Implementation of Rapid HIV Testing at Publicly Funded Counseling and Testing Sites in New Jersey

Evan M Cadoff, MD[1], Sindy M Paul, MD, MPH[2], Franchesca N Jackson[1], Maureen Wolski[2], Lorhetta Nichol[2], Rhonda Williams[2], Karen Stralkus, RN[1], Gratian Salaru, MD[1], Eugene G Martin, PhD[1]

[1]Robert Wood Johnson Medical School, New Brunswick, New Jersey, and [2]New Jersey Department of Health and Senior Services, Trenton, New Jersey

ABSTRACT

Background/Objective: Efforts by public health authorities to control the spread of HIV in the United States have been frustrated by the inability to provide HIV testing and results in a single client encounter. The New Jersey Department of Health and Senior Services, Division of HIV/AIDS Services (DHAS) funds Counseling and Testing Sites (CTS) that provide free, confidential HIV testing. The CTS sites employ state-trained HIV counselors with no laboratory background. During 2002, approximately 35% of over 70,000 clients visiting these CTS centers did not receive their results because they failed to return for a scheduled follow-up visit. Recently, the FDA approved the first CLIA waived, rapid (fingerstick) point-of-care test for HIV (OraQuick® Rapid HIV-1 Antibody test, OraSure Technologies, Inc., Bethlehem, PA). With point-of-care testing (POCT) testing, it is hoped that nearly 100% of clients will receive their results, appropriate counseling, and immediate referral for care and treatment, if needed. FDA approval included a contingency that mandated a Quality Assurance program be in place before testing is offered. In New Jersey, state licensure is also required. In September 2003, DHAS and UMDNJ-Robert Wood Johnson Medical School (RWJMS) started to set up a program to bring POCT to the CTS sites using OraQuick. Specific objectives were 1) to implement a program that included appropriate quality assurance safeguards, and 2) to bring to near 100%, the percentage of clients who receive their test results.

Methods: By expanding on the existing multi-facility POCT program at RWJMS, a statewide implementation plan was developed, consistent with the CDC's quality assurance guidelines (www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm), state regulations, and accepted standards of laboratory medicine. The program is managed centrally by a state licensed and board certified pathologist. A centralized core staff of clinical laboratorians are responsible for: development of uniform policies and procedures, staff training and re-certification, reagent inventory control and validation, standardization and validation of equipment, review of mandated and supplemental proficiency testing, bulk management of lab supplies, and a core communication hub (www.njhiv.org). The core staff monitors compliance with key policies using an A,B,C,D,F grading scale, and works with site coordinators to improve compliance.

Results: Under this program, OraQuick® HIV testing began in November, 2003, at the New Brunswick CTS. Using the "Plan, Do, Check, Act" Performance Improvement model, procedures were modified and then rolled out to 14 additional sites. Further expansion has brought the program to over 50 satellite locations, with at least 150 sites expected by the end of 2005. Compliance with quality assurance procedures has resulted in fully meeting CLIA standards. External proficiency test performance has been at 100%. Grades for compliance with other procedures not required by CLIA, such as evidence of regular review of records by site coordinators and documentation of corrective action, have shown a decrease in 'Fs' and an increase in 'As' over time. Of the first 8,000 clients tested under this program, 99.9% have received their HIV test results.

Conclusions: Based on the success of rapid testing thus far, DHAS plans to expand rapid testing to 179 publicly funded counseling and testing sites statewide.

INTRODUCTION

- New Jersey is a high prevalence state:
  - 5th in the US in cumulative reported AIDS cases,
  - 3rd in cumulative reported pediatric AIDS cases, and
  - 1st in the proportion of women with AIDS among its cumulative reported AIDS cases.
- It is estimated that undiagnosed and unreported cases amount to approximately one third of all estimated infections, or about 700 unreported cases per year in New Jersey.
- Approximately 65,000 HIV tests are performed at publicly funded counseling and testing sites annually in New Jersey. In 2003,
  - only 65% of persons tested received their results,
  - 2.6% of persons tested had positive results,
  - only 1/3 of positive results were newly diagnosed cases, and
  - 1/4 of new cases in the state were detected through CTS sites.
- To improve the proportion of high risk persons tested for HIV and to increase the proportion of people who learn their test result, the New Jersey Department of Health and Senior Services Division of HIV/AIDS Services (NJDHSS DHAS) sought to provide rapid HIV testing at publicly funded counseling and testing sites using OraQuick®.

METHODS

- The RWJMS Department of Pathology and Laboratory Medicine had an established Point of Care Testing (POCT) program, as shown by the blue triangles in Figure 1.
- In September, 2003, the NJDHSS DHAS and RWJMS started to set up OraQuick® Rapid HIV testing at CTS sites statewide based on the RWJMS POCT program.

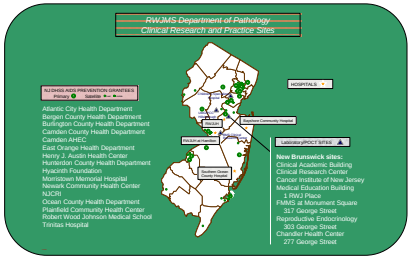

Figure 1. RWJMS Pathology clinical sites

- A Quality Assurance (QA) plan was put in place, conforming to the following requirements:
  - All sites are accountable to a strong central administration under the direction of a New Jersey licensed Pathologist laboratory director. Sites are visited, and their compliance evaluated, monthly by a qualified medical technologist.
  - Each site operates under a New Jersey laboratory license.
  - Proficiency testing is in place for each site, using the CAP's RHIV survey and the CDC's MPEP program.
  - An on-site coordinator is responsible for QA compliance at each site.
  - Sites are registers with a single CLIA certificate of waiver, under the multiple site public health provision.
  - The Quality Assurance plan meets the characteristics of the CDC QA guidelines for OraQuick testing, and state laboratory regulations.
  - All testing staff meet CLIA requirements for moderate complexity testing. None have prior laboratory training or experience.

Elements of the NJHIV Quality Assurance Plan:

- Centralized, uniform policies and procedures
- Competency assessment and operator certification
- Proficiency testing
- Centralized reagent validation and inventory control
- Temperature control and temperature logs
- Quality control
- Uniform test records (Patient, QC, PT)
- Monitoring of preliminary positive results
- On-site supervisor review of CTS records
- Central review of CTS records
- Core communication hub at www.njhiv.org
- On-site compliance review by central RWJMS staff

Figure 2. The QA plan

- Compliance with the quality assurance plan is monitored at each site by the program coordinator, and on a monthly basis by Technologist staff from RWJMS.
  - Each site's performance on seven key elements of the quality assurance plan is graded by the Technologist at each visit, using a letter grade scale.
  - Grades below A require remediation.
  - Grades below C require immediate corrective action, with the assistance of the NJDHSS Program Management Officer.

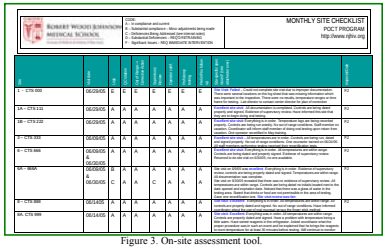

Figure 3. On-site assessment tool.

RESULTS

- Sites that have been licensed to performing testing in this program include:
  - State funded sites which provide confidential or anonymous, free HIV counseling and testing
  - Federally Qualified Health Centers
  - Hospital Emergency Departments
  - STD clinics
  - Family planning centers
  - Prenatal care programs
  - Community Base Organizations and their outreach efforts
  - One-day, one-time health fairs
  - Mobile vans
- Plans are underway for outreach workers to transport reagents in temperature monitored coolers, and test clients in the field.
- Testing began at the RWJMS CTS site on November 1, 2003. Current licenses, shown in green in Figure 1, include
  - 16 primary CTS sites and
  - 33 licensed satellite locations, including:
    - 7 mobile vans
    - 5 hospital Emergency Departments
    - over 80 individual CTS testing venues.
- Quality Assurance compliance is depicted in Figures 3 and 4.
  - All sites but one have shown improvement in QA compliance scores
  - When Supervisor Oversight is graded A, compliance score is usually 4.0
  - For the one site with low initial scores, the start of testing was delayed until compliance improved
  - One site had deteriorating performance . Continuation of OraQuick® testing is in jeopardy

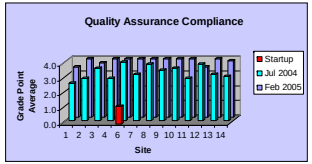

Figure 4. QA Compliance scores

- Through March 2005, for all rapid testing sites in New Jersey:
  - 15,733 rapid tests were done,
  - 99.8% of clients received their test results,
  - 359 (2.3%) were positive,
  - 216 of the positives (60%) were newly diagnosed as positive, and
  - 7 positive OraQuick® results (0.04%) were negative on confirmatory testing. All of these false positive OraQuick® results were reproducible by laboratory personnel.

CONCLUSIONS

- Rapid HIV testing has been successfully implemented at publicly funded counseling and testing sites in New Jersey, with over 80 counselors with no prior laboratory training performing testing at over 80 CTS sites—including hospital Emergency Departments.
- Quality assurance compliance grades have improved with the monitoring tool, and are in compliance with CLIA and state regulations. Adequate supervisor review is essential for full compliance.
- Rapid testing identified more previously undiagnosed persons than had been detected with conventional testing, increasing from 1/3 to 59%.
- The percentage of persons receiving test results and post-test counseling increased from 65% prior to rapid testing to 99.8% with rapid testing.
- Based on the success of rapid testing thus far, New Jersey has begun to expand rapid testing to about 200 publicly funded counseling and testing sites. Outreach workers in the field will begin OraQuick® testing once temperature monitoring can be assured.