



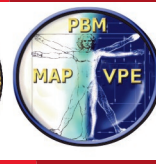
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# Medication *safety in seconds*

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

## Helping to achieve safe medication use

### PHARMACY BENEFITS MANAGEMENT SERVICES (PBM) WITHIN THE VA



Pharmacy care within the Department of Veterans Affairs (VA) falls under the national guidance of the Pharmacy Benefits Management Services (PBM), a team of medical and pharmacy authorities, whose primary functions include:

- Maintaining the national drug formulary, which ensures that veterans have improved access to the same drug products and supplies across the system nationwide while keeping pharmacy costs at a low level; and
- Promoting, optimizing, and assisting VA practitioners with the safe and appropriate use of all medications, enhancing both patient outcomes and satisfaction. PBM achieves this second goal by:
  - Developing recommendations and policies for drug use based on current evidence reported in the published medical literature demonstrating clinically relevant outcomes; and
  - Identifying, tracking, monitoring, and preventing adverse drug events, in collaboration with the VA Center for Medication Safety (VA MedSAFE), a comprehensive pharmacovigilance center.

Since its establishment in 1995, the PBM oversees the national drug plan for the entire VA system, which serves more than 8.34 million Veterans enrolled in the VA Health Care System and provides more than 139 million prescriptions per year.

PBM has utilized various contracting techniques to maintain a generous and standardized drug benefit nationally while at a low cost, even as drug expenditures continue to rise. PBM has helped the VA to keep its average acquisition cost for a 1-month supply of medication stable for

nearly 10 years (\$12.79 in October 1998 compared to \$13.57 in May 2007, which is a change of less than 1% per year). However, PBM's management of VA's national drug plan relies first and foremost on comprehensive review of a medication's evidence in the scientific literature demonstrating safe and effective patient outcomes. In this way, the best value drugs may not necessarily equate to the least expensive, but because they demonstrate the most efficacy as well as safety, they become preferred drugs on the formulary.

PBM collaborates with VA MedSAFE to undertake quality-improvement and safety initiatives that ultimately assess, monitor, and enhance the safe and appropriate use of medications in Veterans within the VA Health Care System nationwide. These efforts make use of VA integrated databases to help identify and evaluate drug safety issues and utilization trends. Because the VA has a closed system, PBM/VA MedSAFE has the ability to track medication use at a national or patient-specific level and encourage the use of evidence-based therapies. For example, several years ago, PBM/VA MedSAFE identified all patients within the VA system-wide receiving short-acting nifedipine for the treatment of hypertension and arranged for a switch in their prescriptions to safer medications due to reports in the medical literature associating its use with an increased risk of myocardial infarction.

For more information on the PBM and formulary management within the VA, please visit: <http://www.pbm.va.gov/>.

#### REFERENCES:

1. Sales MM, Cunningham, FE, Glassman PA, Valentino MA, Good, CB. Pharmacy benefits management in the Veterans Health Administration: 1995 to 2003. *Am J Managed Care*. 2005; 11:104-112.
2. Good CB, Valentino MA. Access to affordable medications: The Department of Veterans Affairs pharmacy plan as a national model. *Am J Public Health*. 2007 December; 97(12): 2129-2131.



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# NEWS YOU CAN USE

FROM THE FOOD AND DRUG ADMINISTRATION (FDA)

## NEUROLOGY

### [Seizure risk for multiple sclerosis patients who take Ampyra \(dalfampridine\)](#)

07/23/2012

FDA's review of seizure risk associated with dalfampridine (Ampyra) therapy in multiple sclerosis patients showed seizures occurring at the recommended dose in the product label and within the first week of starting therapy. Seizures, a known and documented adverse event with dalfampridine (Ampyra), can increase with higher levels of the drug since elimination occurs via the kidneys. FDA recommends assessing renal function before starting dalfampridine (Ampyra). Dalfampridine (Ampyra) is contraindicated in patients with moderate to severe renal impairment (creatinine clearance  $\leq 50$  mL/min) or with a history of seizures. For patients with mild renal impairment (creatinine clearance  $\leq 51$ -80 mL/min), consider risk versus benefits before initiating treatment with dalfampridine (Ampyra).

## ONCOLOGY

### [New information regarding QT prolongation with ondansetron \(Zofran\)](#)

06/29/2012

Preliminary information from a recent study indicates dose-dependent QT-prolongation with ondansetron (Zofran), and specifically with the 32mg single intravenous dose. Patients at risk for this adverse event include those with congenital long QT syndrome, congestive heart failure, bradyarrhythmias, uncorrected electrolyte abnormalities, and use of concomitant medications that prolong the QT interval. The manufacturer (GlaxoSmithKline) will update product labeling to state that no single intravenous dose should exceed 16 mg due to risk of QT prolongation. A lower intravenous dose of 0.15mg/kg every 4 hours for 3 doses may be used in adults with chemotherapy-induced nausea and vomiting. Oral dosing recommendations as well as lower intravenous dosing recommendations remain the same. FDA will reveal final study results when available.

## INFECTIOUS DISEASES

### [Cefepime and risk of seizure in patients not receiving dosage adjustments for kidney impairment](#)

06/26/2012

According to reports found in the FDA's Adverse Event Reporting System (AERS) database as well as in the medical literature, nonconvulsive status epilepticus has occurred with the use of cefepime. Cases involved patients greater than 50 years of age, having renal dysfunction, inappropriate dosing adjustments, underlying concurrent illness, or history of seizures on beta-lactam or cephalosporin antibiotics. Seizures resolved upon discontinuation of cefepime and/or after hemodialysis. FDA recommends adjusting cefepime doses in patients with a creatinine clearance equal to or below 60 mL/min. If seizures occur during treatment with cefepime, FDA recommends discontinuing cefepime or adjusting the dose for those with renal impairment.

## Getting the most from our safety surveillance

### IMPROVING DRUG SAFETY MONITORING IN THE VA: COMBINING DATA FROM THE ADVERSE REACTION TRACKING SYSTEM (ARTS) AND THE VA ADVERSE DRUG EVENT REPORTING SYSTEM (VA ADERS)

The VA uses two separate spontaneous adverse drug event (ADE) reporting systems to manage provider- and patient-reported ADEs:

- the Allergy/Adverse Reaction Tracking System (ARTS), which resides within the VA electronic medical record and houses all allergies as well as adverse drug reactions (ADR) entered into the Computerized Patient Record System (CPRS) by providers for use in direct patient care; and
- the VA Adverse Drug Event Reporting System (VA ADERS), a web-based spontaneous ADE reporting system that allows for system-wide tracking/monitoring of ADEs on an aggregate or individual level, and from which MedWatch reports can be generated from provider entries for electronic submission to the FDA.

ARTS serves as a safety tool, with utility occurring at the point of care when providers enter patient-reported allergies or adverse events associated with medications into the Allergy/Adverse Re-

Rank	Primary Suspect Drug
1	LISINAPRIL
2	SIMVASTATIN
3	PRAVASTATIN
4	ROSUVASTATIN
5	TERAZOSIN
6	METFORMIN
7	HYDROCHLOROTHIAZIDE
8	SULFAMETHOXAZOLE/TRIMETHOPRIM
9	AMLODIPINE
10	GABAPENTIN

TABLE 1. Suspect drugs ranked by number of reports after cross-referencing ARTS with VA ADERS.

actions section of the patient chart in CPRS during a clinic visit. ARTS stores patient- and drug-specific data regarding unwanted medication effects in a centralized database. During each prescription order entry in CPRS, the information is cross-checked for any previously associated and documented adverse reaction/event. This helps to prevent repeat exposure of patients to the same potentially harmful drug or class of drugs.

VA ADERS is the VA's nationwide web-based ADE reporting system available at all VA Facilities, also used for safety purposes. Users with access to read notes in CPRS can submit ADE reports to the VA ADERS database. VA ADERS standardizes ADE reporting within the VA, and enables completion of MedWatch forms from the application with electronic submission directly to the FDA. Additionally, VA ADERS provides ADE trending reports and a platform for medical centers to share process improvements.

(Continued on page 3)

# Getting the most from our safety surveillance

## IMPROVING DRUG SAFETY MONITORING IN THE VA: COMBINING DATA FROM THE ADVERSE REACTION TRACKING SYSTEM (ARTS) AND THE VA ADVERSE DRUG EVENT REPORTING SYSTEM (VA ADERS)

(Continued from page 2)

Relating data from the ARTS and VA ADERS programs strengthens VA's capability for capturing adverse event information when compared to using each system alone, since underreporting remains an issue with spontaneous reporting. Also, at this time, there is no automatic link between ARTS and VA ADERS to allow for entries in one system to automatically populate the other. To bridge the gap between systems and to increase the overall reporting to VA ADERS, the ARTS information is screened on a monthly basis by VA ADERS staff. Information from ARTS is then cross-referenced with VA ADERS datasets to identify ADE entries captured in ARTS (but not entered into VA ADERS) for inclusion into the VA ADERS database. This allows for detection of a greater number of true observed reactions.

Merging data from the two sources allows for more ADE information to be collected, compounding the potential to identify, monitor, and report adverse reactions associated with medications within the VA. VA ADERS creates one draft report per ADE imported from ARTS data that contains the basic components for the event: patient identifiers, reactant (drug), event (symptom or reaction) and the date of the event. This results in multiple draft reports loaded into the VA ADERS application for most facilities on a monthly basis so that reporters on-site can access for evaluation and completion. Regardless of severity or complexity of the event, additional information is required for submitting a final report to the VA ADERS database. Completion of these reports by site reporters and submission into the VA ADERS system helps to establish a more comprehensive database of observed ADEs in VA to use in tracking and trending, as well as reviewing for events of interest within and among facilities. VA ADERS applies two criteria to identify events of interest from the monthly ARTS files in the creation of its draft reports:

- **Criteria 1:** ARTS entries marked as "**Observed**" with no corresponding VA ADERS entry.

**Rationale:** These "**Observed**" events appear as documented in the patient chart, but not in VA ADERS. The inclusion of all known observed drug reactions in VA patients within VA ADERS helps strengthen its potential for use by providers in monitoring ADEs at the facility level as well as reducing risk of harm at the patient level.

- **Criteria 2:** ARTS entries marked as "**Historical**" with no corresponding VA ADERS entry, but with prescription records reflecting that VA dispensed the reactant drug within the 6 months prior to the "**Historical**" ARTS entry.

**Rationale:** A patient who has a "**Historical**" entry for an ADR and who has also received the suspect drug associated with the ADR from the VA within the last 6 months may, in fact, have experienced that ADR due to use of the VA provided medication. In this case, it would represent an "**Observed**" ADR entered incorrectly as "**Historical**".

Since July 2009 to present, ARTS entries of all VA facilities are screened using **Criteria 1**, from which subsequent draft VA ADERS reports are created for each event meeting criteria. In addition to **Criteria 1**, individual facilities or entire VISNs may request to use **Criteria 2** for "**Historical**" entries with a VA prescription within the last 6 months in their facility or network. At this time, 15 facilities and 1 network have requested **Criteria 2** be applied at their facility to identify potential reactions to report.

Integration of data from the two programs has enabled improved system-wide identification of most commonly reported medications associated with an allergy/adverse reaction within the VA. The most common agents reported with adverse events (regardless of severity) as a result of linking ARTS and VA ADERS data appear in Table 1 (see page 2).

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## PROVIDER RECOMMENDATIONS

- Providers should continue to report any adverse events associated with medication use by entering the information into CPRS' Allergies/Adverse Reactions field and via local reporting mechanisms.
- Facilities should continue to report adverse events into VA ADERS and from VA ADERS to the FDA (as appropriate).
- As previously mentioned, the two systems (ARTS and VA ADERS) are not automatically linked, but their contents complement each other by providing a more robust collection of adverse event/reaction information available for VA facilities to review as they work to meet their patient and facility safety goals. Therefore, reporting to the ARTS file by entering the Allergy/Adverse Reaction information in the patient chart remains first and foremost, since this process directly impacts patient care activities. The subsequent link and population of the VA ADERS database with ARTS information equips the VA with more detailed ADE data to help enhance system-wide awareness of ADEs occurring in the VA as well as future medication risk reduction efforts.
- For more information about the ARTS and VA ADERS programs, please click on the following link: [VA Adverse Drug Event Reporting System \(VA ADERS\): Monitoring Adverse Drug Reactions Across A Nationwide Health Care System Using Information Technology](#).