New Hampshire Health Alert Network
Health.Alert@nh.gov

Status:	Actual
Message Type:	Alert
Severity:	Severe
Sensitive:	Not Sensitive
Message Identifier:	NH-HAN #20121204 Fungal Meningitis Update #8
Delivery Time:	12 hours
Acknowledgement:	No
Originating Agency:	NH Department of Health and Human Services, Division of Public Health Services

DATE: December 4, 2012 **TIME:** 1600 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 and Administrators, 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 Update #8

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

- Review of the attached CDC Health Alert Advisory with additional microbial contamination identified in medical products from the New England Compounding Center (NECC).
- Awareness that at this time there has not been a lab confirmation of infection related to the use of non-methylprednisolone NECC products.
- Ongoing clinical evaluation and timely reporting to NH DPHS and FDA's MedWatch of symptomatic patients who received NECC contaminated products.
- Consultation with infectious disease specialists to help make treatments decisions when evaluating patients.

National Outbreak Update:
As of December 4, 2012, a total of 541 cases have been reported in 19 states with 36 deaths. As previously reported, *Exserohilum rostratum* is the predominant fungus identified in patients and confirmed by the CDC laboratory from the three initially recalled lots of methylprednisolone from NECC. CDC has continued to recommend to healthcare providers to remain vigilant for the possibility of infections that may have resulted from the injection of NECC products.

NH Specific Information:
To date, New Hampshire has reported 13 cases associated with this national outbreak, 9 with meningitis and 4 with joint infection. All patients have been in care and any patient who received an injection with the three contaminated lots of methlyprednisolone has been contacted. Of the 24 facilities that received additional non-methylprednisolone acetate NECC injectable products, NH DPHS has previously contacted those facilities with the updated CDC and FDA laboratory test results. To date, all facilities have conducted patient notifications and healthcare

providers are encouraged to maintain a continued awareness for reports of illness and perform clinical evaluation as appropriate.
Please refer to previous HANs (10/4/12, 10/6/12, 10/10/12, 10/14/12, 10/19/12, 11/1/12, 11/21/12) http://www.dhhs.nh.gov/dphs/cdcs/alerts/han.htm for additional information on this outbreak.

For any questions regarding the contents of this message, or to report cases, 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.

Attachments: CDCHAN-00337

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 UPDATE

Distributed via the CDC Health Alert Network
December 03, 2012, 4:55 ET
CDCHAN-00337

Update: Additional Contamination Identified in Medical Products from New England Compounding Center

Summary: As part of the ongoing investigation of the multistate outbreak of fungal meningitis and other infections, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) continue to test medical products from the New England Compounding Center (NECC) in Framingham, Mass. CDC and FDA are reporting today additional microbial contamination identified in NECC products, which updates the November 1, 2012 Health Alert Network advisory. This update includes the following key points:

- CDC and FDA have identified additional microbial contamination in unopened vials of betamethasone, cardioplegia, and triamcinolone solutions distributed and recalled from NECC.
- These include bacteria known as *Bacillus*, and fungal species including *Aspergillus tubingensis*, *Aspergillus fumigatus*, *Cladosporium* species, and *Penicillium* species.
- Although rare, some of the identified *Bacillus* species can be human pathogens. Some of the fungal organisms identified, particularly *Aspergillus fumigatus*, are known to cause disease in humans. It is not known how product contamination with these organisms could affect patients clinically.
- To date, although CDC has received reports of illness in patients who have received the medications listed in the table below, including some patients who had evidence of meningeal inflammation, CDC and public health officials have no reports of laboratory-confirmed bacterial or fungal meningitis, spinal, or paraspinal infections caused by these products.
- The available epidemiological and laboratory data do not, at this time, support evidence of an outbreak of infections linked to usage of non-methylprednisolone NECC products.
- CDC's recommendations to healthcare providers for diagnosing and treating symptomatic patients who have received NECC products have not changed as a result of these findings.
- CDC continues to recommend that clinicians remain alert for the possibility that infections may have resulted from injection of NECC products, and that routine laboratory and microbiologic tests, including bacterial and fungal cultures, should be obtained as deemed necessary by treating clinicians.
- Clinicians should continue to report infections potentially related to NECC products to FDA's MedWatch and to state health departments.

Background

On September 26, 2012, NECC voluntarily recalled three lots of preservative-free methylprednisolone acetate (PF) 80mg/ml[1] associated with the multistate outbreak of fungal meningitis and other infections. As previously confirmed by CDC and FDA, the fungus *Exserohilum rostratum* was identified from two different lots of NECC-supplied, preservative-free methylprednisolone acetate (Lot #06292012@26 and Lot #08102012@51); testing on the third implicated lot of preservative-free methylprednisolone acetate (Lot #05212012@68) has yet to identify fungal growth. Two types of fungus not known to be human pathogens were also identified from product from the two tested lots, namely *Rhodotorula laryngis* and *Rhizopus stolonifer*. Among these fungal organisms, only *Exserohilum rostratum* has been associated with human infections in this outbreak.

On October 6, NECC expanded its recall to include all products in circulation that were distributed from its facility in Framingham, Mass. As part of the ongoing investigation, FDA and CDC have been testing various NECC products for evidence of contamination. Laboratory testing at CDC and FDA has found bacterial and/or fungal contamination in unopened vials of betamethasone, cardioplegia, and triamcinolone solutions distributed and recalled from NECC, as shown in the table below.

Laboratory-Confirmed Organisms from Product Samples Associated with NECC Recalled Lots of Betamethasone, Cardioplegia, and Triamcinolone Solutions

Medication	Lot Number	Bacterial and Fungal Contamination
Betamethasone 6 mg/mL injectable –5 mL per vial	08202012@141	*Paenibacillus pabuli/amolyticus, Bacillus idriensis, Bacillus flexus, Bacillus simplex, Lysinibacillus* sp., *Bacillus niacini, Kocuria rosea, Bacillus lentus*
Betamethasone 6 mg/mL injectable –5 mL per vial	07032012@22	*Bacillus niabensis, Bacillus circulans*
Betamethasone 12 mg/mL injectable – 5 mL per vial	07302012@52	*Bacillus lentus, Bacillus circulans, Bacillus niabensis, Paenibacillus barengoltzii/timonensis*
Betamethasone 6mg/mL injectable – 5 mL per vial	08202012@44	*Bacillus lentus, Bacillus firmus, Bacillus pumilus*
Betamethasone 6 mg/mL injectable – 5 mL per vial	08152012@84	*Penicillium* sp., *Cladosporium* sp.
Triamcinolone* 40mg/mL injectable – 1 mL per vial	06062012@6	*Bacillus lentus, Bacillus circulans*
Triamcinolone 40 mg/mL injectable – 2 mL per vial	08172012@60	*Aspergillus tubingensis, Penicillium* sp.
Triamcinolone 40mg/mL injectable – 10 mL per vial	08242012@2	*Aspergillus fumigatus*
Cardioplegia solution 265.5 mL per bag	09242012@55	*Bacillus halmapalus/horikoshii, Brevibacillus choshinensis*

*Identification of other bacteria for this product is pending.

Recommendations to Healthcare Providers

FDA released a MedWatch Safety Alert on October 15 stating that the sterility of any injectable drugs, including ophthalmic drugs that are injectable or used in conjunction with eye surgery, and cardioplegic solutions produced by NECC is of significant concern. The safety alert further advised healthcare providers to follow-up with patients who were administered any of these products purchased from or distributed by NECC on or after May 21, 2012. A sample notification letter to assist with this process is available.

CDC's recommendations to healthcare providers for diagnosing and treating symptomatic patients who have received NECC products have not changed as a result of the laboratory findings reported here. CDC continues to recommend that clinicians remain vigilant for the possibility that infections may have resulted from injection of NECC products, and that routine laboratory and microbiologic tests, including bacterial and fungal cultures, should be obtained as deemed necessary by treating clinicians.

There has been no prior systematic surveillance for adverse events following epidural steroid injections; however, infection is a known, although likely rare, risk that has been documented in the medical literature. To date, although CDC is aware of reports of illness in patients who have received these medications, including some patients who had evidence of meningeal inflammation, CDC and other public health officials have no reports of laboratory-confirmed bacterial or fungal meningitis, or spinal or paraspinal infections caused by these products. The available epidemiological and laboratory data do not, at this time, support evidence of an outbreak of infections linked to usage of non-methylprednisolone NECC products.

However, because it is possible that some of the organisms listed in the table above can cause human disease, clinicians should continue to include bacterial and/or fungal infection in the differential diagnosis when evaluating symptomatic patients who were exposed to these medications, including consideration of empiric antifungal therapy.

Consultation with an infectious disease specialist is strongly encouraged to help make treatment decisions in these cases. If the evaluation of these patients is suggestive of fungal infection, please consult existing CDC treatment guidance associated with this outbreak.

Physicians should continue to report infections potentially related to NECC products to FDA's MedWatch and to state health departments.

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[1] NECC 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

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.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention; highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, public information officers, epidemiologists, HAN coordinators, and clinician organizations##