

Remarks by Dr. Kathleen Brady Regarding HIV Reporting Regulation Change

Once considered an acute illness characterized by progressive immune system deterioration, HIV infection is now considered a treatable chronic condition. Since the mid-1990s, when highly active antiretroviral therapy became widely available, HIV-infected persons have been able to live longer and more productive lives. 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.

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

1) Change CD4 reporting from results less than 350 cells/ μ L and/or 25% total lymphocytes to reporting of all CD4 results.

Because of the clinical use of CD4 and viral load testing, the results of these tests in surveillance data are often used as markers for the receipt of health care. In July 2010, the President released the *National HIV/AIDS Strategy for the United States*. Among other objectives, the strategy aims to “establish a seamless system to immediately link people to continuous and coordinated quality care when they are diagnosed with HIV.” The 2015 objectives include increasing to 85% the percentage of HIV-infected persons who are linked to clinical care within 3 months after HIV diagnosis. This objective can only be measured with complete reporting of all CD4 counts.

In addition to marking the progression from HIV infection, stage 1 or 2 to HIV infection, stage 3 (AIDS), CD4 test results at the time of HIV diagnosis can be used at the population level to determine the level of immunosuppression and the stage of disease at diagnosis of HIV infection. The level of immunosuppression, in turn, reflects the time from initial infection to diagnosis: in general, the longer the delay between acquisition of HIV infection and HIV testing, the greater the immunosuppression and the lower the CD4 count. Complete CD4 reporting can therefore evaluate HIV testing and screening activities. Increased testing should shift the distribution of diagnosed persons toward a larger number of persons with earlier-stage infection. As more diagnoses are made earlier in the course of disease, the median CD4 test result at diagnosis should increase.

Surveillance data are also used to estimate the number of HIV-infected persons not in care and thereby to estimate unmet health care needs. Persons without reported CD4 or viral load test results after HIV diagnosis may be persons with unmet health care needs. U.S. Department of Health and Human Services (DHHS) guidelines hold promise for increasing the percentage of HIV-infected persons with prompt receipt of baseline care, including CD4 and viral load testing. Because of possible underreporting due to the current reporting regulation, the data on CD4 testing received by HIV-infected patients residing in Philadelphia is incomplete.

2) Require submission of specimens for HIV Incidence Testing (Serologic Testing Algorithm for Recent HIV Seroconversion or STARHS)

Two goals of the *National HIV/AIDS Strategy for the United States* are to lower the annual number of new infections by 25 percent and to reduce the HIV transmission rate, which is a measure of annual transmissions in relation to the number of people living with HIV, by 30 percent. Evaluation of these goals will utilize HIV incidence surveillance data.

HIV incidence surveillance is the systematic collection, analysis, interpretation, dissemination, and evaluation of population-based information about persons recently infected with HIV. The goal of HIV incidence surveillance is to obtain the data needed to provide national and area-specific population-based estimates of the number of new HIV infections per year. A biological marker of recent infection is used to classify new diagnoses of HIV infection as either of recent or long-standing duration, and additional data on HIV testing and treatment history are collected to determine sampling weights for estimating HIV incidence.

In Philadelphia, residual biologic specimens are currently collected on a voluntary basis to measure HIV incidence. The change in the HIV reporting regulation will mandate submission of a biologic specimen if available for HIV incidence estimation. This will allow for more accurate HIV incidence estimates and will allow Philadelphia to evaluate these NHAS goals at the local level.

3) Reporting of HIV resistance testing results

Antiretroviral therapy (ART) has substantially slowed disease progression and improved the quality of the lives of persons infected with HIV. Published studies estimate that 4 to 20% of persons newly diagnosed with HIV infection have transmitted drug resistance, with the highest prevalence occurring in countries with long-established ART. The emergence of drug-resistant HIV strains hinders ART response and limits treatment options in affected individuals. Widespread ART use has resulted in the development of drug-resistant HIV strains that can be transmitted and can compromise the effectiveness of first-line treatment regimens among drug-naïve individuals. Alternate regimens can be more costly and make adherence more difficult.

Drug resistance continues to be an important limitation to successful HIV therapy and prevention. 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 will be 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.

4) Change in reporting of 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]. The CLSI consensus guideline outlines recommended laboratory testing procedures for the diagnosis of HIV infection and includes testing algorithms for supplemental testing that do not include the Western blot or indirect immunofluorescence assay (IFA). Other antibody tests are acceptable as supplemental tests, including some that might alternatively be used as initial screening tests, provided that the screening and supplemental tests are used together as parts of an algorithm.

In order to continue accurate and complete reporting of HIV infection, the HIV reporting regulation must be updated to reflect these new testing algorithms. Reporting of all test results conducted in the approved algorithms is necessary to confirm and report a case of HIV infection. Preliminary positive test results will be reported from healthcare providers if supplemental testing confirms HIV infection or in the cases where no supplemental testing is conducted after preliminary testing. Supplemental testing done at another healthcare provider can then be used to assign an accurate date of HIV diagnosis. If no additional testing is completed, PDPH follow up can be initiated for post-test counseling if requested.

HIV reporting/diagnosis data is the primary outcome of several NHAS objectives including: 1) By 2015, increase from 79 percent to 90 percent the percentage of people living with HIV who know their serostatus (from 948,000 to 1,080,000 people) and 2) By 2015, increase the proportion of newly diagnosed patients linked to clinical care within three months of their HIV diagnosis from 65% to 85% (from 26,824 to 35,078 people). This proposed change in the HIV reporting regulation will allow Philadelphia to evaluate this measure.

In addition, use of laboratory HIV indicators both at the individual and community levels have been proposed to ensure and monitor access to and quality of care and treatment. A number of surveillance areas are using HIV data at the individual level to initiate partner services, to help medical providers re-engage persons living with HIV who have dropped out of care, to establish linkages to enhance CD4 cell count and viral load information for clients receiving services from a Ryan White Part B programs, and the use of surveillance data in a health information exchange partnership to reach people needing important public health follow-up (see CDC consultation notes). Philadelphia proposes to use HIV surveillance data to follow up with individuals who have preliminary positive test results but no additional supplemental testing performed if requested by the testing healthcare provider.