Abstract #41

Comparing the Performance of the APHL/CDC Proposed POC Testing Strategies and Other Potential Options Using Data from the CDC's Evaluation of FDA Approved Rapid Tests

Abstract Category:	Performance of Point of Care Strategies Using Combinations of Rapid Tests
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BACKGROUND

Recently APHL/CDC working groups have proposed strategies using multiple rapid HIV tests at point-of-care (POC). However, rapid HIV tests are currently only being used as single screening tests which require confirmation by Western blot or immunofluorescent assay (IFA). The strategies proposed by the working groups offer alternatives that provide more information at the point of testing, but which still require sending a specimen to the lab in some cases. However, a true POC strategy that resolves all individuals as infected or uninfected was not included in those proposed. Data collected for the purpose of evaluating FDA-approved rapid tests for use singly and in combination can be used to evaluate the relative performance of various testing strategies.

METHODS

In this study, 5764 persons seeking HIV testing at two high prevalence clinics in Los Angeles, CA were tested in on site lab space with the 6 FDA-approved HIV rapid tests. Serum and plasma specimens were collected and tested with EIA and Western blot. Individual test results were evaluated and six potential POC strategies (the 4 proposed by the APHL/CDC working groups and two additional alternatives which resolve all clients as infected or uninfected) were followed as if the tests were being performed real time, e.g. for specimens testing positive in the sequential three test algorithm, an initially reactive specimen was subjected to testing with a second test, and the results of that test determined whether the specimen was considered 'presumptive positive' (when the 2nd test was reactive) or a third test was performed (when the 2nd test was non-reactive.) To compare the relative merits of the strategies, independent of the tests included in them, a bootstrap sample of the results of 51 two-test and 154 three-test potential combinations was constructed. The bootstrap re-sampling allows comparison of the strategies, and includes variability introduced by both individual test combinations and problematic specimens that should be expected to be present in a sample of specimens of this size. Medians and bootstrap confidence intervals are reported.

RESULTS

Confidence intervals for all performance measures evaluated were similar for each of the various strategies. Requiring three tests to agree before considering someone to be infected with HIV was the only strategy to completely eliminate false positive strategy results. All other 2 and 3 test strategies evaluated produced between 0 and 10 false positives and between 0 and 11 specimens that would require laboratory follow-up in the study population (n=4518 tests) with a prevalence of nearly 5%. In lower prevalence (p) settings the predictive value positive (PV+) of a single test is decreased (PV+=88% at p=1% to PV+=43% at p= 0.1%.) In these settings a three test strategy which classifies persons with negative second and third tests as uninfected is the only way to resolve the majority of initially reactive specimens at POC.

CONCLUSIONS

All of the strategies evaluated appear to be adequate for identifying persons likely to be HIV-infected and those that are likely uninfected. The decision of which tests to use in which strategy may be based largely on other factors such as the setting in which testing is conducted, prevalence of HIV in the population to be tested, and cost.