

Frequently Asked Questions

Implementing HIV Testing in Nonclinical Settings: A Guide for HIV Testing Providers

- 1. I'm not sure if my agency is a clinical setting or a nonclinical setting. Based on the definition in this Implementation Guide, how do I decide which strategy my agency should follow?**

The distinction between clinical and nonclinical HIV testing settings is sometimes blurred because many agencies are beginning to offer clinical services within nonclinical settings. If your agency is located within the community—either at a fixed venue or mobile/outreach site, conducts recruitment services to get high-risk populations in for targeted HIV testing, and is accessed specifically for HIV testing by persons who might not access other medical services regularly—you may be considered a nonclinical testing setting.

- 2. Which targeting and recruitment strategy will be most effective for helping my agency meet our objective of testing previously undiagnosed HIV-positive persons?**

It is not easy to say what strategy is most effective for recruiting previously undiagnosed HIV-positive persons. Agencies should be familiar with the high-risk populations in their area (i.e., their focus population), and then design a strategy that takes into consideration: 1) who is their focus population; 2) where is the best place to locate them; 3) when is the best time to reach them; 4) what messages should be delivered; 5) how these messages should be delivered; and 6) who should deliver these messages. Studies have shown that social networking strategy can be very effective for recruiting high-risk persons for HIV testing, but it must be done well in order to be successful. There is increasing evidence about the use of social media, including social networking apps, for recruiting high-risk HIV testing clients. Sometimes the most effective way is through internal referrals from other services offered at an agency, such as needle exchange or substance abuse treatment services. Social marketing (i.e., posters, billboards, advertisements on public transportation) can be helpful for creating general awareness, but may need to be tailored in order to reach the highest-risk clients. It may be helpful to use a combination of multiple recruitment strategies at the same time. Agencies should look at their HIV testing data on a regular basis and make changes to their recruitment strategy if they are not meeting their objective of testing previously undiagnosed HIV-positive persons.

- 3. How often should people get tested for HIV, especially key populations such as men who have sex with men (MSM) and people who inject drugs (PWID)?**

CDC recommends that clinicians and providers test everyone between the ages of 13 and 64 at least once as part of routine healthcare, and test persons who engage in behaviors that put them at high risk for HIV infection—such as sexually active MSM, PWID and their sex partners, or persons who exchange sex for money or drugs—at least once a year. Additionally, for sexually active MSM, providers should consider the benefits of more frequent screening (e.g., 3-6 months).

4. Why is the laboratory-based HIV testing algorithm recommended for nonclinical settings? Isn't it easier for nonclinical settings to just do onsite rapid HIV testing?

The CDC-recommended laboratory-based HIV testing algorithm can identify HIV infections earlier than point-of-care rapid tests that use whole blood specimens, which are often used in nonclinical settings. If a nonclinical testing site has the option of performing laboratory-based testing following this algorithm—including the capacity for venipuncture sample collection—then they may choose this algorithm because it allows them to detect HIV as early as possible after a client's exposure. It may be particularly important for clients with a considerable risk of acute HIV infection. However, rapid HIV antibody tests can be attractive for use in settings that may not be equipped to conduct venipuncture, and clients can get the results from their screening test quickly. Agencies should also consider other factors, such as feasibility of implementation, likelihood of being able to follow-up with the client, and cost.

5. With all the advances in new HIV testing technologies in recent years, why does CDC still recommend a window period of 3 months?

The window period refers to the time from when a client is exposed to HIV to when an HIV test can detect infection. The initial portion of the window period (the eclipse period) may last from a few days to several weeks. During this time the virus replicates near the site of infection but is not yet detectable in the blood by any HIV test, which makes it hard to know how long this period is. Additionally, current estimates for the window period time frame are based on plasma specimens, and plasma is not used for HIV testing in nonclinical settings. These estimates are currently under review. Estimates of the window period for tests conducted with blood or oral fluid do not currently exist, but a study is under way to quantify the delay in detection in blood and oral fluid rapid tests, compared to tests conducted on plasma. When data from these studies become available, window period estimates will be updated accordingly.

6. The Implementation Guide states that the evidence is inconclusive about the ability of combination antigen/antibody rapid tests (4th generation rapid tests) to accurately detect the p24 antigen in whole blood specimens. CDC has not provided recommendations about the use of these tests, but some agencies have started to use them. Why has CDC not provided recommendations about the use of these tests?

CDC has not provided definitive guidance on the use of combination antigen/antibody rapid tests because we are still gathering data on their performance. For HIV testing done on plasma specimens in laboratory settings, it appears as though the combination antigen/antibody rapid tests do not perform as well as other tests currently recommended in CDC's laboratory testing guidelines, but do perform better than tests that detect antibody alone, which are no longer recommended for use in laboratory settings (<http://www.cdc.gov/hiv/testing/laboratorytests.html>). However, for HIV testing done on whole blood specimens in nonclinical settings, combination antigen/antibody rapid tests may perform as well or better than other rapid tests. The results of these assessments will be presented as they are finalized, and guidelines and recommendations will be updated, as appropriate.

7. Oral fluid antibody tests have been shown to detect infection a month or more later than blood-based tests because there is a lower concentration of HIV antibodies in oral fluid than in blood. Should my agency stop performing oral fluid testing?

Using a laboratory test, oral fluid was shown to detect infection a month later than blood. CDC is conducting a study to quantify the delay in detection in oral fluid rapid tests relative to blood tests. Oral fluid tests

adequately detect established infections, but should not be used if early infection is a possibility. If they are used when early infection is possible and the result is negative, a retest should be conducted using a more sensitive test. In addition, there is evidence that oral fluid tests do not sufficiently detect infection when persons are taking pre-exposure prophylaxis. While oral fluid is not ideal for identifying early HIV infection, including infections occurring while taking pre-exposure prophylaxis, it may be appealing in outreach or mobile settings because collecting oral fluid does not involve a fingerstick or venipuncture to perform the test. If there are options, agencies should choose an algorithm that allows them to detect HIV as early as possible after exposure. Agencies should also consider other factors, such as feasibility of implementation, likelihood of being able to follow-up with the client, and cost.

8. How should HIV testing providers report a preliminary HIV-positive test result if they are not doing onsite confirmation?

In most cases a nonclinical HIV testing site will not report a preliminary HIV-positive test result to the health department without a supplemental or confirmatory result. The supplemental or confirmatory test may be done onsite. If supplemental or confirmatory test is not done onsite but instead either the client or their specimen is sent to another healthcare provider or laboratory for supplemental testing, then the result of the preliminary test should also be sent to that healthcare provider or laboratory (where sharing the result with a party other than the health department is not restricted by law). This is so that whoever runs the supplemental test can report both results to the health department, so that both results can be linked to the patient more easily. If the supplemental or confirmatory test is not done onsite and healthcare provider or laboratory reports the result of the supplemental test back to the original testing site that did the preliminary test, then that site should report both results to the health department if they have not already been reported. In the rare case that a supplemental test is not performed, or the original testing site does not receive results of the supplemental test, it may still be worthwhile to report the preliminary result to the health department in the event that they have the ability to track down the patient or link the result of the supplemental test to the patient.

9. Should agencies integrate HIV testing with STI testing and other tests such as Hepatitis C virus (HCV)?

Many nonclinical HIV testing sites are starting to offer other services in addition to only HIV testing. Due to high rates of co-infection it may be important to offer diagnostic services for other sexually transmitted infections (STIs) and HCV. Where funding and resources allow, HIV testing sites are encouraged to integrate other diagnostic services such as STI and HCV testing.

10. What is the role of nonclinical HIV testing sites in supporting home-based HIV testing? How can agencies support clients who use home HIV tests and/or offer home-based HIV testing kits?

Some HIV testing providers in nonclinical settings have supported home-based HIV testing by strengthening relationships with shops and pharmacies where these test kits are sold, so that shopkeepers and pharmacists can refer clients to them with questions or for follow-up. Some agencies have developed palm cards or other informational inserts with their contact information that can be distributed with the test kits (if the store agrees). Some agencies—through an agreement with the test kit companies—have also distributed the kits for clients and their partners to use at home on their own. The agency then serves as a resource for follow-up and referrals once the client(s) know their HIV status. These are just a few examples of how nonclinical HIV testing providers are currently supporting home-based testing, and more opportunities are being explored.

11. CDC recommends that HIV testing sessions in nonclinical settings be brief, information-based, and tailored to clients' needs. Why is extensive pretest and posttest prevention counseling no longer part of the HIV testing event?

Based on emerging evidence suggesting the limited benefit of HIV prevention counseling, best practices in the field for making HIV testing as easy and accessible as possible, and the reality that many people accessing HIV testing have already been tested and received HIV prevention counseling before, the HIV testing protocol recommended in this Implementation Guide no longer includes extensive pre- and posttest counseling. Clients who need HIV prevention counseling may still receive it through one of CDC's evidence based interventions (EBIs) or as a separate service. HIV testing providers should still have strong communication skills and be prepared to help clients address the various issues that may arise during an HIV testing session, but in general the emphasis is on making HIV testing service delivery as smooth and seamless as possible and empowering clients to access appropriate follow-up services based on their HIV test results and their specific needs.

12. Since extensive pretest and posttest prevention counseling is removed from the HIV testing event, how can HIV testing providers make sure that clients are still getting the services they need, such as mental health services, substance abuse treatment, housing, etc.?

Despite the separation of HIV prevention counseling from the HIV testing event, HIV testing services should still be client-centered, and HIV testing providers should have strong communication skills that prepare them to help clients address the various issues that may arise during an HIV testing session. Different clients will have different needs, and every effort should still be made to link clients with services that address their HIV-related health and wellness needs. Testing providers are encouraged to establish strong relationships with agencies that provide medical care, social and behavioral services in order to provide referrals to meet client's needs.

13. How much flexibility do agencies, including Health Departments, have in adapting this guidance to develop their own HIV testing protocols for nonclinical settings that are even more streamlined?

Some HIV testing agencies have already been moving toward a more streamlined approach to HIV testing with less emphasis on counseling. HIV testing agencies and health departments are encouraged to follow the general structure presented for an HIV testing session in this Implementation Guide, and to continue identifying ways of making HIV testing service delivery as smooth and seamless as possible. Protocols can be streamlined even more than what is presented in the Implementation Guide, but should allow for some flexibility with clients who need a bit more attention in order to access appropriate follow-up services based on their HIV test results and their situations.

14. Why isn't there more emphasis on pre-exposure prophylaxis (PrEP) and nonoccupational postexposure prophylaxis (nPEP) and screening HIV-negative clients for PrEP as part of the HIV testing session?

PrEP guidelines and additional resources can be accessed at <http://www.cdc.gov/hiv/risk/prep/index.html> and nPEP guidelines can be accessed at <http://www.cdc.gov/hiv/risk/pep/index.html>. Clients receiving an HIV-negative test result should receive information about the availability and benefits of PrEP and should be referred to a PrEP or nPEP counselor or medical provider if they are at substantial risk for acquiring HIV, as

outlined in step 5 of the HIV testing protocol for individuals, “Develop a Care, Treatment, and Prevention Plan Based on Results.”

15. CDC recommends couples or partner HIV testing, but doesn’t this violate HIPAA regulations?

Couples or partner HIV testing does not violate HIPAA regulations. As long as both partners give their informed consent, then they may be tested together and receive their results together.

16. My agency’s leadership is afraid that couples or partner HIV testing will lead to violence in the relationship, especially if the couple’s test results are different. What information exists about the possibility of violence following couples or partner testing?

There is no evidence that couples or partner testing leads to increased violence in a relationship. However, intimate partner violence is a concern for both individuals and couples who test for HIV, and HIV testing providers should know what resources exist in their communities to help address clients facing intimate partner violence, and should build relationships with these services. This is discussed in more detail in the training for couples HIV testing and counseling, or Testing Together. Information about training for Testing Together is available at <http://effectiveinterventions.cdc.gov>.

17. Why has the recently updated National HIV/AIDS Strategy changed the time for linking people living with HIV to care and treatment from 90 days to 30 days?

Earlier access to HIV care and treatment can help HIV-positive clients stay healthy and prevent transmission to HIV-negative partners.