

Resources to support Joint Commission Accredited organizations implementation of NPSG.03.05.01, effective July 2019: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.



SELECTION OF RESOURCES

Purpose

The purpose of this document is to help organizations comply with the revised NPSG 03.05.01 effective July 1, 2019: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy in hospitals, critical access hospitals, nursing care centers, and medical centers (accredited under the Ambulatory Health Care program). The document provides accredited organizations with a compendium of resources that may be used to meet the requirements of the standard. Joint Commission staff have verified that the resources meet the requirements of the standard and elements of performance with which they are associated. The resources were compiled from key stakeholders including national organizations, federal and state agencies, professional associations, relevant academic institutions, peer reviewed publications and private entities.

Note: The resources identified in this document are intended to provide organizations with a range of options that may be used to meet the requirements of the NPSG. Specific resources however may not be appropriate for all organizations. The list of resources is also not intended to be exclusive (i.e., other approved protocols or evidence-based resources that are not found on this list may also be used to meet the NPSG requirements). Organizational leaders are encouraged to review multiple options and to select approved protocols / evidence-based tools and resources that meet the needs of their specific organization or systems.

How to use this resource list

Resources are organized into six sections according to the first six Elements of Performance in NPSG 03.05.01. EP1 initiation and maintenance of anticoagulant therapy; EP2 reversal of anticoagulation and management of bleeding events related to each anticoagulant medication; EP3 perioperative management of all patients on oral anticoagulants; EP4 laboratory testing to monitor and adjust anticoagulant therapy; EP5 anticoagulation safety practices; and EP6 provide education to patients and families specific to the anticoagulant medication prescribed.

A brief description of the resources, the organizations that supported development of materials, authors and resource availability are included. For easy access to the resources, this document should be viewed in electronic format rather than printed in hard copy, because the website URLs are hyperlinked. A table at the end of the document presents resources for each EP at a glance.

Joint Commission project staff: Direct oral anticoagulant therapy workgroup

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Disclaimer: This compendium of resources is not intended to be a comprehensive source of all relevant information relating to reducing the likelihood of patient harm associated with the use of anticoagulant therapy. Resources that are evidence-based and/ or have been widely and effectively used in healthcare settings were selected based on their relevance to the revised NPSG 03.05.01. The inclusion of a product name, vendor, or service should not be construed as an endorsement of such product, vendor, or service, nor is failure to include the name of a resource, product, vendor, or service be construed as disapproval. Because the information contained herein is derived from many sources, the Joint Commission cannot guarantee that the information is completely accurate or error free. The Joint Commission is not responsible for any claims or losses arising from the use of, or from any errors or omissions in this compendium of resources.

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Questions

Please direct questions or comments about this compendium of resources to:

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Resources to support Joint Commission-accredited organizations implementation of NPSG.03.05.01, effective July 2019: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

EP1 – 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.

Resources	Brief Description
<p>The American Heart Association (AHA), the American College of Cardiologists (ACC), and the Heart Rhythm Society (HRS) Focused Update of the 2014 AHA/ACC/HRS Guideline for The Management of Patients with Atrial Fibrillation: A Report of The American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and The Heart Rhythm Society.</p> <p>© 2019 by the American Heart Association, Inc., the American College of Cardiology Foundation, and the Heart Rhythm Society</p> <p>Authors: Craig JT, Wann LS et al., (2019)</p> <p>Published in: <i>Circulation</i>. 2019;139:e000–e000.</p> <p>Co-published in the <i>Journal of the American College of Cardiology and Heart Rhythm</i></p> <p>Availability: Free https://www.ahajournals.org/doi/pdf/10.1161/CIR.000000000665 This document is also available on the websites of the American</p>	<p>The Guideline for The Management of Patients with Atrial Fibrillation is a collaboration of the American College of Cardiologists (ACC), the American Heart Association (AHA) and the Heart Rhythm Society (HRS) as a partner and the Society of Thoracic Surgeons as a collaborator.</p> <p>The document provides an update to the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation (S1.3-1) (2014 AF Guideline) in areas for which new evidence emerged since its publication.</p> <p>The scope of this focused update of the 2014 AF Guideline includes:</p> <ul style="list-style-type: none"> • Revisions to the section on anticoagulation (because of the approval of new medications and thromboembolism protection devices) • Revisions to the section on catheter ablation of atrial fibrillation (AF) • Revisions to the section on the management of AF complicating acute coronary syndrome (ACS) • New sections on device detection of AF and weight loss. <p>Specific recommendations provided include:</p> <ul style="list-style-type: none"> • Selecting an Anticoagulant Regimen - Balancing Risks and Benefits • Anticoagulant options. Non-Vitamin K Oral Anticoagulants • Interruption and Bridging Anticoagulation • Nonpharmacological Stroke Prevention <ul style="list-style-type: none"> ○ Percutaneous Approaches to Occlude the LAA ○ Cardiac Surgery—LAA Occlusion/Excision • Rhythm Control <ul style="list-style-type: none"> ○ Prevention of Thromboembolism in Electrical ○ Pharmacological Cardioversion of AF ○ Atrial Flutter under Rhythm Control • Specific Patient Groups and AF <ul style="list-style-type: none"> ○ AF Complicating ACS • Device Detection of AF and Atrial Flutter • Weight Loss in Patients With AF (new)

<p>College of Cardiology (www.acc.org), the American Heart Association (professional.heart.org), and the Heart Rhythm Society (www.hrsonline.org).</p>	<p><u>Recommending Organizations:</u></p> <ol style="list-style-type: none"> 1. American College of Cardiology 2. American Heart Association 3. Heart Rhythm Society 4. Society of Thoracic Surgeons <p><u>Evidence/ Development:</u> The guidelines were developed using evidence-based methodologies including systematic review of literature and existing registries.</p>
<p>American Society of Hematology 2018 guidelines for management of venous thromboembolism: prophylaxis for hospitalized and non-hospitalized medical patients.</p> <p>Authors: Schünemann HJ, Cushman M, Burnett AE, Kahn SR, Beyer-Westendorf J, Spencer FA, Rezende SM, Zakai NA, Bauer KA, Dentali F, Lansing J, Balduzzi S, Darzi A, Morgano GP, Neumann I, Nieuwlaat R, Yepes-Núñez JJ, Zhang Y, Wiercioch W (2018)</p> <p>Published in: <i>Blood Adv.</i> 2(22):3198-3225.</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6258910/</p>	<p>In 2018 The American Society of Hematology issued clinical guidelines intended to support patients, clinicians, and others in making decisions about preventing VTE in medical inpatients, long-term care residents, persons with minor injuries, and long-distance travelers are at increased risk. The panel agreed on 19 recommendations for acutely ill and critically ill in these populations.</p> <p>A summary of recommendations is provided.</p> <p>Strong recommendations included</p> <ul style="list-style-type: none"> • Provision of pharmacological VTE prophylaxis in acutely or critically ill inpatients at acceptable bleeding risk • Use of mechanical prophylaxis when bleeding risk is unacceptable, Against the use of direct oral anticoagulants during hospitalization • Against extending pharmacological prophylaxis after hospital discharge <p>Conditional recommendations included</p> <ul style="list-style-type: none"> • Not to use VTE prophylaxis routinely in long-term care patients or outpatients with minor VTE risk factors. <p>The panel conditionally recommended use of graduated compression stockings or low molecular-weight heparin in long-distance travelers only if they are at high risk for VTE.</p> <p><u>Recommending Organizations:</u></p> <ol style="list-style-type: none"> 1. American Society for Hematology <p><u>Evidence/ Development:</u> The guidelines were developed by a multidisciplinary panel. The process included updating or performing systematic evidence reviews. Clinical questions and outcomes were prioritized according to their importance for clinicians and adult patients. The Grading of Recommendations Assessment, Development and Evaluation approach was used to assess evidence and make recommendations, which were subject to public comment.</p>

<p>Anticoagulation Toolkit (Version 1.9) A Consortium-Developed Quick Reference for Anticoagulation Version 1.9, reviewed/updated 1/3/19</p> <p>Authors: Michigan Anticoagulation Quality Improvement Initiative (MAQI2) Copyright 2014-2018, MAQI2</p> <p>Availability: Free http://www.anticoagulationtoolkit.org/</p> <p>For questions or permissions, please email info@maq2.org</p>	<p>The Anticoagulation Toolkit was produced by the Michigan Anticoagulation Quality Improvement Initiative (MAQI2), a consortium of anticoagulation clinics and experts from across the state of Michigan. Funding for MAQI2 was provided by Blue Cross Blue Shield of Michigan and Blue Care Network through the Collaborative Quality Improvement (CQI) program.</p> <p>The goal of this toolkit is to provide practitioners with an up-to-date, reliable, and easy to use source of information for anticoagulation. The content is based on the available evidence-based guidelines and research.</p> <p>The toolkit includes several tools under the following topics:</p> <ul style="list-style-type: none"> • Determining need and evaluating risk <ul style="list-style-type: none"> ○ Atrial fibrillation risk evaluation tools ○ Venous Thromboembolism risk evaluation tools ○ Other risk evaluation tools • Anticoagulant selection • Warfarin initiation, patient education and long-term management • DOACs initiation, patient education and long-term management • Other resources including quality improvement tools and links to Other organizations that focus on anticoagulation. <p><u>Recommending Organizations:</u></p> <ol style="list-style-type: none"> 1. Michigan Anticoagulation Initiative (MAQI2) <p><u>Evidence/ Development:</u> The toolkit was developed by a consortium of anticoagulation experts. The content was based on available evidence-based guidelines and research.</p>
<p>Anticoagulation Forum Patient Order Set: VTE Prophylaxis for the Medically Ill © 2018 AC Forum.</p> <p>Authors: Anticoagulation Forum</p>	<p>The Anticoagulation Forum Patient Order Set is a reference document from Anticoagulation Forum which provides examples of order sets intended to facilitate standardized venous thromboembolism (VTE) prophylaxis risk stratification of hospitalized medically ill patients for:</p> <ul style="list-style-type: none"> • Hospital-acquired VTE • Prophylaxis-associated bleeding on anticoagulation administration • Prescription of risk-appropriate VTE prophylaxis <p>The administration form includes sections to cover various elements of risk assessment including:</p> <ol style="list-style-type: none"> 1. VTE Risk Assessment (based on IMPROVE, Padua, Caprini tools) 2. Bleeding Risk Assessment

<p>Availability: Free https://acforum-excellence.org/Resource-Center/resource_files/1320-2019-03-07-111353.pdf</p>	<ol style="list-style-type: none"> 3. Baseline Information 4. Risk-Appropriate VTE Prophylaxis Orders 5. Additional Orders 6. References include links to publications used to inform development of this resource <p>A variety of VTE Risk Assessment tools are provided as appendices:</p> <ul style="list-style-type: none"> • IMPROVE: 7- element in-hospital risk model • IMPROVE: 4-element in-hospital risk model • Caprini Score • Padua Prediction Score • Apex Criteria <p>Additional Order Sets can be found at https://acforum.org/web/education-sets.php</p> <p>Recommending Organizations:</p> <ol style="list-style-type: none"> 1. The Anticoagulation Forum
<p>Hematology 2018 Guidelines for Management of Venous Thromboembolism: Optimal Management of Anticoagulation Therapy.</p> <p>Authors: Witt DM, Nieuwlaat R, Clark NP, Ansell,J, Holbrook A, Skov,J, Shehab N Mock,J, Myers T, Dentali F, Crowther MA, Agarwal A, Bhatt M, Khatib R, Riva JJ, Yuan Zhang Y, and Guyatt G. (2018)</p> <p>Published in: <i>American Society of Blood Adv.</i> 2(22):3257–3291.</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6258922/</p>	<p>These evidence-based guidelines of the American Society of Hematology (ASH) are intended to support patients, clinicians and other health care professionals in their decisions about the use of anticoagulants in the management of VTE. These guidelines assume the choice of anticoagulant has already been made.</p> <p>The guidelines are provided in the form of 25 recommendations and 2 good practice statements to optimize management of patients receiving anticoagulants. Recommendations focus on commonly used anticoagulant medications, including UFH, LMWH, fondaparinux, VKA, and the DOACs apixaban, dabigatran, edoxaban, and rivaroxaban. The specific objectives of the recommendations are to improve patient-important outcomes, including overall mortality, recurrent VTE, major bleeding, and quality of life. Key management strategies for optimal use of anticoagulants include:</p> <ul style="list-style-type: none"> • Initial anticoagulant dose selection (recommendation 1) • Drug-interaction management (recommendation 2) • Point-of-care international normalized ratio (INR) testing (recommendations 3 and 4) • INR recall interval selection (recommendations 5 and 6) • Laboratory monitoring of the anticoagulant response (recommendations 7-9) • Transitions between anticoagulants (recommendation 10) • The use of specialized anticoagulation-management services (AMSS) (recommendation 11) • Structured patient education (recommendation 12) • Efforts to improve adherence to anticoagulant medication regimens (recommendations 13a-d), • Invasive procedure management (recommendations 14 and 15)

	<ul style="list-style-type: none"> • Excessive anticoagulation and bleeding management (recommendations 16, 17, 18a and b, 19, and 20) • Anticoagulant resumption following bleeding (recommendation 21) • Renal function monitoring (good practice statements) <p><u>Recommending Organizations:</u></p> <ol style="list-style-type: none"> 1. The Anticoagulation Forum <p><u>Evidence/ Development:</u> Developed by a multidisciplinary guideline panel and included systematic evidence reviews. The panel prioritized clinical questions and outcomes according to their importance for clinicians and patients. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used to assess evidence and make recommendations, which were subject to public comment.</p>
<p>Guidance for the Practical Management of Warfarin Therapy in the Treatment of Venous Thromboembolism.</p> <p>Authors: Witt DM, Clark , Kaatz S, Schnurr T, Ansell JE. (2016)</p> <p>Published in: <i>J Thromb Thrombolysis.</i> 2016;41(1):187–205. doi:10.1007/s11239-015-1319-y</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pubmed/26780746</p> <p>Published with open access at Springerlink.com</p>	<p>This published article initiated by the Anticoagulation Forum aims to increase providers’ ability to achieve optimal outcomes for their patients with venous thromboembolism (VTE). The publication provides clinical guidance for the practical management of warfarin therapy in the treatment of VTE based on existing guidelines and consensus expert opinion where guidelines are lacking.</p> <p>The guidance is organized around a set of ten pivotal practical questions pertaining to the management of warfarin. For each question, a summary of the evidence is provided, followed by guidance representing unanimous consensus of the authors.</p> <ol style="list-style-type: none"> 1. Who are good candidates for warfarin therapy versus the direct oral anticoagulants? 2. How should warfarin be initiated? 3. How can I optimize anticoagulation control? 4. How do I manage warfarin during invasive procedures? 5. How do I manage warfarin-induced over-anticoagulation and bleeding? 6. How do I manage sub-therapeutic anticoagulation and recurrent VTE? 7. How do I manage warfarin drug–drug and drug-dietary interactions? 8. How do I switch between anticoagulants? 9. What is an appropriate follow-up and care transitions strategy? 10. How do I manage challenging clinical situations? <p><u>Recommending Organizations:</u></p> <ol style="list-style-type: none"> 1. The Anticoagulation Forum <p><u>Evidence/ Development:</u> Pivotal practical questions pertaining to this topic were developed by consensus of the authors and were derived from evidence-based</p>

	<p>consensus statements whenever possible. Medical literature was reviewed and summarized using guidance statements that reflect the consensus opinion(s) of the authors and the endorsement of the Anticoagulation Forum’s Board of Directors.</p>
<p>Antithrombotic Therapy for Atrial Fibrillation. CHEST Guideline and Expert Panel Report Copyright _ 2018 American College of Chest Physicians. Published by Elsevier Inc. All rights reserved</p> <p>Authors: Lip, GY.H. Banerjee A, Boriani G, Chiang C, Fargo R, Freedman B, Lane DA, Ruff CT, Turakhia M, Werring D, Patel S, and Moores L, et al. (2018)</p> <p>Published in: <i>CHEST</i>, 2018 Volume 154, Issue 5, 1121 - 1201</p> <p>Availability: Free https://journal.chestnet.org/article/S0012-3692(18)32244-X/fulltext</p>	<p>Evidence-based guidelines publication from American College of Chest Physicians provide recommendations for antithrombotic treatment based on net clinical benefit for patients with Atrial Fibrillation (AF) at varying levels of stroke risk and in a number of common clinical scenarios. Sixty recommendations are provided and include a range of grading from weak recommendation with low quality evidence to strong recommendation with moderate quality evidence. Ungraded consensus-based statement recommendations are also provided.</p> <p><u>Recommending Organizations:</u> 1. American College of Chest Physicians</p> <p><u>Evidence/ Development:</u> Development included literature review of evidence published from the last formal search performed for the Antithrombotic and Thrombolytic Therapy: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (9th Edition). The overall quality of the evidence was assessed using the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach. Consensus voting method was used to approve graded recommendations and ungraded consensus-based statements.</p>
<p>The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation.</p> <p>Authors: Steffel J, Verhamme P, Potpara TS, Albaladejo P, Antz M, Desteghe L, Haeusler KG, Oldgren J, Reinecke H, Schilling VS, Rowell N, Sinnaeve P, Collins R, Camm AJ, Heidbüchel H. (2018)</p>	<p>The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation is the second update of the original Practical Guide, published in 2013 by The European Heart Rhythm Association (EHRA). The guide provides practical answers to 20 topics of concrete clinical scenarios identified by a writing group of multiple experts. The 20 topics are as follows:</p> <p>(1) Eligibility for NOACs; (2) Practical start-up and follow-up scheme for patients on NOACs; (3) Ensuring adherence to prescribed oral anticoagulant intake; (4) Switching between anticoagulant regimens; (5) Pharmacokinetics and drug–drug interactions of NOACs; (6) NOACs in patients with chronic kidney or advanced liver disease; (7) How to measure the anticoagulant effect of NOACs; (8) NOAC plasma level measurement: rare indications, precautions, and potential pitfalls; (9) How to deal with dosing errors; (10) What to do if there is a (suspected) overdose without bleeding, or a clotting test is indicating a potential risk of bleeding; (11) Management of bleeding under NOAC therapy; (12) Patients undergoing a planned invasive procedure, surgery or ablation;</p>

<p>Published in: <i>European Heart Journal</i>, Volume 39, Issue 16, 21 April 2018, Pages 1330– 1393, https://doi.org/10.1093/eurheartj/ehy136</p> <p>Availability: Free https://academic.oup.com/eurheartj/article/39/16/1330/4942493?guestAccessKey=e7e62356-8aa6-472a-aeb1-eb5b58315d49</p>	<p>(13) Patients requiring an urgent surgical intervention; (14) Patients with AF and coronary artery disease; (15) Avoiding confusion with NOAC dosing across indications; (16) Cardioversion in a NOAC-treated patient; (17) AF patients presenting with acute stroke while on NOACs; (18) NOACs in special situations; (19) Anticoagulation in AF patients with a malignancy; and (20) Optimizing dose adjustments of VKA.</p> <p>Evidence/ Development: A writing group formulated practical answers to 20 clinical scenarios, based on available and updated knowledge.</p>
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Anticoagulation Forum Centers of Excellence Resource Center

For other VTE guidelines currently available, future guidelines, examples of excellence including drug monitoring assays and clinical protocol examples developed and shared by other hospitals or health systems see the **Anticoagulation Forum Centers of Excellence Resource Center** <https://acforum-excellence.org/Resource-Center/>.

Enter EP1 in into the search tool to find more resources specific to this NPSG.

Resources to support Joint Commission-accredited organizations implementation of NPSG.03.05.01, effective July 2019: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

EP2 - 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.

Tools	Brief Description
<p>2017 American College of Cardiology (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.</p> <p>Authors: Tomaselli GF, Mahaffey KW, Cuker A, Dobesh PP, Doherty JU, Eikelboom JW, Florido R, Huckler W, Mehran R, Messé SR, Pollack CV Jr., Rodriguez F, Sarode R, Siegel D, Wiggins BS. (2017)</p> <p>Published in: <i>Journal of the American College of Cardiology</i> 70, no. 24 (Dec 19, 2017): 3042-67.</p> <p>Availability: Free (Science Direct Open Access) https://www.sciencedirect.com/science/article/pii/S0735109717409387?via%3Dihub</p> <p>Also available at American College of Cardiology website.</p>	<p>The primary goal of this decision pathway is to guide the management of acute bleeding in patients treated with oral anticoagulants (OACs) and to supplement the 2017 American College of Cardiology (ACC) Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients With Non-valvular AF (10), which addresses the management of patients undergoing planned surgical or interventional procedures.</p> <p>The guidance in this document is designed to address the clinical problem of bleeding management of patients treated with anticoagulants and will consider both DOACs and VKAs used for any indication. The decision pathway considers the severity of the bleed (major vs. non-major), acute medical and surgical management, the need for reversal, the appropriateness and time of restarting anticoagulation, and the impact of pertinent comorbidities and concomitant drug therapy. The authors caution the need for patient specific factors to be considered at each step in the decision pathway algorithms.</p> <p>A pathway summary graphic provides an overview of what is covered in the decision pathway.</p> <p>In addition to detailed guidance, the decision pathway algorithm graphics provide guidance summary for the following:</p> <ul style="list-style-type: none"> • Assessing bleed severity and managing major and nonmajor bleeds in patients on DOACs and VKAs, • Guidance for administering reversal agents • Considerations for restarting anticoagulation • Restarting anticoagulation • Factors to consider in delaying restart of anticoagulation <p>Recommending Organizations:</p> <ol style="list-style-type: none"> 1. The American College of Cardiology (ACC) <p>Evidence/ Development: Developed by systematically collecting expert stakeholder input</p>

<p>Reversal of Direct Oral Anticoagulants: Guidance from the Anticoagulation Forum</p> <p>Authors: Cuker, A, Burnett, A, Triller, D, Crowther M, Ansell J, Van Cott EM, Wirth D, Kaatz S. (2019)</p> <p>Published in: <i>American Journal of Hematology.</i> 2019; 94: 697– 709</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pubmed/30916798 https://doi.org/10.1002/ajh.25475</p>	<p>The purposed of this published review document is to provide comprehensive guidance from the Anticoagulation Forum, regarding use of DOAC reversal agents. The authors discuss:</p> <ul style="list-style-type: none"> • Indications for reversal • Provide guidance on how the individual reversal agents should be administered • Offer suggestions for management strategies and stewardship at the health system level <p>The guidance is organized around a set of nine key questions regarding DOAC reversal. For each question, a summary of the evidence is provided, followed by guidance representing unanimous consensus of the authors.</p> <ol style="list-style-type: none"> (1) When should reversal agents be used to manage DOAC-associated bleeding? (2) How should reversal agents be used to manage dabigatran-associated bleeding? (3) How should reversal agents be used to manage factor Xa inhibitor-associated bleeding? (4) When should reversal agents be used before an invasive procedure? (5) How should reversal agents be used to manage dabigatran-treated patient before an invasive procedure? (6) How should reversal agents be used to manage a factor Xa inhibitor-treated patient before an invasive procedure? (7) Are reversal agents indicated for patients who present with DOAC overdose without bleeding? (8) Are reversal agents indicated for DOAC-treated patients who present with trauma without bleeding? (9) What strategies can be employed by health systems to promote optimal utilization of DOAC reversal agents? <p>Recommending Organizations:</p> <ol style="list-style-type: none"> 1. The Anticoagulation Forum <p>Evidence/ Development: Development included literature review of published evidence and information in US FDA product package inserts and on www.clinicaltrials.gov. Guidance statements represent the unanimous consensus of the authors.</p>
<p>Measurement and Reversal of the Direct Oral Anticoagulants. Blood</p>	<p>This published article reviews the utility of currently available assays for assessment of Direct Oral Anticoagulants (DOAC) effect and recommends an optimal assessment strategy for each drug, including calibrated dilute thrombin time or ecarin-based assays for dabigatran and calibrated anti-Xa activity assays for the factor Xa inhibitors.</p>

<p>Authors: Samuelson BT and Cuker A. (2017)</p> <p>Published in: <i>Reviews 31, no. 1 (Jan 2017): 77-84.</i></p> <p>Availability: Free</p>	<p>The authors also discuss drug reversal strategies, including the preferential use of idarucizumab for reversal of dabigatran, andexanet for reversal of anti-Xa agents (e.g., rivaroxaban, apixaban and edoxaban), as well as ciraparantag, another reversal agent currently under development</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5296289/</p>
<p>Resumption of anticoagulant therapy after anticoagulant-related gastrointestinal bleeding: A systematic review and meta-analysis.</p> <p>Authors: Little D, Chai-Adisaksopha C, Hillis C, Witt DM, Monreal M, Crowther MA, Siegal DM. (2019)</p> <p>Published in: <i>Thrombosis Research, March 2019. Volume 175, 102 - 109</i></p> <p>Availability: For purchase https://www.thrombosisresearch.com/article/S0049-3848(19)30029-5/fulltext</p>	<p>This published literature review article is an updated meta-analysis that aimed to determine the risks of recurrent GI bleeding, thromboembolism, and death in patients who resumed OAC compared to those who did not.</p> <p>The review identified 12 observational studies involving 3098 patients. Highlights of the results include the following:</p> <ul style="list-style-type: none"> • 40% of oral anticoagulant (OAC)-related bleeds are gastrointestinal (GI) bleeds. • OAC is discontinued in 41–51% of patients after a GI bleed. • Resuming OAC is associated with an increased risk of recurrent GI bleeding. • Resuming OAC is associated with a reduced risk of thromboembolism and mortality. <p>Evidence/ Development: Development included search of EMBASE, MEDLINE, and the Cochrane Central Register of Controlled Trials for new references from January 2014 to September 2017. Search included randomized controlled trials and observational studies involving adults with OAC-related GI bleeding.</p>

Anticoagulation Forum Centers of Excellence Resource Center

For examples of excellence on bleeding management and reversal of anticoagulation guideline and decision tree developed and shared by other hospitals or health systems see the **Anticoagulation Forum Centers of Excellence Resource Center** <https://acforum-excellence.org/Resource-Center/>.

Enter EP2 in into the search tool to find more resources specific to this NPSG.

Resources to support Joint Commission-accredited organizations implementation of NPSG.03.05.01, effective July 2019: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

EP3 - The hospital uses approved protocols and evidence-based practice guidelines for perioperative management of all patients on oral anticoagulants.

Tools	Brief Description
<p>2017 American College of Cardiology (ACC) Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients with Nonvalvular Atrial Fibrillation.</p> <p>Authors: Doherty JU, Gluckman TJ, Hucker WJ, Januzzi Jr. JL, Ortel TL, Saxonhouse SJ, Spinler SA. (2017)</p> <p>Published in: <i>J Am Coll Cardiol</i> 2017;69:871–98.</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pubmed/28081965</p>	<p>In an effort to increase the effect of ACC policy on patient care, an ACC Presidential Task Force was formed in 2014 to examine the ACC’s clinical documents. The main recommendation of the Task Force was a new focus on concise decision pathways and/or key points of care. The Expert Consensus Decision Pathways are designed to complement the guidelines and bridge the gaps in clinical guidance that remain</p> <p>The Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients with AF was approved by the American College of Cardiology Board of Trustees in November 2016.</p> <p>The goal for the pathway is to help guide clinicians in the complex decision making related to potential anticoagulant interruption in preparation for a procedure. Specifically the document aims to:</p> <ol style="list-style-type: none"> 1) Validate the appropriateness of the decision to chronically anticoagulate 2) Guide clinicians in the decision of whether to interrupt anticoagulation 3) Provide direction on how to interrupt anticoagulation with specific guidance for vitamin K antagonists and direct-acting oral anticoagulants 4) Evaluate whether to bridge with a parenteral agent peri procedurally 5) Offer advice on how to bridge 6) Outline the process of restarting anticoagulation post-procedure <p>The Pathway Decision Algorithm Summary graphic provides an overview of what is covered in each section of the decision pathway. Algorithms provided are actionable and can be implemented into tools or applications to accelerate use at the point of care.</p> <p>Recommending Organizations:</p> <ol style="list-style-type: none"> 1. American College of Cardiology <p>Evidence/ Development: Developed by expert consensus approach to collecting stakeholder input.</p>

<p>American College of Cardiology (ACC) ManageAntocoag app</p> <p>Availability: Free http://tools.acc.org/ManageAnticoag/?_ga=2.56608363.1324068214.1560091872-2136600217.1527776853#!/content/manager/</p>	<p>The ManageAnticoag app is an accompaniment of The Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients with AF described above.</p> <p>The app is intended for use by clinicians to help navigate periprocedural planning and bleed management scenarios for patients on oral anticoagulants (OAC). The app is comprised of three tools to support the following clinical decisions:</p> <p>Planning Periprocedural Interruption and Bridging</p> <ul style="list-style-type: none"> - Evaluates whether and how to interrupt and bridge anticoagulation as part of periprocedural planning for patients with nonvalvular AFib <p>Addressing an Acute Bleed</p> <ul style="list-style-type: none"> - Manages acute major and non-major bleeds, including the suggested use of reversal agents <p>Determining Anticoagulation Restart</p> <ul style="list-style-type: none"> - Determines whether and how anticoagulation should be restarted for patients in whom anticoagulation has been interrupted. <p>A quick reference section provides access to supporting information and details such as ‘Guidance for Administering Reversal Agents’, and ‘Components of the Clinician-Patient Discussion.’</p> <p>Recommending Organizations:</p> <ol style="list-style-type: none"> 1. American College of Cardiology <p>Evidence/ Development: The content of the App and its design were refined and vetted by ACC member clinicians, and through user testing with clinicians practicing in relevant specialties.</p>
<p>Interventional Spine and Pain Procedures in Patients on Antiplatelet and Anticoagulant Medications (Second Edition)</p> <p>Authors: Narouze S, Benzon HT, Provenzano D, Buvanendran A, De Andres J, Deer T, Rauck R, and Huntoon MA. (2018)</p>	<p>This published special article presents Interventional Spine and Pain Procedures in Patients on Antiplatelet and Anticoagulant Medications (Second Edition): Guidelines from the American Society of Regional Anesthesia (ASRA) and Pain Medicine, the European Society of Regional Anaesthesia and Pain Therapy, the American Academy of Pain Medicine, the International Neuromodulation Society, the North American Neuromodulation Society, and the World Institute of Pain.</p> <p>These guidelines are an update to previous guidelines published in 2015. The guidelines aim to facilitate clinical decision making by interventional spine and pain physicians.</p>

<p>Published in: <i>Regional Anesthesia & Pain Medicine</i> 2018;43:225-262.</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pubmed/29278603</p>	<p>Differences between these and the ASRA regional anesthesia guidelines are pointed out throughout the text and summarized in Table 8.</p> <p>A procedural anticoagulation management checklist is provided in Table 9.</p> <p>The ASRA Coags App developed based on these ASRA anticoagulation guidelines provides quick access to drug-specific summary information. https://www.asra.com/page/150/asra-apps</p> <p>Recommending Organizations:</p> <ol style="list-style-type: none"> 1. American Society of Regional Anesthesia and Pain Medicine, 2. European Society of Regional Anaesthesia and Pain Therapy, 3. American Academy of Pain Medicine 4. International Neuromodulation Society 5. North American Neuromodulation Society 6. World Institute of Pain <p>Evidence/ Development: Development included extensive literature review of published evidence. Recommendations were based on evidence where available but the authors indicate that many recommendations are primarily based on pharmacological principles and/or consensus due to limitations in the body of evidence.</p>
<p>American College of Surgeons' Guidelines for the Perioperative Management of Antithrombotic Medication.</p> <p>Authors: Horner MA, Duane TM, Ehlers AP, Jensen EH, Brown PS Jr, Pohl D, DaCosta PM, , Ko CY, Laronga C. (2018)</p> <p>Published in: <i>J Amer Coll Surg</i> 2018;227(5):521</p> <p>Availability: Free for ACS members upon sign in:</p>	<p>The American College of Surgeons' guidelines for the perioperative management of antithrombotic medication are intended to update, summarize, and combine previously published guidelines by other professional organizations into a clinically rigorous format suitable for a broad surgical readership. Specifically the objective of these guidelines is to update the surgeon reader in the following content areas:</p> <ol style="list-style-type: none"> 1. Assess thromboembolic risk if the antithrombotic agent is discontinued perioperatively (Section I); 2. Determine the bleeding risk of the surgical procedure and patient factors that modify this risk (Section II); 3. Discuss heparin bridging for perioperative thromboembolism prevention in high risk patients (Section III); 4. Develop an evidence-based perioperative antithrombotic medication management strategy for elective surgical patients (Section IV); and 5. Outline perioperative antithrombotic medication management in the nonelective surgical setting (Section V).

<p>https://www.journalacs.org/article/S1072-7515(18)31331-o/fulltext</p>	<p>Case vignettes developed by the authors are also provided as an appendix.</p> <p><u>Recommending Organizations:</u></p> <ol style="list-style-type: none"> 1. American College of Surgeons <p><u>Evidence/ Development:</u></p> <p>Specific topics were identified through an iterative process that involved the review of existing guidelines and a systematic review of contemporary literature, as well as multi-iterative feedback from an internal expert panel. The guidelines were drafted based on evidence provided by the foundational guidelines and pertinent literature updates and reviewed with input from an expert panel, who served as members of the 2017-2018 American College of Surgeons’ Board of Governors Practice Guidelines Workgroup, and external content experts. A consensus agreement approach was applied to the final guidelines presented.</p>
<p>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</p> <p>Authors: Raval AN, Cigarroa JE, Chung MK, Diaz-Sandoval LJ, Diercks D, Piccini JP, Jung HS, Washam JB, Welch BG, Zazulia AR, Collins SP. (2017)</p> <p>Published in: Circulation. 2017 Mar 7;135(10):e647</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5404934/</p>	<p>This scientific statement from the American Heart Association (AHA) reviews the literature and offers practical suggestions for providers who manage patients who are actively bleeding and who are at risk for bleeding in the acute care and periprocedural setting. Members of this American Heart Association (AHA) writing group were from diverse expertise in cardiovascular medicine, emergency medicine, critical care, neurology, surgery, and pharmacology. The document covers the following topics:</p> <ul style="list-style-type: none"> • Pharmacology of NOACs • Laboratory measurement of NOAC effect • NOAC reversal • Management of life-threatening bleeding • Management of patients on NOACs who are at risk for bleeding • Transitioning between NOACs and other anticoagulants in the acute care setting • Periprocedural management of patients who take NOACs <p>The statement includes detailed tables comparing different NOACs, drug interactions, and guidance on anticoagulation transitions. Figures present practical illustrations of a “Serious Bleeding on a NOAC” protocol, periprocedural management of patients on NOACs (non–vitamin K antagonist oral anticoagulants). The publication cites contemporary guidelines and scientific statements where appropriate.</p> <p><u>Recommending Organizations:</u></p> <ol style="list-style-type: none"> 1. American Heart Association

	<p>Evidence/ Development: Development included a systematic literature review of published evidence. Section development included multiple writers and reviewers and expert consensus before independent peer review and publication.</p>
<p>Perioperative Management of Direct Oral Anticoagulants (DOACs): A Systemic Review.</p> <p>Authors: Sunkara T, Ofori E, Zarubin V, Caughey ME, Gaduputi V, Reddy M. (2016)</p> <p>Published in: <i>Health Serv Insights</i>. 2016;9(Suppl 1):25–36. Published 2016 Dec 13. doi:10.4137/HSI.S40701</p> <p>Availability: Free</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5156547/</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5156547/pdf/hsi-suppl.1-2016-025.pdf</p>	<p>This systematic literature review article provides guidance on the management of DOACs in the perioperative period. The review serves as a concise resource that would aid a practicing clinician in making an informed decision.</p> <p>Four direct-acting oral anticoagulants are included in the review:</p> <ol style="list-style-type: none"> 1. Dabigatran etexilate mesylate (Pradaxa) 2. Rivaroxaban (Xarelto) 3. Apixaban (Eliquis) 4. Edoxaban (Savaysa) <p>The following detail information is provided for each drug:</p> <ul style="list-style-type: none"> • Mechanism of action • Pharmacokinetics including route of administration, half-life and peak concentration in hours • Indications • Drug interactions • Side effects • Contraindications • Category • Antidote • Peri-operative management for procedures • Peri-operative management for endoscopy <p>Evidence/ Development: Guidance development included extensive systematic literature review of published evidence.</p>

Anticoagulation Forum Centers of Excellence Resource Center

For clinical protocol examples on periprocedural care developed and shared by other hospitals or health systems see the **Anticoagulation Forum Centers of Excellence Resource Center**
<https://acforum-excellence.org/Resource-Center/>.

Enter EP3 in into the search tool to find more resources specific to this NPSG.

Resources to support Joint Commission-accredited organizations implementation of NPSG.03.05.01, effective July 2019: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

EP4 - The hospital/organization has a written policy addressing the need for baseline and ongoing laboratory tests to monitor and adjust anticoagulant therapy.

Tools	Brief Description
<p>Direct Oral Anticoagulants (DOACs) in the Laboratory: 2015 Review</p> <p>Authors: Adcock, D.M. and Gosselin RC (2015)</p> <p>Published in: <i>Thrombosis Research</i> , Volume 136 , Issue 1 , 7 - 12</p> <p>Availability: Free https://www.thrombosisresearch.com/article/S0049-3848(15)00226-1/fulltext</p>	<p>This published review article describes briefly the clinical utility and mechanism of action of direct oral anticoagulant therapies, including direct anti-Xa and thrombin inhibitors. Detailed information is provided on effect of these agents on routine assays including the APTT and PT as well as their impact on specialty laboratory assays. Also included are the use of drug specific assays and a discussion of alternative methods to determine relative drug concentration, such as evaluating drug calibrators in APTT and PT assays and using heparin calibrated anti-Xa assays to measure direct Xa inhibitors.</p> <p>The publication presents a review of the literature on each of the following:</p> <ul style="list-style-type: none"> • An Overview of Laboratory Assays and DOACS. Includes challenges and recommendations for measuring DOAC anticoagulant effect. • Dabigatran –Routine Screening Assays. Examines responsiveness and reliability in distinguishing therapeutic from subtherapeutic levels of dabigatran. • Dabigatran – Drug Specific Assays and review of literature related to their accuracy. • Dabigatran-Interference in Specialty Coagulation Assays • Anti-Xa DOACs-Routine Screening Assays. Includes response variations by specific anti-Xa DOAC and PT reagent used. • Direct Anti-Xa DOAC – Drug Specific Assays. Methodology for obtaining accurate measurement and limitations. • Anti-Xa DOAC-Interference in Special Coagulation Assays. Includes multiple interference indicated in available literature and underscores implications for laboratories without sufficient patient clinical and medication history. <p>The authors caution on interpretation of results performed in the presence of DOACs and the need to use the results from coagulation assays in conjunction with the patients’ clinical presentation when assessing bleeding or thrombotic risk.</p> <p><u>Evidence/ Development:</u> Extensive review of published evidence.</p>

<p>"The Laboratory's 2015 Perspective on Direct Oral Anticoagulant Testing."</p> <p>Authors: Gosselin RC and Adcock DM. (2016)</p> <p>Published in: <i>Journal of Thrombosis & Haemostasis</i> 14, no. 5 (May 2016): 886-93.</p> <p>Availability: Free https://onlinelibrary.wiley.com/doi/pdf/10.1111/jth.13266</p>	<p>The purpose of this review article is to describe the use of laboratory tests in assessing DOAC anticoagulation. The authors review laboratory assays that can be used to determine drug presence and to measure drug concentration and provide recommended testing algorithms. The authors identify two common questions that clinicians have regarding DOAC-treated patients and describe implications for related scenarios:</p> <p>i). The clinical question: is a DOAC present?</p> <ul style="list-style-type: none"> • Known dabigatran treatment • Known anti-FXa DOAC treatment • Unknown medication history <p>ii). The clinical question: how much DOAC is present?</p> <ul style="list-style-type: none"> • How much dabigatran is present? • How much anti-FXa DOAC is present? <p>The authors also review Impact of DOACS on specialty coagulation assays and present a table on select special coagulation assays with the potential to give false-positive and false-negative results.</p> <ul style="list-style-type: none"> • Factor assays • Inherited and acquired thrombophilia screening <p>A list of guidance statements is provided in the conclusion section of the article.</p> <p><u>Evidence/ Development:</u> Extensive review of published evidence.</p>
<p>An update on laboratory assessment for direct oral anticoagulants (DOACs)</p> <p>Authors: Robert C. Gosselin RC, Adcock DM, Douxfils J. (2019)</p> <p>Published in: <i>Int J Lab Hematol.</i> 2019;41(Suppl. 1):33–39.</p> <p>Availability: Free https://onlinelibrary.wiley.com/doi/full/10.1111/ijlh.12992</p>	<p>This published review article provides an update on laboratory guidance and progress of methods for measuring DOACs. The article provides detailed review, guidance and references related to:</p> <ul style="list-style-type: none"> • DOAC laboratory interference • Laboratory guidance myths and facts • Laboratory guidance needs • Laboratory DOAC testing <p>The authors present laboratory assays that can be used to determine drug presence and to measure drug concentration, and provide recommended testing algorithms. They also review tests with the potential to give false-positive and false-negative results.</p>

<p>Laboratory testing in patients treated with direct oral anticoagulants: a practical guide for clinicians.</p> <p>Authors: Douxfils J, Ageno W, Samama CM, Lessire S, Ten Cate H, Verhamme P, Dogné JM, Mullier F. (2018)</p> <p>Published in: J Thromb Haemost. 2018 Feb;16(2):209-219. doi: 10.1111/jth.13912. Epub 2017 Dec 28. Review. PMID: 29193737</p> <p>Availability: Free https://onlinelibrary.wiley.com/doi/full/10.1111/jth.13912</p>	<p>This review article offers recommendations on the tests to use for measuring DOACs and practical guidance on laboratory testing to help patient management and avoid diagnostic errors.</p> <p>The article provides detailed review on the following:</p> <ul style="list-style-type: none"> • What test to use to determine the presence of DOACs and their plasma concentrations? • When to measure direct oral anticoagulants and how to interpret the results of the different assays? <ul style="list-style-type: none"> • Emergency situations: is a direct oral anticoagulant present and how much? • Elective perioperative setting: is a direct oral anticoagulant still present? • Impact of direct oral anticoagulants on coagulation function assessments
<p>Practical Management of Anticoagulation in Patients With Atrial Fibrillation</p> <p>Authors: Kovacs RJ, Flaker GC, axonhouse SJ, Doherty JU, Birtcher KK, Cuker A, Davidson BL, Giugliano RP, Granger CB, Jaffer AK, Mehta BH, Nutescu E, Williams KA. (2015)</p> <p>Published in: Journal of the American College of Cardiology, Volume 65, Issue 13, 2015, Pages 1340-1360, ISSN 0735-1097</p> <p>Availability: Free https://www.sciencedirect.com/science/article/pii/S0735109715005100?via%3Dihub</p>	<p>This state-of-the-art review publication presents the findings of a roundtable of experts from multiple specialties convened by The American College of Cardiology to discuss topics important to the management of patients requiring anticoagulation and to make expert recommendations on issues such as the initiation and interruption of anticoagulation, quality of anticoagulation care, management of major and minor bleeding, and treatment of special populations.</p> <p>The review highlights management of anticoagulation as a “team sport” and focuses on the practical aspects of anticoagulation care for the patient with atrial fibrillation.</p> <p>Discussions cover four general topics:</p> <ol style="list-style-type: none"> 1. Initiation and interruption of anticoagulant therapy 2. Quality, cost, and team-based management of anticoagulation (includes baseline and periodic monitoring and coordinating care through anticoagulation clinics) 3. Management of bleeding and emergency care 4. Complex disease states and special populations. <p>Comprehensive tables and flow charts are also provided.</p>

<p>Laboratory Measurement of the Anticoagulant Activity of the Non–Vitamin K Oral Anticoagulants</p> <p>Authors: Cuker A, Siegal DM, Crowther MA, Garcia, DA (2014)</p> <p>Published in: <i>Journal of the American College of Cardiology</i>, Volume 64, Issue 11, 2014, Pages 1128-1139, ISSN 0735-1097</p> <p>Availability: Free https://doi.org/10.1016/j.jacc.2014.05.065</p>	<p>This published article is a systematic review and summary of evidence regarding laboratory measurement of the anticoagulant activity of dabigatran, rivaroxaban, and apixaban.</p> <p>Suggestions for laboratory measurement (and interpretation where applicable) of the anticoagulant activity of dabigatran, rivaroxaban, and apixaban based on the following clinical objectives are provided:</p> <ul style="list-style-type: none"> • Determine if clinically relevant below on-therapy drug levels are present • Estimate drug levels within on-therapy range • Determine if above on-therapy drug levels are present <p>Evidence/ Development: Systematic review of published evidence.</p>
<p>Guidance for the Practical Management of the Direct Oral Anticoagulants (DOACs) in VTE Treatment.</p> <p>Authors: Burnett AE, Mahan CE, Vazquez SR, Oertel LB, Garcia DA, Ansell J. (2016)</p> <p>Published in: <i>J Thromb Thrombolysis</i>. 2016;41(1):206–232. doi:10.1007/s11239-015-1310-7</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4715848/</p>	<p>This published manuscript was initiated by the Anticoagulation Forum. The publication provides guidance to the practical management of DOACs for VTE treatment. It examines key questions, summarizes the evidence (where it exists) pertaining to those questions, and provides guidance that may be applied to real-world practice by frontline clinicians. One of the detailed guidance questions addressed is:</p> <p>Guidance Question 3. How should the anticoagulant activity of DOACs be measured?</p> <p>The authors emphasize that specificity, predictability and wide therapeutic index of the DOACs allow for fixed dosing without a need for routine monitoring. However, there are instances during which measurement of DOAC activity would be useful to direct therapy and inform long-term treatment decisions.</p> <p>Table 7 presents potential indications for DOAC measurement for the following:</p> <ul style="list-style-type: none"> • Detection of clinically relevant levels • Detection of expected on-therapy levels • Detection of excessive levels <p>Table 8 presents suggestions for laboratory measurement of dabigatran, rivaroxaban, apixaban and edoxaban. It includes suggested tests and interpretation to determine the following:</p> <ul style="list-style-type: none"> • Determine if clinically relevant below on-therapy drug levels are present • Estimate drug levels within on-therapy range • Determine if above on-therapy drug levels are present

<p>Availability: Free https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4715848/</p>	<p>Guidance statement related to measurement: The authors suggest that clinicians do not routinely measure DOAC activity. If measurement of a DOAC is indicated, they suggest that clinicians use assays that are validated either locally or in a reference laboratory and that are readily available. The chosen assay should be suitable for the DOAC being used, as well as for the indication for measurement as detailed in Table 8.</p> <p>Recommending Organizations:</p> <ol style="list-style-type: none"> 1. The Anticoagulation Forum <p>Evidence/ Development: Development included literature review of published evidence. Guidance statements represent the consensus opinion(s) of all authors and are endorsed by the Anticoagulation Forum’s Board of Directors.</p>
<p>Measurement and Reversal of the Direct Oral Anticoagulants.</p> <p>Authors: Samuelson BT and Cuker A. (2017)</p> <p>Published in: Reviews 31, no. 1 (Jan 2017): 77-84.</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5296289/</p>	<p>This published article reviews the utility of currently available assays for assessment of Direct Oral Anticoagulants (DOAC) effect and recommends an optimal assessment strategy for each drug, including calibrated dilute thrombin time or ecarin-based assays for dabigatran and calibrated anti-Xa activity assays for the factor Xa inhibitors.</p> <p>The authors also discuss drug reversal strategies, including the preferential use of idarucizumab for reversal of dabigatran and exanet and ciraparantag, currently under development for reversal of rivaroxaban, apixaban and edoxaban.</p>

Anticoagulation Forum Centers of Excellence Resource Center

For examples of anticoagulation service policy and procedure or clinical guideline and practice protocol developed and shared by other hospitals or health systems see the **Anticoagulation Forum Centers of Excellence Resource Center** <https://acforum-excellence.org/Resource-Center/>.

Enter EP4 in into the search tool to find more resources specific to this NPSG.

Resources to support Joint Commission-accredited organizations implementation of NPSG.03.05.01, effective July 2019: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

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

Tools	Brief Description
<p>Engaging with quality improvement in anticoagulation management.</p> <p>Authors: Barnes, G. D., & Kline-Rogers, E. (2015).</p> <p>Published in: <i>Journal of thrombosis and thrombolysis</i>, 39(3), 403–409. doi:10.1007/s11239-015-1184-8</p> <p>Availability: Free https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4822820/</p>	<p>This published article highlights activities from the Michigan Anticoagulation Quality Improvement Initiative (MAQI2), a six-center quality improvement collaborative of anticoagulation management services in Michigan. The review includes discussion on the following:</p> <ul style="list-style-type: none"> • Potential quality improvement measures and targets for quality improvements in anticoagulation management • Michigan anticoagulation quality improvement initiative • Example quality improvement projects including specific metrics for the following: <ul style="list-style-type: none"> ○ Low risk atrial fibrillation ○ Provoked deep venous thrombosis anticoagulation ○ Extended INR testing interval ○ Adverse events reviews • Other anticoagulation quality improvement efforts <ul style="list-style-type: none"> ○ Targeting high-risk patients ○ Concurrent medication use ○ Direct oral anticoagulation management <p>Table 2 provides brief description and links to a variety of quality improvement resources</p> <p><u>Recommending Organizations:</u></p> <ol style="list-style-type: none"> 1. Michigan Anticoagulation Quality Improvement Initiative (MAQI2) 2. The Anticoagulation Forum

<p>National Action Plan for Adverse Drug Event (ADE) Prevention</p> <p>Authors: U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2014).</p> <p>Availability: Free https://health.gov/hcq/ade-action-plan.asp</p>	<p>The Adverse Drug Events (ADE) Action Plan from the Office of Disease Prevention and Health Promotion (ODPHP) addresses a defined group of ADEs that are considered to be common, clinically significant, preventable, and measurable; resulting from high-priority drug classes; and occurring largely in high-risk populations.</p> <p>Anticoagulants (primary ADE of concern: bleeding) are one of the three key drug classes identified as initial targets for the ADE Action Plan.</p> <p>Information on anticoagulants is presented in section 5 of the Plan. This includes:</p> <ul style="list-style-type: none"> • Magnitude of the problem of anticoagulants as causes of ADEs • Surveillance including a summary of metrics related to anticoagulant ADEs collected by federal surveillance systems. • Evidence-based prevention tools including resources for safer care; patient and family engagement; and resources for communication and coordination of care. • Incentives and oversight by federal agencies including a table on National Quality Forum (NQF)-endorsed health care quality measures specific to anticoagulation safety. • Health Information Technology (Health IT) including opportunities to leverage electronic health records (EHR) Meaningful Use requirements to advance ADE prevention • Unanswered research questions related to patient identification and safe use of new oral anticoagulants (NOACs). <p>Recommending Organization:</p> <ol style="list-style-type: none"> 1. The U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion.
<p>Implementation of a Direct Oral Anticoagulation Screening Service at a Large Academic Medical Center Provided by a Pharmacist-managed Antithrombosis Clinic as a Method to Expand Antithrombotic Stewardship Efforts.</p> <p>Authors: Uppuluri EM, McComb MN, Shapiro NL (2018)</p>	<p>This published article reports on the implementation and outcomes of a DOAC screening service as a method to expand antithrombotic stewardship efforts at a large academic medical center. The goal was to improve the safety and efficacy of DOAC use at the institution through patient education, identification and resolution of dosing errors, improved DOAC access, increased provider knowledge regarding ideal patient candidates for DOACs, and improved patient follow-up and laboratory monitoring.</p> <p>The screening service included the utilization of a daily electronic prescribing report of DOAC prescriptions. Prescriptions were reviewed by clinical pharmacists to assess patient insurance, eligibility, and accuracy of prescribed doses.</p> <p>Common interventions with new prescriptions included</p> <ul style="list-style-type: none"> • Contacting the prescriber for a medication or dose change, • Assistance with medication access

<p>Published in: <i>Journal of Pharmacy Practice</i> (online)</p> <p>Availability: For Purchase https://www.ncbi.nlm.nih.gov/pubmed/30213217</p>	<ul style="list-style-type: none"> • Coordinating appropriate lab and provider follow up. <p>Common interventions with refill prescriptions included</p> <ul style="list-style-type: none"> • Recommending appropriate follow-up • Contacting the prescriber for medication or dosage change <p>The authors conclude that implementation of a DOAC screening service identified and resolved dosing errors, improved medication access, provided patient education, and improved follow-up.</p>
<p>The Scope and Value of an Anticoagulation Stewardship Program at a Community Teaching Hospital</p> <p>Authors: Wychowski MK, Christina I. Ruscio CI, Kouides PA, Sham RL. (2017)</p> <p>Published in: <i>Journal of Thrombosis & Thrombolysis</i> 43, no. 3 (Apr 2017): 380-86.</p> <p>Availability: For Purchase https://link.springer.com/article/10.1007%2Fs11239-016-1455-z</p>	<p>This published article reports the impact of an inpatient anticoagulation stewardship program at a community hospital to promote optimal anticoagulant use.</p> <p>The US Department of Health and Human Services recommended application of stewardship (well established in the literature for optimal use of antimicrobials) to promote optimal use of anticoagulants and minimize harm. The anticoagulation team (ACT) at the community hospital focused on three areas at initiation of the program including:</p> <ol style="list-style-type: none"> 1. Oversight of anticoagulation treatment and prophylaxis in medical and surgical patients 2. Management of heparin-induced thrombocytopenia 3. Use of high cost reversal agents such as prothrombin complex concentrate (PCC). This is performed by making interventions regarding drug and dose optimization in special populations and providing ongoing education to providers. <p>The article concludes that implementation of an anticoagulation stewardship program reduced costs and improved clinical outcomes. The authors also expected that anticoagulant optimization and provider education improved overall patient safety.</p>

Anticoagulation Forum Centers of Excellence Resource Center

For more resources and sample of performance merits report developed and shared by other hospitals or health systems see The **Anticoagulation Forum Centers of Excellence Resource Center**
<https://acforum-excellence.org/Resource-Center/>.

Enter EP5 in into the search tool to find more resources specific to this NPSG.

Resources to support Joint Commission-accredited organizations implementation of NPSG.03.05.01, effective July 2019: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

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

Tools	Brief Description
<p>Blood Thinner Pills: Your Guide to Using Them Safely</p> <p>Authors: AHRQ</p> <p>Availability: Free https://www.ahrq.gov/patients-consumers/diagnosis-treatment/treatments/btpills/btpills.html#booklet</p>	<p>The Agency for Healthcare Research and Quality offers resources for patient education: a free booklet and a video about blood thinner medicines.</p> <p><i>Staying Active and Healthy with Blood Thinners</i> is a 10-minute video that features easy-to-understand explanations of how blood thinners work and why it's important to take them correctly.</p> <p><i>Blood Thinner Pills: Your Guide to Using Them Safely</i>, is a 24-page booklet that explains how blood thinner pills can help prevent dangerous blood clots from forming and what to expect when taking these medicines.</p> <p>Both the guide and video are available in English and Spanish.</p> <p>Video—Staying Active and Healthy with Blood Thinners</p> <p>Booklet—Blood Thinner Pills: Your Guide to Using Them Safely</p> <p>Recommending Organization:</p> <ol style="list-style-type: none"> 1. Agency for Healthcare Research and Quality
<p>University of Washington Medicine Anticoagulation Services</p> <p>Availability: Free https://depts.washington.edu/anticoag/home/</p> <p>There is no cost to participate in this program.</p>	<p>University of Washington Medicine (UW Medicine) Anticoagulation Services website is operated by the UW Medicine Department of Pharmacy and collaborates with multidisciplinary specialties and providers across UW Medicine to develop and disseminate guidelines and to coordinate the use of antithrombotic agents across the UW Medicine enterprise.</p> <p>This website contains UW Medicine recommendations, guidelines and protocols for the treatment and prevention of venous and arterial thrombosis, and the clinical use of antithrombotic agents in ambulatory and inpatient settings.</p> <p>The website provides links to a variety of resources including information on anticoagulant conversions ("switching") and patient</p>

	<p>education resources. The website also provides links to UW Medicine Anticoagulation Clinics and detailed information on making referrals to the clinics.</p> <p>Detailed information (including: guidelines, protocols, drug converting, peri-procedural management, renal dose adjustments and renal function effects, drug interactions, monitoring, reversal, patient education and management plans) related to the following drugs is provided as applicable:</p> <p>Drugs:</p> <ul style="list-style-type: none"> • Andexanet alfa (Andexxa) • Apixaban (Eliquis) • Betrixaban (Bevyxxa) • Bivalirudin (Angiomax) • Dabigatran (Pradaxa) • Edoxaban (Savaysa) • Fondaparinux (Arixtra) • Heparin • Idarucizumab (Praxbind) • Low molecular weight heparins (LMWH) • Rivaroxaban (Xarelto) • Warfarin (Coumadin) <p>Conditions addressed include the following:</p> <ul style="list-style-type: none"> • Monitoring Antithrombotic Therapy • Anticoagulation and neuraxial anesthesia • Bleeding Risk Assessment • Central venous catheter management • Chronic antithrombotic therapy • Guidelines for reversal of anticoagulation • Heparin-induced thrombocytopenia (HIT) • Mechanical Circulatory Support • Peri-procedural anticoagulation • VTE
<p>The National Blood Clot Alliance (NBCA)</p> <p>Availability: Free https://www.stopthecлот.org/</p> <p>There is no cost to download resources or participate in this program.</p>	<p>The National Blood Clot Alliance (NBCA) is a is a patient-led, non-profit, voluntary health advocacy organization dedicated to advancing the prevention, early diagnosis and successful treatment of life-threatening blood clots such as deep vein thrombosis, pulmonary embolism, and clot-provoked stroke.</p> <p>The NBCA activities include programs that build public awareness, educate patients and healthcare professionals, and promote supportive public and private sector policy.</p> <p>The webpage includes:</p> <ul style="list-style-type: none"> • Resources about clots • Patient stories • Online VTE curriculum with CE credits • Volunteer information to get involved

<p>What Are Anticoagulants and Antiplatelet Agents? 2-page patient information sheet from AHA, 2017</p> <p>Availability: Free</p> <p>https://www.heart.org/-/media/data-import/downloadables/pe-abh-what-are-anticoagulants-and-antiplatelet-agents-ucm_300338.pdf</p>	<p>“What Are Anticoagulants and Antiplatelet Agents?” is a patient information sheet by the American Heart Association. It provides a description of anticoagulants and highlights specific information that patients should know about anticoagulants and antiplatelets, potential problems while taking anticoagulants, and the need to wear an emergency medical identification.</p> <p>This information sheet is available for download at https://acforum-excellence.org/Resource-Center/.</p>
<p>Patient at-a-glance reference for anticoagulants 1-page reference sheet for warfarin and DOACs, includes descriptions, interactions and compliance tips</p> <p>Authors: Oertel LB. (updated Aug 2018)</p> <p>Availability: Free</p>	<p>This reference sheet provides specific information about warfarin, dabigatran, rivaroxaban, apixaban and edoxaban for patients and their families. Information includes dosage and action to take when dose is missed and need to carry “anticoagulant identification wallet card”. It also emphasizes the need for continued communications by patient to provider and careful planning around transitions of care settings and drug use.</p> <p>The reference sheet is available for download at: https://acforum-excellence.org/Resource-Center/resource_files/1197-2018-08-23-104829.pdf</p>
<p>Implementation of a Direct Oral Anticoagulation Screening Service at a Large Academic Medical Center Provided by a Pharmacist-managed Antithrombosis Clinic as a Method to Expand Antithrombotic Stewardship Efforts.</p> <p>Published in: Journal of Pharmacy Practice</p> <p>Authors: Uppuluri EM, McComb MN, Shapiro NL</p>	<p>This published article reports on the implementation and outcomes of a DOAC screening service as a method to expand antithrombotic stewardship efforts at a large academic medical center. The goal was to improve the safety and efficacy of DOAC use at the institution through patient education, identification and resolution of dosing errors, improved DOAC access, increased provider knowledge regarding ideal patient candidates for DOACs, and improved patient follow-up and laboratory monitoring.</p> <p>The screening service included the utilization of a daily electronic prescribing report of DOAC prescriptions. Prescriptions were reviewed by clinical pharmacists to assess patient insurance, eligibility, and accuracy of prescribed doses.</p> <p>Common interventions with new prescriptions included</p> <ul style="list-style-type: none"> • Contacting the prescriber for a medication or dose change, • Assistance with medication access • Coordinating appropriate lab and provider follow up. <p>Common interventions with refill prescriptions included</p> <ul style="list-style-type: none"> • Recommending appropriate follow-up

Availability: For Purchase
<https://www.ncbi.nlm.nih.gov/pubmed/30213217>

- Contacting the prescriber for medication or dosage change

Education was provided for more than a third of the patients newly prescribed DOACs who did not previously have education documented, and clinical interventions were performed in about a quarter of new prescriptions and a sixth of refill prescriptions to improve DOAC use and follow-up.

The authors conclude that implementation of a DOAC screening service identified and resolved dosing errors, improved medication access, provided patient education, and improved follow-up.

List of resources and related elements of performance EPs

Resource	Authors	EP1	EP2	EP3	EP4	EP5	EP6
2019 AHA/ACC/HRS Focused Update of the 2014 Guideline for The Management of Patients with Atrial Fibrillation: A Report of The American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and The Heart Rhythm Society	Craig JT, Wann LS et al., (2019)	X					
The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K anticoagulants in patients with atrial fibrillation.	Steffel J, Verhamme P, Potpara TS, et al., (2018)	X					
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	Tomaselli GF, Mahaffey KW, Cuker A, et al., (2017)		X				
2017 ACC Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients with Nonvalvular Atrial Fibrillation	Doherty JU, Gluckman TJ, Hucker WJ, et al., (2017)			X			
American College of Cardiology (ACC) ManageAntocoag app	American College of Cardiology (ACC)			X			
American College of Surgeons' Guidelines for the Perioperative Management of Antithrombotic Medication	Horner MA, Duane TM, Ehlers AP, et al., (2018)			X			
American Society of Hematology 2018 guidelines for management of venous thromboembolism: prophylaxis for hospitalized and non-hospitalized medical patients	Schünemann HJ, Cushman M, Burnett AE, et al., (2018)	X					
An update on laboratory assessment for direct oral anticoagulants (DOACs)	Robert C., Gosselin RC, Adcock DM, et al., (2019)				X		
Anticoagulation Forum Patient Order Set: VTE Prophylaxis for the Medically Ill	Anticoagulation Forum	X					
Anticoagulation Toolkit (Version 1.9) A Consortium-Developed Quick Reference for Anticoagulation Version 1.9, reviewed/updated 1/3/19	Michigan Anticoagulation Quality Improvement Initiative (MAQI2)	X					

List of resources and related elements of performance EPs

Resource	Authors	EP1	EP2	EP3	EP4	EP5	EP6
Antithrombotic Therapy for Atrial Fibrillation. CHEST Guideline and Expert Panel Report 2018 American College of Chest Physicians	Lip, GY.H. Banerjee A, Boriani G, et al. (2018)	X					
Blood Thinner Pills: Your Guide to Using Them Safely	AHRQ						X
Direct Oral Anticoagulants (DOACs) in the Laboratory: 2015 Review	Adcock, D.M., Gosselin RC (2015)				X		
Engaging with quality improvement in anticoagulation management	Barnes, G. D., & Kline-Rogers, E. (2015)					X	
Guidance for the Practical Management of the Direct Oral Anticoagulants (DOACs) in VTE Treatment	Burnett AE, Mahan CE, Vazquez SR, et al., (2016)				X		
Guidance for the Practical Management of Warfarin Therapy in the Treatment of Venous Thromboembolism	Witt DM, Clark, Kaatz S, Schnurr T, et al., (2016)	X					
Hematology 2018 Guidelines for Management of Venous Thromboembolism: Optimal Management of Anticoagulation Therapy	Witt DM, Nieuwlaat R, Clark NP, et al., (2018)	X					
Implementation of a Direct Oral Anticoagulation Screening Service at a Large Academic Medical Center Provided by a Pharmacist-managed Antithrombosis Clinic as a Method to Expand Antithrombotic Stewardship Efforts	Uppuluri EM, McComb MN, Shapiro NL (2018)					X	X
Interventional Spine and Pain Procedures in Patients on Antiplatelet and Anticoagulant Medications (Second Edition)	Narouze S, Benzon HT, Provenzano, et al.,			X			
The Laboratory's 2015 Perspective on Direct Oral Anticoagulant Testing	Gosselin RC and Adcock DM. (2016)				X		
Laboratory Measurement of the Anticoagulant Activity of the Non-Vitamin K Oral Anticoagulants	Cuker A, Siegal DM, Crowther MA, Garcia, DA (2014)				X		
Laboratory testing in patients treated with direct oral anticoagulants: a practical guide for clinicians	Douxflis J, Ageno W, Samama CM, et al., (2018)				X		

List of resources and related elements of performance EPs

Resource	Authors	EP1	EP2	EP3	EP4	EP5	EP6
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	Raval AN, Cigarroa JE, Chung MK, et al., (2017)			X			
Measurement and Reversal of the Direct Oral Anticoagulants.	Samuelson BT, Cuker A. (2017)		X		X		
National Action Plan for Adverse Drug Event (ADE) Prevention	U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2014).					X	
The National Blood Clot Alliance (NBCA)	The National Blood Clot Alliance (NBCA)						X
Patient at-a-glance reference for anticoagulants	Oertel LB. (updated August 2018)						X
Perioperative Management of Direct Oral Anticoagulants (DOACs): A Systemic Review	Sunkara T, Ofori E, Zarubin V, et al., (2016)			X			
Practical Management of Anticoagulation in Patients with Atrial Fibrillation	Kovacs RJ, Flaker GC, axonhouse SJ, et al., (2015)				X		
Reversal of Direct Oral Anticoagulants: Guidance from the Anticoagulation Forum	Cuker, A, Burnett, A, Triller, D, et al., (2019)		X				
Resumption of anticoagulant therapy after anticoagulant-related gastrointestinal bleeding: A systematic review and meta-analysis	Little D, Chai-Adisaksopha C, Hillis C, et al., (2019)		X				
The Scope and Value of an Anticoagulation Stewardship Program at a Community Teaching Hospital	Wychowski MK, Christina I. Ruscio CI, et al., (2017)					X	
University of Washington Medicine Anticoagulation Services Website	University of Washington Medicine Anticoagulation Services						X
What Are Anticoagulants and Antiplatelet Agents? Patient information sheet	American Heart Association (2017)						X

The Anticoagulation Forum Centers of Excellence Resource Center

The Joint Commission recognizes The **Anticoagulation Forum** as a key partner in providing resources relevant to anticoagulant therapy. The **Anticoagulation Centers of Excellence** is an online program of the Anticoagulation Forum, a multidisciplinary nonprofit organization of health care professionals that works to improve the quality of care for patients taking antithrombotic medications. The Anticoagulation Centers of Excellence program was created in 2012 to help healthcare professionals provide the highest level of care and achieve the best possible outcomes for their patients on antithrombotic medications.

There are two essential components to the Centers of Excellence program –

- An assessment tool to determine if a healthcare organization’s anticoagulation service is operating at the highest level, with recommendations and resources provided for specific areas that can be improved
- A comprehensive, searchable resource center that provides the guidelines and tools to improve towards excellence.

Users can search the Resource Center for resources related to specific Elements of Performance for Joint Commission NPSG 030501. <https://acforum-excellence.org/Resource-Center/>
Enter any of the terms EP1, EP2, EP3, EP4, EP5 or EP6 into the search tool to find resources specific to the NPSG.

In addition to many of the resources provided in this compendium the **Anticoagulation Forum Centers of Excellence Resource Center** provides multiple **examples of excellence** which showcase resources developed by a variety of health systems and hospitals to improve quality of care for their patients taking antithrombotic medications. Such example resources shared by other healthcare organizations include:

- Care process models
- Laboratory assays
- Bleeding management reversal decision trees
- Periprocedural clinical protocols
- Service operational policy and procedures
- Performance metrics report samples

The resource center is continually updated when new resources become available. There is no cost to participate in this program.