

ALERT – CDC Health Alert Network Advisory

Update: Multistate Outbreak of Meningitis and Stroke Associated with Potentially Contaminated Steroid Medication

Please check <http://www.cdc.gov/hai/outbreaks/clinicians/index.html> daily, updated for clinician guidance, including treatment guidance, case definitions, testing, and prophylaxis.

Investigation and Recall

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 among patients who received an epidural or joint steroid injection. The contaminated steroid medication was prepared by New England Compounding Center (NECC), located in Framingham, Mass. No Alabama healthcare facility received the initial three recalled products, but some have received NECC's sterile injectable products and other NECC products. NECC is recalling all products and notifying its customers of this recall by fax. Clinics, hospitals and healthcare providers that have product, which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice. For more information about all NECC recalled products, go to <http://www.neccrx.com/>.



The FDA investigation into the NECC facility is ongoing. On October 5, FDA reported observing “fungal contamination by direct microscopic examination of foreign matter taken from a sealed vial of methylprednisolone acetate collected from the New England Compounding Center.” Further analysis is ongoing. 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.

Fungus has been identified in specimens obtained from at least nine patients, one of whom also had *Propionibacterium acnes*, of unclear clinical significance, isolated from a post-mortem central nervous system specimen. In addition to an *Aspergillus* spp. isolated from a Tennessee patient, the fungus *Exserohilum rostratum* was identified in other patients, indicating the possibility of infections caused by multiple organisms. Fungal meningitis is not transmitted from person to person.

Recommendations

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

- Healthcare professionals should cease use of any product produced by NECC, all of which have been recalled.

- CDC is currently not asking clinicians to actively contact patients who received other products from NECC, aside from the three initially recalled lots of steroid injectables, to assess for symptoms. However, clinicians should remain vigilant, and report to the state public health department, any infection identified in a patient known to have received a product from NECC.

Case Definitions for Meningitis and Septic Arthritis

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A person who received an injection with methylprednisolone acetate produced by the New England Compounding Center (NECC) who has developed any of the following:

1. Fungal meningitis or non-bacterial and non-viral meningitis^a of sub-acute onset, following epidural injection on and after May 21, 2012.
2. Basilar stroke following epidural injection after May 21, 2012^b, who has not received a diagnostic lumbar puncture.
3. Evidence of spinal osteomyelitis or epidural abscess at the site of injection following epidural or sacroiliac injection after May 21, 2012.
4. Septic arthritis^c or osteomyelitis of a peripheral joint (e.g., knee) diagnosed following joint injection after May 21, 2012.

^a Clinically diagnosed meningitis meaning one or more of the following symptoms: headache, fever, stiff neck, or photophobia and a cerebrospinal fluid (CSF) profile showing pleocytosis (>5 white blood cells, adjusting for presence of red blood cells) regardless of glucose or protein levels.

^b These people, if possible, should have a lumbar puncture.

^c Clinically diagnosed septic arthritis meaning new or worsening pain with presence of effusion or new or worsening effusion.

Suspect Case:

A person who has developed an infection of a normally sterile site (e.g., blood, CSF, pleural fluid, peritoneal fluid, pericardial fluid, surgical aspirate, bone, joint fluid, or internal body site [e.g., lymph node, brain]) following use of a product labeled as sterile prepared by the New England Compounding Center (NECC).