

Health Advisory: Meningitis and Stroke Associated with Potentially Contaminated Product

October 5, 2012

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The Missouri Department of Health & Senior Services (DHSS) is now using 4 types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

Health Advisory
October 5, 2012

**FROM: MARGARET T. DONNELLY
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**SUBJECT: Meningitis and Stroke Associated with Potentially
Contaminated Product**

The Centers for Disease Control and Prevention (CDC) along with public health officials in several states are currently investigating a multi-state outbreak of fungal meningitis among patients who received an epidural steroid injection. **No cases have been reported to date in Missouri**, but medical providers in the state need to be aware of this situation so they can appropriately identify such cases should they occur.

A CDC Health Advisory was issued yesterday (October 4), and is reproduced below. It provides a description of current cases as well as recommendations for medical providers. In Missouri, suspected cases should be reported to the local public health agency, or to the Missouri Department of Health and Senior Services at 800/392-0272 (24/7). Questions should be directed to DHSS' Bureau of Communicable Disease Control and Prevention at 573/751-6113, or 800/392-0272.

This outbreak demonstrates the potential for the occurrence of post-procedural meningitis, and the need, when performing spinal injection procedures, to consistently adhere to basic infection control recommendations including the following:

- Facemasks should always be used when injecting material or inserting a catheter into the epidural or subdural space.
- Use aseptic technique when preparing and administering medications.
- Cleanse the access diaphragms of medication vials with 70% alcohol before inserting a device into the vial.
- NEVER administer medications from the same syringe to multiple patients even if the needle is changed or the injection is administered through intravenous tubing.
- Do not reuse a syringe to enter a medication vial or solution.
- Do not administer medications from a single use or single dose vial to more than one patient.
- Do not use fluid infusion or administration sets (e.g., IV tubing) for more than one patient.
- Dedicate multi-dose vials to a single patient whenever possible. If used for more than one patient, restrict their use to a central medication area. Multi-dose vials should never be taken into the patient treatment area.

CDC Health Advisory

Distributed via Health Alert Network, October 4, 2012, 17:05 ET (5:05 PM ET)

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

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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 *Propionibacterium 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 www.cdc.gov/hai. 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.

*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 CSF profile consistent with meningitis (elevated protein/low glucose/pleocytosis)

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