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Title: Using a multi-test algorithm to improve the positive predictive value of rapid HIV testing and linkage to HIV care in non-clinical HIV test sites.

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Running Head: Rapid HIV test algorithm evaluated in 2 US Cities

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Abstract:

Background: Use of a rapid HIV testing algorithm (RTA) in which all tests are conducted within one client appointment could eliminate off-site confirmatory testing and reduce the number of persons not receiving confirmed results.

Methods: An RTA was implemented in 9 sites in Los Angeles and San Francisco; results of testing at these sites were compared with 23 sites conducting rapid HIV testing with off-site confirmation. RTA clients with reactive results on >1 rapid test were considered HIV+ and immediately referred for HIV care. The positive predictive value (PPV) of a single rapid HIV test and the RTA were calculated compared to laboratory-based confirmatory testing. A Poisson risk-regression model was used to assess the effect of the RTA on the proportion of HIV+ persons linked to HIV care within 90 days of a reactive rapid test.

Results: The PPV of the RTA was 100% compared to 86.4% for a single rapid test. The time between testing and receipt of RTA results was on average 8 days shorter than laboratory-based confirmatory testing. For risk groups other than MSM, the RTA increased the probability of being in care within 90 days compared to standard testing practice.

Conclusions: The RTA increased the PPV of rapid testing to 100%, giving providers, clients, and HIV counselors timely information about a client's HIV-positive serostatus. Use of an RTA could reduce loss to follow-up between testing positive and confirmation, and increase the proportion of HIV-infected persons receiving HIV care.

Keywords: HIV testing; Linkage to HIV care; rapid HIV testing

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Introduction:

HIV testing in non-clinical settings, such as outreach or other sites that do not offer disease management or treatment services, has been shown to be effective at increasing the proportion of persons aware of their infection (1-2). In the United States, a single reactive rapid HIV test result is considered a "preliminary positive" result (3). Although CDC and HRSA recommend referral of eligible clients to HRSA-funded clinics after a preliminary positive result (4) to facilitate timely linkage to care, supplemental laboratory-based testing is recommended after a reactive rapid HIV test (3,5). When test sites use offsite laboratory testing to confirm a preliminary positive result clients must wait until their laboratory result is ready to get a definitive result. Although referral after a preliminary positive result is permissible, many sites do not offer referrals until after supplemental laboratory test results confirm infection. HIV testing programs in nonclinical settings that do not offer immediate referrals have experienced difficulty convincing clients to provide venipuncture specimens for confirmatory testing (6) and recontacting clients to deliver confirmatory test results and subsequently linking clients to medical care (1-2, 6-9).

CDC guidelines for HIV testing in non-clinical settings (10) indicate that "if two or more sensitive and specific rapid HIV tests became available, one positive rapid test could be confirmed with a different rapid test," and this was reiterated as an acceptable criteria for confirmation of diagnosis for Ryan White HIV/AIDS program eligibility by CDC and HRSA in 2013 (4). Since 2001, the FDA has approved eight rapid HIV tests for use in multi-test algorithms (11-13) to determine the presence of HIV antibodies. Therefore, alternatives to the current testing algorithm that use multiple rapid tests, which have been used extensively in resource-limited settings (14-18), have been proposed for use in United States (19). To date,

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these alternatives have principally been used to increase the positive predictive value (PPV) of the rapid HIV screening test. However, same-day referral of those with reactive rapid test results may also improve the linkage to HIV medical care (6,19-21). A goal of the President's National HIV/AIDS Strategy (NHAS) is to increase the proportion of all HIV-infected clients successfully linked to HIV medical care within 90 days from 65 to 85% by 2015(22).

In this study, we evaluated the PPV of a rapid HIV test algorithm (RTA) employing three tests in non-clinical HIV counseling and testing (HCT) sites in Los Angeles and San Francisco, California, and the impact of testing with the RTA on receipt of confirmed HIV test results and linkage to HIV medical care.

Methods

A total of 32 agencies funded by the collaborating local public health departments in Los Angeles and San Francisco offered rapid HIV counseling and testing services (HCT) prior to study initiation in August 2007. HCT sites included mobile units, storefronts, health clinics, community-based organizations, a methadone clinic and county jail services. Four programs in Los Angeles and five programs in San Francisco were selected to implement an HIV RTA as their standard method of providing HCT services for an 18-month period (intervention sites) from August 2007 through March 2009. The other 23 sites served as comparison sites. Clients testing confidentially or anonymously at both intervention and comparison sites were eligible to participate in the study. Anonymous testers could provide their name to convert to confidential testing at any point during the testing session; only those testing confidentially could be reported to the HIV surveillance system or referred for HIV medical care.

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