DEPARTMENT OF HEALTH

Transcript: HIV Molecular Data
Using HIV data to prevent infections and improve health

Hello, my name is Jared Shenk, and I'm the HIV care and prevention epidemiologist at the Minnesota Department of Health. Thank you for the opportunity to speak today about a new tool for HIV prevention, which is the use of molecular data to inform our response to HIV in the state. Molecular epidemiology is not a new concept, because some states have been using it for the last few years, but it is now a nationwide CDC requirement, and Minnesota will be participating. In this presentation, I will cover some ways that HIV molecular epidemiology has been used in the past and how both the HIV prevention and partner services programs at the Minnesota Department of Health will implement this new HIV prevention strategy.

So what are HIV molecular data? The collection of DNA sequences of an individual HIV virus can be used to identify when and where HIV is spreading quickly within populations. It is an additional tool to help make traditional public health methods more effective, though partner services programs have been collecting data about HIV case relation and clustering for decades. HIV molecular data cannot prove the direction in which HIV transmission occurred – it can only identify groups of HIV infections that are closely related. This is a new CDC requirement for all health departments. The role that the HIV surveillance unit will play in molecular data collection is largely set and controlled by CDC, but what the HIV prevention and partner services units at the health department do with those data has some more flexibility, and that's where community input will be very useful. At MDH, we understand and respect that this intervention may be concerning for some members of the community, for a range of reasons, and we are committed to gathering and using your feedback as we plan to implement this requirement.

As part of the implementation of HIV molecular epidemiology, the CDC would like for state and local health departments to engage community members to:

1. Increase understanding about HIV molecular data and how they will be used
2. Increase understanding about concerns that community members may have about the collection of public health data
3. Work together to both address community concerns and minimize any risks identified in conversations with community members

First, we will cover how HIV prevention has evolved over time.

We are at an exciting time in HIV prevention. Testing is faster and can detect infection earlier. If that test is positive, we have improved treatment options that can save lives and prevent future transmissions. For those that are negative but are at risk, we have effective prevention options, including PrEP and PEP, condom distribution, and syringe service programs. And we now have improved strategies and interventions to reach populations in need of prevention, care, and related services.

We all share these HIV prevention goals, which include ensuring that people with HIV live healthy lives, reducing the number of new HIV infections, and reducing HIV-related health disparities. As I just mentioned, we have some great prevention options. However, we still have some major challenges. Some groups are at very high risk of getting HIV during their lifetime; for example, communities of color, gay, bisexual, and other men who have sex with men, and people who inject drugs. We also know that we have groups at risk for outbreaks. People's health is on the line, and to achieve these prevention goals, we need to use all tools available to us.

Let's start by talking about traditional public health practice.

Public health helps people and communities. In order to understand public health problems, CDC and health departments monitor and report illness and other health conditions. This is called public health surveillance. The word surveillance can have different meanings in different situations, but public health surveillance has a very different goal than some other types of surveillance, and the information health departments gather guides public health policy and prevention strategies to keep people healthy.

Public health surveillance has been used for more than 100 years for a wide variety of conditions, like foodborne illness, cancer, and tuberculosis.

This monitoring is important for detecting developing outbreaks. For example, public health data help to find outbreaks associated with contaminated food and keep the food supply safe. It's also important for helping people at risk to stay well. For example, when public health identifies a community with increases in tuberculosis, it can help to get testing and treatment to the people who need it. Overall, public health surveillance helps us to target limited resources to the people and areas that need them most. For example, public health data help to identify states with high rates of drug overdoses. Those states can then work to prevent overdoses and address opioid use. Without public health surveillance, our society couldn't prevent illness or provide care as effectively.

Public health surveillance systems have evolved over the past century, with the availability of new technologies.

The public health data that we collect through HIV surveillance systems have evolved over time, and how we use those data –including the extent to which data are used for public health prevention and response activities– has also evolved, along with our understanding of HIV treatment and prevention. From early on, public health data were the best source of information to describe who was being affected by HIV and where the virus was spreading.

Until effective antiretroviral treatment became available, communities saw few benefits from health departments collecting HIV data. HIV is highly stigmatized, and people often faced serious social and personal risks, including loss of employment and health insurance. Without good antiretroviral treatment available, the risks of loss of confidentiality outweighed the benefits. These issues were central to the debates around name-based reporting of HIV to health departments, including when Minnesota implemented HIV name-based case reporting in 1985.

In response to these concerns, CDC and health departments implemented strict policies and procedures to ensure security and confidentiality of the HIV data collected, beyond what was required for other reportable conditions. The use of these data was severely restricted. Because of community input, coupled with the fact that there weren't good prevention and treatment options, most programs did not use the data to implement individual-level prevention efforts.

So let's talk a bit about how we use HIV public health data. As a result of strict data use policies, our initial uses of public health HIV data were primarily focused on describing populations. Over the years, that has changed as health departments have built more trust with communities impacted by HIV. Additionally, as our prevention options have broadened, we have begun using public health data in new ways. Health departments can now use public health data to identify people who appear not to be receiving HIV care. They may need additional support to access HIV care and succeed at maintaining viral suppression. This is sometimes called Data to Care.

We can also use public health data to determine when there might be an increase in HIV transmission. For example, we might find that a particular county, which typically has only a few new HIV diagnoses in

a typical year, all of a sudden has a lot more than expected. This might signal that there is an outbreak, perhaps like the outbreak of HIV that occurred among people who inject drugs in Scott County, Indiana, in 2015. This would be a signal that public health should respond to try to stop HIV transmission.

Now, we have a new tool for identifying situations where there is increased transmission. We can use laboratory information to identify when there are groups of infections that are very similar, much like public health does when looking at outbreaks of tuberculosis or foodborne illness. For HIV, when we find a group of similar infections, it suggests that they are all part of a common network. These similarities also tell us that HIV likely spread quickly through this network. So let's zoom in on one of these networks.

Here we have a network where HIV is spreading quickly. All of these people know that they are HIV-positive, but may or may not be managing their infection. Looking at traditional HIV surveillance data in this population is helpful, but it would not identify rapid transmission within the network without molecular epidemiology.

Within this network of rapid HIV transmission, there are also people who do not know they are HIV-positive. Because of this, they are not managing their infection and likely have higher HIV viral loads, ultimately leading to even more rapid HIV transmission.

Finally, there are HIV-negative people within this network who are at very high risk of acquiring HIV infection. The collection and use of HIV molecular data allows health departments to identify these populations and target resources for HIV prevention, testing, and linkage to care for those who have recently acquired HIV infection.

So we just saw how we can use laboratory data to identify networks in which HIV is spreading rapidly. What exactly are these lab data? Well, as part of HIV care, health care providers order testing to learn which treatments will work best for a person's HIV strain. This is called drug-resistance testing, and it involves determining the genetic sequence of the virus (but not the person). We sometimes call this 'molecular data.' This information helps the provider to make treatment choices, and you might have heard people refer to the collection of this information by public health as 'molecular surveillance.' It's also important to note that drug resistance testing is important for monitoring drug resistance in the population. If many people develop resistance to commonly used drugs, it can make HIV more difficult to treat.

These molecular data can be used to help inform public health activities. HIV mutates, and it mutates a little bit differently in each person. These mutations add up and over time and lead to changes in the genetic sequence of the virus. Public health agencies can analyze the sequences, or molecular data, to find groups of infections that are very similar. This indicates that HIV is spreading quickly, because it hasn't had time to change much between transmissions. In fact, CDC has found that HIV is spreading 10 times faster in these networks, compared to the average.

We can then reach out to those networks to provide the services that people need, understand barriers to care and prevention, and develop approaches to overcome them. This can be done through a variety of methods, such as social network strategies, which involve people recruiting people that they know for services like testing and PrEP.

As I mentioned earlier, molecular epidemiology is not a new concept in the United States, but it is a new HIV prevention method we're implementing in Minnesota. We've already seen some examples of how identifying networks of rapid transmission using molecular data can strengthen prevention efforts. For example, in 2017 Texas identified a large group of Latinx gay and bisexual men in San Antonio with similar HIV strains. 24 people were initially identified as having similar strains of HIV.

After the CDC and the health department in Texas followed up, another 87 people were identified as being sexual or needle sharing partners.

Additional information gathered by the health department revealed that HIV testing wasn't always conducted according to guidelines, and as a result, providers had missed some opportunities to diagnose people at the stage of acute infection, resulting in delayed treatment. In response, the health department sent an alert to providers clarifying the guidelines for, and importance of, HIV diagnostic testing and acute infection.

The investigation also highlighted a lack of access to PrEP for many who could benefit from it, so the health alert sent out also worked to increase awareness of PrEP. In addition, health department funds were redirected to increase access to PrEP in specific areas of the city.

Responding to this situation brought together a new coalition made up of community members, providers, and public health staff in San Antonio, and as a result the coalition provided the support that enabled San Antonio to sign on as a Fast Track City, with commitment from the Mayor and City Council to working together to reduce stigma, improve care, and eliminate new cases of HIV.

So these are things that some other health departments are already working on… making sure that people are educated about HIV, and that prevention services are reaching the right populations. This is an example of cluster detection leading to an opportunity to detect gaps in those services, and how health departments can redirect efforts to make sure that the services are reaching the populations that need them most.

Sometimes we identify a possible increase in transmission by seeing an increase of cases of HIV. Here's one example of that scenario. The West Virginia Health Department identified an increase in HIV diagnoses among gay and bisexual men in a part of the state that typically has few HIV diagnoses. Because injection drug use is common in the area, the health department was also concerned that HIV might spread into communities of people who inject drugs, so, with help from the CDC, they conducted in-depth interviews. Molecular data were also used to help better understand the increase.

As a result of what they learned, they increased access to HIV testing by relocating some testing sites, and increased awareness of the need for testing through radio and social media ads. The health department also established syringe service programs in counties that did not previously have them.

Descriptions of the previous two examples have been published. The following has not, so we will not name the jurisdiction in this presentation.

Sometimes, it's actually a healthcare provider that identifies a possible increase in transmission. In this example, which occurred in a medium-sized city in a northeastern state, a healthcare provider called the health department to report concern about increased diagnoses among heterosexuals. Laboratory data showed rapid transmission among this group. As a result of the findings, the health department worked to establish a PrEP provider in the region, held a regional provider meeting, and expanded HIV testing in jails and reproductive health clinics.

The main take home point from all three of these examples is that molecular HIV data are useful as another tool to inform existing health department responses to emerging clusters of HIV in communities.

Now that we've discussed a few examples of public health response with molecular HIV data, let's look at a couple situations where HIV molecular data demonstrated effective response to preventing new infections:

1. In 2015, Scott County in Indiana had an outbreak of HIV in populations of people who inject drugs that was so serious that it made national news for a period of time. While molecular HIV data reporting was not available in Indiana at that time, analyses done later on samples from that outbreak showed that the outbreak began in 2011 and could have been prevented years earlier had HIV molecular data been available.
2. In a rural part of Maryland that reports very few HIV cases in any given year, the health department received reports of six new cases within weeks of each other. Normally, this would cause great concern and lead to a shifting of resources to respond. However, molecular HIV data were able to identify that none of the cases showed genetic relation, which allowed the health department to follow up in the way they would normally respond to a new case of HIV in the region.

As CDC has been working on cluster detection and response activities, they have recognized the need for more community engagement, and we've heard some concerns at the Minnesota Department of Health, which we'd like to discuss.

Building trust within communities impacted by HIV is the foundation of our work at the Minnesota Department of Health. As we have discussed, MDH collects HIV data. Those data are protected by strict privacy and confidentiality guidelines set by the CDC. And through trust that we build with impacted communities, we use those data to understand what HIV looks like in communities, create programs for people living with HIV or at risk for HIV infection, identify health disparities, and reach out to people who may benefit from additional support or services.

State and local health departments have a duty to improve the public's health, and as part of that responsibility they collect personal information when people are diagnosed with reportable illnesses, including HIV. These agencies have many protections in place to safeguard people's information. Some of these policies and procedures to protect the data are required by CDC, and health departments have additional protections in place specific to their area. Whether at CDC or the local health department, we keep all HIV public health information on secure data systems, and only allow people to access information if they need to know it to do their job.

We also require that people with access to the data complete a data security training annually and sign a binding confidentiality agreement. Personally identifiable information, such as name, address, or phone number, is not sent to CDC. And this will not change with HIV molecular data.

When we talk about collecting information for DNA sequencing of a person's HIV virus, it's understandable to have concerns about how those data will be kept private at the health department and how those data will be used. The Minnesota Department of Health will use the same strict privacy guidelines for HIV molecular data that we have used for other HIV data collected and entered into the surveillance system since name-based reporting began in 1985.

It is our goal to use these data to help improve people's health. We've been talking with a variety of people about this work, and there have been a number of questions and concerns raised, including the extent to which public health activities will be conducted in ways that are culturally sensitive and non-coercive, which is certainly our goal. People have also raised questions about the levels of protections for public health data. People understandably need to feel sure their data are protected from improper use. Data held by both MDH and CDC are maintained securely according to strict guidelines and regulations.

Some community members have concerns that molecular analysis could tell who infected whom and be used in criminal proceedings. We have specific state statutes in Minnesota that protect against that use,

and that will be covered in more detail in a later slide. Currently, molecular technology and analysis cannot tell us who infected whom. We can only tell that strains of the HIV virus are closely related. We don't want or need molecular analysis to provide a direction. We need it to detect growing networks of rapid transmission. Finally, people have wondered how CDC and health departments will engage the community, which is part of why we're having this discussion.

Community engagement is critical. We are all working toward the same goals and community members have a lot to offer. Given that cluster detection and response is new and there is still a lot to be worked out, engaging community is particularly important. Community engagement aims to inform communities about molecular HIV data, engage stakeholders, and hear their priorities and ideas. This offers an opportunity to build support and identify ways that we can partner with communities to achieve our common goals. It also honors past processes and agreements with communities. And finally, it acknowledges that government has participated in public health activities that have damaged trust within communities. We want to both own that past and find out ways to work to change the future of our work.

We are at an exciting time in HIV treatment and prevention. We can detect infection, and networks of infection earlier than ever – saving lives and preventing transmission.

CDC and MDH are committed to using both traditional public health tools and the new tools in our toolbox to address HIV in communities. We are also committed to responsible use of the data, to hearing your concerns and working with community to address them, and to using the data we have to more effectively reach and serve more people with or at risk for HIV.

We've talked about the national response to HIV with molecular data, so let's focus on what the STD/HIV/TB section at the Minnesota Department of Health will do.

So we've talked a lot about molecular HIV data, but what does it actually look like? In the graphic on the right side of this slide, you can see the steps a clinical laboratory uses to amplify HIV DNA, compare it to known sequences, and generate a report for health care providers to make decisions about the most appropriate HIV treatment. The only piece of information that MDH receives in this process is the genetic sequence of letters.

The requirements for molecular HIV data that surveillance programs will have to meet are largely set by CDC. We will not have a lot of control at MDH in terms of what we have to do, but we want to make sure communities understand what we have been asked to do. At MDH, the surveillance unit will:

1. Collect molecular data for newly identified HIV cases through mandated reporting of genotype test results.
2. Collect molecular data for any prevalent HIV cases through mandated reporting of genotype test results when they are run.
3. Store data securely in the Minnesota HIV Surveillance System, which is also known as eHARS.
4. And on a monthly basis, these data will be included in our regular de-identified datasets securely uploaded to CDC.

In addition, the surveillance unit will:

1. Receive quarterly reports from CDC about clusters of rapid transmissions both within Minnesota and involving Minnesotans in other states.
2. These results will be shared with the partner services unit using unique identifiers.

3. They will also be shared with the prevention unit using de-identified population data.

With data provided by the surveillance unit at MDH, the prevention unit will have more flexibility in our response to molecular data. The unit will coordinate efforts to address emerging clusters with both community stakeholders and health department grantees. The prevention team will also respond by adjusting HIV testing and syringe services as needed to reach communities with the most rapid transmissions.

In addition, the prevention unit will work with health department grantees to address identified clusters within targeted populations and make allowances and provide additional support and education for those grantees who need to work outside of their funded populations.

Like the response from the prevention unit at MDH, the partner services unit will also have more flexibility in how we respond to molecular HIV data. The team will conduct confidential case interviews and provide partner notification services – much like we already do for any newly identified HIV case in the state. But to address HIV in networks with rapid transmission, the team may ask additional questions and re-interview people as needed.

MDH is committed to protecting all HIV public health data, not just genotype results. We will continue to store all personally identifiable information according to strict CDC guidelines. Access to these data will be limited to only staff with a business need. And as previously mentioned, all datasets will be de-identified before monthly submissions to CDC.

As mentioned before, there are two Minnesota statues that protect public health data from use in criminal investigations. This includes statute 13.3805, which classifies all identifiable health data as private data, meaning it is subject to more strict privacy rules, and statute 144.658, which specifically prohibits the use of public health surveillance data by law enforcement or other entities in any kind of legal action. Both of these statues apply to molecular HIV data.

Thank you for your time today. If you have any questions, please call or e-mail the health department with the information on this slide. **Thank you!**

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