



## Cover Sheet

**DATE:** October 5, 2012

**SUBJECT:** Meningitis and Stroke Associated with Epidural Steroid Injection.

**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.**

**For LOCAL HEALTH DEPARTMENT reference only**

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

**Dr. Randy Nett  
Epidemiology Section  
1-406-444-0273**

**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:**

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

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

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

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

# Information Sheet

**Date:** October 5, 2012

**Subject:** Meningitis and Stroke Associated with Epidural Steroid Injection

**Information:** Please see the attached CDC Health Alert Network (HAN) Advisory regarding MENINGITIS and STROKE associated with epidural steroid injection.

## Key Points & Recommendations:

Preliminary distribution lists do not show Montana as receiving the methylprednisolone acetate products that are the present concern. However, we recommend all physicians and pharmacies should check any inventories for the lot numbers in question (see attached CDC HAN Advisory). Any product found should be returned to the pharmacy and reported to the local public health jurisdiction.

Patients receiving a methylprednisolone acetate injection (e.g. spinal, joint) with any of the three lot numbers in questions should be contacted to determine if they are having symptoms listed in the attached HAN advisory. Patients receiving other types of injection with methylprednisolone acetate from those three lots should also be contacted to assess for signs of infection and should be encouraged to seek evaluation if such symptoms exist. For guidance on diagnostic testing that should be performed on patient specimens, physicians can go to <http://www.cdc.gov/hai/outbreaks/meningitis.html>

Please inform your local public health department of patients undergoing evaluation and local health will pass information along to DPHHS. 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](http://www.fda.gov/medwatch).

CDC will be posting outbreak updates to <http://www.cdc.gov/hai/outbreaks/meningitis.html>

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

Distributed via Health Alert Network  
October 4, 2012, 17:05 ET (5:05 PM ET)  
CDCHAN-00327-2012-10-04-UPD-N

**Meningitis and Stroke Associated with  
Potentially Contaminated Product**

**Summary**

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are coordinating a multi-state investigation of fungal meningitis among patients who received an epidural steroid injection. Several of these patients also suffered strokes that are believed to have resulted from their infection. As of October 4, 2012, five deaths have been reported. Fungal meningitis is not transmitted from person to person. These cases are associated with a potentially contaminated medication. Investigation into the exact source is ongoing; however, interim data show that all infected patients received injection with preservative-free methylprednisolone acetate (80mg/ml) prepared by New England Compounding Center, located in Framingham, MA.

**Background**

On September 21, 2012, CDC was notified by the Tennessee Department of Health of a patient with the onset of meningitis approximately 19 days following epidural steroid injection at a Tennessee ambulatory surgery center (ASC). Initial cultures of cerebrospinal fluid (CSF) and blood were negative; subsequently, *Aspergillus fumigatus* was isolated from CSF by fungal culture. On September 28, investigators identified a case outside of Tennessee, possibly indicating contamination of a widely distributed medication. As of October 4, a total of 35 cases\* in the following six states have been identified with a clinical picture consistent with fungal infection: Florida (2 cases), Indiana (1 case), Tennessee (25 cases, including 3 deaths), Maryland (2 cases, including 1 death), North Carolina (1 case), and Virginia (4 cases, including 1 death). Fungus has been identified in specimens obtained from five patients, one of whom also had *Propionobacterium acnes*, of unclear clinical significance, isolated from a post-mortem central nervous system specimen.

Infected patients have presented approximately 1 to 4 weeks following their injection with a variety of symptoms, 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. CSF obtained from these patients has typically shown elevated white cell count (with a predominance of neutrophils), low glucose, and elevated protein.

**Recommendations**

On September 25, 2012, the New England Compounding Center located in Framingham, MA 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 3, 2012, the compounding center ceased all production and initiated recall of all methylprednisolone acetate and other drug products prepared for intrathecal administration.

Physicians should 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 FDA recommend that healthcare professionals cease use of **any** product produced by the New England Compounding Center until further information is available.

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 aware of infections occurring only 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, physicians can go to <http://www.cdc.gov/hai/outbreaks/meningitis.html>. State health departments should be informed of patients undergoing evaluation. 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](http://www.fda.gov/medwatch).

**\*Case Definition**

- 1: A person with meningitis<sup>1</sup> 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, 2012<sup>2</sup>.
- 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.

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

<sup>2</sup>These people, if possible, should have an LP.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

---

Categories of Health Alert messages:

- Health Alert** conveys the highest level of importance; warrants immediate action or attention.
- Health Advisory** provides important information for a specific incident or situation; may not require immediate action.
- Health Update** provides updated information regarding an incident or situation; unlikely to require immediate action.

##This Message was distributed to State and Local Health Officers, Public Information Officers, Epidemiologists and HAN Coordinators as well as Clinician organizations##

=====

You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail or fax address that you would like us to use please contact your State-based Health Alert Network program at your State or local health department.

=====