R³ Report | Requirement, Rationale, Reference

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National Patient Safety Goal for anticoagulant therapy

Effective July 1, 2019, eight new elements of performance will be applicable to all Joint Commission-accredited hospitals, critical access hospitals, nursing care centers, and medical centers (accredited under the ambulatory health care program). These new requirements are at NPSG.03.05.01 in the "National Patient Safety Goals" chapter.

For years, this NPSG has played an important role in improving the safety of patients receiving anticoagulation therapy. However, there has been a rise in adverse drug events associated with direct oral anticoagulants (DOACs), and The Joint Commission believes that relevant updates to this NPSG to address DOACs may help reverse that trend.

Engagement with stakeholders, customers, and experts

In addition to an extensive literature review and public field review, The Joint Commission obtained expert guidance from the following groups:

Technical advisory panel (TAP) of clinicians from health care and academic organizations and professional associations.

Standards review panel (SRP) consisted of representatives from organizations or professional associations who provide a "boots on the ground" point of view and insights into the practical application of the proposed standards.

The prepublication version of the standards will be available on the Prepublication Standards section of the Joint Commission website until June 30, 2019. After July 1, 2019, access the standards in the E-dition or standards manual.

National Patient Safety Goals

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).

Requirement	EP 1: The [hospital/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.

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Rationale	Anticoagulation medications are high-risk medications due to complex dosing, insufficient monitoring, and inconsistent patient compliance. The introduction of direct oral anticoagulants, as an alternative to heparin and warfarin, requires organizations to modify existing protocols and use evidence-based practice guidelines to address the initiation and maintenance of all anticoagulation medications and their associated risk factors.
References*	Reardon DP, et al. "Implementation of a Hemostatic and Antithrombotic Stewardship Program." *Journal of Thrombolysis & Thrombolysis* 40, no. 3 (Oct 2015): 379-82. Raschi E, et al. "Emerging Therapeutic Uses of Direct-Acting Oral Anticoagulants: An Evidence-Based Perspective." *Pharmacological Research* 120 (Jun 2017): 206-18. Witt DM, et al. "Guidance for the Practical Management of Warfarin Therapy in the Treatment of Venous Thromboembolism," *Journal of Thrombosis & Thrombolysis* 41, no. 1 (Jan 2016): 187-205.
Requirement	EP 2: The [hospital/organization] uses approved protocols and evidence-based practice guidelines for reversal of anticoagulation and management of bleeding events related to each anticoagulant medication.
Rationale	Bleeding is the most common complication of all anticoagulants. In addition to heparin and warfarin, each of the direct oral anticoagulants have different reversal mechanisms. It is important for organizations to use evidence-based practice guidelines when developing protocols to manage bleeding events. For timely and appropriate management, providers need to be aware of the variations in presentation severity (e.g., location and severity of bleeding, indication for reversal) and appropriate reversal agents (e.g., drug discontinuation, use of concentrated clotting therapy) for each anticoagulation medication used by patients coming to their organization.
References*	Tomaselli GF, et al. "2017 ACC Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways." *Journal of the American College of Cardiology* 70, no. 24 (Dec 19, 2017): 3042-67. Samuelson BT and Cuker A. "Measurement and Reversal of the Direct Oral Anticoagulants." *Blood Reviews* 31, no. 1 (Jan 2017): 77-84.
Requirement	EP 3: The hospital uses approved protocols and evidence-based practice guidelines for perioperative management of all patients on oral anticoagulants. Note: *Perioperative management may address the use of bridging medications, timing for stopping an anticoagulant, and timing and dosing for restarting an anticoagulant.*
Rationale	Patients taking oral anticoagulation medications need to be managed appropriately during the perioperative period to minimize bleeding risks during surgery. The decision to stop an anticoagulant, use a bridging medication, or to restart an anticoagulant should be based on organization-approved protocols and evidence-based practice guidelines that address the patient's bleeding risk and renal function, as well as the half-life of the medication.
References*	Burnett AE, et al. "Guidance for the Practical Management of the Direct Oral Anticoagulants (DOACs) in VTE Treatment," *Journal of Thrombosis & Thrombolysis* 41, no. 1 (Jan 2016): 206–232. Spyropoulos AC, et al. "Uptake and Utilization of the Management of Anticoagulation in the Periprocedural Period App: Longitudinal Analysis," *JMIR Mhealth Uhealth*. (Dec 21, 2018);6(12): e11090. Sunkara T, et al. "Perioperative Management of Direct Oral Anticoagulants (DOACs): A Systemic Review," *Health Services Insights* 9, no. Suppl 1 (Dec 13, 2016): 25-36.

Requirement	EP 4: The [hospital/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.
Rationale	Baseline and ongoing laboratory tests ensure that patients on anticoagulation medications are monitored and dosed appropriately. For patients receiving heparin and warfarin, routine laboratory testing includes partial thromboplastin time (PTT) and international normalized ratio (INR). Although direct oral anticoagulants (DOACs) were designed to be given at fixed doses and do not require routine coagulation monitoring, in selected instances, the interpretation of coagulation laboratory results is important for optimal management of DOAC toxicity or reversal. Regular monitoring of renal function and liver function should also be considered.
References*	Gosselin RC and Adcock DM. "The Laboratory's 2015 Perspective on Direct Oral Anticoagulant Testing." *Journal of Thrombosis & Haemostasis* 14, no. 5 (May 2016): 886-93. Holbrook A, et al. "Evidence-based Management of Anticoagulant Therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines," *Chest* 141, no. 2 Suppl (Feb 2012): e152S-e184S. Levenson D. "Testing Dilemmas for Direct Oral Anticoagulants," *Clinical Laboratory News* (July 1, 2016). https://www.aacc.org/publications/cln/articles/2016/july/testing-dilemmas-for-direct-oral-anticoagulants Witt DM, et al. "Guidance for the Practical Management of Warfarin Therapy in the Treatment of Venous Thromboembolism," *Journal of Thrombosis & Thrombolysis* 41, no. 1 (Jan 2016): 187-205.
Requirement	EP 5: The [hospital/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
Rationale	The prevention of adverse drug events (ADEs) is an important patient safety priority. 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 ADEs. Identification of common, preventable, and measurable healthcare-associated anticoagulant ADEs is a key component of quality improvement efforts to drive prevention, benchmark progress, and promote a culture of anticoagulation safety.
References*	Agency for Healthcare Research and Quality. *AHRQ National Scorecard on Rates of Hospital-acquired Conditions; Updated Baseline Rates and Preliminary Results 2014-2016*. Rockville, MD: AHRQ, June 2018. https://www.ahrq.gov/professionals/quality-patient-safety/pfp/index.html Wychowski MK, et al. "The Scope and Value of an Anticoagulation Stewardship Program at a Community Teaching Hospital," *Journal of Thrombosis & Thrombolysis* 43, no. 3 (Apr 2017): 380-86.

Requirement	EP 6: The [hospital/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
Rationale	Nonadherence to anticoagulation therapy places patients at risk for bleeding and/or clotting that can lead to severe adverse drug events. It is important that patient and family education emphasizes medication adherence, dose and schedule compliance, drug and food interactions, and the need for follow-up appointments and ongoing laboratory tests. It is important to educate patients taking anticoagulants that some foods and medicines can cause adverse interactions that can lead to an increase risk of bleeding while others can lead to an increase risk of developing blood clots.
References*	Burnett A, et al. "Guidance for the Practical Management of the Direct Oral Anticoagulants (DOACs) in VTE Treatment," *Journal of Thrombosis & Thrombolysis* 41, no. 1 (Jan 2016): 206-232. Office of Disease Prevention and Health Promotion, "Section 5: Anticoagulants." IN: *National Action Plan for Adverse Drug Event Prevention.* Rockville, MD: U.S. DHHS, ODPHP, 2014, 50-98. https://health.gov/hcq/pdfs/ade-action-plan-508c.pdf Reardon DP, et al. "Implementation of a Hemostatic and Antithrombotic Stewardship Program," *Journal of Thrombosis & Thrombolysis* 40, no. 3 (Oct 2015): 379-82.
Requirement (existing)	EP 7: The [hospital/organization] uses only oral unit-dose products, prefilled syringes, or premixed infusion bags when these types of products are available. *Note: For pediatric patients, prefilled syringe products should only be used if specifically designed for children.*
Rationale	Use of oral unit-dose products, prefilled syringes and premixed infusion bags reduces the risk of dosing and medication errors, while increasing patient safety because of their high level of accuracy in delivering medications. *This is an existing Joint Commission requirement that has been renumbered.*
Requirement (existing)	EP 8: When heparin is administered intravenously and continuously, the [hospital/organization] uses programmable pumps to provide consistent and accurate dosing.
Rationale	Use of programmable pumps ensures consistent and accurate administration of heparin. *This is an existing Joint Commission requirement that has been renumbered.*

*Not a complete literature review.