



Update on Implementation of HIV Rapid Testing in Health Department Supported HIV Prevention Programs, July 2008

Executive Summary

INTRODUCTION

In late 2007, NASTAD conducted a survey of health departments to continue monitoring health department efforts to implement and support rapid HIV testing. The survey was designed to obtain a fuller understanding of the use of rapid HIV testing in conjunction with health department supported HIV prevention efforts. Specifically, this survey examined the mechanisms and resources used by health departments to procure rapid HIV test devices; the types of test technologies and volume of tests conducted by health department supported testing programs; the venues in which rapid HIV testing was conducted; and health department priorities for expansion of rapid HIV testing. This survey expands on previous survey efforts conducted in 2006 by examining issues associated with adoption of rapid HIV tests from various manufacturers, performance of rapid HIV tests and use of multi-test algorithms. The findings from this survey will contribute to the development and prioritization of technical assistance activities, guide education and advocacy efforts and contribute to the development of multi-test rapid HIV testing algorithms.

METHODS

In November 2007, AIDS directors from the 65 CDC-funded state, territorial and directly-funded city health departments were asked to participate in an on-line survey. Health departments were given two weeks to respond to the survey. Follow-up was conducted with non-responders after the close of the submission deadline. A total of 51 health departments responded to the survey including 45 of the 50 state health departments, five of the six directly-funded cities and the District of Columbia.

The survey questionnaire (Appendix A) included nineteen questions, encompassing five sections: implementation of rapid HIV testing; procurement of rapid HIV tests; rapid HIV test performance; use of combinations of multiple rapid HIV tests; and technical assistance needs.

KEY FINDINGS AND DISCUSSION

Implementation and Expansion of Rapid HIV Testing

- The vast majority 47 (94.0 percent) of health departments indicated they use rapid HIV testing in conjunction with health department supported HIV testing programs.
- Rapid HIV testing is in wide use by health departments in a variety of settings. Health departments reported a total of 3,371 unique sites operated by 1,439 agencies that provide rapid HIV testing.
 - A large majority of health departments offer rapid HIV testing in a range of community-based settings such as outreach sites (95.7 percent), community-based organizations (93.6 percent), free standing HIV test sites (93.6 percent) and local health departments (80.9 percent).
 - Many health departments offer rapid HIV testing in a variety of health care settings including sexually transmitted disease (STD) clinics (74.5 percent), substance abuse treatment centers (66.0 percent), community health clinics (53.2 percent) and hospital emergency departments (31.9 percent).
- Twenty-three health departments support routine HIV testing (i.e., screening) in health care settings and almost all (95.7 percent) reported using rapid HIV testing in conjunction with these efforts.

The expansion of rapid HIV testing is likely due to multiple factors including health department capacity to support rapid HIV testing, decreasing cost of rapid HIV tests and increased funding for expansion of HIV testing, particularly in high volume clinical settings. Continued reductions in federal funding and increasingly constrained state and local funding make it essential to monitor this trend and, in particular, to examine the extent to which funding issues impact the adoption and expansion of HIV testing programs, specifically the uptake of rapid HIV testing.

Rapid HIV Testing in the Context of Overall HIV Testing Efforts

- Eighty-one percent of health departments reported plans to expand the number of sites offering rapid HIV testing in 2008, with a total minimum addition of 562 sites that will begin offering rapid HIV testing.
- The overall volume of rapid HIV tests conducted in health department supported programs is expected to increase from a minimum of 1,678,952 in 2006 to an estimated 2,093,339 in 2008.
 - In 2008, health departments expect that rapid HIV tests will account for 51.8 percent of all tests conducted in health department supported programs, compared with 42.2 percent in 2006.
 - Oral fluid HIV tests account for 21.5 percent of all conventional HIV tests conducted in health department supported programs.

While rapid HIV testing appears to be increasing in prominence in health department supported HIV testing efforts, conventional HIV testing continues to play an important role in these efforts, with nearly 700,000 such tests projected

for 2008. For this reason, it is important for health departments to maintain and enhance capacity for laboratory-based HIV testing.

Oral fluid HIV testing continues to be an important technology. Development of an oral fluid screening assay is essential in order to ensure the continued capacity of health department laboratories to provide oral fluid HIV testing and to ensure the sustainability of health department HIV testing programs. It would also be highly desirable to develop an alternative oral fluid Western blot, in light of recent reports of increasing cost of this product.

Selection and Utilization of Specific Rapid HIV Tests

- Health departments reported on the types of rapid HIV tests used in their HIV testing programs. OraQuick Advance® is used by 95.5 percent of health departments; UniGold™ is used by 45.5 percent; and Clearview® is used by 20.5 percent of health departments. (Percents reflect the number of health departments using a particular manufacturers' product not the actual number of rapid HIV tests performed.)
 - Most health departments reported using multiple rapid HIV tests and many also reported, at the time of the survey, that a final decision had not been made about the specific rapid HIV test(s) they would use in 2008.
 - Price appears to be the single most important criteria used by health departments in determining which rapid HIV test(s) to use. Nearly 71 percent of respondents cited price as one of the three most important factors, and 38.6 percent cited price as the most important determining factor. Shelf life, sensitivity, ease of specimen collection and approved for oral specimens also received mention as important criteria in selection of specific rapid HIV tests.

Price was the single most important factor cited by health departments in deciding which rapid HIV test(s) to use. Increased competition from multiple manufacturers of rapid HIV tests is expected to continue to drive down the cost of rapid HIV tests. At the same time, health departments will likely continue to deploy rapid HIV testing in a wide range of settings and for diverse populations and thus may increasingly seek to "match" test features to venues, settings and populations in order to optimize HIV testing efforts.

Procurement

- In 2007, health departments purchased 1,077,428 rapid HIV tests and they plan to purchase 1,553,858 rapid HIV tests through one or more procurement mechanisms in 2008.

Health departments expect to increase by nearly 500,000 the number of rapid HIV tests they will purchase in 2008, compared with 2007. This is likely a reflection of increased federal funding for HIV testing coupled with the decreasing price of rapid HIV tests. Most health departments utilize their health department

procurement process to purchase rapid HIV tests, which generally takes the form of a competitive bidding process.

Performance

- Through November 2007, twelve health departments reported having experienced a total of twenty clusters of false positive HIV test results in conjunction with rapid HIV testing. All the false clusters reported involved OraQuick Advance®.

While a number of factors were thought to play a role in the clusters of false positive HIV rapid test results including over-collection of specimen, storage temperatures, operating temperatures and lot manufacture, none of the health departments responding to the survey could pin-point a single cause for the clusters. Health departments will need to continue to monitor performance of rapid HIV tests, particularly as they adopt rapid HIV tests from different manufacturers.

Multi-Test Algorithms

- Four health departments reported having implemented a sequential multi-test algorithm. Only two of these report using rapid HIV tests produced by different manufacturers.
- One health department reported having implemented a parallel multi-test algorithm.

Development of new national guidelines which address the application of rapid HIV tests in multi-test algorithms for use in diagnosing HIV infection are needed and desired by health departments. Such guidelines may stimulate health departments to consider adopting multi-test algorithms for diagnosing HIV infection using rapid HIV technologies. At the same time, as more rapid HIV tests classified as CLIA-waived become available and the prices of testing technologies drop, more health departments may wish to explore adoption of multi-test algorithms as a means to increase the efficiency and effectiveness of HIV testing programs.

Technical Assistance Needs

- Health departments report a very limited need for basic training and skills development on the technical aspects of rapid HIV testing. Only 8.7 percent reported a need for laboratory or test device training.
- Health departments identified guidance and assistance in adopting multi-test algorithms as an important technical assistance need (45.7 percent). Technical assistance to evaluate the cost-effectiveness of rapid HIV testing (43.5 percent) and the impact of rapid HIV testing (37.0 percent) were also identified as important technical assistance needs.

Survey findings suggest that health departments have rapidly built internal capacity for providing necessary training and technical assistance on the technical aspects of HIV testing with rapid technologies. Priority technical assistance needs identified by health departments include adoption of multi-test algorithms for diagnosing HIV-infection at point-of-care, evaluating the impact of rapid HIV testing programs and evaluating the cost-effectiveness of rapid HIV testing. This assistance would be invaluable in helping health departments enhance the efficiency of HIV testing programs and optimize use of increasingly constrained resources.

LIMITATIONS

There are several limitations to these findings. All data were self-reported and are subject to the knowledge and interpretation of the individual(s) who completed the survey. Several health departments were unable to provide data related to the volume of HIV tests (both conducted and procured), so responses to these questions likely under represent the total volume of HIV tests. Questions that asked health departments to estimate the number of HIV tests to be purchased in the future should be interpreted with caution as the estimates can be influenced by multiple factors including, but not limited to, funding and implementation issues.

This survey asked health departments to provide retrospective data regarding HIV test performance. This proved challenging for health departments, particularly where data had not been compiled and managed in electronic file formats. Two health departments provided two separate sets of data which were not entirely consistent and required additional investigation to reconcile data.