Talking Points
Medication Recall / Fungal Meningitis from Injection Investigation
October 11, 2012
Update #5

NOTE: All new and/or updated information is highlighted and noted with asterisks (**).

- The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), in partnership with state health departments are investigating a cluster of clinical meningitis cases following spinal injections.

- Most patients received epidural spinal injections and developed meningitis within one month of the injection (range 1-4 weeks). The source of the infections has been linked to steroid medication (methylprednisolone acetate) that was used for all of the infected patients. This is a medication commonly used for epidural spinal injections.

- **New Jersey Department of Health (NJDOH) is reporting two confirmed cases.

- **As of 2pm today, the current case count is as follows:

State	Cases*	Deaths
Florida	7	2
Idaho	1	0
Indiana	21	1
Maryland	13	1
Michigan	39	3
Minnesota	3	0
New Jersey	2	0
North Carolina	2	0
Ohio	3	0
Tennessee	49	6
Virginia	30	1
Total	170	14

*Case Definition

- **The case definition for Meningitis and Septic Arthritis has been updated/expanded as of October 10, 2012.

  A person who received an injection with methylprednisolone acetate produced by the New England Compounding Center (NECC) who has developed any of the following is considered a confirmed case.

  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.

  An individual with the following is considered a 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).

- On September 25, 2012, three lots of methylprednisolone were recalled:
  - 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

- Facilities in New Jersey that received affected shipments include orthopedic specialists, ambulatory surgery centers and pain centers and physician offices and a health system. The affected facilities are:
    - Central Jersey Orthopedics Specialists, PC in South Plainfield
    - Edison Surgical Center, Edison
    - IF Pain Associates, Teaneck
    - Premier Orthopedics Surgical Assoc, LLC, Vineland
    - Comprehensive Pain Management, Sparta
    - South Jersey Healthcare, Elmer and Vineland

- Physicians at the facilities who received affected product are asked to contact patients who have had any injection (e.g., spinal, joint) using any of the three lots of methylprednisolone acetate listed above to determine if they are having any symptoms.

- An investigation indicates that infected patients received injection with preservative-free steroid medication prepared by the New England Compounding Center (NECC), located in Massachusetts. The NECC has been shut down as of October 3/12.

- The medication was shipped to healthcare facilities in 23 states across the country, including New Jersey. All facilities that received shipments were notified by the pharmacy and NJDOH. The product has been recalled.

- The CDC and FDA recommend that healthcare professionals discontinue use of any product produced by the NECC until further information is available. A link to expanded recall products from NECC may be found on the FDA website at: http://www.fda.gov/Drugs/DrugSafety/ucm322752.htm
    - The CDC is currently recommending active surveillance for the original three lots of preservative free methylprednisolone only.

- An expanded recall included any/all products distributed by the NECC.
  Below is a list of facilities in NJ who received shipments of interthecal (injected into fluid surrounding the spinal cord) medication and products from the NECC. The NJDOH has notified all facilities and advised to discontinue using any/all products from the NECC.

Facility Name	City	County	Item
Ambulatory Surgery Ctr of Union Co	Union	Union	Beta 6/5 Triam AC 40/1 PF
Atlantic Coast Surgery Center	Egg Harbor Twp	Atlantic	Beta SP 6/2 PF
Campus Eye Surgery	Hamilton Square	Mercer	Triam AC 40/1 PF
Capital Health Medical Center-Hopewell	Pennington	Mercer	HY150/1 PF
Central Jersey Orthopedics Specialists	So. Plainfield	Middlesex	Beta 6/5 PF Methyl 80/5 PF
Cumberland Orthopedics	Vineland	Cumberland	Beta 6/10
Edison Surgical Center	Edison	Middlesex	Methyl 40/1 PF

			Methyl 80/1 PF
Englewood Hospital & Medical Center	Englewood	Bergen	Bupiv 0.5% PF 30 ml vial Bupiv 0.25% PF 30 ml vial Lido 1% 30 ml (PF) Lido 1% (PF) 30 ml 5yr Beta 6/2 PF
Garden State Pain Medicine, PC	Whiting	Ocean	Triam AC 40/10 Beta 6/10
Hackensack Surgery Center, LLC	Hackensack	Bergen	Omni 300/2
IF Pain Associates/Isaiah Florence	Teaneck	Bergen	Methyl 80/1 PF
JFK Medical Center	Edison	Middlesex	Beta SP 6/2 PF
Kennedy Memorial Hospital	Turnersville	Gloucester	Beta SP 6/2 PF
Kennedy Health System ASC, LLC	Sewell	Gloucester	Omni 240/5
Metropolitan Surgical Institute, Inc	South Amboy	Middlesex	Triam AC 40/2 PF
Middlesex Surgery Center, LLC	Edison	Middlesex	Beta 6/5 PF Beta SP 6/5 PF Lido 1% 30 ml (PF) Lido 2% (PF) 5 ml
New Jersey Center for Pain Management	Freehold	Monmouth	Triam AC 40/10
New Jersey Eye Center	Bergenfield	Bergen	Hy 150/1 PF
Ocean Surgery Center	Toms River	Ocean	Omni 240/5
Overlook Hospital	Summit	Union	Glyc-Inj SML
Premier Orthopedics Surg Assoc, LLC	Vineland	Cumberland	Methyl 80/1 PF Omni 240/5
Retinal & Opthalmic Consultants, PC	Northfield	Atlantic	Hy 150/1 PF
Retinal and Opthalmic Consultajnts, PC	Vineland	Cumberland	Hy 150/1 PF
Retina-Vitreous Center, PA	Eatontown	Monmouth	Triam AC 40/1 PF
	Toms River	Ocean	Triam AC 40/1 PF
	New Brunswick	Middlesex	Triam AC 40/1 PF
	Bridgewater	Somerset	Triam AC 40/1 PF
	Edison	Middlesex	Triam AC 40/1 PF
	Lakewood	Ocean	Triam AC 40/1 PF
	Lawrenceville	Mercer	Triam AC 40/1 PF
Seaview Orthopedics	Ocean	Monmouth	Omni 240/10
Comprehensive Pain Management	Sparta	Sussex	Methyl 80/1 PF
Somerset Eye Institute	Somerset	Somerset	Triam AC 40/1 PF
South Jersey Health Care	Elmer	Salem	Methyl 80/5 PF
	Vineland	Cumberland	Methyl 80/5 PF Methyl 80/1 PF
South Jersey Orthopedic Assoc.	Voorhees	Camden	Triam AC 40/10
Sparta Medical Associates	Sparta	Sussex	Omni 300/5 ISOV 200-5
St. Francis Medical Center	Trenton	Mercer	Triam AC 40/1 PF
Surgical Center of Burlington Co, LLC	Willingboro	Burlington	Hy 150/1 PF
The De Sio Pain Institute, PA	Toms River	Ocean	ISOV 200-2 Triam AC 40/10

- Patients who received a steroid injection and are experiencing symptoms such as new or worsening headache, fever, neck stiffness, or pain at the injection site, should contact the provider who administered the injection to determine if they may have received one of the recalled products and to receive further evaluation. If they are unable to reach their healthcare provider, they should seek medical attention at the nearest emergency department.

- The NJDOH is working with the facilities within NJ that received the recalled lots of the medication to assess patient outcomes. Facilities that received shipments of the medication should report patients who meet clinical criteria provided by the CDC.

- The NJDOH continues to monitor the situation.

- In cases of deaths that may be potentially associated to this investigation, please contact the local medical examiner's office.

Frequently Asked Questions
Medication Recall / Meningitis from Injection Investigation
October 11, 2012

Overview

CDC is coordinating a multistate investigation of meningitis among patients who received epidural steroid injections (medication injected into the spine). Several of these patients have had strokes related to the meningitis. In several patients, the meningitis was found to be caused by a fungus that is common in the environment but rarely causes meningitis. This form of meningitis is **not contagious**.

For the Public

****What is meningitis?**

- Meningitis is swelling of the protective membranes, or meninges, covering the brain and spinal cord. The swelling is usually caused by an infection with a bacteria or virus, but meningitis can also be caused by a fungus. Meningitis caused by a fungus is called fungal meningitis. The severity of illness and the treatment for meningitis differ depending on the cause, so knowing the specific cause of meningitis is important.

What is fungal meningitis?

- Fungal meningitis occurs when the protective membranes that cover the brain and spinal cord are infected with a fungus. Fungal meningitis can develop after a fungus spreads through the bloodstream from somewhere else in the body, as a result of the fungus being introduced directly into the central nervous system, or by direct extension from an infected body site next to the central nervous system.

****What are symptoms of fungal meningitis?**

- Symptoms are similar to other forms of meningitis; however they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea and neck stiffness, people may also experience sensitivity to bright lights.

****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.

Is fungal meningitis common after epidural injections?

- Epidural injections are generally very 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 given to patients affected by this outbreak is **not** the same type of medication as that given to women during childbirth.

What is Exserohilum?

- Exserohilum is a mold, which is a type of fungus. This fungus is commonly found in soil and on plants, especially grasses. It has not typically been associated with infections in humans.

What is Aspergillus?

- Aspergillus is a mold, which is a type of fungus. This fungus is common to the environment and is found in places such as soil and on plants. It is also found in household dust and building material.

What is the treatment for fungal illnesses?

- Antifungal medication is available to treat fungal infections. Your health care provider can determine the best treatment for you if you should develop an infection.

How would I know if I am at risk for fungal meningitis?

- If you received a methylprednisolone acetate epidural injection on or after May 21, 2012 from the medicine lots that were recalled, you may be at risk. If you are concerned, contact your health care provider to determine if you received medication from the implicated batches.

What are the symptoms associated with this investigation?

- Patients typically developed symptoms that included worsening headache, stiff neck, sensitivity to light and fever within 1-4 weeks following their injection. Some also experienced stroke symptoms including new weakness or numbness in any part of the body and slurred speech.

If I had a pain injection at my doctor's office, should I be concerned?

- This investigation focuses on medication that was shipped to facilities in seven locations in New Jersey. Most of the medications used in these types of injections is safe and is not involved in the recall.

How could this happen?

- This investigation is ongoing. The NJDOH is working with our federal and local partners to evaluate the products and preparation practices.

What facilities received the contaminated medication?

- Affected facilities in New Jersey include orthopedic specialists, ambulatory surgery centers and pain centers and physician offices and a health system. The affected facilities include:
    - Central Jersey Orthopedics Specialists, PC in South Plainfield
    - Edison Surgical Center, Edison
    - IF Pain Associates/Isaiah Florence, Teaneck
    - Premier Orthopedics Surgical Assoc, LLC, Vineland
    - Comprehensive Pain Management, Sparta
    - South Jersey Healthcare, Elmer and Vineland

How do I know my doctor has been informed of the medication recall?

- The pharmacy notified all facilities that received shipments of medication that were later recalled. The NJDOH issued a notification to all public health and healthcare partners regarding the investigation.

I just received a cortisone shot from my doctor, should I be concerned about a fungal infection?

- Individuals receive injections for many reasons. This investigation is focusing on the medication methylprednisolone acetate from the New England Compounding Center. If you are concerned, contact your health care provider to determine if you received medication from the implicated batches.

Is there a difference between this meningitis and the one I usually hear about?

- Meningitis is an inflammation of the covering of the brain and spinal cord. It is spread from person to person by saliva. Fungal meningitis is different. It is not

spread from person to person. This investigation is looking at a contaminated product as the cause of the disease.

What is an epidural?

- An epidural is an injection given into the back. The injection can be given for different purposes and contain different medications.

I just gave birth and had an epidural, should I be concerned?

- The type of medication used during an epidural during childbirth is different than the medication that was recalled with this investigation.

****Where can I find updates and additional information on this outbreak?**

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

I was contacted because I received an epidural injection with one of the potentially contaminated steroid medications approximately 4 weeks ago but I feel fine. Do I still need to be concerned?

- Patients with infections have typically developed symptoms within 1-4 weeks after their injection. However, shorter and longer timeframes between injection and onset of symptoms have been reported. The timeframe is still being investigated. Patients should watch vigilantly for symptoms if they were injected with potentially contaminated steroids and see a doctor if they have any of the following symptoms, even if they have been previously evaluated: fever, new headache or headache that is getting worse, stiff neck, sensitivity to bright light, new weakness or numbness in any part of your body, slurred speech, new or worsening back pain, redness, or warmth or swelling at your injection sight.

I was contacted because I received a joint injection with one of the potentially contaminated steroid medications approximately 4 weeks ago but I feel fine. Do I still need to be concerned?

- As of October, infections from steroid injections into joints other than the spine (e.g., knee, hip) have not been reported. The investigation is ongoing and joint infections may take longer to develop than meningitis. The timeframe is still being investigated. Patients should watch for symptoms if they were injected with potentially contaminated steroids and see a doctor if they have any of the following symptoms: fever, increased pain, redness, warmth, or swelling in the joint that received the injection or at the injection site.

Are other medications from the New England Compounding Center (NECC) located in Framingham, Massachusetts associated with infections?

- To date, CDC has not received reports of infections linked to other products from the New England Compounding Center. However, out of an abundance of caution, CDC recommends that patients cease use of any product produced by the NECC until further information is available. A list of products produced by the NECC can be found through the FDA website at http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm.
- If patients have taken or used medications from NECC, and they are worried that they are ill because of use of one of these products, they should seek medical attention. The CDC has not received any reports of infection linked to other products from NECC.

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

- Compounding pharmacies create special formulations of medications in order to fit patients' healthcare needs. For example, they may change the dose or change the formulation of a medication from a solid to a liquid.

For Health Care Providers

Guidance for clinicians may be found on the CDC website:
http://www.cdc.gov/HAI/outbreaks/clinicians/index.html

I am a healthcare provider who received the original batches of contaminated medication. What should I do?

- The NJDOH will coordinate a pick-up of the affected vials with the CDC and FDA. Facilities will be advised regarding pick-up.
- Additionally, NJDOH is asking all providers who administered steroid injections using the three affected lots of methylprednisolone acetate prepared by the New England Compounding Center (NECC) to contact all patients.

I am a healthcare provider who did not receive batches from the original recall, but I have products from the NECC. What should I do with these products?

- All healthcare providers who ordered items from the NECC are requested not to use the products. Providers are advised to pull all NECC products from their shelves and to sequester, until further notice.
- Healthcare providers who received products from NECC outside of the initial recall of methylprendisolone do not need to contact patients, at this time.

What signs/symptoms am I looking for in an infected patient?

- Infected patients have presented approximately one to four weeks following their injection with a variety of symptoms including: fever, new or worsening headache, nausea, and/or new neurological deficit (consistent with deep brain stroke). Some of these patients' symptoms were very mild in nature. Cerebrospinal fluid (CSF) obtained from these patients has typically shown elevated white cell count (with a predominance of neutrophils), low glucose, and elevated protein.

I have a patient(s) who received spinal injections and meets case definition. What should I do?

- Providers are advised to work with the regional epidemiologist in their county/jurisdiction. The contact information for regional epidemiologists in the counties that received the affected medication is below:
    - Bergen: Karen Alelis (551) 497-8256
    - Cumberland: Betsy Cubbage (609) 805-4646
    - Middlesex: Sherrie Wolpert (732) 684-4892
    - Salem: Shatrughan Bastola (856) 466-5293
    - Sussex: Lama Chaddad (973) 818-3662

I have patient(s) with meningitis or basilar stoke. What further testing is needed?

- 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 only aware of infections occurring 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, refer to the diagnostic protocol developed by CDC for this outbreak. Guidance is posted at: http://www.cdc.gov/HAI/outbreaks/meningitis.html
- Clinicians are also requested to 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.

****What is the recommended treatment?**

- When treating patients with meningitis who meet the outbreak case definition, clinicians should continue to follow routine treatment protocols for meningitis of unclear etiology, including covering for potential bacterial causes of meningitis. In addition, until the etiology is better defined, clinicians are encouraged to add empiric antifungal therapy to the treatment regimen because of the severe adverse outcomes of untreated fungal meningitis. CDC has consulted with national experts on the following guidance; these treatment options for fungal meningitis in patients associated with this cluster are interim and may change as new information becomes available.
- It is important to note that infected patients have presented with mild symptoms, only slightly worse than baseline.
- Refer symptomatic patients for a diagnostic procedure. For patients who received epidural injection with medication from the lots listed above and have any 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 only aware of infections occurring in patients who have received epidural steroid injections, patients who received other types of injection (e.g., joint injection) with potentially contaminated methylprednisolone acetate 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.
- Interim instructions regarding diagnostic testing and treatment options are available at http://www.cdc.gov/HAI/outbreaks/meningitis.html.

****What fungus been isolated in clinical specimens?**

- At present, the etiologic agent of this cluster of meningitis has not been clearly identified. However fungus has been identified in specimens. In addition to an *Aspergillus* spp. isolated early in the investigation, the fungus *Exserohilum rostratum* was also identified, indicating the possibility of infections caused by multiple organisms. Fungal meningitis is not transmitted from person to person.

****Is there a role for prophylaxis?**

- At this time, CDC does **not** recommend initiation of antifungal prophylaxis in exposed patients who are asymptomatic. These patients should be closely monitored for development of symptoms, with a low threshold for performing lumbar puncture should the patient become symptomatic.
- In addition, CDC does **not** recommend empiric antifungal therapy for symptomatic patients who have normal cerebrospinal fluid laboratory examination. These patients should be closely monitored and re-evaluated should their symptoms worsen. Should the patient have progression of symptoms, a lumbar puncture should be repeated immediately.

****Is there a role for lumbar puncture in asymptomatic patients?**

- At this time, CDC does not recommend performing lumbar puncture in exposed patients who are currently asymptomatic. These patients should be closely monitored for development of symptoms, with a low threshold for performing lumbar puncture if the patient should become symptomatic. The clinical investigation of patients associated with this outbreak is ongoing, and this recommendation may change as new information becomes available.

****Were the three lots mentioned above only used for spinal injections?**

- No. These medications were used for other types of injections, including injections into the joint (e.g., knee). To date, CDC has only identified infections in patients who received epidural steroid injections with these medications. However, patients who received other types of injections with these products may also be at risk.