

**New Hampshire Department of Health and Human Services
Frequently Asked Questions
Multi-State Fungal Infection/Meningitis Investigation
October 16, 2012**

What is this new investigation about?

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are currently coordinating a multi-state investigation of a fungal meningitis and infection outbreak among patients who received medications from a Massachusetts company that were contaminated with fungus. Several of these patients also suffered strokes that are believed to have resulted from their infection. New Hampshire is one of the 23 states where patients were infected.

What is the name of the medication involved?

The currently implicated medication is called Methylprednisolone Acetate (80 mg/ml). Three particular lots of this product are the focus of the national investigation at this time and were initially recalled on September 26, 2012. This is a type of steroid that can be injected by providers for patients with back or joint pain.

What is the name of the facility where the medication was manufactured?

The facility is New England Compounding Center (NECC), in Framingham, Massachusetts, which has suspended operations. They have also voluntarily recalled all the medications produced by the facility going back to January 1, 2012.

What is a compounding pharmacy? Why are these medications compounded when they are also commercially available?

Compounding pharmacies create special formulations and combinations of medications. For example, they may change the dose or change the form of a medication from solid to liquid.

What lots and expiration dates are involved?

The implicated product lots recalled on September 26, 2012 are:
Methylprednisolone Acetate 80 mg/ml injection, lot #05212012@68, BUD 11/17/2012
Methylprednisolone Acetate 80 mg/ml injection, lot #06292012@26, BUD 12/26/2012
Methylprednisolone Acetate 80 mg/ml injection, lot #08102012@51, BUD 2/6/2013

A complete list of all recalled products is available on the FDA website at <http://www.fda.gov/Drugs/DrugSafety/ucm322752.htm>.

How many facilities and patients in New Hampshire are affected?

The three lots of Methylprednisolone Acetate were only shipped to two facilities in New Hampshire, Pain Care LLC locations in Somersworth and Merrimack. Pain Care LLC received this medication June 11 and further distributed the implicated medication to their office in Newington, but no patients in Newington received spinal injections with the medication.

Records show that 217 patients received this medication with a spinal injection between June 11, 2012 and September 26, 2012 and they have been directly contacted by telephone by the Pain Care Center and NH DPHS with specific recommendations.

Approximately 524 patients at the Somersworth, Merrimack and Newington Pain Care LLC locations had steroid injections in other peripheral joints or sites (not the spine). These patients have also been contacted and will need to be assessed for a potential joint infection at the site of the injection.

Has anyone in New Hampshire been identified as ill related to this outbreak?

There have been six cases announced in New Hampshire of patients who received this medication and who have compatible symptoms. The clinical investigation is ongoing and more patients may be identified.

How can you be sure it was only the Pain Care LLC centers involved in New Hampshire?

This is based on the shipping lists from NECC.

How do you know these are the only products involved?

October 7, 2012, New England Compounding Center voluntarily expanded its recall to include all products compounded at and distributed from its facility. CDC and DPHS are actively investigating patients who were exposed to all NECC products.

What type of infection has been seen?

Most people who were exposed to this recalled product have been diagnosed with meningitis caused by one of two species of fungus. Patients who received injections in other sites of the body besides the back have also developed symptoms of fungal infection, but this is less common. One of these fungi has not been previously been reported in humans. The investigation is still ongoing so it is possible that other types of organisms may be eventually identified in this outbreak.

What is fungal meningitis?

Meningitis is the collective term for inflammation of the tissue surrounding the brain and spinal cord. This outbreak meningitis is fungal meningitis, which means it is caused by a fungus, in contrast to the more common types of viral and bacterial.

Is this type of meningitis contagious?

No, a patient with fungal meningitis cannot give it to anyone else.

What is the incubation period?

Based on the cases reported so far, symptoms usually develop 1-4 weeks after the injection but it is possible for someone to have later onset.

Is fungal meningitis common after epidural injections?

Epidural injections are generally 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 causing this outbreak is **not** the same type of medication that is given to women during childbirth.

What are the symptoms of fungal meningitis?

Symptoms of fungal meningitis are similar to symptoms of other forms of meningitis, however they often appear more gradually and can be initially mild. Symptoms may include headache, fever, nausea, stiff neck, confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

Patients who underwent injection of the product to other parts of the body (such as joints) should be evaluated for local symptoms and signs that may indicate infection, such as swelling, redness, warmth, and/or pain at the injection site. Patients with these types of symptoms may need to have fluid drawn from the affected site to collect fluid for evaluation.

If I am sick with meningitis, which test do I need to diagnose it?

A lumbar puncture (also known as a spinal tap), which requires taking a sample of cerebrospinal fluid from the back, is used to diagnose meningitis. Sometimes imaging studies are also helpful to make the diagnosis.

If I received an injection in another body part other than my back (e.g., knee, shoulder, hip), what should I do?

Every patient who received a steroid injection with the implicated product after June 11, 2012 at the Pain Care, LLC in Somersworth, Merrimack, or Newington who has symptoms should be evaluated. If you have the above symptoms, you should be evaluated by your primary care doctor or other healthcare professional.

If I've had an injection of this medication somewhere besides Pain Care LLC and am feeling sick, should I be tested and how?

Any patient who had an injection and feels sick should be evaluated by their primary care physician.

Are certain patients more at risk than others?

Usually patients who are immunosuppressed are at increased risk for developing severe disease. In this outbreak, given the direct injection of contaminated medication, the disease has also developed in patients who were otherwise healthy.

Is it more of a risk to have had multiple injections than just one?

That is not known yet.

Can the fungus be dormant in my system and cause disease weeks or months from now?

Normally, symptoms will develop within the first month after exposure, although it may take a bit longer for some people.

How can I be sure if I am scheduled for an injection in the future that it is safe?

The implicated product has been taken off the shelf and there has been a new voluntary recall of all products from NECC.

If I had a pain injection in another state besides New Hampshire, how do I find out if it was safe?

The list of all 79 facilities that received the implicated product across the U.S. is posted on the CDC website at <http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html>.

Are patients who did not receive an injection at risk?

No. Fungal meningitis is not transmitted from person to person. These infections are associated with a potentially contaminated medication that is injected into the body.

What is the source of the contamination and who is at fault?

This is not yet clear.

Who is investigating the contamination?

The Centers for Disease Control and Prevention and the Food and Drug Administration are conducting the multi-state investigation in cooperation with public health officials in the affected states.

Who is investigating cases in New Hampshire?

The Division of Public Health Services is responsible for the investigation in New Hampshire. Visit the DHHS website for more information: www.dhhs.nh.gov.

Where can I find updates and additional information about this outbreak?

For complete information and updates on this outbreak, visit www.cdc.gov/hai/outbreaks/meningitis.html.