

ANTICOAGULATION THERAPY MANAGEMENT

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive outlines policy and procedures for optimal management of patients receiving anticoagulation therapy
- 2. SUMMARY OF MAJOR CHANGES:** The most significant changes include:
 - a. Re-defined roles and responsibilities for the Anticoagulation Management Program at the facility level;
 - b. Required elements for the Anticoagulation Management Program;
 - c. Expanded definition of the term anticoagulant as any medication that inhibits blood coagulation to include, but not limited to, warfarin, unfractionated heparin, low molecular weight heparin, other parenteral anticoagulants (e.g., fondaparinux, argatroban), and target-specific anticoagulants; and
 - d. Updated requirements for the facility anticoagulation quality assurance plan.
- 3. RELATED ISSUES:** VHA Handbook 1106.01.
- 4. RESPONSIBLE OFFICE:** The Chief Consultant, Pharmacy Benefits Management (PBM) Service (10P4P) in the Office of Patient Care Services, is responsible for the content of this Directive. Questions may be addressed to 202-461-7326.
- 5. RESCISSIONS:** VHA Directive 2010-020, dated May 14, 2010, is rescinded.
- 6. RECERTIFICATION:** This VHA Directive is scheduled for recertification on or before the last working day of July 2020.

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DISTRIBUTION: Emailed to the VHA Publications Distribution List on 07/30/2015.

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1. PURPOSE: This Veterans Health Administration (VHA) Directive outlines policy and procedures for optimal management of patients receiving anticoagulation therapy.

AUTHORITY: 38 U.S.C. 7301(b).

2. BACKGROUND:

a. Anticoagulants are commonly used for both the treatment and prevention of cardiac disease, cerebrovascular accident, and thromboembolism in both the inpatient and outpatient setting. Although these medications can confer substantial benefits, their use or misuse, carries a significant potential for patient harm. Subtherapeutic levels can increase the risk of thromboembolic complications while supratherapeutic levels can increase the risk of bleeding complications.

b. Anticoagulants have been implicated in adverse drug events due to many factors such as complexity of dosing and monitoring, patient compliance, and numerous drug-drug and drug-food interactions. The National Center for Patient Safety (NCPS) continually reviews root cause analysis reports involving adverse events related to anticoagulation therapy. NCPS reports the lack of communication between providers about anticoagulation treatment plans has been identified as an area of vulnerability. The Joint Commission National Patient Safety Goal (NPSG) 3.05.01 focuses on improving anticoagulation safety to reduce patient harm and states "...anticoagulation medications are more likely than others to cause harm due to complex dosing, insufficient monitoring, and inconsistent patient compliance." The rationale offered suggests outcomes improvements facilities may achieve through development of patient education, face-to-face interaction between patient and clinician, utilizing trained professionals to manage anticoagulation, and consistent application of standardized practices.

c. Laboratory monitoring is a key component of safe anticoagulant therapy management with warfarin. Results for International Normalized Ratio (INR) testing may vary dependent on the methods used (e.g., accredited laboratory, point of care testing (POCT) device or patient self-testing device); the competency of the person performing the test; and the accuracy of the testing equipment or device.

d. Appropriate staffing of the anticoagulation management program is essential to achieving optimal patient care outcomes and improves operational efficiency. Evidence has shown that a simple numerical ratio of anticoagulation provider full-time equivalent (FTE) to patients does not fully capture whether staffing is adequate or appropriate. It is important to consider the number, type, and training of anticoagulation support staff (including clinical pharmacy technicians, nurses, and others) in addition to anticoagulation providers, in determining appropriate staffing. Many of the day-to-day activities in an anticoagulation clinic can be performed by properly trained support staff, including answering and triaging patient telephone calls, contacting patients who have missed appointments, sending letters to patients, communicating with outside laboratories, and other similar tasks. Accordingly, with minimal or lack of support staff, much of the day-to-day activities described above will necessarily be performed by

anticoagulation providers rather than spending time on clinical decision making, thus reducing operational efficiency and requiring a higher provider-to-patient ratio. It is also important to consider that several other factors have been shown to affect outcomes achieved in anticoagulation clinics, including standardized practices, integrated quality assurance plans, identified anticoagulation champions, and an emphasis on ongoing learning and quality improvement.

3. POLICY: It is VHA policy that each parent VA medical facility must have a defined anticoagulation management program that meets the standards identified in this Directive. Providing high-quality, evidence-based management of anticoagulants will reduce the likelihood of patient harm.

4. RESPONSIBILITIES:

a. **VA Medical Facility Director.** The VA medical facility Director is responsible for ensuring:

(1) A medical facility policy exists at the facility that meets all standards identified in this Directive, Appendix A. An interprofessional approach should be utilized in accordance with this policy to ensure the safe management of anticoagulation therapy.

(2) The medical facility has an established anticoagulation management program for management of inpatients and outpatients on anticoagulants.

(3) An Anticoagulation Program Manager has been designated to lead the medical facility's anticoagulation management program and has been provided with appropriate time to fulfill these duties consistent with the complexity of the local anticoagulation program. **NOTE:** *The role of the anticoagulation program manager involves a considerable time commitment and the dedicated effort of a highly committed individual ensures a program that is high functioning, successful, and sustainable.*

(4) Adequate staff and resources are allotted for the anticoagulation management program to include anticoagulation providers, nurses, pharmacy technicians, registered dietitian/nutritionists, program administration, and information technology support, as appropriate. This includes ensuring anticoagulation providers have adequate anticoagulation support staff to work at the top of their license and maximize operational efficiency. For an anticoagulation management program to be successful, active leadership and ongoing maintenance is required.

(5) The anticoagulation management program has an appropriate staff-to-patient ratio to provide safe and appropriate care as defined in Appendix A.

(6) Competencies specific to anticoagulation management are established for anticoagulation providers and clinical staff directly involved in caring for patients receiving anticoagulation therapy. Competencies, at a minimum, must include knowledge of standard terminology, pharmacology of anticoagulants, monitoring requirements, dose calculations, common side effects, nutrient interactions, and drug to drug interactions associated with anticoagulation therapy.

(7) The medical facility ensures care is coordinated for traveling patients on anticoagulants in accordance with VHA Handbook 1101.11, Coordinated Care Policy for Traveling Veterans, or subsequent policy issue.

(8) For medical facilities employing INR Patient self-testing, a written policy is in place that includes a systems assessment for safety prior to implementation and is in compliance with all applicable laboratory accreditation standards and policies.

(9) The medical facility uses programmable infusion pumps for inpatients receiving parenteral anticoagulants, including, but not limited to unfractionated heparin, argatroban, and bivalirudin.

(10) The medical facility employs standardized, evidence-based, algorithms for the management of patients on anticoagulants as defined in Appendix A.

(11) Anticoagulants are included on the medical facility's list of high-alert medications.

b. **Facility Chief of Staff and Associate Director for Patient Care Services.** The facility Chief of Staff and Associate Director for Patient Care Services (PCS) is responsible for:

(1) Ensuring that a physician is identified as anticoagulation management champion, to be actively involved in defined components of the anticoagulation management program. This champion will serve collaboratively with the pharmacy anticoagulation management champion to advocate for, provide consultation on anticoagulation issues, and support anticoagulation initiatives at the facility level. **NOTE:** *In the event a facility-level physician lead cannot be identified, a Veterans Integrated Service Network (VISN)-level physician champion may be utilized.*

(2) Ensuring that all medical facility policies governing the provision of anticoagulation management are approved by the Executive Committee of the Medical Staff (ECMS). Anticoagulation providers will collaborate in the development of medical facility guidelines/algorithms for anticoagulants.

(3) Ensuring that clinical staff directly involved in caring for patients receiving anticoagulation therapy (e.g., nurses, clinical pharmacists, pharmacy technicians, registered dietitian/nutritionists, Advanced Practice Registered Nurses (APRN), physician assistants, and physicians) are educated on the importance of anticoagulation safety and its associated risks, as well as the principles of anticoagulation management, as appropriate.

(4) Reviewing quality assurance (QA) information for the facility anticoagulation management program at appropriate and regular intervals through the Pharmacy and Therapeutics (P&T) Committee (or appropriate facility governing body) and ECMS, as appropriate.

(5) Ensuring the competency of non-pharmacist anticoagulation providers and clinical staff directly involved in caring for patients receiving anticoagulation therapy to include minimum components outlined in paragraph 4.a.(6).

(6) Ensuring that anticoagulation providers have adequate anticoagulation support staff (e.g., pharmacy technicians or other anticoagulation staff) to maximize operational efficiency.

c. **Facility Chief Pharmacy Service.** The facility Chief, Pharmacy Service, is responsible for:

(1) Ensuring that a clinical pharmacist anticoagulation provider is identified as the pharmacy anticoagulation management champion to be actively involved in defined components of the anticoagulation program at the facility level. This champion may be the anticoagulation program manager and serves to advocate for and support anticoagulation initiatives at the facility.

(2) Assessing the competency of clinical pharmacist anticoagulation providers and pharmacy technicians who serve in the anticoagulation management program to include the minimum components outlined in paragraph 4.a.(6).

(3) Ensuring clinical pharmacists that serve as anticoagulation providers have adequate anticoagulation support staff to work at the top of their license and maximize operational efficiency. Tasks that support the duties of the clinical pharmacist may be performed by pharmacy technicians or other anticoagulation support staff to maximize time for clinical pharmacists to perform direct patient care.

(4) Ensuring that only oral unit dose products, pre-filled syringes, or pre-mixed infusion bags for anticoagulants are dispensed for inpatients when these types of products are available.

(5) Ensuring that the number of concentrations and quantities of heparin vials stocked in patient care and procedural areas are limited to the minimum needed to meet patient care needs. No multi-dose heparin product more concentrated than 5,000 units per milliliter is stocked without the prior approval of the Chief of Pharmacy.

(6) Ensuring the safe storage of anticoagulants in automated dispensing devices if the medical center uses automated dispensing devices to store anticoagulants. If multiple strengths or concentrations of the same anticoagulant are stored in the same automated dispensing device they need to be stored in separate drawers (or single access cubie) and clearly labeled as high alert medications.

d. **Facility Chief, Nutrition and Food Services.** The facility Chief, Nutrition and Food Services is responsible for ensuring that:

(1) Warfarin is included in Nutrition and Food Services' established food and medication interaction program.

(2) A process is established to notify Nutrition and Food Services of patients receiving meal services that are also receiving warfarin therapy.

(3) Nutrition and Food Services responds according to its established food and medication interaction program to patients receiving meal services and warfarin therapy. Meal planning and educational efforts are focused on steady Vitamin K intake, individualized to meet the overall health needs, and supporting an adequate dietary reference intake for Vitamin K.

e. **Facility Chief or Director, Pathology and Laboratory Medicine Service.** The facility Chief or Director, Pathology and Laboratory Medicine Service is responsible for:

(1) Ensuring a critical INR value is established and listed in the Laboratory Veterans Health Information System and Technology Architecture (VistA) software package.

(2) Establishing a Standard Operating Procedure, in conjunction with the anticoagulation program manager, for the communication of critical INR results from the laboratory to the ordering provider (or designee).

(3) Ensuring the correct International Sensitivity Index (ISI) value for the lot number of thromboplastin, currently in use, is entered into the coagulation testing instrumentation.

(4) Ensuring there is documentation of periodic monitoring to ensure the entered value remains accurate.

(5) Ensuring the correct Geometric Mean Prothrombin Time (PT) is calculated for the current lot number of thromboplastin and is entered into the coagulation testing instrumentation as required for calculation of the INR. The Geometric Mean PT needs to be recalculated with each change of lot number of thromboplastin reagent.

(6) Ensuring the availability of reliable testing of heparin levels (factor Xa levels), heparin associated antibodies and a serotonin release assay for the evaluation of heparin induced thrombocytopenia.

(7) Ensure the availability of appropriate laboratory tests for Target Specific Oral Anticoagulants (TSOAC) in special situations (e.g., suspected overdose, bleeding, urgent procedure, etc.).

(8) Educating staff providing clinical services in an outpatient anticoagulant clinic and staff involved in home anticoagulation therapy management on national and local Laboratory policies related to POCT and patient self-testing.

f. **Facility Ancillary Testing Coordinator.** The facility ancillary testing coordinator is responsible for:

(1) Assessing the competency of staff involved in ancillary testing; and

(2) Documenting training, authorization, and annual competence evaluation for all staff that perform ancillary testing.

g. **Facility Anticoagulation Program Manager.** The facility anticoagulation program manager is responsible for the following functions related to the anticoagulation program at the facility level:

(1) Serving as a leader or co-leader and subject matter expert in the oversight, design, implementation, and function of the anticoagulation management program.

(2) Developing medical facility policy related to use of anticoagulants. This encompasses policies to govern practice within the anticoagulation management program, but may also include policies relating to the use of anticoagulants in other areas (e.g., surgical or specialty areas), as directed by the ECMS. A multidisciplinary approach to policy development should be employed to include meeting with all disciplines involved in caring for patients receiving anticoagulants to assist with unified practice and education to patients.

(3) Promoting learning and unified practice for the anticoagulation management program through activities such as educational initiatives, regular staff meetings, and journal clubs.

(4) Coordinating and reporting quality assurance activities and results for the anticoagulation management program through the P&T Committee (or appropriate facility governing body) and ECMS, as appropriate.

(5) Coordinating the facility educational program for clinical staff directly involved in caring for patients receiving anticoagulation therapy (e.g. clinical pharmacists, pharmacy technicians, registered dietitians/nutritionists, nurses, APRNs, physician assistants, and physicians).

(6) Ensuring availability of appropriate patient education materials and classes, as applicable.

h. **Facility Anticoagulation Providers.** The facility anticoagulation providers are responsible for:

(1) Managing anticoagulation patients in accordance with facility and VHA policy including, but not limited to, coordination of anticoagulation management for patients transitioning between care settings (e.g., inpatient to outpatient), peri-procedural anticoagulation, and traveling Veterans.

(2) Serving as subject matter experts on anticoagulation management to patients and health care professionals throughout the facility.

(3) Delivering initial and ongoing patient and family education that includes the importance of follow-up monitoring, compliance issues, dietary restrictions, and potential for adverse drug reactions and interactions.

(4) Conducting appropriate and periodic risk-benefit assessments for all patients receiving anticoagulant therapy and communicating recommendations to the original referring provider and/or Patient Aligned Care Team (PACT) provider as appropriate.

(5) Performing and/or facilitating the day-to-day operations of the anticoagulation management program.

(6) Reporting, as per local policy, adverse drug events (ADE), close calls, and any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an adverse event or close call to the facility Patient Safety Manager (PSM) in accordance with VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, or subsequent policy issue.

5. REFERENCES:

- a. VHA Directive 1070, Adverse Drug Event Reporting and Monitoring.
- b. VHA Directive 2009-019, Ordering and Reporting Test Results.
- c. VHA Handbook 1100.19, Credentialing and Privileging.
- d. VHA Handbook 1101.10, Patient Aligned Care Team (PACT) Handbook.
- e. VHA Handbook 1101.11, Coordinated Care Policy for Traveling Veterans.
- f. VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures.
- g. VHA Handbook 1108.05, Outpatient Pharmacy Services.
- h. VHA Handbook 1108.06, Inpatient Pharmacy Services.
- i. VHA Handbook 1108.11, Clinical Pharmacy Services.
- j. Antithrombotic Therapy and Prevention of Thrombosis, 9th edition: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. CHEST. 2012; 141(2): February Supplement.
- k. National Patient Safety Goals 2014, The Joint Commission http://www.jointcommission.org/assets/1/6/HAP_NPSG_Chapter_2014.pdf
- l. Rose AJ, Berlowitz DR, Miller DR, et al. INR targets and site-level anticoagulation control: results from the Veterans Affairs Study to Improve Anticoagulation (VARIA). *J Thromb Haemost* 2012; 10: 590–5.
- m. Rose AJ, Hylek EM, Berlowitz DR, et al. Prompt Repeat Testing After Out-of-Range INR Values A Quality Indicator for Anticoagulation Care. *Circ Cardiovasc Qual Outcomes*. 2011;4:276-282.

n. Rose AJ, Hylek EM, Oronoff A, et al. Risk-Adjusted Percent Time in Therapeutic Range as a Quality Indicator for Outpatient Oral Anticoagulation, Results of the Veterans Affairs Study To Improve Anticoagulation (VARIA). *Circ Cardiovasc Qual Outcomes*. 2011;4:22-29.

o. Rose AJ, Miller DR, Oronoff A, et al. Gaps in Monitoring During Oral Anticoagulation, Insights Into Care Transitions, Monitoring Barriers, and Medication Nonadherence. *CHEST* 2013; 143(3):751–757.

p. Rose AJ, Petrakis BA, Callahan P, et al. Organizational Characteristics of High- and Low-Performing Anticoagulation Clinics in the Veterans Health Administration. *HSR: Health Services Research* 2012; 47:4: 1541-1560.

6. DEFINITIONS:

a. **Algorithm.** The term algorithm refers to a standardized care process which outlines steps used to manage a patient's anticoagulation therapy and utilized across the facility. Algorithms must be evidence-based, approved by the Pharmacy and Therapeutics (P&T) Committee and ECMS, and follow the guidance included in this directive. An algorithm may contain protocols which are outlined in policy that outline specific actions to be implemented based on patient parameters by designated individuals for anticoagulation patient care management, e.g., unfractionated heparin protocols by nursing staff. Any actions or processes outlined in algorithms or protocols must be within the scope of practice of the individual performing the function and competency must be assessed on an ongoing basis as appropriate.

b. **Ancillary Testing.** Ancillary testing is defined as laboratory testing or services performed within a VA medical facility or its outreach functions (clinic, et al.), but outside the physical facilities of the main clinical laboratory. It is often referred to as point-of-care testing (POCT).

c. **Anticoagulant.** The term anticoagulant refers to a medication that inhibits blood coagulation. Anticoagulants include, but are not limited to, warfarin, unfractionated heparin, low molecular weight heparin, other parenteral anticoagulants (e.g., fondaparinux, argatroban), and target-specific anticoagulants (TSOAC) such as dabigatran, rivaroxaban, or apixaban. For purposes of this directive, the term "anticoagulant" refers to anticoagulation therapy or long-term anticoagulation prophylaxis (e.g., atrial fibrillation) and does not include routine situations in which short-term prophylactic anticoagulation is used for venous thromboembolism prevention (e.g., related to procedures or hospitalization). In addition, medications whose primary purpose is to inhibit platelet function are not included under this definition.

d. **Anticoagulation Management Program.** The term anticoagulation management program, often commonly referred to as an "anticoagulation clinic", refers to a coordinated program where anticoagulation providers manage anticoagulants for inpatients and outpatients within the facility. In addition to the clinical practice aspect, the program also encompasses broader functions including coordinating policy and quality assurance relevant to anticoagulation management at the facility.

e. **Anticoagulation Provider.** The term anticoagulation provider refers to a provider who is currently trained and skilled in managing anticoagulant therapy. Anticoagulation providers may be clinical pharmacists, Advanced Practice Registered Nurses (APRN), physician assistants, and/or physicians. The anticoagulation provider is an active member of the anticoagulation management program, responsible to monitor the quality of his or her clinical practice, and has prescriptive authority defined in their scope of practice or clinical privileges that includes anticoagulants.

f. **Anticoagulation Program Manager.** The anticoagulation program manager is an anticoagulation provider that serves as a leader for the anticoagulation management program and is responsible for ensuring that the program meets all elements in this directive. This individual maintains a high standard for continuing education in the area of anticoagulation therapy and serves as a local subject matter expert regarding anticoagulation management. The anticoagulation program manager collaborates with other services to ensure that the anticoagulation management program meets all standards outlined in this directive. The anticoagulation program manager is generally a clinical pharmacist with a scope of practice, however other providers may be designated based on local facility needs.

g. **Anticoagulation Support Staff.** Anticoagulation support staff refers to a group of professionals assigned to the anticoagulation management program who perform day-to-day operational support functions. Anticoagulation support staff may include, but are not limited to, pharmacy technicians, nurses, health technicians, and clerical associates. Anticoagulation support staff may assist with many of the technical issues associated with the anticoagulation management program under the supervision of an anticoagulation provider. All anticoagulation support staff must have functional statements, coupled with a competency assessment that accurately reflects the job responsibilities and tasks they perform. Responsibilities may include, but are not limited to, answering and triaging patient telephone calls, contacting patients who have missed appointments, sending letters to patients, communicating with outside laboratories, and other similar tasks.

h. **Bridge Therapy.** Bridge therapy is the temporary use of a short and immediate acting injectable anticoagulant (usually a heparin) during periods when the INR level is sub-therapeutic (e.g., when warfarin therapy is started) or when warfarin is being held in order to perform invasive procedures (peri-procedural bridging).

i. **Geometric Mean PT.** The Geometric Mean PT is a calculation of the mean PT for the laboratory patient population using the current Thromboplastin Reagent. It is used to calculate the INR.

j. **International Normalized Ratio (INR).** INR is a standardized measure of the PT, which is used to determine the clotting tendency of blood for a patient receiving warfarin therapy. The INR is the ratio of a patient's PT to a normal (control) sample, raised to the power of the ISI value for the reagent system used.

k. **International Sensitivity Index (ISI)**. ISI is a measure of Thromboplastin sensitivity to an international standard. Each lot number of Thromboplastin used in Prothrombin or INR testing is assigned its own unique ISI value from the manufacturer.

l. **Parent Facility**. The term parent facility, also called the primary facility, refers to a VA medical facility that has a three-digit Station Number. A parent facility may be a stand alone medical facility, or it may be the parent facility of an integrated set of facilities, often called a healthcare network.

m. **Target Specific Oral Anticoagulant**. A Target Specific Oral Anticoagulant (TSOAC) encompasses several drug classes, and includes, but is not limited to, dabigatran, rivaroxaban, and apixaban. TSOAC refers to oral anticoagulant medications that target one or more specific steps in the coagulation cascade.

REQUIRED COMPONENTS OF THE ANTICOAGULATION MANAGEMENT PROGRAM

In addition to required elements contained in this Directive, the following are minimum components for the anticoagulation management program.

1. ORGANIZATION OF THE ANTICOAGULATION MANAGEMENT PROGRAM:

a. Every Department of Veterans Affairs (VA) medical facility must maintain a well-organized anticoagulation management program. The program must provide coordinated processes and policies to ensure that patients are treated appropriately and receive appropriate follow-up. These policies must also ensure smooth transitions between inpatient and outpatient status, and address continuity and safety of anticoagulation care. Processes must be in place to minimize patient loss to follow-up and to address patient no-shows and noncompliance with the treatment plan.

b. The anticoagulation program manager is allotted an adequate amount of administrative time to perform leadership functions for the anticoagulation management program, including quality assurance, promoting evidence-based practice, and coordinating educational activities related to anticoagulation both inside and outside the anticoagulation management program. **NOTE:** *On average, 4 to 6 hours of administrative time per week is recommended based on strong practices identified. Four to 6 hours may not be sufficient administrative time for this position, particularly at larger, more complex facilities. At large, multi-campus referral facilities, 8 hours or more per week may be necessary.*

c. The anticoagulation management program must have an appropriate staff-to-patient ratio to provide safe and appropriate care determined at the facility level. The program staffing needs may vary based on a number of factors including, but not limited to, the complexity of patients referred, the availability of telehealth capabilities, the use of different International Normalized Ratio (INR) testing methodologies, the types of anticoagulants managed by the clinic, and the role and numbers of support staff. Although Veterans Health Administration (VHA) Handbook 1101.10, Patient Aligned Care Team (PACT), describes recommended staffing ratios for the anticoagulation clinical pharmacist specialist as at least 1.0 clinical pharmacy specialist full-time equivalent (FTE) for every five PACT patient panels, this is an estimate based on the number of warfarin patients expected in a typical PACT panel and may not be representative of the number of patients who require anticoagulation management services on any given team. In evaluating facilities with strong practices in VHA, evidence suggests that anticoagulation providers achieve optimal clinical outcomes when patient ratios are maintained at approximately 350 to 400 patients per anticoagulation provider, with strong assumption of adequate support staff (e.g., 1 pharmacy technician FTE per 2 clinical pharmacist anticoagulation provider FTE). As stated, this number may vary depending on the factors outlined previously.

d. During normal business hours, the anticoagulation management program must have a direct telephone extension that is staffed by trained administrative personnel and

accessible to facility staff and anticoagulation patients as appropriate. VA medical facilities must also have a clearly defined process for addressing patient calls and facility staff questions regarding anticoagulation in a timely manner outside of normal business hours.

2. POLICIES AND PROCEDURES:

a. Algorithms should be developed and standardized within the medical facility. The facility must develop standardized algorithms for the initiation of warfarin, maintenance of warfarin, peri-procedural management of anticoagulants, and the use of weight-based, unfractionated heparin. Sample algorithms strongly recommended for use at the medical facility level are available at:

<http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/Clinical%20Specialty%20Pages/Anticoagulation.aspx>. **NOTE:** *This is an internal VA Web site not available to the public.*

b. Algorithms developed at the facility level must follow the guidance listed below:

(1) **Initiation of Warfarin.** All patients initiated on warfarin must have an INR measurement within 7 days of initiation, although INR measurement within 4 days is recommended. Patients currently stabilized on warfarin outside VA are exempted from this requirement.

(2) Maintenance of Warfarin.

(a) The algorithm must encompass guidance and recommendations for management of critical INR values and bleeding.

(b) The algorithm must include recommendations for maximum follow-up intervals for patients receiving ongoing warfarin therapy.

(3) Peri-Procedural Management of Anticoagulants.

(a) The peri-procedural management of anticoagulant algorithm should encompass intentional interruptions of anticoagulation therapy (e.g., warfarin, Target Specific Oral Anticoagulants (TSOAC)).

(b) The algorithm should contain the following elements:

1. How the anticoagulation management program is informed of patients on anticoagulation therapy undergoing procedures, both within or outside VA;

2. The prescriber responsible to suspend anticoagulation therapy;

NOTE: *It is highly recommended that the anticoagulation provider be responsible to suspend anticoagulation therapy, with input from the surgeon and/or the primary care provider, as needed.*

3. The prescriber responsible to restart anticoagulation therapy;

NOTE: *It is highly recommended that the decision of when to restart therapy should be made by the provider performing the procedure with communication to the anticoagulation provider as appropriate.*

4. The prescriber responsible for providing peri-procedural anticoagulation therapy management; and

NOTE: *It is highly recommended that the anticoagulation provider be responsible for providing peri-procedural (or bridging) management. In some circumstances it may be necessary for the patient's primary care provider to provide peri-procedural management, however it is imperative that there be communication with the anticoagulation provider when this occurs.*

5. The peri-procedural management algorithm should take into consideration recommendations from the most recent version of the Chest Guidelines for interruptions of anticoagulation, and other pertinent evidence as appropriate.

(4) Weight-based, unfractionated heparin algorithms (includes heparin bolus and infusion dosing). The algorithm must require the prescriber to document the patient's weight or body surface used to determine appropriate dose to allow an independent review of the calculation by a clinical pharmacist prior to administration.

c. All patients receiving warfarin or long-term parenteral anticoagulants from VA on an ongoing basis must be managed by the VA anticoagulation management program. Exceptions to this principle may exist; however, each facility must outline in policy any exceptions.

d. All laboratory tests for anticoagulation management should be performed at a VA laboratory, to ensure accuracy of results and retrievability of information. **NOTE:** *When this is not possible, VA medical facilities must establish a formal process (included within facility policy) for documenting INR results received from a non-VA laboratory that ensures that these results are readily available.*

e. The local policy must outline appropriate laboratory tests utilized to monitor patients on anticoagulants. The following is a list of evidence-based baseline and ongoing laboratory tests and other measurements which are recommended by the American College of Chest Physicians, American Heart Association, and medication product labeling. At minimum, the policy must include:

(1) Required baseline laboratory tests for patients on anticoagulation therapy:

(a) Heparin: Complete blood count (CBC), activated partial thromboplastin time (aPTT).

(b) LMWH and Factor Xa Inhibitors (Fondaparinux): CBC, serum creatinine.

(c) Warfarin: CBC, prothrombin time (PT), international normalized ratio (INR).

NOTE: *Initial INR should not be performed using point of care testing (POCT) devices.*

(d) TSOAC: CBC, serum creatinine.

(2) Required Ongoing Laboratory tests for patients on anticoagulation therapy:

(a) Heparin: CBC, aPTT.

(b) LMWH and Factor Xa Inhibitors (Fondaparinux): CBC, serum creatinine.

(c) Warfarin: CBC, PT, INR.

(d) TSOAC: CBC, serum creatinine.

f. The policy must establish a defined process that ensures appropriate follow-up for patients identified with a critical drug-drug interaction with anticoagulant medications. Anticoagulation providers must be notified in a timely manner of critical drug interactions. The policy must identify the responsible provider for each of the items below:

(1) Responsibility for assessment of the interaction;

(2) Adjustment of the anticoagulant dose, as appropriate;

(3) Order and follow-up of subsequent laboratory tests; and

(4) Communication that will occur between the ordering prescriber and the anticoagulation provider.

g. The policy must define processes to minimize the risk associated with incorrect tablet strength dosing errors with warfarin. Whenever possible, patients should only be prescribed one tablet strength of warfarin to minimize risk for confusion. Additional strategies may include, but are not limited to:

(1) Limiting the number of warfarin strengths dispensed for outpatient prescriptions (e.g., 2 mg and 5 mg tablets only);

(2) Creating a separate outpatient orderable items for each warfarin tablet strength;

(3) Providing written patient education with instructions whenever a dose change is made;

(4) Limiting outpatient warfarin ordering to specific prescribers; and

(5) Using standardized quick order sets that promote uniformity of dosing.

h. Anticoagulation providers must add the appropriate International Classification of Diseases (ICD) Diagnosis Codes to the problem list of patients on long-term anticoagulation therapy. In addition, appropriate Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) codes may be used as applicable. The current

ICD, Ninth Revision (ICD-9) diagnosis code is V58.61 for “Long-term current use of anticoagulants” (Similarly in the Tenth Revision (ICD-10) the diagnosis code is Z79.01).

i. All INR results must be evaluated in a timely manner by the close of the next business day (or within 48 hours) and in accordance with VHA Directive 2009-019, Ordering and Reporting Test Results, or subsequent policy issue, and facility policy. The policy should also outline the appropriate time frames and management of critical INR values to include that appropriate action has been taken and documentation of those actions has occurred within 24 hours of the critical INR result.

j. Outpatient prescriptions for warfarin should be labeled appropriately to avoid patient confusion with changes to the instructions for use. It is strongly recommended to add a statement such as “refer to the latest anticoagulation clinic dosing sheet”, “use as directed by the anticoagulation clinic”, and/or to “call the anticoagulation clinic at XXX-XXXX with any questions or concerns”.

k. Anticoagulation providers should perform appropriate and periodic risk-benefit assessments for all patients receiving anticoagulant therapy and managed in the anticoagulation management program. In addition, most patients receiving long-term anticoagulants, whether with warfarin, a TSOAC, or another agent benefit from this review. This is particularly important for patients treated for venous thromboembolism, but is also important in the setting of atrial fibrillation. Some patients may require lifelong therapy due to a highly compelling indication, such as multiple venous thromboembolic or a prosthetic heart valve. Recommended components of the risk-benefit assessment include, but are not limited to:

(1) Patient adherence to therapy;

(2) Degree of control with warfarin, measured by Time in Therapeutic Range (TTR) (when appropriate) or proportion of values in therapeutic range (if TTR is not available);

(3) Risk of bleeding and any major changes to that risk;

(4) Risk of thrombosis and any major changes to that risk;

(5) Changes in patient parameters such as kidney and/or liver function; and

(6) Changes in general health, frailty, fall risk, and other possibly relevant considerations.

l. The facility should outline the educational plan for clinical staff directly involved in caring for patients receiving anticoagulation therapy. Education should include:

(1) The results of anticoagulation quality assurance program and performance improvement activities, as appropriate;

(2) Education based on locally identified learning needs, new algorithms or policies, emerging information regarding anticoagulants, or anticoagulant topics identified as important to the facility;

(3) VA educational programs as options for staff education; and

(4) Education may be provided in forums such as staff meetings, newsletters, grand rounds, external programs or other venues.

m. At a minimum, ongoing patient and family education provided by anticoagulation providers should address the following issues:

(1) Indication for therapy;

(2) Interactions (drug, diet, and disease);

(3) Daily dosage;

(4) The importance of medication adherence;

(5) The management of missed doses;

(6) Signs and symptoms of bleeding and thromboembolic events, and what to do if such an event occurs;

(7) The need to inform other health care providers about long-term anticoagulation therapy;

(8) The need to inform the anticoagulation provider when changes in medications occur or upcoming procedures are expected;

(9) Risks associated with falling;

(10) Proper tablet identification (for warfarin);

(11) Need to inform the anticoagulation provider about acute illness, major changes in diet, or upcoming travel (for warfarin);

(12) The dangers of using medication from different sources (especially for warfarin);

(13) Monitoring requirements (specifically for warfarin); and

(14) Proper medication storage (specifically for dabigatran).

n. If patient self-testing is used, the facility should incorporate patient self-testing into local policy and ensure the clinical program meets standards of the health care system's laboratory and VHA Handbook 1106.1, Pathology and Laboratory Medicine

Service Procedures, or subsequent policy issue. At a minimum, the policy should include:

- (1) Oversight and ongoing patient monitoring,
- (2) Defined patient admission and exclusion criteria;
- (3) A defined communication plan with the primary care provider and other teams as indicated;
- (4) Criteria for selection and purchase of INR self-testing devices;
- (5) Device testing and validation, including correlation of self-testing devices with other methods of INR testing utilized within the facility that meets laboratory standards, prior to issuing of device;
- (6) Comprehensive education and training for the veteran enrolled in the program; and
- (7) Defined competencies for staff involved.

3. QUALITY ASSURANCE:

a. An ongoing quality assurance plan must be in place to evaluate the anticoagulation management program. This provides the opportunity to identify practice improvements, ensures appropriate action is taken to improve the practice, and measures the effectiveness of those actions on a regular basis. The plan should include:

- (1) Reports for tracking and trending of INR values at the National, Veterans Integrated Service Network (VISN), and facility levels;

NOTE: Reports should include those such as time in therapeutic range (TTR), proportion of patients on warfarin that have not had an INR in the last 42 days, or other reports that assess the quality of care provided at the facility level.

- (2) Proportion of patients with pathologic bleeding events;
- (3) Proportion of patients with thromboembolic events; and
- (4) Patient incidents, close calls, and near misses associated with an anticoagulant. Adverse drug events (ADEs) involving anticoagulants should be assessed and analyzed in accordance with the facility Pharmacy and Therapeutics (P&T) Committee and VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, or subsequent policy issue.

NOTE: *Appropriate capture of non-VA INR values and non-VA warfarin prescriptions, will greatly improve the accuracy of the quality assurance plan. The use of a health factor to capture such information is highly recommended.*

b. Any identified issues found in the quality assurance program should be tracked and trended by the facility Anticoagulation Program Manager and reported through the P&T Committee to the Executive Committee of the Medical Staff (ECMS) as appropriate.