

## **D.21 ANTICOAGULATION MANAGEMENT PROGRAM**

U. S. Department of Veterans Affairs  
New York/New Jersey VA Health Care Network  
Albany VA Medical Center

Standard Operation Procedure D&T 119-03  
March 23, 2017

### **ANTICOAGULATION MANAGEMENT PROGRAM**

1. **PURPOSE:** To establish uniform quality of care for all outpatients and inpatients on therapeutic anticoagulants and to ensure continuity of care upon transfer between inpatient and outpatient services. The pharmacy will provide recommendations for the proper and safe use of all therapeutic anticoagulant products (warfarin, heparin, low-molecular weight heparin (LMWH), pentasaccharides, direct oral anticoagulants (DOACs), etc.) while patients are actively receiving these products and are actively treated and monitored by a VA provider. The goal of the service is to maximize therapeutic outcomes, minimize adverse events, and assure patients have a documented plan of care. This includes appropriate monitoring of anticoagulation therapy while ensuring patients and caregivers receive necessary education regarding the use of oral and parenteral anticoagulation. The anticoagulation monitoring service is comprised of an Outpatient Anticoagulation Clinic and an Inpatient Anticoagulation Monitoring Service. Both services function within the scope of the Standard Operating Procedure (SOP) as described below.
2. **RESPONSIBILITY:**
  - a. **OUTPATIENT ANTICOAGULATION CLINIC (OAC):**
    - (1) The clinic assumes responsibility for laboratory monitoring, dosage adjustment, and initial assessment of complications associated with anticoagulation medications including warfarin, DOACs and LMWH in the outpatient setting in which the patient continues to receive therapeutic anticoagulation and continues to be monitored by a VA provider.
    - (2) Direct Roles and Responsibilities of OAC staff (i.e. Clinical Pharmacy Specialist(CPS), clinic support staff includes:
      - (a) Assigning follow-up dates and communicating them to the patient. Patients are responsible for making their appointments for blood work at the CBOCs.
      - (b) Monitoring drug therapy via laboratory levels and/or clinical outcomes and adjust doses accordingly.
      - (c) Documentation of anticoagulation therapy and evaluation.
      - (d) Identify and contact patients who are lost to follow-up for labs.
      - (e) Maximizing therapeutic outcomes for patients enrolled in the clinic.
      - (f) Patient and caregiver education, as appropriate.(Attachment A)
    - (g) Communicating outcomes of drug therapy to patients, caregivers and providers.
    - (h) Assisting with the education of VA staff (i.e. pharmacists, nurses, medical residents) on anticoagulation therapy.
    - (i) Quality Assurance monitoring of the OAC, including review of policies and procedures on a biannual basis.
    - (j) Semi-Annual Quality Report to the local Pharmacy and Therapeutics (P&T) Committee. The dashboard report should minimally consist of: number of actively enrolled patients; percent INRs (International normalized ratios) in range, time in therapeutic range(TTR),

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- percent of adverse drug event reports (bleeds, thromboembolic events, etc.), percent ER visits, percent admissions for bleed, number of deaths, etc.
- (3) Clinical Pharmacy Supervisor will be responsible for administrative supervision of the CPS and clinical pharmacy technician(s) assigned to the OAC.
  - (4) Prescribers are responsible for following the policies and procedures as outlined in this SOP. Additionally, each referring provider is responsible for making arrangements for anticoagulation therapy management and follow-up until the patient is established as a new patient into the OAC and for regular medical follow-up at a minimum of every twelve months.
  - (5) Careline Managers are responsible for ensuring prescribers follow these policies and procedures as outlined in this SOP.
  - (6) The Albany P&T Committee will be responsible for implementation, maintenance and monitoring of quality improvement and outcomes reports as it pertains to the policies and procedures set forth in this document.
  - (7) The Executive Committee of the Medical Staff in conjunction with the Performance Management Staff will be responsible for the review of performance measures as it pertains to anticoagulation therapy.
  - (8) The Chief of Staff and Primary Care Physician Lead are responsible for ensuring that there is an identified physician point of contact for referral of emergent patient problems, or traveling veterans who will require monitoring for greater than 3 months.
  - (9) **NOTE:** Patients who request or have a need to receive anticoagulation therapy and monitoring from a non-VA provider will not be monitored by the OAC and will not be eligible to receive warfarin from the VA pharmacy per the VA co-managed care policy and the VISN 2 anticoagulation program memorandum.

### b. INPATIENT ANTICOAGULATION MONITORING SERVICE (IAMS)

- (1) The admitting provider is responsible for identifying patients requiring anticoagulation therapy via a completed documented risk assessment, entering electronic orders for treatment selection according to established guidelines, utilizing CPRS order sets to promote appropriate treatment and monitoring, ordering labs and adjusting doses and intervals as appropriate. The patient's provider institutes all medication changes and other recommendations made by the pharmacist if deemed appropriate.
- (2) The CPS is responsible for assessing initial therapeutic anticoagulation therapy and interval as ordered by the provider and making recommendations, as needed, to the provider through an electronic medical record progress note.
- (3) Dietary services are responsible for follow-up of these patients with regards to dietary interactions; to include patient education and notification to the provider, with documentation, of vitamin K content in any ordered oral or tube feeding supplement.
- (4) The discharging nurse, pharmacist or provider will provide education to the patient and/or caregivers to allow safe and effective use of anticoagulation. If significant barriers to understanding, which would not allow safe use of anticoagulants are determined by the nurse or pharmacist, the provider will be notified.
- (5) Clinical Pharmacy Supervisor will be responsible for administrative supervision of the OAC CPS assigned to the IAMS.

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- (6) The Albany P&T committee will be responsible for implementation, maintenance and monitoring of quality improvement and outcomes reports as it pertains to the policy and procedures set forth in this document.
- (7) The Executive Committee of the Medical Staff in conjunction with the Performance Management Staff will be responsible for the review of performance measures as it pertains to anticoagulation therapy.
- (8) The Clinical Pharmacy Supervisor or designee is responsible for the ongoing review and update of the procedures outlined in the inpatient anticoagulation monitoring services SOP as appropriate.

### **3. PROCEDURES:**

#### **a. OUTPATIENT ANTICOAGULATION CLINIC (OAC)**

- (1) Initiation of Outpatient Anticoagulation Therapy: The referring VA physician and/or the patient's VA primary care provider retain responsibility for determining the need for the initiation and termination of anticoagulation therapy as well as the patient's overall medical management. However, the OAC may prescribe the initial prescription of anticoagulant as well as discontinue therapy based on clinical practice guidelines and individual patient need. The OAC clinic will provide comprehensive, on-going education to patients and their caregivers about their anticoagulant therapy. The OAC staff will maintain a staff-to-patient ratio of approximately 350-400 patients per anticoagulation provider to ensure safe and appropriate care.
- (2) 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) DOAC: CBC, serum creatinine, LFTs.
- (3) Referrals to OAC: Once the decision has been made to start anticoagulation, a provider may refer patients to the OAC directly from the VA inpatient/outpatient setting. A request for consultation must be sent electronically through a standardized template to the OAC staff via a consult in VISTA/CPRS. A request for admission into OAC may be made directly on a DOAC medication request, if applicable. Once reviewed, a reply to this consult will be forwarded electronically to the referring provider as well as the primary care provider. Each referring provider is responsible for making arrangements for anticoagulation therapy management and follow-up until the patient is established as a new patient into the OAC. All patients receiving warfarin or long-term parenteral anticoagulants from VA on an ongoing basis must be managed by OAC. Exceptions to this principle may apply to hematology/oncology providers on a case by case basis.

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- (4) Eligibility for enrollment into OAC: All new patients referred to the OAC will be comprehensively evaluated with regard to the indication, benefits, risks, and goals of anticoagulation therapy. Patients will be given appropriate and thorough instruction on the safe and effective use of their prescribed anticoagulation therapy. Acceptance and follow-up in the clinic will be dependent upon consideration of the following criteria:
- (a) Patient must have a documented indication for anticoagulation therapy. Duration of therapy will be agreed upon by the referring provider and the anticoagulation clinic based on current practice guidelines and any patient specific factors.
  - (b) Patients and/or their caregivers should have the capacity to understand the patient's condition and implications of anticoagulant therapy. If there is a question on competency, clinic will refer the patient and/or caregiver to the primary care provider for a competency assessment.
  - (c) Patients and/or their caregivers must be able to administer the medication.
  - (d) All patients must have an established primary care provider within the VA Healthcare Network, and agree to receive appropriate comprehensive follow-up with their provider at least once per year. For patients who are new to VA and new to warfarin, CPS may contact the primary care provider with whom the patient has a future appointment, or the primary care lead physician if the pharmacist needs primary care provider input.
  - (e) Patients must be willing and able to follow instructions provided to them by the OAC staff regarding their anticoagulation therapy.
  - (f) Patients must be able to physically travel to and from their lab appointments. (Note: exception will be HBPC and patients who have blood drawn at home from outside laboratories). Patients who have blood drawn in the home by VNA will only be accepted if the VNA association accepts a standing order from the primary care provider allowing prescribing changes by a CPS (i.e. a Collaborative Care Agreement). Patients may also use privately obtained point of care (POC) testing devices in certain situations where a routine venipuncture is a hardship (i.e.-hard stick, unable to travel). Patients will be required to have a venipuncture with any INR reading of 4.5 or greater as determined by the CPS. All testing supply and device costs for POC testing are incurred by the patient thru private pay.
  - (g) Patients must be accessible by telephone or My HealtheVet (MHV) secure messaging. In cases where the patient does not have a phone, the patient must wait for lab results and dose changes at the Stratton VA Medical Center. Preferably, the patient should have an answering machine or voicemail to accept messages.
  - (h) Patients must be compliant with maintaining their anticoagulation monitoring and taking their medication as prescribed.
  - (i) Patients may be excluded from the clinic for reasons which will be explained to the patient and their medical care provider by OAC staff.

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- (5) Excluded Patients: Patients may not be enrolled in the Anticoagulation Clinic if they have any contraindication (per package insert and medical literature) to their prescribed anticoagulation therapy. In addition, patients residing in an adult home, assisted living facilities or nursing homes will not be accepted to the clinic unless the facility accepts a standing order from the primary care provider allowing prescribing changes by a CPS. (i.e. a Collaborative Care Agreement).
- (6) Clinic Management
- (a) The CPS will function under a point of contact physician with a scope of practice as defined and approved through the Chief of Pharmacy, Chief of Staff, the Executive Committee of the Medical Staff and the Medical Center Director. The CPS will use initiation and maintenance algorithms as a guide to providing therapy for warfarin along with evidence based medicine and clinical judgement. Other anticoagulants are dosed based on package insert; evidence based medicine; and clinical judgement.
  - (b) The clinic will convene Monday through Friday from 0800 to 1600. The clinic will not be available federal holidays, weekends or after 1600 on business days. Patients will be provided with the direct telephone extension that is staffed by OAC staff during normal business hours: 518-626-5735.
  - (c) All referring providers must complete and submit a consult in CPRS. For DOACs, request for clinic enrollment can be made directly on the consult for the medication request.
  - (d) Consults for enrollment into OAC will be received within 7 days of request for admission to the clinic. These consults may take up to 30 days for completion and the referring provider is responsible for therapy management during this time until the consult has been completed and the patient is officially enrolled in OAC.
  - (e) Enrollment into clinic: Upon receipt and admittance to the clinic:
    - 1. The referring provider and/or primary care provider will be notified as to the admission of the patient to the clinic when the consult has been completed.
    - 2. Assessment of indication and laboratory goal ranges as determined based on current CHEST guidelines or as clinically indicated by primary care provider or specialist.
    - 3. Risk/benefit assessment: clinic staff will educate the patient as to the risk of bleeding vs. risk of recurrent thromboembolism. This will also address the importance of compliance with anticoagulation therapy.
- (7) Follow-Up Visits: All patients followed by the anticoagulation clinic will be closely monitored for thromboembolic events, bleeding complications, and medication adherence. It is recommended that patients directly communicate with OAC staff via telephone or face-to-face following results of lab work. Warfarin therapy will be expertly managed with the goal of maintaining the patient within an appropriate range of anticoagulation based on the literature and patient-specific considerations. Required ongoing laboratory tests for patients on anticoagulation therapy:
- (a) Heparin: CBC, aPTT.

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- (b) LMWH and Factor Xa Inhibitors (Fondaparinux): CBC, serum creatinine.
- (c) Warfarin: CBC, PT, INR.
- (d) DOAC: CBC, serum creatinine, LFTs
- (8) Communication to the patient of every lab result will be as follows for warfarin patients:
  - (a) If PT/INR result is within the goal therapeutic range; patient will be notified by OAC staff within 48 hours via telephone and also by letter, unless specified otherwise by the patient. This letter will confirm the previous dose the patient had been taking and instruct them to continue with the specified dosage until their follow-up PT/INR is due.
  - (b) If PT/INR result is outside of the goal therapeutic range; an attempt will be made to contact the patient face-to-face or via telephone within 24 hours of notification of lab results. If patient is unable to be contacted directly, a message with detailed instructions will be left either on an answering machine, MHV secure messaging, and/or their designated emergency contact (Health Care Proxy).
  - (c) If PT/INR result is in the critical range (as presently defined by the Medical Center Lab Policy as greater than 4.5), priority is made to contact the patient on the same day as the lab result is back. Every attempt must be made to reach either the patient or their emergency contact by the end of the day. If the patient is unable to be contacted directly, a message with detailed instructions will be left either on an answering machine and/or their designated emergency contact (Health Care Proxy). If unable to reach the patient or emergency contact, the hospitalist will be notified.
  - (d) If CBC/ serum creatinine /LFT result is within acceptable limits and require no action; patient will be notified by the CPS or clinic support staff via telephone and by letter within 14 calendar days, unless specified otherwise by the patient. This letter will confirm the previous dose the patient had been taking and instruct them to continue with the specified dosage until their follow-up in approximately 4 weeks.
  - (e) If CBC/ serum creatinine /LFT result is outside of the goal therapeutic range; an attempt will be made to contact the patient face-to-face or via telephone within 7 calendar days of lab notification. If patient is unable to be contacted directly, a message with detailed instructions will be left either on an answering machine, MHV secure messaging, and/or their designated emergency contact (Health Care Proxy). The PCP is also alerted to abnormal labs at the discretion of the CPS based on patient case.
  - (f) Risk-benefit assessment will be performed at each encounter as well as annually. Risk-benefit assessment includes:
    - 1. Patient adherence to therapy
    - 2. Degree of control with warfarin, measured by 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
    - 6. Changes in general health, frailty, fall risk, and other possibly relevant considerations
- (9) The following items will be discussed with the patient and/or caregiver when contacted:
  - (a) Verification of warfarin dose or other anticoagulation therapy.
  - (b) Verification of changes in other medications, including over-the-counter medications, herbals, and vitamins.
  - (c) Determination of any dietary changes and encouragement of a steady, well-balanced diet.

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- (d) Any alcohol use changes
- (e) Determination of missed or incorrect doses of anticoagulation therapy.
- (f) Determination of any bruising or bleeding and record specific dates and descriptions. If an event is clinically significant, the patient will be instructed to be seen by a physician as soon as possible.
- (g) Determination of any signs and symptoms of a thromboembolic event:
  - 1. Slurred speech, one-sided weakness/numbness, blackouts, sudden vision changes, or mental confusion
  - 2. New swelling in extremities with pain or tenderness or accompanied by difficulty breathing or increase in chest pain
- (h) Determination of any disease state changes and inquire about recent illness, hospitalizations and/or ER visits. If a facility other than the VA has been used, instruct patient to sign a release of information for records if not already done at outside facility.
- (i) Record other information which may be relevant to anticoagulant therapy (planned travel, surgery, dental work, or other procedures)
- (j) Obtain a follow up appointment for PT/INR.
- (k) Determine the need for travel consult to be placed, if applicable.
- (10) After collection and assessment of data, dosage adjustment will be made by the OAC staff based on current literature, ACCP (Chest) guidelines and clinical judgment. A follow-up letter will be sent to the patient reiterating instructions given during the telephone conversation if needed.
- (11) Medication Reconciliation: In order to maintain patient understanding of their medications, each patient will be provided with written instructions regarding any changes to their anticoagulation dosage based on either current laboratory values (i.e. PT/INR) or clinical events necessitating a change in their therapy. These instructions will provide the patient with their most recent laboratory value, current dose (including tablet strength) and directions on the quantity of medication to be taken on a daily basis.
- (12) Prescriptions for anticoagulation therapy may be written by the CPS if a patient requires a new supply or change in therapy. Patients may refill their prescriptions in accordance with current VA policy for outpatient refills.
- (13) Frequency and Scheduling of Laboratory Testing:
  - (a) Warfarin Monitoring: The recommended frequency of PT/INR monitoring is up to every 6 weeks for stable INRs. More frequent PT/INR testing will be necessary if a patient is not within their goal therapeutic range or circumstances exist that warrant more closely monitored PT/INR (e.g. medication changes, pending cardioversion, instability of recent INRs etc.). PT/INR testing may be extended beyond 6 week intervals on a case-by-case basis. It is recommended that appointments for PT/INR testing occur with other medical appointments for patient convenience. However, it is the clinic policy to avoid drawing a PT/INR on a Friday from a CBOC due to inability to receive, interpret and notify patients of the results in a timely fashion. Patients who require a PT/INR on a Friday are advised to get blood drawn at the Medical Center or from a regional facility with on-site testing equipment at their own expense. In these cases, the results will be called into the OAC before the close of business on Fridays.
  - (b) LMWH Monitoring: It is typically not recommended to perform any laboratory testing to monitor LMWH therapy. However, if a patient is experiencing any side effects, has

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- fluctuating renal function or is greater than 150 kilograms (above the approved indication), it may be necessary to order a factor Xa test. CBC and serum creatinine are monitored periodically.
- (c) DOAC Monitoring: It is typically not recommended to perform any laboratory testing to monitor drug level. However, CBC, Serum creatinine, and liver function testing frequency will be determined based on the medication prescribed typically every 3 to 6 months.
  - (d) Documentation of Laboratory values: All PT/INRs and CBCs ordered for patients will be tracked in the anticoagulation clinic's database(located in a secure folder on the X drive)
  - (e) Anticoagulation Management Tool (AMT) and CPRS. A progress note is to be entered into the patient's medical chart for all lab results ordered by the anticoagulation clinic as well as any issues surrounding anticoagulation therapy. All other lab work associated with warfarin and other anticoagulants is documented in CPRS.
  - (f) Frequency of urinalysis and stool guaiac: These tests shall be ordered and monitored by the patient's primary care provider annually as per standard of care. However, if a patient presents with indications for these tests, the OAC staff may recommend that these tests be ordered by the primary care provider.
- (14) Bridge Therapy for High Risk Patients: A bridge consult may be entered for patients on anticoagulation scheduled for procedures that require interruption in oral anticoagulation. Upon receipt of this consult, CPS in the OAC will evaluate patients for use of LMWH in the periprocedural period and prepare recommendations for primary care provider's review.
- (a) Patients on DOACs will not require LMWH in most cases given shorter interruptions in therapy. Recommendations regarding number of doses to hold will be dependent on the specific DOAC, the patient's renal function, bleeding risk of the procedure, patient's thromboembolic risk, and available literature regarding periprocedural management (i.e., package insert, pharmacokinetic studies).
  - (b) Patients on warfarin considered low risk will hold without LMWH therapy. This includes patients with single thromboembolic events, remote history of thromboembolic events, or lower CHADS2 scores in absence of thromboembolic events.
  - (c) Patients on warfarin considered moderate risk will often hold without LMWH therapy though specific patient history and individual CPS judgement will be taken into account to evaluate if LMWH therapy should be recommended. Date and number of thromboembolic events will be taken into consideration.
  - (d) Patients on warfarin considered highest risk for thromboembolism will be bridged with LMWH. This includes patients with history of significant history of thromboembolic events, recent history of thromboembolic event, certain mechanical valves (mitral valves, older aortic valves), high risk hypercoagulable states (including but not limited to protein C deficiency, protein S deficiency, thrombin deficiency, antiphospholipid antibody syndrome, or multiple abnormalities), and active cancer.
  - (e) Patients that have a contraindication to LMWH will not be bridged with LMWH. This includes poor renal function and thrombocytopenia.

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- (f) Input from specialty services including Hematology, Oncology, and Cardiology will be obtained for difficult cases.
- (15) Management of Supratherapeutic INRs: Following notification of a critical INR from the laboratory, the clinic will make every effort possible to contact the patient. The clinic will follow the guidelines for administration of vitamin K as per current ACCP (CHEST) guidelines. (Attachment B)
- (16) Management of Non-adherent patients and discharges from clinic: A daily report of the patients who are lost-to-follow-up (>2 business days past their scheduled follow-up with the clinic) will be run and patients will be called to reschedule their follow-up lab work as soon as possible.
  - (a) Warfarin lost to follow-up policy
    - 1. First call is a reminder and a no show letter is sent. (minimum of 3 days overdue for bloodwork)
    - 2. Second call tells the patient they have 5 business days to obtain their bloodwork or they will be discharged from the clinic. Pending discharge letter is then mailed. PCP is alerted. (Minimum of 5 business days after first call)
    - 3. A patient who is discharged from the Anticoagulation Clinic due to noncompliance with blood work must demonstrate 3 months' worth of compliance with blood work with a VA provider BEFORE being reenrolled into clinic.
    - 4. Discharge from the clinic due to any reason will be documented electronically using a note titled "Anticoagulation Clinic Discharge Note".
  - (b) DOAC lost to follow-up policy:
    - 1. First call is a reminder and a no show letter is sent 2 weeks following due date for lab work.
    - 2. Two weeks following first reminder, a second phone call is made. The patient will be pending discharge at this time.
    - 3. If two weeks pass following second phone call, patient is discharged from clinic.
    - 4. Discharge from the clinic due to any reason will be documented electronically using a note titled "Anticoagulation Clinic Discharge Note".
- (17) Management of patients after clinic hours: The OAC is available Monday thru Friday from 0800 to 1600. If a patient has a question or needs assistance at non-clinic times, they are instructed to report to their local ED for evaluation if an emergency (i.e. fall or symptoms of bleeding) or call the VA Telecare line at 1-888-838-7890 for further assistance. After clinic hours, all critical lab values will be triaged by the hospitalist.
- (18) Extended Travel: Patients must inform the OAC staff of any travel plans that will affect scheduled laboratory monitoring and follow up at the clinic.
  - (a) Prior to travel, the patient will be interviewed by clinic staff and the following information will be obtained:
    - 1. Dates and duration of travel

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2. Contact address and telephone number during period of travel
    3. Name, address, and telephone number of other providers the patient has at travel destination
  - (b) If the patient will be away for an extended period that will affect scheduled PT/INR monitoring and follow up in the OAC, arrangements must be made with the patient prior to travel to ensure proper monitoring of anticoagulation during period of travel. If the patient continues to receive warfarin from the OAC during this period of travel, the patient must either:
    1. Have PT/INR faxed to the OAC for evaluation. This can be done at the patient's own expense by a private physician or medical center. In such cases, a standing order (signed by primary care provider or other responsible physician) will need to be sent to the provider of the service.
    2. Have PT/INR evaluated at another VA Medical Center, where the data can be accessed remotely via computer. Communication between the traveling veteran coordinator and the OAC should occur so that there is continuity of care between the providers.
- (19) Home Blood Draws: Patients who are part of the Home Based Primary Care (HBPC) program or patient's recovering from serious illness may require home blood draws. These may be provided by the VA Medical Center or may be contracted by an outside agency. In cases where an outside agency is utilized the following steps should be taken:
  - (a) A standing order for the PT/INRs will be prepared with the patient's VA primary care provider's signature and faxed to the outside agency. Outside agency must accept orders from CPS.
  - (b) Standing orders will have the OAC contact information for reporting INRs.
  - (c) The patient is responsible for any charges associated with the outside agency's service.
- (20) Release of Information:
  - (a) The OAC will follow the VA policy for maintaining patient's confidential health information.
  - (b) The OAC will track any release of patient information that may occur during the course of patient care. For all non-emergent communication, i.e. general reporting of INRs to outside cardiology, patients and providers will be directed to the Medical Records Office.
- (21) Quality Assurance/Reporting and Competencies:
  - (a) The OAC staff is responsible for drafting a semi-annual report on the quality assurance of the care provided in the clinic. The Clinical Pharmacy Supervisor or designee will report biannually to the local P&T Committee and Executive Committee of the Medical Staff (ECMS). Key parameters to be reported are;
    1. Number of patients admitted and discharged to the clinic over the reporting period.
    2. Percentage of patients within their goal range for various time frames throughout the year (i.e. 25%, 50%, 75% of the time).
    3. Percentage of patients with critical lab values per year with clinical demographics. Review of each case of critical INR>5 is reported for preventability purposes.
    4. Clinic Adverse Events:
      - a. Proportion of patients with pathologic bleeding events
      - b. Proportion of patients with thromboembolic events

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- c. 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 P&T Committee and VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, or subsequent policy issue.
  - 5. Review VA provided warfarin orders to ensure appropriate VA monitoring is occurring.
- (b) The OAC staff is responsible for completing competencies in anticoagulation therapy and monitoring as it pertains to their scope of practice as well as TMS training. In addition to these competencies, the clinical pharmacy supervisor will assign other pertinent anticoagulation training as deemed necessary. 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:
- 1. Knowledge of standard terminology
  - 2. Pharmacology of anticoagulants
  - 3. Monitoring requirements
  - 4. Dose calculations
  - 5. Common side effects
  - 6. Nutrient interactions and drug to drug interactions associated with anticoagulation therapy.
- (22) Safety considerations:
- (a) OAC staff will aim to minimize the risk associated with incorrect tablet strength dosing errors with warfarin. 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, if deemed necessary.
  - 3. Providing written patient education with instructions whenever a dose change is made
  - 4. Limiting outpatient warfarin ordering to specific prescribers
  - 5. Using standardized quick order sets that promote uniformity of dosing
  - 6. Anticoagulants are included on the medical facility's list of high-alert medications
  - 7. Adding statement to outpatient prescription labels that states: "As directed by Anticoagulation clinic dosing card"
- (b) Anticoagulation providers must be notified in a timely manner of critical drug interactions with anticoagulants by prescribing provider in order to ensure appropriate follow-up:
- 1. Assessment of the interaction
  - 2. Adjustment of the anticoagulant dose, as appropriate
  - 3. Order and follow-up of subsequent laboratory tests
- (23) Contingency/Emergency Planning: In the event of an emergency, including a natural disaster or power outage, the clinic will close for safety reasons. In case of an extended down-period or VISTA, CPRS, or Database failure, the following measures will be done to prevent disruptions in care;
- (a) The clinic staff will work with laboratory to identify INR specimens of patient's within the anticoagulation clinic to ensure proper follow up.

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- (b) Patients with immediate need will be contacted first, followed by less emergent cases.
- (c) All patient interventions will be documented on a hard copy for later entry when the computer system is fully functioning again.
- b. INPATIENT ANTICOAGULATION MONITORING SERVICES (IAMS)
  - (1) THERAPEUTIC ANTICOAGULANTS
    - (a) Initiation of Therapy
      - 1. Prior to initiation of treatment with therapeutic anticoagulants (including but not limited to: warfarin, LMWH, argatroban, DOACs, hirudins, fondaparinux sodium, etc.), the provider is responsible for ordering baseline laboratory values for the respective agents.
      - 2. Providers initiating treatment with anticoagulation therapy are required to enter the order into CPRS and document the risk assessment that correlates with the anticoagulation therapy selected.
      - 3. Once therapy has been initiated, providers are responsible for ordering laboratory values for the respective agents.
      - 4. Upon receipt of an initial anticoagulation inpatient medication order, a CPS will evaluate the dose and interval based on the current accepted guidelines as approved through Pharmacy and Therapeutic (P&T) Committee. This assessment excludes routine situations where short-term prophylactic anticoagulation is used for venous thromboembolism prevention (for example, related to procedures or hospitalization where the clinical expectation is that the patient's laboratory values for coagulation will remain within, or close to, normal values). Dietary services run daily reports to alert them to patients on warfarin so food/drug interactions can be avoided. When dietary services are not available, pharmacists, physicians and nursing may provide food/drug interaction education.
      - 5. The CPS will run a report Monday thru Friday (excluding weekends/holidays) for new or continuing patients on anticoagulation therapy. The CPS will enter an Inpatient Anticoagulation Monitoring Progress Note into the electronic medical record within 72 hours of the initiation of therapy. Once the initial note is completed the patient will be monitored by the CPS through discharge or until discontinuation of the anticoagulation therapy.
      - 6. The pharmacist will identify the ordering provider as an additional signer on the initial progress note, which will generate a view alert. The pharmacist will contact the ordering provider and provide recommendations for dose modification, as necessary. The type of contact used should be in accordance with the severity/imminence of the potential patient safety issue. This contact will be documented in a progress note.
    - (b) Continuation of Therapy
      - 1. The CPS will run a report Monday thru Friday (excluding weekends/holidays) for continuing patients on anticoagulation therapy.
      - 2. Inpatient anticoagulation therapy will be assessed and recommendations documented by the CPS daily upon review and completion of a pending anticoagulation order during the day shift, Monday through Friday excluding holidays. This will be accomplished utilizing the Inpatient Anticoagulation Progress Note template.

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3. The CPS will enter a progress note into the electronic medical record to document dosing/monitoring recommendations. In addition the practitioner will be identified as an additional signer on the progress note in order to generate a view alert.
4. The CPS will continue therapeutic monitoring and make recommendations as necessary based on appropriate laboratory values, concentrations and/or or fluctuations in renal status. All recommendations will be documented in a progress note.

### (2) HEPARIN CONTINUOUS INFUSION ORDERING:

#### (a) Initiation of Therapy:

1. Prior to initiation of treatment with therapeutic heparin the provider is responsible for ordering baseline laboratory values including, complete blood counts with platelets and an APTT (activated partial thromboplastin time).
2. Providers initiating treatment with therapeutic heparin therapy are required to enter the order into CPRS and document the appropriate risk assessment.
3. Once therapy has been initiated, providers are responsible for ordering laboratory values including, complete blood counts with platelets and an APTT.
4. Protocol-driven therapeutic heparin therapy will be assessed upon initiation of therapy and labs will be verified. If needed, the pharmacist will enter a progress note every 3 days.
5. The provider is responsible for the selection of the appropriate duration of heparin therapy and for the discontinuation of the order once the patient has been deemed to not require heparin.



Heparin Protocol  
Flowsheet and Nomogram

6.



Heparin Protocol.doc

7.

#### (b) Continuation of Therapy:

1. The CPS will review the manufacturing list for all heparin drip orders processed Monday thru Friday (excluding holidays). The CPS will enter an Inpatient Anticoagulation Progress Note Initial or Follow-Up note into the electronic medical record accordingly.
2. CPS are responsible for routine monitoring of all inpatients on therapeutic anticoagulation with continuous heparin. Monitoring will be done every 3 days to assess APTT, platelets, potential drug interactions, noted hematologic complications and other recommendations as required and in adherence with accepted practice guidelines.

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(c) Discontinuation of anticoagulation therapy:

1. The provider is responsible for the selection of the appropriate duration of anticoagulation therapy and for the discontinuation of the anticoagulation medication order once the patient has been deemed to not require anticoagulation.

(3) QUALITY ASSURANCE AND COMPETENCIES of IAMS

- (a) CPS are responsible for completing annual competencies and TMS training in anticoagulation therapy and monitoring as it pertains to the Inpatient Anticoagulation Monitoring Service. Records will be maintained in the competency tracking database. Competencies, at a minimum, must include:

1. Knowledge of standard terminology
2. Pharmacology of anticoagulants
3. Monitoring requirements
4. Dose calculations
5. Common side effects
6. Nutrient interactions and drug to drug interactions associated with anticoagulation therapy.

#### 4. **REFERENCES:**

- a. 10N2-229 Network 2 Anticoagulation Policy 9-7-12
- b. 10N2-232 VISN 2 Medication Reconciliation Policy 4-27-11
- c. Department of Veterans Affairs VHA Directive 2015-1033 Washington, DC 20420 7-29-15
- d. Ansell, Jack E., Oertel, Lynn B., Wittkowsky, Ann K., Managing Oral Anticoagulation Therapy, Clinical and Operational Guidelines, Aspen Publishers, Inc. 2005
- e. The Ninth ACCP Consensus Conference on Antithrombotic Therapy. CHEST 2012.
- f. VHA National Dual Care Policy, 8-25-2009



PBM CPPO Strong  
Practice Recommendation



PBM CPPO Strong  
Practice Recommendation

- g.  
h. SL-11-21 Communication of Lab Results Memorandum 1-12-2016

5. **RESCISSIONS:** D&T 119-03 Anticoagulation Management Program April 8, 2014

6. **FOLLOW UP RESPONSIBILITY:** Pharmacy Manager ext. 65718

7. **REVIEW:** This SOP is to be reviewed by March 23, 2020

8. **CONCURRENCE:** Chief of Pharmacy

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ADPNS  
Chief of Staff  
Associate Director  
Director

Attachment(s):        Attachments: A, B.

### **Attachment A**

#### **Outpatient Anticoagulation Clinic/Patient Education**

Patient education helps patients understand their disease processes and treatment goals. A successful education program can improve patient compliance and quality of life and thus, improve outcomes. An education plan must be designed and adjusted to meet the needs of our veteran population in order to maximize the educational experience and enhance learning. Furthermore, this education needs to be documented, updated based upon current literature and guidelines, evaluated for patient comprehension and reinforced in subsequent visits as necessary.

The following information will be included in an educational program for patients receiving anticoagulation therapy. This education may be done in a variety of formats that may include: group class, individual instruction, audiovisual, pre-tests, and dietary classes. This education may include supplemental materials given to the patient such as pillboxes, calendars, appointment cards, medic alert information, or other handouts. This education will be documented in the patient's electronic record.

- a. Describe and discuss the reasons for anticoagulation therapy
  - (1) Common disease states for which anticoagulants are prescribed
    - (a) Deep Venous Thrombosis
    - (b) Pulmonary Embolism

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- (c) Atrial Fibrillation/Flutter
  - (d) Valvular Surgery, particularly mechanical heart valves
  - (e) Significant Coronary Artery Disease
  - (f) Clotting Disorders (i.e. Antiphospholipid Syndrome)
- b. Review the process of blood clotting
- c. Information on therapeutic agents
  - (1) Describe medication in terms of:
    - (a) Appearance/color
    - (b) Dose/strength
    - (c) Generic vs. brand
    - (d) Storage (patients on dabigatran will be counseled on storage within the original container)
    - (e) Mode/means of administration
    - (f) Action: interference with clot formation and effect on PT/INR
- d. Discuss dosing information
  - (1) Take as prescribed: same time daily, evening administration preferable
  - (2) Missed doses
  - (3) Dose may need to be changed over time
  - (4) Relationship of dose to PT/INR
  - (5) Temporary discontinuance and management
  - (6) Length of treatment
  - (7) Keep all medications away from children and in original bottles
- e. Describe the potential for drug-drug, drug-food and drug-disease interactions.
- f. Medication refill procedures
- g. Discuss implications of dietary changes on the effects of warfarin management
  - (1) Effects of foods high in vitamin K, and
  - (2) Provide list of foods with vitamin K
  - (3) Encourage consistency
  - (4) Avoidance of alcohol
    - (a) Effect of alcohol variable on PT/INR
    - (b) Increased risk of GI bleeding/CNS bleeds/falls

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- (c) Persistent use/abuse of alcohol or other substance abuse behavior may result in discontinuation of warfarin and/or discharge from clinic

### **h. Monitoring Anticoagulation Therapy**

- (1) Explain PT/INR
- (2) Discuss therapeutic range as prescribed by PCP or specialist
- (3) Importance of compliance with routine monitoring
- (4) What to do if unable to have blood drawn
- (5) Relationship of warfarin dose and test results
- (6) Where labs can be drawn/run and where to have results faxed if needed

### **i. Complications/side effects and management of warfarin:**

- (1) Educate patients on bleeding as the most serious side effect of warfarin.
  - (a) Prolonged bleeding or excessive bruising following an injury
  - (b) Presence of abnormal bleeding

- 1. Blood in urine or dark brown urine
    - 2. Blood in bowel movements/tarry stool, rectal bleeding
    - 3. Bleeding gums
    - 4. Coughing up blood
    - 5. Vomit blood/coffee ground emesis
    - 6. Nosebleeds
    - 7. Excessive or abnormal menstrual bleeding
    - 8. Unexplained or very large bruises
    - 9. Severe headache
    - 10. Severe, unexplained stomach pain

- (2) Review first aid measures for bleeding

- (3) Other adverse side effects:

- (a) Skin rash/hives
  - (b) Alopecia
  - (c) Skin necrosis
  - (d) Diarrhea, abdominal cramping, nausea, vomiting
  - (e) Purple toes or fingers
  - (f) Cholesterol emboli
  - (g) Fever

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- (4) Educate patients on the recognition and management of thromboembolism
  - (a) Shortness of breath or unusual difficulty breathing/pleuritic chest pain
  - (b) Neurological symptoms-paresthesia or focal weakness
  - (c) Visual impairment or loss of vision
  - (d) Lightheadedness or dizziness
  - (e) Swelling or pain in an extremity
  - (f) Slurred speech or inability to speak
- (5) Identification of treatment resources and access
  - (a) Who, what and when to call for help
  - (b) Bleeding signs and symptoms
  - (c) Thromboembolic signs and symptoms
  - (d) Fall or injury to head/neck or back, especially if any LOC
  - (e) Persistent fever, nausea, diarrhea
  - (f) Yellowish discoloration of eyes/skin
  - (g) Call clinic if/when admitted to or discharged from another hospital
  - (h) Rash or hives
- j. Lifestyle Implications of Anticoagulation Therapy
  - (1) Personal and grooming
  - (2) Importance of compliance and consistency
  - (3) Travel: Review Extended Travel Policy
  - (4) Emphasize impact of environment and diet on management
  - (5) Sports/Exercise
    - (a) No contact sports
    - (b) Avoid activities that may cause bleeding/bruises or falls
    - (c) Notify provider if sudden change in activity level
  - (6) Pregnancy and birth control/teratogenic effects
- k. Impact of other medications
  - (1) Notify clinic when medication is added or removed from medication regimen
  - (2) Take no OTC or prescription drug, especially antibiotics without discussing with provider
  - (3) Avoid NSAIDs, aspirin or aspirin-containing drugs unless prescribed by provider
  - (4) If sudden marked increase in use of Tylenol(acetaminophen), notify clinic

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- l. Notify clinic of operative or dental procedures
- m. Reinforce importance of good communication to all providers of health care about anticoagulation therapy.

**Attachment B:** Recommendations for Managing Elevated INRs or Bleeding in Patients Receiving VKAs (Chest)

Condition	Intervention
INR more than therapeutic range but <4.5; no significant bleeding	Lower or omit the next dose; monitor more frequently and resume at lower dose when INR therapeutic; if only minimally above therapeutic range, no dose reduction may be required

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<i>INR <math>\geq 4.5</math> but <math>&lt;10.0</math>; no significant bleeding</i>	Omit next one or two doses, monitor more frequently, and resume at an appropriately adjusted dose when INR in therapeutic range. Alternatively, omit dose and give vitamin K (1-2.5mg po), particularly if at increased risk of bleeding. If more rapid reversal is required because the patient requires urgent surgery, vitamin K ( $\leq 5$ mg po) can be given with the expectation that a reduction of the INR will occur in 24 h. If the INR remains high at 24 hours an additional dose of 1 to 2 mg po can be given
INR $\geq 10.0$ ; no significant bleeding	Hold warfarin therapy and give higher dose of vitamin K (2.5-5 mg po) with the expectation that the INR will be reduced substantially in 24-48 h. Monitor more frequently and use additional vitamin K if necessary. Resume therapy at an appropriately adjusted dose when INR is therapeutic.
Serious bleeding at any elevation of INR	Hold warfarin therapy and give vitamin K (10 mg by slow IV infusion), supplemented with FFP, PCC, or rVIIa, depending on the urgency of the situation; vitamin K can be repeated q12h
Life-threatening bleeding or serious warfarin overdose	Hold warfarin therapy and give FFP, PCC, or rVIIa supplemented with vitamin K (5-10 mg by slow IV infusion). Repeat, if necessary, depending on INR.
Administration of Vitamin K	In patients with mild to moderately elevated INRs without major bleeding, give vitamin K orally rather than subcutaneously.
Continuing warfarin therapy indicated after high doses of vitamin K1	Heparin or low-molecular weight heparin can be given until the effects of vitamin K have been reversed, and the patient becomes responsive to warfarin therapy. It should be noted that INR values $> 4.5$ are less reliable than values in or near the therapeutic range.