

**New Hampshire Department of Health and Human Services
Frequently Asked Questions
Multi-State Fungal Infection Investigation
November 1, 2012**

What is this 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 an outbreak of fungal infections among patients who received medications that were contaminated with fungus. These medications were produced by a Massachusetts compounding pharmacy company called New England Compounding Center (NECC), in Framingham, Massachusetts. 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 the implicated medications were shipped to and one of the 19 states with cases associated with the outbreak.

What is a compounding pharmacy?

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 is the name of the medication that has definitely caused infections?

The medication that has caused fungal infections is called Methylprednisolone Acetate (80 mg/ml). Methylprednisolone Acetate is a steroid medication that can be injected into patients to control pain. Three shipments (or lots) of this medication were implicated in infection and recalled on September 26, 2012.

What lots and expiration dates of Methylprednisolone Acetate have caused infections?

The 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

How many facilities and patients in New Hampshire received any of these contaminated Methylprednisolone Acetate lots?

The three lots of Methylprednisolone Acetate were shipped to two facilities in New Hampshire, Pain Care Center, LLC locations in Somersworth and Merrimack. Pain Care Center, LLC received this medication and further distributed the implicated medication to their office in Newington. Records show that about 750 patients received this medication from these locations and they have been notified by the Pain Care Center, LCC and the New Hampshire Division of Public Health Services.

Has anyone in New Hampshire become infected by these three lots of medication?

As of November 1, 2012, DPHS has identified 11 patients in New Hampshire who received this medication and have compatible symptoms. The clinical investigation is ongoing and more patients may be identified.

What types of infections have occurred?

Most people who were exposed to the Methylprednisolone have been diagnosed with meningitis, sometimes complicated by stroke, caused by one of two species of fungus. Patients who received joint injections developed symptoms of joint inflammation. These fungal infections are very uncommon, especially for people who do not have a weak immune system. The investigation is still ongoing so it is possible that other types of organisms may eventually be identified in this outbreak but right now the investigation is focused on fungal infection.

What is fungal meningitis?

Meningitis is the term used for inflammation of the tissue surrounding the brain and spinal cord. The type of meningitis in this outbreak 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 1-6 weeks after the injection, but it may be longer. As more information becomes available, the appropriate time for patient follow up will be better understood.

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.

Are any other medications from NECC dangerous?

NECC voluntarily recalled all their medications produced since January 1, 2012. A complete list of all recalled products is available on the FDA website at <http://www.fda.gov/Drugs/DrugSafety/FungalMeningitis/default.htm>.

Are some medications from NECC more dangerous than others?

For reasons that are not completely clear now, the FDA has asked clinicians to contact patients who received three specific types of NECC products that were shipped on or after May 21, 2012:

- Any injectable medication
- Medications used during eye surgery
- Solution used during open chest surgery.

Were any of these three types of recalled products used in New Hampshire?

Based on the shipping lists NECC provided to the FDA, 24 facilities in New Hampshire received these 3 types of NECC medications. The list of these facilities is available at <http://www.dhhs.nh.gov/dphs/cdcs/documents/meningitis-facilities-list.pdf>. All of these facilities have been contacted by DPHS, and they are reviewing their records to verify that medications were used for patient care, and, if so, they are contacting those patients. NH DPHS will continue to work with healthcare providers in those facilities as the outbreak investigation continues.

What does the Ameridose recall mean and should I be worried that I might have received these products?

The pharmacy company Ameridose has voluntarily recalled all of its products in response to an FDA inspection. This recall is due to concerns about sterility testing at the pharmacy. It is not clear if the pharmacy will remain closed at this time.

Should I be worried that I may have received these products?

There is no recommendation to notify patients who have received Ameridose products. While Ameridose has a shared ownership with NECC, there is no evidence at this time that products are contaminated or that they may cause any infection or illness. More information and a list of the recalled products is available at their website www.ameridose.com.

What are the symptoms to look for in regards to this outbreak?

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. In addition, some cases presented with signs of stroke such as weakness or numbness in any part of the body or slurred speech.

Patients who received joint injection could have local symptoms including increased pain, swelling, redness, or warmth at the site of the injection. Patients who had eye surgery should monitor for visual changes, pain, redness, or discharge from the eye. Patients who had chest surgery should monitor for chest pain, or drainage from the surgical site.

Patients should contact their healthcare provider if they have any of these signs or symptoms or new or worsening symptoms occur that might require appropriate medical 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 am sick with joint infection, which test do I need to diagnose it?

If the joint is swollen, a sample of that joint's fluid should be sampled if possible. Sometimes imaging studies are also necessary for fluid sampling or to make the diagnosis in cases where there is no joint swelling.

If I've had an injection and am feeling sick, how should I be evaluated?

Any patient who had an injection and feels sick should be evaluated by their primary care physician who will decide what evaluation is needed based on the symptoms and type of injection that was given.

Are certain patients more at risk than others?

Usually patients who are immunosuppressed (have a weakened immune system) 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.

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

Normally, symptoms will develop within the first several weeks after exposure, although it may take longer for some people. This is why it is important to monitor symptoms. We do not know yet when someone is “out of the woods.”

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

The implicated products have been taken out of use by physicians and facilities across the country and there has been a voluntary recall of all products produced by NECC, which is now closed.

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 the facilities that received the implicated products across the U.S. is posted on the FDA website at <http://www.fda.gov/Drugs/DrugSafety/FungalMeningitis/default.htm>.

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

This is not yet clear. The investigation remains active and ongoing and the FDA continues to investigate the possible source of contamination of products at this pharmacy.

Who is investigating the contamination?

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are conducting the multi-state investigation in cooperation with public health officials in the affected states. The FDA is actively conducting testing and a full investigation to try to determine the possible source of the contamination.

Who is investigating cases in New Hampshire?

The Division of Public Health Services is responsible for the investigation in New Hampshire. Each facility that has received medications from NECC on or after May 21, 2012 is notifying patients and will be monitoring patients in accordance with the current CDC and NH DPHS guidance. NH DPHS is working closely with these healthcare providers as part of this outbreak investigation.

Visit the DHHS website for more information: www.dhhs.nh.gov.

Who can I call if I have more questions?

NH DHHS has set up a general inquiry line at 603-271-6617 about this outbreak. If you have symptoms or concerns about your health, it is important for you to contact your healthcare provider as you normally would.

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.