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CDC HEALTH UPDATE

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CDC HAN-0338-2012-12-20-U-N

Update: Multistate Outbreak of Fungal Infections among Persons Who Received Injections with Contaminated Medication

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Summary

New information from diagnostic imaging of patients exposed to contaminated methylprednisolone acetate (MPA[1]) from the New England Compounding Center (NECC) in Framingham, Mass., demonstrates the need for assertive clinical evaluation of these patients for the possibility of an unrecognized, localized spinal or paraspinal infection. This Health Alert Network (HAN) notice provides updated guidance and information about the ongoing multistate outbreak of fungal infections as follows:

- CDC and state partners have analyzed new preliminary data based on recent Magnetic Resonance Imaging (MRI) studies among patients who had spinal or paraspinal injection with contaminated MPA from NECC. These findings demonstrate that among patients with no previous evidence of infection, and with **new or worsening symptoms** at or near the site of their injection, more than 50% had findings suggestive of a localized spinal or paraspinal infection, including epidural abscess, phlegmon, arachnoiditis, discitis, or vertebral osteomyelitis.
- This new information suggests that some patients who received spinal or paraspinal injections with implicated MPA from NECC may currently have an unrecognized, localized spinal or paraspinal infection.
- CDC is therefore re-emphasizing the guidance from the November 20 HAN advisory that recommended clinicians remain vigilant for evidence of fungal infection in these patients and use an assertive approach for clinical management and follow-up of these patients. CDC continues to recommend MRI with contrast of the symptomatic area(s) in patients with **new or worsening symptoms** at or near their injection site following spinal or paraspinal injection of implicated MPA.
- In addition, CDC is recommending that clinicians should consider obtaining an MRI with contrast of the injection site in patients with **persistent but baseline symptoms** because the presentation of these spinal or paraspinal infections can be subtle and difficult to distinguish from a patient's baseline chronic pain.

Background

CDC continues to work closely with state public health departments in response to a multistate outbreak of fungal meningitis and other infections among patients exposed to contaminated MPA[1] from one of three lots distributed by NECC. As of December 18, 2012, a total of 620 cases, which includes 39 deaths, have been reported in 19 states. CDC continues to post up-to-date information online, including case count, distribution by state, as well as clinician and patient guidance, at http://www.cdc.gov/hai/outbreaks/meningitis.html.

Since early October, CDC has advised clinicians to closely monitor and evaluate patients who received injections of contaminated MPA from NECC.

On November 20, 2012, CDC issued a HAN notification (CDC HAN-00335-2012-11-20-ADV-N; http://www.bt.cdc.gov/HAN/han00335.asp) that described preliminary information about epidural abscess and other clinical syndromes diagnosed in patients exposed to implicated MPA from NECC. The HAN advisory also noted that CDC has been receiving increasing reports of spinal or paraspinal localized infection (e.g., epidural abscess, phlegmon, discitis, vertebral osteomyelitis, or arachnoiditis). The notification further recommended that physicians obtain an MRI with contrast of symptomatic area(s) in patients with new or worsening symptoms at or near the injection site.

In the last two reporting periods (December 3-17), states have reported to CDC a total of 80 new cases, most of which are spinal/paraspinal infections.

Preliminary Data on Spinal/ Paraspinal Infections

CDC and state health department partners continue to receive data from states about patients under the care of physicians who are acting on CDC's diagnostic recommendations.

- In Michigan, Tennessee, and North Carolina, MRI testing was recently done on 128 patients who had no previous evidence of infection and had **new or worsening symptoms** at or near the site of their spinal or paraspinal injection. Of these, 67 (52%) had findings suggestive of localized infection, including epidural abscess, phlegmon, arachnoiditis, discitis, or vertebral osteomyelitis.
- Furthermore, of 109 different patients reporting **persistent but baseline symptoms** at or near the site of their spinal or paraspinal injection, 15 (14%) also had abnormal MRI findings suggestive of infection. These preliminary data are from a single hospital and may not be generalizable to all exposed patients. An additional 27 (25%) of these patients had non-specific enhancement of soft tissue or other paraspinal structures; the clinical significance of such findings is unclear and may represent either early infection or non-infectious process.

Additional Diagnostic Guidance

These data suggest that some patients who received spinal or paraspinal injections with implicated MPA from NECC may currently have an unrecognized, localized spinal or paraspinal infection. CDC is therefore re-emphasizing the need for clinicians to remain vigilant for evidence of fungal infection in these patients. Additional guidance for evaluating patients and for obtaining MRI testing is as follows:

- **Patients**:
  - **Patients** who have received an epidural injection from one of the three implicated lots of MPA[1] and who have continued, worsening, or new symptoms at or near the site of their spinal injection should seek evaluation by their medical provider for the possibility of a localized infection such as an epidural abscess. **This includes patients who initially received epidural steroid injections for pain and continue to have persistent baseline pain.**

- **Clinicians**:
  - As a part of continued monitoring of patients who received an injection with implicated MPA, clinicians should consider re-evaluating patients for signs and symptoms suggestive of infection, including continued, worsening, or new symptoms at or near the site of their injection.
  - When deciding whether to obtain an MRI, clinicians should take into account the preliminary data presented above and obtain a careful history of the patient's past and current symptoms.

- In general, clinicians should obtain an MRI with contrast of the symptomatic area(s) in patients who received a spinal or paraspinal injection with implicated MPA and have new or worsening symptoms at or near the site of their injection.
- Clinicians should consider obtaining an MRI with contrast of the symptomatic area(s) in patients with **persistent but baseline symptoms** following spinal or paraspinal injection of the implicated MPA because the presentation of these spinal or paraspinal infections can be subtle and difficult to distinguish from a patient's baseline chronic pain.
- Clinicians should also consider reviewing MRI results with a neuroradiologist because of potential difficulties in interpreting imaging results for these patients.

CDC's previous Interim Treatment and Diagnostic Guidance for Central Nervous System and Parameningeal Infections Associated with Injection of Contaminated Steroid Products (http://www.cdc.gov/hai/outbreaks/clinicians/guidance_cns.html) continues to apply.

In November, CDC established a Clinicians Consultation Network telephone service to assist physicians who are directly involved in the treatment of patients associated with this outbreak and may have clinical questions. To access the Clinicians Consultation Network service, physicians should call 1-800-CDC-INFO (1-800-232-4636). A CDC-INFO agent will verify your role as a healthcare provider and help connect you to the service. Operating hours are the same as those for CDC-INFO, 8:00 am to 8:00 pm Monday through Friday (Eastern Time), except federal holidays.

CDC continues to work with state health departments and others to gather data from existing and newly reported cases of fungal infection. This information will be used to inform updates to existing guidance. Healthcare professionals with patients under their care should check CDC's website (http://www.cdc.gov/hai/outbreaks/clinicians/index.html) for the most up-to-date clinical guidance because information is subject to change.

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[1]NECC lots of methylprednisolone acetate (PF) 80mg/ml:

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

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Health Alert	Requires immediate action or attention; highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
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