



New Hampshire Health Alert Network

Health.Alert@nh.gov

Status: Actual
Message Type: Alert
Severity: Severe
Sensitive: Not Sensitive
Message Identifier: NH-HAN #20121010 Fungal Meningitis Update #2
Delivery Time: 12 hours
Acknowledgement: No
Originating Agency: NH Department of Health and Human Services, Division of Public Health Services

DATE: October 10, 2012 **TIME:** 1300 EDT

TO: Physicians, Physician Assistants, Nurses, Infection Control Practitioners, Infectious Disease Specialists, Hospital Emergency Departments, Hospital CEOs, Laboratory Response Network, Manchester Health Department, Nashua Health Department, NHHA, NH School Nurses, Pharmacists, Community Health Centers, DHHS Outbreak Team, DPHS Investigation Team, Ambulatory Surgical Centers, Public Health Network, and DPHS Management Team

FROM: Sharon Alroy-Preis MD, State Epidemiologist

SUBJECT: Fungal Meningitis Outbreak Following Epidural Steroid Injection Update #2

New Hampshire DHHS, Division of Public Health Service (NH DPHS) recommends:

- Awareness of **conference call hosted by CDC** to provide clinical guidance to clinicians regarding the multi-state fungal meningitis **today, 10.10.2012, at 2pm**
 - 1-888-790-6180, passcode: COCA
- Discontinue use of all products distributed by the New England Compounding Center (NECC) of Massachusetts. All products manufactured by NECC since January 2012 have been recalled.
- Consideration of fungal etiology in **any** patient with CNS symptoms (meningitis, brain abscess or stroke), with recent (since 5/21/12) epidural NECC medication injection (especially methylprednisolone), even if symptoms are subtle.
- Consideration of fungal etiology in septic arthritis s/p NECC product injection to a peripheral joint.
- Consideration of fungal etiology in osteomyelitis s/p injection to a peripheral or sacroiliac joint or epidural injection.
- Timely reporting to NH DPHS of any suspect cases that may be related to this outbreak.
- Please refer to previous HANs (10/4/12, 10/6/12) for previous specific information on this outbreak.

National Outbreak Update:

The national case count as of October 9, 2012, related to this outbreak is 119 cases in 10 states and 11 deaths. So far both *Aspergillus* spp. and *Exserohilum* spp. have been isolated in patients from CSF, in addition to *P. acnes* of unknown significance, so other fungal and bacterial organisms may still be involved. All products manufactured by NECC since January 2012 have been recalled.

CDC is hosting a conference call for providers at 2pm today and the details are above.

We encourage any interested provider or facility to join the call on this urgent and time-sensitive topic.

Additional information from CDC on this outbreak (including national epidemiology, case definitions, diagnostic and therapy recommendations from national experts) is available at the following link: <http://www.cdc.gov/HAI/outbreaks/meningitis.html>. Updated case definitions will be posted on the CDC website later today.

NH Specific Information:

In New Hampshire, 3 sites used the currently implicated product (Methylprednisolone Acetate of 3 lots) in Pain Care LLC: Merrimack, Somersworth and Newington locations. Total exposed so far: 742 patients: 214 patients post epidural injections and 528 post other site injections. New Hampshire does not yet have confirmed cases associated with this outbreak although investigation of symptomatic patients who have been exposed is ongoing.

You can refer to NH DHHS website for NH specific information:

<http://www.dhhs.state.nh.us/dphs/cdcs/fungal-meningitis.htm>

Please contact the NH DPHS Infectious Disease Investigation and Surveillance Sections at 603-271-4496 (after hours 1-800-852-3345, x5300) to report any suspect or confirmed cases.

This outbreak is rapidly evolving and NH DPHS will continue to provide updates as new information is learned.

Attachments: CDC HAN 08OCT 12

For any questions regarding the contents of this message, please contact NH DHHS Infectious Disease Investigation and Surveillance Sections at 603-271-4496.

After hours or toll free (In NH) at 800-852-3345, ext. 4496 or 603-271-5300 and ask for the public health professional on call.

DEFINITION OF TERMS AND ALERTING VOCABULARY

Message Type

Alert: Original alert
Update: Prior alert has been updated and superseded
Cancel: Prior alert has been cancelled
Error: Prior alert has been retracted

Status

Actual: Refers to a live event
Exercise: Designated recipients must respond to the communication or alert
Test: Related to a technical and/or system test

Severity

Extreme: Extraordinary threat to life or property
Severe: Significant threat to life or property
Moderate: Possible threat to life or property
Minor: Minimal threat to life or property
Unknown: Unknown threat to life or property

Sensitive

Sensitive: Indicates the alert contains sensitive content
Not Sensitive: Indicates non-sensitive content

Message Identifier

A unique alert identifier that is generated upon alert activation

Delivery Time

Indicates the time frame for the delivery of the alert

Acknowledgement

Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the time frame in which a response is required.

Originating Agency

A guaranteed unique identifier for the agency originating the alert.

Alerting Program

The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.

You have received this message based upon the information contained within our emergency notification database.

If you have a different or additional e-mail or fax address that you would prefer to be used, please contact:

Denise M. Krol, MS
NH HAN Coordinator
Denise.Krol@dhhs.state.nh.us

Business Hours: 8 AM – 4 PM
Tel: 603-271-4596
Fax: 603-271-0545

This is an official
CDC Health Advisory

Distributed via Health Alert Network
October 8, 2012, 13:10 ET (1:10 PM ET)
CDCHAN-00328-2012-10-08-ADV-N

**Update: Multistate Outbreak of Meningitis and Stroke
Associated with Potentially Contaminated Steroid
Medication**

Summary

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) continue to work closely with state public health departments on a [multistate investigation of fungal meningitis](#) among patients who received an epidural steroid injection. Some of these patients also suffered strokes that may have resulted from their infection. These cases are associated with a potentially contaminated steroid medication prepared by New England Compounding Center (NECC), located in Framingham, Mass. This HAN notice provides updated information about the investigation (including a change in the case definition*), laboratory findings, an expanded voluntary recall of products, and recommendations for clinicians

Background

CDC, in collaboration with FDA, state public health departments, and state boards of pharmacy, has been investigating an ongoing outbreak of meningitis associated with a potentially contaminated steroid medication, preservative-free methylprednisolone acetate (80mg/ml) prepared by New England Compounding Center, located in Framingham, Mass. CDC and state public health departments are actively coordinating outreach to patients who have been exposed to this potentially contaminated medication.

As of October 8, 2012, a total of 105 cases, including 8 deaths, have been reported in 9 states: Florida (4 cases), Indiana (11 cases), Maryland (5 cases, including 1 death), Michigan (21 cases, including 2 deaths), Minnesota (3 cases), North Carolina (2 cases), Ohio (1 case), Tennessee (35 cases, including 4 deaths), and Virginia (23 cases, including 1 death). Fungus has been identified in specimens obtained from at least nine patients, one of whom also had *Propionibacterium acnes*, of unclear clinical significance, isolated from a post-mortem central nervous system specimen. In addition to an *Aspergillus* spp. isolated from a Tennessee patient, the fungus *Exserohilum rostratum* was identified in other patients, indicating the possibility of infections caused by multiple organisms. Fungal meningitis is not transmitted from person to person.

The clinical presentation of infected patients remains consistent with the prior report: onset of symptoms is typically 1 to 4 weeks following injection with a variety of symptoms, including fever, new or worsening headache, nausea, and new neurological deficit (consistent with deep brain stroke). Some of these patients' symptoms were very mild in nature. Cerebrospinal fluid (CSF) obtained from these patients has typically shown elevated white cell count (with a predominance of neutrophils), low glucose, and elevated protein. As of October 8, no infections resulting from injection into a peripheral joint space have been reported.

Product Recall

On September 26, 2012, the NECC voluntarily recalled the following three lots of methylprednisolone acetate (PF) 80mg/ml:

- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013

All infections detected as of October 8 have occurred after injections with methylprednisolone acetate products from one of these lots. At this time, there is no evidence of infection related to other NECC products.

The FDA investigation into the NECC facility is ongoing. On October 5, [FDA reported](#) observing "fungal contamination by direct microscopic examination of foreign matter taken from a sealed vial of methylprednisolone acetate collected from the New England Compounding Center." Further analysis is ongoing. On October 6, NECC expanded its previous recalls to include all products currently in circulation that were compounded at and distributed from its facility in Framingham, Mass. More information about this recall is available at the [FDA website](#).

Recommendations

- Physicians should contact (by phone or in person) **any patient who had an injection (e.g., spinal, joint) after May 21, 2012, using any of the following three recalled lots of preservative-free methylprednisolone acetate (80mg/ml) produced by NECC**, to determine if they are having symptoms:

- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot# 05212012@68, BUD 11/17/2012
- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot#06292012@26, BUD 12/26/2012
- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot# 08102012@51, BUD 2/6/2013

Symptoms that should prompt diagnostic evaluation include: fever, new or worsening headache, neck stiffness, sensitivity to light, new weakness or numbness, increasing pain, redness or swelling at injection site. Some of the symptoms of patients who have ultimately been diagnosed with meningitis have been mild and not classic for meningitis (e.g., new or worsening headache without fever or neck stiffness).

- Healthcare professionals should cease use of **any** product produced by NECC, all of which have been recalled.
 - **CDC is currently not asking clinicians to actively contact patients who received other products, beyond the previously listed medications, from NECC to assess for symptoms.** However, clinicians should remain vigilant, and report to the state public health department, any infection identified in a patient known to have received a product from NECC.
- CDC has **updated clinician guidance** addressing:
 - [Interim Instructions Diagnostic Testing and Specimen Submission to CDC](#)
 - [Interim Treatment Guidance for Central Nervous System and/or Parameningeal Infections Associated with Injection of Potentially Contaminated Steroid Products](#)
 - [Role of antifungal prophylaxis in asymptomatic patients](#)
 - [Role for lumbar puncture in asymptomatic patients](#)

*[Case Definition](#) (note: the initial date for an epidural/joint steroid injection has been revised [from July 1, 2012, to May 21, 2012](#)).

1. A person with meningitis¹ of sub-acute onset (1-4 weeks) following epidural injection after May 21, 2012.
2. A person with basilar stroke 1-4 weeks following epidural injection after May 21, 2012², who has not received a diagnostic lumbar puncture.
3. A person with evidence of spinal osteomyelitis or epidural abscess at the site of an epidural injection diagnosed 1-4 weeks after epidural injection after May 21, 2012.
4. A person with septic arthritis³ diagnosed 1-4 weeks following steroid joint injection after May 21, 2012.

¹Clinically diagnosed meningitis meaning one or more of the following symptoms: headache, fever, stiff neck, or photophobia **and** a CSF profile consistent with meningitis (pleocytosis +/- low glucose, elevated protein).

²These people, if possible, should have a lumbar puncture.

³Clinically diagnosed septic arthritis meaning new or worsening pain with presence of effusion or new or worsening effusion.

Additional Information

- [Multistate Meningitis Outbreak Investigation](#)
- [Meningitis and Stroke Associated with Potentially Contaminated Product](#)
- [CDC Website on Fungal Diseases](#)
- [FDA Statement on Fungal Meningitis Outbreak](#)

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Categories of Health Alert messages:

Health Alert conveys the highest level of importance; warrants immediate action or attention.
Health Advisory provides important information for a specific incident or situation; may not require immediate action.
Health Update provides updated information regarding an incident or situation; unlikely to require immediate action.

##This Message was distributed to State and Local Health Officers, Public Information Officers, Epidemiologists and HAN Coordinators as well as Clinician organizations##

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You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail or fax address that you would like us to use please contact your State-based Health Alert Network program at your State or local health department.

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