Ability of Untrained Users to Perform Rapid HIV Antibody Screening Tests

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Revised Abstract

Background: One-step rapid HIV antibody tests suitable for point-of-care testing offer many advantages if they can be performed in outreach settings by persons with minimal training.

Purpose: To evaluate whether persons with no laboratory experience can successfully perform a rapid HIV test.

Methods: In the first phase of a multi-part prospective study Health care workers (including HIV counselors) without laboratory experience performed the OraQuick Rapid HIV Antibody test on specimens previously tested with EIA and Western blot after reading only the written instructions from the manufacturer. In the second phase, a similar cohort of participants (without laboratory experience) each conducted OraQuick on a panel of 4 specimens of known HIV status (including negative, strong- and weak- positive specimens) again using only written instructions. For both phases, performing the test correctly and recording a result that matched the known serostatus of the sample was considered successful completion of the test. Potential covariates, such as occupation and comfort with performing the test, were collected via questionnaire.

Results: The 259 participants performed 943 rapid tests. Eighty-seven tests (11%) were performed incorrectly and yielded no result. Of the remaining 856 tests, participants obtained the correct result on 827 (96.6%). Excluding tests with no result, participants obtained 220 (96.1%) correct results with strong positive specimens, 463 (97.3%) with negative specimens, and 144 (95.4%) with a weak positive specimen. Stratified analyses showed consistent results across study sites and participant characteristics.

Conclusions: Overall, untrained participants obtained a correct result on 96.6% of all Oraquick tests. By comparison, the Clinical Laboratory Improvement Amendments (CLIA) requires trained laboratory technicians to achieve an overall testing score of 80% correct on proficiency testing.

Background

- Simple Rapid HIV tests can dramatically increase availability of HIV testing:
  - Outreach to high risk groups
  - Emergency department screening
  - Point-of-care testing at clinics and in physicians' offices
- The Clinical Laboratory Improvement Amendments of 1988 (CLIA) require that trained laboratory workers achieve a proficiency score of 80% or better on laboratory tests.
- It is not known whether inexperienced persons without training can achieve this level of proficiency with a simple rapid HIV antibody test.

Purpose

- To evaluate how well untrained persons with no laboratory experience can perform a simple rapid HIV antibody test.

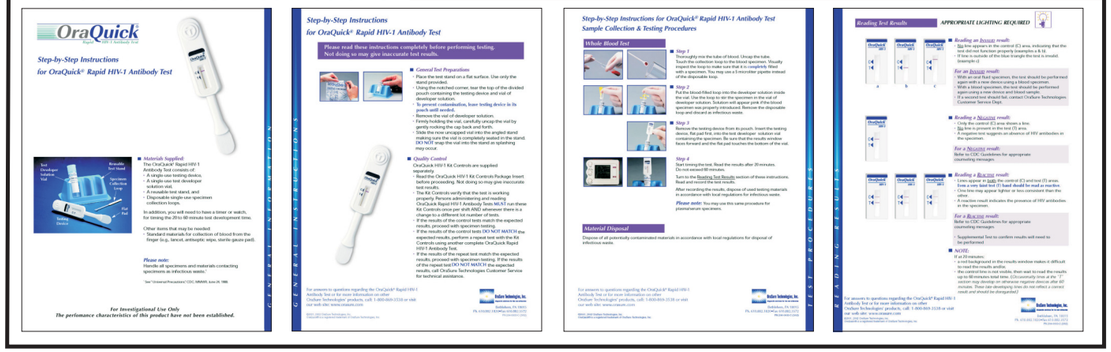
Methods

- The study was conducted in two phases; for both:
  - Health care workers (including HIV counselors,) with NO laboratory experience were recruited to perform the OraQuick Rapid HIV Antibody test after reading only the manufacturer's written instructions
  - Successful completion of the test required:
    1) Performing the test correctly, and
    2) Obtaining a result that matched the known HIV status of the specimen.
  - Potential covariates, such as occupation, education level, and comfort with performing the test, were collected via questionnaire

- Phase 1:
  - Participants recruited at an STD clinic and an HIV testing site in Los Angeles, CA
  - OraQuick Rapid HIV-1 Antibody testing was performed on stored patient sera previously tested with EIA and, if positive, a confirmatory Western blot.
- Phase 2:
  - Participants recruited at an STD clinic in Phoenix and at hospitals in Atlanta, Chicago (3), Miami, New Orleans and New York City.
  - Testing was conducted on a panel of 4 plasma specimens constructed to include negative, strong positive, and weak positive specimens.

- Tests that were performed incorrectly for which a result of "invalid" was recorded were tabulated, but not counted as incorrect, (because no erroneous result would have been given to the patient).
- Calculation of correct or incorrect results includes only those tests that produced a result that would have been given to a patient

Manufacturer's instructions



Results

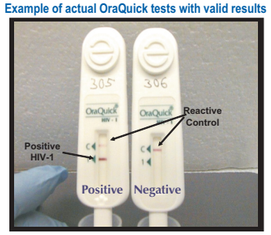
Most untrained, inexperienced users achieved a proficiency score considerably higher than 80%.

Characteristics of Untrained Users

- **The level of accuracy was independent of all measured covariates, including gender, education and occupation**

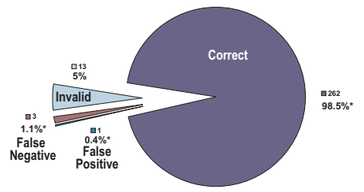
Gender	Number of Tests	Percentage of Correct tests
Male	280	94.64%
Female	571	97.72%
Schooling		
Less than High School	17	100.0%
Some College	165	95.76%
Completed college	177	97.18%
1 or 2 years of Graduate Studies	272	95.96%
More than 2 years of Graduate work	220	98.18%
Occupation		
Administrator	73	93.15%
Administrative assistant/clerical	28	100.0%
Community Outreach/Counseling	81	96.30%
Doctor	146	94.52%
HIV Counselor	87	97.70%
Health Educator	44	95.45%
Midwife	50	94.00%
Nurse	156	95.08%
Other Clinical	68	100.0%
Other research	71	97.18%
Volunteer/student worker	11	100.0%

Example of actual OraQuick tests with valid results



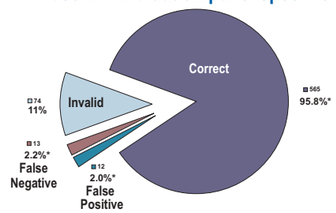
Proficiency Testing

Phase 1– Patient specimens



*Percentage of correct results obtained, does not include 13 "invalid" test results.

Phase 2 – Evaluation panel specimens



*Percentage of correct results obtained, does not include 74 "invalid" test results.

Invalid: Test performed incorrectly, Invalid test result recorded.

Correct: Of the tests performed correctly, results recorded that matched the correct status of the sample

False Positive : Negative specimens misclassified as positive

False Negative: Positive specimens misclassified as negative

- Overall, untrained, inexperienced persons obtained a correct result on 827 (96.6%) of 856 OraQuick rapid tests after reading only the written instructions provided by the manufacturer.

Some ways tests were performed incorrectly:

- Did not completely fill specimen collection loop
- Applied specimen to strip
- Poured entire specimen into developer vial
- Dipped device in developer and then removed it

Participant feedback

How confident are you in your ability to perform these tests?	Prior to conducting the test N (%)	After performing the tests N (%)
Very Confident	112 (44%)	202 (81%)
Somewhat Confident	109 (43%)	40 (16%)
Not Very Confident	28 (11%)	6 (2%)
Not Confident at All	4 (2%)	2 (1%)

What type of additional training, if any, would you have liked to have had before using this test?*	N(%)
No additional training needed	111 (43%)
Video Tape Demonstration	74 (29%)
Demonstration in person by a laboratory worker	86 (33%)
More Detailed Written Instructions	9 (3%)

*Participants could request multiple different types of additional training, thus the categories are not mutually exclusive

Conclusions

- Inexperienced, untrained persons who performed the OraQuick rapid HIV-1 antibody test obtained proficiency scores considerabley higher than the 80% required by CLIA of trained laboratory workers.
- 5% and 11% of tests were performed incorrectly in Phase 1 and Phase 2, respectively. Consistent with the design of the device, these tests produced a result of "Invalid", rather than an erroneous result that might have been given to a patient.
- Further studies are underway to assess what instructional material or training is necessary to eliminate incorrectly performed tests and improve accuracy of reported results.

For questions or comments please contact:
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