From 2nd to 4th Generation Rapid HIV Screening: ‘Rolling-Out' an Enhanced HIV Screening & Linkage Algorithm in New Jersey

ABSTRAT ID: 15
Session F: Performance of CLIA waived HIV Tests

EG Martin[1]*, SM Paul[2,], J Corbo[1], G Salaru[1], and E Saunders[3]

1 Rutgers– Robert Wood Johnson Medical School, Somerset, NJ
[2] New Jersey Division of Consumer Affairs – Board of Medical Examiners, Trenton, NJ
[3] New Jersey State Department of Health, Division of HIV, STD & TB Services, Trenton, NJ

INTRODUCTION

Following CLIA-waiver in December, 2014, NJ began statewide roll-out of the 4th generation rapid Alere Determine™ HIV- 1/2 Ag/Ab Combo (DC), eventually expanded screening to 166 state-funded rapid HIV screening sites. A rapid testing & linkage strategy was implemented at many of these sites to expedite linkage into care and to follow-up on possible discordant results expeditiously.

THE ISSUES

It’s not just a question of how sensitive a test is… it’s also a question of how often we test clients, how effectively we link those who are infected into care, and how well we retain clients in care and treatment.

In use since 2011, the NJ rapid testing algorithm (NJ - RTA), utilizes *orthogonal testing* i.e., independent verification of an initial antibody result by a second, but different HIV rapid test to confirm initial HIV screening results.

FDA approval of a 4th generation test (DC) that detects both HIV-1/2 antibodies and the HIV-1 p24 antigen, offers the *potential* of earlier detection that could improve screening performance, but complicates the issue of confirmation and linkage because it relies upon p24 Ag detection as an indication of recent infection

PLANNING FOR LINKAGE

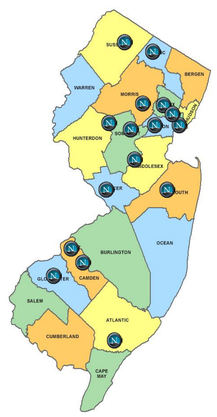
In each of the twenty-one New Jersey counties including both Ryan White (RW) Part A Transitional Grant Areas (TGAs), RW Part A Eligible Metropolitan Areas (EMAs) and Part B Planning regions collaborative groups were established. Additionally, collaboration were expanded to include Federally Qualified Health Care center (FQHCs) and community clinics.

An HIV Specialty Care Clinic or Hospital was designated as the clinical centerpiece. Because sites share a common set of testing policies and procedures, screening could be tailored to experience, frequency of positive events and abilities to provide on-site linkage into a care environment.

To address agencies that only rarely experience a single rapid positive test or discover an out of care client we developed a Rapid-to-Rapid (R2R) option allowing CBOs and non clinical testing sites to facilitate immediate linkage into care and actively encouraged re-engagement with their partnering medical sites.

SPECIALTY CARE LOCATIONS

AtlantiCare Medical Center, [Atlantic City] Atlantic and Cape May Counties
Cooper University Hospital, [Camden], Camden, Burlington, Gloucester & Salem Counties
Henry J. Austin Health Center, [Mercer]
Jersey Shore Medical Center, [Neptune], Monmouth & Northern Ocean Counties
Jersey City Medical Center, [Jersey City], Hudson County
Kennedy EIP Clinic, [Camden] Burlington, Gloucester, Cumberland **and Salem Counties**
Rutgers – NJ Medical School, [Newark], Essex County
St. Michael’s Medical Center, [Newark], Essex County
St. Joseph’s Medical Center, [Paterson], Bergen & Passaic Counties
Trinitas Medical Center, [Elizabeth], Union County
Rutgers – RWJ Medical School, Eric B Chandler Health Ctr., [New Brunswick] Middlesex County
Morristown Medical Center, [Morristown], Morris County
Zufall Health Center, [Dover], Morris, Sussex, & Warren Counties
Zufall Health Center, [Somerset], Somerset & Hunterdon Counties



WHY USE A RAPID TEST ALGORITHM?

The use of the (RTA) was pioneered in New Jersey alongside mandatory HIV-1 Western blot confirmation. We were among the first jurisdictions to employ a two-test RTA and to identify the potential value in shorting linkage delays.

Following rapid-HIV Western blot screening, only 50.6% of 1,997 positive screens were linked within 30 days, compared with RTA linkage through 2014 in which 71.2% were linked within 30 days and 90.1% were linked overall. In order to expedite linkage we needed to identify *presumptive positives* and move them rapidly into care.

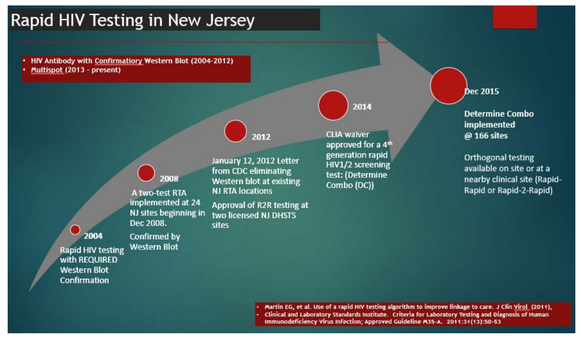
While waiting FDA approval of a more sensitive rapid device, we expanded our RTA system to a total of 39 sites, capable of providing, on-site, a two test RTA and validated additional methods capable of delivering a presumptive result within hours, namely: the Rapid-2-Rapid model. This additional strategy dramatically expanded the ability to provide HIV screening at multiple venues, while providing confirmed results and linkage to care

New Jersey Rapid HIV Testing

102 RWJ sites – 88 sites plus 14 mobile vans
64 Non-RWJ sites – Hospitals, etc.
Total sites: 166

~~**83 are Rapid-Rapid Testing sites (incl. Mobile Vans)**~~
83 sites perform a single Rapid test and verify by a Rapid-2-Rapid (Confirmation & Linkage) strategy

Venues:
COMMUNITY BASED ORGANIZATIONS: 18
MOBILE VANS: 11
CORRECTIONS: 4
FQHC: 24
MOBILE VANS: 1
HEALTH DEPARTMENTS: 18
MOBILE VANS: 4
UNIVERSITY: 4
HOSPITALS: 8
FAMILY PLANNING: 17 - non-RWJMS licensure
ADDICTIONS: 21 Sites: 2 mobile counselors



THE DEVIL IS IN THE DETAILS!

The promise of a Point-of-Care device that would allow rapid screening facilities to identify acutely infected individuals and potentially bring them into care was attractive:

- Optimists thought this might happen as early as 2012!
- In 2010, two of our licensed clinical sites participated in the original FDA submission serving as ‘low prevalence’ sites providing data for the initial submission
  - Henry J. Austin – Trenton, NJ
  - Neighborhood Health – Plainfield, NJ
- This initial contact allowed our medical technologists and scientists to gain experience with the product as the company envisioned it and to begin to think about potential implementation issues and training requirements.

FDA APPROVAL 2013

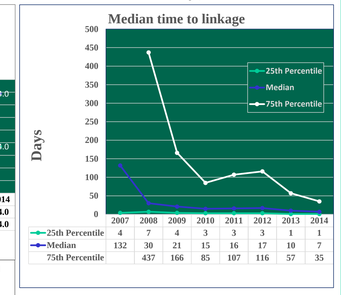
- FDA Approval (CLIA Moderate Complexity) – August 13, 2013
- The absence of waiver limited our ability to employ the 4th generation rapid HIV test as a screening test in the majority of our screening locations – most sites are CLIA waived, but NJ CLIS licensed locations.
- In the fall of 2013, we piloted the product in one of our CLIA moderate complexity sites in Newark: NJCRI and followed use of the product for the next several months as an initial screening device in the NJ Rapid Test Algorithm
  - Performance on standard, required Quality Control
    - QC Issues: No significant increase in QC failures
  - Performance Issues: Increase in ‘Discordant Results’, but not enormous

“Waiting for Godot” – CLIA WAIVER

- For a variety of reasons, FDA Approval (CLIA Waived) did not occur until December 9, 2014
- The decision to seek CLIA WAIVER after initial product resulted in significant delay and changes in the product that was eventually entered distribution
- Many of the required changes resulted in significant changes to planned policies and procedures
- Nevertheless, we began to transition in January, 2015.

Cumulative percentage Linked to Medical Care ≤ 30 and ≤ 90 days

	2007	2008	2009	2010	2011	2012	2013	2014
<=90	47.0	63.8	69.4	75.6	74.5	72.5	79.3	84.0
<=30	35.2	50.1	56.8	63.0	62.2	59.8	66.7	74.0



	2007	2008	2009	2010	2011	2012	2013	2014
25th Percentile	4	7	4	3	3	3	1	1
Median	132	30	21	15	16	17	10	7
75th Percentile		437	166	85	107	116	57	35

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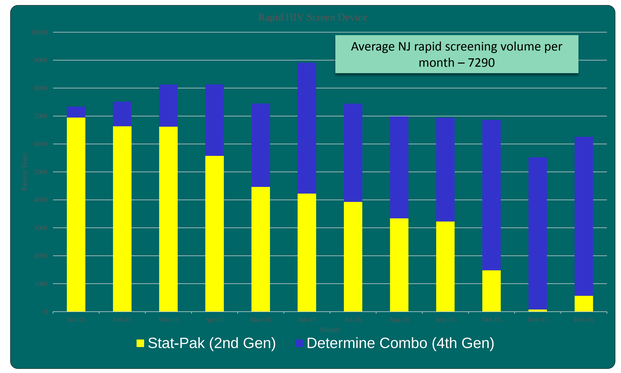
Roll-Out of Determine Combo



PRODUCT	Volume (2015)	PREL. POS	Seropre valence
StatPak	47,091	366	0.75%
Determine	40,391	352	0.78%

- DISCORDANT SUMMARY - 2015

Clearview StatPak

	Marker	Frequency	Notes
True POS			
	TP/FN UG	1	
True POS			TOTAL: 1
False POS	FP Ab	10	
	FP Both Rapids	2	
False POS			TOTAL: **12**

Determine Combo HIV1/2 p24Ag

	Marker	Frequency	Notes
True POS			
True POS	P24 Ag +	1	>10 Million
	TP/FN UG	6	
True POS			TOTAL: 7
False POS	FP Ab	25	
	FP Ag	11	
	FP Ag/Ab	5	
	FP Both Rapids	1	
False POS			TOTAL: **41**

CONCLUSIONS:

1. NJ has established a statewide, collaborative linkage program designed to provide HIV screening at many different venues, with credible verification of screen positives and linkage into care within 2 business days
2. We have adapted an existing two test RTA for use with a 4th generation screening assay
3. We have transitioned throughout NJ rapid HIV screening from a 2nd generation screening device to a newly, FDA waived, 4th generation screening device
4. We have analyzed discordant results from positive HIV screening using both devices and conclude that the p24Ag marker is responsible for a significant number of false positive referrals without substantial gain in number of infections being diagnosed
5. The six additional infections associated with a falsely negative Unigold *may* represent enhanced sensitivity of the Determine Combo device in detecting HIV1/2 antibodies.
6. Although the total of 41 falsely positive results remains within the manufacturer’s product claimed, it is problematic for many sites.

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