
Commissioner's Column

Integrating HIV Testing Into Primary Care

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The Centers for Disease Control and Prevention estimate that there are approximately one million people living with HIV disease in the United States - 25 percent of whom are unaware of their positive serostatus and are potentially spreading the virus unknowingly. In addition, an increasing percentage of individuals is being diagnosed with AIDS within one year of learning of their HIV positive status.

Although New York State has only 6.5 percent of the nation's population, approximately 16 percent of the persons living with AIDS in the United States reside here, making New York the state with the largest proportion of AIDS cases. Of the 57 counties within New York State outside of New York City, Westchester County has the second highest AIDS case rate; the fourth highest HIV case rate; and is home to an estimated 5,000 residents living with HIV disease.

The past two decades have seen a shift in the demographics affected by HIV disease. Although nationwide injection drug use (IDU) is the reported risk factor for one-third of living cases, the proportion of cases attributed to IDU has been on the decline over the past two decades, largely due to targeted prevention interventions. The risk factor that is currently on the rise is heterosexual transmission, which is now the cause of approximately one-quarter of HIV cases. With improvements in medication management for HIV disease, infected individuals are living longer; thus, the HIV epidemic is now also impacting the senior population. These changes in the demographics affected by HIV require a new approach to stemming the tide of the epidemic.

Integrating HIV testing as a component of routine primary care has become the new focus of HIV prevention. In 2005, the New York State Department of Health developed a new procedure for streamlining HIV pretest counseling and testing to facilitate the inclusion of HIV testing as a routine screening tool for the general adult population. The availability of CLIA-waived rapid HIV tests not only allows health care providers to offer HIV testing to their patients but also makes it possible for onsite results to be given within the same office visit.

Rapid HIV testing had previously been available for use at hospitals and other non-waived clinical laboratories. In 2002, the first HIV antibody test received a CLIA waiver. This was the OraQuick® Rapid HIV-1 Antibody test marketed by Orasure Technologies. The initial version of this test required a blood sample, either by fingerstick or venipuncture whole blood. Subsequently, in 2004, this same technology was produced under the new name OraQuick® ADVANCE™ HIV-1/2 Antibody Test and received a CLIA waiver for performance on oral fluid as well as blood and plasma samples. Also in 2004, another rapid HIV test, the Uni-Gold™ Recombigen® HIV Test, marketed by Trinity Biotech received a CLIA waiver for point-of-care testing.

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Each test offers certain advantages. The Uni-Gold™ Recombigen® HIV Test offers results within 10 minutes as opposed to 20 minutes for the OraQuick tests. However, the OraQuick ADVANCE™ test also detects the presence of both HIV-1 and HIV-2 antibodies and may be performed using oral fluid. Similar to conventional HIV testing, rapid HIV testing should be conducted three months after a potential exposure to allow detectable post-exposure antibodies to be produced. However, HIV testing done as part of a routine primary care visit could occur at the time of the annual preventive health screening. As rapid HIV testing is a screening procedure, positive or reactive results still require confirmatory testing by appropriate methods.

Due to the ease of performing the rapid HIV test, in 2005, Orasure Technologies submitted an application to the U.S. Food and Drug Administration (FDA) for approval of an over-the-counter home use rapid HIV test kit. Special considerations with regard to an individual performing his or her own rapid HIV test at home relate to the regulations of public health law in many states, which require signed documentation of informed consent prior to an HIV test being conducted. In addition, another consideration is the establishment of a referral mechanism for performing confirmatory HIV testing after an individual has tested positive on a home HIV test kit. Such issues are being evaluated during the FDA review of Orasure Technologies' application.

Increasing access to HIV counseling and testing is a priority in Westchester. With the increase in heterosexual transmission, a community coalition has recently formed to encourage women to "Request a Test" from their primary care providers. The overall goals of the coalition are geared toward raising awareness of the HIV epidemic in Westchester County; motivating women to be tested for HIV and reducing the stigma around HIV testing; promoting the benefits of early detection and treatment; and encouraging health care providers to be active partners in HIV prevention by increasing the availability of HIV testing. It is through partnerships such as these that Westchester County will be successful in stemming the tide of the HIV epidemic.

For additional guidance on integrating HIV testing into primary care, please contact the HIV program of the Westchester County Department of Health at (914) 813-5227. Additional resources can be found at the following websites:

<http://www.health.state.ny.us/diseases/aids/forms/index.htm>

http://www.hivguidelines.org/public_html/health-bulletins/c-and-t.htm