Department of Veterans Affairs **VHA DIRECTIVE 2010-020**
Veterans Health Administration
Washington, DC 20420 **May 14, 2010**

ANTICOAGULATION THERAPY MANAGEMENT

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

2. BACKGROUND

a. Anticoagulants are commonly used for both the treatment and prevention of cardiac disease, cerebral vascular accident, and thromboembolism in both the inpatient and outpatient setting. 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 to drug and drug and food interactions. The United States (U.S.) Pharmacopeia reported in 2006 that 4.7 percent of all incidents reported through its MEDMARX system involved anticoagulation therapy and that 7.8 percent of incidents causing patient harm were related to anticoagulation therapy.

c. Laboratory monitoring is a key component of safe anticoagulant therapy management. 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. There is limited data on the safety of patient self testing of INR in our veteran patient population and the correlation of INR self test results with laboratory reference methods. If patient self-testing is used in Department of Veterans Affairs (VA) medical programs that have incorporated patient self-testing into anticoagulant therapy management, it is important that it should be part of a clinical program that provides:

(1) Oversight and ongoing patient monitoring,

(2) Defined admission and exclusion criteria,

(3) Device testing that meets standards of the health care system's laboratory,

(4) A defined communication plan with the primary care provider and other teams as indicated,

(5) Comprehensive education and training for the veteran enrolled in the program, and

(6) Defined competencies for staff.

THIS VHA DIRECTIVE EXPIRES MAY 31, 2015

d. The rationale for the Joint Commission National Patient Safety Goal (NPSG) 3.05.01 states: "Anticoagulation therapy poses risks to patients and often leads to adverse drug events due to complex dosing, requisite follow-up monitoring, and inconsistent patient compliance. The use of standardized practices for anticoagulation therapy that include patient involvement can reduce the risk of adverse events associated with the use of heparin (unfractionated), low molecular heparin (LMWH), and warfarin."

e. The National Center for Patient Safety (NCPS) has reviewed root cause analysis reports of adverse events related to anticoagulation therapy. NCPS reports the lack of communication between providers about interacting medications has been identified as a vulnerability. As of September 11, 2008, the Pharmacy Benefits Management Services' VA Adverse Drug Event Reporting System (VA ADERS) shows 158 severe reports involving warfarin. Of the 158 severe reactions reported, 44 (28 percent) were due to a drug-to-drug interaction.

f. **Definitions**

(1) **Ancillary Testing.** Ancillary testing is defined as laboratory testing or services performed within a VA medical center 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).

(2) **Anticoagulant.** The term anticoagulant refers to a medication that inhibits blood coagulation. For the purpose of this Directive, anticoagulants include warfarin, heparin (unfractionated and low molecular weight), and factor-Xa inhibitors (fondaparinux is the only medication currently available in this class).

(3) **Defined Anticoagulant Management Program.** The term "defined anticoagulant management program" means a program, specified in writing, for individualizing anticoagulation therapy for each patient. This program involves the use of standardized practices and patient involvement, and is specifically designed to reduce the risk of adverse drug events associated with the use of heparin (unfractionated), LMWH, warfarin, and other anticoagulants.

(4) **Independent Practitioner.** The term "independent practitioner" is any individual permitted by law (the statute which defines the terms and conditions of the practitioner's license) and the facility to provide patient care services independently; i.e., without supervision or direction, within the scope of the individual's license and in accordance with individually-granted clinical privileges. This is also referred to as a licensed independent practitioner (LIP). ***NOTE:*** *Only LIPs may be granted clinical privileges.*

(5) **Mid-level Practitioner.** The term "mid-level practitioner" refers to an associated health professional that is not an independent practitioner and is directly providing management of the anticoagulant therapy (e.g. clinically evaluating and acting on test results, adjusting doses, or prescribing medication).

(6) **International Normalized Ratio (INR).** INR is a standardized measure of the prothrombin time (PT), which is used to determine the clotting tendency of blood. 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.

(7) **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 it own unique ISI value from the manufacturer.

(8) **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.

(9) **BridgeTherapy.** BridgeTherapy 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).

(10) **Therapeutic Anticoagulation Therapy.** Therapeutic anticoagulation therapy includes anticoagulation therapy or long-term anticoagulation prophylaxis (for example, atrial fibrillation) in which the clinical expectation is that when laboratory values reflecting the state of anti-coagulation are measured, they are within the prescribed range. It does not include routine situations in which short-term prophylactic anticoagulation is used for venous thrombo-embolism prevention (for example, related to procedures or hospitalization) and the clinical expectation is that the patient's laboratory values for coagulation will remain within, or close to, normal values.

3. POLICY: It is VHA policy that there must be a defined anticoagulation management program at each facility to individualize patient care provided and reduce the likelihood of patient harm associated with the use of anticoagulants.

4. ACTION

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

(1) There is local written facility or VISN policy developed using an interdisciplinary process, for the safe management of anticoagulation therapy. ***NOTE:*** *Attachment A lists the minimum components for policies.*

(2) For facilities employing INR Patient self-testing, a written facility or VISN 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. ***NOTE:*** *Attachment B lists the minimum components of an INR patient-self testing policy.*

(3) A Scope of Practice is established for each anticoagulant clinic provider that is not a LIP.

(4) Competencies specific for anticoagulation therapy management are established for mid-level practitioners involved in managing anticoagulation therapy. Competencies at a minimum

must include knowledge of the standard terminology, monitoring requirements, dose calculations, common side effects, dietary considerations and drug to drug interactions associated with anticoagulation therapy.

(5) The facility purchases and uses programmable infusion pumps for intravenously administered heparin.

(6) Anticoagulants are included on the Medical Center's list of high-alert medications.

(7) The Medical Center standardizes and limits the number of heparin concentrations available to meet patient care needs and no multi-dose heparin product more concentrated than 5,000 Units per milliliter is stocked without the prior approval of the Chief of Pharmacy.

(8) An Anticoagulant Therapy Program Coordinator has been designated.

b. **Clinical Executives (Chiefs of Staff and Chief Nursing Officers).** Clinical Executives are responsible for ensuring:

(1) Programmable infusion pumps are used for the intravenous administration of heparin.

(2) Competencies specific for anticoagulant therapy management are included in the competency plans for mid level medical and nursing staff practitioners involved in managing anticoagulation therapy. Competencies, at a minimum, must include:

(a) Knowledge of the standard terminology,

(b) Monitoring requirements,

(c) Dose calculations,

(d) Common side effects,

(e) Dietary considerations, and

(f) Drug-to-drug interactions associated with anticoagulation therapy.

(3) Assessment of the competency of mid-level Medical and Nursing staff practitioners involved in managing anticoagulation therapy.

(4) Medical and Nursing staff performing ancillary testing (e.g., point of care INR testing) undergo competency assessment as defined in national and local Pathology and Laboratory Medicine Service Procedures (see VHA Handbook 1106.01).

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

(1) Only oral unit dose products, pre-filled syringes, or pre-mixed infusion bags for anticoagulant medications are dispensed for inpatients when these types of products are available.

(2) 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 millileter is stocked without the prior approval of the Chief of Pharmacy.

(3) 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.

(4) Competencies specific for anticoagulant therapy management are included in the competency plans for mid-level pharmacy practitioners involved in managing anticoagulation therapy. Competencies, at a minimum, must include:

(a) Knowledge of the standard terminology;

(b) Monitoring requirements;

(c) Dose calculations;

(d) Common side effects;

(e) Dietary considerations; and

(f) Drug-to-drug interactions associated with anticoagulation therapy.

(5) Assessment of the competency of mid-level pharmacy practitioners involved in managing anticoagulation therapy.

(6) Pharmacy staff performing ancillary testing (e.g., point of care INR testing) undergo an annual competency assessment as defined in national and local Pathology and Laboratory Medicine Service Procedures.

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

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

(1) 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.

(2) Ensuring a critical INR value is established and listed in the Laboratory Vista software package.

(3) Establishing a Standard Operating Procedure for the communication of critical INR results from the laboratory to the provider.

(4) Ensuring the correct ISI value for the lot number of Thromboplastin, currently in use, is entered into the coagulation testing instrumentation.

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

(6) Ensuring the correct Geometric Mean 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.

f. **Ancillary Testing Coordinator.** The 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. **Anticoagulant Therapy Program Coordinator.** The Anticoagulant Therapy Program Coordinator is responsible for the ongoing monitoring of the facility anticoagulant quality assurance plan and reporting results to the appropriate facility committee designated by the Chief Medical Officer (CMO) for action.

5. REFERENCES

a. VHA Handbook 1108.06, Inpatient Pharmacy Services.

b. VHA Handbook 1108.05, Outpatient Pharmacy Services.

c. VHA Handbook 1106.1, Pathology and Laboratory Medicine Service Procedures.

d. VHA Handbook 1100.19, Credentialing and Privileging.

e. The Joint Commission, 2009 National Patient Safety Goals; NPSG 03.05.01. Consensus Guidance to Ensure the Safe Use of Anticoagulants; National VA Hi-Alert Anticoagulant Workgroup, VHA Pharmacy Benefits Management Services and the Medical Advisory Panel, July 2008.

f. American College of Chest Physicians Guidelines: Antithrombotic and thrombolytic therapy, 8th ed. CHEST. 2008;133(6): June Supplement.

6. FOLLOW-UP RESPONSIBILITY: The Chief Consultant for Pharmacy Benefits Management (PBM) Services (119), in the office of Patient Care Services, is responsible for the contents of this Directive. Questions may be directed to (202) 461-7326

7. RESCISSIONS: VHA Directive 2009-003 is rescinded. This VHA Directive expires May 31, 2015.

Robert A. Petzel, M.D.
Under Secretary for Health

Attachments

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 5/18/2010

ATTACHMENT A

MINIMUM COMPONENTS OF MEDICAL CENTER OR VISN POLICY(S) FOR ANTICOAGULATION THERAPY

The Minimum components of medical center or Veterans Integrated Service Network (VISN) policy(s) for anticoagulation therapy include:

1. The requirement, for inpatients, to use only oral unit dose products, pre-filled syringes, or pre-mixed infusion bags for anticoagulant medications when these types of products are available.

2. The requirement to use programmable infusion pumps for intravenously-administered heparin.

3. Approved, evidenced-based, protocols for the initiation and maintenance of anticoagulation therapy appropriate to the medication used, to the condition being treated, and to the potential for medication interactions. At a minimum, protocols must be established that address:

a. Peri-procedural bridge therapy.

b. Weight-based heparin bolus and infusion dosing that requires the prescriber to include in the calculated dose the weight or body surface used to formulate the dose in order to allow an independent review of the calculation by a pharmacist.

c. Initiation and adjustment of warfarin therapy.

d. Frequency of International Normalized Ratio (INR) testing that is consistent with nationally recognized evidenced-based guidelines (e.g., American College of Chest Physicians). The 2008 CHEST guideline recommends that INRs be checked at no more than 4 week intervals in stable patients. To allow for situations where stable patients are unable to have their INR checked in 4 weeks (e.g., transportation or weather problems), a maximum of a 6-week interval may be used.

e. Management of supratherapeutic INRs or bleeding for patients on warfarin therapy.

f. Management of oral anticoagulation therapy during invasive procedure.

4. A list of baseline and ongoing laboratory tests as recommended by nationally published guidelines from groups such as the American College of Chest Physicians and the American Heart Association, as recommended in the product labeling and as appropriate for the individual medication and patient. At minimum, the policy needs to include:

a. **Baseline Laboratory Results Based on the Anticoagulant(s) the Patients are on.** These are:

(1) **Heparin.** Complete blood count (CBC) with platelets, and activated partial thromboplastin time (aPTT).

(2) **LMWH and Factor-Xa inhibitors (fondaparinux).** CBC with platelets and serum creatinine.

(3) **Warfarin.** CBC with platelets, prothrombin time (PT), and international normalized ratio (INR). ***NOTE:*** *Initial INR should not be performed using point-of-care testing devices.*

b. **Ongoing Laboratory Results Based on the Anticoagulant(s) the Patients are on.** These are:

(1) **Heparin.** Hemoglobin (HGB), hematocrit (HCT), platelet count, and aPTT.

(2) **LMWH and Factor-Xa inhibitors (fondaparinux).** CBC with platelets, and serum creatinine.

(3) **Warfarin.** CBC with platelets, PT, INR.

5. The requirement to review and clinically evaluate all INR results no later than the close of the next business day. ***NOTE:*** *Critical results must be managed according to existing policies.*

6. The requirement for a baseline INR to be available prior to patients starting on warfarin therapy.

7. The requirement for a current INR to be available in the electronic health record for all patients receiving warfarin therapy and to use the current INR to monitor and adjust therapy. ***NOTE:*** *For consistency in documentation and retrieval of information, patients need to be encouraged to use the services of a Department of Veterans Affairs (VA) laboratory for INR testing whenever possible.*

8. A standardized process for documenting INR results received from a non-VA laboratory that ensures they are readily retrievable. This must include documentation of the name of the laboratory, the date of the test, and the reference range on the test, and may include scanning of non-VA laboratory reports or the use of health factors. Staff documenting an INR result from a non-VA laboratory need to verify the authenticity of the result by reviewing the written report provided by the laboratory that includes the laboratory name, address, telephone number, and reference range. If a non-VA INR result is documented in the Veterans Health Information System and Technology Architecture (VistA) laboratory software package a separate entry must be created in file 63 that clearly indicates the lab test was performed at a non-VA laboratory (e.g., the test name is non-VA laboratory INR result). Prior to entering the non-VA laboratory results into the VistA laboratory package, the person must verify the result is from an accredited

(College of American Pathologists, COLA or The Joint Commission) laboratory and must document the laboratory's name, address, and the reference range in the comments field.

9. The requirement to notify Nutrition and Food Services of all patients receiving warfarin therapy and meal services.

10. The requirement for Nutrition and Food Services to respond according to its established food and medication interaction program to patients receiving meal services and warfarin therapy.

11. The requirement to provide 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. At a minimum, patient education needs to include:

a. Warfarin tablet identification;

b. Indication for therapy;

c. Interactions (drug, diet, and disease);

d. Daily dosage;

e. Monitoring requirements;

f. The importance of medication adherence;

g. The dangers of using warfarin from different sources (e.g., VA and community pharmacy);

h. The management of missed doses,

i. Signs and symptoms of bleeding and thromboembolic events, and

j. Risks associated with falling.

12. The requirement to provide anticoagulation therapy education to clinical staff directly involved in caring for patients receiving anticoagulation therapy. Examples include medical, pharmacy, nursing, nutrition, laboratory and mid-level practitioners, but may also include other clinical disciplines if determined appropriate at the local level. In VHA, “staff” includes full and part-time paid employees. Medical Centers should use the results of anticoagulation quality assurance and performance improvement activities in determining educational needs to improve staff competence. Medical Centers may also choose to provide education locally based on identified learning needs, new protocols or policies, emerging information regarding anticoagulants or anticoagulant topics identified as important to the Medical Center. VHA, through the LMS, provides two optional programs that medical centers may choose to use to provide staff education. Medical Centers may choose to provide the education in forums such as staff meetings, newsletters, grand rounds, external programs or other venues.

13. An on-going quality assurance plan to evaluate anticoagulation safety practices. 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. At a minimum, the plan needs to monitor:

a. INRs above the critical value

b. Appropriate action has been taken on critical INRs within 24 hours of INR testing and documentation of action(s) taken.

c. Bleeding events;

d. Thromboembolic events;

e. Sub-therapeutics INRs; and

f. Patient incidents, close-calls, and near misses associated with anticoagulant medications.

14. A defined anticoagulation management program to individualize the care provided to each inpatient receiving anticoagulant therapy. This program needs to provide for the coordinated transition of the patient from inpatient to outpatient status.

15. A defined anticoagulation management program to individualize the care provided to each outpatient receiving anticoagulant therapy.

a. This program must include a defined process to ensure:

(1) Patients are followed-up appropriately, and

(2) The frequency of INR testing is performed according to the established protocol.

b. In addition, this program needs to:

(1) Provide for the coordinated transition of the patient from outpatient to inpatient status.

(2) Address patient no-shows for laboratory testing and clinic appointments, and patient non-compliance with the treatment plan.

16. The requirement for mid-level practitioners involved in managing anticoagulation therapy to have successfully completed a specialty training program in anticoagulation therapy management, <u>or</u> be certified as an anticoagulation care provider (CACP), <u>or</u> complete an on-site anticoagulation training program that includes both experiential and didactic learning strategies.

17. A defined process that ensures appropriate patient follow-up when a new drug that critically interacts with anticoagulants is added to the medication regimen of out-patients on anticoagulant therapy. This process needs to address:

(1) Responsibility for assessment of the interaction,

(2) Adjustment of the anticoagulant dose if needed,

(3) Order and follow-up of any needed laboratory tests, and

(4) Communication between the ordering provider and the anticoagulant clinic provider.

18. The requirement to add a V code (currently the applicable V code is V58.61) that denotes 'Long-term (current) use of anticoagulants' to the problem list of outpatients on anticoagulant therapy.

19. A defined process to minimize the risk associated with incorrect tablet strength dosing errors, in order that outpatients are supplied only one tablet strength of warfarin. Strategies may include:

(1) Limiting selection of warfarin strengths for outpatient prescriptions to 2 milligrams (mg) or 5mg tablets,

(2) Creating a separate outpatient orderable item for each warfarin tablet strength,

(3) Educating providers to <u>always</u> view the order in the Computerized Patient Record System, as it is built with emphasis on noting the tablet strength the software assigns based on the dose selected,

(4) Providing patient education with written instructions whenever a dosage change is made,

(5) Limiting outpatient warfarin ordering to select providers, and

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

ATTACHMENT B

MINIMUM COMPONENTS OF MEDICAL CENTER OR VETERANS INTEGRATED SERVICE NETWORK (VISN) POLICY FOR PATIENT SELF TESTING OF INTERNATIONAL NORMALIZED RATIO (INR)

1. Defined patient selection criteria.

2. A comprehensive face-to-face patient educational program and demonstration of patient's or family member's ability to properly use the testing equipment, that includes demonstration of the patient's or family member's ability to evaluate a number of unknown test samples prior to issuing of equipment.

3. Ongoing patient competency assessments on using the testing equipment that includes objective criteria for evaluation and assess more than the patient's or family member's ability to retain academic knowledge.

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. Defined communication plan between the patient and provider for reporting of results to assure the patient is not adjusting their medication on their own.

7. The requirements for self testing as defined in VHA Handbook 1106.1, Pathology and Laboratory Medicine Service Procedures.

8. Defined situations that would require confirmation of the INR result from an accredited laboratory (e.g., INR outside of therapeutic range, signs and symptoms of toxicity).

9. Documentation of patient or family education, such as: assessment, competency testing, a communication plan, and the recording of these results in the patient's electronic medical record.