Georgia Department of Public Health

Board of Public Health Meeting

Tuesday, November 13, 2012

We Protect Lives.

Swearing in of New Board Member

Cynthia A. Mercer, M.D.

Board Member Introduction

James Curran, M.D.

Commissioner's Update

Brenda Fitzgerald, M.D.

Board Update:
Emergency Preparedness Coordination with the Military

J. Patrick O'Neal, M.D.

Board Update: Accreditation

Gary Nelson, Ph.D.
Carole Jakeway RN, MPH

Public Health Accreditation

Deliberate process to strengthen performance management and measureable improvements in the efficiency, effectiveness, performance, accountability and results of public health

Overview

- Public Health Accreditation Board (PHAB) is the Accrediting Body
- Eligible applicants are tribal, state, local and territorial public health departments
- Accreditation for health departments is voluntary
- Accreditation standards and process were developed by practitioners and beta tested
- PHAB offers online orientation and resource materials to assist with application
- A community health assessment, community health improvement plan, and a department strategic plan are required in the application
- A fee schedule exists based on the population served by the applicant's jurisdiction

7 steps of PHAB accreditation

1. Pre-application
2. Application
3. Document selection and submission
4. Site visit
5. Accreditation decision
6. Reports
7. Reaccreditation

Proposed Learning Community for Seeking Public Health Accreditation

- Interest Among Districts
- Purpose
- Goals
- 6 Components
- Sustainability

Multi-State Fungal Meningitis Outbreak, 2012

Cherie Drenzek, DVM, MS

Overview

- Outbreak Detection
- Epidemiologic Investigation
- Laboratory Investigation
- Environmental Investigation
- Control Measures
- Lessons Learned (and still learning)

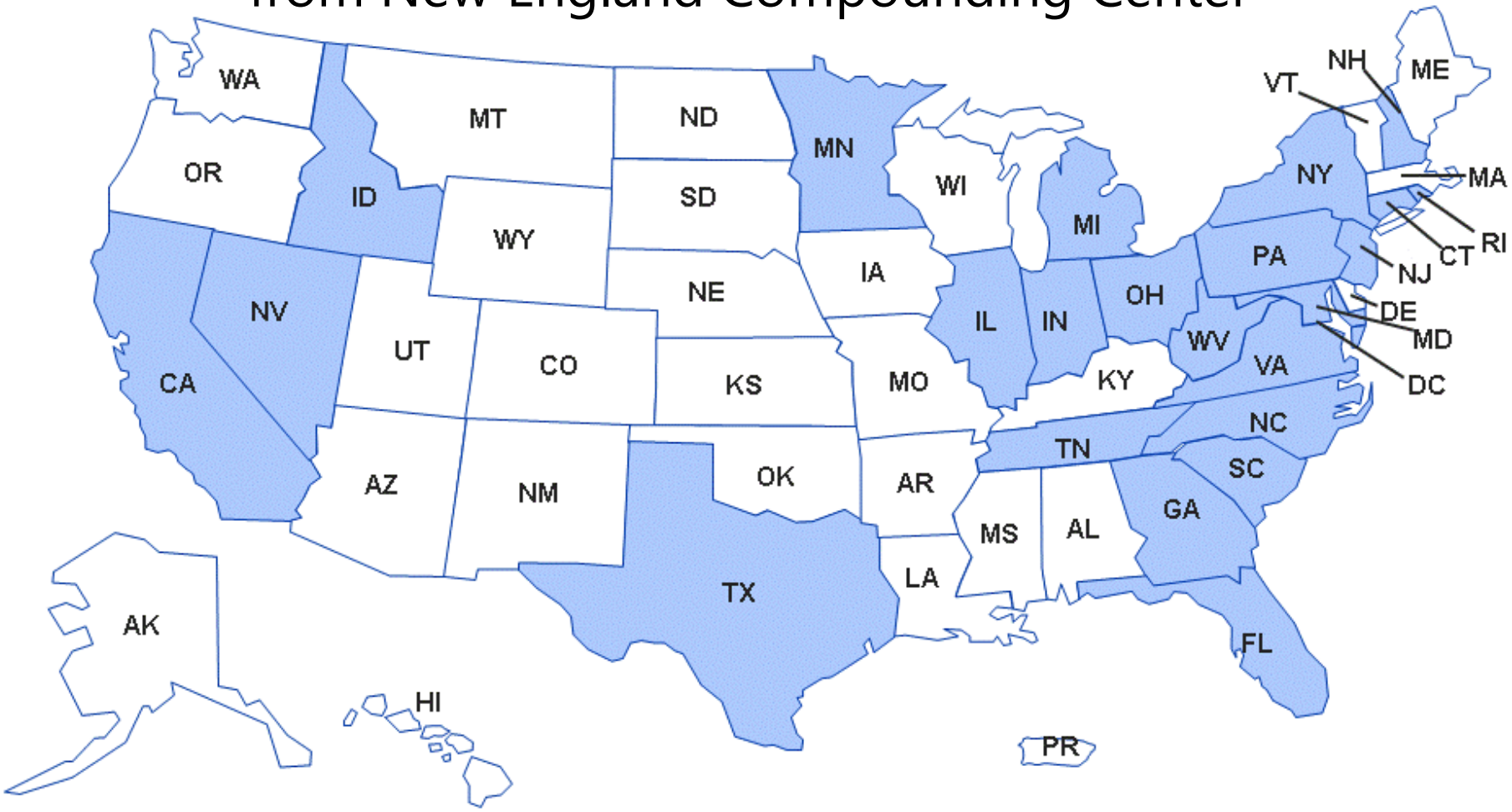
Outbreak Detection

- On Sep. 18, 2012, a clinician in TN reported a case of *Aspergillus* meningitis following receipt of an epidural steroid injection.
- Fungal meningitis is rare and typically occurs in immunosuppressed persons.
- CDC was notified; by Sep. 25, active surveillance had identified 7 more patients with fungal meningitis from the same TN clinic and one from a NC clinic.
- All 9 patients received one of 3 lots of preservative-free methylprednisolone acetate from the New England Compounding Center (NECC) in Framingham, MA.

Initial Recall

- On Sep. 26, 2012, FDA worked with NECC to issue a voluntary recall of the three lots of methylprednisolone (05212012@68, 06292012@26, and 08102012@51).
- Since May 21, 2012, vials from these lots had been distributed to 76 facilities in 23 states.
- CDC notified all affected states (including Georgia) on Sep. 28, 2012.

States Receiving Recalled Methylprednisolone Acetate (MPA) from New England Compounding Center



In Georgia, only one facility (an ambulatory surgery center in Macon) received MPA from the recalled lots—a total of 240 doses.

Epidemiologic Investigation: Initial Findings

- Median case-patient age ~68 years
- Median incubation period ~19 days
- Tennessee data showed infection significantly associated with age > 60 years, female sex, multiple injections, and receipt of Lot 06
- Many case-patients had mild symptoms yet elevated white cells in their CSF indicating meningitis
- Among case-patients, the first presenting symptom often was headache

Epidemiologic Investigation

- Goals:
  - Identify population at risk (those exposed to the 3 implicated lots of steroid)
  - Identify period of risk (initial data suggested up to 6 week incubation period)
  - Identify cases of fungal meningitis as early as possible
  - Elucidate risk factors for infection
  - **Facilitate early treatment**
- Nationally, 14,000 patients received MPA injections from the three implicated lots (180 patients in Georgia)

GA Epidemiologic Investigation: Priority #1

- **Rapid recognition of illness and prompt initiation of therapy to prevent severe complications**
  - Notified all 180 patients about exposure.
  - Warned patients to pay attention to mild symptoms and alerted physicians to consider fungal meningitis in such cases.
  - Electronic communication to 32,000 physicians/PAs in Georgia
  - Monitored exposed cohort for at least 6 week period (last injection was given Sep.24).

DPH
Georgia Department of Public Health

Brenda Fitzgerald, MD, Commissioner | Nathan Deal, Governor

2 Peachtree Street NW, 15th Floor
Atlanta, Georgia 30303-3142
www.health.state.ga.us

NEWS RELEASE

FOR IMMEDIATE RELEASE:
October 5, 2012

CONTACT:
Nancy Nydam

Georgia Health Officials Warn of Potential Fungal Meningitis Associated With Potentially Contaminated Injection

ATLANTA – The Georgia Department of Public Health (DPH) is working with the CDC and the FDA to investigate an outbreak of fungal (*Aspergillus*) meningitis among patients who received an epidural steroid injection. Several of these patients also suffered strokes that are believed to have resulted from their infection. As of Oct. 4, 2012, five deaths have been reported – none, however, occurring in Georgia and no infections have been found in Georgia to date. Because the greatest risk for patients infected with fungal meningitis is delayed diagnosis, DPH is working to inform the state's physicians and physician assistants.

Current U.S. cases are associated with a potentially contaminated medication – an injection to treat back pain prepared by New England Compounding Center in Framingham, Mass.

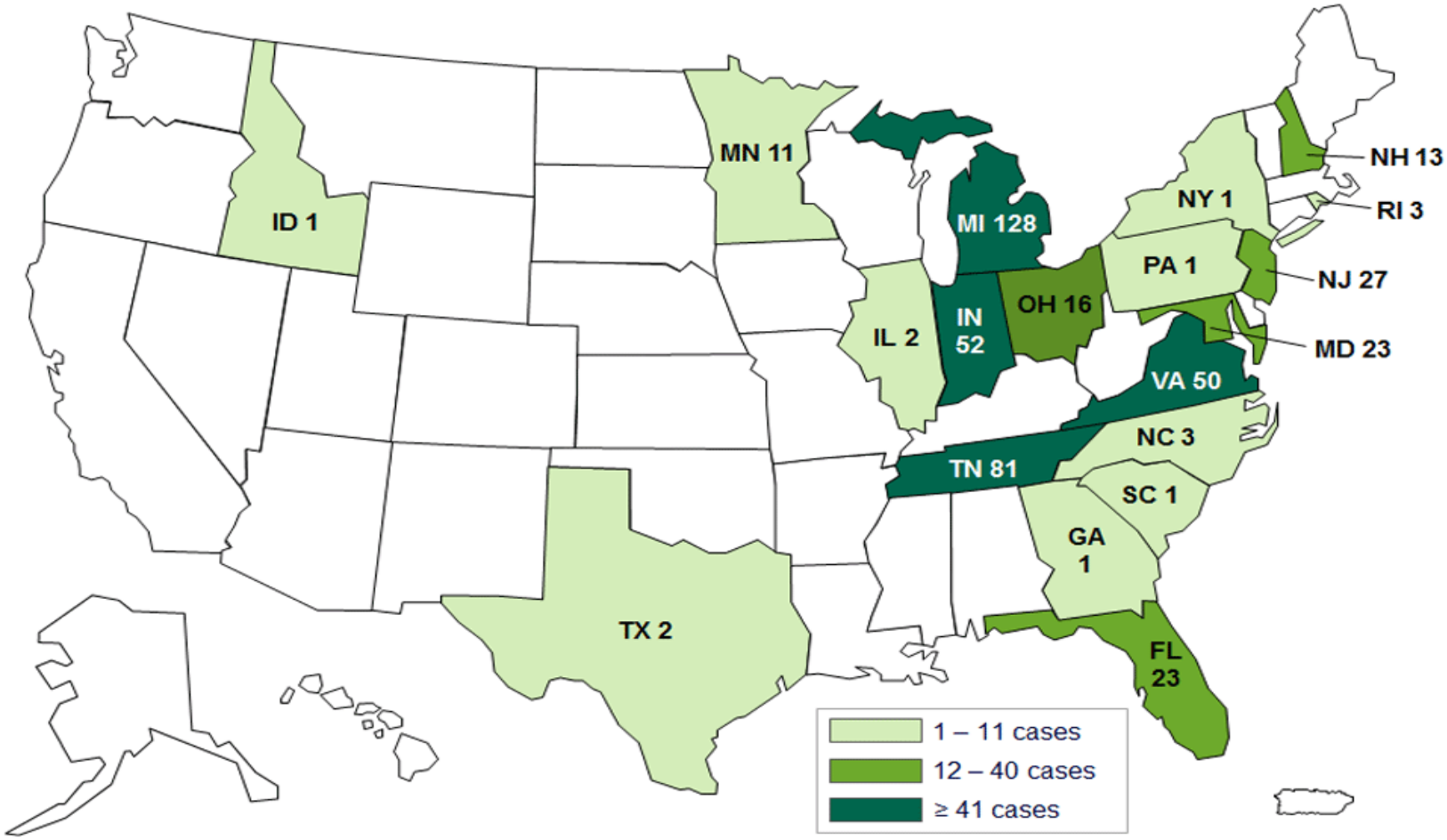
"Georgia has been notified that affected medication was delivered to the Forsyth Street Ambulatory Surgery Center in the Macon area," said J. Patrick O'Neal, M.D., director, Division of Health Protection. "We're asking clinicians in that area to be extra vigilant."

"To date, DPH is aware of no other affected shipments arriving in Georgia," said Cherie Drenzek, D.V.M., M.S., state epidemiologist.

As of today, CDC has identified a total of 43 cases nationwide.

Multistate Fungal Meningitis Outbreak - Current Case Count

As of Nov. 9, 2012: 438 cases in 19 states, 32 deaths



We Protect Lives.

Georgia Case

- First case of fungal meningitis in Georgia identified on Oct. 23
- 66 year-old female from Bibb County
- Received MPA injection from 06 lot in late August
- Was not hospitalized, is doing well

DPH
Georgia Department of Public Health

Brenda Fitzgerald, MD, Commissioner | Nathan Deal, Governor

2 Peachtree Street NW, 15th Floor
Atlanta, Georgia 30303-3142
www.health.state.ga.us

NEWS RELEASE

FOR IMMEDIATE RELEASE:
October 23, 2012

CONTACT:
Nancy Nydam

Georgia Confirms First Case of Fungal Meningitis Amid Nationwide Outbreak

ATLANTA – The Georgia Department of Public Health (DPH) is confirming the state's first case of fungal meningitis related to contaminated epidural steroidal injections. The patient is a 66-year-old female who lives in Bibb County (Macon), Ga. The patient is clinically stable, not hospitalized and is under the care of an infectious disease physician.

The patient received an injection of preservative-free methylprednisolone acetate from one of three implicated lots prepared by the New England Compounding Center (NECC), located in Framingham, Mass. The patient is among those who reported symptoms after receiving an injection for back pain at the Forsyth Street Ambulatory Surgery Center in Macon.

At least two other drugs produced by NECC also are being investigated by FDA. One is an ophthalmic drug used in eye surgery and the other is a cardioplegic used to paralyze the heart during heart transplant surgery. To date there has not been any positive link between these two drugs and the fungal meningitis outbreak. Out of an abundance of caution, the FDA is advising doctors to follow-up with patients who received any NECC injectable product shipped after May 21, 2012.

These fungal infections are not transmitted person-to-person. DPH has been working with Georgia physicians and physicians assistants to raise awareness about patients who have symptoms that suggest possible fungal infection. The symptoms include fever, headache, stiff neck, nausea and vomiting, sensitivity to light and altered mental status. Symptoms of other possible infections may include fever; swelling, increasing pain, redness, warmth at injection site; visual changes, pain, redness or discharge from the eye; chest pain; or drainage from the surgical site. People who received medications

We Protect Lives.

Laboratory Investigation

- During the outbreak, CDC developed a rapid polymerase chain reaction (PCR) test to identify fungi in patients' CSF (research test).
- Although the index case had an *Aspergillus* infection, the predominant fungus identified in patients was *Exserohilum rostratum.*
- *Exserohilum* species are environmental fungi common in grass and soil but have rarely been identified as human pathogens.
- On Oct. 4, CDC and FDA confirmed *Exserohilum* in unopened vials of MPA from two of the three implicated lots (06 and 08).

Environmental Investigation

- FDA investigated the NECC facility in Framingham and observed multiple problems with the clean room, including physical proximity to a recycling plant generating dust, dirt, and debris.
- Observed numerous medication vials “greenish black foreign matter” and “white filamentous material.”
- Identified several species of *Bacillus* bacteria present in the NECC products betamethasone and cardioplegia solution.

Control Measures

- On October 6, NECC voluntarily recalled **all products** compounded at and distributed from its facility in Framingham, MA.
- On October 15 , FDA recommended that physicians follow up with patients who were administered any NECC injectable product since May 21, 2012.
- On October 31, FDA announced that Ameridose, LLC (sister company to NECC) also voluntarily recalled **all** of its unexpired products in circulation.
- To date, there is no evidence of another outbreak (or infections) linked to other NECC or Ameridose products.

Control Measures (cont'd)

- The Georgia Drug and Narcotics Agency seized any remaining NECC products in Georgia.
- We continue to monitor the originally-exposed cohort of 180 patients.
- No new cases identified to date.

What have we learned? What questions remain?

- Zebras do exist (expect the unexpected!)
- Much about clinical presentations, clinical course, rapid laboratory tests, and treatment for rare fungal infections
- Recently, spinal epidural abscesses and arachnoiditis have been reported among case-patients undergoing treatment for fungal meningitis.
  Dosage/monitoring/duration of antifungal treatment?
- The cycle of disease control and prevention is founded upon and informed by surveillance and epidemiologic investigation

Acknowledgments

- Laura Edison, DVM, MPH
- Amber Erickson, MPH
- Matthew Crist, MD, MPH
- Hope Dishman, MPH
- Audrey Martyn, MPH
- Melissa Tobin-D'Angelo, MD, MPH
- Georgia Public Health Laboratory
- Facility A staff

SHAPE Program

Dan Fesperman

Closing Comments

Gary Nelson, Ph.D.