PB50 Testing for HIV: Field performance of two rapid tests in a South African population

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ABSTRACT TEXT

Background:

Rapid HIV testing is convenient for both clients and service providers. The sensitivity and specificity of rapid HIV tests is considered to be high. However, there has been concern over the high rate of false positive results from certain tests in selected populations in Africa.

Methods:

1089 women were counselled and tested for HIV, as part of screening procedures prior to entry into a feasibility study. Enrolled participants were followed up for 12 months, and counseled and tested at quarterly visits. Trained research nurses collected whole blood from participants through either finger prick or venous sampling. Rapid tests were performed in parallel in the study clinic, using either Determine [™] HIV1/2 (Abbott Laboratories) or Uni-Gold[™] Recombigen ® HIV (Trinity Biotech). Quality control was performed on the first 200 samples, as well as on a 10% sample of all specimens tested during the study, which were sent to a laboratory for confirmation by HIV ELISA.

Results:

For this analysis, results were available for 766 specimens tested with Determine, 557 tested with Uni-gold and 811 confirmatory HIV ELISA results. HIV prevalence was 27% by Determine, 32% by Uni-gold and 30% by HIV ELISA. There were 13 discordant HIV rapid test results, which were resolved by HIV ELISA: all but one of these cases was positive on Determine, but negative on Uni-gold. The Determine results were confirmed by HIV ELISA in all but one case. Concordant false positive results were detected in 3 cases. Concordant false negative results were detected in 20 cases.

Table 1. Sensitivity, specificity and positive predictive value			
	Sensitivity %	Specificity %	Positive predictive value %
Determine	91%	99%	98%
Uni-gold	85%	99%	98%

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Conclusion:

In our setting, specificity of HIV rapid tests was high. Lower than expected sensitivity in the field may be related to challenges in performing and interpreting tests. All three false positive results were identified early on in the study, when staff was inexperienced. The high number of concordant false negatives may have been due to a problem with the test, or problems with interpreting results. Quality control programs remain a key element of HIV rapid testing programs.

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