

**October 19, 2012**

**TO:** Healthcare Providers, Hospitals, Healthcare Facilities, Pharmacists, and Local Health Departments (LHDs)

**FROM:** New York State Department of Health (NYSDOH) Bureau of Communicable Disease Control (BCDC)

**HEALTH ADVISORY: CLUSTER OF CLINICAL MENINGITIS : UPDATE #3**  
Please distribute to the Emergency Department, Infectious Disease, Neurosurgery, Anesthesia, Pharmacy, Infection Control, Medical Director, Director of Nursing, Laboratory Service and all patient care areas.

*This advisory updates the previous advisory dated October 8, 2012  
Information that has been revised is highlighted*

## **SUMMARY**

- This Health Advisory transmits the most recent CDC Health Advisory dated October 17, 2012 (see attached).
- New York State has identified one case associated with this outbreak. This case has not resulted in death. This patient received joint injections of methylprednisolone acetate from one of the three lots listed below.
- As of October 18, 2012, 254 cases, which include 3 peripheral joint infections, have been reported in 15 states. Twenty of the cases have resulted in death.
- The pathogen *Exserohilum rostratum* has been reported in clinical specimens from multiple cases with fungal meningitis and other spinal infections. Investigations are ongoing to determine if other organisms are involved in these infections. At this time, one clinical specimen tested positive for the fungus *Aspergillus fumigatus*, and another for the fungus *Cladosporium*.
- On October 18, 2012, CDC and FDA have confirmed the presence of *Exserohilum rostratum* in unopened medication vials of preservative-free methylprednisolone acetate (80mg/ml) from one of the three implicated lots from NECC (Lot #08102012@51, BUD 2/6/2013). Testing on the two other implicated lots of methylprednisolone acetate and other NECC injectables continues.
- All cases reported to date have occurred after injections with methylprednisolone acetate products. However, on October 15, a MedWatch Safety Alert was issued by FDA, announcing the identification of a patient with possible fungal meningitis who had received an epidural injection of triamcinolone acetonide produced by NECC, though no laboratory evidence supports the infection. In addition, there has been one report of a cardiac transplant patient with *Aspergillus fumigatus* infection who was

administered NECC cardioplegic solution, though other causes of this infection have not been ruled out.

- FDA cannot confirm the sterility of any of the NECC products. Out of an abundance of caution, FDA is currently advising clinicians that if, after May 21, 2012, a health care professional administered to a patient an injectable product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution purchased from or produced by NECC, the healthcare professional should follow up with those patients and make sure the patients are aware of the signs and symptoms of infection and instruct them to contact their health care provider immediately if they have any of these symptoms. The FDA has provided a template notification letter for healthcare professionals notifying their patients administered a drug produced by the NECC that has been recalled. The letter is available at <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM324538.pdf>.
- The list attached only includes facilities that received methylprednisolone acetate or other intrathecal medications. FDA has announced that it will release a list of facilities that received any product from NECC after May 2011 on its website in the near future.
- A complete list of all products subject to this recall is available at <http://goo.gl/SJiI7>.
- While providers should remain vigilant, at this time CDC has not requested patient notification or active surveillance of patients who received other NECC products.
- CDC and NYSDOH have requested notification to and active surveillance of patients who were exposed to contaminated lots of methylprednisolone at any time:
  - 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
- Providers who become aware of possible fungal infection related to the site of injection (not necessarily meningitis) in a patient that has received any product from NECC should immediately notify their LHD. LHD contact information can be found at <http://goo.gl/FBccq>.
- Only three New York States facilities received the contaminated lots of methylprednisolone that have been associated with illness:
  - Mineola, NY: Sunil H. Butani, M.D.
  - Mount Vernon, NY: Obosa Medical Services
  - Rochester, NY: Rochester Brain and Spine
- All other locations received NECC products not known to be contaminated and not, to date, associated with illness. NYSDOH has contacted the additional sites to assure that they are pulling these products.
- Providers can access CDC's clinical recommendations, including but not limited to Interim Instructions for Diagnostic Testing, Interim Treatment Options, and the Role of Lumbar Puncture and Antifungal Prophylaxis in Asymptomatic Patients at <http://goo.gl/ZuPZJ>.
- LHDs should immediately notify BCDC upon learning of suspected cases.
- Fungal meningitis is not transmitted from person to person.

If you have any questions regarding this information, please contact your LHD or the NYSDOH Bureau of Communicable Disease Control at [bcdc@health.state.ny.us](mailto:bcdc@health.state.ny.us) or (518) 473-4439.

Listing of New York State facilities that received shipments from NECC of methylprednisolone acetate or other intrathecal medications after May 21, 2012.

Facility	City	State
ALBANY CENTER FOR PAIN MANAGEMENT	ALBANY	NY
AMBULATORY SURG. CTR. OF WESTERN NY	AMHERST	NY
AMBULATORY SURGERY CTR. OF GNY	BRONX	NY
BOULEVARD SURGICAL CENTER	LONG ISLAND CITY	NY
BROOKLYN ENDOSCOPY & AMBULATORY SURG CTR	BROOKLYN	NY
BUTANI, SUNIL H. PHYSICIAN PC	MINEOLA	NY
CENTER FOR SIGHT-NY	ALBANY	NY
COLUMBIA MEMORIAL HOSPITAL-PHARMACY	HUDSON	NY
DUTCHESS ASC	POUGHKEEPSIE	NY
EASTERN LONG ISLAND HOSPITAL	GREENPORT	NY
ELMHURST HOSPITAL CENTER	ELMHURST	NY
EYE HEALTH ASSOCIATES	BUFFALO	NY
F.F. THOMPSON HOSPITAL	CANADAIGUA	NY
GALLERIA PAIN MANAGEMENT	NEW YORK	NY
GLEN FALLS HOSPITAL	GLENS FALLS	NY
GRAMERCY PARK PODIATRY-	NEW YORK	NY
HERITAGE ONE DAY SURGERY	N. SYRACUSE	NY
HUDSON VALLEY AMBULATORY SURGERY LLC	MIDDLETOWN	NY
JOSEPHBERG, ROBERT MD	YONKERS	NY
KULICLINICA	BROOKLYN	NY
LONG ISLAND JEWISH MEDICAL CENTER	NEW HYDE PARK	NY
LONG ISLAND VITREO RETINOLOGISTS	HAUPPAUGE	NY
MID-HUDSON PAIN MANAGEMENT	NEWBURGH	NY
NEW YORK SPINE & SPORT	BRONX	NY
NICHOLAS NOYES MEMORIAL HOSPITAL	DANSVILLE	NY
NISSSEN, MICHAEL MD.	NEW YORK CITY	NY
NORTH COUNTRY ORTHOPAEDIC ASC	WATERTOWN	NY
NORTHEAST ORTHOPAEDICS	ALBANY	NY
NY SURGICAL AND ANESTHESIA SUITES, PC	BRONX	NY
OBOSA MEDICAL SERVICES	MOUNT VERNON	NY
OKSA MEDICAL CENTER	REGAL PARK	NY
OPHTHALMIC CONSULTANTS OF L.I.	EAST SETAUKET	NY
OPHTHALMIC CONSULTANTS OF LONG ISLAND	LYNBROOK	NY
OPHTHALMIC CONSULTANTS OF LONG ISLAND	ROCKVILLE CENTRE	NY
OPHTHALMIC CONSULTANTS OF LONG ISLAND	MINEOLA	NY
ORANGETOWN OPHTHALMOLOGY	WEST NYACK	NY
PAIN MANAGEMENT OF LONG ISLAND	PORT JEFFERSON STATION	NY
PAIN MEDICAL PLLC	BROOKLYN	NY
PAIN MEDICINE AND WELLNESS CENTER	WHITE PLAINS	NY
PLATINUM WELLNESS CENTER	BROOKLYN	NY
QUEENS HOSPITAL CENTER	JAMAICA	NY
RETINA ASSOCIATES OF WESTERN NEW YORK	ROCHESTER	NY
RETINA SPECIALIST PC	NEW YORK	NY
ROCHESTER BRAIN AND SPINE	ROCHESTER	NY
SARATOGA HOSPITAL-PHARMACY	SARATOGA SPRINGS	NY
SPECIALTY SURGERY CENTER OF CNY	LIVERPOOL	NY
STATEN ISLAND OPHTHALMOLOGY	STATEN ISLAND	NY
SURGICARE OF MANHATTAN	NEW YORK	NY
THE MACKOOL EYE INSTITUTE, LLC	ASTORIA	NY
UNITY HOSPITAL-PARK RIDGE	ROCHESTER	NY

# This is an official **CDC Health Advisory**

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## **Update: Multistate Outbreak of Fungal Meningitis and Joint Infections Associated with Contaminated Steroid Medications**

### **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 and joint infections among patients who received a methylprednisolone acetate injection prepared by the New England Compounding Center (NECC) in Framingham, Mass. Some of these patients who received epidural injections also suffered strokes that may have resulted from their infection. This HAN notice provides updated information on the following:

- Status of the investigation.
- FDA issuance of a [MedWatch Safety Alert on October 15](#) advising clinicians to follow-up with patients who received an injectable NECC product, including any ophthalmic drug that is injectable or used in conjunction with eye surgery, and a cardioplegic solution purchased from or produced by NECC after May 21, 2012.
- Recommendations for clinicians.
- Case definition.

### **Background**

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

As of October 16, 2012, a total of 233 cases, which includes 2 peripheral joint infections and 15 deaths, have been reported in 15 states (see [CDC's website](#) for up-to-date information about case count and distribution by state). The fungus *Exserohilum rostratum* has been reported in clinical specimens from multiple patients with fungal meningitis and with other spinal infections (e.g., epidural abscess). CDC and FDA continue to investigate the possibility of contamination with additional organisms. At this time, one clinical specimen has tested positive for the fungus *Aspergillus fumigatus*, and another has tested positive for the fungus *Cladosporium*. Fungal meningitis is not transmitted from person to person.

The clinical presentation of infected patients with fungal meningitis remains consistent with that described in previous reports: onset of symptoms is typically between 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). However, fungal infections can be slow to develop, and there are reports of longer periods between injection and onset of symptoms; and, therefore, patients and their doctors need to watch closely for symptoms for at least several months following the injection. Some of these patients' symptoms were very mild in nature. Cerebrospinal fluid (CSF) obtained from these patients has typically had an elevated white cell count (usually with a predominance of neutrophils), and in many cases low glucose and elevated protein. As of October 16, two peripheral joint infections have

been reported. CDC expects that through ongoing patient notification efforts, additional patients with infections of the joints may come forward.

On September 26, 2012, NECC voluntarily recalled the following 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

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](#).

All cases reported as of October 16 have occurred after injections with methylprednisolone acetate products from one of the three lots recalled on September 26.

#### **FDA MedWatch: Additional NECC Products of Potential Concern**

On October 15, FDA released a [MedWatch Safety Alert](#) announcing that, as a result of the ongoing investigation of NECC, a patient with possible fungal meningitis who had received an epidural injection of triamcinolone acetonide produced by NECC has been identified through active surveillance efforts by CDC and state health departments and reported to FDA. Triamcinolone acetate is a type of steroid injectable product made by NECC. As of October 17, there is no laboratory evidence of fungal infection in this patient. As noted above, all cases of fungal meningitis identified to date have been associated with methylprednisolone acetate, another similar steroid injectable product distributed by NECC.

In addition, FDA received a report of one cardiac transplant patient with *Aspergillus fumigatus* infection who was administered NECC cardioplegic solution, which is used to prevent injury to the heart during surgery. Investigation of this patient is ongoing; there may be other explanations for this patient's *Aspergillus* infection.

This is preliminary information and CDC does not have firm evidence that infections have been caused by exposure to NECC products beyond the three previously listed lots of methylprednisolone acetate. Out of an abundance of caution, FDA has advised clinicians to follow up with patients to whom they have administered an injectable product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, and a cardioplegic solution purchased from or produced by NECC after May 21, 2012.

Clinicians should perform a thorough diagnostic evaluation to exclude infection in those patients who report signs and symptoms of infection following high-risk exposure to one of these NECC products (e.g., exposure of product to sterile body site). If the evaluation of these patients is suggestive of fungal infection, please consult existing CDC treatment guidance <http://www.cdc.gov/hai/outbreaks/clinicians/index.html>. Consultation with an infectious disease specialist is strongly encouraged to help make treatment decisions in these cases.

Products from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo that can be accessed [here](#). Additional information about the MedWatch Safety Alert notice is available on the [FDA website](#).

#### **Recommendations for Clinicians**

CDC and FDA have three recommendations for clinicians.

1. Clinicians 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 fungal meningitis have been mild and not classic for meningitis (e.g., new or worsening headache without fever or neck stiffness).

2. Healthcare professionals should cease use of **any** product produced by NECC, all of which have been recalled.
  - Through its investigation of the NECC facility, FDA cannot confirm the sterility of any of the NECC products. On October 15, FDA issued a [MedWatch Safety Alert](#) advising clinicians to follow-up with patients who received an injectable NECC product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, and a cardioplegic solution purchased from or produced by NECC after May 21, 2012. Clinicians are also requested to report any suspected adverse events following use of these products to FDA's MedWatch program at **1-800-332-1088** or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

As in the past, CDC continues to recommend that clinicians remain vigilant for any possible adverse events related to the use of any NECC product. Clinicians are encouraged to report such events to their state public health department.

3. CDC will continue to update clinical guidance as more information becomes available. As of October 16, CDC has updated clinician guidance addressing:
  - [Interim Treatment Guidance for Central Nervous System \(CNS\) and/or Parameningeal Infections Associated with Injection of Potentially Contaminated Steroid Products](#)
  - [Interim Treatment Guidance for Septic Arthritis Associated with Injection of Potentially Contaminated Steroid Products](#)
  - [Interim Guidance for Management of Asymptomatic Persons Exposed to Potentially Contaminated Steroid Products](#)
  - [Diagnostic Testing for Septic Arthritis and Specimen Submission to CDC – Outbreak Associated with Injection of Potentially Contaminated Steroid Products](#)
  - [Instructions for Clinicians Regarding Diagnostic Testing and Specimen Shipping for Central Nervous System and/or Parameningeal Infections](#)
  - [Role of Antifungal Prophylaxis in Asymptomatic Patients](#)

## CDC Case Definitions

The current investigation is a rapidly evolving situation and information about cases continues to be updated. For the most recent information about case definitions, please see CDC's clinical guidance web

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**Additional Information**

- [Multistate Fungal Meningitis Outbreak Investigation](#)
- [MMWR Early Release: Multistate Outbreak of Fungal Infection Associated with Injection of Methylprednisolone Acetate Solution from a Single Compounding Pharmacy — United States, 2012.](#)
- [CDC HAN Advisory: Meningitis and Stroke Associated with Potentially Contaminated Product](#)
- [CDC HAN Advisory: Update: Multistate Outbreak of Meningitis and Stroke Associated with Potentially Contaminated Steroid Medication](#)
- [CDC Website on Fungal Diseases](#)
- [FDA Statement on Fungal Meningitis Outbreak](#)

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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##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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