

HEALTH ALERT NETWORK HEALTH DISTRICT 4

STEROID RECALL UPDATE FOR HEALTH CARE PROVIDERS

FDA Expands Recommendations to Providers Regarding the Outbreak of Fungal Meningitis and Joint Infections Associated with Contaminated Steroid Medications

October 18, 2012

Idaho health officials continue to work with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and local medical providers on a multistate investigation of fungal meningitis and joint infections among patients who received a methylprednisolone acetate injection prepared by the New England Compounding Center (NECC) in Framingham, Mass.

As of October 17, 2012, a total of 247 cases, which includes 2 peripheral joint infections and 19 deaths, have been reported in 15 states. All cases reported as of October 17 have occurred after injections with methylprednisolone acetate products from one of the three lots recalled on September 26. As of October 16, CDC has updated clinician guidance that can be found at the CDC website: www.cdc.gov/HAI/outbreaks/meningitis.html

Updated Public Health Recommendations for Clinicians

1. Contact (by phone or in person) any patient who had an injection (e.g., spinal, joint) after May 21, 2012, using any of the following three lots of preservative-free methylprednisolone acetate (80mg/ml) produced and voluntarily recalled by NECC on September 26, 2012 to determine if they are having symptoms. The recalled lots are:

- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot# 05212012@68, BUD 11/17/2012
- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot#06292012@26, BUD 12/26/2012
- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot# 08102012@51, BUD 2/6/2013

Symptoms that should prompt diagnostic evaluation include fever, new or worsening headache, neck stiffness, sensitivity to light, new weakness or numbness, increasing pain, and redness or swelling at injection site. Some of the symptoms of patients who have ultimately been diagnosed with fungal meningitis have been mild and not classic for meningitis (e.g., new or worsening headache without fever or neck stiffness).

Serving Valley, Elmore, Boise, and Ada Counties

Ada / Boise County Office
707 N. Armstrong Pl.
Boise, ID 83704
Enviro. Health: 327-7499
Reproductive Health: 327-7400
Immunizations: 327-7450
WIC: 327-7488
FAX: 327-8500

Elmore County Office
520 E. 8th St. North
Mountain Home, ID 83647
Enviro. Health: 587-9225
Family Health: 587-4407
WIC: 587-4409
FAX: 587-3521

Valley County Office
703 N. 1st St.
McCall, ID 83638
Ph. 634-7194
FAX: 634-2174

2. On October 15, FDA issued a MedWatch Safety Alert advising clinicians to follow up with patients who received an injectable NECC product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, and a cardioplegic solution purchased from or produced by NECC after May 21, 2012.

Healthcare professionals should cease use of any product produced by NECC, all of which have been recalled. CDC does not have firm evidence that infections have been caused by exposure to NECC products beyond the three lots of methylprednisolone acetate listed above. However, through its investigation of the NECC facility, FDA cannot confirm the sterility of any of the NECC products.

3. Clinicians should perform a thorough diagnostic evaluation to exclude infection in those patients who report signs and symptoms of infection following high-risk exposure to one of these NECC products (e.g., exposure of product to sterile body site). If the evaluation of these patients is suggestive of fungal infection, please consult existing CDC treatment guidance (<http://www.cdc.gov/hai/outbreaks/clinicians/index.html>) and report the suspected infection to your local public health district or the Idaho Division of Public Health. Consultation with an infectious disease specialist is strongly encouraged to help make treatment decisions in these cases.

Clinical information on current cases reported to CDC by multiple states:

The fungus *Exserohilum rostratum* has been reported in clinical specimens from multiple patients with fungal meningitis and with other spinal infections (e.g., epidural abscess). In addition, one clinical specimen has tested positive for the fungus *Aspergillus fumigatus*, and another has tested positive for the fungus *Cladosporium*.

The clinical presentation of infected patients with fungal meningitis has been: onset of symptoms typically between 1 to 4 weeks following injection with a variety of symptoms, including fever, new or worsening headache, nausea, and new neurological deficit (consistent with deep brain stroke). However, fungal infections can be slow to develop, and there are reports of longer periods between injection and onset of symptoms; therefore, patients and their doctors need to watch closely for symptoms for at least several months following the injection. Some of these patients' symptoms were very mild in nature.

Cerebrospinal fluid (CSF) obtained from these patients has typically had an elevated white cell count (usually with a predominance of neutrophils), and in many cases low glucose and elevated protein. As of October 16, two peripheral joint infections have been reported. With ongoing notification of affected patients, additional patients with infections of the joints may come forward.

PLEASE REPORT SUSPECT INFECTIONS TO THE IDAHO DIVISION OF PUBLIC HEALTH AT 208-334-5939 (1-800-632-2927 AFTER HOURS) OR CENTRAL DISTRICT HEALTH DEPARTMENT AT 327-8625

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