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*Office of AIDS Molecular HIV Surveillance FAQ*

1. ***What is Molecular HIV Surveillance (MHS)?***

Molecular HIV Surveillance (MHS) — formerly referred to as Variant, Atypical, and Resistant HIV Surveillance (VARHS) — incorporates the collection of HIV genotype sequences, which are generated as part of antiretroviral resistance testing, into routine HIV surveillance. Collecting HIV genotype sequence data supports local and state public health departments in monitoring and investigating patterns and trends in HIV transmission. These efforts are part of the National HIV Surveillance System (NHSS), which is a collaborative effort of the Centers for Disease Control and Prevention (CDC), the California Department of Public Health (CDPH), California local health departments, and other state and local health departments.

HIV sequences can be used to achieve three primary goals: (1) to assess prevalence and trends in acquired and transmitted HIV drug resistance; (2) to evaluate HIV genetic diversity; and (3) to describe HIV transmission patterns for the purpose of evaluating the impact of HIV prevention strategies, guiding public health action, and enhancing our understanding of the burden of HIV in California and, in general, the United States.

2. ***How does HIV sequence data detect drug resistant mutations?***

HIV sequence data is used to identify the presence of mutations associated with antiretroviral (ARV) drug resistance. Standard HIV genotypic assays extract viral RNA from the blood plasma of an infected person and amplify regions of the HIV genome targeted by ARVs. Other areas of the HIV genome, the integrase gene in the pol region and the envelope gene, can also be tested for mutations associated with antiretroviral drug resistance. A nucleotide sequence of the person's viral isolate is translated into the corresponding amino acids and compared to a "wild-type" reference strain to identify mutations associated with drug resistance. A final report is generated that provides an interpretation of the level of resistance detected and can be used by health care providers for clinical management of patients.

HIV genotypic testing for detecting ARV resistance is a part of the standard of care for persons infected with HIV. The U.S. Department of Health and Human Services and the International Antiviral Society-USA (IAS-USA) recommend that HIV genotypic testing be performed at entry into care and again as needed to guide treatment.

3. ***How does HIV sequence data identify genetic diversity?***

There are two types of HIV: HIV-1 and HIV-2. Most HIV infections in the United States and around the world are caused by HIV-1. More than 90% of HIV-1 infections belong to Group M, of which at least 9 genetically distinct subtypes (or clades) are known: A, B, C, D, F, G, H, J and K. There are also “circulating recombinant forms” (CRFs) derived from the merging of different subtypes, “unique recombinant forms” (URFs), and numerous unknown variants.

Standard genotyping methods that identify mutations associated with ARV resistance can be used to distinguish between subtype B and non-B variants of HIV. Phylogenetic analyses can also be applied to evaluate the genetic relationships between HIV strains and further classify potential non-B variants to the other subtypes, CRFs, and potential URFs.

4. ***What analyses are used to describe HIV transmission patterns?***

Phylogenetic analysis is a technique used to examine how closely related different viruses are based on how many differences exist between two different DNA sequence patterns. When combined with information on a person’s demographics, geographic location, and risk characteristics, phylogenetic analysis can help describe likely transmission patterns between persons. Analysis of these transmission patterns or networks can help guide HIV prevention efforts and optimize the allocation of resources by identifying persons at highest risk of being infected with HIV.

5. ***Are MHS data required to be reported to the California Department of Public Health?***

Yes. California Health and Safety Code (HSC), Section 121022 requires health care providers and laboratories to report cases of HIV infection to the local health officer, meaning that they are required to report all confirmed HIV tests. The California Code of Regulations (CCR), Title 17, Section 2641.30 defines a confirmed HIV test as:

- (a) “a procedure which verifies the presence of HIV infection as determined by any clinical laboratory test or HIV Test Algorithm or examination used to detect the presence of HIV, a component of HIV, or antibodies to or antigens of HIV, including the HIV antibody (HIV-Ab), HIV p-24 antigen, Western blot (Wb), and immunofluorescence antibody tests; or . . .
- (b) a test used to monitor HIV infection, including HIV nucleic acid detection.”

Given that HIV genotyping data are used to monitor HIV infection, they are required to be reported under HSC and CCR— including raw genetic sequence data and reports on drug resistance.

6. ***What does CDPH do with the HIV sequence data they receive?***

MHS data will be linked and added to the individual surveillance record using a patient’s name. This information will be maintained as part of the HIV surveillance case registry. MHS data must be linked with a patient’s surveillance record so that information on the patient’s demographics, risk characteristics, geographic location, and testing and treatment information are available for necessary analyses.

7. **Are all California jurisdictions participating in MHS?**  
Yes. Los Angeles (LA) and San Francisco (SF) counties are already collecting MHS data. The collection of MHS data outside of LA and SF started in late 2014.
8. **Will MHS data be released to the public?**  
As with other HIV data reported to CDPH and local HIV surveillance programs, HSC sections 121022 and 121025 protect the security and confidentiality of MHS data. Unlawful disclosure of HIV public health information is strictly forbidden and is subject to civil and/or criminal penalties. State and local health departments have long-established procedures in place to ensure the public health records are handled in a secure manner.
9. **Are MHS data protected from subpoena or court orders?**  
State and local public health HIV data are protected from subpoena. California law clearly states that HIV-related public health information “shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding” per HSC Sections 121022, 121023, and 121025.
10. **Does reporting MHS violate Health Insurance Portability and Accountability Act (HIPAA) law?**  
No. Reporting MHS sequence data does not violate HIPAA law. HIPAA law (Code of Federal Regulations, Title 45, Section 164.512 [b]) states a HIPAA-covered entity may use or disclose protected health information without the written authorization of an individual when “a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions . . .” See the CDC’s report on the HIPAA Privacy Rule and Public Health, <http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf>
11. **Are MHS data shared with the CDC?**  
Yes. In 2004, CDC determined that the collection of HIV nucleotide sequence data as a part of NHSS was a non-research disease surveillance activity and that a review by the Institutional Review Board, pursuant to Title 45 Code of Federal Regulations Section 46: Protection of Human Subjects, was not required. As an integral component of the National HIV Surveillance System (NHSS), MHS data are transferred to CDC via a secure system on a regular basis. Providing MHS and other surveillance data to CDC is explicitly allowed under HSC Section 121022.

CDC is prevented from publically releasing data by federal laws and regulations. Patient identifying information, such as name, is removed from data filed before being sent to the CDC. While local, state, and federal public health programs may publish or release MHS data, such information will only be released in aggregate, and in such a way that it could not be used to identify an individual person. At national level, CDC has conducted several analyses using MHS data to assess transmitted HIV-1 drug resistance and to describe transmission networks in the United States.

**For More Information on Health and Safety Code, please visit**

[http://leginfo.legislature.ca.gov/faces/codes\\_displaySection.xhtml?lawCode=HSC&sectionNum=121022](http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=121022).

**For More Information on HIPAA, please visit**

<http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>

If you have questions about MHS for the California Project Area, please contact Jessica Brown, HIV Surveillance Laboratory Coordinator for the HIV Surveillance Section at the California Office of AIDS, at (916) 445-9231 or [Jessica.Brown@cdph.ca.gov](mailto:Jessica.Brown@cdph.ca.gov).

If you have questions about MHS for San Francisco and Los Angeles area, please contact Mia Chen, Epidemiologist for the Applied Research, Community Health Epidemiology, and Surveillance Population Health Division at the San Francisco Department of Public Health, at (415) 437-6237 or [mia.chen@sfdph.org](mailto:mia.chen@sfdph.org) and Virginia Yunyin Hu, Supervising Epidemiologist for the Division of HIV and STD Programs at the Los Angeles County Department of Public Health, at (213) 351-8142 or [vhu@ph.lacounty.gov](mailto:vhu@ph.lacounty.gov).

#### References

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Center for Disease Control and Prevention. Technical Guidance for HIV Surveillance Programs: Molecular HIV Surveillance (MHS). Atlanta, Georgia. HIV Incidence and Case Surveillance Branch. 3-6. Accessed July 25, 2014.