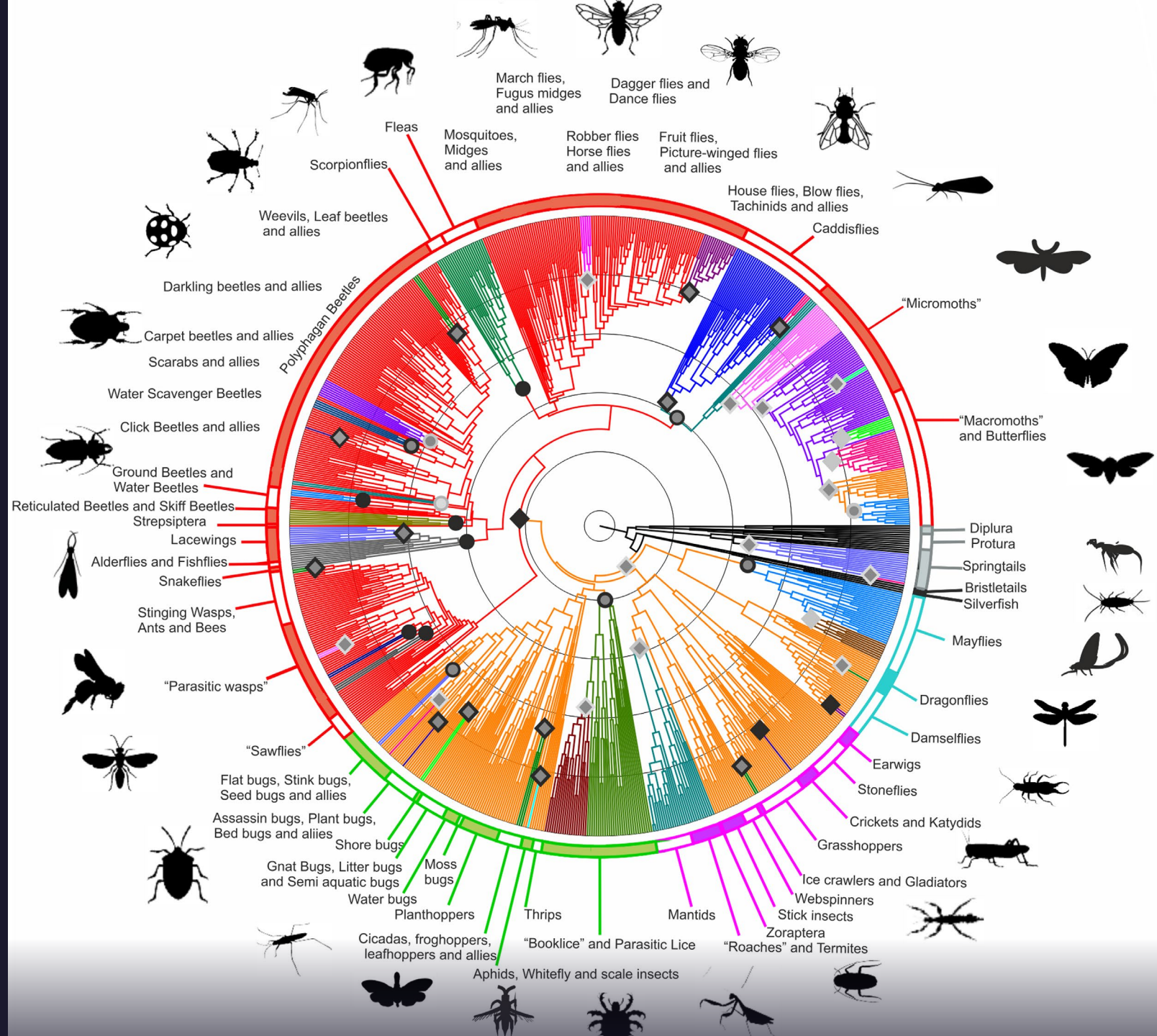
Phylogenetics: the study of evolutionary relationships among biological entities.





Taxonomy

- Morphology
- Behavior
- Phylogenetics



Change of Plans

People \neq Insects

People \neq “Clusters”

HIV \neq COVID

HIV \neq E. coli



Why would we want to understand
HIV phylogenetics?



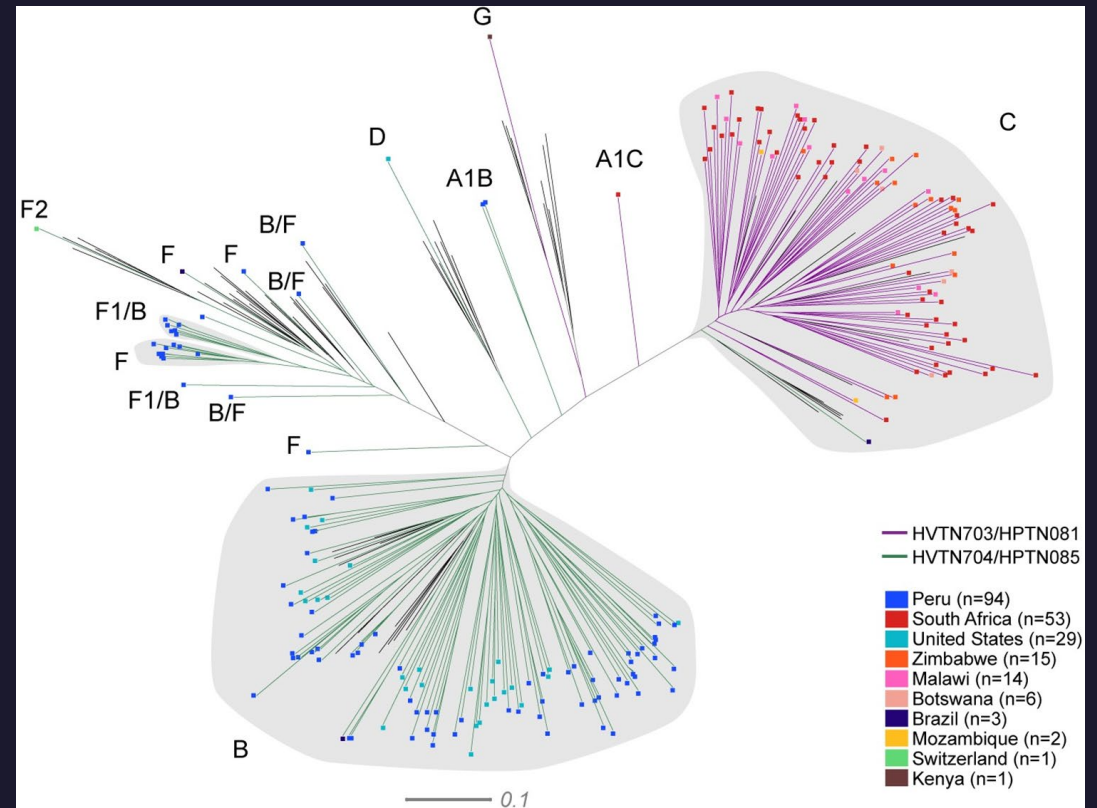
Phylogenetics in HIV Clinical Trials

U=U

- HPTN 052
- PARTNER 1 & 2
- Opposites Attract

0 genetically linked transmission events involving undetectable participants

AMP



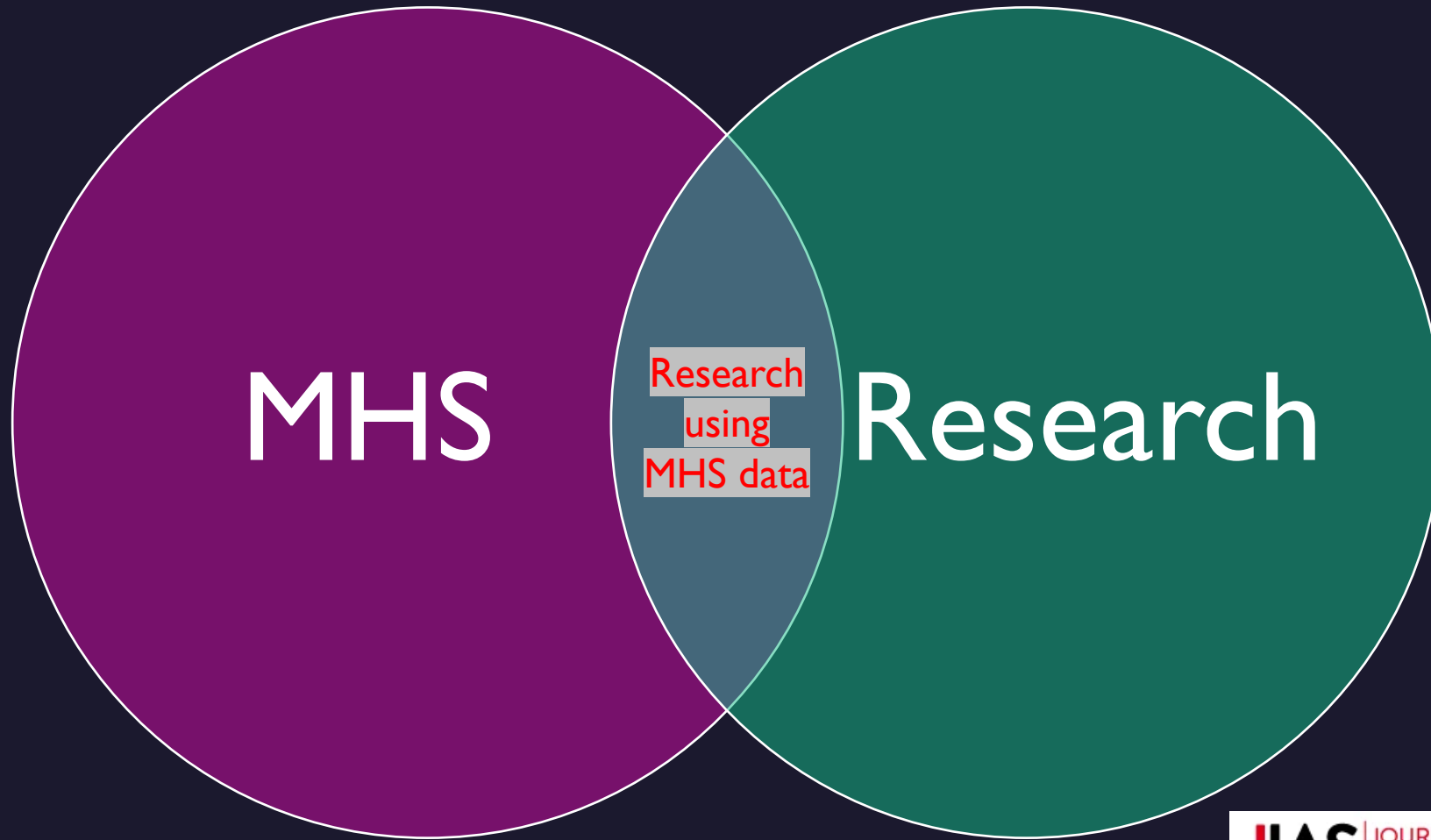
HIV Phylogenetics: Research vs. Surveillance

RESEARCH

- Clear purpose, clear benefit to community and public health.
- Community input (e.g. CABs)
- Informed consent **required**
- IRB, CoC, ethical requirements & checkpoints
- Protections against criminalization (Opposites Attract)

SURVEILLANCE

- Purpose unclear to communities; benefits unproven.
- Implemented without community input.
- No informed consent
- Data protections vary




JIAS | JOURNAL OF THE
INTERNATIONAL AIDS SOCIETY

Open Access



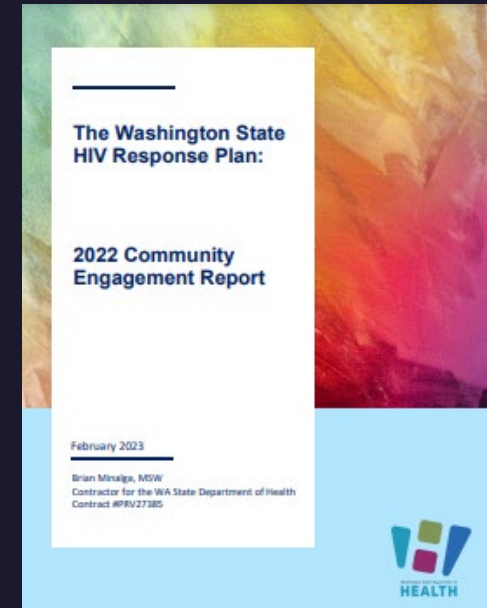
RESEARCH ARTICLE |  Open Access |  

Lessons learned from community engagement regarding
phylogenetic research with molecular HIV surveillance data

Diana M. Tordoff  Brian Minalga, Alfredo Trejo, Alic Shook, Roxanne P. Kerani, Joshua T. Herbeck

First published: 06 July 2023 | <https://doi.org/10.1002/jia2.26111> | Citations: 1

WA State CDR Community Engagement



Themes

- Transparency
- Need
- Context
- Community Input



Transparency

People want to know what is happening
with CDR.



“I can see how they would need more data to make cluster detection effective. I just had my own genetics done through Ancestry.com, and the more people who submit their data, the more information I get into my own ancestry. So I can understand that, and that’s not the problem. The problem is if you’re doing this behind people’s backs and not letting them know. All you have to do is tell me why this is important, and I’m on board. But you’re not letting us know, and that seems shady. That seems very deceptive—and purposely deceptive.”

“I can speak specifically about being a Black woman: Tuskegee is still something that traumatizes us. And what happened in Tuskegee? They didn’t tell the people in that study what was really going on. With molecular analysis, they’re not telling us what’s going on. It’s scary. People are still traumatized about something that happened decades ago—and why? Because it’s still happening today. They’re still not telling us what they’re doing with our data and our medical information.”

Need

Why is CDR needed?



“I am confused about the advantage of molecular analysis. I don’t understand how it is better than speaking with people with an HIV diagnosis and their partners and offering services to communities. Shouldn’t you just outreach to everyone who is out of care no matter what strain of HIV they have? I would also like to know the time and financial costs of molecular analysis in relation to other HIV activities. Is molecular analysis taking resources away from other HIV services?”

“I think this is something that was missing from the DOH presentation. They talked a lot about what’s being done with the data, but not what’s being done with boots on the ground. I didn’t realize that there was any kind of failure going on that necessitated us having to map [HIV] molecularly. So, I think what’s missing there is what kind of services are being provided immediately to individuals.”

Context

CDR is not one-size-fits-all.



“I’m speaking from a place of privilege here. For me...I’m like yeah, go ahead and take my information! But I completely see how this would not be OK for some people. As far as looking at the populations we’re serving, it’s really important to consider how things need to be from their perspective.”

“If I think back to when I was first diagnosed, in that room, I didn’t want you to give me all the molecular stuff. I really just wanted to not be scared that I’m about to die. Think about being a person of color or a woman or transgender. You’re going up against a lot. Your family may or may not accept you, or your community. You’re pretty much by yourself. So people are still battling all these things, and you want to do all this molecular analysis on them? It doesn’t work that way.”

Community Input

Let the community decide what language should or shouldn't be used.



“Language is important, and in this field, there has been so much negative, stigmatizing language thrown at us—everything from *deviants* to *dirty*. DOH needs to think about that. But that’s the thing—if they’re not telling anyone that they’re doing this, then they can use whatever language they want! Because you’re using this terminology that hasn’t been brought through the scrutiny of the public. We’re talking about people—people who are going through what may be the most heartbreaking moment of their lives. So there needs to be more sensitivity around the language. I am not an outbreak. I am not a cluster.”

“Think about how we talk positively about COVID-19 vaccines. We say things like *uptake*, *engagement*, *investment*. Use positive words that aren’t stigmatizing. This is what the planning councils and CABs could really come up with—if they knew about it.”



Summary

“HIV phylogenetics is a powerful technology with the potential to benefit and harm communities of PLHIV. Addressing criminalization and including PLHIV in decision-making processes have the potential to meaningfully address community concerns.”

Working Together

- Goal: End human suffering caused by HIV.
- PLHIV and advocates want to realize this goal.
- Let's unify around this goal.
- Hold each other accountable while remembering we're on the same team.
 - There are those who do not share this goal, who are not on our team.

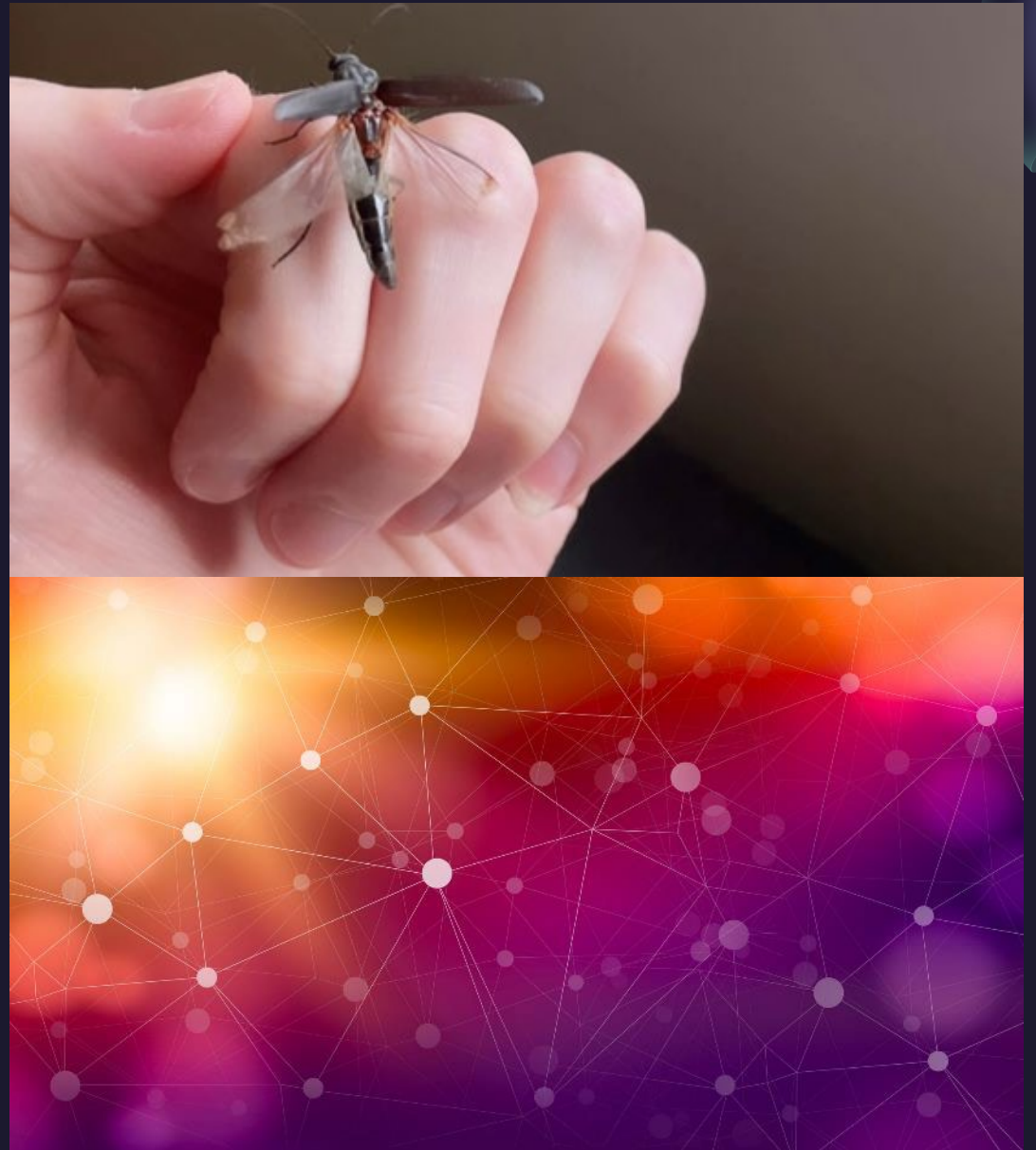
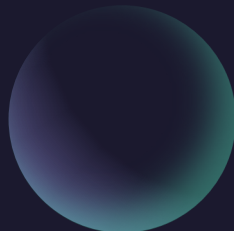


Thank You

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www.hanc.info



Opportunities for Advocacy

Andrew Spieldenner, PhD
Executive Director



- **Lack of community engagement**: When HIV surveillance shifted from anonymous to names-based reporting, there were years of community consultations to establish safety and security protocols
- **HIV Criminalization & Discrimination**: These safety and security protocols did not protect anyone from criminalization or discrimination.
- **Cost Effectiveness**: Cluster detection has revealed that people who use drugs, people who are erratically housed, people of color, and gay, queer and trans people are most likely to not be in care and require targeted HIV services. This is the same data story standard HIV surveillance has given for decades.

Why be concerned?

Can we do anything about this?



Across the world, communities have successfully fought against data collection of biological markers due to discriminatory laws and policies about HIV and the communities most impacted



Talk to the health department and health ministries about their surveillance tools and what they can do to protect community data



Find out if law enforcement is able to access public health data and under what conditions

Examples of Community Advocacy on MHS

[PACHA Resolution in the US](#)

[Kelin](#) in Kenya produces reports, educates the communities, and advocates in legal and policy settings about data protection and rights

US People Living with HIV Caucus, Positive Women's Network, Positively Trans, Sero Project, Thrive SS hosted a series of community education webinars (written about [here](#))

Concerns raised in multiple journals including [Lancet](#), [American Journal of Bioethics](#), [Journal of the International AIDS Society](#) and [Milbank Quarterly](#)

Key Asks

- **Data protection**: Keep individual-level data anonymized and firewalled from other government agencies
- **Safety and Security Assessment**: Has there been a scan of the country or state about safety and security of those most likely to show up in cluster detection (such as people who are erratically housed, trans people, migrants, people of color, gay men, people who use drugs, sex workers)
- **Cost effectiveness**: is this the best use of resources? Why? Remember - for some health ministries, it may be the only way to focus resources
- **Community Engagement**: This should be ongoing and include constituencies of those most impacted by HIV. Public health is a partnership

Fragility of Community Trust

In the first two decades of HIV, communities made demands on governments to treat HIV and people living with HIV in inclusive and respectful ways

Activists insisted on engagement embodied in the [Denver Principles](#), and today with Greater (or Meaningful) Involvement of People living with HIV/AIDS ([GIPA](#), [MIPA](#))

These relationships have improved with decades of ongoing conflict, cooperation and compromise on all sides

Yet when the community raises concerns, then it should be listened out and discussed through ongoing, committed engagement



Questions?