Ebola and Emerging Infectious Disease Lessons Learned in the Laboratory Response Network

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- Discuss ERA
  - What it is and what is done at a visit
  - Who Is Present
  - Day Agenda
  - Guidance Documents
  - Summary of Findings
- Deployments
  - Lessons Learned during Deployments
  - CERT Team
  - Lassa Fever

ERA visits and Deployments

ERA Visits

- ERA Visits
  - What They Are
  - Team Makeup
  - Designation As An Assessment Hospital
  - Assessment versus Treatment
  - Point of Care (POC) lab
    - Requirements
  - Guidance Documents
  - Typical Findings

Some Places I Have Been For ERA

- New Jersey/NYC
- Oklahoma City 3 Hospitals
- Kentucky 3 Hospitals
- Maine 3 Hospitals
- Ohio 1 Hospital
- Utah 2 Hospitals
- Florida 1 Hospital
- South Dakota 2 Hospitals
- West Virginia
- Washington DC

Background

The Ebola outbreak in 2014 pointed out gaps in U.S. laboratory biosafety practices, such as:

- Inconsistent guidance and lack of guidelines
- Confusion about use of PPE
- Lack of risk assessment for handling and testing specimens
- Absence of risk mitigation and biosafety plans
- Lack of instrument decontamination methods
- Confusion concerning waste disposal
- Lack of expertise and materials for packaging and shipping specimens to LRN laboratories

Frontline Healthcare Facility

Quickly identifies and isolates patients with possible Ebola

Notifies facility infection control and state and local public health officials

Has enough Ebola personal protective equipment (PPE) for at least 12–24 hours of care

Prepares for patient transfer, if needed

Ebola Assessment Hospital

Safely receives and isolates a patient with possible Ebola

Provides immediate laboratory evaluation and coordinates Ebola testing

Cares for a patient for up to 5 days (including evaluation and management of alternative diagnoses) until Ebola diagnosis is confirmed or ruled out

Has enough Ebola PPE for up to 5 days of care

Transfers a patient with confirmed Ebola to an Ebola treatment center in consultation with public health officials

Ebola Treatment Center

Safely receives and isolates a patient with confirmed Ebola

Cares for patients with Ebola for duration of illness

Has enough Ebola PPE for at least 7 days of care (will restock as needed)

Has sustainable staffing plan to manage several weeks of care

CDC Ebola Response Teams (CERTs) are ready to deploy to provide assistance as needed

Summary of CDC-led Technical Assistance for ETCs and Assessment Hospitals

- **2 phases**
  - ETC focus (REP), Oct 2014 – Jan 2015
  - Assessment hospital focus (ERA), Feb – Dec, 2015
- **Summary of CDC-led hospital visits through Dec 15, 2015**
  - Multi-disciplinary teams of CDC and HHS/ASPR staff
  - ~145 hospitals in 47 states + D.C.
- **NETEC (National Ebola Treatment and Education Center)**

Preparedness Domains: Specific Observations

- **Infrastructure**
  - Problematic layout of patient care space
  - Inadequate PPE doffing or waste storage space
- **Staffing**
  - Inadequate # of trained staff to provide care for up to 96 hours
  - Planned shift durations not practiced
- **PPE**
  - Inter-facility variability in protocols due to supply chains, personal preference, experience
  - Limitations of locally available expert trainers
  - Adoption of HAZMAT principles and training can be problematic
- **Training**
  - Competency in defined roles is labor intensive to establish and maintain
  - Ideal frequency of retraining not defined
- **Waste management**
  - Local regulations concerning solid waste and sewage
  - Workable solutions usually exist but can be very expensive and/or cumbersome

Other Specific Concerns Observed during ERA Visits

- **Worker safety**
  - Protocols to monitor HCWs
  - Coordination of monitoring with health departments
- **Environmental cleaning and disinfection**
  - Potential overuse or misuse of bleach products (e.g., spraying HCWs in PPE)
  - Need for terminal cleaning protocols
- **Clinical management**
  - Protocols for special populations (e.g., children)
  - Appropriate interventions such as invasive procedures for critically ill patients

Short Form Guidance Document for Laboratory

Laboratory	Diagnostic laboratory procedures and protocols are in place for: • Testing of specimens for Ebola by the nearest Laboratory Response Network (LRN) laboratory capable of testing for Ebola: Select • Space for clinical diagnostic testing: Select • Minimal level of diagnostic testing capability* prior to availability of Ebola test results: Select • Equipment and supply selection: Select • Disinfection: Select • Staffing: Select • Specimen collection/handoff/transport diagnostic test: Select Lab personnel have been trained and have demonstrated proficiency in: • Donning and doffing of PPE: Select • Waste management: Select • Processing specimens while in PPE: Select • Specimen transport: Select **At a minimum this testing capability should include CBC, glucose, potassium, malaria exam, influenza test, liver function tests*	Select

Short Form Guidance Document for Waste

Waste Management	Hospital has in place the services of a waste-management vendor capable of managing and transporting Category A infectious substances*: Select OR Hospital will sequester medical waste until the patient's Ebola test result becomes known; if the patient is confirmed to have EVD, arrangements can be made with a vendor capable of managing the waste as a Category A infectious substance*: Select Hospital has appropriate containers for the safe temporary storage of Category A infectious waste: Select Staff that handle waste are trained in the correct use of PPE and the proper handling and storage of Category A infectious substances at the facility: Select **Yes to either question meets the first Ebola assessment hospital minimum capability element for waste management.*	Select

Minimum Ebola Assessment Hospital Laboratory Capabilities

- Ability to ship specimens to nearest LRN lab (requires certified staff and supplies to pack and ship specimens)
- Adequate space, equipment, staffing
- Written procedures and trained/competent staff to safely perform a minimum menu of laboratory tests
- Specimen management procedures in place
- Disinfection procedures available
- PPE available with procedures and space for donning & doffing
- Waste management procedures available
- Risk assessment performed and risk mitigation controls implemented

Summary of Hospital Laboratory Assessment Data Reported by Grantees (not final numbers)

Reports received from 30 jurisdictions with results from 167 hospitals

- 55 facilities reported as NOT meeting the minimum capability for the laboratory (33%)
- 54 of these facilities are EAH, 14 ETC (13 both)
- These 55 facilities were in 17 jurisdictions

Common Laboratory Gaps Observed by CDC Assessors

- Shipping specimens to LRN labs:
  - Lack of sufficient number of personnel certified to pack and ship Category A specimens or lack of shipping materials
- Test menus:
  - Confusion concerning the minimum menu of laboratory tests to be able to perform on specimens from PUI and confirmed EVD patients
- Staff training and competency assessment:
  - Gaps in documentation for staff training and routine assessment of continuing competency

Common Laboratory Gaps Observed by CDC Assessors

- Space:
  - Insufficient space for personnel performing laboratory testing
  - Separate areas needed for donning and doffing PPE with clean and dirty areas and unidirectional workflow
- PPE:
  - Types of PPE to be used for different roles not identified, e.g. for specimen transport and testing processes
  - Insufficient supply of PPE for lab testing personnel (need minimum for 4 days for EAH)
- Equipment:
  - Lack of guidance from manufacturers on how to decontaminate certain laboratory equipment or not following manufacturer's instructions for decontamination

Common Laboratory Gaps Observed by CDC Assessors

- Waste management:
  - Confusion over how to handle liquid waste from instruments
  - Local water management authorities or regional EPA may need to be engaged
- Communication:
  - Gaps in communication among the laboratory, nursing, infection preventionist and environmental services resulting in differences in procedures.
  - For example:
    - Procedures implemented that had not been reviewed by the laboratory director
    - Procedural changes in waste management not communicated to the laboratory

ERA Visits

- Typical Findings/ Gaps For Labs
- No Written Report From CDC
  - Generated By State Team If Applicable
- Final Debrief Meetings
  - Go Over Any Gaps
  - Recommendations
  - Share Experiences

Emergency Response Deployments Lessons Learned

- CERT Team – CDC Ebola/Emergency Response Team
  - Team Makeup
- Ready to Respond in 4 Hours (Maybe Less)
- Lab Lead or Lab SME for Responses
- Can last up to 3 weeks
- Very Long Hours and Very Fast Paced
- Three Rapid Deployments
  - Dallas TX Presbyterian Hospital
  - NYC Public Health Lab and Bellevue Hospital
  - Newark NJ- Lassa Fever Rutgers University Medical and St. Barnabas Medical

Dallas Deployment Texas Presbyterian

- **First Emergency Deployment**
  - Deployed to Dallas 2.5 weeks
  - Very long hours and lots of craziness going on!
- **Lessons Learned**
  - Expect the unexpected
    - Samples, Shipment, People, Testing, MEDIA, and everything else!
  - Personnel
  - Have plans A-E
  - Develop at GOOD communication plan that is inclusive
  - Train everyone to the same standards
  - Understand the situation
    - Hospital lab workers
  - Safety first
    - Not too safe that its unsafe!
  - Enjoy the situation and Use resources available

Dallas County Health Department Lab

- **Initially Testing was in Austin 3.5 hours away**
  - Developed Transportation Plan To Get Samples There Safely
  - Important to SAFELY get Dallas CPHL approved to test samples
- **On site training and Assessment for Ebola Testing**
  - Space
  - Biosafety
  - Lab and Specimen Flow
  - Answered any Questions
  - Accompanied by Biosafety Officer from SPHL in Austin
- **Lesson Learned**
  - Never Judge by First Impresions
  - Spend time to train the right way and in all aspects
  - Calm in stressful situations
  - Be quiet, stay away from Media and use your resources

NYC Public Health Lab

- **Deployed to NYC the day after I Returned from Dallas**
- **Main purpose of Trip**
  - Lab support for hospital and PHL
  - Train NYC PHL laboratorians on how to perform the CDC Ebola Assays
  - Help with Shipping and Handling of Samples
- **Lessons Learned**
  - NYC is Crazier in these situations (as with most anywhere)
  - Do not take sample transport for granted
  - Time of day doesn't matter
  - Most places can and will do anything to get a result as quickly and accurately as possible
  - Don't take Shipping and Handling for Granted (even if you do the proper steps)
  - Media Media Media!!
  - Make the best of it
  - Use resources available

Lassa Fever Deployment-Newark, NJ

- Deployed Memorial Day
  - After Being in the EOC All Day and All Weekend for DoD Anthrax
- Positive Lassa Fever Patient Saturday Evening Newark, NJ
  - Was On Calls Associated with Case
  - No Indication of Deployment until 430pm on the Plane at 815pm
- Investigation at Two Hospitals
- Team Consisted of: Me, Dr. Pierre Rollin, Dr. Marie Del Perio, Kenneth Meade, and Craig Manning

Lassa Fever Deployment-Newark, NJ

- Overview of Typical Steps Involved in Investigation
  - Case Briefing at Involved Hospitals Upon Arrival
  - Develop and Discuss Communication Plan
  - Create Timeline of Events and Lab Tests Ordered and Results
  - Review and Discuss Any Transport Policies and Procedures if Applicable
  - Review PPE and Biosafety Procedures
  - Review of Patient Care and Charts
  - Review of Laboratory and Laboratory Procedures
  - Education of Hospital Staff Involved, Including Night Shift Personnel
  - Community Education and Outreach
    - Town Hall Meetings in Newark

Lassa Fever Deployment-Newark, NJ

- Lab Investigation
  - Looking at Lab Practices Including a Walk Through of Sample Path and Lab Flow
  - Watching and Discussing Procedures and Instrumentation Used
  - Review Procedures for Sample Delivery
  - Determination of Gaps and Noting Recommendations
    - Two Lab Locations at Rutgers and One at St. Barnabas
  - Collection of All Samples and Destroying With Proper Documentation
    - Explain DSAT Implications
    - Determination If Samples Were Outsourced (In this case yes!!)
    - Coordinate With EOC and Others to Track Down These Samples

Lassa Fever Deployment-Newark, NJ

- Lab Recommendations
  - Recommended To Improve Work Flow and Processes (Gloves, Procedures)
  - Space for Safe Lab Practices
  - Communication and Specimen Transport
  - Biosafety and PPE
  - Sequester of Samples

Thank You
Questions?