the Remedi Pulse

EVOLVING ANTICOAGULANT RISK

A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

JUNE 2016

Survey Solutions

with William Vaughan, BSN, RN VP of Education & Clinical Affairs

Anticoagulants: Think Beyond F329

Like throwing a pebble into a lake and watching the ripples expand, a single error, involving an anticoagulant, can and often does find its way into deficiencies cited under numerous F-Tags. The practice, known as cross referencing, is addressed by CMS in a guidance document called "The Principles of Documentation."[1] While surveyors are cautioned to cross-reference deficiencies only when "the linked citations have a direct cause and effect relationship to the deficient practices described in both citations," providers often complain that cross referencing is overused. Below we review several F-Tags that can be cited when high-risk medications, such as anticoagulants, are improperly managed:

- **F154:** This F-Tag focuses on a provider's obligation to fully inform residents regarding their "total health status, a term that's broadly defined in the guidance to surveyors. Certainly discussing the risks and benefits of medications, such as anticoagulants, is required under this regulation.

- **F155:** This regulation addresses several rights including that of formulating an advance directive. The use of high risk drugs, such as anticoagulants, should always be consistent with a resident's goals of care. When residents are no longer able to communicate their wishes, an advance directive can often provide important guidance regarding their preferences and values.

- **F157:** The failure to "immediately" notify the physician of significant changes in a resident's condition is a consistently cited deficiency nationwide. Delays in notification related to anticoagulants (e.g., falls, bleeding, the need to hold the medication, etc.), can quickly escalate deficiencies to the actual harm or immediate jeopardy severity level.

continued on page 4

... a single error, involving an anticoagulant, can and often does find its way into deficiencies cited under numerous F-Tags.

FOR MORE INFORMATION
RemediRx.com

EDITORIAL STAFF

JENNIFER HARDESTY Pharm.D., FASCP
Chief Clinical Officer
Jennifer.Hardesty@RemediRx.com

ROB SHULMAN BS, R.Ph., CGP, FASCP
Director of Consultant Pharmacy Services
Rob.Shulman@RemediRx.com

REBECCA OGDEN BSN, RN, CRNI
Corporate Account Manager
Rebecca.Ogden@RemediRx.com

Please do not hesitate to contact your Remedi Consultant Pharmacist or Account Manager if you have any questions or concerns.

MODERNIZING OLD PRESCRIBING HABITS PART II: Selecting a Novel Oral Anticoagulant

Prepared by Sarah Brett, Pharm.D., Clinical Consultant Pharmacist

As the therapeutic options for oral anticoagulation expand, so does the need to better understand both their pharmacological advantages and limitations. While properties, such as rapid onset/offset, fewer drug interactions, and predictable action are appealing, it is also necessary to consider patient specific factors to help direct prescribing towards the best treatment option. These considerations include indication for use, renal dysfunction, medication adherence, and administration limitations. It should be noted that argatroban (Acova) was intentionally left out of this article. Although it is in the same therapeutic class, it is only available in IV form, and is rarely administered in the long-term care (LTC) setting.

I. INDICATIONS

A practical factor to consider when comparing novel oral anticoagulants (NOACs) is the indication for use. None of the NOACs have been approved for prophylaxis of thromboembolic complications associated with cardiac valve replacement, which may still warrant therapy with Coumadin. After indication, other factors, such as dosing frequency, administration, interactions, and renal implications should then be considered.

INDICATIONS

	Dabigatran (Pradaxa)	Rivaroxaban (Xarelto)	Apixaban (Eliquis)	Edoxaban (Savaysa)
Non-Valvular AFib (NVAF)	Yes	Yes	Yes	Yes, Unless CrCl > 95mL/min
VTE Prevention/ Treatment	Yes, after 5-10 days of parenteral Tx	Yes	Yes	For Treatment, after 5-10 days of parenteral Tx
Post-op Prevention	Hip replacement	Knee or Hip replacement	Knee or Hip replacement	No

VTE: venous thromboembolism
Tx: treatment

II. DAILY FREQUENCY

Often, the dose and duration of the NOACs is indication specific, making confidence in patient compliance with a certain regimen worth considering. For instance, depending on indication, edoxaban (Savaysa) and rivaroxaban (Xarelto) may often be given once daily, while dabigatran (Pradaxa) and apixaban (Eliquis) typically require BID dosing. However, since the half-life of each of these agents is considerably shorter than that of warfarin, any missed NOAC doses may present a greater risk for reduced anticoagulation time. Therefore, choosing a NOAC may be reconsidered if a patient is at risk for non-adherence.

III. DOSING

Each of the NOACs requires evaluation of renal function in order to consider use or appropriately dose. The parameters for use and dosing differ between agents, and may also be dependent on indication or other compounding factors, such as weight, age, or concomitant drug therapies. Of interesting note is that Edoxaban is not recommended for use in patients with normal renal function, as there was no demonstrated benefit in this population in clinical trials.

SPECIAL DOSING CONSIDERATIONS

	Dabigatran (Pradaxa)	Rivaroxaban (Xarelto)	Apixaban (Eliquis)	Edoxaban (Savaysa)
NVAF	15-30 mL/min: 75mg BID*	15-50 mL/min: 15 mg QD < 15 mL/min: NR	2.5 mg BID if any two: Age > 79, Wt < 61 kg, SCr > 1.4 mg/dL	> 95 mL/min: NR 15-50 mL/min: 30mg QD <15 mL/min: NR
VTE Prevention/ Treatment	< 30mL/min: patients excluded from trials*	< 30 mL/min: NR	< 25 mL/min or SCr > 2.5 mg/dL: patients excluded from trials	15-50 mL/min OR <61 kg: 30 mg QD <15 mL/min: NR
Post-op Prevention	< 30mL/min: patients excluded from trials*	< 30 mL/min: NR	< 30 mL/min: patients excluded from trials	No

*Further dosage adjustment considerations must be made in patients receiving concomitant P-glycoprotein inhibitors, dronedarone, or oral ketoconazole.
NR = Not recommended

IV: ADMINISTRATION/CRUSHING

Whether or not a patient requires medications to be crushed prior to administration should also be considered.

- **DABIGATRAN:** Should not be opened
- **RIVAROXABAN:** May be crushed and administered in applesauce
- **APIXABAN:** Current data only supports suspending the crushed tablets in 60 mL of D5W and immediately delivering through a nasogastric tube
- **EDOXABAN:** No data available

V: DRUG INTERACTIONS

While the NOACs generally have fewer drug interactions than Coumadin, there are still several drug interactions that may need to be evaluated for each patient. It should be noted that Edoxaban has numerous significant drug interactions and, therefore, should be used with extreme caution in the elderly. As always, check with your pharmacist before adding any medications to an existing drug regimen. The following represents significant/serious drug interactions relevant to LTC with the following NOACs:

- **DABIGATRAN:** carbamazepine, dexamethasone, ketoconazole, phenytoin, primidone, rifampin
- **RIVAROXABAN:** clarithromycin, ketoconazole
- **APIXABAN:** carbamazepine, dexamethasone, phenytoin, rifampin
- **EDOXABAN:** amiodarone, atorvastatin, azithromycin, carbamazepine, carvedilol, clarithromycin, dexamethasone, diltiazem, dipyridamole, erythromycin, grapefruit juice, ketoconazole, nifedipine, paliperidone, pantoprazole, phenytoin, primidone, propranolol, quinidine, rifampin, verapamil

Novel oral anticoagulants have proven to have a beneficial role in treatment for patients requiring anticoagulation. Determining how to best benefit from the pharmacological advantages, while remaining cognizant of each agent's own specific limitations, will continue to be crucial when evaluating drug therapy.

References:

1. Eliquis (apixaban) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; June 2015.
2. Pradaxa (dabigatran etexilate) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; November 2015.
3. Savaysa [package insert]. Parsippany, NJ; Daiichi Sankyo; January 2015
4. Xarelto (rivaroxaban) [prescribing information]. Gurabo, PR: Janssen Pharmaceuticals Inc; December 2014.

Nurse of the Month

DEBBIE FRITTS, RN, ADON
Widows Home of Dayton, Dayton, OH

CONGRATULATIONS to Debbie Fritts, RN, ADON, Widows Home of Dayton, Dayton, OH, for being chosen as the Remedi "Nurse of the Month." Debbie was nominated by her DON, Carol Deblin. Debbie has been a nurse for 10 years and has been employed at the Widows Home for two years. Per Carol, "Debbie is a nurse who goes above and beyond in every way. Not only do the residents of our facility love her, but our employees do as well. The residents love her because she dotes on them and treats every resident like they are part of her family. The employees love her because she is available to them 24/7 and is never too busy to listen to our employees or residents. Debbie's clinical skills are excellent. Since she is in charge of our skin program, Debbie obtained her wound care certification. Wounds have been resolved, and the number of in-house acquired wounds has greatly declined since she took over the program. Debbie takes on projects within our home and works until they are completed. She is organized and diligent at all of her tasks. She makes my job very easy and makes work fun. Debbie always has a contagious, positive attitude. When problems arise, she is there to help find a solution. I am lucky to have Debbie as my ADON and the Widows Home is blessed to have her as an employee."

The Remedi "Nurse of the Month" exemplifies excellence in nursing practice. Email your Nurse of the Month nomination(s) to Rebecca.Ogden@RemediRx.com. Nurses Rock!!

Survey Solutions

continued from page 1

- **F176:** The right to self-administer medications is emphasized under this regulation. Should a resident prefer to self-administer an anticoagulant, a provider would have to assess the resident's ability to do so, and then provide education regarding the safe use of the drug.

- **F279:** This "care-planning" tag is ripe for deficiencies related to anticoagulation management. The expectations for nursing assistants in monitoring for adverse drug reactions, how staff should address abnormal lab results (e.g., INR, Hct, etc.), and even plans related to the dietary management of anticoagulants should be spelled out and periodically updated in the care plan documents. Remember to always involve the residents and/or their surrogate decision maker in the care-planning process.

- **F281:** This regulation requires that the care provided by the nursing home staff meets "professional standards of quality." When it comes to anticoagulants, think published standards, such as those provided by the American College of Chest Physicians.[2] Following such guidance demonstrates an evidenced-based approach to care that can prevent deficiencies from being cited, even when a negative clinical outcome occurs.

- **F501:** Many significant deficiencies involving anticoagulants represent systemic failures of care. Since the Medical Director is charged with the "implementation of resident care policies" and the "coordination of medical care in the facility," it's easy to see how he or she could be cited in cases involving the mismanagement of anticoagulants.

While the above list is not exhaustive, it does highlight the extensive regulatory risk associated with the administration of anticoagulants. Taking a page from the "it takes a village" concept, leaders in nursing homes should look to the involvement of multiple disciplines to reduce the clinical risk to their residents and the regulatory risk to their facility when using anticoagulants.

References

[1] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_007a.pdf

[2] http://journal.publications.chestnet.org/article.aspx?articleid=2479255