



**Emerging Technologies and Advancements in  
HIV and AIDS Surveillance and Testing to  
Enhance Surveillance, Prevention and  
Treatment of HIV and AIDS Infection**

**A Report to the 81<sup>st</sup> Texas Legislature**

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# Table of Contents

<b>I. Executive Summary</b>	<b>3</b>
<b>II. Introduction</b>	<b>5</b>
A. HIV/AIDS in Texas	5
B. Benefits of Early HIV Testing and Diagnosis	5
<b>III. HIV/AIDS Surveillance</b>	<b>6</b>
A. Current HIV/AIDS Reporting and Surveillance System in Texas	6
B. Emerging Technologies in Reporting and Surveillance	8
C. Recommendations for Enhancing HIV/AIDS Reporting and Surveillance	13
<b>IV. HIV Testing</b>	<b>14</b>
A. Current Status of HIV Testing in Texas	14
B. Emerging Technologies in HIV Diagnosis and Testing	16
C. Recommendations for Improving HIV/AIDS Testing	17
<b>V. Conclusion</b>	<b>18</b>
<b>VI. References</b>	<b>19</b>

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## I. Executive Summary

This Texas Department of State Health Services (DSHS) report addresses emerging technologies and advancements in Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) disease surveillance and epidemiology, including use of technologies and advancements to improve testing and reporting of AIDS and HIV infection. Recommendations regarding Texas's use of emerging technologies and advancements to enhance surveillance, treatment and prevention of HIV and AIDS are also included. This report meets objectives outlined in House Bill 246 enacted September 1, 2007.

Surveillance is the ongoing systematic collection, analysis, interpretation, and reporting of information that leads to action being taken to prevent and control disease. Disease reporting mechanisms notify the appropriate health authority of the occurrence of a disease in an individual.<sup>1</sup> Advancements that will enhance the reporting, analysis, and dissemination of HIV and AIDS data include:

- Enhanced HIV/AIDS Reporting System (eHARS): a document based application to collect and manage HIV/AIDS data required by the Centers for Disease Control and Prevention (CDC) to monitor the epidemic;
- Electronic Laboratory Reporting (ELR): electronic transmission of laboratory test results such as HIV diagnostic tests, CD4+ T-lymphocyte(CD4) counts and HIV viral loads to public health agencies;
- Electronic Medical Records: electronic management and storage of patient medical records that would ease electronic disease reporting from health care providers; and
- HIV Incidence Surveillance: monitoring new cases of HIV infection using test results and treatment history as well as evaluating the prevalence of HIV mutations associated with drug resistance (Variant Atypical and Resistant HIV Surveillance).

Further reduction of HIV infections remains a challenge for medical practitioners, public health authorities, and community health leaders. CDC estimates that one in five people living with HIV are unaware of their infection.<sup>2</sup> Additionally, 40 percent of Texans diagnosed with HIV in the last five years were diagnosed late in the course of disease.<sup>3</sup> Research has shown that persons who know of their HIV infection make changes that reduce their chances of transmitting the virus, so persons living with undiagnosed infections and persons who are diagnosed late represent lost opportunities for prevention of new cases of HIV. More widespread adoption of routine HIV screening in health care settings, coupled with continued targeted HIV testing and prevention interventions, strong public health follow-up services, and continued investment in HIV and AIDS care and treatment will greatly increase the chances that Texans will be diagnosed earlier in

the disease's course, that persons living with HIV will stay healthier longer, and that the number of new cases will be reduced.

Since development of the first HIV antibody test in 1985, there have been many advancements in HIV testing technology. Diagnostic tests have been developed that can be used on different specimen types (e.g. whole blood, serum, or oral fluid) and rapid tests have been developed that can quickly detect the presence of HIV antibodies (preliminary test results available within 20 minutes). Nucleic Acid Amplification Testing (NAAT), which has been used to screen donated blood for HIV since 1999 and is now being used to detect acute HIV infections, can detect HIV up to two weeks after infection which is much earlier than standard HIV antibody tests. Integrating NAAT into routine HIV testing in Texas would identify more HIV cases in the earliest stage of infection and would be a formidable tool in stopping spread of HIV.

These improvements in HIV surveillance and testing will enable DSHS to produce more detailed and timely reports about social, demographic, and geographic HIV transmission trends, obtain data regarding new HIV cases (incidence), monitor HIV drug resistance patterns and target behavioral intervention and medical services and programs to individuals most affected by HIV/AIDS, identify persons infected with HIV earlier, and therefore decrease transmission of HIV and AIDS in Texas.

DSHS recommends the following actions for enhancing HIV and AIDS reporting and surveillance and improving HIV testing:

- Deploy eHARS in Texas. CDC plans to deploy eHARS in Texas during 2009. eHARS is a document based system that will allow for evaluation of data pertaining to HIV and AIDS case ascertainment methods.
- Revise the Texas Administrative Code relating to reporting rules for HIV and AIDS to include all HIV related tests (including all CD4 counts, detectable and undetectable viral loads, and drug resistance testing).
- Assist hospitals to report HIV/AIDS laboratory test results electronically.
- Integrate HIV/AIDS surveillance with Sexually Transmitted Disease (STD) surveillance.
- Devise methods for DSHS funded STD clinics to report diseases electronically.
- Explore new HIV testing technology through collaboration with laboratory, research, and public health institutions.
- Seek support to continue laboratory implementation of HIV NAAT technology that decreases time from infection to laboratory detection of HIV.

- Develop new strategies and algorithms to optimize existing technologies that will maximize HIV screening and detection.
- As outlined by the 2006 CDC revised recommendations for HIV testing of adults, adolescents and pregnant women, increase access to HIV testing by pursuing implementation of routine HIV testing in a variety of health care settings.

## **II. Introduction**

This Texas Department of State Health Services (DSHS) report addresses emerging technologies and advancements in Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) disease surveillance and epidemiology, including use of technologies and advancements to improve testing and reporting of AIDS and HIV infection. Recommendations regarding Texas's use of emerging technologies and advancements to enhance surveillance, treatment and prevention of HIV and AIDS are also included. This report meets objectives outlined in House Bill 246 enacted September 2007.

### **A. HIV/AIDS in Texas**

In 2007, there were over 62,000 Texans living with HIV and AIDS. In the five year period from January 1, 2003 to December 31, 2007, the number of people living with HIV and AIDS in Texas increased 30 percent. The number of newly reported HIV/AIDS diagnoses in Texas has remained relatively stable over the last five years, with about 4,600 new HIV/AIDS cases diagnosed each year. Deaths among people with HIV have also been fairly stable over this period, with about 1,300 persons with HIV and AIDS dying each year.<sup>3</sup>

Although HIV/AIDS has affected all racial/ethnic groups, the African-American community has been disproportionately impacted. African-Americans made up 11 percent of the Texas population in 2007; however, they represented 38 percent of people living with HIV/AIDS. The rate for African Americans (one in 112) in Texas living with HIV/AIDS in 2007 were over four times the rate for Whites (one in 498) and five times the rate for Hispanic Texans (one in 565).<sup>3</sup>

There are three major modes of transmission for HIV: male-to-male sex, male-to-female sex and injection drug use. Over half of all new HIV cases in Texas in 2007 reported male-to-male sexual contact, 30 percent reported heterosexual sexual contact, and 13 percent of new cases were acquired HIV through injection drug use.<sup>3</sup>

### **B. Benefits of Early HIV Testing and Diagnosis**

Early diagnosis of HIV infection enables infected persons to obtain the medical care and medications needed to improve their health and can also reduce future high risk behaviors that put others at risk of infection. CDC recommends that every hospital, physician's

office, and clinic offer HIV testing to everyone aged 13-64 to expedite diagnosis of HIV infections.<sup>4</sup> Only 14 percent of Texans were tested for HIV in 2007.<sup>5</sup> Once infected with HIV, people generally do not experience noticeable symptoms for five to ten years before they are diagnosed with AIDS. Many HIV positive people do not learn about their infection status until they begin to experience symptoms of AIDS. In fact, one in three HIV-infected Texans are diagnosed with AIDS within one year of their HIV diagnosis.<sup>3</sup> The majority of Texans who receive a late diagnosis seek HIV testing because they are already sick. Late diagnosis means missed opportunities for preventing HIV infections, since after people become aware they are HIV positive, they are much less likely to engage in high risk sexual behavior.<sup>6</sup> Experts estimate that those who are unaware of their HIV infections are responsible for the majority of sexual transmissions of HIV.<sup>7</sup> Late diagnosis is also associated with poor prognosis and increased medical costs; direct care costs in the year following HIV diagnosis were more than 200 percent higher for patients who presented late.<sup>8</sup> The average lifetime cost of medical care for a person with HIV/AIDS is \$380,000.<sup>9</sup> Preventing new infections, diagnosing infections earlier, and ensuring infected people receive medical treatment reduces the overall costs of the disease.

To prevent, treat, and control the spread of HIV/AIDS in Texas, DSHS must have a disease reporting and surveillance system that is technologically current and can adapt to the future challenges of controlling the HIV/AIDS epidemic. The next section of this report describes how the HIV/AIDS disease reporting and surveillance system currently functions in Texas. The report includes current initiatives and future recommendations to the HIV/AIDS reporting and surveillance. This report also includes recommendations on improving early diagnosis of HIV.

### **III. HIV/AIDS Surveillance**

#### **A. Current HIV/AIDS Reporting and Surveillance System in Texas**

Under the Texas Health and Safety Code §81.041, acquired immunodeficiency syndrome (AIDS) and human immunodeficiency virus infection (HIV) are defined as reportable conditions in Texas. The Texas Administrative Code (TAC) §97.131-134 details reporting procedures for entities (i.e., health care providers and laboratories) that are required to report sexually transmitted diseases (i.e., AIDS, HIV, chancroid, *Chlamydia trachomatis*, gonorrhea, and syphilis). Currently, reporting entities are required to report to their local health authority information from all specimens from adults and children that yield microscopic, cultural, serological or any other evidence of STD infections, including HIV and AIDS.

CD4+ T lymphocyte cell (CD4) counts below 200 cells/microliter or less than 14 percent are also reportable. CD4s are specialized white blood cells that are part of the body's immune system and help protect the body from infection. HIV attacks these types of cells and weakens the immune system, making it unable to protect the body from illness and infection. A CD4 count is an indicator of how strong your immune system is and how far HIV disease has advanced (the stage of the disease). CD4 counts below 200

cells/microliter or less than 14 percent are indicative of an HIV infection that has progressed to AIDS. A plasma HIV viral load test measures how much HIV is in the blood. This is called the patient's "viral load." The lower the viral load, the less HIV virus is in the blood. Detectable viral loads are also currently reportable in Texas but undetectable viral loads are not reportable. An undetectable viral load means that the level of HIV in your blood is below the threshold needed for detection by a viral load test.

Both health care providers and laboratories are required to report HIV and AIDS diagnoses and tests to their local health authority within seven days for providers and at least weekly for laboratories. The local health authorities report all HIV/AIDS and STD infections that they receive to the HIV/STD Epidemiology and Surveillance program at DSHS.

HIV/AIDS disease surveillance is the ongoing and systematic collection, analysis, interpretation, dissemination, and evaluation of population-based information about persons infected with HIV or diagnosed with AIDS. In Texas, HIV/AIDS Core Surveillance is conducted through a statewide network of 12 local and regional health departments and the Texas Department of Criminal Justice (TDCJ) that report HIV/AIDS cases to the central HIV/AIDS registry located at DSHS. Each of these surveillance sites, with the exception of TDCJ, has an installation of the HIV/AIDS reporting system (HARS), which is a secured computerized data collection system developed by CDC. HARS surveillance staff receives information about potential new cases through reports from health care providers, paper and electronic laboratory reports, active surveillance and matching Texas's HIV/AIDS database to other registries (i.e., birth and death records, Texas HIV Medication Program data, Birth Defects Registry, Tuberculosis Registry, Cancer Registry, Hepatitis Registry, and STD Registry). Active surveillance is conducted when health department staff regularly contacts reporting sources to elicit reports instead of passively waiting for disease reports to come into the health department.

The vast majority of case ascertainment is conducted through investigating HIV test results received by paper and electronically from laboratories. Surveillance staffs at each of the local or regional HARS sites investigate potential cases and abstracts medical records to complete the case report forms. Once all required data elements are collected for confirmed cases, the HIV/AIDS case report form is completed. Data from the HIV/AIDS case report form is entered into the local, regional or central HARS database. Data from these databases are combined into one central HARS database, which is used to produce state statistics and reports. State data is also routinely sent electronically via secure means to CDC, who combines the data with data from all other states and areas to produce national statistics that are used to monitor the epidemic.

In addition, to the Core HIV/AIDS surveillance program, Texas has also implemented the following surveillance programs: Enhanced Perinatal Surveillance (EPS), Incidence Surveillance, and Variant, Atypical, and Resistance HIV Surveillance (VARHS). Texas initiated EPS in 1999 in an effort to curb HIV transmission from HIV-infected mothers to

their children. EPS collects additional data on HIV positive mothers and their infants including mother's and child's receipt of antiretroviral medications to prevent HIV transmission from mother to child. EPS data can also identify gaps where prevention intervention opportunities were missed. Incidence is the number of new cases of a disease over a certain period of time. Incidence Surveillance began in late 2005 to better estimate the number of persons newly infected with HIV. VARHS was implemented in 2007 to evaluate distribution of HIV drug resistance among persons newly diagnosed with HIV.

HIV/AIDS surveillance data are used both nationally and in Texas for describing the epidemic, planning for prevention and treatment activities, advocating for resources, and allocating and prioritizing available resources within communities. The Health Resources Services Administration (HRSA) uses HIV/AIDS surveillance data from states to allocate nearly \$2 billion in funding for HIV-related ambulatory care and support services available annually through the Ryan White Program. It is therefore imperative that Texas has an HIV/AIDS surveillance system that provides complete and timely identification of the number of HIV infected individuals.

## **B. Emerging Technologies in Reporting and Surveillance**

### **Enhanced HIV/AIDS Reporting System**

The HIV/STD surveillance system in Texas currently uses the HIV/AIDS Reporting System (HARS) to capture HIV/AIDS data to monitor the epidemic in Texas and to report required data to CDC to monitor the epidemic nationally. HARS is a data operating system program with limited data entry and data management resources. CDC released the Enhanced HIV/AIDS Reporting System (eHARS), a document based surveillance data system, to replace the HARS system in 2005. CDC has been working with states to implement eHARS nationally. As of January 1, 2009, eHARS has not been implemented in Texas, but it should be in place by January 1, 2010.

eHARS represents a significant improvement in HIV/AIDS surveillance technology. eHARS incorporates major advances in database organization and data presentation.<sup>10</sup> eHARS is a document based system, meaning that data from multiple documents are entered for each case and those documents are linked with a unique identification number. eHARS will enable the HIV/AIDS surveillance program to gather and store more information from birth certificates, death certificates, and laboratory reports than is currently possible with HARS. eHARS will allow for evaluation of data pertaining to HIV and AIDS case ascertainment methods. A document based system will also make conducting evaluations of completeness of HIV/AIDS surveillance data much less time intensive and more accurate.

Finally, eHARS provides updated tools to assist in the import and export of data, case investigation, and data transfer to CDC. eHARS has a feature that will allow researchers to create samples for research studies or for investigating a particular demographic group. There is also a component that supports HIV incidence surveillance, (which is detailed later in this report) an activity CDC identified as critical to monitoring the HIV/AIDS

epidemic. Implementing the eHARS system for the HIV/STD program will improve overall data quality and completeness, as well as increase the program's epidemiological assessment, research, and surveillance capabilities.

HARS and eHARS are primarily supported by federal funding from the CDC through the HIV/AIDS Surveillance Cooperative Agreement. DSHS received funding from CDC to support initial deployment of the hardware and software for eHARS. The final configuration of eHARS in Texas has not been determined and any modifications could result in additional costs. Future cooperative agreement budget negotiations will determine whether CDC or DSHS will be responsible for the modest ongoing maintenance costs and any unexpected additional costs for deployment of eHARS in Texas.

### **Electronic Laboratory Reporting**

Laboratories are mandated by law in Texas to report any test results that indicate HIV/AIDS disease to the local health authority. Laboratory reports are used to identify new HIV cases and intervene with stopping spread of disease by notifying patients of their infection status, providing risk reduction counseling, and partner notification. Currently, laboratories report through a variety of mechanisms such as mailing, faxing, or telephoning results. However, today's sophisticated technology enables easy, secure transmission of these data from laboratories to the health authorities electronically.

Advanced electronic lab reporting (ELR) systems enable automated messaging of reportable information directly from a laboratory management system to the appropriate public health jurisdiction.<sup>11</sup> To accomplish this automated process of lab reporting, CDC and its partners have selected Health Level Seven (HL7) as the standard code for ELR messages and data formats used in test names and test result values.<sup>12</sup>

Studies have shown that ELR enhances completeness, timeliness, and accuracy of reporting, thus providing a mechanism for public health officials to rapidly identify problems and prevent further spread of disease.<sup>11-13</sup> Electronic reporting could potentially reduce the number of person hours required to process paper-based laboratory reports. Since 1997, the Council of State and Territorial Epidemiologists (CSTE) as well as CDC have advocated for electronic laboratory reporting.<sup>13</sup> Additionally, several states require electronic reporting of reportable conditions in their jurisdiction.

In Texas, many large commercial laboratories have been reporting electronically for several years, although not all have adopted the standard codes suggested by CDC and its partners. This lack of standardization in electronic reporting means that many staff hours must be dedicated to cleaning the electronic data, including follow-up activities which require staff to contact laboratories to complete missing fields. Currently, eleven laboratories (two public health laboratories and nine commercial laboratories) report their HIV/AIDS test results electronically, but it is estimated that more than 20 laboratories that conduct HIV/AIDS tests continue to report their results via paper or other slower and less efficient means. These 20 laboratories that continue to report laboratory results via paper are primarily hospital-based .

Moving to electronic laboratory reporting by hospital-based and commercial laboratories will require varying degrees of internal laboratory resources depending on the baseline technology level of their current reporting system. The DSHS HIV/STD program in conjunction with the National Electronic Disease Surveillance System (NEDSS) staff at DSHS is conducting collaborative outreach to hospital-based and commercial laboratories both to facilitate initiation of electronic disease reporting and standardization of electronic disease reporting. This outreach is done on a case by case basis starting with those laboratories that conduct the highest volume of HIV/AIDS reporting as top priority. DSHS can provide some limited technical assistance to commercial and hospital based laboratories but the cost of creating an electronic disease reporting system or reconfiguring current diseases reporting systems will be the responsibility of the laboratories.

## **Electronic Medical Records**

Active surveillance is very time consuming for surveillance staff. Active surveillance requires state and local health department personnel to contact health care practitioners and review medical records in physician's offices, hospitals, and clinics to collect HIV/AIDS data. For a state as large as Texas, collecting HIV/AIDS data quickly and effectively can be challenging. According to the Department of Defense Center for Deployment Health Research, there can be up to 18 months of time between a patient office visit and entry of patient information into an office database.<sup>14</sup>

An electronic medical record (EMR) is an electronic version of a patient's medical record stored in a centralized database that allows healthcare professionals easy access to patient data and information.<sup>15</sup> To address issues of reporting delays and accuracy, a study was conducted that compared using electronic medical records for disease reporting compared to paper disease reporting. Results suggest that EMR based reporting allows more cases to be identified and reported: Chlamydia cases increased 39 percent and gonorrhea cases increased 53 percent compared with passive paper reporting.<sup>16</sup> An EMR surveillance system implemented at Northwestern Medical Hospital in Chicago to identify adverse events revealed a similar improvement in the number of adverse events reported to the hospital.<sup>17</sup>

Use of electronic medical records for disease reporting will play a key role in advancing HIV/AIDS surveillance in the future; it is part of an overall movement toward a web-based system of HIV/AIDS reporting and surveillance. The main advantage of using EMR is that all of a patient's information, including general medical history, laboratory reports, x-ray reports, testing history and drug therapy regimens will be easily accessible to physicians, disease intervention specialists, surveillance staff and public health researchers. EMR will expand the capabilities of specialty community clinics and hospitals, such as those focusing on HIV/AIDS, allowing them to identify population health trends earlier, and monitor treatment compliance.<sup>18</sup> Another benefit of using EMR is that records can be quickly linked with other reporting systems to determine if a patient has been exposed to other infectious diseases, such as tuberculosis or influenza. In

addition, electronic medical records linked to a national death registry can be a more efficient and thorough method of ascertaining deaths among individuals with HIV/AIDS than manual linkage limited to in-state death certificates.

The development and implementation of EMR in both private and public health care settings is an issue that affects the entire health care system in Texas and nationwide. Within the public health care system some clinics are already using EMR technology, some have other data systems that may be reconfigured or augmented to create an EMR system and some are not using electronic records or systems. However, no comprehensive list has been compiled of those health care entities using EMR in Texas and the costs of implementing EMR will vary depending on the degree of current technology in place, including personal computers, servers, network hardware, application licensing agreements, network wiring, electrical wiring, and current IT support operations. This technology must be documented, reviewed, and assessed to ensure that the current technology environment can support an EMR system. In the context of enhancing HIV/AIDS surveillance and disease reporting in Texas, DSHS could begin evaluating what EMR systems are currently in place in DSHS sexually transmitted disease clinics and HIV clinics supported with federal and state monies and analyze the costs and benefits of implementing EMR systems in those settings. This would be an important first step in moving towards broader use of EMR in public health care settings in Texas.

## **CD4+ T-lymphocyte and HIV Viral Load Reporting**

CD4 and HIV viral load testing are key components of monitoring and managing HIV disease. Viral load and CD4 testing are also markers of a person's access to care. Presence of viral load and CD4 test results indicates the patients' clinical status is being monitored, and they are thus receiving some health care. CD4 tests are used to assess immunosuppression in HIV-infected patients and to guide therapeutic decisions.

CD4 testing at diagnosis and every three to six months thereafter is recommended in the management of HIV disease. CD4 results are also used in determining whether an HIV-infected person meets the AIDS immunologic case definition (i.e., CD4 count <200 cells/microliter or CD4 percentage <14 percent of total lymphocytes); in 1993, these immunologic criteria were added to the AIDS-defining diseases and conditions. In Texas, CD4 tests meeting these criteria have been reportable to disease surveillance authorities since 1993.

Viral load monitoring is also important in managing HIV disease care and treatment. A plasma HIV viral load test measures how much HIV is in the patient's blood. The lower the viral load, the less HIV virus is in the blood. A viral load should be obtained at diagnosis and may be a factor in deciding when to initiate antiretroviral therapy. Viral load tests are also used to monitor HIV therapy once it has been initiated. A goal of therapy is to reduce viral load levels below the level of test detection (i.e., undetectable

viral load result). The Texas STD disease reporting rules were amended to incorporate the reporting of *detectable* HIV viral loads in January 2000.

Currently, Texas reporting rules require that only CD4 counts below 200 cells/microliter or a CD4 percentage of less than 14 percent and viral load results showing detectable viral load be reported. Complete data on laboratory tests indicative of HIV infection including *undetectable* viral loads and *all* CD4 tests would increase identification of unreported HIV/AIDS cases, allow assessment of levels of immunosuppression and virus replication among persons diagnosed with HIV, and enhance accuracy of estimates of HIV infected persons *not* in medical care because of better data received on those persons that are receiving care.

In an analysis conducted by the Oregon State Public Health HIV/STD/TB Program, nearly twice the number of new HIV cases was identified in Oregon when the state changed their laboratory reporting rules to include reporting of all CD4 and viral load test results.<sup>19</sup> CDC and CSTE recommend that all states require laboratory reporting of all levels of CD4 and both detectable and non-detectable viral load results to their state public health departments. The CSTE position paper states that “having all levels of CD4 and both detectable and non-detectable viral loads reportable would allow states to describe the clinical status of persons recently infected with HIV and to estimate the population of persons who are infected but are not in care, study factors associated with not being in care, and design effective interventions to link persons to care”.<sup>20</sup> Further, of the 54 states and U.S. territories, 33 require reporting of both undetectable and detectable viral loads and 23 require all level of CD4s to be reported.

CD4 counts are not only used for monitoring HIV disease. Normal CD4 counts in adults range from 500 to 1,500 cells per cubic millimeter of blood. Higher than normal T-cell counts may be caused by acute lymphocytic leukemia, infectious mononucleosis, and multiple myeloma. Lower than normal levels may be due to acute viral infection, cancer, congenital T-cell deficiency (rare), Hodgkin’s disease, and leukemia. Cancer chemotherapy and radiation therapy can dramatically lower the CD4 count and health care providers monitor cancer therapy with CD4 counts. Therefore, if all CD4 counts are reportable in Texas, some non-HIV/AIDS related CD4 count results will be reported to local health authorities and DSHS. DSHS estimates that a very small percentage of the total CD4 test results received will not be related to HIV/AIDS. Currently, some laboratories voluntarily report all CD4 counts through electronic laboratory reporting. In 2008, based on the electronic laboratory reports that DSHS receives, only 1.7% of the CD4 test results, representing 2.3% of the individuals tested, were not related to HIV/AIDS. Data from other states implementing all CD4 reporting show that up to 6% of CD4 counts are non HIV-related.

All HIV viral loads and CD4 counts received will first be matched to the HARS database and if matched to a known HIV case they will be added to the HARS database. DSHS plans to decrease the number of non-HIV related CD4 tests that need surveillance investigation and public health follow-up by excluding those CD4 counts that do not have an accompanying HIV viral load test. DSHS will also match the provider or facility

ordering the CD4 count with a list of known HIV care providers and facilities and those CD4 tests that come from non-HIV care providers or facilities will be excluded from further investigation. After the matching and exclusion process described above, the remaining CD4 counts that are received will need to be investigated by public health staff by contacting the ordering health care provider or facility to determine if the CD4 is related to a non-reported case of HIV or not related to HIV disease. Initially there will be a larger number of CD4 counts that will need to be investigated by public health staff, however, over time this number will decrease as a database of non-HIV healthcare providers and facilities such as cancer treatment centers that routinely order non-HIV related CD4 counts is developed and used to exclude those CD4s from public health follow-up.

If all CD4 count levels and HIV viral load reporting is implemented in Texas, a triage system for prioritizing surveillance investigation and public health follow-up of HIV related tests will be developed with highest priority given to those tests with the highest probability of indicating a new HIV infection or development of AIDS. Positive confirmatory HIV tests, detectable HIV viral loads, CD4 counts below 200 cells per microliter or a CD4 percentage of less than 14 percent (AIDS defining level) would be given higher priority for surveillance investigation and public health follow-up and lower priority would be given to non-detectable viral loads and CD4 counts greater than 200 cells per microliter.

## **HIV Incidence Surveillance**

Incidence is a measure of new infections within a specified period of time, and represents the risk of infection within a population. For HIV, incidence has traditionally been difficult to accurately estimate. HIV data currently captured in the HIV/AIDS surveillance system is based on when a person is first diagnosed with HIV, not when the person first became infected with HIV. Currently, when a person receives an HIV test it is a standard antibody detection test with a confirmatory western blot test that indicates the person is infected with HIV but does not indicate how long the person has been infected with HIV. However, a new testing technology, referred to as the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) has emerged that allows the incidence of HIV/AIDS to be measured at the population level.

The laboratory test for STARHS is the BED-capture enzyme immunoassay (BED-CEIA). The test works by measuring the level of HIV-specific antibodies circulating in a patient's blood. Among individuals with recent infections, the proportion of HIV-specific antibodies is low compared to non-HIV-specific antibodies. As infection progresses over time, however, that ratio shifts towards an increased immune response, which is marked by an increase in HIV-specific antibodies. Since the BED-CEIA can determine what proportion of an individual's immune response is HIV-specific, it can distinguish between a recent and longstanding infection.

This test, along with supplemental testing and treatment histories (TTH), forms the operational core of STARHS, as it is currently administered by the CDC through participating states. Remnant blood samples are collected by the State and submitted to the CDC for testing. Results are combined with State-collected TTH data to determine an annual incidence rate for Texas and for the United States as a whole. Along with other participant states, the STARHS program constitutes approximately 85 percent of reported HIV cases in the United States.<sup>21</sup>

STARHS represents a major advance in HIV surveillance that allows for more precise estimates of HIV incidence than ever before possible. In the future, the STARHS-based surveillance system will provide the most reliable way to monitor incidence trends in Texas and the United States. Trend information from this system will allow for improved targeting and evaluation of prevention efforts for the populations at greatest risk.<sup>22</sup>

### **Variant Atypical and Resistant HIV Surveillance**

Texas implemented Variant Atypical and Resistant HIV Surveillance (VARHS) in 2007 to evaluate the prevalence of HIV-1 mutations associated with drug resistance and distribution of HIV-1 subtypes among individuals who are newly diagnosed with HIV. The terms ‘variant’ and ‘atypical’ refer to, respectively, the different subtypes and unusual genetic combinations of HIV that can be found in infected populations. These circulating strains can have different prognoses, may have implications for treatment decisions and, if widely identified within a given community, may present an opportunity for intervention.

There are several variant strains of HIV circulating through human populations. Scientists organize HIV into two distinct strains, HIV-1 and HIV-2. HIV-1 is further subdivided into three groups, known as group M (major group), group O (outlier group), and group N (new group). Group M is then divided again into distinct subtypes labeled by letters denoting the order they were discovered. In the United States, HIV-1, subtype B, is the most commonly diagnosed strain.

Resistance to drug therapy is common in many microbial diseases; however, HIV is particularly susceptible due to both its high rate of reproduction, frequency of mutations, and lack of certain proteins needed to correct mistakes during reproduction. HIV’s genetic structure consists of RNA, proteins and enzymes. Mutations cause changes in the genetic structure of HIV; thus, interfering with the mechanism of action of certain drugs, leading to decreased susceptibility of the virus to these drugs.

Determining the genetic code of the virus (genotyping) is generally performed through DNA sequencing tests. Sequencing assays yield the complete genetic code of the virus, which can then be examined for known mutation-resistance associations.

The purpose of the VARHS program is to track emerging HIV drug resistance so that policies regarding the choice of medications and their proper use can be effectively established. With the exception that participation is limited to public health laboratories,

the logistics of this surveillance effort are comparable to the STARHS program described above; leftover diagnostic HIV positive blood samples are routinely collected by the state and submitted to a CDC-contracted laboratory. This laboratory (located in Stanford, CA) identifies the specific HIV subtype and its genetic code so that markers of drug resistance can be identified.

VARHS is currently only being implemented in Texas for remnant HIV positive blood samples from public health laboratories. VAHRS is providing valuable data on HIV drug resistance, however, implementation of such an approach on a statewide basis is cost prohibitive. A more cost-effective system would entail collection of HIV gene sequences (usually referred to as a FASTA file) that result from drug-resistance tests conducted by clinical laboratories as ordered by a physician in the course of providing care to an infected patient. This approach requires reporting only results of tests that have already been conducted. Reporting of HIV gene sequences for drug resistance testing would require a change in STD reporting rules in the Texas Administrative Code. Desired rules' changes would require clinical laboratories that conduct HIV drug-resistance testing to submit a report containing the nucleotide sequences of the HIV in an electronic format (FASTA file). This change would require reporting of the virus' genetic sequence alone and not any human genetic information. The nucleotide sequences are an indicator of the types of resistance present and suggest which HIV medications that may not work for clinical treatment of the person's infection.

Technological improvements over the past decade have increased the quality and speed of genotyping, while lowering costs per test, which has allowed genotyping to become an important tool in HIV surveillance. Cumulative results of this surveillance will help the state to identify clusters of drug-resistant HIV within certain high risk groups and communities and allow for more targeted prevention interventions.

### **C. Recommendations for Enhancing HIV and AIDS Reporting and Surveillance**

To provide accurate and timely demographic and medical data about HIV/AIDS cases in Texas and more comprehensive information regarding new HIV infections, access to care, treatment options and prevention services, DSHS recommends the following actions:

- Deploy eHARS in Texas. CDC plans to deploy eHARS in Texas during 2009. eHARS is a document based system that will allow for evaluation of data pertaining to HIV and AIDS case ascertainment methods.
- Revise the Texas Administrative Code relating to reporting rules for HIV and AIDS to include all HIV related tests including all CD4 counts, detectable and undetectable viral loads, and drug resistance testing, to identify more people who are HIV infected, reduce the number of HIV infected persons who are not currently reported, and to gain a better understanding of patterns of new infections (incidence) and patterns of drug resistant HIV occurring in Texas.

- Assist hospitals to report HIV and AIDS laboratory test results electronically. Most hospital laboratories currently report HIV and AIDS test results by hard copy to the local health department. Electronic reporting would increase timely receipt of laboratory reports, allowing field staff to investigate cases more quickly, and standardizing information received from hospitals pertaining to HIV and AIDS laboratory results.
- Integrate HIV/AIDS surveillance with STD surveillance. The application that collects patient interview information from the public health follow-up process is called STD\*MIS. Currently, field staff will access this system to abstract information to complete HIV/AIDS case report forms and this information is subsequently entered into HARS. A more efficient system would combine STD surveillance and HIV/AIDS surveillance data to reduce redundant data entry and to improve reporting of cases between the two systems. There will be many opportunities to streamline reporting of these diseases into one surveillance system during the next several years.
- Devise methods for DSHS funded STD clinics to report diseases electronically to DSHS. Currently, each clinic has a unique method of capturing data which is later abstracted by field staff to complete the case report form. Moving to an electronic medical record would allow more complete, accurate and timely reporting from these clinics.

## **IV. HIV Testing**

### **A. Current Status of HIV Testing in Texas**

#### *Current Testing Technology*

Texans access HIV testing through a variety of settings; the largest proportion of HIV tests performed in Texas (37 percent) occurs at the private doctor's office or Health Maintenance Organizations (HMOs). Hospitals across the state account for the second largest proportion, performing 20 percent of all HIV tests in 2006. Public health departments provide an important access site for low cost HIV tests for persons without private insurance. Aside from these sites, DSHS supports a number of testing programs that target populations at very high risk of becoming HIV infected, such as injection drug users and men who have sex with men. Most sites, whether public or private, obtain test samples and send them to laboratories that use the Enzyme Immunosorbent Assay (EIA) and Western Blot testing technologies. While new generations of the EIA have emerged over the years, the EIA and the Western Blot have been the standard in HIV testing technologies since the late 1980's.

#### *HIV Rapid Testing*

Although HIV rapid testing only became available within the past few years, its use has become more widespread. Offering results within 20 minutes, the HIV rapid test has gained appeal with both clients and practitioners alike. Clients like receiving their results

immediately, rather than returning one to two weeks later. Providers find greater success ensuring all persons testing HIV-positive receive their results and linking them into medical care, two core measures of successful practice. HIV rapid testing has proven especially useful when testing occurs in the field and has allowed increased testing of hard-to-reach populations.

Perinatal HIV transmission accounts for nearly all pediatric AIDS cases.<sup>23</sup> CDC recommendations support opt-out testing of all pregnant women early in pregnancy and again during the third trimester.<sup>4</sup> Furthermore, CDC recommends that all hospitals adopt a policy of routine, rapid or expedited HIV testing using the opt-out approach for women who have no documented HIV test result when presenting to labor and delivery. Rapid HIV testing has proven ideal for determining the HIV status of women during labor and delivery. Rapid testing can determine the infection status of the mother and determine the need for any antiretroviral prophylaxis, or other procedures, which can significantly reduce viral transmission to the newborn. Texas law has required HIV, syphilis, and hepatitis B opt-out testing at the first prenatal visit and at delivery since 1999.<sup>24</sup> DSHS funds the Harris County Hospital District to provide training to Harris County and other hospitals throughout the state on the implementation of HIV rapid testing at labor and delivery. There are plans to expand the education of local hospitals, obstetricians and pediatricians on HIV test recommendations and use of the rapid test at delivery.

#### *HIV Testing and Vulnerable Populations*

DSHS HIV Prevention contractors perform targeted testing aimed at finding persons most at risk for HIV infection. These sites test the populations most vulnerable to HIV infection, rather than the general population. Locations commonly used to identify high risk populations include: drug rehabilitation centers, local bars, county jails, neighborhood hangouts, low income housing projects, and community health fairs. These locations often use research-based interventions in conjunction with HIV testing. Interventions aim to increase client awareness of risk for HIV, determine motivators for change, and ultimately, reduce or eliminate self-destructive behaviors.

Local public health departments play a vital role in providing access to HIV testing, because local public health clinics are geographically dispersed throughout Texas and are accessible in nearly all Texas counties. Many local public health authorities also conduct public health follow-up. These programs seek to intervene in the disease cycle by locating persons in the community who have been exposed to HIV, providing testing, and linking to health care those individuals found to be HIV positive. In 2007, staff identified, counseled and tested 4,834 persons exposed to HIV. Among those tested, staff identified 267 new HIV infected persons and linked 95 percent of them to HIV treatment and health services.

#### *Routine HIV Testing*

In 2006, CDC issued revised recommendations for HIV testing, calling for increased routine, opt-out testing in a variety of health care settings.<sup>4</sup> Routine testing means that every individual entering a particular health care setting is tested for HIV unless they object to the test. Expanding routine HIV testing in this manner is important for the

health of Texans. From 2003 through 2007, over one quarter of all new diagnoses in Texas received an AIDS diagnosis within one month of their HIV diagnosis.<sup>3</sup> Further, over one third of all new diagnoses received HIV and AIDS diagnoses within one year,<sup>3</sup> which suggests these individuals were unaware of their HIV infection for five to ten years. To meet this challenge, the DSHS HIV Program has collaborated with other agency divisions to begin routine testing in settings such as tuberculosis clinics, family planning clinics, and state hospitals. DSHS has used federal and state funds to begin expanding routine testing in STD clinics, hospital emergency departments, drug treatment centers, and within local correctional health services.

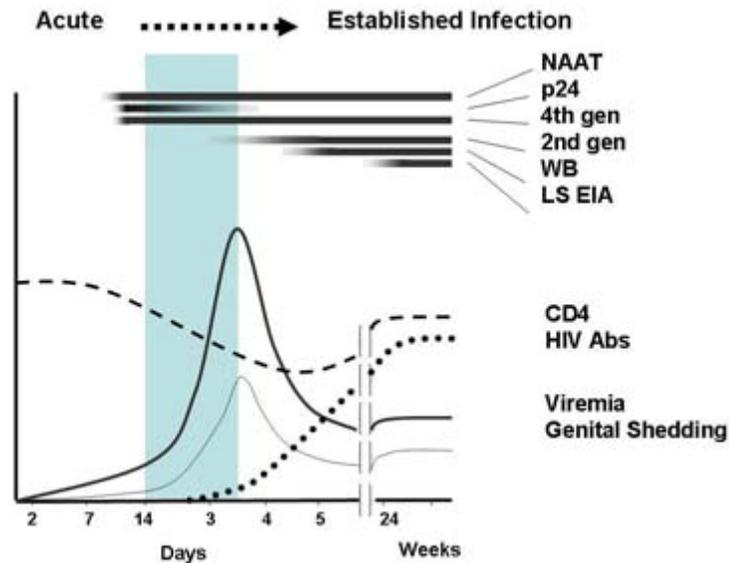
## **B. Emerging Technologies in HIV Diagnosis and Testing**

Evolution of HIV diagnostic testing began almost immediately after researchers identified the virus in 1983. The U.S. Food and Drug Administration (FDA) licensed the first HIV blood test in March 1985. CDC released the first of a series of guidelines on testing and counseling in 1986.

The current testing sequence is a repeatedly reactive antibody test, which is then confirmed with a Western Blot (WB) or immunofluorescent assay (IFA), before results are reported as positive. Over the past decade, there have been major improvements in performance and accuracy of the EIA tests and introduction of rapid tests. There has also been expansion in suitable specimen types (saliva, whole blood finger stick, urine), increasing the options for testing programs. These conventional tests use antibody detection for HIV diagnosis.

Nearly everyone infected with HIV will have detectable antibodies three months after infection.<sup>25</sup> The time between infection with HIV and the ability of a test to detect HIV is called the window period. Testing goals include accurately detecting the infection and decreasing the window period. Conventional HIV tests detect HIV antibodies, but it may take weeks for detectable levels of antibodies to develop in the bloodstream.

Consequently, a recently infected individual may test negative during the window period. By contrast, the Nucleic Acid Amplification Test (NAAT) detects the presence of HIV virus and can do so as early as two weeks after infection. The diagram below illustrates the amount of time required to detect HIV infection using current testing technologies.<sup>26</sup>



HIV NAAT is the most sensitive technology available at this time.<sup>27</sup> Adding NAAT-based screening to standard HIV testing can identify individuals with an acute HIV infection earlier when they may be highly infectious and antibody test results would be negative. Use of NAAT testing technology could potentially increase the number of persons diagnosed during this highly infectious acute period, and these persons could receive enhanced intervention to inform them of their recent infection and the likelihood of infecting others. Partners of persons acutely infected could also receive prioritized attention for testing and counseling. Finally, very early detection would increase the likelihood of persons entering treatment long before development of clinical symptoms. To determine its usefulness, DSHS implemented a HIV NAAT pilot project at the Dallas County Laboratory in 2008.

Routine testing, including use of new technology such as NAAT, has important implications for public health. Multiple studies suggest that persons unaware of their acute HIV infection are important drivers of the epidemic. It is estimated that over half of new sexually transmitted HIV infections are due to people unaware of their infection. Evidence indicates that once individuals become aware of their serostatus, they reduce risky behaviors and decrease HIV transmission.<sup>28</sup>

Future avenues of growth are the improvement of rapid urine tests and development of rapid NAAT testing for oral fluids and finger stick whole blood samples. Rapid NAATs have the potential to revolutionize HIV testing by offering sensitive tests that can identify HIV a week after infection.

### **C. Recommendations for Improving HIV/AIDS Testing**

Since the first diagnostic HIV test was introduced in 1985, HIV testing has become more accessible and less invasive. Unfortunately, national data indicate that a large percentage of new HIV diagnoses are made during the late stages of disease; an estimated one fifth

of the people living with HIV in Texas do not know they are infected<sup>2</sup>. That lack of awareness is critical from the public health perspective.

Early detection through new laboratory technology can detect HIV infection at an early stage for better medical management. Onset of AIDS can be delayed and the quality and length of life can be enhanced significantly. Early detection also helps to minimize risk of transmission to other people, thereby reducing the overall disease burden. DSHS recommends the following actions:

- Explore new HIV testing technology through collaboration with laboratory, research, and public health institutions;
- Seek support to continue laboratory implementation of the HIV NAAT technology that decreases time from infection to laboratory detection of HIV;
- Develop new strategies and algorithms to optimize existing technologies that will maximize HIV screening and detection; and
- As outlined by the 2006 CDC Revised Recommendations for HIV Testing, increase access to HIV testing by pursuing implementation of routine HIV testing in a variety of healthcare settings.

## **V. Conclusion**

The HIV/AIDS epidemic continues to impact the health of Texas citizens. The number of persons living with HIV/AIDS is increasing, particularly for African-Americans who are disproportionately affected by the disease. Primary challenges to slowing the epidemic are:

- Affecting change in high risk behavior;
- Educating the public about the importance of knowing their HIV status; and
- Increasing routine HIV testing among the general population.

The accuracy and completeness of HIV/AIDS reporting and surveillance efforts in Texas will be enhanced if more laboratories use electronic laboratory reporting and hospitals electronically submit HIV/AIDS patient records. eHARS, scheduled to be installed before January 1, 2010, will permit evaluation of HIV case ascertainment methods. These changes will enable DSHS to collect, analyze, and distribute HIV/AIDS case data more efficiently. As a result, DSHS hopes to reduce the impact of the epidemic and provide improved health outcomes for individuals living with HIV/AIDS.

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