

## **Memorial Hospital Outpatient Anticoagulation Management Protocol**

1. Purpose:
  - a. Monitor

To ensure that every patient placed on long and short-term anticoagulation therapy by a referring physician receives safe, efficient, and economical care according to current standards of practice.
  - b. Educate

To provide patient education regarding the safe use of warfarin. This will include but is not limited to dietary considerations, drug-drug and drug- disease interactions, self-monitoring parameters for sign and symptoms of bleeding/bruising as well as thromboembolisms, compliance to medication and follow-up appointments.
  - c. Follow-up

To ensure continuity of care for all patients in order to optimize anticoagulation therapy while minimizing hemorrhagic complications.
2. Applicability: This manual is applicable to all patients consulted to the Memorial Hospital Anticoagulation Clinic and should be followed by all credentialed pharmacists. The clinical manager will exercise oversight over the Anticoagulation clinic to ensure the protocol is followed correctly. Patients will be managed according to the protocol enclosed. The protocol will be reviewed annually by the clinical manager and the medical director and updated with current practices.
3. Team Members:
  - a. Supervision: The clinical coordinator will exercise oversight over the Anticoagulation clinic; using periodic quality assessment reviews to ensure the protocol is followed correctly. In addition, Dr. Thomas Troeger, MD is the medical director of the anticoagulation clinic and will be overseeing care.
  - b. Personnel: All patients consulted to the Anticoagulation Clinic will be followed by credentialed Anticoagulation clinic pharmacists.
4. Policy and Procedures:
  - a. Each patient must be referred to the Anticoagulation Clinic by a physician. The referring consult must include:
    - i. Referring physician contact information
    - ii. Patient name, date of birth, gender, social security #, Phone number, address, and PMH
    - iii. Patient anticoagulation start date and indication, INR goal, duration of therapy, current or previous warfarin dosage if applicable, pertinent labs, exams or anticoagulation history.
  - b. The consulting provider is ultimately responsible for overseeing the care of the referred patients. Collaboration with the Anticoagulation clinic pharmacist is essential in facilitating the quality and continuity of care for the patients. The provider should notify the pharmacist if any of the below listed items occur.
    - i. When the patient is hospitalized and discharged. The pharmacist will not be responsible for anticoagulation management during this time.
    - ii. When the patient's dosage is changed by a provider other than the clinic pharmacist.

- iii. When the patient is released from care or discharged from anticoagulation therapy.
- c. Laboratory Monitoring

This is critical to successful management of anticoagulated patients. The narrow therapeutic range, long half-life, and the seriousness of the potential complications require diligent monitoring of their anticoagulant state. Patients will be monitored using INR values. The clinic pharmacists will check the INR using the Coaguchek XS system. The following schedule will be used unless otherwise specified by the consulting physician.

  - i. Patients new to anticoagulant therapy will be checked weekly until 2-3 consecutive lab reports within goal, then every 4-5 weeks.
  - ii. Patients stabilized on anticoagulant therapy will be checked every 4-5 weeks.
  - iii. Following a change in dosage, a change in lifestyle or medications that could alter the INR, weekly to biweekly follow-up until stable and an adequate INR established.
  - iv. Procedures for patients with unstable INRs is discussed later.
  - v. Arrangements will be made in an attempt to set up labs if needed at other facilities for patients that will be temporarily out of town and unable to have labs checked in the clinic.
  - vi. The pharmacists may also order other labs pertinent to the safe use of other concurrent medications (i.e. Chem 7, CBC, LFTs).
- d. Missed Appointments

If a patient does not attend a scheduled clinic visit, the following steps will insure adequate follow-up:

  - i. Contact the patient within 48 hours and reschedule the patient for the next available appointment after the missed appointment.
  - ii. Document missed appointments in the Anticoagulant Clinic patient's profile.
  - iii. If the patient has missed three (3) consecutive Anticoagulant Clinic appointments, a note will be inserted in the patient's chart indicating the patient's non-compliance with appointments and the patient may be discharged from the anticoagulation clinic and referred back to their primary care physician.
- e. Pharmacist responsibilities: The Anticoagulation Clinic pharmacist is responsible to the consulting provider for the safe and efficient management of assigned patients. Each clinic pharmacist will be responsible for the following:
  - i. Ensuring all warfarin naive patients receive an initial education session with the designated written information and documentation within 2 weeks from enrollment.
  - ii. Reviewing need for ongoing anticoagulation therapy on all patient visits.
  - iii. Ordering appropriate labs, receiving and responding appropriately to lab results and communicating them to the provider and patient in a timely manner (within 24 hrs).
  - iv. Adjusting medications and managing therapy according to the approved protocol.
- f. Pharmacist Training: Pharmacists must complete the following to be credentialed

to work in the Anticoagulation clinic:

- i. Complete a clinic approved anticoagulation certification course.
- ii. Train on site with a credentialed clinic pharmacist
- iii. Receive approval to practice by the pharmacy clinical manager.
- iv. Credentialed pharmacists must complete 2 hrs of CE credit per year related to outpatient anticoagulation management.
- v. Pharmacists must keep up to date annually with ongoing changes in anticoagulation management.
- vi. Random periodic evaluations of patient therapeutic management will be completed by the clinical manager and/or medical director for all credentialed clinic pharmacists to ensure the protocol is adhered to.

g. Patient visit procedures:

- i. Each patient will be seen in clinic during normal clinic hours unless extenuating circumstances exist and are approved by a credentialed clinic pharmacist.
- ii. Initial patient education will be conducted in a private setting with individualized counseling. The new patient will be provided with information concerning dietary considerations, drug-drug and drug-disease interactions, self-monitoring parameters for symptoms of bleeding/bruising as well as thromboembolisms, compliance to medication and follow-up appointments via verbal instruction and written handouts. The patient will be made aware of clinic hours and contact information. The need to contact the clinic should any changes in their medication and disease states occur will be stressed.
- iii. During each clinic visit, the patient will be evaluated for the following:
  1. Missed/double doses
  2. Proper dose
  3. Diet (vit K greens, caffeine intake, etc) and EtOH use
  4. Medication changes
  5. Bleeding signs/sx and/or signs/sx of thromboembolism
  6. Health problems (fever, illness, diarrhea, dehydration, poor nutrition, etc.).
- iv. These variables will be assessed with current INR results and followed up according to clinical pathways.
- v. Any additional patient education reinforcement regarding warfarin as well as other medications will be provided.
- vi. A brief note will be written following the protocol within 24 hrs and placed in the patient's medical record, then faxed to the referring physician.
- vii. Patients will be encouraged to schedule their next clinic appointment while at the clinic, but may call back later to reschedule.

h. Management of Non-therapeutic INRs: Management of anticoagulation is a patient-specific and highly variable process. Guidelines for managing anticoagulated patients as well as clinical judgment based upon patient's presentation will be utilized.

i. Subtherapeutic INRs

1. A dose change is warranted when 2 consecutive INRs are below

range.

2. Given the individual patient dose response with warfarin, dosing changes will be made in small increments of ~10% of weekly dose.
3. For those patients who remain subtherapeutic despite repeated small dose increases, a larger change of ~10-20% of the weekly dose may be necessary given the thromboembolic risk of continued subtherapeutic INRs.

ii. Supratherapeutic INRs : Follow the 8th ACCP Consensus Conference recommendations (below)

For all patients with INR > 9 or INR > 5 and clinically significant bleeding, verbal consultation will be made first to the referring provider. If the referring provider is unavailable, another provider on staff will be consulted. The medical director of the anticoagulation clinic, Dr. Thomas Troeger, will also be notified of the situation. Clinically significant bleeding includes: hematemesis, hemoptysis, red or black tarry stools, red or brown urine, unexplained bruising, severe headache or stomach ache, frequent nose bleeds, bleeding gums, or unusual bleeding

5. Management of Elevated INRs<sup>1</sup>

<b>INR</b>	<b>Symptoms/Situation</b>	<b>Treatment</b>
< 5.0	No clinically significant bleeding and rapid reversal for surgery is unnecessary	Lower or omit dose, monitoring more frequently, and resuming therapy at a lower dose. If only minimally above therapeutic range or associated with a transient causative factor, no dose reduction may be required.
5.0 – 9.0	No clinically significant bleeding and rapid reversal for surgery is unnecessary  No clinically significant bleeding, but rapid reversal is required for surgery	If no additional risk factors for bleeding: Omit next 1-2 doses, recheck INR, and resume warfarin at a reduced dose. If at increased risk of bleeding: Omit next dose of warfarin and give vitamin K (1-2.5mg) orally.  Give vitamin K 1-4mg orally, with the expectation that a reduction in INR will occur in 24 hours. If the INR is still high, give an additional 1-2 mg of vitamin K orally.
>= 9.0	No clinically significant bleeding	Hold warfarin and give vitamin K 2.5 -5mg orally (expect significant reduction in INR in 24-48hrs). Monitor INR closely. May repeat vitamin K if needed. Resume therapy at lower dose when INR is therapeutic.
Any	Serious bleeding	Hold warfarin and administer vitamin K 10mg by slow IV infusion and supplement w/fresh frozen plasma transfusion or prothrombin complex concentrate. Recombinant factor VIIa may be considered as an alternative to prothrombin complex concentrate. May repeat vitamin K q12h as necessary.
Any	Life-threatening bleeding (eg. Intracranial bleed)	Hold warfarin and give fresh frozen plasma, prothrombin complex concentrate, or recombinant factor VIIa supplemented with vitamin K 10mg, by slow IV infusion. Repeat as necessary.

<sup>1</sup> American College of Chest Physicians Evidence-Based Clinical practice Guidelines (8<sup>th</sup> Edition)

6. Anticoagulation management of patients undergoing procedures: The following are the recommendations of the Anticoagulation Clinic for those patients undergoing procedures.
  - a. Perioperative Management
    - i. In patients who require temporary interruption of a VKA before surgery or a procedure and require normalization of the INR for the surgery or procedure, it is recommended to stop VKAs 5 days before surgery and resume therapy 12-24 hours after surgery.
    - ii. Bridging Therapy: bridging therapy with LMWH is recommended in patients at high risk for thromboembolism (see below for High Thromboembolic Risk Conditions)
  - b. Dental Procedures
    - i. For patients undergoing minor dental procedures and local bleeding must be controlled, coadministration of an oral prohemostatic agent (Gelfoam, Helistat, Surgicel) without interrupting anticoagulant therapy is recommended.
  - c. Invasive Procedures
    - i. For patients requiring a reversal of the anticoagulant effect for an urgent surgical or other invasive procedure, treat with a low-dose (2.5 to 5.0 mg) IV or oral vitamin K. For more immediate reversal of the anticoagulant effect, treat with fresh-frozen plasma in addition to low-dose IV or oral vitamin K.
    - ii. High Hemorrhagic Risk Procedures:

The following procedures are considered to involve a higher risk for hemorrhagic complications. Others may be determined by providers.

      - a) Coronary artery bypass or heart valve replacement
      - b) Intracranial or spinal surgery
      - c) Aortic aneurysm repair
      - d) Peripheral artery bypass
      - e) Other major vascular surgery
      - f) Major orthopedic reconstruction
        - i. Hip or knee replacement
      - g) Reconstructive plastic surgery
      - h) Major cancer surgery
      - i) Prostate and bladder surgery
    - iii. The following procedures may appear to be associated with a low risk of bleeding but perioperative anticoagulation should be undertaken with caution:
      - a) Resection of colonic polyps
      - b) Biopsy of the prostate or kidney
      - c) Cardiac pacemaker and defibrillator implantation
  - d. Low Thromboembolic Risk Conditions: These lower risk patients may discontinue warfarin perioperatively to any of the high hemorrhagic risk procedures listed above.
    - i. Single VTE occurred >12 months ago and no other risk factors
    - ii. Bileaflet aortic valve prosthesis without atrial fibrillation and no other risk of stroke
    - iii. CHADS<sub>2</sub> (Congestive heart failure-Hypertension-Age-Diabetes-Stroke) score of 0-2 and no prior stroke or transient ischemic attack

e. High Thromboembolic Risk Conditions

- i. Any mitral valve prosthesis
- ii. Older (caged-ball or tilting disc) aortic valve prosthesis
- iii. Recent (within 6 months) stroke or transient ischemic attack
- iv. CHADS<sub>2</sub> score of 5-6
- v. Rheumatic valvular heart disease
- vi. Recent (within 3 months) VTE
- vii. Severe thrombophilia (*eg*, antithrombin or protein C or S deficiency, antiphospholipid antibodies)

These high thromboembolic risk patients who undergo any of the high hemorrhagic risk procedures listed above justify the need for bridging anticoagulation or perioperative continuation of antithrombotic therapy.

For patients with a mechanical heart valve, atrial fibrillation, or history of VTE at low risk for thromboembolism, low-dose SC LMWH or no bridging is recommended.

REVIEWED AND APPROVED:

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MEDICAL DIRECTOR

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DATE

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PHARMACY CLINICAL MANAGER

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DATE