

**BY ORDER OF THE COMMANDER  
59TH MEDICAL WING**

**59TH MEDICAL WING INSTRUCTION  
44-139**



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**Medical**

**ANTICOAGULATION MANAGEMENT  
PROTOCOL**

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This instruction implements Air Force Policy Directive 44-1, *Medical Operations* and *Joint Commission National Patient Safety Goal 03.05.01*. This instruction defines the 59th Medical Wing's anticoagulation management program as it pertains to the Anticoagulation Clinic at Wilford Hall Ambulatory Surgical Center (WHASC). This program is designed to provide safe, individualized, and appropriate anticoagulation therapy management. It outlines guidance for starting warfarin therapy; referral to the Anticoagulation Clinic, which is a key component of the anticoagulation management program; and professional staff education requirements. Patients taking anticoagulants other than Warfarin and Enoxaparin should be managed by their Primary Care Manager (PCM). This instruction applies to all cardiology and pharmacy personnel involved in anticoagulation therapy management. This instruction does not apply to Air National Guard or Air Force Reserve. This publication requires the collection and or maintenance of information protected by the Privacy Act of 1974 authorized by 10 U.S.C. 55, *Medical and Dental Care*, and E.O. 9397 (SSN). The applicable SORN F044 AF SG D and Automated Medical/Dental Record System are available at: <http://dpclo.defense.gov/privacy/SORNs/SORNs.htm>. Refer recommended changes and questions about this publication to the Office of Primary Responsibility (OPR) using the AF Form 847, *Recommendation for Change of Publication*. The authority to waive requirements is the publication approval authority. Ensure that all records created as a result of processes prescribed in this publication are maintained IAW Air Force Manual (AFMAN) 33-363, *Management of Records*, and disposed of IAW Air Force Records Information Management System (AFRIMS) Records Disposition Schedule (RDS). The use of the name or mark of any

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### ***SUMMARY OF CHANGES***

This publication has been revised. This revision of 59 MDWI 44-139 includes added Guidance for PCMs; added an Attachment 4; added a reference; added an acronym; added Direct Oral Anticoagulation Therapy (DOAC) initiation and follow up algorithm Figure; added

Indications for DOAC use Table; and added a checklist to use during DOAC follow up Table.

#### **1. Responsibilities.**

##### 1.1. Referring Physician.

1.1.1. Completes Electronic Consultation Sheet in Armed Forces Health Longitudinal Technology Application (AHLTA).

1.1.2. A complete consult must include the patient's name and social security number (SSN) or DoD ID number, date of request, indication for anticoagulation therapy, target INR range, duration of therapy, referring physician name and contact, and PCM/physician name and contact.

1.1.3. The consult also includes the current dose of warfarin if any, baseline or current INR, tobacco or alcohol or illicit drug habits, drug allergies, and reproductive status for female patients.

1.2. PCM. Manages anticoagulation-related complications and any issue that is unrelated to anticoagulation therapy such as infection, bone fracture, organ failure, etc.

##### 1.3. Staff Cardiologist.

1.3.1. Provides oversight of the overall clinic operations.

1.3.2. Provides guidance and mentorship to pharmacists, nurse practitioners and physician assistants providing care within the Anticoagulation Clinic.

##### 1.4. Pharmacists, Nurse Practitioners and/or Physician Assistants.

1.4.1. Monitor all aspects of the daily anticoagulation management activities, supervise and ensure staff complies with standards of practice.

1.4.2. Evaluate patients for possible anticoagulation-related complications or failure of therapy.

1.4.3. Manage patients with minor anticoagulation complications including dose adjustments, therapy initiation or discontinuation where needed.

1.4.4. Notify the staff cardiologists of any anticoagulation-related complications or patients requiring referral to their PCM or the emergency department

1.4.5. Document all patient encounters in AHLTA within 3 duty days.

1.4.6. Provide education to newly acquired anticoagulation patients on pharmaceutical aspects of anticoagulation therapy.

1.4.7. Assist with the development and implementation of orientation training for the anticoagulation clinic nurses and medical technicians.

1.4.8. Oversee collection of data for quality improvement monitoring.

1.5. Anticoagulation Clinic Nursing Services Registered Nurses, Licensed Vocational Nurses (LVNs).

1.5.1. Monitor all aspects of the Anticoagulation Clinic operations.

1.5.2. Nursing manager will supervise licensed vocational/practical nurses and medical service technicians and ensure staff complies with standards of practice.

1.5.3. Assist with the review and acceptance of clinical consults to the Anticoagulation Clinic, ensuring the completeness of information required within the consult.

1.5.4. Review the clinic patient workload and ensure adequate staffing is available to provide safe, effective care to the patients through communication with the Cardiology Clinic's nurse manager.

1.5.5. Assess and triage patients who present with complications secondary to anticoagulation therapy.

1.5.6. Ensure monitoring and evaluation activities are accomplished concerning patients' compliance with therapy.

1.5.7. Collaborate with Anticoagulation Clinic providers on plan of action when a patient is consistently non-compliant with anticoagulation therapy.

1.5.8. Coordinate in-services related to Anticoagulation Clinic management and patient care.

1.5.9. Maintain monthly clinic patient computer log with basic information (i.e., patient name, date of birth, date of class attendance, prefix with SSN or DoD ID number, diagnosis, duration of therapy, desired INR range, primary provider, discontinuation date of anticoagulation therapy, and reason for discontinuation).

1.5.10. Generate Anticoagulation Clinic monthly patient count report. Includes monthly patient population, total number of patient visits to the clinic each day, total number of patient visits to the clinic each month, and total number of new patients receiving anticoagulation instruction each month.

1.5.11. Review weekly AHLTA appointment schedule to ensure that patients that are facility/patient cancelled and/or no-show for their anticoagulation appointments have been properly rescheduled for an appointment.

1.5.12. Attempt to call cancel/no-show patients three times and document attempts in AHLTA.

1.5.13. If unable to reach patient by telephone, contact patient's PCM so they can follow up and discuss with the patient their non-compliance. In addition, forward telephone message (t-con) to Anticoagulation Clinic provider for disenrollment from Anticoagulation Clinic.

- 1.5.14. Prepare disenrollment letter for Anticoagulation Clinic provider to sign. Send letter via certified mail to patient's last known address. Update patient's status in the Anticoagulation Clinic Patient Log and remove patient from command-directed listing.
- 1.5.15. Ensure patients with blood-related disorders are sent to lab to have blood work drawn and orders are entered in electronic health record (EHR).
- 1.5.16. Perform Point-of-Care Testing (POCT) or order Prothrombin Time (PT)/INR via EHR and instruct patient to report to the lab to have blood work drawn for any POCT critical results.
- 1.5.17. Ensure a stat PT/INR is obtained on all patients presenting with anticoagulation-related complications or critical lab value via POCT.
- 1.5.18. Inform Anticoagulation Clinic provider(s) of all critical lab values or complications secondary to anticoagulation therapy.
- 1.5.19. Perform and document POCT quality checks daily prior to clinic opening (when POCT is in use).
- 1.5.20. Ensure all patients are identified by WHASC patient identifiers (i.e. name/date of birth).
- 1.5.21. Generate end-of-day processing report.
- 1.5.22. Contact new patients and schedule for next available class date.
- 1.5.23. Prepare Anticoagulation Record-outpatient record.
- 1.5.24. Prepare for and teach New Patient Anticoagulation Class.
- 1.5.25. Review all new patient consults and contact patient and physician when patients miss scheduled class. Reschedule for class and document in AHLTA.
- 1.5.26. Screen all Anticoagulation Clinic patients to have INR checked and document results.
- 1.5.27. Document results received by fax in patient's record.
- 1.5.28. Medical technicians and LVNs are not to provide medical advice or triage at any time. Any medical question or issue should be immediately referred to a provider.
- 1.5.29. Obtain pertinent information from Anticoagulation Clinic patients and document in patient's record.

## **2. New Patient Anticoagulation Class Preparation and Instruction.**

### **2.1. Anticoagulation Class Preparation.**

- 2.1.1. Contact new patients and schedule for next available class date. All new patient consults must be received within 24 hours of the scheduled class date. Instruct patients to bring all current medications to class.
- 2.1.2. A maximum of 8 new patients will be scheduled per anticoagulation class.
- 2.1.3. If new patient is unable to attend next available class date, notify primary physician that they are responsible for monitoring and dosing patient until patient completes class and document notification. Patients should be seen within 3-5 days of

anticoagulation initiation, within 1 week if patient is established but unstable on warfarin, within 2 weeks if patient is established and stable on warfarin or if patient is to initiate warfarin upon initial visit.

2.1.4. Prior to initial visit, pertinent labs will be obtained to include PT/INR, complete blood count (CBC), urinalysis, liver function tests, human chorionic gonadotropin (HCG) test, and any hypercoagulable labs if applicable.

2.1.5. Ensure patient name (with correct spelling) and prefix with SSN or DoD ID number is on all paperwork in outpatient record.

2.1.6. Enter patient name/prefix with SSN or DoD ID number into Composite Health Care System (CHCS) database with an edit command interest (ECI).

2.1.7. Verify all patient information: patient identification, address, telephone number, primary care provider, treatment duration, desired INR range, diagnosis, and allergies. Document results.

2.1.8. Complete 59 MDW Form 32, *New Anticoagulation Patient Intake*. List all medications, vitamins, herbal pills to include start dates, patient identification, pertinent habits, allergies, pertinent hospitalizations/chronic illness.

2.1.9. Initiate and complete AF IMT 2519, *New Patient Checklist*.

## 2.2. Anticoagulation Class Instruction.

2.2.1. Pharmacy staff teaches pharmaceutical aspect of anticoagulation therapy.

2.2.2. WHASC dietary staff teaches dietary aspect of anticoagulation therapy according to outline.

2.2.3. Cardiology staff coordinates the overall class teaching process including the completion of all required documents.

2.2.4. Patients read, sign, and date Clinic Therapy Compliance Letter, Memorandum for All Anticoagulation Patients.

2.2.5. Patients read and take 59 MDW Form 25, *WHASC Peri-Procedure Anticoagulation Management*, to the provider performing the patient's procedure, have provider fill out Part 1 of the form and sign the form at the bottom of the page, and return the form to the Anticoagulation Clinic to be uploaded into Health Artifact and Image Management Solution (HAIMS).

2.2.6. Patients complete, sign, and date DD Form 2569, *Third Party Insurance Collection Form*.

2.2.7. Females of childbearing age are educated on potential teratogenic effects of warfarin and instructed on importance of notifying Anticoagulation Clinic of any chance of pregnancy.

2.2.8. Ensure patient has the appropriate supply of prescribed warfarin.

2.2.9. Obtain prescription from Anticoagulation Clinic provider for warfarin refills as needed.

## 2.3. Patient Teaching Information and Supplies to Take Home.

- 2.3.1. Anticoagulation Clinic Guidelines.
  - 2.3.2. Your Diet and Vitamin K.
  - 2.3.3. Brief Patient Guide to anticoagulation therapy.
  - 2.3.4. Anticoagulation Clinic Information Sheet.
  - 2.3.5. Preparations Containing Aspirin.
  - 2.3.6. A Patient's Guide to Using Warfarin Booklet.
  - 2.3.7. Warfarin Dosage Calendar.
- 2.4. The following will be assessed, discussed, or occur at initial visit.
- 2.4.1. Patient's anticoagulation history.
    - 2.4.1.1. Indication for anticoagulation therapy, desired INR range, duration of therapy, and risk factors for a thrombotic event.
    - 2.4.1.2. Any history of anticoagulant use including initiation and current dose. Prior adverse experiences with anticoagulation therapy.
  - 2.4.2. Medical, medication, and dietary history.
    - 2.4.2.1. Review past and current medical history (as pertains to anticoagulation therapy, including malabsorption causing conditions).
    - 2.4.2.2. Review of past surgical history (e.g. gastric bypass).
    - 2.4.2.3. Review family history of thromboembolic events.
    - 2.4.2.4. Review of current prescription medications, non-prescription medications, nutritional supplements, and herbal products.

### **3. Patient Education.**

- 3.1. The following information will be presented to the anticoagulation class.
  - 3.1.1. Purpose of anticoagulation therapy for specific indication and warfarin mechanism of action.
  - 3.1.2. Anticoagulation monitoring including: what PT/INR measurement indicates, patient's desired therapeutic INR range, how the INR is used to adjust warfarin therapy, and the importance of routine monitoring and follow-up.
  - 3.1.3. Dosing considerations such as consistency in dosing schedule, handling and reporting of missed doses, use of correct strength and dose, and importance of adhering to prescribed therapy.
  - 3.1.4. Drug-drug interactions: patients will be advised to inform all health care providers that they are on warfarin (due to large number of drug interactions) and to contact the Anticoagulation Clinic before using new non-prescription or over-the-counter medications, vitamins, dietary supplements, or herbal products.
  - 3.1.5. Patients will be instructed to report changes in medication therapy to Anticoagulation Clinic as soon as possible and to avoid using non-steroidal anti-

inflammatory drugs for pain management as these medications may increase risk for bleeding (appropriate doses of acetaminophen may be recommended).

3.1.6. Drug-food interactions. Patients will be educated to understand the importance of maintaining consistency in vitamin K intake.

3.1.7. Alcohol use: patients will be educated of the potentiation of anticoagulant effect of warfarin when alcohol is consumed.

3.1.8. Teratogenicity, including potential and risks, need for appropriate birth control, alternative anticoagulation if pregnancy is desired, and need to contact PCM and Anticoagulation Clinic if pregnancy is suspected.

3.1.9. Advise patient to carry identification of anticoagulation therapy to alert others. Patient education materials will be provided detailing above information.

3.1.10. Provide a brief overview on available alternatives to warfarin and what patient populations may be considered for the alternatives.

3.1.11. Allow sufficient time for patients to ask questions regarding warfarin therapy.

3.1.12. Document patient education on AF IMT 2519.

#### **4. Standard of Practice.**

##### 4.1. Encounter Assessment.

4.1.1. Prior to blood work being drawn, nurses obtain the following information for all patients:

4.1.1.1. Bleeding, bruising or clotting complications; changes in medications or dosages of medications.

4.1.1.2. Current/actual warfarin dosage taken and if patient missed and/or took extra doses of warfarin.

4.1.1.3. Any recent hospitalizations. Inform the patient to report to the clinic upon discharge for lab and for medication review.

4.1.1.4. Changes in alcohol consumption, tobacco use, diet, and/or exercise regimen.

4.1.1.5. For females of childbearing age: any chance of being/getting pregnant.

4.1.2. Perform finger sticks using POCT device or enter request in CHCS to obtain a PT/INR value at the lab.

4.1.3. If patient is having complications or POCT PT/INR are beyond POCT range limits, order in CHCS to perform STAT PT/INR confirmatory test and annotate in the EHR.

4.1.4. Ensure that all patient visits are documented properly. All documentation will be completed on the chart/encounter prior to sending to providers.

4.1.5. Inform Anticoagulation Clinic providers of complications/problems or compliance issues.

##### 4.2. Dosing.

4.2.1. The standard starting dose for warfarin is 5 mg. However, starting doses such as 2.5 and 10 mg may be used in select patients. (Attachment 2).

4.2.2. Initial warfarin therapy may require an overlapping fast-acting anticoagulant such as enoxaparin until therapeutic INR is reached.

4.2.3. Treatment dose of enoxaparin (1 mg/kg twice a day or 1.5 mg/kg once daily) is recommended unless specified otherwise. (Attachment 2).

#### 4.3. INR Testing Intervals.

4.3.1. For new patients, or patients who had warfarin interruption, an INR should be obtained within 3-5 days after starting warfarin to assess initial response.

4.3.2. For patients who require frequent dose adjustments, who report changes in lifestyle or dietary habits, or who have change in clinical status, a 1-week follow up will be scheduled until the dose and a stable, therapeutic INR can be established.

4.3.3. Patients who have had  $\geq 2$  consecutive in-range INRs may be monitored less frequently (i.e. a patient on a 1-week follow up who has had at least 2 consecutive therapeutic INRs can be safely scheduled for a 2-week appointment).

4.3.4. A patient on a 2-week follow up who has had 2 consecutive therapeutic INRs can be safely scheduled for a 4-week appointment.

4.3.5. Patients should have at least 12 weeks of uninterrupted therapeutic INRs to be considered for a 6-week follow up appointment.

4.3.6. Patients with a long history (at least 6 months) of uninterrupted therapeutic INRs may be considered for a 12-week appointment.

#### 4.4. Monitoring.

4.4.1. A CBC will be obtained every 6 months, or more frequently for patients who have had  $\geq 2$  INR readings of  $\geq 4.5$  within 30 days, or as determined by the provider.

4.4.2. Anti-Xa: at least one anti-Xa test will be obtained in overweight or obese patients requiring  $>200$  mg/day of enoxaparin.

4.4.3. An annual CMP, renal and liver function will be obtained or sooner in patients with unexplained changes in INRs.

4.5. Management of Out of Range INRs: for patients with previously stable, therapeutic INR who present with a single out-of-range value (up to 0.25 below or above therapeutic), current dose can be continued with testing the INR within 1 to 2 weeks.

4.5.1. Management of sub-therapeutic INRs: assess signs and symptoms of possible thrombotic events, evaluate possible causes of low INR (missed dose, lifestyle changes, diet, drug-drug interactions, etc.).

4.5.1.1. Patients at high or moderate risk for thrombosis who present with an INR  $\leq 1.7$  can be considered for additional anticoagulation with treatment dose of enoxaparin until at least one therapeutic INR is obtained.

4.5.1.2. Routine use of heparin for low INRs or in patients suspected of being non-adherent is not recommended.

- 4.5.1.3. Available warfarin nomogram may be used as guide for dose adjustment. (See Attachment 2)
- 4.5.2. Management of supra-therapeutic INRs.
  - 4.5.2.1. Assess signs and symptoms of bleed, evaluate possible causes of high INR (took extra pill, lifestyle changes, diet, drug-drug interactions, etc.).
  - 4.5.2.2. Consider holding a dose when INR is one unit above goal (e.g.: INR  $\geq$  4 for goal range of 2-3 and INR  $\geq$  4.5 for 2.5-3.5).
  - 4.5.2.3. Consider holding one or more doses when INR is  $>$  1 unit above the goal.
  - 4.5.2.4. Daily warfarin can be held for up to 3 days with a repeat PT/INR at the end of the hold period.
  - 4.5.2.5. Routine use of vitamin K for INR  $\leq$  10 without signs of bleed is not recommended.
  - 4.5.2.6. For INR  $>$  10 with no significant bleeding:
    - 4.5.2.6.1. 2.5 to 5 mg oral or subcutaneous. Recheck INR in 24 to 48 hours.
    - 4.5.2.6.2. Patients with signs of bleeds at any INR value will be transferred to the emergency department and PCM will be notified.
- 4.6. Perioperative Management.
  - 4.6.1. In order for the clinic to provide perioperative anticoagulation therapy, written information about the procedure must be provided.
  - 4.6.2. Required information includes date and time of the procedure, type of procedure, name and contacts of the provider who will perform the procedure.
  - 4.6.3. Provider performing the procedure must determine the length of warfarin interruption and the desired INR prior to surgery.
  - 4.6.4. Unless indicated by the provider performing the procedure, providers at the Anticoagulation Clinic may use standard recommendations (See Attachment 2) on the following:
    - 4.6.4.1. Bridge therapy.
    - 4.6.4.2. Start date/time for heparin.
    - 4.6.4.3. LMWH dosing.
    - 4.6.4.4. LMWH stop day/time.
    - 4.6.4.5. Day/time to resume anticoagulation therapy (warfarin and heparin).
  - 4.6.5. For procedures requiring  $\leq$  3 days of warfarin interruption, bridging may not be required.
  - 4.6.6. For procedures requiring  $\geq$  5 days of warfarin interruption, patients at high and moderate risk for thrombosis will be considered for bridging. (See Attachment 3)

#### 4.7. Patients with compliance problems.

4.7.1. Records reviews are conducted monthly to ensure patient compliance with recommended therapy.

4.7.2. For any record that indicates a patient is two weeks late in obtaining labs as ordered, the following will be accomplished:

4.7.2.1. The patient will be called and asked why he or she has not followed up. The conversation will be documented in AHLTA.

4.7.2.2. If the patient cannot be contacted by telephone after three attempts, the patient's PCM will be contacted so they can follow up and discuss with the patient their non-compliance.

4.7.2.3. The primary PCM must then initiate a new consult to reinstate the patient into the Anticoagulation Clinic if further management is desired.

4.7.2.4. The patient will be sent a disengagement letter from the Anticoagulation Clinic stating they are being referred back to their PCM.

#### 4.8. Care once reinstated after disengagement for noncompliance.

4.8.1. The patient is encouraged to follow up and provide a reminder of risks inherent to treatment with anticoagulation therapy.

4.8.2. The patient is offered an opportunity for a refresher course and/or to discuss their concerns with the Anticoagulation/Cardiology Clinic nurse or their PCM.

4.8.3. The patient is provided a copy of the clinic's policy letter outlining non-compliance and is to sign the letter. A copy of the signed letter is then scanned into HAIMS. The original is given to the patient.

4.8.4. If a patient is documented as non-compliant, the PCM will be notified and the patient will be disengaged from the Anticoagulation Clinic and referred back to their PCM. Patient disenrollment from the clinic is documented in AHLTA.

4.9. Patients on short-term anticoagulation therapy, upon reaching end of term, will be referred back to their PCM, requesting them to re-evaluate the patient for continued therapy. The referral will be on an Electronic Consultation Sheet in AHLTA/CHCS.

#### 4.10. Inpatient Monitoring/Tracking.

4.10.1. When an Anticoagulation Clinic patient is discharged from the hospital, the nurse/medical technician tracks receipt of narrative summaries and patient follow-up.

4.10.2. Upon discharge from hospital, Anticoagulation Clinic patients should be scheduled for a return visit to the Anticoagulation Clinic.

4.10.3. Anticoagulation Clinic nurse reviews narrative summaries and nursing discharge summaries.

4.10.4. Monthly and quarterly statistics are compiled for receipt of narrative summaries and follow up of patients after discharge from the hospital, including number of hospital days related to anticoagulation therapy.

4.10.5. New medications, which interact with warfarin, are identified by the nurse/medical technician and documented in patient's EMR.

4.11. Patients who are changed to other anticoagulants (i.e. Xarelto, Eliquis, etc.) will be discharged from the Anticoagulation Clinic and referred back to their PCM for further management. Guidance for PCMs (See Attachment 4) on direct oral anticoagulants (DOAC) initiation and follow up algorithm may be found in Figure A4.1. Indications for DOAC use may be found in Table A4.1. A checklist to use during DOAC follow up may be found in Table A4.2.

**5. General Information.** The Anticoagulation Clinic and Laboratory Services are open for business Monday thru Friday from 07:30 to 16:30 hours. The Anticoagulation Clinic is closed on federal holidays.

DANIEL K. FLOOD, Colonel, USAF, MC  
Chief of the Medical Staff

## Attachment 1

### GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

#### *References*

AFPD 44-1, *Medical Operations*, 9 June 2016

Joint Commission, *National Patient Safety Goals*, Current Edition

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Absher. *Patient-specific factors predictive of warfarin dosage requirements*. *Ann Pharmacotherapy*. 2002 October

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#### *Prescribed Forms*

59 MDW Form 25, *WHASC Peri-Procedure Anticoagulation Management*

59 MDW Form 32, *New Anticoagulation Patient Intake*

#### *Adopted Forms*

DD Form 2569, *Third Party Insurance Collection Form*

AF Form 847, *Recommendation for Change of Publication*

AF IMT 2519, *Anticoagulation Clinic New Patient Group Education*

#### *Abbreviations and Acronyms*

**AHLTA**—Armed Forces Health Longitudinal Technology Application

**CBC**—Complete Blood Count

**CHCS**—Composite Health Care System

**ECI**—Edit Command Interest

**EHR**—Electronic Health Record

**HAIMS**—Health Artifact and Image Management Solution

**HCG**—Human Chorionic Gonadotropin

**IAW**—In Accordance With

**INR**—International Normalized Ratio

**LVN**—Licensed Vocational Nurse

**DOAC**—Direct Oral Anticoagulation Therapy

**OPR**—Office of Primary Responsibility

**PCM**—Primary Care Manager

**POCT**—Point of Care Testing

**PT**—Prothrombin Time

**SSN**—Social Security Number

**WHASC**—Wilford Hall Ambulatory Surgical Center

### *Terms*

**Complication**—Any adverse event secondary to anticoagulation therapy that requires intervention, hospitalization, or results in serious injury or death.

**Critical Lab Value**—An INR greater than 4.5 or less than 1.5, Prothrombin time: >30 seconds.

**Stable INR**—Uninterrupted “within range” INRs for  $\geq 90$  days.

**Therapeutic INR**—An INR value within target range for a given diagnosis. For purposes of management, an INR at 0.1 above the upper limit or 0.05 below the lower limit of the target range is considered to be at goal.

**Thromboembolic**—Arterial or venous thrombosis despite therapy. Note: this does not include initial thrombosis requiring initiation of therapy in new anticoagulation patients.

## Attachment 2

## DOSING RECOMMENDATIONS

Table A2.1. Considerations for Warfarin Therapy Initiation.

| Consider lower starting dose (2 mg-2.5 mg)                   | Consider standard to higher starting dose (5 mg-10 mg) |
|--|--|
| Baseline INR >1.2  | Baseline INR < 1.2                                     |
| Advanced age (>65)   | Younger age (<55)                                      |
| Female gender  | Male gender  |
| Asian origin   | >200 pounds  |
| Impaired nutritional status                                  | Patient of Black African Origins                       |
| Low body weight (<110 pounds)                                |  |
| Recent surgery and blood loss                                |  |
| Acute illness such as diarrhea, vomiting, or fever           |  |
| Comorbidities: CHF, renal disease, liver disease, and cancer |  |

Table A2.2. Warfarin Therapy Initiation Nomogram.

| Days | INR<br>(Goal range:<br>2.0-3.0) | Dose<br>(Standard) | Dose<br>(Sensitive<br>patients) | Dose<br>(Less sensitive<br>patients) |
|------|---------------------------------|--------------------|---------------------------------|--------------------------------------|
| 1&2  |                                 | 5 mg               | 2-3 mg                          | 10 mg                                |
| 3    | <1.5                            | 5-10 mg            | 3-5 mg                          | 12.5-15 mg                           |
|      | 1.5-1.9                         | 2.5-5 mg           | 2-2.5 mg                        | 5-10 mg                              |
|      | 2.0-3.0                         | 0-2.5 mg           | 1-1.5 mg                        | 2.5-5 mg                             |
|      | >3.0                            | 0 mg               | 0 mg                            | 0 mg                                 |
| 4    | <1.5                            | 10 mg              | 4-5 mg                          | 12.5-15 mg                           |
|      | 1.5-1.9                         | 5-7.5 mg           | 2-3 mg                          | 5-10 mg                              |
|      | 2.0-3.0                         | 0-5 mg             | 1-1.5 mg                        | 2.5-5 mg                             |
|      | >3.0                            | 0 mg               | 0 mg                            | 0 mg                                 |
| 5    | <1.5                            | 10 mg              | 5 mg                            | 15 mg                                |
|      | 1.5-1.9                         | 7.5-10 mg          | 2.5-3 mg                        | 7.5-10 mg                            |
|      | 2.0-3.0                         | 0-5 mg             | 1-1.5 mg                        | 5-7.5 mg                             |
|      | >3.0                            | 0-2.5 mg           | 0-1 mg                          | 0-2.5 mg                             |
| 6    | <1.5                            | 10-12.5 mg         | 5-7.5 mg                        | 15 mg                                |
|      | 1.5-1.9                         | 5-10 mg            | 2.5-3 mg                        | 7.5-10 mg                            |
|      | 2.0-3.0                         | 0-7.5 mg           | 1-1.5 mg                        | 5-7.5 mg                             |
|      | >3.0                            | 0-2.5 mg           | 0-1 mg                          | 0-2.5 mg                             |

**Table A2.3. Warfarin Maintenance Therapy Nomogram.**

| <b>Goal INR Range 2.0-3.0</b> |               |                  |                  |                  |                                    |  |   |
|-------------------------------|---------------|------------------|------------------|------------------|------------------------------------|--|---|
| <b>INR</b>                    | <b>≤1.5</b>   | <b>1.51-1.99</b> | <b>2.00-3.00</b> | <b>3.01-4.00</b> | <b>4.01-4.99</b>                   | <b>5.00-10.00</b>                                    | <b>&gt;10.003</b>   |
| <b>Dose Change</b>            | Increase 15%  | Increase 10%     | No change        | Decrease 10%     | Hold for one day then decrease 10% | Hold until INR therapeutic then decrease by 15%      | Hold until INR therapeutic and then decrease by up to 20% |
| <b>Follow Up</b>              | 3-7 days      | 7-14 days        | Standard         | 7-14 days        | 3-7 days                           | End of hold period                                   | End of hold period  |
| <b>Goal INR Range 2.5-3.5</b> |               |                  |                  |                  |                                    |  |   |
| <b>INR</b>                    | <b>≤ 2.00</b> | <b>2.01-2.49</b> | <b>2.50-3.50</b> | <b>3.51-4.50</b> | <b>4.51-5.49</b>                   | <b>5.50-10.00</b>                                    | <b>&gt;10.00</b>  |
| <b>Dose Change</b>            | Increase 15%  | Increase 10%     | No change        | Decrease 10%     | Hold for one day then decrease 10% | Hold until INR therapeutic and then decrease by 15%* | Hold until INR Therapeutic then decrease by up to 20%     |
| <b>Follow Up</b>              | 3-7days       | 7-14 days        | Standard         | 7-14 days        | 3-7 days                           | End of hold period                                   | End of hold period  |

**Table A2.4. Enoxaparin Dosing Considerations.**

| <b>Population</b>      | <b>Severe Renal Impairment : (CrCl &lt; 30 mL/min in Non-Dialysis Patients)</b> | <b>Dialysis</b>       | <b>History of HIT</b> | <b>Chronic Thrombocytopenia (Not HIT related)</b> | <b>Obese</b>  |
|------------------------|---|-----------------------|-----------------------|---|---|
| <b>Recommendations</b> | Enoxaparin (treatment dose): 1 mg/kg once daily. Avoid in CrCl < 15 mL/min      | Consider alternatives | Consider alternatives | Consider alternatives                             | Enoxaparin : 1mg/kg q 12 hrs<br>Consider adjusting with anti-Xa level for doses >200 mg/day |

## Attachment 3

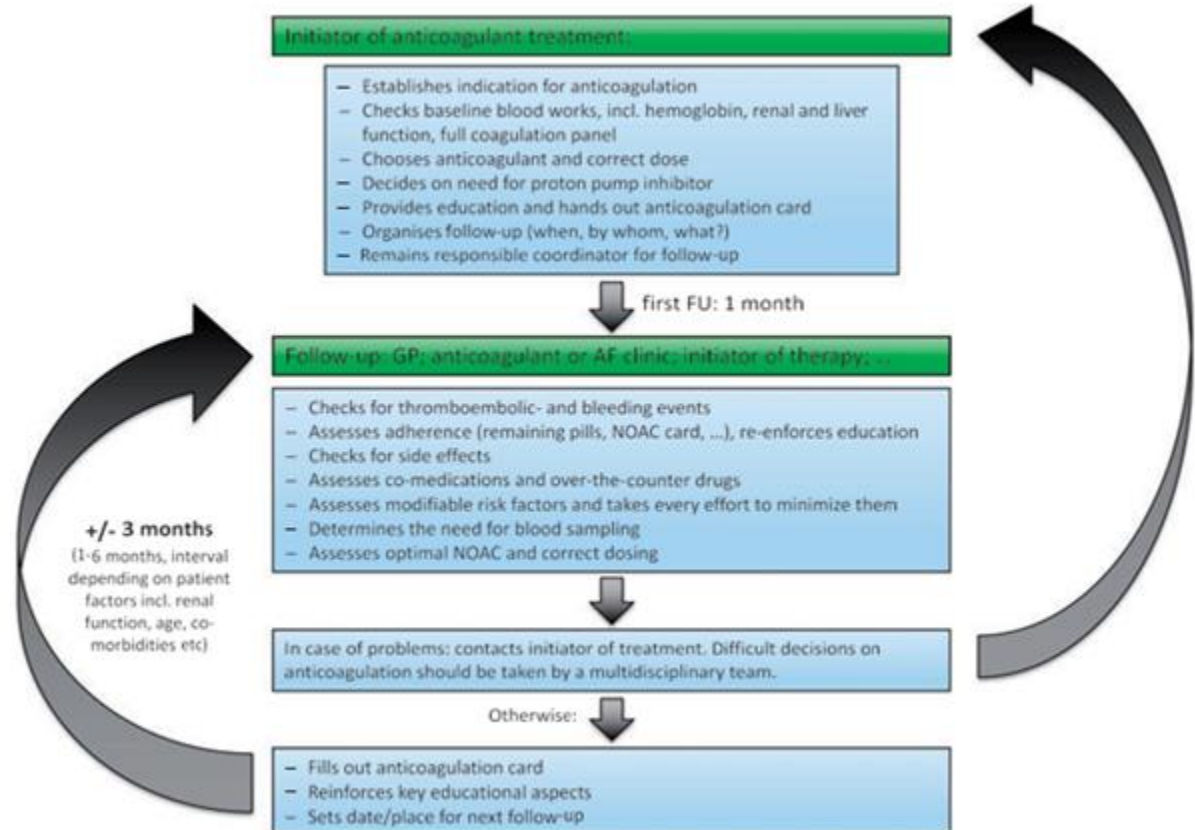
## THROMBOTIC EVENTS RISK STRATIFICATION

Table A3.1. Thrombotic Events Risk Stratification.

| <b>Risk</b>   | <b>Mechanical Heart Valve</b>   | <b>Atrial Fibrillation</b>   | <b>VTE</b>   |
|---|---|--|--|
| <b>High</b>   | Mitral valve<br>Cage-ball or tilting disc aortic valve<br>CVA/TIA within 6 months | CHADS <sub>2</sub> score 5 or 6<br>CVA/TIA within 3 months<br>Rheumatic valvular heart disease | VTE <3 months prior<br>Severe thrombophilia  |
| <b>Moderate</b>   | Bileaflet aortic valve and other risk factors                                     | CHADS <sub>2</sub> score 3 or 4  | VTE within 3–12 months<br>Non-severe thrombophilia<br>Recurrent VTE<br>Active cancer |
| <b>Low</b>  | Bileaflet aortic valve <i>without</i> other risk factors                          | CHADS <sub>2</sub> score 2 or less without prior CVA/TIA                                       | VTE >12 months prior without other risk factors                                      |
| <b>Note:</b><br><b>Severe thrombophilia:</b> Deficiency of protein C, protein S, or antithrombin; antiphospholipid antibodies; multiple abnormalities.<br><b>Non-severe thrombophilia:</b> Heterozygous factor V Leiden or prothrombin gene mutation. |   |  |  |

**Attachment 4**  
**DOAC GUIDANCE FOR PCMS**

**Figure A4.1. Initiation and Follow up Algorithm.**



**Note:** Structured follow-up. Initiation and structured follow-up of patients on non-vitamin K antagonist oral anticoagulants. It is mandatory to ensure safe and effective drug intake. The anticoagulation card is intended to document each planned visit, each relevant observation or examination, and any medication change, so that every person following up the patient is well-informed. Moreover, written communication between different healthcare providers is required to inform them about the follow-up plan and execution. FU, follow-up.

**Table A4.1. Indications for DOAC Use.**

| <b>Note:</b> Selected indications and contraindications for non-vitamin K antagonist oral anticoagulant therapy in atrial fibrillation patients.     |   |
|--|---|
| <b>Condition</b>   | <b>Eligibility for DOAC therapy</b>   |
| <b>Mechanical prosthetic valve</b>   | Contraindicated   |
| <b>Moderate to severe mitral stenosis (usually of rheumatic origin)</b>  | Contraindicated   |
| <b>Mild to moderate other native valvular disease (e.g., mild-moderate aortic stenosis or regurgitation, degenerative mitral regurgitation etc.)</b> | Included in DOAC trials   |
| <b>Severe aortic stenosis</b>  | Limited data (excluded in RE-LY) Most will undergo intervention                             |
| <b>Bioprosthetic valve (after &gt; 3 months post operatively)</b>  | Not advised if for rheumatic mitral stenosis  |
|  | Acceptable if for degenerative mitral regurgitation or in the aortic position               |
| <b>Mitral valve repair (after &gt; 3 months post operatively)</b>  | Some patients included in some DOAC trials  |
| <b>PTAV and TAVI</b>   | No prospective data yet<br>May require combination with single or dual antiplatelet therapy |
| <b>Hypertrophic cardiomyopathy</b>   | Few data, but patients may be eligible for DOACs  |

**Table A4.2. Checklist during DOAC follow-up.**

| <b>Note:</b> Checklist during follow-up contacts of atrial fibrillation patients on anticoagulation. |            |  |
|--|------------|--|
|  | Interval   | Comments   |
| 1. Adherence   | Each visit | <ul style="list-style-type: none"> <li>Instruct patient to bring DOAC card and complete list of medication: make note and assess average adherence</li> <li>Re-educate on importance of strict intake schedule</li> <li>Inform about adherence aids (special boxes; smartphone applications; ..). Consider specific adherence measuring interventions (review of pharmacy refill data; electronic</li> </ul> |
| 2. Thromboembolism   | Each visit | <ul style="list-style-type: none"> <li>Systemic circulation (TIA, stroke, peripheral)</li> <li>Pulmonary circulation</li> </ul>  |
| 3. Bleeding  | Each visit | <ul style="list-style-type: none"> <li>'Nuisance' bleeding: preventive measures possible? Motivate patient to diligently continue anticoagulation</li> <li>Bleeding with impact on quality-of-life or with risk: prevention possible? Need for revision of anticoagulation</li> </ul>  |
| 4. Other side effects  | Each visit | Carefully assess relation with DOAC: decide for continuation (and motivate), temporary cessation, or change of anticoagulant   |

|  |            |  |
|--|------------|--|
| 5. Co-medications  | Each visit | <ul style="list-style-type: none"> <li>• Prescription drugs; over-the-counter drugs (Pharmacokinetics and drug–drug interactions of non-vitamin K antagonist oral anticoagulants section).</li> </ul>        |
| 6. Blood sampling (incl. hemoglobin, renal and liver function)   | Yearly     | Patients other than those specified below  |
|  | 6-monthly  | >_75 years (especially if on dabigatran) or frail (see chapter 2)  |
|  | x-monthly  | If renal function CrCl <_60 mL/min: recheck interval =   |
|  | If needed  | If intercurrent condition that may impact renal or hepatic   |
| 7. Assessing and minimizing modifiable risk  | Each visit | <ul style="list-style-type: none"> <li>• As recommended by current guidelines<sup>3</sup></li> <li>• Particularly: uncontrolled hypertension (systolic &gt;160 mmHg), medication predisposing for</li> </ul> |
| 8. Assess for optimal DOAC and correct dosing  | Each visit | <p>Especially based on the above, re-assess whether</p> <ol style="list-style-type: none"> <li>a. The chosen DOAC is the best for the patient</li> <li>b. The chosen dose is correct</li> </ol>              |
| <p><b>Note:</b> For frequency of visits: see Figure A4.1.</p> <p><b>Note:</b> CrCl, creatinine clearance (preferably measured by the Cockcroft–Gault method); NSAID, non-steroidal anti-inflammatory drugs; PPI, proton pump inhibitor; TIA, transient ischaemic attack.</p> |            |  |