Real-time 4th Generation HIV Algorithm Implementation in the STD Clinic at the City of Milwaukee Health Department

Wisconsin Department of Health Services

Think Health Act Now! CITY OF MILWAUKEE HEALTH DEPARTMENT

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INTRODUCTION

The City of Milwaukee Health Department Laboratory (MHDL), Keenan Health Center STD Clinic (KHC), and the Wisconsin Division of Public Health AIDS/HIV Program (WDPH) implemented the CDC 4th generation (4th Gen) HIV testing algorithm (Figure 1). This will soon provide same-day confirmatory results and counseling for HIV positive patients.

MATERIALS AND METHODS

4th GENERATION HIV TESTING

Testing includes (Figure 1): HIV Antigen/Antibody enzyme immune assay (EIA) on the Architect 1000i system (Abbott, IL) to screen blood samples (serum/plasma) for p24 antigen and HIV 1/2 antibodies; Multispot assay (Bio-Rad, CA) for differentiation of HIV 1& 2 antibodies from reactive samples at MHDL; HIV 1-Proviral DNA PCR referral to the Wisconsin State Laboratory of Hygiene.

COLLABORATION

Over two years the MHDL worked with the WDPH to convert state support for the manual HIV rapid screening into support for the automated 4th Gen HIV testing (Figure 2).

RENOVATION

MHDL implemented several remodeling options for the KHC STD Lab in order to accommodate the Architect instrument. The KHC STD Lab was temporarily relocated during renovation.

CLINIC WORKFLOW OPTIMIZATION

Numerous planning and logistics meeting among local, state, clinic, lab and adminsitative staff resulted in detailed workflow analysis using LEAN tools (Figure 3.)

VALIDATION

326 serum or plasma specimens were analyzed to validate assay sensitivity and specificity (Tables 1 & 2).

RESULTS

- In late 2014 HIV Architect instrumentation and methodology was installed and validated at KHC STD Lab (Figure 2).
- Sensitivity and specificity was based on a 95 confidence internal (CI 95) (Tables 1 & 2).
- Several workflow inefficiencies were defined and removed in order to save 15 minutes from each patient's wait time, as a result of LEAN workflow analysis.
- As of May 2015, four HIV positive screened patients were confirmed within 24 hours of examination. This is compared to the 1-2 week turn-around-time associated with the prior system (Figure 4).

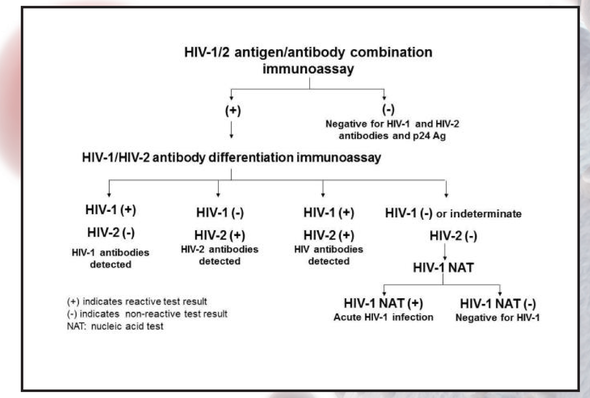

Figure 1. *Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens (MMWR 2014)*

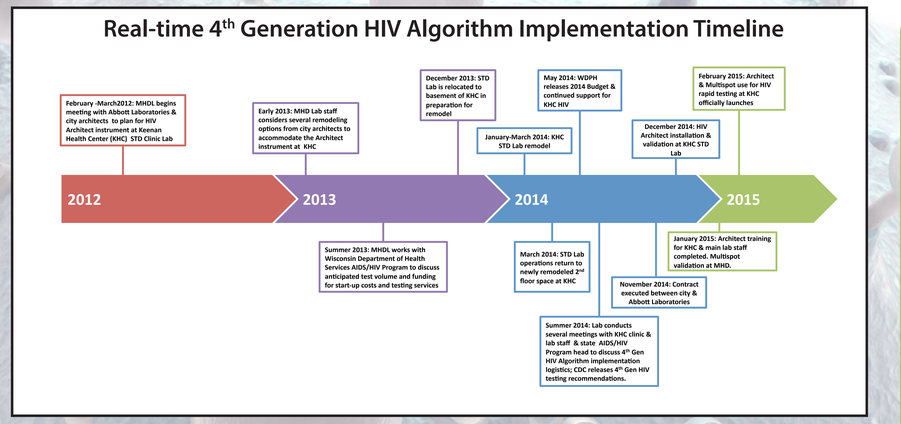

Figure 2. *Timeline for implementing 4th Gen HIV Testing Algorithm at MHD laboratory*

Table 1 *(Serum specimens)*

	Condition		
	Absent	Present	Totals
Test Positive	0	18	18
Test Negative	200	1	201
Totals	200	19	219

	Estimated Value	95% Confidence Interval	
		Lower Limit	Upper Limit
Prevalence	0.086758	0.054429	0.134184
Sensitivity	0.947368	0.718926	0.997246
Specificity	1	0.97651	1

PPV 100% (78 -100%); NPV 99.5% (96 - 100%)

Table 2 *(Plasma specimens)*

	Condition		
	Absent	Present	Totals
Test Positive	0	1	1
Test Negative	106	0	106
Totals	106	1	107

	Estimated Value	95% Confidence Interval	
		Lower Limit	Upper Limit
Prevalence	0.009346	0.000488	0.058479
Sensitivity	1	0.054621	1
Specificity	1	0.956416	1

PPV 100% (5 -100%); NPV 100% (95.6 - 100%)

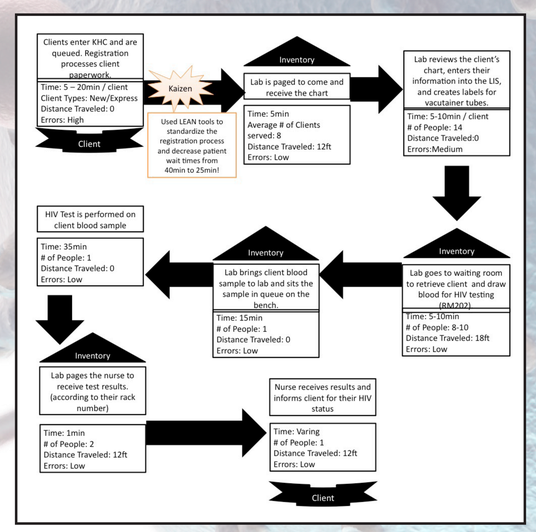

Figure 3. *Value Steam Mapping for KHC Workflow for HIV Client Services*

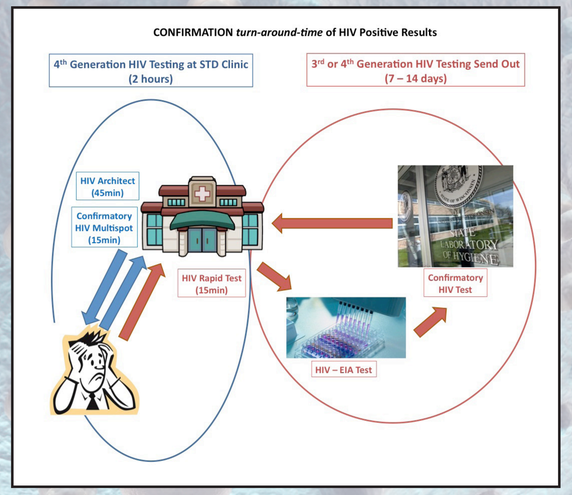

Figure 4. *Overall Impact on Process Improvement*

CONCLUSIONS

- Manual HIV rapid screening was replaced with the CDC 4th Gen HIV testing algorithm at the KHC STD Clinic for same day screening, typing, and confirmation.
- Turn-around-times for HIV screening , typing, and confirmation were improved from 1-2 weeks via outsourcing to the WSLH, to 1 day via in-house 4th Gen HIV testing.
- 4th Gen HIV testing improved and enhanced Milwaukee's local public health system's capacity for early detection and follow up of HIV cases. This improves clinician case management capabilities, and holds the promise of decreasing morbidity and mortality locally and statewide.

FUTURE DIRECTIONS

- 4th Gen HIV screening, typing and confirmation at the KHC STD Lab prior to client departure.
- Enhanced community capacity directed to KHC STD Lab.
- HIV 1 & 2 real-time PCR at MHDL.

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