NASTAD

National Alliance of State and Territorial AIDS Directors

Implementing Rapid HIV Testing: A Primer for State Health Departments

The Food and Drug Administration (FDA) approval of OraQuick provides health departments with a new tool to enhance the effectiveness of HIV prevention programs. OraQuick represents the first of the so-called "second generation" rapid HIV tests to be approved by the FDA. The performance of OraQuick is superior to the only other rapid HIV test, the Single Use Diagnostic System (SUDS), developed by Abbott Laboratories, licensed for use in the US. With a waiver under the Clinical Laboratory Improvement Amendments (CLIA), OraQuick can now be performed relatively easily in a wide variety of non-clinical and outreach settings.[1] Adoption of rapid HIV testing, however, presents health departments with a number of challenges ranging from policy or laws which may restrict or prevent use of rapid HIV testing to the practical implications of modifying prevention counseling strategies to respond to new testing technologies.

The National Alliance of State and Territorial AIDS Directors (NASTAD) has developed this primer to assist health departments in adopting rapid HIV testing technologies and specifically focuses on use of a waived test. This primer describes the potential benefits of rapid HIV testing; suggests key steps in planning for implementation and highlights key issues and challenges that health departments may face in adopting rapid HIV testing. The development of this document was informed by input from the Centers for Disease Control and Prevention (CDC) and health departments and local agencies planning to or currently conducting rapid HIV testing. Because OraQuick is the first "second generation" rapid HIV test to be approved for use in the US, this primer specifically references this test. However, it is expected that the information in this primer will continue to be relevant as additional rapid HIV tests are approved for use the US. [2]

The Revised Guidelines for HIV Counseling, Testing, and Referral

[1] The Clinical Laboratory Improvement Amendments (CLIA), passed in 1988, regulates medical testing in the U.S. The Centers for Medicare and Medicaid Services (CMS) is charged with interpreting CLIA and works closely with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) on its implementation. For more information on CLIA, see http://www.cms.gov/clia/.

[2] While OraQuick met the requirements for a waiver under CLIA, future HIV rapid tests may not and could be classified as moderate or high complexity. See http://www.cms.gov/clia/ for more information.

In November 2001, CDC released the *Revised Guidelines for HIV Counseling, Testing and Referral*. The *Revised Guidelines* set a higher standard for the provision of counseling, testing and referral (CTR) services than have past guidelines, and contain a conceptual change in how CTR services are provided. For the first time, counseling, testing, and referral are viewed as distinct activities that may not always occur together. In addition, the *Revised Guidelines* provide guidance on "routinizing" testing in a setting, targeting high-risk individuals, providing referrals, developing quality assurance, and providing services in non-traditional settings. Sections also specifically address HIV rapid tests. Implementation of HIV rapid tests should always be considered in the larger context of the guidance provided in the *Revised Guidelines*, and this primer will refer to the *Revised Guidelines* at times for more specific information. CDC's *Revised Guidelines on HIV Counseling, Testing and Referral* can be viewed at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm.

Why adopt rapid HIV testing? Rapid HIV testing can assist health departments in enhancing counseling, testing and referral (CTR).

- OraQuick requires only a finger prick to obtain a specimen. This may make HIV testing more acceptable to clients who are afraid of venipuncture techniques or who are venous compromised.[3] It also allows OraQuick to be used more easily in non-clinical settings where individuals may not be trained in phlebotomy and where infrastructure does not allow for handling and storage of blood specimens.
- OraQuick is a relatively simple test system that utilizes whole blood, thus mitigating the need for preparation of the sample through use of specialized equipment. OraQuick can be used by a variety of agencies, including non-traditional providers of CTR services such as community-based and non-governmental organizations. It can also be used in conjunction with outreach and field services (e.g. mobile van outreach).
- The convenience of obtaining results within minutes or on the same day of the test may encourage some individuals to get tested for HIV, some of whom may have never before been tested.
- Rapid testing will ensure that more clients who are tested for HIV learn their test results. HIV-positive clients and higher risk negative clients can be provided with prevention counseling and referred to other prevention, care, and support services. HIV-positive clients can be provided with assistance to ensure timely access to medical services to treat their HIV infection.
- Rapid HIV testing can improve the cost-effectiveness of CTR by:

[3] For example, injecting drug users may have trauma at the site which they use for injection or their veins may have collapsed, making it difficult to collect a blood specimen.

- Increasing the number of clients at increased risk who are tested.
- Increasing the number of clients who learn their test results.
- Decreasing the need for follow-up activities for clients who do not return for their HIV test results and associated prevention counseling.

Is rapid HIV testing right for your jurisdiction? In most cases, health departments are likely to consider rapid HIV testing "right" for particular settings within a jurisdiction rather than for a jurisdiction as a whole. In general, if there are settings or agencies within your state where rates of return for test results are sub-optimal, rapid HIV testing may be a useful tool to improve these rates. Similarly, if there are communities at increased risk for HIV who are not currently availing themselves of HIV CTR services, rapid HIV testing may be one mechanism for encouraging use of these services. CDC's *Revised Guidelines for HIV Counseling, Testing, and Referral* provides technical guidance on the uses of testing technologies, including HIV rapid tests, and should be used to help determine the benefits of a particular technology within your jurisdiction.

How do we get started? Health departments that have already begun planning for implementation of rapid HIV testing report that this process is more complicated that might be expected. The experience of these health departments suggests key steps in planning for implementation of rapid HIV testing:

Identify Objectives for Implementation. To help guide decisions about how and where to make best use of rapid HIV testing, it is important that you clearly define objectives for implementation. For example, is your primary interest in adopting rapid HIV testing to increase the number/proportion of clients who receive their HIV test results? Is it to increase the number/proportion of individuals at increased risk who accept HIV CTR? Do you wish to enhance a specific program such as determining whether someone qualifies for post-exposure prophylaxis (PEP) or offering immediate results to high-risk individuals through partner counseling and referral services (PCRS)? Is it some combination of these? Are there other objectives?

In addition to identifying objectives, it is important to develop methods by which achievement of these objectives will be measured. This information can be helpful in guiding refinement or expansion of HIV CTR using rapid testing. Such information can also aid in obtaining support from policy makers, funders and communities to continue or expand rapid HIV testing efforts.

Identify and Engage Stakeholders. It is essential to identify and engage stakeholders in the process of planning. In this way you can ensure that all stakeholders are in agreement about the objectives associated with adoption of rapid HIV testing; the methods by which achievement of objectives will be

measured; that all concerns, barriers and facilitators associated with implementation are identified and addressed; and that all are aware and have agreed upon roles and responsibilities for implementation.

Obvious stakeholders include: state and city/county health department HIV/AIDS programs, state/city health department laboratories (or other laboratories used by health departments), local providers of HIV CTR services, medical providers serving HIV-infected individuals, other relevant health and human service providers and community planning groups. State health departments with experience in planning for or providing rapid HIV testing indicate that it is important to recognize that within each of the stakeholder "groups" identified above, there are likely to be issues, interests and biases which will impact on implementation of rapid HIV testing.

For example, health department HIV/AIDS program staff with responsibility for training of counseling and testing staff of local provider agencies in some health departments initially expressed reluctance in adopting rapid HIV testing. Four key areas where these staff expressed skepticism and discomfort were:

- Client readiness to test and receive results on the same day;
- The potential adverse client reaction associated with providing "preliminary positive results";
- Ensuring client return for confirmatory results; and
- Counselor ability to clearly explain the test, including meaning of results.

Prevention counselors mirrored these concerns. In addition, prevention counselors report having experienced anxiety in counseling clients who accept rapid HIV testing, particularly as it relates to having to give preliminary positive results. However, counselors and program managers with experience in using rapid HIV tests report that this initial reluctance and anxiety diminished within approximately one month after implementation of rapid HIV testing.

Similarly, laboratorians have expressed concerns with rapid HIV testing in two key areas:

- Performance of the test(s); and
- Quality assurance of testing, particularly in relation to use of rapid HIV testing outside of more "traditional" settings which may lack experience and capacity to properly perform laboratory tests.

Laboratorians have expressed particular concern about any environmental conditions (e.g. poor lighting, excessive heat, etc.) related to outreach and other non-clinical settings that could impact test performance. Manufacturers instructions must be carefully followed to ensure the quality of the results in these settings.

Community planning groups (CPGs) may have interests or expectations with rapid HIV testing which may be incompatible with those of the health department and/or of state policy, law or regulation. For example, the health department may identify rapid HIV testing as an appropriate tool to improve rates of receipt of results and may determine the deployment of rapid HIV testing is most efficient and effective in high prevalence settings. This plan may be in response to state policy or regulation. The CPG may, on the other hand, view rapid HIV testing as a tool to make HIV testing more convenient and accessible in certain communities, by using it in conjunction with outreach activities. In this case, it is important that the CPG be provided with information essential to helping them understand the health department's direction and decisions including research related to the performance of the test in particular settings, interpretation of state policies or statutes and an analysis of the probable cost-effectiveness of planned deployment.

Health departments indicate that the process of planning for adoption of rapid HIV testing is about education and consensus building as much as it is identifying and addressing practical issues such as site selection, training and quality assurance. This underscores the importance of identifying concerns, interests and biases early in the planning process and addressing such issues through discussion, provision of information to facilitate clear understanding of rapid HIV testing (counseling and test performance) and its potential impact for improving services. It may be helpful to provide all stakeholders with at least summaries of relevant research to ensure a clear and accurate understanding of rapid HIV testing. The CDC makes research abstracts; fact sheets and other resources related to rapid HIV testing easily available on its web site: www.cdc.gov/hiv/testing.htm. The web site includes resources that are appropriate for a variety of audiences.

Identify Capacity and Resources. Adoption of rapid HIV testing will require additional resources, both human and fiscal. To help in the planning process, it is important to identify what resources are currently available to support implementation and what resources will be required. Health departments may have to redirect, or require contractors and grantees to redirect, resources to support implementation of rapid HIV testing. At minimum, health departments should plan on resources to address and support:

Laboratory Capacity. Laboratory capacity is perhaps the most challenging issue facing health departments with regard to adopting rapid HIV testing, particularly with respect to CBOs or NGOs adopting this technology for use at the "point of care" with outreach and educational activities. In such settings, counselors, outreach workers or other individuals who have limited experience with laboratory procedures may conduct HIV tests.

OraQuick has been classified under the Clinical Laboratory Improvement Amendments (CLIA) as "waived." This requires that agencies conducting rapid HIV testing using OraQuick, that are not already conducting other laboratory testing under CLIA certification, enroll in the CLIA program as a waived laboratory. The fee is $150, and it must be renewed every two years. Waived laboratories must ensure that tests are used according to manufacturer's instructions and that quality assurance measures are in place.

Alternately, some agencies, particularly community based organizations (CBOs), may be able to partner with existing public health or non-profit laboratories. Through such partnership, existing laboratories may be able to offer an "umbrella" to CBOs. CLIA provides a "limited public health use" exception, under which a licensed laboratory can operate multiple "satellite" sites under the "umbrella" of a single CLIA certificate. The lab holding the certificate agrees to provide required supervision and oversight. Formal arrangements, such as a contract or memoranda of agreement may be required in such circumstances.

Although a waived test is considered simple to use, with little chance of error if used correctly, there are important issues that must be considered to ensure the accuracy of test results. In addition, some states have regulations about laboratory testing which exceed CLIA or may have stricter regulations that make them exempt from CLIA. Information about CLIA, including regulations, applications for certification and technical resources can be found through the CDC website at www.phppo.cdc.gov/clia or through the Centers for Medicare and Medicaid Services website at www.cms.gov/clia/.

In general, there are a number of key issues related to laboratory capacity and quality assurance of testing that should be addressed by agencies wishing to adopt rapid HIV testing:

- Supplemental or confirmatory testing
- Occupational health and safety issues (e.g. universal precautions, sterilization, exposure control planning, HBV vaccinations)
- Liability insurance to cover potential blood borne pathogen exposure
- Training and proficiency testing for staff conducting tests
- Specimen collection (i.e. fingerstick techniques)
- Management and disposal of bio-hazardous waste
- Quality assurance procedures including:
    - Controls.
    - Storage and transport of tests
    - Record-keeping
    - Maintenance of laboratory equipment

Health departments should work closely with state and local public health laboratories to facilitate the development of these protocols and training essential to assuring the quality of testing.

Test Kits and Controls. Rapid HIV test kits and required controls will be much more expensive than test systems currently used. Currently, OraSure Technologies (manufacturer of OraQuick) and Abbott Laboratories sell OraQuick. Although the test has been initially offered at a price of around $12, the final price could be higher, potentially as high as $20. Discounts may be available for large purchases. Health departments should also factor for required controls and validation testing, as appropriate, into cost projections, as well as the costs of proficiency panels and tests for training and quality assurance. Costs associated with confirmatory testing should also be considered.

Confirmatory Testing. OraQuick is a screening test and as such, reactive results must be confirmed by a Western blot or IFA. Some laboratories may decide to progress directly to the Western blot or IFA to confirm a reactive rapid test result. Others may decide to continue to run a second EIA, prior to performing a Western blot, as occurs with standard testing algorithms. However, because OraQuick has a higher sensitivity than most blood/serum EIAs, a reactive result with OraQuick must be confirmed with a Western blot or IFA regardless of the results of a second EIA to prevent clients from receiving a false negative result. Specimens sent to a lab for confirmatory testing must be flagged so the lab will know that a positive OraQuick result has already been received.

Whole blood or serum-based Western blots or IFAs are appropriate for confirmatory testing. Dried blood-spots may be desirable for confirmatory testing when venipuncture is not appropriate or possible. However, because OraQuick has a higher sensitivity than most blood/serum EIAs, a reactive result with OraQuick must be confirmed with a Western blot or IFA regardless of the results of a second EIA. (See Quality Assurance below.) An oral fluid Western blot may be used. However, the oral fluid Western blot is less specific than blood/serum Western blots. In rare situations where the oral fluid Western blot result is discordant with the OraQuick result, additional testing with serum or blood is recommended.

Training and Quality Assurance. Rapid HIV testing will require modifications to current counseling protocol and associated quality assurance activities including training. Also, health departments should identify the number of counselors (and their supervisors) who will need to be trained on the modified protocol and allocate resources accordingly. In planning for implementation, health departments will need to identify resources necessary to accomplish these modifications.

Rapid HIV tests allow for a very different approach to specimen collection and testing. Prevention counselors or other designated staff can assume responsibility for both collection and testing. Previously all testing had to be conducted in a

laboratory. Resources must be made available to train staff on how to administer the test and provide appropriate quality assurance to ensure that the test continues to be administered pursuant to manufacturer instructions. Health departments will need to work to develop, implement and maintain capacity to provide training and quality assurance on an ongoing basis to staff conducting rapid HIV testing.

Medical, Prevention and Support Services. A key issue that has been raised by health departments and other stakeholders relates to the adequacy of existing medical, prevention and support services to respond to increased demand. Particular concern has been expressed regarding the availability of adequate resources for HIV-infected individuals. Rapid HIV testing has the potential to increase the number of HIV-infected individuals who learn their HIV serostatus and who are subsequently in need of access to medical, prevention and support services. Therefore, it is extremely important that health departments assess the extent to which existing resources can meet increased demand and monitor this on an ongoing basis.

In preparing for potential increases in demand on community resources, health departments should consider involving local providers of health and human services in implementation planning. At a minimum, such providers should be made aware of specific plans to implement rapid HIV testing and the potential impact on their services. Health departments should also consider facilitating periodic opportunities for HIV CTR providers using rapid HIV testing and health and human service providers to "cross-train". In this way, HIV CTR providers who may experience increased numbers of HIV-infected clients or HIV-negative clients at increased risk are well prepared to assist those clients in accessing needed prevention and care services. Similarly, agencies, which provide medical, prevention or support services, will maintain a better understanding of client needs and priorities.

Scale of Effort. Health departments and agencies already using rapid testing report being overwhelmed by demand for rapid HIV testing, once it became available. Few agencies advertised the availability of rapid HIV testing. Instead, demand was driven by word of mouth. Health departments will need to carefully consider the potential impact of increased demand for HIV CTR services associated with rapid HIV testing in the context of available resources and current or expected capacity. In some cases, an expansion of the availability of HIV CTR services may be warranted and feasible. In other cases, demand may be more appropriately addressed through modifications to the hours during which services are available; increasing the number of trained counselors or other staff available to provide rapid HIV testing; modifying client flow; or making referrals to other providers.

To make adoption of rapid HIV testing more feasible, some health departments plan to implement rapid testing modestly, at least initially. Based on the objectives that they have identified for rapid HIV testing, these health departments have established specific criteria to guide their decisions about where rapid HIV testing will be implemented. These criteria include: setting HIV prevalence; HIV-related risk of clients served in a setting; rate of return for test results; availability of trained personnel; and situational factors of clients served (e.g. transient, homeless). Some health departments also indicate that agency willingness to participate and cooperation of agencies in implementation were also key factors in determining where to implement rapid HIV testing.

Develop an Implementation Plan. Health departments with experience in planning for implementing rapid HIV testing suggest that a formal implementation plan is helpful in ensuring that objectives associated with adoption of rapid HIV testing are clear; key issues and challenges associated with adoption of rapid HIV testing are identified and addressed and that stakeholders understand their roles and responsibilities.

What should be addressed in an implementation plan? There are several key areas that the health department should address in developing its plan to implement rapid HIV testing:

Policy and Law: Most states have some type of policy or law that will impact adoption of rapid HIV testing. It is important that any such structural issues be identified and addressed early in the planning process. Adoption of rapid HIV testing may require changes to statute or regulation or development or modification of specific policies. Some of the policies and laws, which health departments may need to consider, include:

Medical Diagnoses. In many states, providers are prohibited from giving a medical diagnosis of HIV disease on the basis of a screening test. In these cases, it will be essential to ensure that all reactive rapid HIV tests undergo appropriate confirmatory testing. It will also be important to highlight confirmatory testing requirements in formal implementation plans.

Mechanisms for Provider Reimbursement. In some jurisdictions, HIV CTR services are supported on a fee for service basis. Health departments may need to make adjustments to reimbursement procedures to accommodate confirmatory testing (i.e. will confirmatory testing be considered two distinct tests or service episodes, or will it be part of one?). Health departments may also need to work with third-party payers to facilitate payment of HIV CTR services that include rapid HIV testing technologies.

Some jurisdictions rely on laboratories to monitor HIV testing activity and provide data needed to determine reimbursement of providers. In this case, health departments will have to develop mechanisms for monitoring and verifying testing activity that will not pass through central laboratories for the purposes of determining reimbursement. Also, some jurisdictions "count" pre- and post- test counseling and testing as discreet units of service in formulas or other funding schemes. In these cases, health departments may need to adjust funding schemes to ensure reasonable and appropriate support of HIV CTR services where rapid HIV testing is used.

Waiting Period for Results. There are a few states that have laws or policies that require individuals tested for HIV to wait for results for a pre-determined period of time (e.g. one week). It will be necessary to change these laws or policies in order to adopt rapid HIV testing.

Counseling. Prevention counseling associated with rapid HIV testing has often been referred to as "single-session counseling". However, counseling associated with rapid testing (both "test decision" and prevention counseling) may occur in a single session, in two sessions (i.e. pre and post-test), or through referral to appropriate providers. Additional prevention counseling may be available in association with disclosure of confirmatory test results. The choice of how best to provide information and prevention counseling should be determined by each jurisdiction in accordance with statutes, regulations, and policies. Within jurisdictions, it may be appropriate to make this determination on a site-by-site basis.

Some states, either by policy, statute or regulation, require counseling to be delivered in two sessions (i.e. "pre-" and "post-" test). This may make adoption of rapid HIV testing a challenge that requires either changes to policy or statute or changes to the logistics of delivery of CTR using rapid HIV tests.

Pregnant and Delivering Women. Many states have laws or regulations that address HIV testing for pregnant and delivering women. These laws may make adoption of rapid testing desirable in settings serving pregnant and delivering women.

Training and Credentialing of Laboratory Personnel. Some states have laws or regulations regarding training, education and credentialing for persons performing laboratory tests. These laws may exceed the requirements of CLIA and may therefore act as a barrier to adoption of rapid HIV testing in many settings, particularly those that are community-based.

Exposure to Blood Borne Pathogens. The Occupational Safety and Health Administration (OSHA) provides standards for employees who are at risk for

exposure to HIV, hepatitis B and C, and other blood borne pathogens through needles sticks, etc. In addition, some states may also have specific laws on occupational exposure to blood borne pathogens. Because OraQuick requires that blood be drawn through a finger prick, counselors and other personnel that administer OraQuick are considered at risk.

Individuals that administer OraQuick should follow universal precautions and all regulations for disposal of bio-hazardous materials. In addition, personnel that administer OraQuick should be offered the hepatitis B vaccine. Agencies should keep a log of all needle stick injuries. In addition, state laws or regulations may require agencies to carry liability insurance, or agencies may decide to get liability insurance on their own. State laws and regulations related to liability for blood borne pathogen exposure and occupational safety should be carefully reviewed. Health departments and agencies should seek appropriate legal counsel for any questions. For more information, see the Blood Borne Pathogens section of the OSHA website at www.osha.gov/SLTC/bloodbornepathogens/index.html.

Policies Specific to Rapid HIV Testing. Some states have policies that specifically address rapid HIV testing. These policies may set parameters for adoption of rapid HIV testing based on factors such as setting type, prevalence, population served, type of provider, training or certification requirements or performance of the test.

States may consider developing policies specific to rapid HIV testing to assist with cost-efficient and quality assured deployment of rapid HIV testing, particularly in publicly supported sites. Such policies might establish specific criteria or "thresholds" for eligibility. For example, under such a policy, rapid HIV testing might be limited to sites with HIV seroprevalence of at least 1% and a "rate of return" for test results of less than 60%. Such policies might also require specific training or certification for personnel at sites that provide rapid HIV testing. For example, some states are considering requiring all prevention counselors to complete a course in "counseling for rapid HIV testing" as a pre-requisite for using rapid HIV testing.

Site Selection. Most health departments are likely to use rapid HIV testing to achieve specific objectives and therefore will use rapid HIV testing in addition to rather than instead of current testing systems. Many health departments indicate that they will deploy rapid HIV testing, at least initially, in a limited fashion, using the technology to achieve very specific objectives through the participation of a relatively few pilot sites. For most jurisdictions, it will be important to identify the criteria by which sites will be selected to implement rapid HIV testing. Health departments may wish to consider the following criteria in

making decisions about sites where implementation of rapid HIV tests may be appropriate to achieving agreed upon objectives:

- The rate of return for HIV test results in a particular setting (e.g. STD clinics) or at specific sites.
- The HIV prevalence in a particular setting or site. Setting HIV prevalence influences the performance of HIV tests. For example, the positive predictive value of rapid HIV tests decreases along with HIV prevalence (i.e. the chance of receiving a false positive increases in settings with a low prevalence).
- The behavioral or clinical HIV-related risk of clients in particular settings or sites. Use of HIV rapid tests will be more cost effective in sites that yield relatively greater numbers of HIV-infected clients.
- Whether the site or agency provides services to a population for which medical intervention can reduce the likelihood of transmission (i.e. pregnant and childbearing women).
- The capacity of agencies or sites to conduct tests and perform necessary quality assurance, pursuant to CLIA or other state-specific requirements (e.g. appropriately trained counselors, etc.).
- The interest and willingness of sites or agencies to implement rapid HIV testing and comply with required training and quality assurance activities.
- Other diseases for which a site may be testing. Sites testing for STDs and hepatitis may not wish to offer rapid testing if they are already drawing a blood specimen.

HIV Counseling. Implementation plans should address counseling associated with rapid HIV testing and in particular, required modifications specific to rapid testing. HIV counseling encompasses two components: provision of information and prevention counseling. Clients tested with rapid HIV tests should be given the same types of information as those clients tested with the "standard" EIA. In addition, clients tested with rapid HIV tests should be advised that results of their rapid HIV test will be available quickly, within approximately 20 minutes of administering the test or the same day at the latest depending on how the site manages client flow. Clients should be informed that confirmatory testing is required if the rapid HIV test result is reactive. The FDA also requires that an information pamphlet on OraQuick, developed by OraSure Technologies, be given to the client.

The elements of prevention counseling will not necessarily change with rapid tests, but the logistics of how prevention counseling is delivered may change. Information about the test should be given and informed consent should always be obtained prior to obtaining a specimen for testing. However, in some jurisdictions or sites, it may be preferable to provide prevention counseling in advance of obtaining a specimen. In others, it may be preferable to provide

prevention counseling while tests are run, or it may be appropriate to provide prevention counseling through referral to other providers.

Detailed discussion of CDC's recommendations related to HIV counseling and HIV counseling with rapid testing is available in CDC's *Revised Guidelines for HIV Counseling, Testing and Referral* and in a document entitled "HIV Counseling with Rapid Tests".[4] The *Revised Guidelines* describe prevention counseling a discreet activity from testing and referral and provides guidance regarding the routine versus targeted offering of HIV prevention counseling. Refer to the *Revised Guidelines* for more information.

Agencies with experience in using rapid HIV tests, including OraQuick, have a number of practical suggestions for counseling associated with rapid testing. These are included below.

Meaning of "Rapid Testing". Some clients assume that rapid testing means the entire encounter will require 20-30 minutes of their time. It is important to explain to clients that "rapid" refers to the time that it takes the test to yield results. Obtaining informed consent, explaining rapid HIV testing, providing HIV prevention counseling, obtaining a specimen and waiting time related to client flow, time spent obtaining other services (e.g. STD screening and treatment), etc., will extend the time required for HIV CTR services. Agencies currently using rapid HIV tests suggest using terminology such as "same day results" to help ensure that clients have realistic expectations.

Health departments will need to examine client flow and logistics of services where rapid HIV tests are used to understand the factors that impact the efficiency and timeliness of HIV CTR using rapid tests. For example, some sites have reported that laboratory technicians or other testing personnel get backlogged with tests. This may extend the time of the client visit. Similarly, counselors get backlogged when demand is high. Client flow and scheduling issues should be examined and adjustments made as appropriate.

For example, it may be helpful to "block" time in the morning for HIV testing and associated counseling. Clients can be instructed to return at lunch or in the evening to receive results. Such adjustments can reduce client anxiety associated with unanticipated waiting and can reduce the number of clients in a waiting room. However, the rate at which clients return for results at a particular site may determine whether or not clients should be routinely instructed to return for results. If clients fail to return the same day for results or leave without results due to extended waiting, then client flow and scheduling should be reexamined.

[4] Available from the CDC web site at www.cdc.gov/hiv/testing.htm.

It has also been reported that some clients mistakenly believe that "rapid" refers to the ability of the test to detect recent infection and therefore seek HIV testing in relation to recent exposure. Counselors should be prepared to respond to and correct misinformation related to the meaning of rapid HIV tests. If a client is seeking testing related to recent potential exposure (within approximately 72 hours), test sites should consider referral for counseling related to post exposure-prophylaxis where available.

Client Readiness to Test. Just because clients request and accept rapid HIV testing does not necessarily mean that they are prepared for results. It is important that counselors be attentive to client readiness and clearly explore the extent to which clients are prepared to receive results, particularly preliminary positive results. Counselors with experience in providing rapid HIV testing suggest that it is important that clients be offered the option of being tested for HIV using the standard EIA. Counselors also suggest that clients who accept rapid HIV testing be offered the option of returning at a later date to receive results, if this is appropriate to client need.

Meaning of Test Results. Clients with a negative rapid HIV test can be told that they are not infected, unless they have a known or possible exposure within the three months prior to testing. Reactive rapid HIV tests must be confirmed with standard testing systems, either a Western blot or IFA. Counselors with experience in providing rapid HIV test results recommend simple and straightforward explanations of reactive test results. Discussions of "likelihood of infection" or "probabilities" should be avoided. Similarly technical discussions of the performance of the test should also be avoided. The CDC recommends a simple message such as "Your preliminary test result is positive, but we won't know for sure if you are infected with HIV until we get results from your confirmatory test. In the meantime, you should take precautions to avoid transmitting the virus."

Through the RESPECT-2 Project, CDC has developed a protocol for prevention counseling for use with rapid HIV testing. This counseling model was developed to be used in conjunction with SUDS (Single Use Diagnostic System for HIV-1). Counseling associated with OraQuick may require some adjustments because the SUDS test had to be sent to a laboratory. The protocol for counseling can be obtained from the CDC web site at www.cdc.gov/hiv/projects/respect2/default.htm.

With OraQuick counselors will be able to both perform the test as well as provide counseling (although in some settings other testing personnel or even a lab technician may administer and/or interpret the test). Many states may want to consider adopting their current counseling protocols for use with rapid tests. Some state health departments have also developed prevention counseling

protocols and associated counselor training curriculum for use with rapid HIV testing. NASTAD can assist you in contacting these health departments to obtain additional information.

HIV Testing. Implementation plans should address HIV testing. In particular, health departments should identify and address modifications to protocol around provision of test results and logistics of "client flow" resulting from adoption of rapid HIV testing.

Testing Options. Rapid HIV testing is appropriate to addressing the needs and preferences of some clients. Other clients, however, may be best served through standard EIA testing that requires a second, follow-up appointment to receive HIV test results. Health departments should consider making standard EIA testing available in addition to rapid HIV testing, either on site or through referral. Implementation plans should address dual HIV test systems in terms of resources, training, technical assistance and quality assurance.

Service Flow. Rapid HIV testing is likely to be integrated into HIV CTR services somewhat differently at each site, depending on established client flow, other services offered, whether HIV CTR services are offered on a walk-in or appointment basis and client volume. These and other factors will influence how quickly results can be provided to clients and the total time that will be required for a visit. For example, HIV rapid tests may be provided at the "point of care" (i.e. at the same site and time as the client is receiving services). The counselors may get informed consent, administer the test, provide counseling, and interpret and provide results in a single session. In this example, the wait by clients for results is minimized.

In another scenario, the counselor may seek informed consent and provide counseling while another person actually administers the test and/or interprets the results. In some clinics and emergency rooms (ERs), the test may actually be sent to a central laboratory that does all the lab work for the clinic or ER. The lab may be processing other tests for the clients as well. The possibility of significant delays in getting back a client's results exists as the individual interpreting the test or the laboratory becomes backlogged.

Where clients will experience some wait time related to service flow, consideration should be given to ensuring a confidential and comfortable waiting area for clients. Some agencies report it is helpful to clients waiting for test results to have a separate waiting room stocked with videos, reading material or other activities to occupy attention. Some counselors suggest that, if appropriate to client need, clients contact friends or family for support during the wait time and provide private telephone facilities for this purpose. Clients may also be given the option of returning for results later the same day, but

return rates for results should be considered before routinely offering this option. If a site finds that the length of the wait causes clients to leave without results, then other options to manage client flow should be implemented.

Confirmation Testing. Consideration should be given to the provision of confirmation testing. Where possible, health departments should consider making confirmation testing available at the same sites administering rapid testing. This allows clients to immediately access confirmation testing upon provision of a reactive OraQuick result. Sites may collect dried blood spots through a finger prick or use OraSure to collect an oral specimen. Clinics and other settings with the capacity and personnel to draw blood may consider using venipuncture. In settings where offering immediate access to confirmation testing is not possible, health departments should ensure that clients are clearly linked to confirmatory testing and consider mechanisms to determine whether clients access confirmation testing.

Informed Consent. Implementation plans should clearly and specifically address informed consent issues as they relate to rapid HIV testing. Adoption of rapid HIV testing may require adjustments to informed consent procedures, including modification of forms. Some health departments may consider modification of forms to specifically address rapid HIV testing (e.g. meaning of test results, confirmatory testing, etc.).

Training and Technical Assistance. Implementation plans should address the required or recommended training, education and certification associated with rapid HIV testing. Health departments should address what type of "special" training and certification, if any, will be required for:

- Prevention counselors
- Laboratory or other staff (including prevention counselors) responsible for testing
- Supervisors of prevention counselors, testing or laboratory staff

The implementation plan should also address how such training or certification will be provided, eligibility criteria, if any, and the frequency with which it will be offered. Training plans should be responsive both to the identified objectives for implementation and the scope of implementation. For example, if the health department intends to implement rapid testing on a limited basis, eligibility for training may be limited to staff of designated agencies or sites.

Implementation plans should also address technical assistance needs of sites adopting rapid HIV testing and their staff, especially during the early phases of implementation. Agencies with experience in providing rapid HIV testing suggest that counselors benefit from additional emotional support, particularly related to the intensity of providing preliminary positive results and increased numbers of clients who are positive, owing to increased utilization of HIV CTR

services. Health departments may wish to consider case conferencing or similar activities to provide counselors with opportunities to "debrief".

Quality Assurance. Quality assurance (QA) is a key consideration for HIV CTR services. Routine QA protocol and procedures should continue to be observed for counseling. Adjustments to QA protocol and procedures should be made to reflect the context of rapid HIV testing and should be addressed in implementation plans. Manufacturer's instructions regarding training and quality assurance of testing should be followed.

Performance and proficiency of counseling/testing staff should receive emphasis. This may include the use of a proficiency panel of five to six specimens or pictures of positive, weak positive, negative, and invalid results during training. Periodic evaluation of physical space, client flow and time concerns should also receive particular attention in QA activities associated with rapid HIV testing. The collection, handling and processing of specimens should be emphasized in implementation plans. Additional information and recommendations for quality assurance of HIV CTR services are available in the *Revised Guidelines.* In addition, the Public Health Practice Program Office at CDC will be issuing guidelines that address quality assurance of HIV testing sometime in 2003.

Data Collection and Evaluation. Data collected in association with rapid HIV testing activities should allow health departments to assess the extent to which objectives are being met (e.g. return rates, client characteristics) and provide quality assurance. Health departments may also consider whether to evaluate the behavioral impact, cost-effectiveness, or client satisfaction with services. This may require modification of current data collection tools and methods or development of new tools. It will necessitate training of counselors, supervisors or others and may also require review by a human subjects committee.

Health departments should consider the mechanism by which data associated with rapid HIV testing services will be collected. In particular, linking data associated with screening and confirmatory tests should be addressed. For example, the current CDC "bubble form" does not reflect rapid HIV tests as a testing method.[5] It also does not accommodate recording provisional positive results in addition to confirmatory testing. Health departments will need to determine if such information is desired and, if so, whether reserved fields can be used for this purpose or if some other mechanism is more appropriate. Because these forms do not include client-identifying information, health departments will need to decide whether or how to "link" data associated with

[5] CDC is currently in the process of revising the Counseling and Testing Data System (CTS) and future forms will include variables related to rapid testing. In addition, CDC may provide assistance prior to any CTS revisions to assist health departments in collecting rapid testing data.

screening and confirmatory testing. Linking screening and confirmatory testing will be important in ensuring that laboratories run a Western blot or IFA related to a positive OraQuick, regardless of the results of a second EIA.

For jurisdictions using other systems of data collection, data systems will likely require adjustments responsive to the context of rapid HIV testing. In particular, jurisdictions which use laboratory test requisition forms, which are submitted to a "central laboratory", to collect client data may need to develop alternate means of data collection.

In addition to data already collected as part of the HIV counseling and testing process, additional data which health departments should consider collecting include:

- Number of OraQuick tests performed
- Number of reactive OraQuicks
- Number of clients that receive OraQuick results (i.e. return rate)
- Number of rapid testing clients that receive confirmatory testing
- Confirmation test results related to OraQuick
- Number of OraQuick clients that receive confirmation test results

This data may help health departments ensure that rapid testing programs are meeting objectives and identify potential problems in how OraQuick is being used. For example, if there is a high level of false positives related to OraQuick at a particular site, health departments may need to investigate whether the test is being used correctly.

Surveillance and Reporting – For surveillance purposes, most states will not report a client as being positive until the HIV rapid test results have been confirmed. However, as noted above, health departments should consider the data it wishes to collect related to preliminary positives. Health departments may also wish to consider follow-up steps (if any) for clients that do not receive their results or do not seek confirmation testing.

Where can I get more help? Through its peer-to-peer technical assistance program, NASTAD can link health departments with colleagues in other states who have experience in planning and implementing rapid testing. For additional information and assistance, contact Alberto Santana, Technical Assistance Coordinator at (202) 434-8056 or asantana@nastad.org. NASTAD also convenes an ad-hoc Rapid Testing Work Group. This group convenes periodically for the purposes of sharing information about rapid HIV testing including development of new technologies, strategies for implementation, and development of policy supportive of rapid HIV testing in the public health environment. If you are interested in this work group, contact Chris Aldridge at (202) 434-8067 or caldridge@nastad.org.