

MEDICATION

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

SAFETY IN SECONDS

Helping to achieve safe medication use

CHEMOTHERAPY ORDERING SYSTEM USE AND RISK FOR MEDICATION ERRORS

A recent Patient Safety Alert issued by VHA Central Office addresses the potential for medication errors when using Document Storage Systems (DSS), Inc., VistA Chemotherapy Manager (VCM) due to vulnerabilities in the software, specifically:

- VCM does not contain all dosing frequencies (i.e., standard schedules) in their ordering system;
- VCM does not calculate doses correctly for continuous infusions greater than 1 day (24 hours);
- Not all drug-drug interactions are displayed to the ordering provider due to a lack of automatic cross-referencing between VCM and the Veterans Health Information Systems and Technology Architecture (VistA) Pharmacy software.
- VCM still has other issues under investi-

gation (i.e., height/weight, lab display, dose calculations, allergy order checks, etc.).

VCM is a chemotherapy ordering system developed by DSS, Inc., and is not a part of VA's VistA Pharmacy suite. The decision to purchase and use VCM occurs at the facility or network level.

The following examples of errors associated with VCM could lead to inappropriate dose or inappropriate use of a medication resulting in unintended harm. In one instance, a close call occurred when a provider did not have the desired dose frequency presented for selection from the program's drop down list in the ordering menu. The provider chose an available frequency (i.e., every day) in the required field entry and typed the actual correct frequency as "Miscellaneous

(continued on page 2)

IN THIS ISSUE:

- ▶ CHEMOTHERAPY ORDERING SYSTEM USE AND RISK FOR MEDICATION ERRORS..... 1, 2
- ▶ MEDICATION SAFETY NEWS FROM THE VA NATIONAL PHARMACY BENEFITS MANAGEMENT SERVICES [PBM] AND THE FOOD AND DRUG ADMINISTRATION [FDA]..... 1-2
- ▶ PATIENT SAFETY: IMPROVING ALLERGY ASSESSMENTS..... 3



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.

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NEWSWORTHY...

from the pbm

- Ferumoxytol and Risk of Serious Allergic Reactions - 04/28/2015 - [National PBM Bulletin](#)

During initial distribution, this alert incorrectly attributed the analysis described in paragraph 3 of the Discussion section to the FDA whereas in actuality the analysis was done by Bailie and colleagues by obtaining and utilizing reports from FDA's adverse events database. This has since been corrected in the online version, available at the link above.

(continued on page 2)

from the fda

(continued from page 1)

NEUROLOGY

[FDA determines 2013 labeling adequate to manage risk of retinal abnormalities, potential vision loss, and skin discoloration with anti-seizure drug Potiga \(ezogabine\); requires additional study](#)

6/16/2015 ***UPDATE FROM 10/31/2013***

FDA's review of additional safety reports associated with the use of the antiepileptic agent ezogabine (Potiga) indicates that:

- pigment changes in the retina observed in some patients does not affect vision; and
- skin discoloration seems cosmetic and not linked to more serious adverse effects.

FDA recommends that:

- Pigment changes in the retina and skin discoloration can be adequately managed by following the current recommendations in the product labeling.
- A modification of the Risk Evaluation and Mitigation Strategy (REMS) is not needed at this time.
- The manufacturer will be required to conduct a long-term observational study to provide more information on:
 - vision loss or other long-term side effects connected to pigment changes in the retina; and
 - the relationship between pigment changes in the retina and skin discoloration.
- Health care professionals should continue to follow the recommendations provided in the *Boxed Warning, Warnings and Precautions, and Indications and Usage* sections of the labeling.

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(continued from page 1)

Instructions" in a free text field. Pharmacy staff caught this discrepancy and manually corrected the dosing schedule in VA's VistA Pharmacy software to avoid a wrong dose. Next, in an actual error, a patient was prescribed fluorouracil 2000 milligrams (mg) each day for 4 days for a total dose of 8000 mg. However, the VCM software calculated the dose as a total of 2000 mg to be administered over 4 days, resulting in an under-dose as the patient received only 1 days' worth of medication stretched over the course of 4 days. Lastly, another close call involved a potential drug-drug interaction since VCM only manages the ordering process for oncology agents and does not link to the rest of the patient's prescription profile in VA's VistA Pharmacy program. An order for a patient's chemotherapy treatment did not trigger an alert for possible drug-drug interactions with noncancer-related medications. However, Pharmacy staff caught the interaction using VA's VistA Pharmacy software, preventing any inappropriate medications from reaching the patient.

Because of the identified safety risks with the VCM software, Central Office's Patient Safety Alert recommends that:

- Sites who have fully implemented VCM (i.e., VCM is incorporated into daily oncology practice) should:
 - Notify users of VCM of the aforementioned limitations in using the software;
 - Ensure a local process to communicate all applicable moderate and all severe drug-drug interactions to users of VCM during the ordering process;

- Ensure a local process for quality assurance when entering, editing, and processing chemotherapy orders, which includes demonstrating competency;
- Ensure a local process for quality assurance when evaluating current and future VCM treatment protocols for patient safety issues;
- Ensure use of the most current version of the VCM Graphic User Interface;
- Provide a copy of the Patient Safety Alert to any fee-basis contractors or other outside providers receiving any VCM output from a local facility for situational awareness.
- Sites who have installed VCM software but have not fully implemented VCM are to cease any further plans for implementation until further notice is provided from VHA Central Office.
- Sites in various stages of purchase up to installation are to cease any further plans for purchase or installation.

Refer to the Patient Safety Alert (AL15-02) for full details regarding this issue as well as specific action plans and associated deadlines for completion available at the following link:

<http://vaww.ncps.med.va.gov/Guidelines/alerts/Docs/AL15-02.pdf>. (Note: This is an internal VA site.)

REFERENCE:

VHA Central Office Patient Safety Alert: Document Storage Systems (DSS), Inc. VistA Chemotherapy Manager (VCM) software can lead to medication errors. AL15-02 April 30, 2015.

Getting the most from our safety surveillance

PATIENT SAFETY: IMPROVING ALLERGY ASSESSMENTS

Contributed by: Von Moore, Pharm.D.

The VA ADERS (VA Adverse Drug Event Reporting System) Advisory Committee routinely reviews adverse drug event (ADE) reports for potentially preventable ADEs. One marker of preventability is the answer to a question within the report that asks whether there was a history of an allergy or previous adverse reaction to the drug or drug class, specifically:

“WAS THERE A HISTORY OF ALLERGY OR PREVIOUS REACTIONS TO THE DRUG OR DRUG CLASS THAT WAS SEVERE OR WOULD INDICATE THE DRUG SHOULD NOT BE USED AGAIN?”.

Reviewing the ADE reports where this question was answered ‘yes’, revealed the following observation:

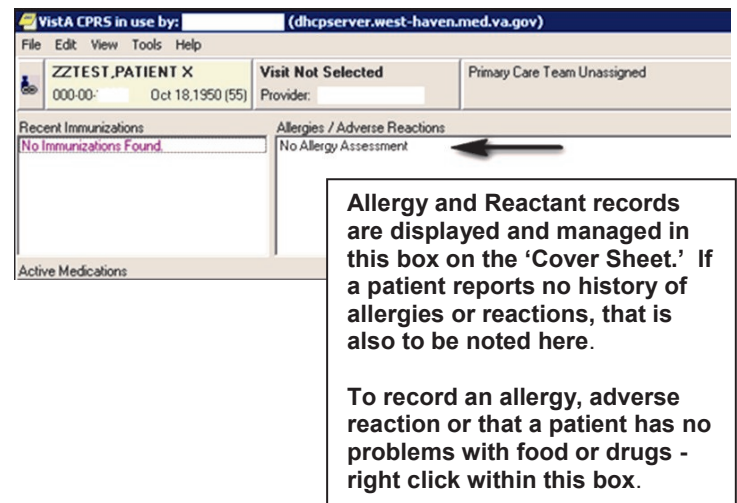
- Allergies were documented in progress notes or “text” sections of the patient chart but not in the Allergies/ Adverse Reactions section of the patient chart in CPRS.
- Allergies documented in a progress note are not screened in order checks. For the allergy/adverse drug reaction (ADR) order checks to function appropriately during medication order entry, the allergy/ADR needs to be entered in the Allergies/Adverse Reactions section of the patient chart.

Over the last quarter (Q2 FY 2015), there have been 124 reports submitted to VA ADERS where the question of history of allergy or previous reaction was answered YES. A severe outcome was reported on 21 of these 124 reports. While there may be situations where the patient has had a previous reaction to the drug or drug class (example: lipid lowering agents) and use of another drug in the same class is warranted, the preventability question is targeted at instances where the previous reaction was severe and the medication or class may not be safe to use. The potential for a severe outcome (death, life-threatening condition, permanent impairment) is significant when considering the past treatment and reaction history in these cases.

To review how to enter an Allergy or Adverse Reaction in the

patient chart, please go to: <http://www.pbm.va.gov/PBM/vacenterformedicationsafety/tools/HowToEnteranAllergyorAdverseDrug.ppt> . (Note: This was for a previous version of CPRS.)

To enter an allergy/adverse reaction, simply right click on the Allergies/Adverse Reactions field:



Allergy and Reactant records are displayed and managed in this box on the 'Cover Sheet.' If a patient reports no history of allergies or reactions, that is also to be noted here.

To record an allergy, adverse reaction or that a patient has no problems with food or drugs - right click within this box.

When performing Allergy Assessments, consider:

- Carrying out an assessment on every patient if medications are ordered;
- Documenting the allergy/reaction in the Allergies/ Adverse Reactions section of the patient chart (CPRS, VistA); and
- Updating the Allergies/ Adverse Reactions section when the patient returns for an appointment or a new allergy/ adverse reaction occurs.

These steps are significant as previous severe allergic or adverse reactions should be known prior to selecting a medication for a patient’s condition in order to prevent any untoward outcomes. ■