
Meningitis and Stroke Associated with Potentially Contaminated Product – FDA Urging Expanded Patient Follow-up

To: Healthcare Providers, Hospitals, Pharmacies, and Ambulatory Care Centers
From: Patsy Kelso PhD, State Epidemiologist for Infectious Disease

– Please Distribute Widely –

Background

The Centers for Disease Control & Prevention (CDC) and the Food & Drug Administration (FDA) are coordinating a multi-state investigation of fungal meningitis among patients who received injections of steroid products from the New England Compounding Center (NECC). All cases identified to date have been associated with three lots of methylprednisolone acetate.

As a result of the ongoing investigation of NECC, a patient with possible meningitis potentially associated with epidural injection of an additional NECC product, triamcinolone acetonide, has been identified. In addition, two transplant patients with *Aspergillus fumigatus* infection who were administered NECC cardioplegic solution during surgery have been reported. Investigation of these patients is ongoing; there may be other explanations for their *Aspergillus* infection.

Current Situation

As of October 15, a total of 214 cases have been identified in 15 states, including 212 fungal meningitis cases plus 2 peripheral joint infections (e.g. knee, hip, shoulder, elbow). There have been 15 deaths. No cases have been reported to date in Vermont. Health Department staff are participating on daily national CDC conference calls to monitor the situation.

Requested Actions

- Follow up with patients for whom you administered an injectable product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution purchased from or produced by NECC after May 21, 2012.

FDA does not urge patient follow-up at this time for NECC products of lower risk, such as topicals (for example lotions, creams, eyedrops not used in conjunction with surgery) and suppositories.

Use your clinical judgment in deciding which patients are at risk, and contact those patients in whatever communications mode you prefer (email, phone or letter). Face-to-face communication with patients is not necessary.

- Inform patients who received the NECC products noted above of the symptoms of possible infection, and instruct them to contact you or another healthcare provider immediately if they experience any of these symptoms:

Signs and symptoms of meningitis include fever, headache, stiff neck, nausea and vomiting, photophobia (sensitivity to light) and altered mental status.

Symptoms for other possible infections may include: fever, swelling, increasing pain, redness or warmth at injection site; changes in vision, pain, redness or discharge from the eye; chest pain or drainage from the surgical site (infection within the chest).

- Visit <http://www.cdc.gov/hai/outbreaks/meningitis.html> for daily updates on this investigation, clinician guidance, and laboratory testing information.
- *If you administered an injectable product or a cardioplegic solution purchased from or produced by NECC after May 21, 2012*, please report to the Health Department the number of patients potentially at risk by calling (802) 863-7240.
- *Report any symptomatic patients undergoing evaluation* to the Health Department 24/7 at (802) 863-7240.
- *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.
- Contact FDA's Drug Information Line at 855-543-DRUG (3784) and press * to get the most recent information regarding the meningitis recall and speak directly to a pharmacist.

Previous advisories on this topic:

October 5, 2012

http://healthvermont.gov/advisory/documents/100512_fungal_meningitis.pdf

October 9, 2012

http://healthvermont.gov/advisory/2012/documents/100912_fungal_meningitis_update1.pdf

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