

# BIG IDEAS

ENDING THE HIV EPIDEMIC —  
SUPPORTING ALL PEOPLE WITH HIV AND REDUCING NEW INFECTIONS

## POLICY ACTION CAN INCREASE COMMUNITY SUPPORT FOR HIV CLUSTER DETECTION

Responding to clusters of HIV transmission has been a component of federal and state HIV prevention activities for years, but technological advancements enabling the use of HIV molecular data can enhance the ability to identify and respond to clusters. Using this new cluster detection tool is a central pillar of the Administration's **Ending the HIV Epidemic (EHE) Initiative**. To maximize its success and utility, however, affected communities and policy makers must work together to maximize the prevention potential of cluster detection while working to ensure that people and communities are not harmed in the process.

### PRIORITY POLICY ACTIONS ARE:

#### **RESTRICTING DISCLOSURES TO LAW**

**ENFORCEMENT:** HIV molecular data was generated for the purpose of treating individuals and can be used to protect the public's health. It is not intended for use by law enforcement. Permitting such use would be inappropriate and harmful. This is a moment of opportunity to create new legal protections to prevent law enforcement access to such data. Additionally, consistent with CDC guidance, health departments need to meaningfully engage community stakeholders and establish written policies to resist disclosures of HIV molecular data before cluster detection is implemented.

#### **RE-IMAGINING HOW HEALTH DEPARTMENTS ENGAGE INDIVIDUALS AND COMMUNITIES:**

Across the country, there is significant variation in how health departments interact with individuals and communities most heavily impacted by HIV. A new commitment is needed to raise the bar for all health departments and move away from paternalistic and moralizing approaches to HIV prevention. Critical starting points are to create stronger uniform federal standards for partner

services and the disease intervention specialist (DIS) workforce and to promote adoption of best practices for community-health department collaboration.

#### **MONITORING COMPLIANCE WITH CDC DATA AND SECURITY STANDARDS:**

With the adoption of name-based reporting for HIV and AIDS diagnoses, CDC adopted unprecedented data and security standards for health departments. Recently, CDC instructed health departments to review their policies and practices. A needed next step is to develop an audit and compliance plan to ensure that health department practices protect data and prevent harm.

#### **EDUCATING STAKEHOLDERS ON PUBLIC HEALTH PRACTICES:**

HIV cluster detection has generated significant questions and concern. Moreover, many community stakeholders are unaware of longstanding public health practices that are critical to protecting the public. Health departments, with CDC support and guidance, should do more to broaden the understanding of how they operate to promote and support the health of communities heavily impacted by HIV.

**INTERVENING** rapidly when HIV is transmitted is critical to reducing the impact of HIV on the most impacted communities. Molecular cluster detection and response is a longstanding public health tool used for purposes such as controlling the spread of tuberculosis. Recently, it has been applied to HIV cluster detection. This is possible because HIV drug resistance testing, conducted as the standard of care for the clinical management of HIV, yields data about the HIV virus in individuals and is collected by law by health departments. Health departments report these data, in anonymized form, to the Centers for Disease Control and Prevention (CDC). By analyzing differences in the genetic sequence of the HIV virus circulating within a community, both health departments and CDC can identify clusters where transmission is occurring rapidly.

The effectiveness of prevention and care interventions can be enhanced through timely and intensive services and supports in places where HIV transmissions are occurring most frequently. Nationally, the HIV transmission rate, which is the number of infections per year for every 100 people living with HIV, has fallen to about 4. In the first 60 clusters identified by CDC since it began its cluster detection efforts, the transmission rate was 44, eleven times the national rate.<sup>1</sup> Cluster analysis creates a compelling opportunity to intervene in places where HIV transmission rates are high and can therefore be a highly useful tool, in combination with traditional detection and response, for guiding the delivery of intensive services to stop transmission, offer prevention services, and get people into care.<sup>2,3</sup>

## ENHANCING TRUST IS CRITICAL TO THE SUCCESS OF HIV CLUSTER DETECTION

If the case for using HIV molecular data to identify and initiate a public health response to transmission clusters is clear, the risks must be acknowledged and mitigated. Priority issues for successful implementation of cluster detection and response are:

### LIMITING DISCLOSURES OUTSIDE OF PUBLIC HEALTH:

While individuals have a theoretical right to control and limit access to their health information, this right is constrained in significant ways. For example, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides federal standards for the use and disclosure of individually identifiable health information and gives individuals an array of rights, including rights to examine and obtain copies of their health records and to request corrections.<sup>4</sup> The Privacy Rule, however, only applies to “covered entities” (i.e. health plans, health care clearinghouses, or health care providers who conduct certain financial and administrative transactions electronically) and their “business associates.” Health departments are not required to comply with the Privacy Rule unless they function as covered entities (though many state-level laws and privacy rules specific to HIV provide greater privacy protections than the Privacy Rule). There also are broad exceptions for when the Privacy Rule’s protections do not apply and disclosures can be made without an individual’s consent, including when

## FROM CLUSTER DETECTION TO PUBLIC HEALTH RESPONSE

### HIV Cluster Among People Who Inject Drugs in Seattle-King County

Seattle-King County, Washington has been at the forefront of the HIV response, and new diagnoses declined there by 51% from 2008-2017. In 2018, an HIV cluster was identified among people who were homeless, most of whom were people who inject drugs (PWID). Fourteen cases were diagnosed in 2018 within a 3-square mile area, and cluster analysis linked them to a total of 23 cases diagnosed since 2008. In response, the health department:

- Issued an alert to medical and social services providers concerning the cluster.
- Worked with local emergency departments to increase screening of people who are homeless and PWID.
- Expanded outreach testing, condom distribution, and syringe services in north Seattle.

- Expanded HIV testing and pre-exposure prophylaxis (PrEP) among PWID through its STD clinics and syringe services programs, as well as through a mobile clinic in north Seattle serving women who engage in transactional sex or who are homeless.
- Is assessing needs and preferences for medical and social services among PWID or people who are homeless in north Seattle.

Also, the King County jail expanded HIV testing, including opt-out testing at health assessments at 10-14 days, and when resources permit, at time of booking.

**SOURCE:** Golden MR, et al. Outbreak of Human Immunodeficiency Virus Infection Among Heterosexual Persons Who Are Living Homeless and Inject Drugs — Seattle, Washington, 2018. *MMWR Morb Mortal Wkly Rep* 2019;68(15):344-349.

## IT IS IMPERATIVE THAT STATE POLICY MAKERS CONSIDER UPDATING STATUTES AND REGULATIONS TO PROHIBIT HEALTH DEPARTMENTS FROM DISCLOSING INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION TO LAW ENFORCEMENT.

required by law and for disclosure to law enforcement in certain instances. Covered entities may disclose protected health information to comply with a court order or subpoena and to prevent or lessen a serious and imminent threat to the health and safety of an individual or the public. Given that many jurisdictions prosecute people living with HIV, real harm could result from disclosing health information like HIV molecular data to law enforcement.

In addition to continued efforts to modernize HIV criminal laws and end the unjust prosecution of people living with HIV, greater protections are needed to limit the disclosure of individually identifiable health information, including surveillance data, field interviews, and partner services information collected by health departments, to law enforcement. A priority focus should be on prohibiting disclosure of individually identifiable HIV molecular data. Federal and state public health officials have stated that HIV molecular data collected for public health functions

should not be disclosed to law enforcement.<sup>5</sup> At the same time, law enforcement has requested HIV non-molecular data in the past and may seek to obtain molecular data in the future as awareness of these data increases and genetic sequence technology evolves. Beyond HIV, it is important to consider prohibiting health departments from disclosing other individually identifiable health information to law enforcement, such as information related to viral hepatitis and sexually transmitted infections (STIs). Another priority should be to regulate health information disclosures to law enforcement from academic institutions, laboratories, and other sources.

State and federal action is needed to create new protections to prevent law enforcement access to HIV molecular and other data. The most actionable approaches are likely at the state level. State policy makers should consider opportunities for amending statutes and regulations to prohibit health departments from disclosing individually identifiable

## HIV MOLECULAR DATA: HOW TO RESPOND TO REQUESTS

Extensive work is taking place across the country to modernize HIV criminal statutes and educate law enforcement, prosecutors, and judges about the science of HIV transmission. In HIV criminal cases, prosecutors may subpoena or request health department data to prove that a person has been diagnosed with HIV. We believe that such disclosures should be resisted to the extent possible. Prosecutors also may request HIV molecular data for purposes beyond proving knowledge of HIV status, and this raises additional issues. In some states, criminal statutes criminalize actual transmission and not simply failure to disclose one's HIV status. HIV molecular data have limited value in proving this element of the law because they can only show that persons are part of a molecular cluster but cannot conclusively demonstrate whether one person transmitted HIV to another. For this reason, disclosure of HIV molecular data should also be resisted.

State laws and regulations authorize health departments to disclose individually identifiable HIV data without consent for purposes such as disease surveillance, investigation, or control. The public good of HIV surveillance justifies this approach

(Wertheim et al, 2019). Almost all states also authorize health departments to share HIV data with law enforcement, and most states provide discretion to health departments and their legal counsel to approve, narrow, or deny data sharing requests (Killelea & Molozanov, 2018). Legal counsel for health departments should review requests and determine whether compliance is consistent with HIPAA, state law and regulations, and health department policy and if there are grounds for objections. Counsel can (1) formally challenge requests, (2) resolve requests informally, or (3) comply with requests. In the case of HIV molecular data, counsel could argue that disclosure is irrelevant to any legal proceeding or investigation. Counsel may also argue that the data is inadmissible in a legal proceeding because it is likely to confuse or mislead a jury and lead to an unfair prejudice against the defendant.

**SOURCES:** Killelea A, Molozanov D. *HIV Data Privacy and Confidentiality: Legal and Ethical Considerations for Health Department Sharing*. June 2018; Wertheim JO, et al. Consent and criminalization concerns over phylogenetic analysis of surveillance data—Authors' reply. *Lancet HIV* 2019;6(7):e420-421.

health information to law enforcement or to authorize disclosure only pursuant to a court order. Given the potential for obstacles in state reform efforts and the need for more immediate action, legal counsel for health departments should be prepared to act readily and interpret existing statutes and regulations as narrowly as possible to preclude release of this information to law enforcement.

Federal encouragement of state action is also key. CDC should provide technical assistance to health departments on responding to requests for individually identifiable health information, and it should condition HIV testing and surveillance grant funds on documentation of state policies that prohibit law enforcement access to this information. While there is a clear need for cluster detection and

response to focus and enhance HIV prevention efforts and implementation of this strategy must continue, CDC should make clear that health departments have some flexibility not to implement the strategy right away if time is needed to engage community stakeholders around law enforcement access to HIV molecular data. CDC has released guidance to this effect.<sup>6</sup> In some cases, allowing time for community engagement may require health departments to temporarily stop cluster detection activities. CDC must be proactive in working with health departments and other partners to prevent disclosure to law enforcement.

**MEANINGFUL PARTNERSHIPS BETWEEN COMMUNITIES AND PUBLIC HEALTH:** A critical challenge for CDC and health departments is

## POTENTIAL STATE AND FEDERAL ACTIONS FOR LEGAL REFORM

### STATE LEGISLATURES COULD:

- Modernize HIV criminal laws to end the unjust prosecution of people living with HIV
- Prohibit health department disclosure of individually identifiable health information or HIV molecular data to law enforcement
- Authorize health department disclosure to law enforcement only pursuant to a court order
- Direct health department legal counsel to interpret existing laws as narrowly as possible to preclude the release of HIV molecular data
- Impose additional restrictions on HIPAA covered entities that seek to share HIV molecular data or other health information with law enforcement

### STATE PUBLIC HEALTH AUTHORITIES COULD:

- Support the modernization of HIV criminal laws by working with their legislatures or taking administrative action
- Adopt regulations to prohibit the health department from disclosing individually identifiable health information or HIV molecular data to law enforcement
- Establish written policies for responding to subpoenas and requests for information
- Educate law enforcement, prosecutors, and judges about current HIV science, harm reduction, and the limits of HIV molecular data, including that it is impossible to use these data to accurately determine whether one person transmitted HIV to another

### CONGRESS COULD:

- Enact a generally applicable law to prohibit any entity from disclosing HIV molecular data to law enforcement (Note: a federal statute regulating only disclosure from health departments to law enforcement may raise constitutional issues)
- Consider opportunities for amending HIPAA or directing the Department of Health and Human Services to regulate entities that create, maintain, or use health information databases, from which health departments conduct HIV cluster detection analysis
- Amend the Public Health Service Act that funds CDC to condition the receipt of federal funds on states enacting policies to prohibit disclosure of individually identifiable health information or HIV molecular data from health departments to law enforcement

### CDC COULD:

- Establish a funding condition that prohibits health department disclosure of individually identifiable health information or HIV molecular data to law enforcement
- Fund and provide technical assistance to health department legal counsel on establishing written policies for responding to subpoenas and other requests for information
- Promote collaborations with the National Association of Attorneys General, the American Bar Association, and the American Judges Association

## HIV CLUSTER DETECTION: WHY IT MATTERS

HIV cluster detection complements traditional public health activities and can identify situations where HIV is spreading rapidly. When a cluster is identified, CDC works with state and local health departments to respond. In 2013, CDC started working with 27 health departments to conduct cluster detection analysis, and this was expanded in 2018 to all health departments. To date, CDC has identified 145 high priority transmission clusters.

### BENEFITS OF ADDING CLUSTER DETECTION TO TRADITIONAL PUBLIC HEALTH METHODS

**SUPPORT COMPREHENSIVE AND EFFECTIVE RESPONSE:** By understanding where clusters are arising, health departments can respond in a more comprehensive way with more intensive resources than would be possible if resources were spread evenly across the population. Cluster detection supports health departments to identify gaps in HIV prevention and address those gaps through targeted provision of services, including HIV testing, linkage to care, partner services, condoms and PrEP, syringe services and other harm reduction services, and outreach to affected communities. For example, in 2017, Texas investigated a cluster of HIV cases among Latinx gay and bisexual men around San Antonio. Molecular data found 24 individuals were part of the cluster, but by pairing this with partner services information, they determined that the network of sexual or needle-sharing partners comprised 87 individuals, all of whom were prioritized for services.

**AVOID UNNECESSARY RESPONSE:** A Maryland town that typically saw one HIV diagnosis a year saw six within a few weeks. Molecular data demonstrated that these infections were unrelated.

## HIV CLUSTER DETECTION: WHAT CAN GO WRONG

Living with HIV continues to have consequences, and it is imperative that in using cluster detection to better respond to outbreaks, we do not increase the vulnerability of individuals or communities.

**CRIMINAL PROSECUTION:** 34 states have HIV criminal laws and/or sentence enhancements that are applicable to people with HIV, and 24 states have prosecuted people with HIV using general criminal statutes. Allowing HIV molecular data to be accessed by law enforcement could have a serious chilling effect that inhibits HIV screening or treatment decisions. While the technology itself cannot show that one individual transmitted HIV to another even if two people have HIV viruses that are closely related, advances in this technology that allow inference of directionality in transmission may be available in the future.

**STIGMA AND DISCRIMINATION:** A benefit of cluster detection is that it enables identification of networks of individuals for intensive prevention and care services. The publicity around such networks has the potential to further stigmatize already marginalized individuals or groups. Therefore, strong partnerships between community stakeholders and public health are needed to provide a context for new clusters and communicate with the public in sensitive and appropriate ways.

**IMPACT ON OTHER PUBLIC SERVICES:** At a time when many HIV communities are feeling threatened by government policy makers, focused efforts need to ensure that the use of cluster detection has no impact on immigration proceedings or public charge determinations, eligibility for health or human services, or leads to diminished social support for groups such as people who use drugs, immigrants, transgender people or other LGBTQ people, or racial/ethnic minorities.

**HIV MOLECULAR DATA ENABLES THE IDENTIFICATION OF AND RESPONSE TO TRANSMISSION CLUSTERS MISSED BY STANDARD SURVEILLANCE.**

how to leverage their resources to ensure that all health departments learn and adopt best practices for engaging community stakeholders. CDC and health departments must elevate the standard for partner services (that are provided to the sexual and needle-sharing partners of persons diagnosed with HIV and STIs) and the disease intervention specialist (DIS) workforce (that finds and counsels individuals and their partners). In some jurisdictions, HIV cluster detection has been deployed with minimal controversy because health departments engaged with community stakeholders before implementing this practice and there was meaningful collaboration.<sup>7,8</sup> In other places, communities have reacted with alarm to cluster detection. Much of this appears to stem from longstanding distrust of health departments, as well as unease (or even anger) at how partner services are used. Some individuals report shaming, threats to withhold services, and other problematic practices. CDC, working with health departments at all levels, should disseminate best practices and establish and enforce clear training criteria for DIS programs to effectively meet community needs.

**DATA AND SECURITY COMPLIANCE:** CDC funds state and local health departments to carry out essential HIV public health functions, including managing their surveillance and other data systems. This funding includes well-developed standards and requirements for how health departments must secure their data, restrict access, and prevent against privacy breaches and inappropriate disclosures. Given the heightened level of concern over emerging public health tools, CDC should engage stakeholders to review current safeguards and assess whether additional actions are needed. Additionally, CDC may consider developing an audit and review timetable to periodically assess and improve compliance with federal requirements.

**KNOWLEDGE OF PUBLIC HEALTH EFFORTS:** Renewed efforts are needed to educate HIV community stakeholders about how public health operates, including how health departments collect and use information, protect confidentiality, and use longstanding public health tools and emerging technology to prevent HIV. CDC has begun to conduct

webinars and develop consumer education materials about HIV cluster detection. More such activities are needed at the federal, state, and local levels. These activities must extend beyond education about HIV cluster detection to full engagement with affected communities that bolsters their understanding of public health efforts in general.

## THE TIME IS NOW

With cluster detection and response being a primary focus in the EHE Initiative, taking concrete steps to minimize the risks to individuals and communities is essential. Now is the time for bold action to establish policies and practices that enable communities and public health to work as collaborative partners toward a shared goal of ending HIV transmissions and supporting all people with HIV to remain safe and to lead long and healthy lives.

- 1 Frances AM, et al. Rapidly growing HIV transmission clusters in the United States, 2013-2016. Conference on Retroviruses and Opportunistic Infections 2018; Boston. Abstract 40.
- 2 Centers for Disease Control and Prevention. Detecting and Responding to HIV Transmission Clusters: A Guide for Health Departments. June 2018.
- 3 Dennis AM, et al. HIV-1 transmission clustering and phylodynamics highlight the important role of young men who have sex with men. *AIDS Res Hum Retroviruses* 2018;34(10):879-888.
- 4 45 CFR Parts 160 and 164.
- 5 Oster A. Hugging phylogenetic trees: Use of molecular analysis for public health intervention. Conference on Retroviruses and Opportunistic Infections 2019; Seattle. Abstract 68.
- 6 Centers for Disease Control and Prevention. Additional Implementation Guidance for PS18-1802 Strategy 3: Cluster Detection and Response. November 2018.
- 7 Watson J, et al. Collaborative state and local health department response to intervene in a rapidly expanding molecular HIV cluster in Michigan. 2019 National HIV Prevention Conference; Atlanta. Abstract 5893.
- 8 McNeese M, et al. Biomedical intervention meets community engagement: Introducing molecular HIV surveillance (MHS) cluster analysis to community and stakeholders. 2019 National HIV Prevention Conference; Atlanta. Abstract 5788.