



PHARMACY NEWSCAPSULE
MARCH 20 APRIL 19

DEPARTMENT OF HEALTH SERVICES/DIVISION OF QUALITY ASSURANCE

Douglas Englebert, R. PH. 608-266-5388 douglas.Englebert@dhs.wisconsin.gov

IN THIS ISSUE

Warfarin Therapy for a Trial Fibrillation in Patients on Dialysis	1
What is a REMS Program?	2
Consultant Corner	2
Newsletter Feature: Surveyor Pharmacy Tips	3

WARFARIN THERAPY FOR A TRIAL FIBRILLATION IN PATIENTS ON DIALYSIS

by Tanya Haasbeek, DPH-4

Recently, there was a case where an immediate jeopardy citation was issued that related to a resident bleeding while on warfarin. This resident was also on venlafaxine, which can increase the risk of bleeding when taken concurrently with warfarin, and hemodialysis (HD). The resident had multiple occurrences of pink-tinged stool to dark, bloody stool and the physician was not contacted with these details. The resident’s hemoglobin and hematocrit was also decreased. As a result of the resident continuing the anticoagulant and having blood loss, the resident experienced two episodes of seizures and went into cardiac arrest, which the emergency room attributed to hypovolemic shock. Upon arriving at the emergency department, the patient was also found to have an international normalized ration (INR) of 9.9 and hemoglobin of 4.4 (normal range: 13.5-17.5).

Should residents with atrial fibrillation be on warfarin if they are undergoing HD? There are many factors to consider. Patients on HD are at an increased risk of bleeding. One reason for this is that the process of HD usually requires systemic anticoagulation with heparin. The primary provider should be in communication with the resident’s dialysis center in order to determine the type and amount of anticoagulant the resident receives as a part of care at the dialysis center.

Many observational studies have investigated whether or not the presumed benefits of stroke risk reduction outweigh the harm of bleeding risk in this patient population. The results of the individual studies differ in terms of the outcomes (ischemic stroke, hemorrhagic stroke, gastrointestinal bleeding, and all-cause mortality). Therefore, the decision to use anticoagulants in this population remains controversial. Overall, the analyses suggest that if patients are on warfarin with other anticoagulants or aspirin, they have a higher risk of bleeding events and there is no reduction in ischemic stroke risk. If patients are only on warfarin

therapy (no other anticoagulants or aspirin), warfarin is associated with a significantly decreased risk of ischemic stroke and is not associated with increased bleeding risk.

Recently, there has been pharmacokinetic data to support using apixaban (Eliquis®) 2.5 mg twice daily in patients with dialysis who require HD sessions three times a week. Using the standard 5 mg tablet twice daily has resulted in suprathreshold drug exposure. Further research is still needed on the outcomes of using apixaban in this population. Warfarin remains the anticoagulant of choice in patients undergoing HD. If warfarin therapy is initiated and continued in patients undergoing HD, INR monitoring should be done frequently to ensure that the patient is at a therapeutic level in order to prevent ischemic stroke and unnecessary bleeding events. Patient INR can differ significantly based on the timing of the blood draw in relation to when dialysis is done, although there is not much guidance on the ideal timing of the INR blood draw.

In conclusion, it may be appropriate for residents to be on warfarin for atrial fibrillation management while undergoing dialysis. However, it's imperative that these residents require close monitoring. Surveyors should assess the following:

- Is there documentation of close contact between the long-term care facility and dialysis center to determine the type of anticoagulation received during the resident's dialysis procedure?
- Is the resident on other medications that could increase the patient's bleeding risk (e.g., acetaminophen, amiodarone, tricyclic antidepressants, venlafaxine)?
- Is the resident on other anticoagulants or antiplatelets?
- Is there documentation of frequent INR testing?
- Is it written on the resident's care plan to monitor for bleeding (bruising, blood in stool, blood in urine, coughing up blood, etc.) and who to contact if bleeding is noticed by nursing staff?

Surveyors in nursing homes where residents in the pool process are on anticoagulants and also receiving hemodialysis should briefly review the resident record or care plan to make sure the above monitoring is occurring.

WHAT IS A REMS PROGRAM?

by Doug Englebert, R. PH.

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure that the benefits of the medication outweigh its risks. REMS are designed to reinforce medication-use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS.

REMS are not designed to mitigate all the adverse events of a medication as these are communicated to health care providers in the medication's prescribing information. Rather, REMS focus on preventing, monitoring, and/or managing a specific serious risk by informing, educating, and/or reinforcing actions to reduce the frequency and/or severity of the event.

Sometimes REMS programs may delay the medication being available in facilities. If a medication is being delayed, this information should be provided to the physician. Sometimes REMS will require specific storage, disposal, or dispensing limits. Facilities should be aware of the REMS requirements and implement them as necessary in their facilities.

Surveyors can access the list of medications with REMS programs along with the specific REMS program for each medication on the [FDA website](#).

CONSULTANT CORNER

by Doug Englebert, R. PH.

- 1. In assisted living facilities, is a physician's order needed to use essential oils? Do you know if they do? I have asked other assisted living surveyors and none of them are aware of the need to have a prescription to use oils in assisted living facilities.**

For those interested in exploring aromatherapy, links to some useful information are provided below:

- This link to the [National Association for Holistic Aromatherapy](#) provides general information on essential oil safety.
- This link provides [information on essential oils from the Food and Drug Administration \(FDA\)](#)

Depending on how the product is packaged, it's possible that essential oils would need to have an order in a community-based residential facility (CBRF). If the product is labeled as a drug or dietary supplement, an order would be required per CBRF regulations. However, if the product is labeled as a cosmetic, an order would not be required. Oftentimes it is very difficult to determine where essential oils fall in that spectrum. From an enforcement standpoint, if the oils are being used cosmetically, an order would not be required. However, if the essential oils are being used to "treat" something like pain, an order would be required.

As a surveyor, the requirement for an order may be secondary to safety issues. There are possible drug-essential oil interactions, and allergies and skin irritations that may occur. For these reasons it's a good idea to consider a safety evaluation prior to using essential oils, including notification of essential oil use to physicians, pharmacists, and others. Sometimes, getting an order for the essential oils puts these products into traditional communication paths where safety evaluations are considered. For these reasons many facilities may require orders for essential oils.

- 2. Recently, a resident in a community-based residential facility (CBRF) was ordered the Freestyle Libre®. This device uses a disc sensor that is placed on the back of a resident's arm to read blood sugars and is changed every 14 days. Instead of using finger lancets, blood sugar readings are obtained by waving a reader over the disc. The question I want to ask is: Are staff at a CBRF allowed to place the sensor or is it considered a delegated task?**

Blood sugar checks, whether by finger sticks or Freestyle Libre®, isn't something that is required to be delegated in the CBRF rule. Staff would need to be trained on the device. If the resident is getting injectable insulin administered by staff, that would need RN delegation in a CBRF. The RN who is delegating insulin injections may decide to also delegate the Freestyle Libre®.

- 3. In Wisconsin, is it legal for a family to give CBD to resident in a facility (CBRF, nursing home, hospital, etc.)?**

This was discussed in the [March/April 2018 Pharmacy Newscapsule](#).

SURVEYOR PHARMACY TIPS – BUD

What is BUD? BUD is "beyond use date." It's like an expiration date; however, it's the date placed on medications once it's opened, compounded, or repackaged. These are the dates that pharmacists will, for example, apply to intravenous drugs that are made. If you see the abbreviation BUD, just think about expiration dates.