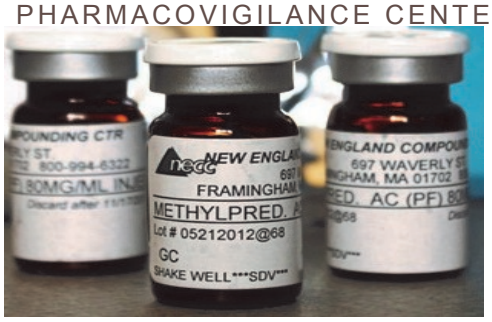
ISSUE 9 | VOLUME 2 | OCTOBER 2012

Medication safety in seconds

A MONTHLY PUBLICATION FROM VA MEDSAFE:
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER

Helping to achieve safe medication use



FUNGAL MENINGITIS OUTBREAK AND INJECTABLE PRODUCTS FROM NEW ENGLAND COMPOUNDING CENTER [NECC]

As of October 24, 2012, an outbreak of fungal meningitis associated with compounded steroid injections (for epidural and other joint administration) prepared and distributed by **New England Compounding Center, Inc (NECC)**, in Framingham, Massachusetts, has resulted in 312 cases of fungal meningitis, stroke from presumed fungal meningitis, or other central nervous system-related infection, plus 5 peripheral joint infections (e.g., knee, hip, shoulder, elbow), as well as 24 deaths. No deaths have occurred in association with the peripheral joint infections. All infected patients received **preservative free (PF) methylprednisolone acetate 80mg/ml injection** from 3 lots voluntarily recalled by NECC on September 25, 2012. NECC has since voluntarily suspended operations, surrendered their license, and expanded its recall to include all methylprednisolone acetate prepared by their specialty pharmacy as well as all of their other drug products prepared and/or sold.

Department of Veterans Affairs (VA) has issued a National PBM Communication on October 5, 2012 with recommendations for facilities to:

- Cease use and immediately remove from their pharmacy inventory ANY product produced by the NECC [not just methylprednisolone acetate (PF)]; and
- Contact all patients who received methylprednisolone acetate (PF) injections from any of the three recalled lots to determine if they are having any symptoms.

Department of Veterans Affairs (VA) circulated an updated National PBM Communication on October 18, 2012 with additional actions for facilities to:

- 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).

(continued on page 2)

NEWS YOU CAN USE

FROM THE VA NATIONAL PBM: BULLETINS, COMMUNICATIONS, & RECALLS

- ADDENDUM: Fungal Meningitis Outbreak and Additional Patient Notification – 10-18-2012 - National PBM Communication
- Compounded Epidural Steroid Injections and Meningitis Outbreak - 10-05-2012 - National PBM Communication

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Helping to achieve safe medication use

FUNGAL MENINGITIS OUTBREAK AND INJECTABLE PRODUCTS FROM NEW ENGLAND COMPOUNDING CENTER [NECC]

(continued from page 1)

Department of Veterans Affairs (VA) facilities have removed any product from the New England Compounding Center, Inc. (NECC), based on the recall of all NECC products issued by the Food and Drug Administration (FDA). VA has found no evidence that any VA medical facility used the injectable steroid product from NECC identified as being contaminated. VA's top priority is to ensure the safety of all patients. To date, a detailed review of data from the VA Adverse Drug Event Reporting System (VA ADERS) from May 21, 2012 until October 16, 2012 shows no reports of meningitis or any infection related to any injectable steroid use within the VA healthcare system.

FDA continues to work with CDC and state health officials to investigate the source of contamination, scope of exposure, and impact on patient outcomes. As investigations unfold, new information can be accessed via the following links:

- CDC updated case counts: http://www.cdc.gov/hai/outbreaks/meningitis-map.html
- CDC Map of Healthcare Facilities that received lots of Methylprednisolone Acetate (PF) recalled from New England Compounding Center on September 26, 2012: http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html
- CDC Health Alert for clinicians: http://www.cdc.gov/hai/pdfs/outbreaks/HAN-Advisory_Meningitis_and_Stroke_Associated_with_Potentially_Contaminated_Product-10-4-12.pdf
- CDC instructions for clinical teams regarding diagnostic testing: http://www.cdc.gov/hai/pdfs/outbreaks/Outbreak-diagnostic-protocol-cleared.pdf
- CDC interim treatment options for patients: http://www.cdc.gov/hai/pdfs/outbreaks/Treatment-Options-10-3-2012-cleared.pdf
- CDC website: http://www.cdc.gov/hai/outbreaks/meningitis.html
- FDA website: http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm

REFERENCES

1. Multistate Fungal Meningitis Outbreak Investigation. http://www.cdc.gov/hai/outbreaks/meningitis-map.html . (Accessed 10/16/12).
2. FDA Statement on Fungal Meningitis Outbreak: Additional Patient Notification Advised. http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm . (Accessed 10/16/12).
3. Internal VA data.

NEWS YOU CAN USE

FROM THE FOOD AND DRUG ADMINISTRATION (FDA)

NEUROLOGY

Ongoing safety review of Parkinson's drug Mirapex (pramipexole) and possible risk of heart failure

9/19/2012

FDA suggests a potential risk for heart failure with pramiprexole (Mirapex®) based on preliminary evaluations of a pooled analysis of randomized trials and two epidemiologic studies, with further review underway. The pooled analysis (from randomized, placebo-controlled, parallel phase 2 and 3 clinical trials of pramiprexole [Mirapex®] submitted by the manufacturer to the FDA) showed a non-significant greater incidence of newly diagnosed heart failure occurring in patients taking pramiprexole (Mirapex®) compared to patients receiving placebo. One epidemiologic study showed a statistically significant increase in risk for heart failure (risk ratio [RR] = 1.58; 95% confidence interval [CI]: 1.26-1.96) with use of any dopamine agonist compared to no use of a dopamine agonist. Another epidemiologic study looked at ergot dopamine agonists as a class, as well as non-ergot dopamine agonists as a class, and saw no increased risk of heart failure when compared to levodopa. However, of the non-ergot dopamine agonists, use of pramiprexole (Mirapex®) increased the risk of heart failure when compared to levodopa (odds ratio [OR] = 1.61; 95% CI: 1.09-2.38). Study limitations from these epidemiologic trials prevent FDA from reaching any definite conclusions. These limitations include the participation of patients using anti-Parkinson drugs for other uses (such as restless legs syndrome, treatment of hyperprolactinemia, and for unidentified reasons); limited or no validation of heart failure cases via medical record review; the appearance of risk factors more frequently in cases than in controls; and the presence of peripheral edema (even if adjusted for by sensitivity analysis).

PAIN MANAGEMENT

Rare cases of serious burns with the use of over-the-counter topical muscle and joint pain relievers

9/13/2012

First- to third- degree chemical burns have occurred when applying over–the-counter (OTC) topical muscle and joint pain relievers (creams, ointments, and patches) containing menthol (>3% concentration), methyl salicylate (10% concentration), or capsaicin. Burns occurred after only one application, with severe blistering or burning occurring within 24 hours after initial use. Current product labelling for OTC muscle and joint pain relievers do not carry a warning regarding burns. Healthcare providers should counsel patients on appropriate use of OTC muscle and joint pain relievers in addition to care for the site of application, including:

- Do not bandage affected area(s) tightly;
- Do not apply local heat to affected area(s) [heating pads, lamps, hot water in bags or bottles];
- Do not apply to wounds or damaged, broken, or irritated skin;
- Do not allow contact with eyes or mucous membranes;
- Discontinue use if experiencing pain, swelling, or blistering of the skin at the site(s) of application.

Getting the most from our safety surveillance

OPPORTUNITIES TO PARTICIPATE IN VA SAFETY INITIATIVES

ATTENTION PHARMACISTS: CALL FOR PARTICIPANTS

- **Multi-Site Medication Use Evaluation (MUE) of Pharmacological Treatment of Dementia**

The purpose of this MUE is to collect information as a quality assurance and improvement (QA/QI) initiative to describe the current prescribing landscape of cholinesterase inhibitors (Ch-I) and memantine in relation to the VHA PBM Criteria for Use guidance. Aggregate data will be evaluated to determine rate of compliance to PBM National Criteria for Use of Ch-I's with regards to indication, monitoring, management of adverse event, and timeliness of follow-up. Looking for 10-15 geographically dispersed sites. Sites with pharmacy residents are encouraged to participate; however, participation is open to all . If interested, or for more information, contact Muriel.Burk@va.gov .

- **Allergy/Adverse Reaction Tracking System (ARTS) Multi-Site Validation**

VA MedSAFE is currently recruiting Pharmacist Residents to participate in a multi-site validation of the observed and historical classification of adverse drug reaction entries documented in the Allergy/Adverse Reaction Tracking System (ARTS) package, located in the Computerized Patient Record System (CPRS). This information will help evaluate the true incidence of Observed and Historical events as well as potential submission to the VA Adverse Drug Event Reporting System (VA ADERS) and the Food and Drug Administration's (FDA) MedWatch. If interested, or for more information, contact Anthony.Au@va.gov and Von.Moore@va.gov .