Research Update

In 1995, approximately 25 million people in the United States tested to see if they were infected with HIV, and publicly funded test sites conducted about 2.5 million of these tests. One-quarter of people testing negative and one-third of people testing positive in the United States did not return for test results.1 Of 276,000 HIV tests conducted at publicly-funded sites in California in 1996, 18 percent of clients did not return for their results. Return rates were similar regardless of results.2

A primary goal of HIV testing is to provide clients with their results and counsel them appropriately. New technologies attempt to increase the rate at which people test as well as the rate at which they receive results. The following sections provide an overview of existing tests and those that may become widely used in the future.

Blood Tests

The most common HIV test is the enzyme-linked immunosorbent assay (ELISA or EIA) blood test. An ELISA blood test determines if a person is infected by detecting the presence of HIV antibodies. Many of these tests require drawing a client’s blood, but new procedures allow for screening oral and urine samples. This issue of PERSPECTIVES describes various testing technologies and examines their implications for HIV test counselors.

The ELISA test’s “sensitivity,” or the probability that an infected person will test positive once antibodies develop, is greater than 99 percent, and its “specificity,” or the probability that an uninfected person will test negative, is also greater than 99 percent. There is a small chance that false-positive test results may occur in people who have recently received a vaccination against influenza or hepatitis B, pregnant women, people who have had multiple blood transfusions, and people with other immune disorders.5 Decreases in antibody production in late stages...
of HIV progression can also result in false-negative test results. Recent improvements in the ELISA have significantly reduced the number of false-positive results.

After a phlebotomist draws a client’s blood, this sample is generally sent to a laboratory for screening, and the client must return for a follow-up disclosure session to receive the test results. In recent years, many test sites have shortened the time between testing and the disclosure of results, most often from two weeks to one. Although the faster turnaround time has not greatly affected counseling techniques, anecdotal reports link it to increased client satisfaction. Turnaround times are typically the same regardless of whether test results are positive or negative.

**The OraSure Test**

In 1997, some counseling and testing sites in California began using the OraSure test, a type of ELISA that screens oral samples rather than blood. The OraSure test uses a pad placed between the client’s cheek and gum to collect a sample of oral mucosal transudate (OMT) from the tissues of the cheek and gum. OMT contains a high concentration of HIV antibodies in infected people and is usually free of bacteria and other contaminants present in saliva. The pad is then placed in a preservative solution and sent to a laboratory for an ELISA.

The OraSure test has several advantages over a blood test. Anecdotal reports suggest that clients tend to prefer it to blood tests. According to client questionnaires from the Los Angeles Gay and Lesbian Center’s Alternative Test Sites, a majority of people testing for the first time cited fear of needles as one of the reasons for not testing in the past. Counselors can administer OraSure tests during risk assessment sessions, and, although OraSure test kits are more expensive than blood tests, counseling and testing sites can reduce overall costs because phlebotomists and supplies—such as syringes, bandages, and alcohol swabs—are not necessary to collect the sample.

The OraSure test is also more convenient than blood tests for mobile testing sites, such as street fairs, and other non-clinical environments, particularly those involving community health outreach workers (CHOWs). It also eliminates the risk of needle-stick injuries and exposure to blood-borne illnesses to health care workers. In addition, OraSure is more effective than a blood test for injection drug users whose veins may be difficult to locate. For some former injection drug users, blood tests may also “trigger” old behaviors because of

**Related Issue: Home HIV Testing**

Home HIV testing enables people to test outside of clinical environments by collecting a blood sample themselves and sending it to a laboratory for processing. In 1996, the Food and Drug Administration (FDA) granted its first approval of an HIV home-collection testing service to Johnson and Johnson’s Confide HIV Testing Service. Confide is no longer on the market, and the Home Access Health Corporation’s Express Test is currently the only such service with FDA approval.

Home HIV tests can be appealing for various reasons: people may fear that their results will not be confidential at a counseling and testing site; people may not want a health-care provider they have met face-to-face to know their results; people may find home testing more convenient than visiting a test site; and home tests may be the only way to test privately for people in rural areas, where anonymity at a test site may not be possible.

The Express Test includes equipment that allows a person to draw a few drops of blood from a finger and send the sample to a laboratory with a unique numerical code. After three business days, the test results are available by calling the company’s toll-free telephone number and providing the identification code. A trained counselor then discloses the results. As with other ELISA tests, Home Access uses the Western Blot or IFA tests to confirm positive and inconclusive results.

Despite some of the advantages of home testing, it remains controversial. Experts have expressed skepticism regarding the value of telephone counseling, especially for high-risk clients who test negative. Advocacy groups for people with HIV, counseling and testing programs, and several medical groups were initially opposed to the FDA’s approval of home test kits. However, some of these groups now support home testing because it increases the number of people learning their HIV test results. As of June 1997, 152,044 people have used Home Access, 148,039 of whom called to obtain results, and 0.9 percent of these people tested positive.
Related Issue: Viral Load Testing

Viral load refers to the concentration of HIV in the blood, usually expressed in copies of the virus per milliliter of blood. Viral load tests, such as the polymerase chain reaction (PCR) and branched chain DNA assays, can help monitor disease progression and help determine the effectiveness of an antiviral drug regimen. A PCR test can also detect an HIV infection in the absence of antibodies.22

Viral load measurements are better predictors of HIV progression than CD4+ cell counts. CD4+ cells are immune system cells that are destroyed by HIV, and CD4+ cell counts can also be used to monitor HIV progression. CD4+ cell counts typically vary considerably over the course of a few months, but viral load levels are usually fairly constant for asymptomatic patients if drug regimens are consistent. Viral load tests, however, do not measure an HIV infection’s effect on the immune system and are of limited value in clinical management unless they are supplemented by other tests. Viral load tests cost between $100 and $200.22

Viral loads below the level at which tests can detect them have been called “undetectable.” New technologies are increasing the sensitivity of viral load testing. In 1995, the most sensitive viral load tests could measure only a minimum of 500 copies per milliliter. Commercially available tests are currently sensitive to 400 copies per milliliter. Some tests in research settings, meanwhile, are sensitive to 20 copies per milliliter. As more sensitive viral load tests become available, people with older results below the level of detection may find that they suddenly have detectable viral loads. This would not necessarily mean that viral load has increased; it merely means that more advanced technology is better able to detect lower concentrations of virus.23
the FDA allows rapid tests to be used as confirmatory tests for each other, it will be possible for clients who test positive in the United States to receive conclusive results in one visit. California law, however, does not currently allow ELISA to be the only confirmatory test for positive results.

Other Tests

Most confirmatory tests determine infection by detecting specific segments of the virus called “viral antigens.” The Western Blot and the Immunofluorescence Assay (IFA) are common antigen tests. Many laboratories use these procedures to confirm positive ELISA results. Antigen tests are sensitive soon after a person becomes infected, and using them as initial tests can shorten the window period. Testing agencies, however, generally believe that the high cost of these tests outweighs this benefit.

In June 1998, the FDA approved Calpyte Biomedical Corporation’s urine-based Western Blot test. Although an ELISA urine test had already been available, this was the first urine-based confirmatory test to gain FDA approval.

Like the OraSure test, urine tests are safer for health care workers than blood tests and are less expensive because they do not require a phlebotomist. In one study, more than 80 percent of participants said they would prefer a urine test to a blood test. According to Calpyte, clinical trials indicate that the sensitivity and specificity of this test are comparable to those of blood-based Western Blot tests, but with fewer indeterminate results. The ELISA urine test, however, has a slightly lower sensitivity and specificity than ELISA blood tests, especially in later stages of HIV progression.

Urine tests can be especially useful at sexually transmitted disease (STD) clinics because a laboratory can use a single urine sample to test for HIV antibodies as well as other STDs. This can eliminate the need for a separate HIV test.

A newly-available procedure called a “genotype” test can measure whether or not a person is infected with a strain of HIV that is resistant to a particular antiviral drug. This can be valuable information for determining treatment interventions.

Low-Sensitivity ELISA

An experimental procedure called the “low-sensitivity ELISA” test can determine if a client who tests positive for HIV became infected within the previous six months. The low-sensitivity ELISA, also known as the “detuned ELISA,” does not detect HIV antibodies within six months of infection; therefore, if this test detects antibodies in a client who received a positive test result, the infection occurred more than six months prior to the procedure.

Some researchers believe that newly infected people are more infectious than those who have an established infection, and the low-sensitivity ELISA can help identify these individuals for appropriate intervention to help prevent them from transmitting the virus. This test may also be important to treatment decisions that depend upon how long a person has been infected.

The FDA has not yet approved the low-sensitivity ELISA, which is currently being studied at some counseling and testing sites to determine its effectiveness. If approved, the low-sensitivity ELISA test may be able to determine more precisely when a person became infected.

The OraSure test is more convenient than blood tests for mobile testing sites and other non-clinical environments, and it eliminates the risk of needle-stick injuries and blood-borne illnesses to health care workers.
Implications for Counseling

Advances in HIV testing technology and testing methods have resulted in increased flexibility and new responsibilities for test counselors. Counseling can now occur in mobile settings beyond the walls of traditional clinic sites, and counselors can administer oral-based tests in addition to those that require the drawing of blood.

Advances have also introduced new options for clients. Those who fear needles, for instance, can now use an oral test, and those who do not want to test at a public site can buy a home-collection testing kit.

These changes have not affected the counselor’s basic role or the nature of prevention messages for clients, but they have raised new issues, and future advances may bring more significant changes.

Testing technologies and procedures—whether they involve drawing blood or taking tissue samples—can appear complicated or mysterious to clients, and advances or changes in these methods can cause further confusion. The following sections examine issues related to HIV testing technologies and procedures that may arise during counseling sessions.

Oral Testing

HIV counseling and testing programs in California continue to use standard blood-based ELISAs, but many also use the oral-based OraSure test. The state of California provides equipment to counseling and testing programs to perform a limited number of OraSure tests.

At sites that offer both the standard ELISA and the OraSure test, counselors can assess for themselves if an OraSure test might be more appropriate for a client. When this is the case, counselors can let clients know that there is an alternative to the traditional blood test. They can then explain the OraSure test and address questions or concerns clients might have about it. An injection drug user whose veins are difficult to locate, for example, would be a good candidate for an OraSure test.

Because the OraSure test involves an oral sample, some clients may question the idea of being able to detect HIV in saliva as being contrary to established prevention messages that HIV levels in saliva are too low to be infectious. Clarify that OraSure does not rely on saliva but on a sample drawn from the tissues of the cheek and gum called oral mucosal transudate (OMT). Explain that the presence of HIV antibodies in oral mucosa has long been known and that oral fluids, like saliva, can contain HIV, but the amount of the virus at any one time is not enough to be transmittable. Anecdotal reports suggest that clients understand this message when counselors explain it simply and clearly.

Some clients have questioned the accuracy of the OraSure test because traditional methods of detecting infections typically involve taking significant amounts of blood, and OraSure requires a much smaller specimen. Explain that extensive research has proven the reliability and accuracy of the OraSure test in comparison with blood-based ELISAs.

The Relevance of Home Testing

Another option for people seeking HIV testing is the home-collection method, or home testing. Anecdotal reports suggest that some people who use a home-collection method subsequently visit a publicly funded test site to confirm their results, perhaps because they are less apprehensive about the test after receiving a result or because they have questions about the accuracy of home testing.

For clients who have used a home-collection method, ask which test it was. The Home Access Express Test and Johnson and Johnson’s Confide test are the only two home HIV tests to receive approval from the Food and Drug Administration (FDA), and the Confide test is no longer available. If a client has used a different home HIV test, explain that it was not approved for use in the United States and may not be accurate.

Explore the client’s reasons for now choosing to visit a test site. If the client has tested in the past only by a home-collection method, he or she may have received little counseling and may not be aware that testing at publicly funded programs involves thorough risk assessment and disclosure sessions. Explain these procedures and their roles.

Clients who have used the Home Access test may express uncertainty about its accuracy. Clarify that the Home Access test is accurate, and learn more about this uncertainty and the extent to which it might relate to other factors. For instance, did clients test negative but believe they were infected? If this is the case, explore this issue and ask if they are aware of the window period of infection. Explain this concept if it is relevant, and use this opportunity to discuss concerns about past risk behaviors that clients think may have led to HIV infection.

A Counselor’s Perspective

“Some of my clients question how the OraSure test can work if HIV cannot be transmitted through saliva. A simple explanation usually helps them understand.”
For clients who inquire about alternatives to publicly-funded counseling and testing sites, present the home-collection method as an option, along with the use of their own health care providers. While supporting clients in their decisions about the manner in which they test, learn their reasons for seeking alternatives. Explore these, as appropriate, and clarify any misinformation clients may have. Some clients may, for instance, incorrectly believe that the Home Access test offers an immediate result or that this method is more accurate than the test offered at publicly-funded sites.

Inform clients that the Home Access test offers only telephone counseling, that a risk assessment session prior to the test is not available, and that the training of telephone counselors who provide results is different from the training of HIV test counselors in California. Home testing can also be a more expensive alternative to testing at a publicly-funded site.

Faster Results

Advances in laboratory procedures and technology have enabled many counseling and testing sites in California to reduce the time between the risk assessment and disclosure sessions from two weeks to one. The development of rapid test technologies could potentially lead to a change from the current two-visit counseling protocol to one in which the risk assessment, HIV test, and disclosure all occur in a single visit. The only rapid test the FDA has approved—the Murex Single-Use Diagnostic System (SUDS)—is limited in its usefulness because results may take up to several hours, it may not be as accurate as current tests, and it cannot be used as a confirmatory test.

Because rapid tests that can be used as confirmatory tests are being developed, it may be useful for counselors to have a general understanding of issues that may arise if rapid tests become widely used. Providing an immediate result can be valuable for someone who is unlikely to return to a test-site for a follow-up visit. It can also eliminate the anxiety many people experience while waiting for the return visit. However, the two-visit protocol and the period between taking a test and getting a result can provide clients with an opportunity to change behaviors, initiate

References


8. OraSure HIV-1 Western Blot Kit cleared for professional marketing by FDA. Epitope, Inc. and SmithKline Beecham Consumer Healthcare. 1996.


Contact with a referral, reflect on the process of testing, and then discuss changes and thoughts during the disclosure session.

Non-Antibody HIV Tests
When clients state that they have recently engaged in high-risk behaviors, counselors can refer them to primary-care providers or research studies to learn more about tests that detect HIV infection.

A polymerase chain reaction (PCR) test can detect the presence of HIV infection in the absence of antibodies. In some parts of the state, including Los Angeles, San Diego, and San Francisco, research studies provide PCR and viral load testing as well as a regimen of antiviral drugs for people in the initial weeks and months after infection. This program is commonly called post-exposure prevention (PEP) and is based on the idea that treatment in the primary stage of infection could protect against irreversible immune system damage and infection while possibly providing other benefits. The effectiveness of post-exposure treatment is currently being studied and has not been proven. Be knowledgeable about such research studies and make referrals to them, particularly if they exist in the area.

For clients who test positive, explain that viral load testing has become a standard procedure for people seeking medical care following a positive result. Testing for Recent Infection
An experimental technology called the low-sensitivity ELISA, can help clients who received a positive test result determine whether or not an HIV infection occurred within the previous six months. An unreactive result with the low-sensitivity ELISA means the infection is less than six months old.

A client who knows that he or she was infected within the previous six months may be better able to work with a counselor and discuss the process of notifying and referring sex and needle-sharing partners he or she has had during this time.

The low-sensitivity ELISA may affect a person’s willingness and ability to share the information with relevant partners. Identifying partners who may be infected but not aware of it has always been important, and this can take on increased personal significance if the person is a recent partner. This test has unique emotional implications, particularly with people who have had multiple risk exposures. By narrowing the field of possibility regarding the time of HIV infection, a client may then have a focus for the multitude of feelings about his or her own infection. The prospect of knowing the probable source of an HIV infection may also raise feelings the client had not anticipated. It is important to explore these feelings and, if appropriate, provide referrals for follow-up support services.

Case Study
Sue is a 28-year-old heterosexual woman. She is a recovering heroin addict who injected and shared drug-using equipment for many years. She has not used drugs in the past year and recently decided that she wants to know her HIV status. Friends have assured her that the testing process is relatively easy and involves giving only a small amount of blood. During the counseling session, however, she seems somewhat nervous and says she has not “so much as looked at a rig” all these months and does not like the idea of having a needle enter her arm.

Counseling Intervention
Acknowledge Sue’s apparent discomfort with the idea of being tested with a needle, and let her know she is not alone in her feelings. Tell her she can choose to be tested without the use of a needle.

Explain the procedure for the OraSure test. If she questions how this test can work given that she has consistently heard that “there’s no HIV in saliva,” clarify the facts of this test and give her assurances that the message about infection from saliva remains the same as before. Explore further the significance of her resistance to needles, and use this as a transition into a discussion about her history of drug use and the possibility of being infected.

While validating any concerns Sue may have about the use of needles, do not get sidetracked from other concerns. Sue may have fears about knowing her HIV status, which may be leading her to focus her attention on the issue of the test procedure rather than on the significance of the result.

Explore with her how she will react to the possibility of both a positive and negative test results and what she would do in these situations. Ask her directly how knowing her HIV status will affect her recovery, or ask her to visualize each outcome and describe what her responses, feelings, and behavior might be. From this point, proceed with the remainder of the session.

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Test Yourself

Review Questions

1. Which of the following is the most common type of HIV test? a) ELISA; b) SUDS; c) IFA; d) Western Blot.

2. True or False: The OraSure test draws a sample from saliva to screen for HIV antibodies.

3. Which of the following is currently not used to confirm preliminary test results? a) ELISA; b) SUDS; c) IFA; d) Western Blot.

4. In 1996, what percentage of people testing for HIV at publicly-funded sites in California did not return for their results? a) 4 percent; b) 18 percent; c) 60 percent; d) 75 percent.

5. True or False: In California, an unreactive, or negative, ELISA result requires a confirmatory test.

6. True or False: It takes an average of 25 days from when a person is initially infected with HIV before he or she develops antibodies to the virus.

7. The OraSure test provides which of the following advantages over blood tests? a) it eliminates the risk of needle-stick injuries to health care workers; b) it is more convenient for mobile testing sites and other non-clinical environments, especially if they involve community health outreach workers (CHOWs); c) it is more effective for injection drug users whose veins may have collapsed; d) all of the above.

8. True or False: There is currently only one HIV home-collection testing product on the market.

Discussion Questions

1. How does the use of the oral-based OraSure test affect counselors’ work in mobile settings?

2. When using the OraSure test, counselors are in a position not only to provide counseling but also to administer the test. Does this raise any challenges about the counselor’s role? If so, what are these challenges, and how can counselors address them?

3. Many counseling and testing sites have reduced the time between the risk assessment and disclosure sessions from two weeks to one week. Does this have an impact on the work of test counselors and how clients use the period between sessions? If so, what is this impact and how can counselors respond to it?

4. What knowledge should counselors have about testing technologies and procedures? How can counselors stay abreast of advances in testing technology and related resources and referrals?

5. In settings that use the OraSure test, how can counselors respond to clients who express concern about the accuracy of this test?

Answers to Test Yourself

1.  a.

2.  False. The OraSure test draws a sample from the tissues of the cheek and gum called oral mucosal transudate (OMT), which contains a high concentration of HIV antibodies in infected people and is usually free of bacteria and other contaminants present in saliva.

3.  b.  

4.  b.

5.  False. Only reactive, or positive, test results need to undergo confirmatory tests in California.

6.  True.

7.  d.

8.  True.
DID YOU KNOW?

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