

## NATIONAL PBM COMMUNICATION • October 18, 2012

### ADDENDUM: Fungal Meningitis Outbreak and Additional Patient Notification

- As of October 16, 2012, the Centers for Disease Control (CDC) reports 231 fungal meningitis cases plus 2 peripheral joint infections (e.g., knee, hip, shoulder, elbow), as well as 15 deaths, associated with epidural and other joint injections compounded by the New England Compounding Center (NECC).
  - All cases identified have occurred after injection with preservative free (PF) methylprednisolone acetate 80mg/mL from any of the 3 lots recalled by NECC on September 25, 2012.
  - No deaths have been associated with peripheral joint infections.
- On October 6, 2012, NECC expanded its recall to include all of their products, with a complete listing of affected agents available at: [http://www.neccrx.com/List\\_of\\_all\\_products\\_manufactured\\_since\\_January\\_2012.pdf](http://www.neccrx.com/List_of_all_products_manufactured_since_January_2012.pdf) or <http://www.fda.gov/Safety/Recalls/ucm322979.htm?source=govdelivery>.
- To date, the Food and Drug Administration (FDA) has received reports of 2 infections related to injectable solutions outside of NECC's original 3 recalled lots of methylprednisolone acetate (PF), but the agency has not fully confirmed NECC as the source of these products.
  - FDA has identified (through active surveillance) 1 patient with meningitis related to the use of another possible NECC steroid injection, triamcinolone acetonide, with ongoing investigation pending.
  - One health care facility notified CDC of 1 transplant patient who developed an *Aspergillus fumigatus* infection after receiving a cardioplegic solution (possibly produced by NECC) during surgery, with further investigation underway.
- A detailed review of data from the VA Adverse Drug Event Reporting System from May 21, 2012 until October 16, 2012 shows no reports of meningitis or any infection related to any injectable steroid use.

#### **PRODUCT SEQUESTERING ACTIONS**

- All healthcare practitioners must cease use and immediately remove from their pharmacy inventory ANY product produced by the NECC [not just methylprednisolone acetate (PF)].

#### **PATIENT NOTIFICATION ACTIONS**

- Facilities must contact all patients who received methylprednisolone acetate (PF) injections from any of the three previously recalled lots ([National PBM Communication](#)) to determine if they are having any symptoms of meningitis or other possible infection(s).
- Facilities must contact patients who received ANY 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, to determine if they are having any symptoms of meningitis or other possible infection(s).
- The signs/symptoms of meningitis include fever, headache, stiff neck, nausea/vomiting, photophobia, and altered mental status. Signs/symptoms for other possible infection(s) may include fever; injection site reactions (e.g., swelling, increasing pain, redness, warmth at injection site); visual changes or ocular pain, redness and/or discharge; chest pain or drainage from the surgical site denoting infection within the chest.
- If an affected lot(s)/product(s) was administered to a patient(s), then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product(s) by any appropriate method. *Contact any contract and/or fee basis clinic(s)/provider(s) to determine whether NECC products were used on any patient(s). If so, make a plan to contact the patient[s] (if not done so already) either by the fee basis clinic or VAMC/CBOC to assess for meningitis or other infection(s).*
  - Provide patient(s) who received the recalled product(s) with instructions on reporting to their respective VA medical center for further evaluation of the aforementioned signs/symptoms of meningitis as well as other possible infection(s).
- Providers should continue to report any adverse reactions with the use of methylprednisolone acetate, or any injectable product produced by or purchased from NECC, by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA 0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

#### REFERENCES

Multistate Fungal Meningitis Outbreak Investigation. <http://www.cdc.gov/hai/outbreaks/meningitis-map.html> . (Accessed 10/16/12).

FDA Statement on Fungal Meningitis Outbreak: Additional Patient Notification Advised. <http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm> . (Accessed 10/16/12).

Internal VA data.

#### **FEEDBACK NOTIFICATION ACTIONS:**

- Facility Director** (or physician designee): Report completion of actions to the VISN Director.
- Facility COS and Chief Nurse Executives:** Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, surgery, anesthesiology staff, pain specialists, neurology, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.
- ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).
- VISN Directors:** Within 10 business days of issue (due 11/01/2012), communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the Feedback tool: [https://vawww.cmopnational.va.gov/cmop/PBM/visn\\_drug\\_recalls\\_alerts/default.aspx](https://vawww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx).