ISSUE 3 | VOLUME 7 | MARCH 2017

MEDICATION SAFETY IN SECONDS

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

Helping to achieve safe medication use

VACCINE ABBREVIATIONS AND ACRONYMS MAY LEAD TO ERRORS

Long and complex generic names for vaccines have prompted the use of abbreviations and acronyms to specify the type of vaccine and distinguish among vaccines used for the same disease. The Center for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) provides a list of standardized abbreviations or acronyms for FDA-approved vaccines in order to promote accuracy and consistency while reducing medical errors (available at: www.ismp.org/sc?id=2866). These abbreviations are encouraged for scientific publications but not specifically required for use in the clinical setting. The CDC site also catalogues abbreviations often used on immunization records, including abbreviations for vaccine-targeted diseases and non-standard abbreviations (available at: www.ismp.org/sc?id=2867).

A recent alert from the Institute for Safe Medication Practices (ISMP) discusses vaccine errors due to similar abbreviations or acronyms. A search of the ISMP Vaccine Errors Reporting Program (VERP) from September 2012 to February 2017 tallied the most frequent abbreviations or acronyms involved in reported mix-ups (see Table 1, page 3). Errors with vaccines can result in an inadvertant vulnerability that renders patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, pneumonia, and many others.

Within the VA, a recent Patient Safety Alert issued by VHA Central Office describes two similar pneumococcal immunizations incorrectly documented in the Veterans Health Information Systems and Technology Architecture/Computerized Patient Record System (VistA/CPRS) as given to patients on the same day, when only one immunization was actually given on that day. These errors

(continued on page 3)

NEWSWORTHY...

from the pbm

- Direct-Acting Antiviral Safety Issues - 03/14/2017 – National PBM Bulletin
- ADDENDUM: Mirtazapine Tablets, USP 45mg – Ongoing Recall Due to Commingled Tablets - 03/08/2017 – National PBM Patient Level Recall Communication
- Mirtazapine Tablets, USP 45mg – Recall Due to Potential of Commingled Tablets – 03/07/2017– National PBM Patient Level Recall Communication
- Alprostadil for Injection (Edex®) – Recall Due to Potential Lack of Sterility Assurance – 03/06/2017– National PBM Patient Level Recall Communication

(continued on page 2)

IN THIS ISSUE:

VA PHARMACY BENEFITS MANAGEMENT SERVICES (PBM)

PBM maintains VA's national drug formulary, as well as promotes, optimizes, and assists VA practitioners with the safe and appropriate use of all medications.

VA CENTER FOR MEDICATION SAFETY (VA MedSAFE)

VA MedSAFE performs pharmacovigilance activities; tracks adverse drug events (ADEs) using spontaneous and integrated databases; enhances education and communication of ADEs to the field; and promotes medication safety on a national level.

EDITOR-IN-CHIEF

Marie Sales, Pharm.D.
VA Pharmacy Benefits Management Services [PBM] & Center for Medication Safety [VA MedSAFE]; 1st Avenue—1 Block North of Cermak Road | Building 37; Room 139 | Hines, Illinois | 60141;
www.pbm.va.gov

NEWSWORTHY...

from the fda

GASTROENTEROLOGY

FDA warns about increased risk of serious pancreatitis with irritable bowel drug Viberzi (eluxadoline) in patients without a gallbladder

3/15/2017

Hospitalizations and deaths due to pancreatitis have been reported with eluxadoline (Viberzi) use in patients who do not have a gallbladder. Eluxadoline (Viberzi) is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D). FDA received reports of 120 serious cases of pancreatitis or death associated with eluxadoline (Viberzi) use in the FDA Adverse Event Reporting System (FAERS) database from May 2015 (date of FDA approval) through February 2017. Out of the 120 reports:

- 76 cases resulted in hospitalization,
  - 2/76 deaths
    - Both deaths occurred in patients who did not have a gallbladder.
    - One patient exhibited pancreatitis symptoms such as acute, severe abdominal pain, nausea, and vomiting within 60 minutes of taking a single dose of eluxadoline [Viberzi]; death ensued within 3 days of the initial dose.
    - The other death involved a patient who experienced sphincter of Oddi spasm with severe abdominal pain and vomiting occurring shortly after taking the first dose.
- 6 reported sphincter of Oddi spasm
- 16 reported abdominal pain
- 84 cases reported a time to onset of the adverse event:
  - 48/84 serious cases of pancreatitis or death occurred after one or two doses.
  - 36/84 experienced pancreatitis with prolonged use.
- 68 cases reported gallbladder status:
  - 56/68 cases of pancreatitis or death occurred in patients without a gallbladder.
    - 44/56 received the currently recommended dosage of eluxadoline [Viberzi] (75 mg) for patients who do not have a gallbladder.
    - 21/56 did not abuse alcohol and
    - 35/56 did not report alcohol use status.

FDA recommends that health care professionals should:

- Be aware that symptoms of pancreatitis have occurred with just one or two doses of eluxadoline (Viberzi) at the recommended dosage for patients who do not have a gallbladder (75 mg) and who do not consume alcohol.
- Consider alternative treatment options before using eluxadoline (Viberzi). **Do not prescribe eluxadoline (Viberzi) in patients who do not have a gallbladder.**
- Avoid use of eluxadoline (Viberzi) in the following patients with:
  - No gallbladder
  - Current or prior blockage of the gallbladder or a sphincter of Oddi problem
  - Pancreatitis or other pancreas problems, including a blockage of the pancreas
  - History of serious liver problems
  - History of chronic or severe constipation
  - Current or prior intestinal obstruction
  - History of alcohol abuse, alcohol addiction, or drinks more than three alcoholic beverages a day
- Educate patients on diet and lifestyle changes as well as stress management to help control symptoms of IBS-D.
- Instruct patients to talk with a health care professional before taking any anti-diarrhea medicine, including over-the-counter medicines.

Getting the most from our safety surveillance

EVALUATION OF HEPATITIS B REACTIVATION IN VA

A recent publication describes a national surveillance effort within the Department of Veterans Affairs (VA) to quantify and characterize hepatitis B virus (HBV) reactivation among veterans undergoing treatment with oral direct-acting antiviral (DAA) therapy for hepatitis C virus (HCV) infection . The evaluation looked at veterans receiving the following DAAs: sofosbuvir, simeprevir, ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir plus dasabuvir, elbasvir/grazoprevir, and sofosbuvir/velpatasvir. Baseline HBV status was assessed via HBV laboratory data (hepatitis B surface antigen [HBsAg], hepatitis B core antibody [anti-HBc], hepatitis B surface antibody [anti-HBs] and HBV DNA). HBV reactivation was identified by a >3 log increase in HBV DNA or a positive HBsAg, either occurring while on treatment with DAA medication or within seven days following the last day of DAA therapy; hepatitis was identified via alanine aminotransferase (ALT) values >2 times the upper limit of normal. Results from this retrospective database evaluation showed that out of 62, 290 veteran patients treated with DAAs from January 2014 through September 2016:

- 9 patients had evidence of HBV reactivation (defined by >3 log increase in HBV DNA occurring while on treatment with DAA).
  - 8 were HBsAg positive;
  - 1 was isolated anti-HBc positive;
  - 3 had peak ALT >2 times the upper limit of normal.

These findings suggest a low signal for HBV reactivation within the VA and that accompanying hepatitis was rare. For further details, the full article can be accessed at: https://www.ncbi.nlm.nih.gov/pubmed/28240789 .

REFERENCE:

Belperio PS, Shahoumian TA, Mole LA, Backus LI. Evaluation of Hepatitis B Reactivation among 62,920 Veterans treated with Oral Hepatitis C Antivirals. *Hepatology*. 2017 Feb 27. doi: 10.1002/hep.29135. [Epub ahead of print]

Helping to achieve safe medication use

VACCINE ABBREVIATIONS AND ACRONYMS MAY LEAD TO ERRORS

(continued from page 1)

resulted from an erroneous link between immunization entries (IMM) and Current Procedural Terminology (CPT) codes found in Patient Care Encounter (PCE) code mapping, leading to documentation in VistA/CPRS that the patient received two vaccines when only one has been given. Incorrect entries affect clinical reminders and may prevent a patient from getting a pneumococcal immunization. The pneumococcal vaccines involved were PCV13 [Prevnar 13® Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)] and PPSV23 [PNEUMOVAX®23 (Pneumococcal Vaccine Polyvalent)]. Of note, this pair has also been identified among ISMP's most frequently reported mix-ups due to vaccine abbreviations and acronyms. This issue has prompted a national review and assessment of facility processes for adult vaccination and immunization within VA.

ISMP offers recommendations to reduce the risk of errors ensuing from vaccine abbreviation/acronym confusion, some of which include:

- Allow use of only current, CDC-approved abbreviations and acronyms for vaccines where permitted instead of non-standard names.
- Where CDC-approved abbreviations and acronyms for vaccines are permitted, list both the full nonproprietary name (and brand, if needed) along with the approved abbreviation or acronym on all order sets to reinforce their correct use.
- Establish regular review (at least annually) of all standard order sets for vaccines, and update as needed (e.g., change in vaccine brands).

Table 1. Most Common Mix-Ups Reported to ISMP Associated with Vaccine Abbreviations and Acronyms

Tdap and DTaP
DT and Td
MMR and MMRV
PCV13 and PPV23, or PCV and PPV (PPV23 is now replaced by PPSV23)
Hib and HepB
HepA and HepB
DTaP-HepB-IPV, DTaP-IPV/Hib, and DTaP-IPV
HPV and IPV
HPV and HBV (HBV was used to abbreviate hepatitis B vaccine; HepB is the correct abbreviation)
MCV and PCV (MCV4 is the correct abbreviation; PCV7, PCV13, or PPSV23 is the correct abbreviation)
MCV and MMR (MCV4 is the correct abbreviation)
VAR and HZV
IPV and PPD (PPD [purified protein derivative tuberculin test] is not a vaccine)
IIV and PPD (PPD is not a vaccine)
PCV and PPD (PPD is not a vaccine)
HPV and Hib
MMRV and MPSV (MPSV4 is the correct abbreviation)
HepA and HPV4 (4vHPV is the correct abbreviation)
HepB and HPV4 (4vHPV is the correct abbreviation)

REFERENCES:

1. Institute for Safe Medication Practices (ISMP). DTaP, LAIV, MCV4, PPSV23, HZV, 9vHPV… Alphabet soup vaccine abbreviations and acronyms lead to errors. *ISMP Medication Safety Alert! Acute Care* February 2017; 22 (4): 1-4.
2. VHA Central Office. Pneumococcal immunizations can be incorrectly documented as given within VistA/CPRS. Veterans Health Administration Patient Safety Alert. March 27, 2017; AL17-02: 1-23. Available at : http://vaww.ncps.med.va.gov/Guidelines/alerts/Docs/AL17-02.pdf (internal VA access only) ■