



Press Release

Friday, October 5, 2012

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Update on Nationwide Meningitis Outbreak *CDC providing updated guidance for clinicians and patients*

In response to a nationwide outbreak of meningitis and stroke associated with a widely distributed medication, CDC is providing updated [guidance to clinicians](#) and [patients](#) about contaminated medication products received from the New England Compounding Center located in Framingham, Mass. Patients have suffered a variety of symptoms, including those associated with a rare form of fungal meningitis (brain infection) and stroke. On October 3, 2012, the pharmaceutical compounding center ceased all production and initiated recall of all methylprednisolone acetate (a steroid medication) and other drug products prepared for injections in and around the spinal cord (known as intrathecal administration). In addition, CDC and state health departments have released the [names of approximately 75 healthcare facilities](#) in 23 states that have received contaminated product.

As of October 5, a total of 47 cases* in 7 states and 5 deaths have been identified with a clinical picture consistent with fungal infection: Florida (2 cases), Indiana (3 cases), Maryland (2 cases, including 1 death), Michigan (4 cases), North Carolina (1 case), Tennessee (29 cases, including 3 deaths), and Virginia (6 cases, including 1 death). Fungus has been identified in specimens obtained from 9 patients, including *Aspergillus* and *Exserohilum*.

“All patients who may have received these medications need to be tracked down immediately. Patients can find the names of the clinics that used these medications on the CDC website,” said Benjamin Park, M.D., medical officer, Mycotic Diseases Branch, CDC. “It is possible that if patients with infection are identified soon and put on appropriate antifungal therapy, lives may be saved.”

Infected patients have developed a variety of symptoms approximately 1 to 4 weeks following their injection, 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 obtained from these patients has shown findings consistent with meningitis.

On September 26, 2012, the New England Compounding Center 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

Physicians should immediately contact patients who have had an injection (e.g., spinal, joint) using any of the three lots of methylprednisolone acetate listed above to determine if they are having any symptoms. Although all cases detected to date occurred after injections with products from these three lots, out of an abundance of caution, CDC and the Food and Drug Administration (FDA) recommend that healthcare professionals cease use of **any** product produced by the New England Compounding Center until further information is available.



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Patients who have had an epidural steroid injection since July 2012, and have any of the following symptoms, should talk to their doctor as soon as possible.

- Worsening headache
- Fever
- Sensitivity to light
- Stiff neck
- New weakness or numbness in any part of your body
- Slurred speech

CDC has activated its Emergency Operations Center in an effort to maximize its response capabilities and to ensure that CDC recommendations are distributed as broadly as possible. CDC has provided guidance to clinicians on diagnostic testing that should be performed on patient specimens: <http://www.cdc.gov/hai/pdfs/outbreaks/Outbreak-diagnostic-protocol-cleared.pdf>

Clinicians should inform their State health department of any patients undergoing evaluation for this infection. Clinicians should 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.

The 23 states where the contaminated product was shipped are California, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, North Carolina, New Hampshire, New Jersey, Nevada, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Virginia, Texas, and West Virginia. For a list of all of the facilities who have received contaminated product, please see: <http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html>

*CDC Case Definition

1: A person with meningitis¹ of sub-acute onset (1-4 weeks) following epidural injection after July 1, 2012.

2: A person, who has not received a lumbar puncture, with basilar stroke 1-4 weeks following epidural injection after July 1, 2012².

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 July 1, 2012.

¹clinically diagnosed meningitis meaning 1 or more of the following symptoms: headache, fever, stiff neck, or photophobia **and** a cerebrospinal fluid profile consistent with meningitis (elevated protein/low glucose/pleocytosis)

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

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