

Quality assurance monitoring, the lynchpin of rapid HIV screening in 10 publicly funded New York City sexually transmitted disease clinics, NYC, January, 2004

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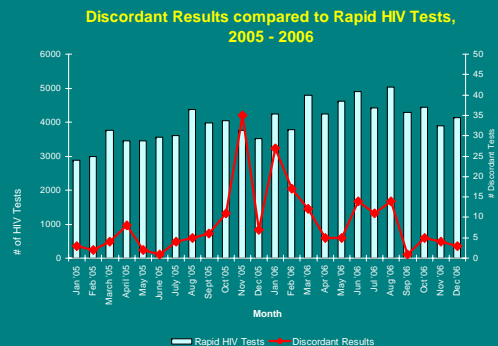
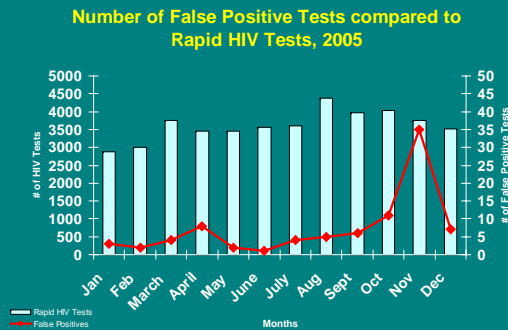
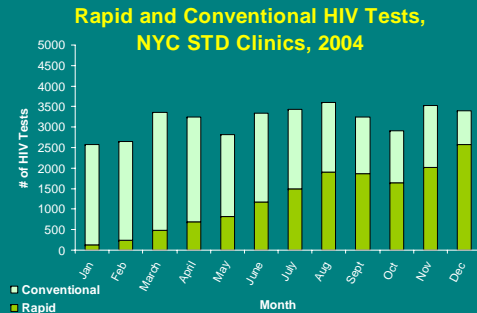
PROJECT

- The New York City Department of Health and Mental Hygiene's Bureau of Sexually Transmitted Disease Control (NYCDOHMH BSTDC) operates 10 STD clinics throughout New York City.
 - Services are free and offered to individuals 12 years and older, without parental consent, proof of insurance or citizenship.
 - Irrespective of chief complaint, all patients are offered HIV testing and counseling (confidential or anonymous).
- Approximately 500 cases of HIV are diagnosed annually in BSTDC STD clinics.
- In January of 2004, BSTDC implemented the OraQuick Advance Rapid HIV-1/2 Antibody test
 - HIV test results are provided within 20 minutes of specimen collection.
- OraQuick Advance Rapid HIV-1/2 Antibody test provides either a final negative result or a preliminary positive result (confirmed via Western Blot testing at the NYC Public Health Laboratory).

ISSUE

- Operational issues were addressed prior to implementing OraQuick Advance Rapid HIV-1/2 Antibody testing in the clinics
 - Developed Rapid HIV testing protocols for staff and laboratory permits
 - Re-engineered clinic workflows to accommodate high volume testing
 - Trained and re-assigned staff to conduct testing, as conventional EIA screening had been previously performed in a reference laboratory
 - Customized patient materials and pre/post test counseling messages for Rapid HIV testing
 - Instructed staff to monitor and report unexpected results (e.g. preliminary positive, followed by western blot negative).
- A monthly average of 5 false-positives per 3900 tests was established as the false-positive baseline.
- A false-positive cluster was identified by BSTDC STD clinic staff in November, 2005.

RESULTS



- Prior to the introduction of OraQuick Advance Rapid HIV-1/2 Antibody test (January, 2004), BSTDC performed approximately 33,000 HIV tests annually.
- During the roll-out of rapid testing, 38,297 HIV tests were conducted, of these 15,047 were rapid tests.
- In January of 2004, BSTDC implemented the OraQuick Advance Rapid HIV-1/2 Antibody test
 - Rapid testing continued to increase HIV testing volumes in BSTDC STD clinics.
 - During November, 2005 a cluster of false-positive (preliminary-positive OraQuick, Western Blot negative) tests was detected.
 - Quality assurance monitoring data gathered over the next two months showed a decline in test specificity.
 - 35 false-positive tests/3,753 tests (test specificity 99.07%; below the lower limit of FDA and manufacturer's specificity level of 99.8 (95% CI: 99.6%-99.9%)).
 - A monthly average of 5 false-positives per 3900 tests was observed as the false-positive baseline.
- BSTDC took immediate actions to identify the source and modify practices in BSTDC STD clinics.
- Investigations showed no correlation between false-positive tests and kit lots, storage temperatures, or test processing.
 - BSTDC implemented immediate repeat testing using whole-blood (finger-stick) on all preliminary-positive OraQuick specimens.
 - Immediate counseling messages were adjusted based on the second test result.
- By December 10th 2005, the number of false-positive tests returned to acceptable levels (81/47,204 rapid tests; test specificity 99.82%).

LESSONS LEARNED

- Aggressive quality assurance monitoring and good communication enabled BSTDC to preserve the capacity to offer rapid oral-fluid testing.
- BSTDC adapted policy and protocols for rapid HIV testing.
 - BSTDC STD clinics follow all preliminary-positive cases with a whole-blood (finger-stick) rapid HIV test.
 - Regardless, of the results of the second rapid HIV test (whole-blood), Western Blot testing is still conducted.
- BSTDC's ability to offer additional rapid whole-blood (finger-stick) HIV testing restored confidence in rapid oral-fluid test technology for staff and patients.
- Rapid oral-fluid HIV testing continues to increase HIV testing volumes in BSTDC STD clinics.
- BSTDC STD continues to monitor oral-fluid rapid testing.
 - Monthly data runs are created each month to highlight discordant HIV test results.
 - Clinic staff is required to report discordances in HIV test results in BSTDC STD clinics.

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