

CDC Consultation: Implementing Rapid HIV Testing in the United States

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The potential advantages of rapid HIV tests have been well documented in several studies in the United States and in numerous voluntary testing programs throughout the world.(1-6) Recently, the Food and Drug Administration (FDA) notified 2 test manufacturers that their rapid HIV tests were approvable: the Oraquick HIV-1 Antibody Test (OraSure Technologies Inc., Bethlehem, Pa.) and the Reveal HIV Test (MedMira Laboratories, Toronto, Ontario). *Approvable* means that the FDA concluded that data from clinical trials were sufficient to prove these tests to be safe and effective. Because these rapid tests are expected to be approved soon, use of rapid HIV tests in the United States must be put into operation.

CDC's goal for this consultation is to pinpoint the specific planning, information, and technical assistance needed to make point-of-care rapid HIV testing widely available and to ensure the continued quality and reliability of HIV test results. The consultation has 3 objectives:

- To provide a forum for an interchange of viewpoints and opinions from the diverse constituencies that have had responsibility for HIV testing, will be responsible for the deployment of rapid HIV tests and those that will be affected by the use of the tests
- To identify barriers to the implementation of rapid HIV testing
- To outline the steps necessary to facilitate access to rapid HIV tests in a variety of settings and to minimize adverse consequences associated with use of the tests

Counseling and testing (CT) have been mainstays of CDC's HIV prevention efforts since the first HIV antibody test was introduced in 1985. Through 2000, CDC-funded CT programs have conducted more than 26 million HIV tests, 510,000 of which have been positive (unpublished data, CDC HIV Counseling and Testing database). CT programs continue to perform slightly more than 2 million HIV tests annually. However, the overall percentage of HIV-positive test results has declined from 3.8% in 1990 to an average of 1.3% since 1997.(7) This represents approximately 30,000 positive test results per year. Approximately 25% of positive test results go undelivered because clients do not make the second clinic visit necessary to receive them. Rapid HIV tests can eliminate this problem and provide additional opportunities to increase knowledge of serostatus among the estimated 225,000 persons who are still unaware of their HIV infection.

CDC has launched a new strategy for HIV prevention called the Serostatus Approach to Fighting the Epidemic (SAFE). CDC has also established a goal of reducing new HIV infections in the United States 50% by 2005.(8) To reach that goal, it is critical to increase by 30,000 each year the number of infected people who become aware of their

HIV status and become linked to appropriate care and prevention services.(9) In view of the medical and public health benefits from learning one's HIV status as early after infection as possible, CDC is placing additional emphasis on encouraging those at high risk for infection to seek testing and on expanding access to voluntary testing.

Simple, rapid tests provide opportunities to dramatically increase the availability of HIV testing.(8) An obvious example is their expected use for outreach by community-based organizations in areas where large numbers of people are at risk for HIV infection. Outreach workers who approached young men who have sex with men (MSM) in social venues as part of CDC's Young Men's Survey found that 10% of the men were HIV-positive and that 77% were unaware of their infection.(10) Among young black MSM, 16% tested positive for HIV, and 93% were unaware of their infection.(11) Of those who reported they had previously tested negative, 16% were found to be infected. These findings underscore the need to encourage all MSM at risk for HIV to be tested at least annually.(12)

Rapid HIV tests can also be used for routine voluntary testing in emergency departments or other medical settings where large numbers of HIV-infected people may seek care for illnesses unrelated to HIV. In recent studies in which rapid HIV testing was offered to patients in the emergency departments of 3 urban hospitals, 3% of the patients were newly identified as HIV-positive. One of these studies also demonstrated that rapid testing, to be effective, must indeed be rapid. When the average time for testing (done in the hospital laboratory) was 107 minutes, 55% of patients left before receiving their test results. However, only 20% of patients left before learning their test results when testing (done in the emergency department) took an average of 48 minutes.(13)

Of the 20 million HIV antibody tests performed annually for diagnosis and screening, publicly funded testing accounts for only about 10%. (CDC, unpublished data) There are 173,000 sites registered as laboratories under the Clinical Laboratories Improvement Amendments (CLIA) program.(14) CDC's Public Health Practice Program Office estimates that approximately 1800 laboratories perform HIV antibody testing. The introduction of simple, rapid HIV tests that require almost no laboratory equipment promises to swell that number substantially. With this increase comes the challenge to augment systems for training and quality assurance so that the reliability of HIV testing can be maintained. Considerations of how specific rapid-test procedures are categorized by CLIA are central to plans for bringing rapid HIV testing to settings where it offers the greatest benefit. This background document describes the procedures for performing the OraQuick and Reveal rapid tests and details the CLIA regulations that pertain to these tests. For the purposes of this meeting, we presume that, upon approval, rapid HIV tests will be categorized as moderate complexity under CLIA. During this consultation, we seek to increase familiarity with the options for using rapid HIV tests under conditions of moderate complexity. We will also briefly discuss alternative regulatory routes that could ensure even wider access to rapid point-of-care HIV tests that are technically simple but the results of which are of great consequence.

Finally, we plan to explore how to best meet the new challenges for counseling and confirmatory testing brought about by HIV tests that can provide preliminary results within minutes after blood is collected. To serve as a starting point for these discussions, we have invited speakers who can share their recent experience with rapid HIV tests at traditional testing sites, in clinics, outreach settings, emergency departments, and hospital labor and delivery suites. We will also publish a meeting summary of this consultation so others can benefit from the perspectives and advice shared with CDC over these two days.

References

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