Consider new DOACs as high alert medications

Vizient PSO Safety Alert

May 2017

Situation

Earlier this year, Vizient PSO convened an expert multidisciplinary team to discuss their highest priority for medication safety. Experts agreed that the new direct oral anticoagulants (DOACs) were their top safety concern and presented significant safety risks to patients in both the inpatient and outpatient environments.

Background

In the past, Warfarin had been the primary drug on the market to help prevent blood clots and reduce patients' chances of developing serious conditions such as strokes and heart attacks. Through standardized practices, enhanced education, and closer monitoring of patients in anticoagulant clinics, the safety for patients on Warfarin improved; however the need for frequent blood tests to maintain a safe, therapeutic range for blood clotting places high compliance-demands on patients. With no requirements for regular blood testing, no dietary limitations, fewer drug interactions and a rapid onset of action, the new DOACs—rivaroxaban, apixaban, dabigatran and edoxaban—offer an attractive alternative for patients (Institute for Safe Medication Practices, 2015, Q4)i . These benefits led to a rapid increase in their use. Data from 2016 in the Vizient Clinical Data Base (CDB) suggests that while the number of patients on Warfarin is decreasing, the number of patients on the DOACs is increasing and there may be unintended consequences associated with the introduction of these new medications.

Assessment

An initial review of almost 150 near miss and adverse events involving DOACs in the Vizient PSO database substantiates that these new anticoagulants pose serious risk at discharge.Preventable adverse events resulted from inaccurate dosing of DOACs, unintentional duplication of anticoagulants, poor coordination of therapy during transitions in care and before procedures as well as inadequate patient education and engagement. The clinical impact of these events included gastrointestinal or intracranial bleeds, delays in procedures, extended length of stays and readmissions. The contributing factors identified in these events were:

- Gaps in provider knowledge about DOACs

- The complexity of managing medication orders via electronic health record and paper prescription processes simultaneously
- The failure to create a complete medication reconciliation list
- The failure to perform clinical medication reconciliation of a complete and accurate medication list, including acknowledgment of prescribed medication's purpose, mechanism of action and drug interactions
- The lack of clear discharge instructions that the patient could teach back
- Insufficient post-discharge follow up to ensure:
  - The patient understands the discharge plan and can carry it out
  - The patient understands appropriate dosing
  - The patient understands signs and symptoms of bleeding
  - The patient is monitored based on their risk for renal impairment complications (e.g. patients on nephrotoxic medications).
  - The patient is monitored for hepatic dysfunction
  - The patient is monitored for appropriate perioperative/periprocedural interruption in therapy

Anticoagulants are often prescribed for older patients. Prescribing medications for older patients requires more care and monitoring (American College of Cardiology, 2017) ii. Over 50% of DOAC events reported to the PSO involved patients 65 years of age and older.

Recommendations

The Vizient PSO, with a team of experts in medication safety, is creating a comprehensive DOAC Tool Kit for PSO members. Below are a few recommendations on how you can begin evaluating your DOAC safety needs at your organization today and mitigating risk. Please watch for further alerts focused on these high risk, high volume and problematic medications. Raise awareness of the DOACs (rivaroxaban, apixaban, dabigatran and edoxaban) in your organization by placing them on your high alert medication list. In addition, conduct ongoing concurrent surveillance of these medications use and adverse drug events. Report findings of DOAC related adverse drug events to nurses, physicians and pharmacists within your organization. Share findings from the review of safety events with front line providers, pharmacists and nurses. Report near miss and actual DOAC safety events to your PSO to accelerate the pace of learning on this important safety topic.

1. Implement a discharge checklist or timeout for patients prescribed DOAC therapy.
   a. The pharmacist must reconcile manual (paper prescriptions) and electronic instructions at discharge to identify therapeutic duplication and/or drug interaction.
   b. Verify if the patient has insurance approval for prescribed DOAC, ensuring there are no roadblocks to drug access.

c. Prior to discharge, schedule a follow-up appointment with an anticoagulation clinic or with a provider who can monitor post-hospitalization therapy.
d. Ensure the patient and/or caregiver is able to demonstrate that he/she can teach back their medication plan (including any planned dose changes or therapy discontinuations). Explain the importance of their follow-up care, knowing when to call a provider and when to return to the emergency department. Include a phone number for patient or caregiver to call if they have questions specific to their discharge and medication instructions. © 2017 Vizient Inc. 3
e. Call all patients discharged on DOACs within 24-48 hours to ensure they received their prescription and that the prescription is accurate. The patient should confirm an understanding how to take the medication, including an ability to describe tapering instructions (if applicable). The provider should also review all home medications to ensure patient is not taking dual antithrombotic therapy without a provider's knowledge.

For additional questions or information, please contact Jessica Schoenthal or Tammy Williams. The Vizient PSO Team This is the first in a series of alerts Vizient PSO will be releasing on this topic.

Resources

1. ISMP Quarterly Watch: Perspectives from new adverse event reports available at http://www.ismp.org/QuarterWatch/pdfs/2016Q2.pdf
2. Management of Patients on Non–Vitamin K Antagonist Oral Anticoagulants in the Acute Care and Periprocedural Setting: A Scientific Statement from the American Heart Association available at http://circ.ahajournals.org/content/early/2017/02/06/CIR.0000000000000477
3. 2017 ACC Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients with Nonvalvular Atrial Fibrillation available at **http://www.onlinejacc.org/content/early/2017/01/05/j.jacc.2016.11.024**
4. Guidance for the practical management of the direct oral anticoagulants (DOACs) in VTE treatment available at **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4715848/**
5. The ISMP anticoagulation self-assessment is now live at **http://www.ismp.org/selfassessments/Antithrombotic/2017/Default.aspx**
6. ISMP Quarterly Watch: Perspectives from new adverse event reports available at **http://www.ismp.org/QuarterWatch/pdfs/2016Q2.pdf**
7. ISMP Quarterly Watch: Perspectives from new adverse event reports available at **http://www.ismp.org/QuarterWatch/pdfs/2016Q2.pdf**

2017 ACC Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients with Nonvalvular Atrial Fibrillation available at http://www.onlinejacc.org/content/early/2017/01/05/j.jacc.2016.11.024