Smallpox as a Bioterrorism Threat

Wadsworth Center Response

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Topics.......

- CDC & Laboratory Response Network
- Wadsworth Center specific response
- Variola-specific assays
- Rapid assays for diagnosis of pathogens with a similar clinical presentation
New York State’s Laboratory Response Network (LRN)

The LRN is a statewide clinical and environmental laboratory testing network intended to provide a coordinated, timely and effective response to bioterrorism threats and public health emergencies involving infectious agents.
Which critical agents is the LRN currently focusing on?

- *Bacillus anthracis* (anthrax)
- *Yersinia pestis* (plague)
- *Francisella tularensis* (tularemia)
- *Brucella* sp.
- Variola major (smallpox)
LRN Laboratory Levels

LEVEL D: CDC

LEVEL C: Typing Labs, Public Health Labs

LEVEL B: Public Health Labs

LEVEL A: Clinical Labs
Assay requirements

- Rapid turnaround time
- Highly specific, low false positive rate
- Highly sensitive, low false negative rate
- Rugged
- Based on not growing pathogen
- Best approach at this time is real-time PCR (rtPCR)
Status of CDC-LRN assays

Orthopox rtPCR screening assay - identifies a pathogen as a poxvirus - does not identify a virus as variola

In development, will be validated by Wadsworth and other labs in November

When available - 2-3 months?
Variola-specific rtPCR assay in development — where will it be validated? availability?

Varicella LRN rtPCR assay has been validated

Available to LRN Level B (and higher) laboratories in 2-3 months
Wadsworth Center Focus

- Biodefense versus Clinical Labs
- Immediate needs versus long term needs

For example VZV
- Classic approach of culture and IFA
- Coupled to conventional PCR and sequencing
- 2 days to 10 days

NOT USEFUL FOR BIODEFENSE
Wadsworth Center assays - Where are we now?

- rtPCR Orthopox screening assay developed, validation in progress, will submit for CLEP approval
- Varicella and HSV rtPCR assays in development
- Have electron microscope capability - need more work in area of sample collection and orthopox identification
Where we want to be ASAP

- LRN orthopoxvirus screening assay and variola (?) rtPCR assays performed in parallel
- Multiplex rtPCR assay for pox, VZV, HSV and enterovirus aimed at rapid rule-in/rule-out
- EM as a confirmatory procedure
What do we do in the meantime?

Work within the CDC vesicular pustular rash illness algorithm

Use DFA at hospital lab where possible to rule in VZV for low risk specimens
  - Chemicon Light Diagnostics Assay

Contact CDC and NYSDOH Epidemiology for expert advice

At this time high risk specimens are sent to CDC
What about moderate risk specimens?

- Fuzzy area of the algorithm
- Essential to work through the algorithm with Epidemiology and CDC
- Decide on where sample should be tested on a case-by-case basis based on risk analysis
CDC Information

www.bt.cdc.gov/

- Select Agent Facts
- Contact Information/Algorithms
- News Updates
NYS Contact Information

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