

## DPHHS HAN

# Information Service

**NOTE:** The **Information Service** HAN is a new distribution category. This level of message is sent to email **ONLY** and will not go to your listed contact phone.

## Cover Sheet

**DATE:** December 4, 2012

**SUBJECT:** Multistate Outbreak of Fungal Meningitis and Other Infections Associated with Contaminated Steroid Medication: Additional Contamination Identified

**For LOCAL HEALTH DEPARTMENT reference only**

DPHHS Subject Matter Resource for more information regarding this HAN, contact:

**DPHHS CDCP  
Epidemiology Section  
1-406-444-0273**

### INSTRUCTIONS:

***DISTRIBUTE*** to your local HAN contacts. This HAN is intended for general sharing of information. **Remove this cover sheet before redistributing and replace it with your own.**

**DPHHS Health Alert Hotline:  
1-800-701-5769**

**DPHHS HAN Website:  
[www.han.mt.gov](http://www.han.mt.gov)**

**Remove this cover sheet before redistributing and replace it with your own.**

**Please ensure that DPHHS is included on your HAN distribution list.**

### Categories of Health Alert Messages:

**Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.

**Information Service:** passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

**Please call DPHHS to update contact information at 444-0919**

**DPHHS policy is to forward all HAN messages from the Centers for Disease Control and Prevention (CDC)**

# Information Sheet

**Date:** December 4, 2012

**Subject: Multistate Outbreak of Fungal Meningitis and Other Infections Associated with Contaminated Steroid Medication: Additional Contamination Identified**

**Information:** Please see the attached CDC Health Alert Network (HAN) Advisory regarding Additional contamination associated with the New England Compounding Center multistate outbreak of meningitis and other infections associated with epidural steroid injection.

## Key Points & Recommendations:

This HAN notice provides updated information on the following:

- 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.
- CDC and public health officials have no reports of laboratory-confirmed bacterial or fungal meningitis, spinal, or paraspinal infections caused by these products.
- CDC's recommendations to healthcare providers have not changed.

# 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<sup>1</sup> 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.

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

\*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.

---

<sup>1</sup> 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##