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Rapid HIV Test Distribution --- United States, 2003--2005

At the end of 2003, an estimated 1 million persons in the United States were living with human immunodeficiency virus (HIV) infection, including those with acquired immunodeficiency syndrome (AIDS); approximately one fourth of these persons had not had their infections diagnosed (1). In 2003, CDC implemented a new initiative, Advancing HIV Prevention (AHP) (2), focused, in part, on reducing the prevalence of undiagnosed HIV infection by expanding HIV testing (2) and taking advantage of rapid HIV tests that enable persons to receive results within 30 minutes, instead of the 2 weeks typically associated with conventional tests (3). In support of AHP strategies, during September 2003--December 2005, CDC purchased and distributed rapid HIV tests to expand testing and assess the feasibility of using rapid tests in new environments (e.g., outreach settings or emergency departments). This report summarizes the results of this rapid HIV-test distribution program (RTDP), in which CDC distributed tests to 230 organizations in the United States and identified 4,650 (1.2%) HIV infections among 372,960 rapid tests administered. The results suggest that RTDP helped scale up rapid HIV-testing programs in the United States and enabled diagnosis of HIV in persons who might not have had their infections diagnosed otherwise.

During 2003--2004, any publicly funded organization providing HIV testing was eligible to participate in RTDP. During 2005, participation was limited to organizations in 21 states and the District of Columbia (DC) funded by the CDC AHP initiative. In all 3 years, participating organizations were required to 1) have appropriate quality-assurance plans and Clinical Laboratory Improvement Amendments (CLIA) certification, 2) run periodic external quality controls, and 3) use either Western blot or immunofluorescent assays to confirm all reactive (i.e., preliminary positive) rapid HIV test results. Clients with test results that were confirmed positive were referred to HIV-care clinics.

During September 2003--December 2005, CDC distributed 790,310 OraQuick® Advance™ Rapid HIV-1/2 Antibody Tests (OraSure Technologies, Bethlehem, Pennsylvania) to 107 coordinators representing 230 organizations (121 state and local health departments, 101 medical centers and community-based organizations, and eight correctional facilities) in 37 states, DC, Puerto Rico, and the Virgin Islands. RTDP generally distributed more rapid tests to states and territories with higher estimated numbers of persons aged

≥13 years living with AIDS (Figure). Evaluation of RTDP was performed using two methods. First, coordinators of participating organizations were asked to submit quarterly reports regarding the number of rapid HIV tests used for training, external controls, and diagnostic purposes and the number of confirmed results (i.e., positive, negative, or indeterminate) for clients with preliminary positive rapid HIV test results. Quarterly reports also included data on the total number of conventional HIV tests administered, and of these, the number that were confirmed positive. Second, 52 RTDP coordinators, representing a random sample of all 107 coordinators, were telephoned during February 23--April 6, 2006, to assess challenges to implementing rapid HIV testing and the impact of RTDP on HIV testing services overall.

Of the 230 organizations, 128 (56%) submitted quarterly reports that accounted for 606,951 (76.8%) of the rapid tests distributed. Of these tests, 372,960 (61.4%) were administered for diagnostic purposes, 60,294 (9.9%) were used for external quality control, and 25,378 (4.2%) were used for training. The remaining 148,319 (24.4%) tests either had not yet been used at the time the reports were submitted, had been returned to CDC and redistributed to other organizations, or had expired before they could be administered. On average, approximately one rapid test was used for external quality control for every six rapid tests used for diagnostic purposes (60,294 versus 372,960). Among tests administered, results from 5,385 (1.4%) were preliminary positive for HIV, and 4,650 (1.2%) were confirmed as HIV positive from samples drawn at the rapid testing sites; similarly, during 2003--2005, the same 230 organizations reported that 1.5% of results from 600,732 conventional tests were confirmed positive. Of preliminary HIV-positive rapid tests, 4,262 confirmed positive, negative, or indeterminate results (79.1%) were provided to clients; data were not collected on the number of clients who refused confirmatory testing or left the site before confirmatory specimens could be drawn, or on other reasons clients did not receive results of confirmed tests.

Of the 52 coordinators telephoned for interview, four were no longer employed by the organization and could not be contacted; 48 (92%) participated, representing 97 organizations from 27 different states. Forty-six (96%) reported one or more challenges that delayed the start of their rapid-test programs, including training of staff (63%); meeting local, state, or federal regulations (48%); and creating operating procedures and quality-assurance protocols (35%). A total of 22 (46%) coordinators reported one or more expired test kits. The most commonly reported reasons for expiration were receipt of rapid tests from the manufacturer too near their expiration dates or unexpected expiration date changes by the manufacturer (i.e., because annual stability testing suggested the shelf life should be reduced [4]) (cited by 11 [50%] coordinators); overestimating demand for rapid testing (nine coordinators [41%]); delay in starting programs (nine [41%]); and inadequate inventory control (e.g., tracking of expiration dates or test supplies) (eight [36%]). Of the 22 coordinators, 15 (68%) reported using expired tests for training purposes.

Of the 48 coordinators interviewed, 43 (90%) said RTDP enabled their organizations to screen more clients for HIV because the program provided them with additional tests (cited by 35 coordinators [81%]) or because clients did not have to make a second visit to the clinic and meet with staff members a second time to receive their results (33 [79%]), increasing client acceptance of testing and increasing staff availability for testing additional clients. During 2005, when participation was limited to AHP-funded organizations, 26 (54%) of the interviewed coordinators were not eligible to participate in RTDP. Four (15%) of these coordinators said their rapid testing was discontinued at one or more test sites because of lack of funding, and one reported that a rapid test site was closed for other reasons; however, 21 (80%) reported continuing rapid testing by using non-RTDP federal, state, or local resources.

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Editorial Note:

The findings in this report suggest that HIV testing might be increased by using rapid tests and that RTDP might have enabled diagnosis of HIV infection in persons who would not have known their HIV status otherwise. Although follow-up client data were not collected on the 4,650 confirmed HIV-positive test results, previous research has indicated that the majority of persons who learn they are infected with HIV take steps to prevent transmission to others (5) and obtain health care that can prolong the quality and duration of their lives (6). Previous research also has suggested that many providers and clients prefer rapid HIV tests, which allow clients to receive test results in <30 minutes (6--8), eliminating for those with negative results the 2-week waiting period typically associated with conventional tests. Rapid tests also are simple to use and accurate. For example, the sensitivity of the OraQuick Advance test is 99.3% using oral fluid specimens and 99.6% using whole blood specimens; the specificity is 99.8% and 100.0%, respectively (3).

Despite the considerable utilization of rapid HIV tests provided through RTDP, nearly all coordinators identified challenges to implementing their programs, including receipt of tests with a short shelf life or notices of reduction in the shelf life of devices that had already been distributed. The short shelf life of OraQuick Advance (currently 6 months [4]) and lack of programmatic experience in rapid testing resulted in some devices expiring before their use. To help prevent expiration of tests, RTDP organizations also should ensure that comprehensive inventory-control mechanisms are in place and that initial orders for rapid HIV tests are based on accurate estimates.

The results of this assessment, combined with other CDC data, suggest that an excessive number of rapid tests might have been used for external quality control. External controls for rapid HIV tests should be run 1) by a new operator before performing testing, 2) when opening a new test lot or when a new shipment of rapid tests is received, 3) if the temperature in the test storage or testing area falls outside of specified ranges, or 4) at periodic intervals as dictated by the user facility (3). Many of the RTDP recipient organizations participated in another CDC evaluation of rapid HIV test quality-control procedures, which documented that rapid HIV tests were rarely exposed to temperatures outside of specified ranges (CDC, unpublished data, 2006). Thus, the high ratio of controls to tests in RTDP likely reflects running periodic controls at short user-defined intervals (e.g., daily). With increased experience in using rapid HIV tests, the New York State Department of Health, in March 2006, reduced its minimum requirement for periodic external controls from daily to monthly and with change in lot number and receipt of new shipments.*

The findings in this report are subject to at least four limitations. First, because 44% of participating organizations did not submit any reports, the number of tests reported as administered, expired, and used for training or external control should be considered minimum estimates. Second, some organizations that submitted quarterly reports operated multiple testing sites; the quality of test utilization data might not have been consistent among these multiple sites. Third, the organizations used different data collection methods that might have changed over time and might not have been able to distinguish rapid tests provided by RTDP from those purchased by the organizations. Finally, although organizations used RTDP devices on both oral fluid and whole blood specimens, RTDP quarterly reports did not differentiate between the two specimen

types.

Despite obstacles associated with implementing a new diagnostic technology, RTDP has helped initiate rapid HIV testing at sites throughout the United States. Many organizations, although no longer associated with RTDP in 2005, continued to offer rapid HIV testing. CDC will procure an additional 211,800 OraQuick Advance rapid HIV tests for RTDP distribution during June 2006--June 2007. Currently, a total of six rapid HIV tests have been approved by the Food and Drug Administration (FDA) and are available in the United States; two of these tests are CLIA waived and can be used in nonlaboratory settings. However, OraQuick Advance remains the only FDA-approved, CLIA-waived rapid test for use on oral fluid (3). CDC will continue to work with federal, state, and local partners to increase the efficient use of rapid HIV tests, providing more access to HIV testing in settings and communities in which many HIV infections are undiagnosed.

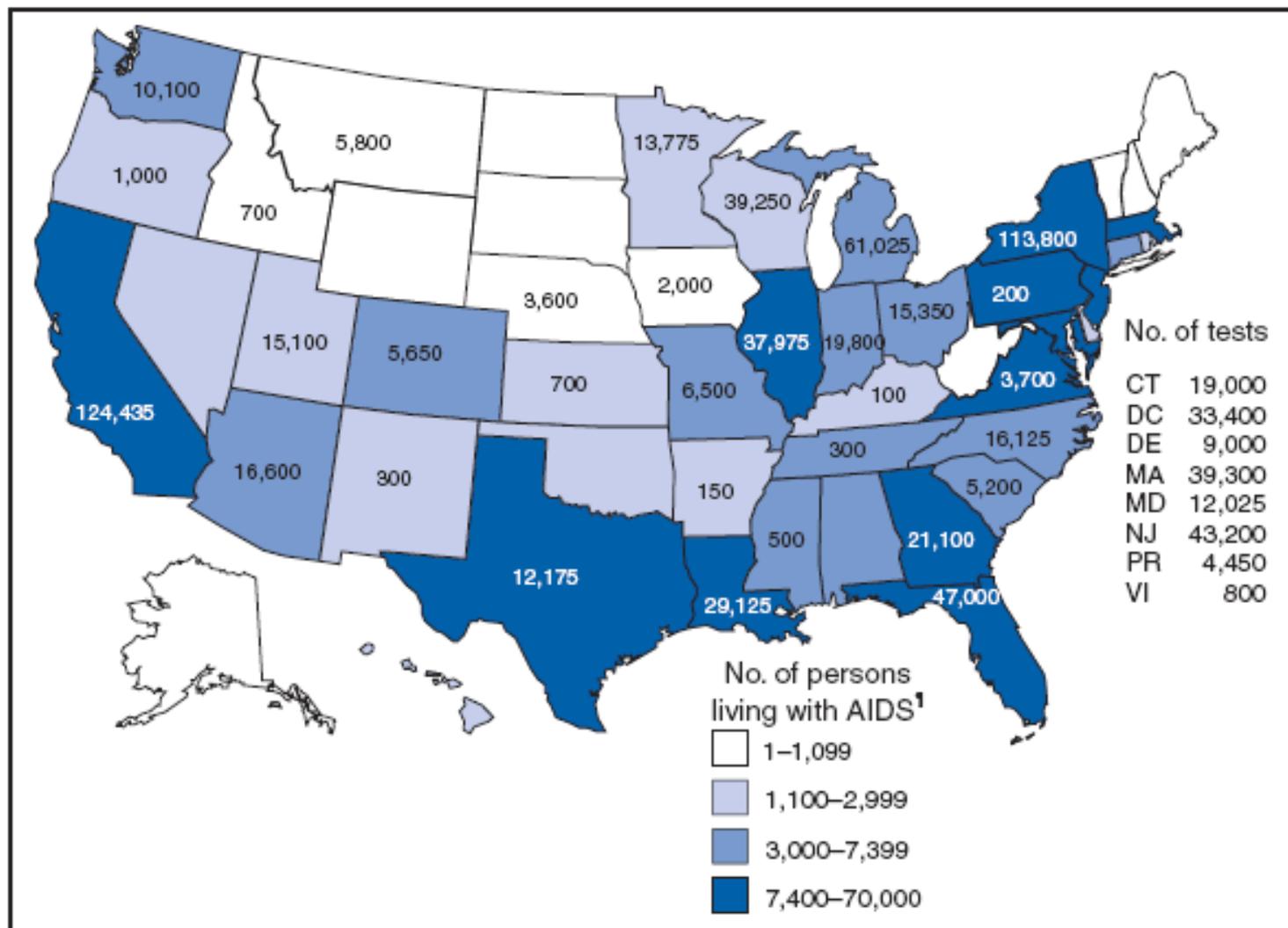
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* Available at http://www.cdc.gov/hiv/rapid_testing/materials/NYquality-control.pdf.

Figure

FIGURE. Number of rapid HIV* tests distributed by CDC during September 2003–December 2005 and estimated number of persons† living with AIDS‡ at the end of 2004, by state/territory — United States



* Human immunodeficiency virus.

† Aged ≥ 13 years.

‡ Acquired immunodeficiency syndrome.

¶ CDC. HIV/AIDS surveillance report, 2004. Vol. 16. Atlanta, GA: US Department of Health and Human Services, CDC; 2005:22. Available at <http://www.cdc.gov/hiv/stats/2004surveillancereport.pdf>.