HIV Reporting Regulation Change

The National HIV Strategy (NHAS) updated to 2020 has four goals.

- Reduce new HIV infections
- Increase access to care and improve health outcomes for people living with HIV
- Reduce HIV-related disparities and health inequities
- Achieve a more coordinated national response to the HIV epidemic

HIV surveillance is the primary method that is used to evaluate progress in implementation of the NHAS. As a result, the nature of HIV/AIDS surveillance has changed. HIV surveillance data is now used not only to identify persons with HIV infection but to mark access to care and treatment, determine the stage of HIV infection, measure unmet health care needs, evaluate HIV testing activities and measure HIV incidence and drug resistance.

Data to Care is a new public health strategy that aims to use HIV surveillance data to identify HIV-diagnosed individuals not in care, link them to care, and support the HIV Care Continuum. Data to Care impacts the NHAS goals of reducing new HIV infections and improving access to care and health outcomes for people living with HIV. Central to achieving these goals are identifying persons living with HIV who are not in care and linking – or reengaging – them to HIV care and treatment services. Among various strategies that can be used to help identify and link HIV-positive individuals to care is the use of routine HIV surveillance data that are reported to health departments. The CDC strongly encourages state and local health departments to use HIV case surveillance data to improve the continuum of care in their communities, including the use of individual-level data to offer linkage and re-engagement to care services when appropriate.

In order to better improve the HIV surveillance system to meet these goals, the following changes to the HIV reporting regulation are requested:

1) Clarification in reporting of HIV test results

In June 2011, the Clinical and Laboratory Standards Institute (CLSI) published Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection: Approved Guideline [CLSI document M53-A, ISBN 1-56238-758-8] and in 2014, the Centers for Disease Control and Prevention updated their recommendations for laboratory testing for the diagnosis of HIV infection. Both recommend the use of an algorithm to diagnoses HIV infection. The algorithm is a sequence of tests used in combination to improve the accuracy of the laboratory diagnosis of HIV based on testing of serum or plasma specimens (see flow diagram). These updated recommendations for HIV testing are necessary because of

- FDA approval of improved HIV assays that allow detection of HIV sooner after infection than previous immunoassays;
- Evidence that relying on Western blot or indirect immunofluorescence assay (IFA) for confirmation of reactive initial immunoassay results can produce false-negative or indeterminate results early in the course of HIV infection;
- Recognition that risk of HIV transmission from persons with acute and early infection is much higher than that from persons with established infection;
- Recent indications for the clinical benefits from antiretroviral treatment (ART) of all persons with HIV infection, including those with acute infection; and
- Demonstration that the majority of HIV-2 infections detected by available HIV antibody immunoassays are misclassified as HIV-1 by the HIV-1 Western blot.

Wording of the current regulation has caused confusion regarding which specific tests are reportable to the PDPH. Reporting of all test results conducted in the approved algorithms is necessary to confirm and report a case of HIV infection. All individual results of the algorithm including positive, negative, or indeterminate results will be reported to the PDPH if the patient is determined to have either a confirmed HIV infection, a probable or possible HIV infection. This includes a positive preliminary result if no supplemental testing was performed or a negative supplemental test where an additional nucleic acid test has not been performed. This change allows for reporting of preliminary positives from Point of Care testing where no supplemental testing was performed. If supplemental testing is done at another healthcare or laboratory provider, this information can then be used to assign an accurate date of HIV diagnosis. If additional testing is required to determine the presence or absence of HIV infection, PDPH can follow up with patients to provide additional counseling and linkage to testing.

2) Positive and negative results within 180 days of a new HIV positive test

HIV testing technology continues to improve and evolve. With the current HIV testing algorithm, persons with acute HIV infection can be identified. As previously indicated, HIV transmission from persons with acute and early infection is much higher than from persons with established infection.

Preliminary data indicate that treatment of early HIV-1 infection with ART improves laboratory markers of disease progression. The data, though limited, indicate that treatment of early HIV-1 infection may also reduce the severity of acute disease, lower the viral set point, reduce the size of the viral reservoir, delay disease progression, enhance CD4 T lymphocyte (CD4) cell recovery, and decrease the rate of viral mutation by suppressing viral replication and preserving immune function. Because early HIV-1 infection is often associated with high viral loads and increased infectiousness, and ART use by HIV-1-infected individuals reduces transmission to uninfected sexual partners, treatment during early HIV-1 infection is expected to substantially reduce the risk of HIV-1 transmission. Many of these potential benefits may be more likely to occur with treatment of acute infection (within 2 months), but they also may occur if treatment is initiated during recent HIV-1 infection defined as 2-6 months after infection.

Receipt of previous positive and negative results within 180 days of a new HIV positive test result will allow the PDPH to accurately determine cases of acute and recent HIV infection. These cases can be prioritized for partner services where staff can provide linkage assistance to patients who have not yet been linked to medical care.

3) Molecular HIV Surveillance updates

The purpose of reporting HIV resistance results is to estimate the prevalence of transmitted drug resistance mutations in individuals newly diagnosed with HIV and to monitor the distribution of HIV subtypes in the United States. Data obtained and analyzed from resistance reporting is used to assist local HIV prevention and treatment program planning and evaluation. In addition, the PDPH funds programs to assist persons living with HIV to implement HIV prevention strategies, maintain healthy lifestyles, and to improve adherence to treatment regimens. The regulation is being updated to reflect changes in acceptable formats for submission of HIV genotype results and to include the integrase region of HIV, which is a newer class of antiretroviral therapy.

4) Recency testing changes

CDC will discontinue having health departments and laboratories collect remnant blood specimens for STARHS testing after 2016. Alternative methods for HIV incidence surveillance and the assessment of the recency of infections are being developed by CDC. These may rely on identification of acute infection (by a negative or indeterminate HIV antibody test result on or near the date of a positive result from a nucleic acid test or a detectable viral load) or on tests of recency based on other criteria (e.g., protein band pattern) that might become available commercially in 2016 or later. To reflect these current and future changes, the reference to STARHS testing within the regulation has been removed and updated to request that laboratories submit an HIV recency test result, if available, on persons 13 years of age or older with a confirmed positive HIV test result.

5) Addition of pregnancy

The availability of effective interventions to prevent mother-to-child HIV transmission and the significant reduction in the number of HIV-infected infants in the United States have led to the concept that elimination of mother-to-child HIV transmission (EMCT) is possible. Towards this end, CDC recommends comprehensive, real-time case finding of pregnancy in women with HIV infection early enough for appropriate interventions to be implemented to further reduce mother-to-child HIV transmission. Currently, the majority of perinatal HIV exposures are reported to the PDPH after the birth of the infant when it is too late to intervene. The addition of reporting in pregnancy would allow the PDPH to ensure that HIV-infected pregnant woman are linked to care and offered supported services.

6) Timing of reporting

The previous regulation did not include a timeframe for reporting of HIV to the PDPH. All HIV laboratory results and case report forms with two exceptions will be reportable to the PDPH within 5 business days. This timeframe was chosen to be consistent with the State of Pennsylvania HIV reporting regulation. There are two exceptions to this rule: 1) the reporting of acute cases; and 2) the reporting of pregnancy in an HIV-infected woman.

A shorter time period for acute HIV infection is based upon clinical guidelines to refer persons with acute infection immediately to care and on performance indicators included in recent CDC funding opportunity announcements. These indicators call for the following in persons with acute HIV infection; linkage to HIV care within 14 days of diagnosis, initiating antiretroviral therapy within 21 days of diagnosis; and completing partner services interviews within 14 days of diagnosis. Timely reporting of acute HIV infection is necessary to assure that that linkage and partner services have been offered to patients within the timeframes of these indicators.

7) Access to medical records

With implementation of integrated electronic health records, questions have been raised from reporting facilities regarding what information can be accessed by PDPH staff in the process of disease surveillance. We have added a section on access to medical records to the regulation to clarify what is and is not permissible under HIPAA and Act 59, Pennsylvania's Confidentiality of HIV- Related Information Act and the City of Philadelphia's Health Code. The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. Under Act 59, release of confidential HIV-related information is permissible to State

and local health departments for disease prevention and control. Last, under the Philadelphia Health Code Section 2.f. Authority to Obtain Medical Information, The Commissioner of Health or his designated representative has the authority to obtain medical information, including photocopies, of hospital records and medical summaries, about these reportable conditions without a signed authorization release form from the patient."

The following text has been added to the regulation to indicate that access to medical records is necessary. "The PDPH will have access to and may review the patient medical records of physicians, hospitals, persons providing HIV services and persons in charge of entities providing HIV services, who make diagnoses of HIV, or who receive or provide any HIV test results. Access and review will enable the PDPH to conduct case investigations, to determine whether under-reporting is occurring, to investigate reporting delays and to investigate other reporting problems."

Box 1. Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens