



Talking Points
 Medication Recall / Meningitis from Injection Investigation
 October 5, 2012

- The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), in partnership with state health departments are investigating a cluster of clinical meningitis cases following spinal injections.
- Most patients received epidural spinal injections and developed meningitis within one month of the injection (range 1-4 weeks).
- As of 2pm today, the current case count is as follows:

State	Cases* (deaths)
TN	29 (3)
VA	6 (1)
FL	2 (0)
MD	2 (1)
NC	1 (0)
IN	3 (0)
MI	4 (0)
Total	47 (5)

* 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 (LP), with basilar stroke 1-4 weeks following epidural injection after July 1, 2012.

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: HA, fever, stiff neck, or photophobia **and** a CSF profile consistent with meningitis (elevated protein/low glucose/pleocytosis)

²These people, if possible, should have an LP.

- Affected facilities in New Jersey include orthopedic specialists, ambulatory surgery centers and pain centers and physician offices and a health system. The affected facilities are:
 - Central Jersey Orthopedics Specialists, PC in South Plainfield
 - Edison Surgical Center, Edison
 - IF Pain Associates/Isaiah Florence, Teaneck
 - Premier Orthopedics Surgical Assoc, LLC, Vineland
 - Comprehensive Pain Management, Sparta
 - South Jersey Healthcare, Elmer and Vineland

- The source of the infections has been linked to steroid medication (methylprednisolone acetate) was used for all of the infected patients. This is a medication commonly used for epidural spinal injections.

- An investigation indicates that infected patients received infection with preservative-free steroid medication prepared by the New England Compounding Center (NECC), located in Massachusetts. The NECC has been shut down as of 10/3/12.

- Three lots of methylprednisolone have been recalled:
 - 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

- In addition, the CDC and FDA recommend that healthcare professionals discontinue use of any product produced by the NECC until further information is available.

- A link to expanded recall products from NECC may be found on the FDA website at: <http://www.fda.gov/Drugs/DrugSafety/ucm322752.htm>
 - The CDC is currently recommending active surveillance for the original three lots of preservative free methylprednisolone only.

- The medication was shipped to healthcare facilities in 23 states across the country, including New Jersey. All facilities that received shipments were notified by the pharmacy and NJDOH. The product has been recalled.

- Physicians at the facilities who received affected product are asked to contact patients who have had any injection (e.g., spinal, joint) using any of the three lots of methylprednisolone acetate listed above to determine if they are having any symptoms.

- Patients who received a steroid injection and are experiencing symptoms such as new or worsening headache, fever, neck stiffness, or pain at the injection site, should contact the provider who administered the injection to determine if they may have received one of the recalled products and to receive further evaluation.
- At this time, there are no confirmed cases in New Jersey.
- The New Jersey Department of Health (NJDOH) is working with the facilities within NJ that received the recalled lots of the medication to assess patient outcomes. Facilities that received shipments of the medication should report patients who meet clinical criteria provided by the CDC. The NJDOH will continue to monitor the situation.
- South Jersey Healthcare has set up a hotline for patients in Cumberland and Salem Counties to call with their questions/concerns. The number is: (856) 641-6010. A clinic has been opened for individuals who received a steroid injection either of the South Jersey Healthcare sites (Vineland and Elmer) and for patients from Premier Orthopedics in Vineland. Patients may come to the hospital to receive an evaluation October 5-7.
- All affected facilities are working with the NJDOH during the investigation to notify patients and provide medical evaluation, as needed.



Frequently Asked Questions
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Overview

CDC is coordinating a multistate investigation of meningitis among patients who received epidural steroid injections (medication injected into the spine). Several of these patients have had strokes related to the meningitis. In several patients, the meningitis was found to be caused by a fungus that is common in the environment but rarely causes meningitis. This form of meningitis is **not contagious**. The source of the fungus has not yet been identified, and the cause of infections in the other patients is still being assessed.

For the Public

What is fungal meningitis?

Fungal meningitis occurs when the protective membranes that cover the brain and spinal cord are infected with a fungus. Fungal meningitis can develop after a fungus spreads through the bloodstream from somewhere else in the body, as a result of the fungus being introduced directly into the central nervous system, or by direct extension from an infected body site next to the central nervous system.

Is fungal meningitis common after epidural injections?

Epidural injections are generally very safe procedures, and complications are rare. Fungal meningitis is an extremely rare cause of meningitis overall, including after epidural injections. The type of epidural medication given to patients affected by this outbreak is **not** the same type of medication as that given to women during childbirth.

What is Aspergillus?

- Aspergillus is a mold, which is a type of fungus. This fungus is common to the environment and is found in places such as soil and on plants. It is also found in household dust and building material.
- There are many species of the Aspergillus fungus and Aspergillus fumigatus is one of the most common species.

What is Aspergillosis?

- Aspergillosis is the name of the condition when a person is infected with the Aspergillus fungus. Aspergillus usually causes illness in people with weakened immune systems.

If this fungus is found in the environment, should I worry?

- Normally the body can fight off disease and prevent infections. However, because the medication (which may include the mold) was injected directly into the body, the body may not be as effective in fighting germs.

What is the treatment for Aspergillosis?

- Antifungal medication is available to treat fungal infections. Your health care provider can determine the best treatment for you if you should develop an infection.

How would I know if I am at risk for Aspergillosis?

- If you received a methylprednisolone acetate epidural injection on or after July 1, 2012 from the medicine lots that were recalled, you may be at risk. If you are concerned, contact your health care provider to determine if you received medication from the implicated batches.

What are the symptoms associated with this investigation?

- Patients developed symptoms that included worsening headache, stiff neck, sensitivity to light and fever within 1-4 weeks following their injection. Some also experienced stroke symptoms including localized weakness (on one side of the face, drooping face), numbness, slurred speech.

If I had a pain injection at my doctor's office, should I be concerned?

- This investigation focuses on medication that was shipped to facilities in seven locations in New Jersey. Most of the medications used in these types of injections is safe and is not involved in the recall.

How could this happen?

- This investigation is ongoing. The New Jersey Department of Health is working with our federal and local partners to evaluate the products and preparation practices.

What facilities received the contaminated medication?

- Affected facilities in New Jersey include orthopedic specialists, ambulatory surgery centers and pain centers and physician offices and a health system. The affected facilities include:
 - Central Jersey Orthopedics Specialists, PC in South Plainfield
 - Edison Surgical Center, Edison
 - IF Pain Associates/Isaiah Florence, Teaneck
 - Premier Orthopedics Surgical Assoc, LLC, Vineland
 - Comprehensive Pain Management, Sparta
 - South Jersey Healthcare, Elmer and Vineland

How do I know my doctor has been informed of the medication recall?

- The pharmacy notified all facilities that received shipments of medication that were later recalled. The New Jersey Department of Health issued a notification to all public health and healthcare partners regarding the investigation.

I just received a cortisone shot from my doctor, should I be concerned about a fungal infection?

- Individuals receive injections for many reasons. This investigation is focusing on the medication methylprednisolone acetate from the New England Compounding Center. If you are concerned, contact your health care provider to determine if you received medication from the implicated batches.

Is there a difference between this meningitis and the one I hear about?

- Meningitis is an inflammation of the covering of the brain and spinal cord. It is spread from person to person by saliva. Fungal meningitis is different. It is not spread from person to person. This investigation is looking at a contaminated product as the cause of the disease.

What is an epidural?

- An epidural is an injection given into the back. The injection can be given for different purposes and contain different medications.

I just gave birth and had an epidural, should I be concerned?

- The type of medication used during an epidural during childbirth is different than the medication that was recalled with this investigation.

For Health Care Providers

I am a healthcare provider who received contaminated medication. What should I do?

- The NJDOH will coordinate a pick-up of the affected vials with the CDC and FDA. Facilities will be advised regarding pick-up.
- Additionally, NJDOH is asking all providers who administered steroid injections using methylprednisolone acetate prepared by the New England Compounding Center (NECC) to contact all patients.

What signs/symptoms am I looking for in an infected patient?

- Infected patients have presented approximately one to four weeks following their injection with a variety of symptoms including: fever, new or worsening headache, nausea, and/or 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.

I have a patient(s) who received spinal injections and meets case definition.

What should I do?

- Providers are advised to work with the regional epidemiologist in their county/jurisdiction. The contact information for regional epidemiologists in the counties that received the affected medication is below:
 - Bergen: Karen Alelis (551) 497-8256
 - Cumberland: Betsy Cabbage (609) 805-4646
 - Middlesex: Sherrie Wolpert (732) 684-4892
 - Salem: Shatrughan Bastola (856) 466-5293
 - Sussex: Lama Chaddad (973) 818-3662

I have patient(s) of meningitis or basilar stroke. What further testing is needed?

- For patients who received epidural injection and have symptoms of meningitis or basilar stroke, a diagnostic lumbar puncture (LP) should be performed, if not contraindicated. Because presenting symptoms of some patients with meningitis have been mild and not classic for meningitis (e.g., new or worsening headache without fever or neck stiffness), physicians should have a low threshold for LP.
- While CDC is only aware of infections occurring in patients who have received epidural steroid injections, patients who received other types of injection with methylprednisolone acetate from those three lots should also be contacted to assess for signs of infection (e.g., swelling, increasing pain, redness, warmth at the injection site) and should be encouraged to seek evaluation (e.g., arthrocentesis) if such symptoms exist.
- For guidance on diagnostic testing that should be performed on patient specimens, refer to the diagnostic protocol developed by CDC for this

outbreak. Guidance is posted at:

<http://www.cdc.gov/HAI/outbreaks/meningitis.html>

- 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.

What is the recommended treatment?

- At present, the etiologic agent of this cluster of meningitis has not been clearly identified. However, a mold species has been isolated from CNS specimens from at least two patients linked to the outbreak, one of whom also had *Propionobacterium acnes* of unclear clinical significance isolated from a post-mortem CNS specimen. Two additional patients have preliminary histopathologic evidence of fungal infection. When treating patients with meningitis who meet the outbreak case definition, clinicians should continue to follow routine treatment protocols for meningitis of unclear etiology, including covering for potential bacterial causes of meningitis. In addition, until the etiology is better defined, clinicians are encouraged to add empiric antifungal therapy to the treatment regimen because of the severe adverse outcomes of untreated fungal meningitis. CDC has consulted with national experts on the following guidance; these treatment options for fungal meningitis in patients associated with this cluster are interim, and may change as new information becomes available.