A Novel Application of Syndromic Methods to Monitor Temporal Changes in the Specificity of an Oral HIV Test

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OBJECTIVE

To apply syndromic techniques in assessing whether the false-positive rate (FP rate) of a rapid oral HIV test, routinely used for screening in New York City's STD clinics, deviated from the manufacturer's claim; results of which have important implications for assessing clinical test performance.

BACKGROUND

In March 2005, The New York City Department of Health and Mental Hygiene (NYC DOHMH) began performing HIV antibody testing using oral fluid (OraQuick Advance Rapid HIV-1/2). Oral fluid testing replaced finger-stick whole-blood testing, which had been in use since January 2004. A recent review of the specificity of the oral test suggested that since 2005 there have been two distinct peaks in the FP rate of the test, first in late 2005 and again in late 2007[1](Figure1).

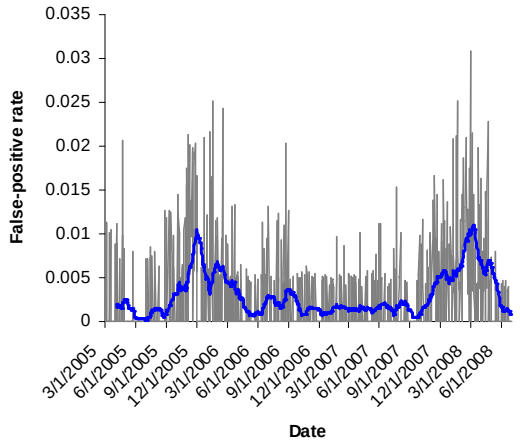

Figure 1. Daily false-positive rate (grey line) with a 30-day moving average (blue line) of the oral fluid rapid HIV test, New York City, March 2005-June 2008.

In particular, from October 2007 through April 2008, the specificity of the oral test was 99.3%, below the manufacturer's claim for the product (95% CI=99.6-99.9%). Because the prevalence of HIV viruses is low in New York City, a small decrease in specificity can lead to a large decrease in the positive predictive value (PPV). For example, a drop in specificity of the oral test from 99.8% to 99.3% translates to a decrease in PPV from 78% to 50% in this population. It could be argued that, over time, the performance of this test will vary purely by chance and that periods with a high FP rate, such as those during the Winters of 2005-06 and 2007-08, can be expected. We calculated a temporal scan statistic to formally test if the FP rate of the oral HIV test rose significantly above the expected level. Applying a simple temporal scan statistic in this way represents a useful approach to the surveillance of test performance.

METHODS

Results of all oral HIV tests from New York City's 10 STD clinics from March 1st, 2005 to June 30th, 2008 were aggregated by day. The number of FP tests was calculated using confirmatory Western Blot tests. A SAS program created the necessary case and control files and invoked SaTScan software to run a temporal scan analysis. The case and control files were the daily total number of false-positive HIV tests and negative tests, respectively. The baseline FP rate was 0.003 - the observed rate over the entire study period. Statistical significance was evaluated using Monte Carlo hypothesis testing.

RESULTS

The temporal scan analysis detected a cluster in the FP rate from October 30, 2007 to April 21, 2008 (LL ratio=80.5, p=0.001). The specificity during this time was 99.3%, with a PPV of 49.4%. Assuming this period represents a true cluster, and thereby limiting the analysis to dates before November 2007, a second cluster was detected from September 2005 to March 2006; however, this cluster was absent when including the full time series.

CONCLUSIONS

Results support the clinical observation that the FP rate of the oral test increased substantially in NYC STD clinics during the winter of 2007-08. Future analyses will investigate potential causes of this temporal cluster and will explicitly test whether the FP rate deviated from the manufacturer's expected lower limit of 0.004. The applicability of this method in public health practice will also be discussed. This work presents a simple and novel method of monitoring the temporal pattern in test specificity and may help public health officials to better assess when a test fails to meet expected performance targets.

1. *False-positive oral fluid rapid HIV tests--New York City, 2005-2008.* MMWR, 2008. **57**(24): p. 660-5.