Public Health Informatics Working Group

Webinar Series

Contact and Suggestions:

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The contents of this webinar will be recorded and posted, along with the presentation materials, on the Public Health Informatics Working Group webpage.
At least 44 people have died and more than 678 people in 19 states have become ill from fungal meningitis, epidural abscesses, and other infections after receiving contaminated steroid shots made by the New England Compounding Center in Massachusetts. Public health response to these events required coordination among multiple Federal and State organizations, recommendations for the management of possible and confirmed cases and strong patient and physician communications. This webinar will focus on data and informatics needs of this event and what capabilities could facilitate similar responses in the future.

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The Data and Informatics Needs of the Recent Fungal Meningitis Events

- Data and informatics stages of outbreaks and other events
  1. Detection
  2. Investigation
  3. Management
  4. Follow-up

- Unique event attributes
Initial Events

- Notified of first patient with fungal meningitis and history of epidural steroid injection (ESI)
- Initial case finding at Clinic; site visit to Clinic; THAN
- Epidemiologic investigation (Cohort study) launched to identify source of exposure at Clinic A
  - Chart abstractions for exposure procedures on every patient (many patients had multiple procedures)
    - Unable to obtain electronic data extract from electronic medical record system on procedures in a timely manner
    - Labor intensive manual process (data on 794 patients, 1315 procedures) in newly created database within 60 hours
    - Lot numbers for medications administered not recorded in individual patient charts
  - Methylprednisolone acetate (MPA) from New England Compounding Center (NECC) implicated -- voluntary recall of 3 lots (confirmed by epidemiologic and laboratory data)
Case Finding and Investigation

- 3 clinics in TN, 1009 patients exposed to 3 lots of MPA from NECC

- Two resource-intensive outreach efforts to all exposed individuals
  - Initial outreach for case finding & follow-up and second effort to identify additional local infections
  - Joint effort between public health and clinics
  - Engaged local and regional public health nurses
  - Use of Tennessee Countermeasures and Response Network (TN CRN) Patient Tracking Module

<table>
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<th>10/10/12</th>
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</table>
Electronic Health Records (EHR)

- Information in EHRs essential for public health response (initial plus follow-up)
  - Provide critical information to describe initial clinical presentation, clinical progression, response to treatment to inform real-time national guidance (e.g., case definition, diagnostic and treatment guidance)
  - Lessen burden on healthcare facility responding to public health requests

- Types of information
  - History and physical admission notes, blood and CSF laboratory observations; imaging reports (head and spine MRI/CT); treatment data (orders and actual administration); infectious disease and neuro consults; operative notes; discharge summary; ED notes; other progress notes

- Learning curve regarding characteristics of data and how to interpret
Access to EHR Data

- Public health granted remote direct access to specific areas of the systems
  - Manual abstraction process – labor intensive
  - Learning curve with variety of products across hospital systems

- Opportunities
  - More automated exchange for types of information that are commonly needed in public health
  - Important for public health to participate in national initiatives (interoperability, standards development and harmonization)
  - Still need to have other mechanisms (such as direct access) available during certain types of events
Data Quality

- Information in the EHR
  - How well do EHRs support provider workflow and reflect what is occurring
  - Use of standards to assist with interpretation

- Data capture
  - Variety in data abstraction process and data entry
    - Different skill sets for these tasks
  - Public Health data collection instruments
    - Learning curve regarding data in EHRs

- Workforce Development
  - Helpful to have data management as a specific function
  - Epidemiologists with informatics skills
  - Epidemiologists with skills in investigating healthcare associated infection outbreaks

- Public Health Infrastructure critical
Early Publications/References


- http://www.cdc.gov/hai/outbreaks/currentsituation/
Each 30-day case-fatality rate is calculated for patients diagnosed during the corresponding week. TDOH indicates Tennessee Department of Health; NECC, New England Compounding Center; CDC, Centers for Disease Control and Prevention; FDA, US Food and Drug Administration. JAMA. 2013();1-2. doi:10.1001/jama.2013.526
Persons with Fungal Infections Linked to Steroid Injections, by State

- MN 12
- MI 244
- IL 2
- IN 81
- OH 20
- VA 52
- NC 17
- TN 148
- FL 25
- GA 1
- SC 2
- TX 2
- NH 14
- RI 3
- NJ 48
- MD 25
- WV 5
- NY 1
- PA 1
- 1 - 11 cases
- 12 - 40 cases
- ≥ 41 cases
Acknowledgements

- Tennessee Department of Health
  - Data Management Team: Jennifer Ward, Andrew Wiese, Caleb Wiedeman
  - TNCRN: Paul Peterson, Jeff Sexton
  - Rest of the TDH fungal infection response team (180+)
- The 3 affected clinics and their staff
- Clinicians, Infection preventionists, hospitals
- CDC
Public Health Data and Informatics Needs during the Fungal Meningitis Outbreak

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Florida Department of Health
Bureau of Epidemiology

AMIA Webinar
February 12, 2013
Florida Department of Health Infrastructure

- Nearly 19 million people, 80 million tourists annually
- State health office
  - *Support and guidance* to county health departments
  - Maintain state surveillance systems
- 67 county health departments
  - Receive case reports
  - Complete outbreak and case investigations and associated case data entry
Outbreak Information

Map 1: Number of Outbreak-Associated Fungal Meningitis Cases by County

Total Number of Cases: 25

- Total exposed 1055, primarily in two of the four affected counties

Map 2: Map of Florida Healthcare Facilities which Received Implicated Lots* of Methylprednisolone Acetate (PF) Recalled from New England Compounding Center on September 27, 2012
Select Fungal Meningitis Challenges...

- New, unexpected, non-infectious
  - Many exposed (but based on exposure setting rather than transmission cycle)
  - Exposure event was in a clinical setting making use of health record and *electronic* health records key

- Long term case identification challenges
  - Long and unknown incubation periods
  - Multiple specimens and diagnostic testing over time
  - Detailed clinical record reviews

- Site investigations needed at multiple settings

- Need to capture, describe and retrieve relationships between people, sites, specific exposures, laboratory results

- Laboratory diagnostics; confirmatory testing at CDC

- Intense information management
  - Need data rapidly, updates often multiple times per day

- Changing role of public health for health care associated infections; patient provider relationships

- Community care structure
Lessons Learned – Electronic Health Records (EHR)

- Access to electronic health records EHR – useful
  - Clinic EHR and hospital EHR
  - Overall easier to identify potential exposed individuals than reviewing paper records
  - Public health unfamiliar with EHR set up; billing focus; query set up based on *individual* not identifying a set of individuals with common trait/aspect *across* records
    - Facility staff were system “users” not database managers able to initiate queries “on-the-fly”
  - After records of interest were identified still required manual process to “transfer” data to public health
    - Printed records of interest and hand data entered into PH management system; No EHR capacity to transfer or export STRUCTURED dataset or records
  - Required on-site access by PH; remote logins not provided; set up on local networks vs web-based
Lessons Learned – Contacting Exposed

• *Reached* all exposed twice
  – Very resource intensive, many staff hours

• Deployed data and database managers to the field to assist
  – Multiple deployments over multiple weeks

• Databases not connected between sites
  – Printed records of interest and hand data entered into PH management system; No EHR capacity to transfer or export STRUCTURED dataset or records

• Need staff trained in informatics at all levels of public health
Lessons Learned – Electronic Laboratory Reporting

- State public health laboratory connection to public health surveillance systems
  - Beneficial
  - Current infrastructure: *All* laboratory results from the state public health laboratory are sent to a central database accessible by outbreak and surveillance systems
    - Quickly established a special test code; results easily identified by state surveillance epidemiologist and attached to corresponding case in the outbreak management system
    - Need further automation: identification of outbreak related test results
Lessons Learned – State Outbreak Management System

• Good for cases and as a single central source for storing key information (accessed by state and CHDs)
  – Difficult to easily identify new information that has been added or updated since the last reporting period
    • Exposure tracking more difficult; utilized separate exposure databases; need central system able to be accessed by CHDs and state
    • Need means to electronically upload case and exposure data

• Link to central ELR database very helpful
• Conducted just-in-time training for CHDs; made modifications quickly to provide additional resources for storing complex paper case report forms

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Further Discussion - Where do we go from here?

- More public health connection with EHR vendors and health care providers – role of public health
- Need for EHR capacity to submit case reports to public health
  - Automated detection
  - Event or case of interest detected by a person
Further Discussion - Where do we go from here?

• Receive ELRs internally as well as externally (receive ELRs from clinical, state public health laboratories); missing link - federal CDC laboratories

• Need ability to perform public health query into EHRs for use after a disease report has been made

• Need a “public health key” or remote access to EHRs to identify events of interest
  – Need a flexible means to access clinical data during outbreaks; perform queries across records and review individual records

• Clinical data in EHRs good but insufficient for outbreak management

• Identify and expand on demonstrated opportunities of returning information from public health to clinical care
Building Effective Outbreak and Event Response

• Establish data flow connections; leverage electronic feeds
  – Prior to events
  – Balance between speed of information vs completeness vs positive predictive value
  – Public health goal: reduce time *accessing* and *gathering* information → patients are contacted sooner → source of illness is identified more quickly leading to improved disease prevention

• Use of federal funds, especially public health emergency preparedness funds in support of surveillance system infrastructure were key!
  – Need for a true ‘Manifesto’, a ‘Call to Action’ to secure funding for public health surveillance system improvements and resources training/capacity building to avoid the ‘new digital divide’ between clinical care and public health
  – Ultimate vision – real-time monitoring of population health/public health across a community
Thank you

- Escambia CHD
- Marion CHD
- Orange CHD
- Miami-Dade CHD
- Florida EIS Program
- Deployed staff: 1) to central office and 2) to field locations
- CDC-CSTE Public Health Informatics Fellowship
Multistate Outbreak of Fungal Meningitis and Other Infections Associated with Contaminated Steroid Injections

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National Center for Emerging and Zoonotic Infectious Diseases

American Medical Informatics Association
Webinar
12 February 2013
## Fungal Meningitis and Other Infections

*(as of February 11, 2013)*

<table>
<thead>
<tr>
<th>State</th>
<th>Total Case Count</th>
<th>Meningitis Only</th>
<th>Meningitis + Paraspinal/Spinal Infection</th>
<th>Stroke w/out Lumbar Puncture Only</th>
<th>Paraspinal/Spinal Infection only</th>
<th>Peripheral Joint Infection only</th>
<th>Paraspinal/Spinal Infection + Peripheral Joint Infection</th>
<th>Deaths</th>
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<td><strong>135</strong></td>
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<td><strong>30</strong></td>
<td><strong>1</strong></td>
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*Deaths reported are from all causes among persons who meet the case definition and may not be directly attributed to a fungal infection. Case counts by state are based on the state where the procedure was performed, not the state of residence.*
Response Objectives

- Prevent severe illness and deaths due to fungal meningitis and other infections in patients exposed to contaminated steroid injections by:
  - Notifying all exposed patients (~14,000)
    - Referring for evaluation if symptomatic
    - Educating to recognize symptoms in future
  - Developing and distributing diagnostic and treatment guidance

- Providing advanced testing at CDC laboratories

- Coordinating with FDA to identify contaminated medication
Patient notification

- State and local health departments identify approximately 14,000 people potentially exposed to medications from at least one of the implicated lots of preservative-free methylprednisolone.
- By October 26, more than 97% of patients had been contacted at least once, by telephone, voicemail, home visit, or registered mail.
- What would have been useful:
  - Single, complete patient list, instead information was held by individual clinics; not by compounding pharmacy which it would have if it was on a Rx per person basis.
  - Lot number received by patient, often absent from patient record.
  - Data on exposure among patients who did not or have not yet become cases. For case controls studies, for follow up, for information on symptoms in the absence of disease, the patient population characteristics, access to care, etc.
  - Data on precise injection methods and others.
## Overview of Outbreak Databases

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<tr>
<th>Database</th>
<th>Description</th>
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<tbody>
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<td><strong>PHA Tracking Database</strong></td>
<td>Contains one record of every single case reported</td>
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<tr>
<td></td>
<td>Data come from:</td>
</tr>
<tr>
<td></td>
<td>- Line lists in Excel are emailed as cases are reported</td>
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<tr>
<td></td>
<td>- <strong>Record for 100% of cases (696 cases)</strong></td>
</tr>
<tr>
<td><strong>Case Report Form Database</strong></td>
<td>Will contain one record for every case</td>
</tr>
<tr>
<td></td>
<td>Data come from:</td>
</tr>
<tr>
<td></td>
<td>- All states: Short forms</td>
</tr>
<tr>
<td></td>
<td>- MI: Epi-aid forms</td>
</tr>
<tr>
<td></td>
<td>- TN: Data transmit in SAS</td>
</tr>
<tr>
<td></td>
<td>- <strong>CRFs on 95% of cases (660/696)</strong></td>
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<tr>
<td><strong>Laboratory Database</strong></td>
<td>Contains lab specimens and results</td>
</tr>
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<td>Data come from:</td>
</tr>
<tr>
<td></td>
<td>- Data are entered from DASH forms</td>
</tr>
<tr>
<td></td>
<td>- <strong>Specimens for 67% (465/696) of cases</strong></td>
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<tr>
<td><strong>Epi-Aid Database</strong></td>
<td>Data come from:</td>
</tr>
<tr>
<td></td>
<td>- FL, IN, MI, TN, NJ, and VA only</td>
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<tr>
<td></td>
<td>- All states: no longer sending forms</td>
</tr>
<tr>
<td></td>
<td>- MI: Epi-aid Forms</td>
</tr>
<tr>
<td></td>
<td>- <strong>Epi-aid forms on 59% (410/696) cases</strong></td>
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</tbody>
</table>
Case investigation and reporting

What would have been useful:

- More facile, real-time transfer of case report and clinical information to CDC from clinics and states
  - Potential benefit: might have allowed earlier feedback on diagnostic and treatment recommendations.
- A data collection tool ready that could allow electronic data entry rather than paper forms to be transcribed later to an electronic data base
  - Potential benefit: More efficient and would have presumably reduced the potential for transcription error
  - Potential benefit: Updates and error correction from states might have been directly uploaded rather than hand corrected, again reducing chance of transcription error
- Consistent electronic format among all data collection forms
  - Potential benefit: combining data sets facilitated for single source of data and data validation
Characterization of the Clinical Syndromes

- **Long term follow up of infected patients (ongoing)**
  - diagnostic and therapeutic approach to patients
  - detail the clinical features of infection
  - describe drug toxicity associated with treatment of these infections
  - follow up and outcome at 3, 6, and 12 months
  - routine and CSF laboratory features

- **What would be useful:**
  - Universal electronic health records
  - Pre-existing safeguards to comply with HIPAA regulations on privacy
  - Potential benefit: Reduced cost, increased accuracy and speed of data collection
“...one of the most shocking outbreaks in the annals of American medicine.”

Acknowledgments

- Hundreds of employees at 23 state health departments
- >300 CDC employees
- FDA and DHHS employees
- Experts in fungal infection
- Physicians and others taking care of patients

Lawrence Altman
New York Times
November 5, 2012
“... one of the most shocking outbreaks in the annals of American medicine.”

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New York Times
November 5, 2012

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For more information please contact Centers for Disease Control and Prevention

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Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
The Data and Informatics Needs of the Recent Fungal Meningitis Events

Questions & Discussion