THE MENINGITIS OUTBREAK AND THE REGULATION OF COMPOUNDING COMPANIES: FEDERAL AND STATE ROLES

Presented by CSG South
Multistate Outbreak of Fungal Meningitis and Other Infections Associated with Contaminated Steroid Injections

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Division of Foodborne, Waterborne and Environmental Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

January 3, 2013
“... 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
Key Early Time Points

**September 18**
- Tennessee Department of Health contacted about a patient with culture-confirmed *Aspergillus fumigatus* meningitis who received epidural steroid injection at a pain clinic on July 30

**September 18-25**
- TN DOH in consultation with CDC investigates additional culture-negative meningitis cases who received epidural steroid injections at the same pain clinic
- Multiple common exposures identified, including to at least one of three lots of methylprednisolone acetate (MPA) compounded by New England Compounding Center (NECC)
- Communications with FDA and MA Board of Pharmacy

**September 26**
- NECC voluntarily recalls three lots of MPA
  - 17,000 vials distributed to 75 facilities in 23 states
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
  - Conducting surveillance to identify risk exposures
  - Coordinating with FDA to identify contaminants in medication
Fungi Confirmed in Patients

- *Exserohilum rostratum*
- *Aspergillus fumigatus* identified in 1 patient
- Variety of other fungi of unclear clinical significance identified in 11 patients
Laboratory Testing of Unopened MPA Vials

- Identified 3 Fungi and confirmed by DNA sequencing in vials from 2 of 3 lots:
  - *Exserohilum rostratum*
  - *Rhodotorula laryngis*
    - Not known human pathogen; no growth at 37C
  - *Rhizopus stolonifer* (in one slant)
    - Not known human pathogen; no growth at 37C
Navigating Uncharted Waters

- Very limited diagnostic tools
  - CDC lab developed PCR assay, optimized for CSF

- Extremely limited clinical experience
  - Convened clinical mycology group to provide advice about diagnosis and treatment to inform CDC guidance. Met frequently (sometimes daily).

- Clinical course unknown
  - Recruited group of ID specialist volunteers to provide ongoing consultation to treating physicians
  - Continue to stay in close contact with centers treating large numbers of patients
  - Keep surveillance strong to detect potential later infection manifestations
Fungal Infections Associated with Contaminated Lots of MPA, by Date of Initial Symptom Onset and Presenting Syndrome (n=356)

# Fungal Meningitis and Other Infections
(as of December 28, 2012)

<table>
<thead>
<tr>
<th>State</th>
<th>Total Case Counts</th>
<th>Meningitis (with or without other infection) *</th>
<th>Stroke without Lumbar Puncture only</th>
<th>Paraspinal/Spinal Infection only</th>
<th>Peripheral Joint Infection only</th>
<th>Paraspinal/Spinal + Peripheral Joint Infection</th>
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Fungal Meningitis and Other Infections
(as of December 28, 2012)
A Few Observations

- Public health showed our value to the American people
- Pivotal role of state health departments
  - Sounding the alarm
  - Contacting 14,000 patients
  - Ongoing surveillance providing vital information
- CDC role with the states
  - Majority of outbreak responders directly supported by CDC’s financial and in kind support to states
    - Key role of Emerging Infections Program, Epidemiology and Laboratory Capacity cooperative agreement, and HAI coordinators
  - Laboratory training
  - Leadership
  - Keeping everyone moving in the same direction
A Few Observations (2)

- CDC’s laboratories again proved critical
  - Assay development
  - Ability to identify rare or obscure pathogens
    - Assist FDA in identification of what’s in the vials
  - Surge capacity to backstop the states
  - To date tested over 800 human clinical specimens from 26 states

- CDC filled huge gap in clinical expertise and knowledge to optimize the quality and timeliness of guidance about diagnosis and treatment
  - Hub for characterizing and sharing clinical experience
  - Convene “best minds” in mycology to provide advice
  - Real time updating of guidance as new information becomes available

- Communication was key
Thank You

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA  30333
Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov  Web: http://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.
Public Health Response to the Outbreak of Fungal Infections from Contaminated NECC Products
Michigan, Oct.–Dec., 2012

Jim Collins, RS, MPH
Director, Division of Communicable Diseases, Michigan Department of Community Health

Jevon McFadden, MD, MPH
Medical Epidemiologist, Michigan Department of Community Health
Career Epidemiology Field Officer, Centers for Disease Control and Prevention
Some Key Dates

- **October 2, 2012** – Michigan Department of Community Health (MDCH) begins outreach to four clinics in Michigan that received recalled lots of NECC MPA. Clinics alerted to stop using product, to watch for infections, and to begin directly reaching out to all patients potentially exposed to one of the three recalled lots.
- **October 3, 2012** – MDCH confirms their first fungal meningitis case.
- **October 5, 2012** – MDCH confirms their first Para-spinal infection case.
- **November 2, 2012** – Mounting evidence that previously treated and released fungal meningitis cases are being readmitted to the hospital for treatment of para-spinal fungal infections localized to the site of the original steroid injection.
- **November 19, 2012** – Last reported case of fungal meningitis in Michigan tied to NECC investigation. Cases of para-spinal and peripheral joint infections continue to be identified.
# Michigan Exposure Information

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<tr>
<th>Location</th>
<th>Recalled Product Received</th>
<th>Exposure</th>
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<tr>
<td>Clinic B</td>
<td>05212012</td>
<td>500 Vials</td>
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<td></td>
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<td>500 Vials</td>
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<tr>
<td></td>
<td>06292012</td>
<td>500 Vials</td>
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<tr>
<td>Clinic C</td>
<td>05212012</td>
<td>100 Vials</td>
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<tr>
<td></td>
<td>06292012</td>
<td>100 Vials</td>
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<tr>
<td></td>
<td>08102012</td>
<td>100 Vials</td>
</tr>
<tr>
<td>Clinic D</td>
<td>05212012</td>
<td>25 Vials</td>
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<tr>
<td>Total For Michigan</td>
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<td>2225 Vials</td>
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# Case Population Description

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<th>Age (years), n=223</th>
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<tr>
<td>Mean</td>
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<tr>
<td>Range</td>
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<table>
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<tr>
<th>Sex (n=223)</th>
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<tbody>
<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<table>
<thead>
<tr>
<th>Race (n=218)</th>
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<tbody>
<tr>
<td>American Indian / Alaskan Native</td>
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<tr>
<td>Asian</td>
</tr>
<tr>
<td>Black / African American</td>
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<tr>
<td>Caucasian</td>
</tr>
<tr>
<td>Unknown</td>
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Fungal Infection Primary Case Definition
(218 Case Patients)

Case Count

Weekly Surveillance Reporting Week

- Peripheral Joint Infection
- Para-spinal Infection
- Meningitis

10/2 MDCH outreach to clinics
NECC-Related Fungal Infections in Michigan as of Sept. 15, 2012

Infection Type
- Red: Meningitis
- Green: Para-spinal Infection
- Blue: Peripheral Joint Infection
NECC-Related Fungal Infections in Michigan as of Sept. 29, 2012

Infection Type
- Meningitis
- Para-spinal Infection
- Peripheral Joint Infection
NECC-Related Fungal Infections in Michigan as of Oct. 13, 2012

Infection Type
- Red: Meningitis
- Green: Para-spinal Infection
- Blue: Peripheral Joint Infection

Map of Michigan with marked infection locations.
NECC-Related Fungal Infections in Michigan as of Nov. 17, 2012

Infection Type
- Red: Meningitis
- Green: Para-spinal infection
- Blue: PeripheralJoint Infection
NECC-Related Fungal Infections in Michigan as of Dec. 18, 2012

Infection Type
- Meningitis
- Para-spinal Infection
- Peripheral Joint Infection
Multi-State Fungal Infection Outbreak Case Count

Centers for Disease Control and Prevention
Types of Infections Reported by Michigan (as of 12/28/2012)
Multi-State Fungal Infection Outbreak Case Count (Reported to CDC as of 12/28/2012)
Important Clinical Considerations

• Impact of early diagnosis and treatment
• Assessment of worsening vs. persistent pain
• Management options
  1. Treatment with 1 or 2 antifungal medications
     – Many adverse effects reported
     – High costs
     – Uncertainty regarding duration of treatment
  2. Surgery
     – Variety of procedures and approaches
  3. Persistent monitoring and repeat diagnostic testing
MDCH Assistance to MI Hospitals

• MDCH Certificates of Need
  – Allowed hospital to obtain additional MRI
  – Allowed hospital to open 1 additional operating suite

• Michigan Healthcare Coalitions
  – Facilitated communication between hospitals
  – Assisted with redirection of patients to less impacted hospitals
  – Assisted with staffing augmentation at overburdened facilities
MRI Screening

• Approach initiated by a single MI hospital
• Targeted 414 patients from one pain clinic
  – Patients with increased pain
  – Patients with no increased pain
• Preliminary Data (238 patients)
  – 19% all patients had **abnormal** findings
  – 14% of patients reporting no new symptoms had **abnormal** findings
Outcomes of MRI Screening (238 Patients)

- **MRI Findings**: 59% Abnormal, 19% Normal, 22% Equivocal
- **Surgery (Yes/No)**: 55% Yes, 45% No
Staffing the Outbreak Response in Michigan – Number of Staff

- Total: 24 Staff

- Administration (Central Staff): 6
- Abstraction (Outbreak Team): 4
- Clinic Assessment: 1
- Public Inquiries: 2
- Clinic Outreach (Regional Staff): 7
- Media Relations: 1
- On-site Hospital Assistance: 2
- Laboratory: 1
- Patient Outreach: 6

Number of Staff
Staffing the Outbreak Response in Michigan – Hours Worked by Staff

Total: 3950 Hours Worked
Impacts of Public Health Response in Michigan

• Notification
  – Facilitated early diagnosis and treatment
• Consultation
  – Supported clinical decision-making
• Responding to Public & Media Inquiries
  – Guided public to appropriate action
• Data Collection and Analysis
  – Informed CDC guidance and recommendations
• Hospital assistance
  – Facilitated large-scale screening
  – Reduced burden on hospitals and staff thereby improving patient care
Fungal Meningitis Outbreak

Timothy Jones, M.D.
Tennessee Department of Health
TENNESSEE DEPARTMENT OF HEALTH NOTIFIABLE DISEASES

The diseases and conditions listed below are declared to be communicable and/or dangerous to the public and are to be reported to the local health department by all hospitals, physicians, laboratories, and other persons knowing of or suspecting a case in accordance with the provision of the statutes and regulations governing the control of communicable diseases in Tennessee.

Category 1: Immediate telephonic reporting required followed with a written report using PH-1600

Anthrax (2)
Botulism
  1. Foodborne (5)
  2. Wound (4)
Diphtheria (11)
Disease Outbreaks
  1. Foodborne
  2. Waterborne
  3. All Other
Encephalitis, Arboviral
  1. California/LaCrosse serogroup (121)
  2. Eastern Equine (122)
  3. St. Louis (123)
  4. Western Equine (124)
Group A Strept Invasive Disease (53)
Group B Strept Invasive Disease (47)
Haemophilus influenzae Invasive Disease (54)
Hantavirus Disease (23)
Hepatitis – Type A acute (16)

Listeriosis (94)
Measles (96 Imported, 26 Indigenous)
Meningococcal Disease (95)
Meningitis – Other Bacterial (102)
Mumps (31)
Pertussis (32)
Plague (33)
Poliomyelitis (34 Paralytic, 35 Nonparalytic)
Prion Disease
  1. Creutzfeldt-Jakob Disease (118)
  2. variant Creutzfeldt-Jakob Disease (119)
Rabies – Human (37)
Rubella & Congenital Rubella Syndrome (40, 10)
Severe Acute Respiratory Syndrome (SARS) (132)
Staph aureus Vancomycin nonsens-all forms (13)1
Tuberculosis – all forms
Typhoid Fever (41)
West Nile Infections
  1. West Nile Encephalitis (125)
  2. West Nile Fever (126)

Category 2: Only written report using form PH-1600 required

Botulism – infant (3)
Brucellosis (6)
Campylobacteriosis (7)
Chancroid (69)
Chlamydia trachomatis (55 Gen, 56 PID, 57 Other)
Cholera (9)
Cyclospora (106)
Cryptosporidiosis (1)
Ehrlichiosis (51 HME, 116 HGE, 117 Other)
Escherichia coli 0157:H7 (52)
Giardiasis (acute) (15)
Gonorrhea (60 Gen, 61 Oral, 62 Rectal, 63 PID, 64 Oph)
Guillain-Barre Syndrome (133)
Hemolytic Uremic Syndrome (58)

Hepatitis, Viral
  1. Type B acute (17)
  2. HBsAg positive pregnant female (48)
  3. HBsAg positive infant (480)
  4. Type C acute (18)
Influenza – weekly casecount (20)
Legionellosis (21)
Leprosy (Hansen Disease) (22)
Lyme Disease (24)
Malaria (25)
Psittacosis (36)
Rabies – Animal (105)
Rocky Mountain Spotted Fever (39)
Salmonellosis – other than S. typhi (42)
Shiga-like Toxin positive stool (115)

Category 3: Requires special confidential reporting to designated health department personnel

Acquired Immunodeficiency Syndrome (AIDS) Human Immunodeficiency Virus (HIV)

Category 4: Laboratories required to report all blood lead test results (#79)
Physicians required to report all blood lead test results ≥ 10 µg/dl

Possible Bioterrorism Indicators

Anthrax (2)
Plague (33)
Venezuelan Equine Encephalitis (108)
Smallpox (107)
Botulism (5)
Q Fever (109)
Staph enterotoxin B pulmonary poisoning110
Viral Hemorrhagic Fever (111)
Brucellosis (6)
Ricin poisoning (112)
Tularemia (113)

Shigellosis (43)
Staph aureus Methicillin Resistant – Invasive (130)
Strep pneumoniae Invasive Disease
  1. Penicillin resistant (50)
  2. Penicillin sensitive (49)
Syphilis (70-76)
Tetanus (44)
Toxic Shock Syndrome
  1. Staphylococcal (45)
  2. Streptococcal (97)
Trichinosis (46)
Vancomycin Resistant Enterococci Invasive(101)
Varicella deaths (114)
Vibrio infections (104)
Yellow Fever (98)
Yersinia (103)
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<td>3. All Other</td>
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<td>(133)</td>
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From: Pettit, April [mailto:april.pettit@Vanderbilt.Edu]
Sent: Tuesday, September 18, 2012 1:50 PM
To: Tim F. Jones
Subject: Aspergillus meningitis

Dr. Jones,

We have a case of a 55yo immunocompetent man with Aspergillus fumigatus meningitis. He...
which is the only explanation we can find to explain this. He also has an L4-L5 1cm epidural...
you feel that an investigation is warranted. I am happy to discuss it further if you like.
Thanks!
April Pettit
Within 96 Hours…

- Notifying medical community
- Identifying additional cases
- Investigating clinic
- Identifying suspect medication
- Tracing product to NECC
- Discussing with CDC
Within Two Weeks...

• Product recalled
• National notification
• Multi-state investigation
• Many agencies
Compounding Pharmacies

- Mix pharmaceutical agents
- Medications otherwise not available
- Respond to shortages
- Reduce costs
- Multiple outbreaks
- Regulation difficult
Meningitis toll in TN reaches 5

Firm settled 2004 suit in similar death case

By Walter F. Roche Jr.
The Tennessean

Search for at-risk Saint Thomas patients expands
Outbreak hits 5 states

TN alerts nation to meningitis crisis that has sickened at least 18 residents

By Tom Wilemon and Walter F. Roche Jr.
The Tennessean

Tennessee’s outbreak of a rare form of fungal meningitis has evolved into a national health crisis that has sickened at least 26 people in five states, killing four of them — and officials say the count is certain to rise.

A Massachusetts specialty pharmacy that already had a record of regulatory violations was linked Wednesday to the disease outbreak and voluntarily surrendered its license. Doctors and health officials in Tennessee had alerted federal officials that the company’s medicine might be the cause of the infections — an action that mobilized the nation’s health care system to identify illnesses in other states and keep more people from getting sick.

Tennessee’s quick response — starting with a young doctor who first realized that the injections could be the culprit — was “a textbook example of how to do things right,” said Dr. William Shaffner, a Vanderbilt professor who is president of the National Foundation of Infectious Diseases.

However, more than 1,000 state residents who had already received the steroid epidual injections will still have to wait and wonder whether the pathogen that causes the disease — a common mold called Aspergillus — is incubating in their spinal columns.

Tennessee residents at risk are

OUTBREAK, 4A

LATEST DEVELOPMENTS

- Official count of illnesses in Tennessee rises to 18.
- Window of concern widens to July 1 to Sept. 28.
- Number of clinics that gave suspect injections rises to three.
- FDA reveals suspect medicine came from a Massachusetts compounding lab.
- Tennessee outbreak becomes national health crisis.

PRESIDENTIAL DEBATE

Obama, Romney in first clash
Outbreak spreads, and so does fear

Knowing that fungal meningitis is rare does little to ease anguish.
Multistate Outbreak of Fungal Infection Associated with Injection of Methylprednisolone Acetate Solution from a Single Compounding Pharm — United States, 2012

Fungal Infections Associated with Contaminated Methylprednisolone Injections — Preliminary Report

Iatrogenic Fungal Meningitis: Tragedy Repeated

Fungal Infections Associated with Contaminated Methylprednisolone in Tennessee
States Receiving Contaminated NECC Steroids
Number of Fungal Infections

* As of 12/17/2012
Outbreak Investigation

- Contacting >1000 patients
- Active case finding
- Epidemiologic study
- Laboratory testing
- Public messaging
Outbreak Investigation

• Over 360 staff assisting
• >> 7000 hours (just central ofc)
• Local, regional, state staff
Still not over...
Critical Aids in Investigation

• Relationships with medical community
  – Reported case
  – Excellent ongoing cooperation
  – Open access to medical records

• Good relationships with media
Critical Aids in Investigation

- Emergency preparedness plans in place
- Broad legal authority
- Flexibility with staff
- Federal, state and local cooperation
Barriers to Investigation

- Stretched resources
- Shrinking budgets
- Interagency communication challenges
Important Lessons

• Robust public health infrastructure critical
  – All-hazards preparedness

• Preexisting plans and relationships key

• Compounding pharmacy regulation complex
Carmen Catizone
Executive Director
National Association of Boards of Pharmacy