Evaluation of the Implementation of the 4th Generation HIV Combo/Multispot Assay Algorithm in Alaska, a Low Prevalence HIV State

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ATLANTA, GA
Public Health in Alaska
Status of HIV in Alaska
Evaluation of 4th Gen. vs 3rd Gen. testing algorithms
Tech Time and Cost Analysis Comparisons
Turn Around Time Analysis
Performance of 4th Gen. algorithm
Alaska is HUGE!!!

- AK population in 2011 = 722,190
  - 296,197 in Anchorage
  - 97,615 in Fairbanks
  - 32,290 in Juneau
Public Health in Alaska

- Many villages off road system - limited access to health care
- Public Health Clinics staffed by traveling nurses and health aids are often the only health care available within hundreds of miles
- Health screenings and education is sporadic
- Alaska has high rates of alcoholism, IVDU, and Hepatitis C infection.
Alaska Public Health Labs

Alaska State Virology Lab (ASVL) in Fairbanks on UAF campus

- 2 PH labs in Alaska - both provide diagnostic and reference services:
  - Fairbanks
    - Immunology/Viral Serology
    - Molecular Virology
    - Viral Cell Culture
  - Anchorage
    - Bacteriology, TB Testing, Mycology
    - Toxicology, LRN BT & CT programs
- Receive specimens statewide from PH clinics, correctional facilities, private clinics, hospitals, and nursing homes
Demographics of HIV in Alaska

- Alaska is a low prevalence HIV state
- We screen about 12,000/yr.
- 1,458 reported cases from 1982-2011 (61 during 2011)
Percentage of HIV Cases by Race/Ethnicity, 1982-2011

- Asian/Pacific Islander 2% (n=34)
- African American 12% (n=169)
- Hispanic 8% (n=113)
- Multiple Race 1% (n=19)
- Alaska Native/American Indian 21% (n=304)
- White 56% (n=819)

Percentage of HIV Cases by Race Compared to the Racial Distribution of Alaska

- Asian/Pacific Islander: 2%
- African American: 12%
- Hispanic: 8%
- Multiple Race: 1%
- Alaska Native/American Indian: 21%
- White: 56%

Percentage in Alaska:

- AK HIV: 67%
- AK Population: 56%
% of HIV Cases by Exposure Category
1982 - 2011

- Men Having Sex with Men (n=708)
- Transfusion/Transplant (n=21)
- Heterosexual Contact (n=235)
- MSM/IVDU (n=117)
- IVDU (n=193)
- Unspecified (n=174)
- Perinatal (n=10)
Men 25-44 are the most affected

Number of HIV Cases by Age at Diagnosis, 1982-2011

- 0-14: 14
- 15-24: 209
- 25-34: 548
- 35-44: 456
- 45-54: 176
- 55-64: 41
- 65+: 14

Total Number of HIV Diagnoses
In 2011, 9 new HIV cases diagnosed in the Fairbanks area
- 8 were MSM (7 met partner on internet sex-seeking site)
- 7 in military or had sex partners in military
- 4 were ≤20 years
- 6 had NEG test w/in 13 months prior to diagnosis
HIV Changing in Alaska

- Heightened concern over increased transmission in Interior AK and within military population

- Average TAT of a Positive HIV with confirmation by WBT was 11.6 days.

- We patiently waited for FDA approval of the 4th gen EIA & endorsement of a new confirmation algorithm!
The Dawn of a New Day

- FDA approval of BioRad 4th Gen EIA in (we use EVOLIS analyzers)
- Recommendation of new algorithm by CDC and APHL
- We were set to go – validated tests, trained employees and notified providers of our change in testing

Fairbanks winter sunrise on the Chena River
But...We underestimated the slow TAT for NAAT tests

- Factors leading to slow TAT:
  - More stringent requirements for specimen type (plasma) and age (<72hrs old)
  - Scheduling shipping to UW for timely receipt
  - Logistical problems for patients getting re-drawn
  - Specimen transfer issues
  - Some providers not prepared to collect plasma
Were Things Better Than Before?

P24 Ag-only Positives and False Positives

Conducted Comparative Analysis

- Analyzed impact of implementing the 4th Gen./differentiation algorithm on Public Health system in Alaska
- Compare tech time, cost, and result turn around time to 3rd generation/WB algorithm
- 98 patient and validation specimens
### 3rd and 4th Gen Algorithms

<table>
<thead>
<tr>
<th>Western Blot Confirmation</th>
<th>Multispot Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Screen on HIV-1/-2 Plus O EIA</td>
<td>• Screen with Ag/Ab Combo EIA</td>
</tr>
<tr>
<td>• Repeat in Duplicate</td>
<td>• Repeat in Duplicate</td>
</tr>
<tr>
<td>• Ship to UW for Western Blot confirmation</td>
<td>• Confirm on Multispot</td>
</tr>
<tr>
<td></td>
<td>• Negative Multispot - sent to UW for PCR confirmation</td>
</tr>
</tbody>
</table>
Results: Tech Time

- No significant change in technician time required for either algorithm for Positive Ab specimens

- Considered time it takes to perform the Multispot (22m) vs time it takes to pack and ship specimen for WB (20m)

- PCR confirmation doubled tech time (42m) (perform Multispot and ship specimen out)
Results: $$$

- **HIV 4\(^{th}\) Gen Reagent**  
  Cost = $3.23 per patient (PP)

- **HIV 3\(^{rd}\) Gen Reagent**  
  Cost = $2.70 PP

- **Multispot** = $45 PP

- **Western Blot** = $185\(^*\) PP

- **HIV RNA** = $257.78\(^*\) PP

\(^*\)including shipping costs
## Results: Turn-Around Time

**Western Blot vs. Multispot Algorithm Time Frames**

<table>
<thead>
<tr>
<th>3rd Gen/Western Blot</th>
<th>4th Gen/Multispot</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Day</strong></td>
<td><strong>Action</strong></td>
</tr>
<tr>
<td>Day 0</td>
<td>Receive Specimen</td>
</tr>
<tr>
<td>Day 1</td>
<td>Screen with HIV-1/-2 Plus O</td>
</tr>
<tr>
<td>Day 2</td>
<td>Repeat in Duplicate</td>
</tr>
<tr>
<td>Day 3</td>
<td>Ship to UW</td>
</tr>
<tr>
<td>Day 4</td>
<td>UW Receives Specimen</td>
</tr>
<tr>
<td>Day 5-??</td>
<td>UW tests specimen</td>
</tr>
<tr>
<td>Day 8-17</td>
<td>Results Reported</td>
</tr>
<tr>
<td>??? (12-25d)</td>
<td>PCR Results from UW</td>
</tr>
</tbody>
</table>
Results: Turn-Around Time

Confirmatory Result Average TAT for Repeat Reactive HIV EIA Specimens

<table>
<thead>
<tr>
<th>Confirmation Test Performed /Result</th>
<th>Average No. of Days (Specimen Receipt to Final Result)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multispot/Pos</td>
<td>1</td>
</tr>
<tr>
<td>Multispot/Neg; NAAT Pos or Neg</td>
<td>16</td>
</tr>
<tr>
<td>Western Blot/Pos</td>
<td>9</td>
</tr>
<tr>
<td>Western Blot/Neg</td>
<td>8</td>
</tr>
<tr>
<td>Western Blot/Indeterminate</td>
<td>12</td>
</tr>
</tbody>
</table>
Multispot Negative/PCR TAT

- Positive EIA/Negative Multispot = longest TAT (17d average)

- Two patients since inception of algorithm
  - 31 yo female from Fairbanks = 13d
  - 17 yo male from Ketchikan= 22d

- Fortuitous for this study: Represent best and worst case scenarios

Ketchikan, AK
Conclusions

- HIV testing cost and TAT vastly improved for true antibody positive specimens. Providers and Section of Epidemiology happy!

- Ag-only positive and false positive EIA HIV is most costly, slowest result, and requires most tech time.

- Increased TAT due to plasma specimen requirements and sending out of state for PCR confirmation.

Aurora Borealis north of Fairbanks
Discussion

- True window period positives remain undetected for two + weeks, the time it would take for Ab to become detectable.

- Purpose for reducing window period of detection
  - get patients into treatment immediately
  - reduce spread of virus during high viral load

- Patients notified when plasma drawn – increases awareness and anxiety

- PCR testing in house not an option ($$$

- Plasma only specimens require mass restructuring and lots of resources (wouldn’t meet 72 hour time frame)
For now, we’ll keep on mushing...

- Low incidence states need more affordable access to in-house PCR confirmation or alternate method to confirm presence of HIV Ag
- Participation in APHL HIV NAT Demonstration Project
- Interested in what others are doing!
Thank You

Thanks to Melissa Boyette, MS (AK Section of Epidemiology) and the staff and technicians at ASVL

Fairbanks Winter Solstice Sunrise (10:58AM) and Sunset (2:40PM); Dec 21, 2011