HIV Diagnostic Testing and Linkage to Care

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Significant advances in the diagnosis and treatment of HIV have occurred in the last 30 years, but many people living with HIV remain unaware of their infection. Others have been diagnosed, but have failed to successfully link to care. Still fewer have been retained in care and have achieved an undetectable HIV viral load. Diagnosis, linkage to care, retention in care, receipt of antiretroviral therapy and achievement of a suppressed HIV viral load represent a spectrum in HIV care called the Continuum of Care (Figure 1). Lack of success at each of these steps has maintained the HIV epidemic with an estimated incidence of 50,000 new infections per year in the United States (U.S.).\textsuperscript{1}

Whether or not we play an active role in treatment of HIV infection, all providers have an important role in making sure patients are appropriately tested and if found to be infected with HIV, supported as they make their first linkages to HIV care.

Epidemiology of HIV in the United States and Florida

The latest estimates from the Centers for Disease Control and Prevention (CDC) indicate that more than 1.2 million people in the U.S. are living with HIV.\textsuperscript{2} Gay, bisexual and other men who have sex with men (MSM) remain the population most at risk of HIV infection. A recent study found that between 2002 and 2011, the rate of new HIV diagnoses in MSM between the ages of 13 and 24 increased by 132%.\textsuperscript{3} Young black/African American MSM are at particularly high risk and accounted for 55% of new HIV infections among young MSM overall in 2010, the most recent year these data are available.\textsuperscript{1}

As a race, African Americans are over-represented in the HIV epidemic. Blacks represent only 12% of the U.S. population, but in 2010 they accounted for approximately 44% of new HIV infections. According to the CDC, “Unless the course of the epidemic changes, at some point in their lifetime, an estimated 1 in 16 black men and 1 in 32 black women will be diagnosed with HIV infection”.\textsuperscript{2}

The HIV/AIDS epidemic is not distributed evenly within the U.S. Urban areas tend to have the highest concentration of infection. In 2013, the rates (number of cases/100,000 people) of HIV infection were highest in the South (20.5), followed by Northeast (15.9), West (10.8), and Midwest (9.0). Florida had the highest number of newly diagnosed HIV cases (n=5,377) in 2013, followed by California (n=5,334), Texas (n=4,854), New York (n=3,803), and Georgia (n=3,020). The three Metropolitan Statistical Areas (MSAs) with the highest infection case rates in 2013 are Miami-Ft. Lauderdale-West Palm Beach.
(44.3), New Orleans-Metaire (43.4), and Baltimore-Columbia-Towson, Maryland (36.5). The CDC has developed an interactive platform for accessing data collected by the CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) available at http://www.cdc.gov/nchhstp/atlas/index.htm?_cid=bb-od-atlas_001. This atlas allows the evaluation of HIV surveillance data down to the county level.

Due to concerns about ongoing HIV transmission, health disparities, and difficulties accessing optimal care for management of HIV infection, the National HIV/AIDS Strategy (NHAS) was developed and released on July 13, 2010. The goals for this strategy are threefold:

1. Reduce new HIV infections
2. Increase access to care and improve health outcomes for people living with HIV
3. Reduce HIV-related health disparities

Specific goals include increasing the number of HIV-positive individuals aware of their serostatus from 79% to 90% and increasing the proportion of newly diagnosed individuals linked to care within three months from 65% to 85%, by 2015. In 2013, President Obama signed an executive order, The HIV Care Continuum Initiative, calling on federal agencies to focus and coordinate HIV prevention resources to improve the HIV care continuum, including diagnosis and linkage to care. In July 2015, the NHAS was updated to 2020 and these goals were reinforced.

Who should undergo HIV testing?
In September of 2006, The CDC released Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. These recommendations include routine HIV testing, regardless of risk, for all patients aged 13-64 years of age in areas with HIV prevalence ≥ 1 percent. Testing is recommended for all patients initiating treatment for tuberculosis, all patients seeking treatment for sexually transmitted infections and all pregnant women. Those at increased risk for HIV infection such as injection-drug users and their sex partners, people who exchange sex for money or drugs, sex partners of people infected with HIV, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test should be tested at least annually. More recent guidance suggests that at-risk MSM should be screened every 3-6 months.

In 2013, the United States Preventive Services Task Force (USPSTF) released updated recommendations to their 2005 recommendation statement on screening for HIV. The USPSTF now recommends HIV screening for adults and adolescents aged 15-65 years, younger adolescents and older adults at increased risk for infection and all pregnant women (Grade A recommendations).

The CDC and the USPSTF agree that screening for HIV infection should be voluntary and only undertaken with the patient’s knowledge and understanding that HIV testing is planned. Patients should be informed verbally or in writing that HIV testing will be performed unless they decline (opt-out screening). Verbal or written information, including
an explanation of HIV infection and the meaning of potential test results should be provided in the languages commonly encountered in a service area. The patient should be offered an opportunity to ask questions and to decline testing. With such notification, consent for HIV screening should be incorporated into the patient’s general informed consent for medical care on the same basis as other screening and diagnostic tests. The CDC does not recommend a separate consent form for HIV testing. However, if a patient declines an HIV test, this information should be documented in the patient’s medical record.

Effective July 1, 2015, Florida statutes now allow for an opt-out approach to HIV testing in healthcare settings, allowing testing for HIV to be a routine part of care in our state. The change in the law amends 381.004, F. S. removing the requirement for informed consent prior to HIV testing in healthcare settings. With this change in statute, the client must be notified that they will be tested for HIV unless they decline testing (opt-out). Notification that HIV testing will be done can be provided orally or in writing. The client must be informed that the results of HIV testing will be reported to the county health department with sufficient information to identify the test subject. If the client opts-out of HIV testing, that decision should be noted in the patient’s medical record and no testing can be done at that time. In nonhealthcare settings, such as community-based organizations informed consent is still required. See the updated Florida statute at [http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0300-0399/0381/Sections/0381.004.html](http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0300-0399/0381/Sections/0381.004.html). Rule 64-D-2.004 of the Florida Administrative Code which details HIV testing requirements, including informed consent, is currently being updated due to the recently updated Florida statute. See [https://www.flrules.org/gateway/RuleNo.asp?title=HUMAN IMMUNODEFICIENCY VIRUS (HIV)&ID=64D-2.004](https://www.flrules.org/gateway/RuleNo.asp?title=HUMAN IMMUNODEFICIENCY VIRUS (HIV)&ID=64D-2.004) for additional information.

**What options exist for HIV testing in 2015?**

Patients seeking HIV testing today have many choices. Options include home, rapid point of care, anonymous or conventional blood based HIV testing. It is important to recognize that there are advantages and disadvantages for each of these options so that patients can be properly counseled.

HIV tests are grouped according to generations. Each successive generation test detects HIV infection earlier than the previous (Figure 2). These improvements are in an effort to shorten the window period – the time between exposure to HIV and the ability to detect infection by available tests. The initial first-generation HIV test was able to detect infection by about day 56, while the current fourth-generation test is able to detect infection within 14-15 days. HIV RNA is detectable within about 10 days of infection.\(^\text{10}\)

Currently, there are two home tests approved by the U.S. Food and Drug Administration (FDA): the Home Access\textsuperscript® HIV-1 Test System and the Oraquick\textsuperscript® In-Home HIV Test.\(^\text{11}\)

The Home Access\textsuperscript® HIV-1 Test System is a home collection kit that requires the patient to provide a blood sample and mail it in for testing. Results are anonymous and available as early as the next business day. Confirmatory testing is automatically done on the sample in the event of a positive screening test. The Oraquick\textsuperscript® In-Home HIV test is the first and
only rapid over-the-counter HIV test approved in the United States. This test can detect antibodies to HIV-1 and HIV-2 with an oral swab sample in as little as 20 minutes. The level of antibody in oral fluid is lower than in blood and up to 1 in 12 people may have a false-negative result with this test. A consumer support center provides 24 hour support with information on HIV/AIDS, instructions on how to properly conduct the test, and referrals to local organizations for follow-up testing and linkage to care. This test costs approximately $40 per test kit. Positive results require separate confirmatory testing. However, these tests provide options for those who would otherwise not seek HIV testing due to concerns regarding privacy.

Rapid HIV tests can make a preliminary diagnosis of HIV in 30 minutes or less and can be used in traditional healthcare settings as well as non-clinic settings by outreach teams. Positive results obtained by rapid HIV tests require confirmatory testing. Ten rapid point-of-care tests have been approved by the U.S. FDA. Most of these rapid tests diagnose only established HIV infection, however, the new Alere Determine™ HIV-1/2 Ag/Ab Combo is a CLIA waived rapid point-of-care test that can detect HIV 1 & 2 antibodies as well as the p24 antigen which allows diagnosis even during acute HIV infection.12

A list of FDA approved HIV tests with advantages and disadvantages of each is available at http://www.cdc.gov/hiv/pdf/testing_AdvDisadvHIVtesting.pdf.

Patients desiring conventional HIV blood testing who do not want their names linked to the test results can seek anonymous HIV testing. This involves linking the result to a unique identifier rather than the patient’s name. The patient must seek the results after testing as they are otherwise not traceable for follow-up. Health departments maintain a list of local anonymous HIV testing sites. However, anonymous testing results are not acceptable as proof of disease status for accessing services.

Conventional blood based HIV testing is typically done in healthcare settings. Until recently, the recommended protocol for conventional blood based HIV testing involved a screening HIV antibody test confirmed with a Western blot or immunofluorescence assay (IFA). This algorithm had several shortcomings including the inability to detect early HIV infection leading to false-negative or indeterminate results in those with acute HIV infection, a time when the viral load is markedly elevated and the risk for transmission is highest. Patients can be falsely reassured by a negative HIV test at this stage leading to ongoing risky behaviors and further spread of HIV in the community. Accurate diagnosis of infection during the acute phase is critical both for initiation of treatment of the infected individual and also for prevention efforts in the community as a whole. An additional problem with the older testing algorithm was the inability to differentiate HIV-1 and HIV-2 infection. This distinction is important because laboratory monitoring for these infections is different and some antiretroviral agents effective against HIV-1 are not effective against HIV-2.

On June 27, 2014, the CDC released a new protocol for HIV testing titled “Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations”.13 The new algorithm replaces the 3rd generation HIV antibody test with a 4th generation combined
HIV antigen/antibody assay (Figure 3). This 4th generation combined HIV antigen/antibody test identifies acute HIV infections while maintaining the same accuracy for detecting established infection. This improvement is critical as it has become recognized that the risk of HIV transmission from those with acute and early infection is much higher than that from people with established infection, accounting for 10-50% of all new HIV transmissions.12-15 Early detection of HIV infection is made possible in the new algorithm by inclusion of testing for the HIV-1 p24 antigen, a viral protein present early in infection.

Other benefits of the new algorithm include:
- a shorter processing time as the tests in the current algorithm are able to be done much more quickly
- the HIV 1/2 differentiation assay can detect HIV-2 infection which has important treatment and monitoring implications
- the addition of an HIV nucleic acid test allows accurate detection of early HIV infection
- elimination of the Western blot confirmatory test decreases the risk of false negative and indeterminate testing results which could occur with the old testing algorithm during early HIV infection

No diagnostic test or algorithm can be completely accurate in all cases of HIV infection and if you get inconsistent or conflicting test results, additional testing of follow-up specimens may be needed, including repeat of a 4th generation HIV antigen/antibody combination test along with an HIV RNA if there is a concern for early infection. For those with a negative HIV test result, a discussion regarding the implications of a negative result is important. Patients should be aware that a negative result does not eliminate the ongoing risk of acquiring HIV infection. Safer sex and needle practices should be encouraged. If a patient tests positive for HIV infection, it is critical to provide support, develop a plan to link to HIV care and encourage ongoing follow-up of HIV infection.

**Linkage to Care**

Linkage to care is a critical first step in providing lifesaving HIV therapy, psychosocial support, and important prevention education for those newly diagnosed with HIV infection. Successful linkage to care is defined as a first visit for HIV care within three months of HIV diagnosis. Ensuring access to quality HIV care is the first issue many providers and their patients face and financial barriers are often perceived as the most challenging. Those with insurance may be able to access care without difficulties and can easily be referred to an HIV specialist. However, even these patients can face obstacles in paying copays for labs, provider visits, and medications. Social programs funded by the Ryan White HIV/AIDS Treatment Extension Act can assist many of these patients so that they receive the ongoing care and support needed.

In Florida today, no patient should expect to go without HIV treatment and medications due to their financial status. Patients without insurance or those lacking adequate funding can receive HIV care and medications as well as many other services through Ryan
Billing for and if both for Florida and the United States, 14% of people aware of their HIV status in 2013, as developed by the Florida Department of Health, HIV/AIDS Surveillance Section (Figure 4), linkage to care in Florida occurs for approximately 86% of those newly diagnosed.16 This is higher than the national average of 79%. However, based on these statistics, 14% of people aware of their HIV status in Florida were not successfully linked to care within three months and thus did not receive timely medical care directed at controlling their HIV infection.

The Florida Continuum of Care further indicates that only 55% of those linked to care remained in care during 2013, of which only 50% remained on antiretroviral therapy and only 35% had a suppressed viral load.16 Improvements in the HIV Continuum of Care both for Florida and the U.S. as a whole are critical for a successful impact on the HIV/AIDS epidemic. This can be supported by testing persons unaware of their HIV status and if diagnosed with HIV, assisting them to fully engage in care.17 (Figure 5)

Billing for Routine HIV Testing

Ensuring that all those living with HIV are aware of their status is a critical issue for both individual and public health reasons. One of the barriers to HIV testing, specifically routine HIV testing, has been its cost. Fortunately, through a combination of a new recommendation in strong support of routine HIV testing and the Affordable Care Act (ACA), there will be greater coverage of HIV testing by various payers of health care. Figure 6 shows recommendations for maintaining sustainability for HIV testing programs. Further information can be found in “A Provider’s Guide to Reimbursement and Sustainability for HIV Testing in Florida Healthcare Facilities”.18

In April 2013, the USPSTF revised its recommendations for routine HIV testing for those
aged 15-65 recommending an “A” grade and reaffirming its previous “A” grade for pregnant women. The USPSTF also gave an “A” grade for those at increased risk for HIV under age 15 and over age 65.9

This grade change acknowledges the benefits of routine HIV testing and the drawbacks to risk-based testing. It is an important step forward in the fight against HIV/AIDS. Now, it is essential that medical providers implement the new USPSTF recommendation and offer routine HIV testing to their patients. It is also important for clinics and health departments that provide HIV testing to bill for these services in order to sustain their testing programs. Reimbursement of HIV testing reduces one barrier to making routine HIV screening a reality.

Private Insurance
Beginning April 2014, private insurance plans were required to cover routine HIV screening outlined in the new USPSTF recommendation. Under the ACA, non-grandfathered private insurance plans are also required to cover a set of “Women’s Preventive Services” defined by the Secretary of the U.S. Department of Health and Human Services (HHS) without cost-sharing. Annual HIV screening and counseling for sexually active women was identified as one of the eight preventive services identified by the Secretary that must be covered.

Medicaid
The State of Florida Medicaid program must cover medically necessary laboratory services under the Social Security Act. This includes medically necessary HIV testing for adults. Currently, Florida Medicaid does not pay for routine HIV testing, which is considered a barrier and will hopefully be addressed in the near future through policy recommendations.

Medicare
In April 2015, Medicare issued a national coverage determination based on the USPSTF’s 2013 recommendations. Medicare now covers once-annual HIV screening for all beneficiaries age 15-65, without co-payment, regardless of risk. However, after undergoing a new coverage determination, Medicare could also cover routine HIV screening for beneficiaries aged 15-65.

Summary
Significant improvements in treatment for people living with HIV/AIDS, has allowed them to live longer and healthier lives. However, many people have not undergone HIV screening or have not successfully linked to care after a positive diagnosis, the critical initial steps in the HIV Care Continuum. More options for HIV testing exist today than ever before. Rapid and home HIV testing is available and provides important options for those who cannot or will not seek testing in traditional healthcare environments, however most of the currently available tests fail to detect infection early after exposure. The newest
blood based 4th generation test is considered optimal because of its ability to detect acute infections.

Recognition of acute HIV infection is important as the HIV viral load is markedly elevated at this time leading to increased risk of further HIV transmission with ongoing unsafe sexual or needle-sharing behaviors. The new CDC recommended laboratory testing protocol includes screening tests that detect acute HIV infection and can differentiate between HIV-1 and HIV-2 infection, which has important monitoring and treatment implications.

HIV testing programs are critical and will require financial reimbursement. Greater insurance coverage for these services is now available.

Healthcare providers continue to have an important role in the control of the HIV epidemic by promoting and discussing options for HIV testing with patients and ensuring successful linkage to care in the event of a positive HIV test. Improvements in all stages of HIV care from diagnosis to suppression of the HIV viral load can help individual patients live longer and healthier and can also reduce the risk of continued HIV transmission in our communities.

References


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Figure 1

United States Continuum of Care

82% 66% 37% 33% 25%

Diagnosed Linked to Care Retained in Care Perscribed ART Virally Suppressed

Percent of All People with HIV

Figure 2 Sequence of Appearance of Laboratory Markers for HIV-1 Infection and HIV Immunoassay Generations

Figure 3 CDC HIV Testing Algorithm

Figure 4

Number and Percentage of HIV-Diagnosed Persons Engaged in Selected Stages of The Continuum of HIV Care — Florida, 2013

(1) Number of cases known to be alive and living in Florida through 2013, regardless where diagnosed, as of 06/30/2014 (used for unmet need calculations).
(2) Ever in Care = 86% of those cases were linked to care, based on persons living with HIV disease in Florida (regardless of where diagnosed) who ever had a CD4 or Viral load (VL) test in the electronic HIV/AIDS Reporting System (eHARS). (2010 National estimates are 79%*).
(3) 55% of cases were in care this year, based on HRSA unmet need definitions, for persons living with HIV in Florida (regardless of where diagnosed) and having at least 1 HIV-related care service involving either a VL or CD4 test or a refill of HIV-related RX. (2010 National estimates for in care are 56%*).
(4) Estimated 90.6% of in care and on ART this year in Florida per 2011 MMP data (2010 National estimates are 80%*).
(5) Estimated 78.0% on ART & the viral load is <200 this year in Florida per 2011 MMP data (2010 National estimates are 70%*).


For additional information please refer to the Florida Continuum of Care slide set accessible at http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/index.html
Figure 5. The Continuum of Engagement in HIV Medical Care

Figure 6

Sustaining an HIV Testing Intervention Program

Coverage of preventive health services, including HIV testing, is required through the Patient Protection and Affordable Care Act (PPACA). Achieving sustainability of an HIV testing intervention may, over time, involve one or more strategies. Recommendations for maintaining sustainability offered in this guide are merely suggestions that may be utilized when evaluating the objectives and needs of the individual healthcare setting.

**Recommendations**
- Seek reimbursement by billing Medicaid, Medicare, or other third-party payers for HIV/AIDS testing services.
- Train staff on billing and coding.
- Make adequate time for staff to address billing and coding issues.
- Assess current billing and reimbursement practices, infrastructure for billing and reimbursement, status of health information technologies, and challenges and technical assistance needs.
- If not already in place, consider using electronic health records (EHR) to maximize health information technology capacity.
- Monitor rate of reimbursement for each payer.
- Update or implement information technology infrastructure (billing software).
- Network and share practices with other agencies.
- Seek technical assistance on third-party billing/reimbursement from other agencies.
- Submit grant applications (to purchase kits).
- Utilize a community-based organization to visit the clinical site to perform HIV testing.
- Identify a “champion” to provide ongoing support and promotion of HIV testing within the health care facility.
- Have an electronic clinical reminder that encourages providers to offer HIV testing.

USF Center for HIV Education and Research, HIV Prevention Program