



Track: Hospital Medicine		
Body System: Hematologic-Immune		
Session Topic: Anticoagulation Management Update		
Educational Format		Faculty Expertise Required
REQUIRED	Interactive Lecture	Expertise in the field of study. Experience teaching in the field of study is desired. Preferred experience with audience response systems (ARS). Utilizing polling questions and engaging the learners in Q&A during the final 15 minutes of the session are required.
OPTIONAL	Problem-Based Learning (PBL)	Expertise teaching highly interactive, small group learning environments. Case-based, with experience developing and teaching case scenarios for simulation labs preferred. Other workshop-oriented designs may be accommodated. A typical PBL room is set for 50-100 participants, with 7-8 each per round table. <u>Please describe your interest and plan for teaching a PBL on your proposal form.</u>
Professional Practice Gap	Learning Objective(s) that will close the gap and meet the need	Outcome Being Measured
<ul style="list-style-type: none"> Family physicians should be familiar with the use of anticoagulants such as heparin, low-molecular-weight heparin, and warfarin to treat and prevent strokes and heart attacks. Family physicians should closely monitor patients taking warfarin to prevent serious bleeding problems and encourage patients to monitor themselves at home for potential adverse reactions or complications. Family physicians should be aware of patients' drug use and medical history to prevent adverse drug interactions associated with anticoagulants and effectively communicate possible risks to patients. Family physicians should know the recommended dosage and correct administration of warfarin, 	<ol style="list-style-type: none"> Utilize a systematic process of care, including initiation and assessment of therapy and dosing adjustments, to optimize effectiveness and minimize adverse effects of patients taking warfarin. Consider new agents in patients, with atrial fibrillation and at least one other risk factor for stroke, that do not require frequent laboratory monitoring are as effective as warfarin for prevention of stroke or systemic embolism and have comparable risks of major bleeding. Develop collaborative care plans with patient education to counsel patients on safe and effective self-administration of anticoagulants, emphasizing self-monitoring to prevent complications. Establish or revise existing practice-level protocols for anticoagulation management, based on current evidence-based recommendations and guidelines, including having clearly defined staff roles and responsibilities. 	Learners will submit written commitment to change statements on the session evaluation, indicating how they plan to implement presented practice recommendations.



<p>heparin, or newer anticoagulation agents and be prepared to instruct patients on how to administer and store the drugs safely at home.</p> <ul style="list-style-type: none"> Family physicians should remain aware of new pharmacologic methods for treatment and prevention of heart attack and stroke as they become available. 			
ACGME Core Competencies Addressed (select all that apply)			
X	Medical Knowledge	X	Patient Care
	Interpersonal and Communication Skills		Practice-Based Learning and Improvement
	Professionalism		Systems-Based Practice
Faculty Instructional Goals			
<p>*NOTE TO FACULTY - This topic is part of the Hospital Medicine Track. Associated topics include: Atrial Fibrillation; Sepsis; Skin Infections; & Clostridium Difficile.</p> <p>Expectation:</p> <ol style="list-style-type: none"> 1. Include an appropriate focus on inpatient care (up to 100%) 2. Collaborate with faculty from associated topics (above) 			
<p>Faculty play a vital role in assisting the AAFP to achieve its mission by providing high-quality, innovative education for physicians, residents and medical students that will encompass the art, science, evidence and socio-economics of family medicine and to support the pursuit of lifelong learning. By achieving the instructional goals provided, faculty will facilitate the application of new knowledge and skills gained by learners to practice, so that they may optimize care provided to their patients.</p> <ul style="list-style-type: none"> Provide up to 3 evidence-based recommended practice changes that can be immediately implemented, at the conclusion of the session; including SORT taxonomy & reference citations Facilitate learner engagement during the session Address related practice barriers to foster optimal patient management Provide recommended journal resources and tools, during the session, from the American Family Physician (AFP), Family Practice Management (FPM), and Familydoctor.org patient resources; those listed in the <u>References</u> section below are a good place to start <ul style="list-style-type: none"> Visit http://www.aafp.org/journals for additional resources Visit http://familydoctor.org for patient education and resources Provide specific strategies and evidence-based recommendations to assist physician-learners in devising a systematic processes of care, including initiation and assessment of therapy and dosing adjustments, to optimize effectiveness and minimize adverse effects of patients taking warfarin Provide evidence-based recommendations for new agents in patients, with atrial fibrillation and at least one other risk factor for stroke, that do not require frequent 			



laboratory monitoring are as effective as warfarin for prevention of stroke or systemic embolism and have comparable risks of major bleeding

- Provide specific strategies and resources to assist physician-learners in devising patient education to counsel patients on safe and effective self-administration of anticoagulants, emphasizing self-monitoring to prevent complications
- Utilize case-based examples to illustrate key aspects of key evidence-based recommendations during the presentation.
- Provide recommendations regarding guidelines for Medicare reimbursement.
- Provide recommendations to maximize office efficiency and guideline adherence to anticoagulation therapy.
- Provide an overview of newly available treatments, including efficacy, safety, contraindications, and cost/benefit relative to existing treatments.
- Provide instructions regarding the incorporation and use of the PCMH/ACO/Primary Care Core Measure Set into practice.

Needs Assessment:

It is estimated that more than 81 million Americans have one or more types of cardiovascular disease (CVD), such as coronary artery disease (CAD), heart failure, and stroke. CVD serves as the leading cause of death for both men and women in the US, accounting for one of every 2.9 deaths—more than cancer, lower respiratory diseases, and accidents combined.¹ Effective anticoagulant therapy is critical in the management of coagulation disorders. Stroke, for example, is a leading cause of death in the U.S., and is a leading cause of serious, long-term disability. Of all strokes, 87% are ischemic, 10% are intracerebral hemorrhage and 3% are subarachnoid hemorrhage. More than 6.5 million people have been affected by some form of a stroke – either first-time or recurring – and blacks have almost twice the risk of first-time strokes than whites.² Additionally, the annual incidence of venous thromboembolism (VTE), which includes deep venous thrombosis and pulmonary embolism, is one or two per 1,000 persons; and within one month of diagnosis, the mortality rate is approximately 6 percent in patients with DVT and 12 percent in patients with pulmonary embolism.^{3,4}

Data from the 2012 American Academy of Family Physicians (AAFP) CME Needs Assessment Survey indicate that while family physicians report having sufficient clinical knowledge and skill to effectively manage anticoagulation therapy generally, there is evidence that family physicians have medical knowledge and skill gaps related to managing cardiovascular pharmacology and conditions such as atrial fibrillation and thromboembolic disease.⁵ Additionally, CME outcomes data from the 2012, 2014-2016 AAFP FMX (formerly Assembly): *Anticoagulation* sessions suggest that family physicians have knowledge and practice gaps with regard to the monitoring and adjustment of anticoagulant therapy dosage; understanding new anticoagulant alternatives and when they are recommended over traditional warfarin; how to develop collaborative care plans with shared decision making; proper use of bleeding risk assessment (e.g. CHADs); and establishing practice-level protocols for anticoagulant management based on current guidelines.⁶⁻⁹

A review of the literature suggests that patients with venous thromboembolism (VTE) who were treated with a direct oral anticoagulant (DOAC) found that dosing differed from the recommended product dosing in 20 to 50 percent of cases, depending on the agent.¹⁰



As bleeding risks are always a concern when using anticoagulation agents, some physicians are reluctant to prescribe warfarin to avoid bleeding, but studies have shown that it prevents 20 strokes for every bleeding episode it causes. Because warfarin has a complex dose-response relationship, family physicians need to understand the drug's pharmacology.^{11,12} Perioperative management of patients receiving an anticoagulant is often challenging because the risks of bleeding and thromboembolism are both increased; therefore, physicians need to be kept up to date on evidence-based recommendations regarding if and how warfarin interruption for surgery should be managed.^{13,14}

Additionally, physicians need continuing medical education to stay abreast of many newer anticoagulants as they have the potential to change the management of coagulation disorders.¹⁴ Physicians are also in need of continuing medical education that assists them with incorporating new evidence-based clinical guidelines (e.g. American College of Chest Physicians Guidelines on Outpatient Management of Anticoagulation Therapy) into their practice-level protocols for anticoagulant management, as some evidence suggests inconsistent adherence to prior evidence-based recommendations and guidelines.¹⁴⁻¹⁷

Research shows that four out of 10 adults use some form of complementary or alternative therapies (also known as integrative medicine).¹⁸ Fifty percent of patients seeing family physicians are using some form of complementary and alternative medicine, and most patients are hesitant to share information about the CAM therapies they're using with their physicians; therefore, physicians are encouraged to use open-ended questions and avoid using terms that patients may perceive as biased.¹⁹ As deleterious effects are highly pronounced with anticoagulants, physicians must have strategies in place for monitoring patient use of herbs, vitamins, dietary supplements, OTC and prescription medications, and foods that may interact with prescribed anticoagulation therapy.^{14,20} Physicians should also have protocols in place to monitor patients who are at higher risk of bleeding, particularly elderly patients taking multiple medications. A recent Cochrane review indicated that Warfarin (Coumadin), insulin, and digoxin accounted for one in three of ER visits, by older patients, because of an adverse drug event, whereas drugs on the Beers list accounted for less than 9 percent. The rate of adverse drug events may be reduced by using validated risk calculators for bleeding in patients taking warfarin, setting less stringent goals for A1C levels in older patients with comorbidities, and avoiding high doses of digoxin or use of the drug without proper indications.²¹

Data from the 2012 AAFP CME Needs Assessment Survey indicates that family physicians have statistically significant and meaningful gaps in medical knowledge to understand how they are impacted by FDA Risk Evaluation and Mitigation (REMS) and how to effectively manage REMS requirements.⁵ In 2011, the FDA called for a risk evaluation and mitigation strategy, or REMS, for the oral anticoagulant drug rivaroxaban (Xarelto), due to increased risk an increased risk of thrombotic events, including stroke, if the drug is discontinued without introducing an adequate alternative anticoagulant, as well as a potential decreased efficacy of the 15 mg and 20 mg tablets if the drug is not taken with an evening meal.²² Physicians should check for FDA REMS and MedWatch for anticoagulation agents before prescribing.^{23,24}



Initiation of oral anticoagulation therapy (OAT) is low among incident atrial fibrillation (AF) patients, despite evidence-based guidelines.²⁵ A patient-centered medical home model may provide the optimal structure for anticoagulation management, with evidence that self-monitoring and self-management of long-term oral anticoagulation therapy reduce the risks of thromboembolism, all-cause mortality, and minor hemorrhage for appropriately selected patients; however, many physicians have not been trained to engage patients in successful self-management.^{14,16,25-27} Physicians should be encouraged to utilize AMA PCPI Performance Measures for *Stroke and Stroke Rehabilitation* and *Atrial Fibrillation and Atrial Flutter* to improve the quality of anticoagulation management; with the ultimate goal of improved patient care.²⁸

Physicians should also be kept up to date on novel oral anticoagulants (NOACs), changes to therapies, or warnings associated with existing therapies. Provide recommendations regarding new FDA approved medications for the treatment of relevant conditions (e.g. atrial fibrillation, artificial heart valve, deep vein thrombosis, pulmonary embolism, clotting disorders, stroke, heart attack, etc.); including safety, efficacy, tolerance, and cost considerations relative to currently available options. Examples include, but are not limited to:²⁹

- Savaysa (edoxaban); Daiichi Sankyo; For the treatment of deep vein thrombosis, pulmonary embolism and risk of stroke and embolism due to atrial fibrillation, Approved January 2015
- Eliquis (apixaban); Bristol-Myers Squibb; For the prevention of stroke and systemic embolism resulting from nonvalvular atrial fibrillation, Approved December 2012
- Xarelto (rivaroxaban); Bayer; For the prophylaxis of deep vein thrombosis during knee or hip replacement surgery, Approved July 2011
- Pradaxa (dabigatran etexilate mesylate); Boehringer Ingelheim; For the risk reduction of stroke and embolism due to atrial fibrillation, Approved October 2010
- Pentoxifylline; Faulding, Mylan Laboratories; Generic equivalent of Trental, Approved July 1997
- Pletal (cilostazol); Cadila Pharmaceuticals Ltd.; the alleviation of the symptoms of intermittent claudication in individuals with peripheral vascular disease, Approved January 1999

Diabigatran, apixaban, and rivaroxaban have been approved for primary and secondary stroke prevention in patients with atrial fibrillation; however, there are questions regarding how to manage emergency situations, as well as in obese patients.³⁰ Physicians should become familiar with the International Society of Thrombosis and Haemastasis guidelines for direct oral anticoagulation therapy.^{30,31}

Physicians are in need of specific strategies and resources to assist them in with incorporating the following evidence-based recommendations into their practice-level protocols for anticoagulation management:^{4,14,32-35}

- Patients taking warfarin (Coumadin) should be treated using systematic processes of care to optimize effectiveness and minimize adverse effects. Health care professionals skilled in the initiation and assessment of therapy and dosing adjustments can dramatically influence outcomes.



- In patients with atrial fibrillation and at least one other risk factor for stroke, newer agents (rivaroxaban [Xarelto] and dabigatran [Pradaxa]) that do not require frequent laboratory monitoring are as effective as warfarin for prevention of stroke or systemic embolism and have comparable risks of major bleeding.
- Compared with usual clinic-based care, patient self-testing for international normalized ratios, with or without self-dosing of warfarin, is associated with significantly fewer deaths and thromboembolic complications without any increase in bleeding complications for a selected group of motivated patients who have completed appropriate training.
- Clinical factors, such as whether the deep venous thrombosis was confined to a distal or proximal vein, whether the thrombotic episode was an initial or recurrent event, or whether transient risk factors were present, should determine duration of anticoagulant therapy in patients with VTE.
- Patients with a VTE and cancer should be treated with low-molecular-weight heparin for at least the first three to six months of long-term anticoagulation therapy. Subsequent treatment with low-molecular-weight heparin or vitamin K antagonist should be continued for as long as the cancer is active.
- An Outpatient Bleeding Risk Index (e.g. CHADS₂, VASc) and evidence-based decision rules to predict bleeding risk in patients taking warfarin should be utilized when considering anticoagulation therapy in patients with atrial fibrillation or venous thromboembolism (VTE); physicians and patients must balance the benefits of anticoagulation with the risk of bleeding, particularly major bleeding complications.
- Rhythm control of atrial fibrillation through electrical or pharmacologic cardioversion requires anticoagulation therapy three weeks before and four weeks after cardioversion.
- Warfarin (Coumadin) is more effective than aspirin in preventing thromboembolic events in patients with atrial fibrillation, although it confers a higher risk of bleeding. Warfarin is superior to aspirin plus clopidogrel (Plavix) and confers the same risk of bleeding. Adding full-dose aspirin to warfarin should be avoided because of the increased risk of bleeding.
- Patients with nonvalvular atrial fibrillation who are at low risk of stroke can be treated with 81 to 325 mg of aspirin per day.
- Aspirin (162 to 325 mg per day) should be given to all patients with suspected acute MI and continued indefinitely at a dosage of 75 to 162 mg per day upon discharge.
- Clopidogrel (Plavix), prasugrel (Effient), and ticagrelor (Brilinta) are recommended in combination with aspirin for a minimum of 12 months in patients receiving drug-eluting stents, and for up to 12 months in patients receiving bare metal stents.
- Clopidogrel and ticagrelor are recommended for conservative medical management of MI in combination with aspirin (162 to 325 mg per day) for up to 12 months.

Physicians should be knowledgeable of key changes in the ninth edition of the ACCP guidelines on outpatient management of anticoagulation therapy, and their implication to practice protocols.¹⁴ Additionally, physicians following the ACCP 9th ed: evidence-based clinical practice guidelines should be aware of a correction in a dose in last paragraph of section 1.1.3 on page e27S. The text should read maximum of 1,000 units/h rather than 1,000 units/kg/hr.³⁶



These recommendations are provided only as assistance for physicians making clinical decisions regarding the care of their patients. As such, they cannot substitute for the individual judgment brought to each clinical situation by the patient's family physician. As with all clinical reference resources, they reflect the best understanding of the science of medicine at the time of publication, but they should be used with the clear understanding that continued research may result in new knowledge and recommendations. These recommendations are only one element in the complex process of improving the health of America. To be effective, the recommendations must be implemented. As such, physicians require continuing medical education to assist them with making decisions about specific clinical considerations.

The American Academy of Family Physicians Academy has participated in the Core Measures Collaborative (the Collaborative) convened by America's Health Insurance Plans (AHIP) since August 2014. The Collaborative is a multi-stakeholder effort working to define core measure sets of various specialties promoting alignment and harmonization of measure use and collection across both public and private payers.

Participants in the Collaborative included Centers for Medicare and Medicaid Services (CMS), the National Quality Forum (NQF), private payers, provider organizations, employers, and patient and consumer groups. This effort exists to decrease physician burden by reducing variability in measure selection, specifications and implementation—making quality measurement more useful and meaningful for consumers, employers, as well as public and private clinicians.

With significant AAFP input, a PCMH/ACO/Primary Care Core Measure Set has been developed for primary care. The goal of this set is to decrease burden and allow for more congruence between payer reporting programs.³⁷

Resources: Evidence-Based Practice Recommendations/Guidelines/Performance Measures

- Updated guidelines on outpatient anticoagulation¹⁴
- ACCP Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines³⁴
- International Society of Thrombosis and Haemastasis Recommendations for the emergency management of complications associated with the new direct oral anticoagulants (DOACs), apixaban, dabigatran and rivaroxaban^{30,31}
- Oral anticoagulants vs. antiplatelet therapy¹²
- Atrial fibrillation: diagnosis and treatment³³
- Myocardial infarction: management of the subacute period³⁵
- Reducing the risk of adverse drug events in older adults³⁸
- Diagnosis of deep venous thrombosis and pulmonary embolism³
- Recurrent venous thromboembolism⁴
- Herbal and dietary supplement--drug interactions in patients with chronic illnesses²⁰
- Complementary and alternative medicine: a primer¹⁹
- Appropriate use of polypharmacy for older patients²¹
- Perioperative antiplatelet therapy³⁹
- FDA Approved Risk Evaluation and Mitigation Strategies (REMS)²³



- FDA MedWatch: The FDA Safety Information and Adverse Event Reporting Program²⁴
- Self-monitoring and self-management of anticoagulation therapy²⁷
- Predicting the risk of bleeding in patients taking warfarin³²
- Engaging Patients in Collaborative Care Plans²⁶
- Health coaching for patients with chronic illness⁴⁰
- A systematic approach to managing warfarin doses⁴¹
- Medication adherence: we didn't ask and they didn't tell⁴²
- Envisioning new roles for medical assistants: strategies from patient-centered medical homes⁴³
- FamilyDoctor.org - Seniors: Managing Your Medications (patient education)⁴⁴
- FamilyDoctor.org. Deep Vein Thrombosis | Treatment (patient education)⁴⁵
- FamilyDoctor.org. Herbal Products and Supplements (patient education)⁴⁶
- FamilyDoctor.org. Hypercoagulation | Overview (patient education)⁴⁷

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