CDC's Laboratory Response to the Recent Anthrax Events

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NCID's laboratory response

- Establishing coordination activities in a Emergency Operations Center (EOC)
- Monitoring/managing laboratory testing
- Dealing with issues as they arose



Organization of the Emergency Operations Center (EOC)

- Established 10/13/01
- Staff provided 24/7: 2-12 hour or 3-8 hour shifts
- BPRP had operational lead
- Preparedness and response activities conducted concurrently
- Written records maintained at all levels

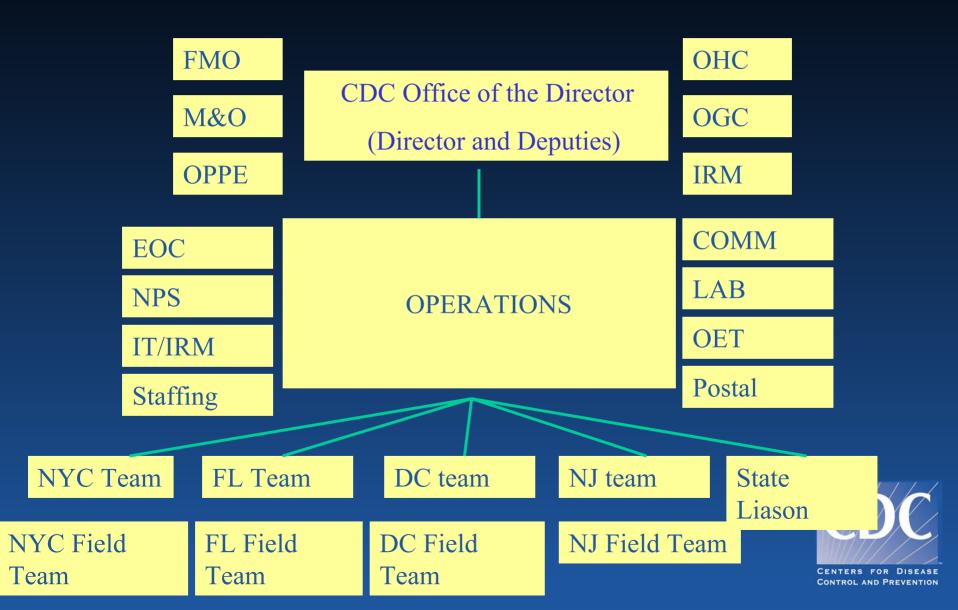


EOC Staffing

- "A teams" with various skill sets identified in each CIO
- Line of authority resides within EOC structure and not dictated by CDC position or CIO
- Volunteer lists compiled by activity
- Coverage:
 - 24/7 coverage in person or "on call" for about 1 month
 - 16/7 coverage for about 3-4 weeks
 - 12/5 coverage for about 2-3 weeks



EOC Operational Design



Emergency Operations Center Laboratory Activities

- Assist NCID laboratories with personnel, supplies, space, etc. in responding to testing needs
- Chair daily meetings to discuss **laboratory results**
- Coordinate receipt of specimens
- Ensure **laboratory reporting** was coordinated
- Coordinate **daily calls** with Federal partners
- Ensure personnel were available to **answer lab questions**
- Develop and track **documents** regarding laboratory testing
- Deal with daily issues for information, coordination, communication
- Communicate with APHL and LRN partners

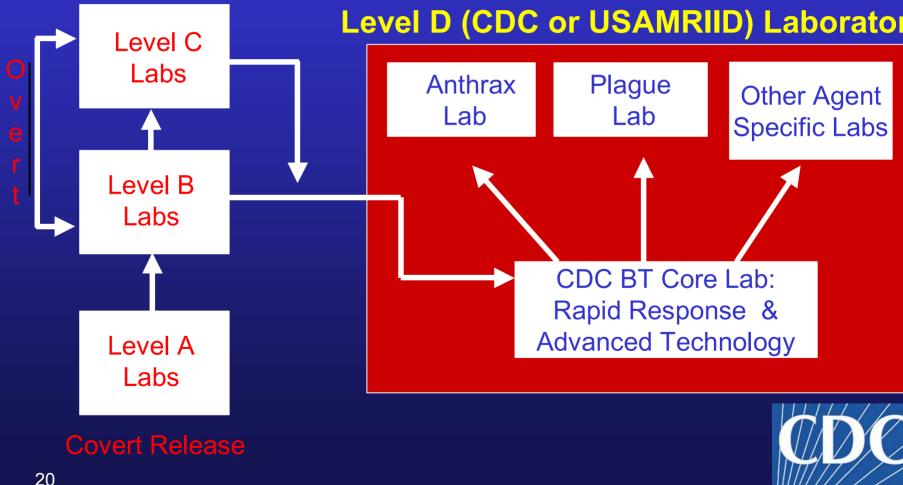


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LRN Structure for Agent Testing & Clinical Specimen Flow

State and Local Labs



NCID Laboratories Testing Anthrax Specimens

- Rapid Response and Rapid Technology Laboratory (BPRP)
- Epidemiologic Investigations Laboratory (DBMD)
- Anthrax Vaccine Research Program (DBMD)
- Infectious Diseases Pathology Activity (DVRD)
- Level A Laboratory (DHQP)



Laboratory Tests in NCID Laboratories

- Gram stain
- Culture
 - colony morphology, hemolysis; motility; sporulation
- Culture confirmation
 - Gamma phage assay
 - Immunofluorescence for both capsule and cell-wall polysaccharide
- PCR
- Immunohistochemistry
- Serology
- Molecular subtyping
- 16s RNA



Specimen Movement



Field information collected for shipment, type of specimen, etc. (EOC Field Team)

Specimen tracked, received at CDC

(Specimen trackers)

Specimen received in BPRP laboratory – logged, aliquotted, distributed (BPRP)

Results provided to Field Team, then requestor Results **reported** at daily meetings

(EOC field teams, NCID labs, NCID leadership) Specimen tested (NCID labs)



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Laboratory Safety

- Clinical specimens
 Level A laboratory
- Environmental specimens

 Level A laboratory
- Culture for confirmation

 Level B laboratory
- Powders
 - Level B laboratory

- BSL-2 laboratory and practices
- BSL-2 laboratory; BSL-3 practices
- BSL-2 laboratory: BSL-3 practices
- BSL-3 laboratory and practices



Challenges

- Planning for laboratory needs
- Result reporting
 - CDC's information systems
 - Single conduit for approving results
- Case definition
- Providing timely documents
- Information flow
- Communication



Challenge: Planning for Laboratory Needs

- Specimen load inpredictable
- Large influx in specimens resulted in backlogs
 - Logging in and aliquotting
 - Testing
 - Timely reporting of results
- Trained personnel in limited supply
- Rapid access to supplies and reagents
- Spaces to test hundreds of specimens needed
- Field teams deployed for some environmental testing



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Challenges: Laboratory Result Reporting (CDC)

- No commonly-used system for reporting in NCID
- Multiple specimen ID numbers
- Needed to develop integrated specimen management system "on fly"
 - Field data
 - Clinical data
 - Laboratory data



Challenges: Patient Results Reporting

- Daily meetings to report results by specimen
- Single point-of-contact to "bless" results—call cases
- Priority test results communicated through point-of-contact, then to field teams
- Results from CDC reported to requestor/patient prior to press releases



Challenge: Case Definition

- Many specimens taken after antibiotics administered
- Positive results based on <u>culture</u>
- PCR results used only for evaluation of the method
- Histology and immunohistochemistry provided some information about presence of anthrax in tissues
- Serology (unvalidated test) results were often positive when culture was negative: how to interpret??
- Cases identified based on clinical, epidemiologic, and laboratory data



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Challenge: Providing Timely Documents

- Laboratory protocols available in public (Level A) and secure (Levels B and C) websites; modifications required further clearance
- Information about laboratory tests, rapid detection technologies, etc. was needed
- Personnel most knowledgeable about technical laboratory issues were overworked in lab
- Review of all CDC communications required multiple approvals
- Single point-of-contact for final review of all documents required



Challenge: Information Flow

- Communication with media through designated persons
- All laboratory results were provided to field teams; CDC did not verify results until all parties were notified
- Contract labs reported "presumptive positive" results; media reported results prior to originator receiving them
- Confidential reports need better levels of control



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Challenge: Communication

- Communication between boxes within the EOC
- Understanding of roles/responsibilities in EOC boxes
- Communication with field teams (specimens, e.g.)
- Communication with Federal partners
- Communication with media
- Communication with state partners and others



Lessons Learned

- Surge capacity is essential (trained staff, space, supplies, reagents, etc.)
- Effective laboratory information system (specimen management) is critical
- Planning based on real scenarios is critical
- Communication about results must be confidential and provided through single point-of-contact
- Documents should be prepared in advance of event
- Technical experts to respond to inquiries are essential



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