New for Ambulatory Care Effective July 1, 2019: National Patient Safety Goal Addresses Direct Oral Anticoagulants
Preparing for July 1, 2019

- This webinar will:
  - Provide a better understanding of the requirements
  - Discuss considerations for implementation
  - Answer participant questions specific to NPSG 03.05.01
  - Provide additional resources
History of NPSGs

- Established in 2002 to help accredited organizations address specific areas of concern in regards to patient safety

- The first set of NPSGs was effective January 1, 2003

- The purpose of the NPSGs was to highlight problematic areas in health care that were widespread and to describe solutions to these problems

- “Affirmatively observed” on all surveys
A New and Revised NPSG

- For years, this NPSG has played an important role in improving the safety of patients receiving anticoagulation therapy

- The goal of revising this NPSG to include direct oral anticoagulants is to further promote patient safety and quality care for patients that take anticoagulant medications and to align with current recommendations from scientific and professional organizations
Patient Safety Priority

The prevention of adverse drug events (ADEs) is an important patient safety priority. According to the U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, ADEs account for an estimated one-third of approximately 280,000 admissions annually.

In recent years, there has been a rise in adverse drug events associated with direct oral anticoagulants (DOACs), and the rapid evolution of these new anticoagulants may lead to an increase of life-threatening bleeding and unsuccessful attempts to reverse bleeding.

The Joint Commission believes that relevant updates to this NPSG to address DOACs may help reverse that trend.
Anticoagulants: High Risk Medication Class

- Anticoagulant medications, which include warfarin, heparin, low-molecular weight heparin, and direct oral anticoagulants, are one of four medication classes commonly identified as a cause of adverse drug events (ADEs)

- Anticoagulant medications are high-risk medications that may cause severe bleeding when not administered or monitored appropriately

- Complex dosing requirements, insufficient monitoring, and inconsistent patient compliance can all contribute to adverse drug events or even death
A New Anticoagulant

- Since 2010 a new class of AC potentially better and safer than warfarin (Direct Oral anticoagulants – or DOACs) entered the market

- Between 2013 and 2014, rivaroxaban and dabigatran were the 5th and 10th most common drugs for adverse drug reactions (ADE) related emergency room visits in older adults

- Many of these events can be prevented
How DOACs are Different

- Less problematic
- More tolerable for both providers and patients
- Fewer drug interactions
- Shorter half-lives—leads to rapid elimination from the body
- Designed to be given at fixed doses
- No routine coagulation monitoring needed
Applicability to Ambulatory Health Care

- Community Health Centers
  - Considered Primary Care Centers
    - Can initiate, manage and adjust anticoagulants
  - Only EPs 1, 2, 4, 5 and 6 are applicable
Standard

- NPSG.03.05.01: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

- Note: *This requirement does not apply to routine situations in which short-term prophylactic anticoagulation is used for venous-thromboembolism prevention (for example, related to procedures or hospitalization).*
Requirements-EP 1

- The organization uses approved protocols and evidence-based practice guidelines for the initiation and maintenance of anticoagulant therapy that address medication selection; dosing, including adjustments for age and renal or liver function; drug-drug and drug-food interactions; and other risk factors as applicable.
Considerations for EP 1

- When creating or updating protocols and evidence-based guidelines consider:
  - How they are implemented?
  - Who approved them?
  - How accessible they are to staff?
- Order sets are acceptable as anticoagulant therapy protocols and guidelines
Considerations for EP 1-Continued

- Develop protocols based on evidence-based guidelines to guide therapy
- Implementation and compliance throughout organization
- Monitor performance and outcomes
- Commitment needed from administration
  - Finances
  - Resources
  - Personnel
Requirements-EP 2

- The organization uses approved protocols and evidence-based practice guidelines for *reversal* of anticoagulation and management of bleeding events related to each anticoagulant medication.
Considerations for EP 2

− DOAC reversal agents do not need to be kept on site.
  − “If reversal agents are not on formulary, what is the process for reversal treatment”?
− Organizations do need protocols and evidence-based practice guidelines addressing the need for reversal of a patient on a DOAC
Consideration for EP 2-Continued

- DOACs entered the market without a reversal agent
- Costs of reversal agents:
  - Idarucizumab-available in 2015 for Dabigatran reversal; ($2500 per dose)
  - Andexanet Alfa-available in 2018 for Apixaban/Rivaroxaban reversal ($27,500-$49,500 per dose)
- Alternative to consider:
  - 4 factor PCCs (prothrombin complex concentrates) may reverse Apixaban/Rivaroxaban; costs about ($1000-$5000 per dose)
Requirements-EP 4

- The organization has a written policy addressing the need for baseline and ongoing laboratory tests to monitor and adjust anticoagulant therapy.

- Note: For all patients receiving warfarin therapy, use a current international normalized ratio (INR) to monitor and adjust dosage. For patients on a direct oral anticoagulant (DOAC), follow evidence-based practice guidelines regarding the need for laboratory testing.
Considerations for EP 4

- Review and/or update your written policy
  - Address laboratory testing and monitoring of anticoagulation medications
  - Consider how staff incorporates baseline testing to monitor and adjust anticoagulant therapy
Considerations for EP 4-Continued

- Need to develop coordinated care for DOACs
  - Baseline labs
    - Hemoglobin, hematocrit, platelets, aPTT, PT/INR, Renal function, Liver function (as needed based on clinical history)
    - Identify issues that may prevent use of anticoagulants
    - Aid in selection of most appropriate regimen
    - Provide initial lab values
  - Ongoing laboratory monitoring
    - NOT typically required for DOACs (predictable dose response)
    - May be indicated in certain circumstances
Requirements-EP 5

- The organization addresses anticoagulation safety practices through the following:
  - Establishing a process to identify, respond to, and report adverse drug events, including adverse drug event outcomes
  - Evaluating anticoagulation safety practices, taking actions to improve safety practices, and measuring the effectiveness of those actions in a time frame determined by the organization
Considerations for EP 5-Continued

- Identification of common, preventable, and measurable healthcare-associated anticoagulant ADEs is a key component of quality improvement efforts to:
  - Drive prevention
  - Benchmark progress
  - Promote a culture of anticoagulation safety
Considerations for EP 5

- Consider conducting mock tracers
  - Interview nursing staff, physicians and pharmacist about anticoagulation safety practices
  - Interview quality improvement staff about data collection, analysis, and any improvement activities addressing anticoagulant medications
Requirements-EP 6

- The organization provides education to patients and families specific to the anticoagulant medication prescribed, including the following:
  - Adherence to medication dose and schedule
  - Importance of follow-up appointments and laboratory testing (if applicable)
  - Potential drug-drug and drug-food interactions
  - The potential for adverse drug reactions
Considerations for EP 6

- Consider “teach back” techniques
- Engage patients and family
  - Face to Face encounter
- Consider timing of education
  - Transitions of care
  - Discharge
    - Use of checklists
Considerations for EP 6-Continued

− Consider talking to nursing staff and physicians about:
  − When they provide education
  − How they provide education
  − Which patients receive education
  − How easily they can access the educational resources
  − Where the evidence that education has taken place lives-electronic medical record?
In Review

− The introduction of direct oral anticoagulants, as alternatives to heparin and warfarin, requires organizations to:

  − Create and or modify existing protocols and evidence-based practice guidelines
  − Update policies to incorporate direct oral anticoagulants (DOACs)

− Implementation July 1, 2019

− Only EP 1, 2, 4, 5 and 6 applicable to AHC

− These new and revised requirements are at NPSG.03.05.01 in the “National Patient Safety Goals” chapter, access the standards in the E-dition or standards manual
Resource

- NPSG .03.05.01 Anticoagulant Therapy R3 Report
  https://www.jointcommission.org/assets/1/18/R3_19_Anticoagulant_therapy_FINAL2.PDF
References


Questions?
Thank you for attending