

CDC-Developed Breakthrough Technology Allows Clearest Picture to Date of HIV Infections in the U.S.: A Methods Discussion

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[Irene Hall, PhD] Hello. I'm Irene Hall and I'm the Chief of the HIV Incidence and Case Surveillance Branch in the Division of HIV/AIDS Prevention at CDC. Our branch has had the responsibility over the past years to develop the national HIV incidence surveillance system, so it is with special pride that I welcome you to this podcast. In it, I will provide an overview of CDC's new method of estimating the number of new HIV infections that occur each year in the United States.

Until now, HIV diagnoses data were the best available national measure of HIV burden in key populations. However, those data are of limited use in guiding HIV prevention efforts since they do not indicate when individuals are actually infected, which can occur many years before they are diagnosed. Even though CDC has provided estimates of the annual number of new HIV infections in past years, those estimates were based on indirect methods. Therefore, CDC has worked for years to marry a groundbreaking new HIV testing method that can distinguish between new and long-standing HIV infections to new statistical methods in order to generate an annual national estimate of new HIV infections.

The laboratory testing method is called STARHS, for Serologic Testing Algorithm for Recent HIV Seroconversion. STARHS involves a combination of two tests: a conventional HIV diagnostic test and a test known as the BED test. Its full name is the BED HIV-1 Capture Enzyme Immunoassay. The conventional test identifies whether HIV antibodies are present in the body. A positive test result indicates that a person is infected, but not when the infection occurred.

The BED test, which measures the level of anti-HIV IgG relative to total IgG, is then applied to leftover serum from a positive HIV test. If the BED test detects a proportion of HIV-specific IgG below a certain threshold, the result indicates that the individual was infected with HIV in the previous five months. Such infections are considered new. The conventional test tells us if the person is infected with HIV, the BED test tells us how recently.

So, at this point, we had the laboratory technology to determine recent HIV infections. Next, CDC needed to be able to use this technology as the basis of a national estimate of new HIV infections. The STARHS work was published in 1998, but the BED test did not become available widely until 2005. It then took until 2008 to obtain the necessary data and develop, test, and refine our statistical methods to achieve a national incidence estimate.

In the United States, we are fortunate to now have a very good HIV case reporting system. This system, which also took years to build, had to be established before any of this work could move forward. Now, all state health departments report new HIV diagnoses to CDC in a systematic manner. We built on this system to apply the new STARHS technology and develop the first national system of its kind to directly measure new HIV infections.

The 2006 incidence estimate was based on data from 22 states with name-based HIV case reporting and HIV incidence surveillance. These states include high-morbidity areas and represent approximately 73 percent of the AIDS burden in the United States. The BED assay was applied to leftover serum from tests with positive results. All infections among patients who progressed to AIDS within six months of their initial HIV diagnosis were classified as long-term infections. This process generated the number of recent infections in those states. We then used the results in recent infections in combination with HIV testing history among those identified as recently infected in a statistical model to determine the number of new infections in these states in 2006. We then extrapolated the results to the entire United States by applying the observed ratio of HIV incidence to AIDS diagnoses in the 22 states to the areas without HIV incidence surveillance. Through this process, we estimated that approximately 56,300 new HIV infections occurred in the United States in 2006 with a confidence interval of 48,200 to 64,500. This means that we are 95 percent confident that the incidence number is contained in this interval.

Because this process was new, we needed to provide corroboration of our results. Therefore, we confirmed our findings with a second method called the extended back-calculation method. For this, we used information from all HIV and AIDS cases diagnosed by the end of 2006 and reported to CDC. This method works backwards to estimate the total number of HIV infections that would need to occur over time to produce the number of diagnoses. For those diagnosed with AIDS at or shortly after HIV diagnosis, the time infection was likely to occur is based on the predictable time of progression from HIV to AIDS in the absence of treatment, that is generally 8 to 10 years. For cases diagnosed with HIV prior to developing AIDS, the time of infection is determined from HIV testing patterns.

The extended back-calculation approach is an indirect measure of HIV incidence and cannot provide single year estimates, but rather average estimates for two- to- four-year time periods. It is based on more than one million reported HIV diagnoses and provides a well- established measure to confirm the STARHS results. The extended back calculation method indicated that an average of 55,400 new infections occurred every year from 2003 through 2006, with a confidence interval of 50,000-60,800. The back calculation method also allowed us to look at trends in HIV infections from the beginning of the epidemic in the late 1970s through 2006. We found that the number of new infections was relatively stable in recent years, although at a level that is higher than we previously knew.

In closing, I would like to note that this work took place over many years and by many people. I am honored to be the one to present this work, but feel it is important to recognize the important contributions of our colleagues in local and state health departments, without whom there could be no HIV surveillance at all. Additionally, I would like to recognize my colleagues at CDC and throughout the nation who developed and refined the statistical methods over the years. This work represents collaboration at its best and the result is the clearest picture to date of new HIV infections in the United States.

[Announcer] For the most accurate health information, visit www.cdc.gov or call 1-800-CDC-INFO, 24/7.