Evolving State Laboratory Diagnostic Capacity During an HIV Outbreak

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In 2015, an outbreak involving 190 new cases of HIV-1 infection were identified in southeastern Indiana, in an area that reports <5 new cases of HIV infection annually.
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Rural community
- County pop. 24,000
- City pop. 4,200

Ranked 92/92 for many health and social indicators
- Life expectancy
- Unemployment
- Poverty
- Lack of high school-level education
- Many uninsured or underinsured
Above: Ed Hartle (Tech), Jessica Gentry (Supervisor), Marta Cruz (Analyst), Erica Vecchio (Analyst), Kathy Backfish (Analyst), Mike Cross (Analyst)

Right – Stephanie Dalenberg (Supervisor), Megan Rinehart (Analyst)
ISDH HIV Testing Algorithm, Prior to Outbreak

In the Field

Rapid Test Oral Fluids Screening (Oraquick)

Reactive
Rapid Test

Non-Reactive
Rapid Test

2nd specimen collected for Confirmation

At the Lab

Oral Fluid: Western Blot (OraSure)

Serum:
1. CIA (Ortho Vitros)
2. Multispot (Bio-Rad)
Phase One:

In March 2015, the ISDHL began testing anti-HIV negative specimens for HIV-1 RNA, using a pooled NAAT (nucleic acid amplification test) as a strategy for the early detection of HIV.

The ISDHL had previously evaluated the use of NAAT over a 2-year period in 2011-2013. Although ~45,000 specimens were screened in this pilot period, zero (0) HIV NAAT positive, antibody negative cases were detected.

The pilot project was terminated in 2013 due to the lack of acute detections.
NAAT Assay Parameters

- Qualitative Assay for HIV-1 RNA
- “Pooled HIV-1 NAT increased the yield of new HIV diagnoses by 2.2% in specimens with a nonreactive 3rd generation immunoassay…”
- Specificity = 99.6-99.9% (study dependent)
- Most cost effective with larger test volumes.
- Previous Baseline: 0.00%
Individual Specimens
(n = 256)

Intermediate Pools (n = 16)

Master Pool

NAAT Pooling Strategy
HIV Pooled NAAT
22,357 tested, 3 reactive
= 0.01% positivity
Phase 2:

Due to the high risk and high prevalence of Hepatitis C in this IDU population, Hepatitis C was automatically added to all serum-testing requests beginning in March 2015. A pooled NAAT protocol for HCV was revived and adapted for outbreak testing in May of 2015.
Data set: Persons tested for both HCV and HIV at the ISDH Laboratories, residing in Scott or surrounding Counties,

- n = 1,662
- 91.5% of HIV-positive persons were also HCV positive
HCV Pooled NAAT
621 tested, 16 reactive
= 2.6% positivity
Phase 3:

Concerns regarding the sensitivity and specificity of the rapid screening test remained.

In May 2015, ISDH requested that all HIV-tested persons in Scott Co. submit a blood specimen, regardless of rapid test result.
ISDHL Opinion: Instead of changing brands of test, consider transitioning the specimen type requested from oral fluids to finger-stick blood. This transition is estimated to enhance sensitivity by 4-8% according to a review of the scientific literature.
Phase 4:

As of December 2015, the ISDH Laboratories have transitioned to the Abbott Architect for the detection of HIV, Hepatitis C, and Hepatitis B.
Final ISDH Outbreak Testing Algorithm

In the Field

Serum collected
(every patient, regardless of risk)

At the Lab

HIV Ab/Ag

Non-reactive
Perform Pooled HIV NAAT

Reactive
Confirm with Multispot

Anti-HCV

Non-reactive
Perform Pooled HCV NAAT

Reactive
Lessons Learned

- Maintaining a scientific curiosity about our population led to the development of useful tools/resources.
- Pilot testing, even if testing is never expanded, is of public health benefit!
- Make use of funding opportunities & collaboration.
- Never say never … outbreaks can occur in every testing area.
Thank you!

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