

POLICIES AND PROCEDURES FOR THE ANTICOAGULATION CASE MANAGEMENT SERVICE

At The University of Iowa Hospitals and Clinics (UIHC)

Department of Pharmaceutical Care

The Anticoagulation Case Management Service (ACMS) is a service provided by pharmacists in conjunction with licensed independent practitioners (LIPs) that will provide coordinated care in a structured and systematic process for monitoring adult patients on anticoagulation. This coordinated care will result in improved patient outcomes and reduced healthcare expenses, as evidenced by a reduction of bleeding episodes, thromboembolic events, and hospitalizations.

A. FAMILY CARE CENTER

1. Patient Eligibility to ACMS

- 1.1. In order for a patient to be eligible for ACMS, each patient **must** have established care with a primary care provider in the Family Care Center (FCC) Internal Medicine or Family Practice Clinics, who will serve as the contact physician for the patient.
- 1.2. If the patient **does not** have a primary care provider, a consult can be placed for the patient to establish care with a provider in the Family Care Center. The patient can be enrolled into the ACMS once the patient has the first visit with the primary care provider. Therefore appropriate anticoagulation monitoring will need to be arranged until the patient can be enrolled into the FCC ACMS. For information or assistance in setting up a visit you may contact ACMS by pager 7700 Monday through Friday from 8 a.m. to 5 p.m.
- 1.3. If a patient has established care with a local Primary Care Physician, it is recommended that monitoring of the anticoagulation be referred back to the local provider.
- 1.4. The FCC ACMS reserves the right to review the eligibility and appropriateness of anticoagulation for any patient being consulted to or currently enrolled in the clinic. If the risk of anticoagulation appears to outweigh the benefit in a given patient, the eligibility for management by the ACMS will be discussed further with the ACMS Director and Primary Care Provider.
- 1.5. If a patient has planned travel out of the area for an extended period of time (>8 weeks), their anticoagulation monitoring should be managed by a local Primary Care Provider. On an individual patient basis, the patient will be temporarily discharged from the ACMS and his/her anticoagulation management will be transferred to a local provider. The ACMS will provide records as appropriate to the local provider upon request.

2. Consulting ACMS

- 2.1. For all new patients being referred to ACMS, a **consult form** (UIHC Consultation Form E-1) or electronic form when established must be completed to allow the ACMS to contact the patient and schedule him/her into the clinic (Attachment I).
- 2.2. The consult **MUST** include the following information:
 - a) Indication for anticoagulation
 - b) Expected duration of therapy
 - c) Target INR range
 - d) Pertinent past medical history
 - e) Bleeding risk assessment
 - f) Name and contact number of the FCC physician to whom the ACMS service will report.

3. Enrollment Procedures

- 3.1. Upon enrollment into the service, the pharmacist will review the patient's medical record to obtain demographic information, past medical history, pertinent laboratory values, medication history, and information regarding past warfarin dosing regimens. In addition, the patient assessment for warfarin therapy will be performed if the patient is currently on anticoagulation.
- 3.2. Formal warfarin education will be provided to the patient. This includes, but is not limited to the following: the purpose of the service and warfarin therapy, the symptoms of bleeding/thromboembolism, adherence, prescription and over-the-counter drug interactions, alcohol use, and dietary precautions.
- 3.3. A Patient-Provider Agreement for anticoagulation therapy (Attachment II) will be presented to the patient and they will be asked to sign it. This document describes promises that the patient will agree to follow while being enrolled in the Anticoagulation Clinic. Documentation that the Patient-Provider Agreement has been signed will be located under the Alert section of the Working Problem list tab in the Contact Summary of Informm Patient Record (IPR).

4. ACMS Policies for Enrolled Patients

- 4.1. All patients will be required to come to UIHC on a quarterly basis (every 3 months) for an Anticoagulation visit and to see their FCC primary care physician at least once yearly.
 - 4.1.1. If patients do not meet these guidelines, their FCC primary care provider will be contacted about this on an individual patient basis.
- 4.2. If travel to UIHC for each INR blood draw is not an option, patients will have the option to go to a community laboratory (otherwise referred to as having a local lab visit) in between quarterly scheduled visits to UIHC ACMS.

- 4.3. If the patient requires a new prescription for warfarin, the patient will be given a prescription signed by the healthcare provider at their scheduled visits. The new prescription may also be telephoned into a pharmacy if this is preferred by the patient.

5. UIHC ACMS Visit Process

- 5.1. Upon arrival to UIHC, the patient will report to the FCC Internal Medicine or Family Practice Clinic for check-in. The patient will receive an Anticoagulation History Review Form to help assist the pharmacist regarding changes in the assessment parameters (Attachment III).
- 5.2. Laboratory Monitoring:
 - 5.2.1. Patients will have their INR drawn at the laboratory using the CoaguChek™ point-of-care (POC) device with results available immediately.
 - 5.2.2. If the INR is elevated using the POC device (INR > 4), a venipuncture INR will be performed. The specimen will be sent to the central laboratory at UIHC for analysis with the INR result posted in the electronic medical record in approximately one hour.
 - 5.2.3. In the event of a critical INR value (INR > 6), the laboratory technician will contact the ACMS clinic pager (6787). The clinical pharmacist will call back the laboratory for a direct report of the critical INR value.
- 5.3. At the time of their appointment, patients will be given a blue warfarin dosing card which will include the result of their INR by CoaguChek™. A clinical pharmacist will provide anticoagulation education and will assess the patient for signs/symptoms of hemorrhage, thromboembolism, changes in diet, medications, or alcohol and adherence to warfarin therapy. There will then be a discussion regarding the warfarin dosage and the date of the next appointment.
 - 5.3.1. Warfarin dosage adjustments are based on clinical knowledge of warfarin, the change(s) in assessment parameters, and individual patient response to dose changes. Providers may refer to dosing protocols as appropriate (Attachment IV and V).
- 5.4. The clinical pharmacist will document their assessment and recommendations in the IPR electronic medical record.
- 5.5. A healthcare provider assigned to ACMS clinic will be briefed on the patient's status by the clinical pharmacist, evaluate the patient, and document their encounter in the electronic medical record. The physician or physician-extender will sign the clinic note as the final reviewer.
 - 5.5.1. In the event that a healthcare provider is not available to see the patient in a timely manner, the visit will be billed as a lab-only visit.
 - 5.5.2. Routine refusal of a patient to see the healthcare provider as part of the ACMS visit will be discussed with the patient's Primary Care Provider.
- 5.6. The visit will be billed as appropriate based on the time and coding requirements.

6. Local Lab ACMS Visit Process

- 6.1. For those patients going to a community laboratory, a one-year standing PT/INR order will be set up or the ACMS clerk will fax a PT/INR order each time prior to the scheduled lab drawn.
- 6.2. Received local lab results are faxed to the ACMS clerk and INR values will be forwarded by the ACMS clerk to the pharmacist in ACMS clinic on the same day.
- 6.3. The ACMS clerk will start a telephone ACMS note and document the PT/INR result in the outside lab section of the note.
- 6.4. The patient ACMS note with the lab result will be added to the shared list in IPR which the pharmacist in ACMS will be checking multiple times per day.
- 6.5. The clinical pharmacist will contact the patient by telephone to discuss the INR value, recommend dose adjustments, provide education, and arrange follow-up as necessary.
- 6.6. The clinical pharmacist will then document their assessments and recommendations in the electronic medical record. The FCC primary care provider will be notified of the telephone consultation and will be assigned as the final reviewer for the documentation in the electronic medical record.
- 6.7. If the lab result has not been faxed for the scheduled patient, the ACMS clerk will contact the lab requesting the INR lab result to be faxed. If the patient has not been to the lab, the ACMS clerk contacts the patient and reminds them to go to their local lab. The ACMS clerk will contact the patient by telephone the same day as the planned appointment and again 24 hours later. If no response, the patient will be sent a no-show letter (see Section 8).
- 6.8. If the patient's INR is within therapeutic range and the patient is unable to be informed of the result within 48 hours, a therapeutic INR letter will be sent to the patient. The letter will instruct the patient to continue their current warfarin dose and outline a planned follow-up date, time and location. (Attachment VI)

7. ACMS Process for Home INR Point-of-Care (POC) Testing

- 7.1. If a patient that is managed by or enrolled to the ACMS has a home INR POC monitor, then the patient will be required to follow all procedures for enrolled patients outlined above in Section 4.
- 7.2. The patient will be asked to bring in the POC monitor at each quarterly ACMS visit.
- 7.3. The home POC machine will be calibrated with the INR POC machine in the ACMS and by venipuncture (0.3 to 0.7 variance allowed) every 6 months.
 - 7.3.1. If the machine is not calibrating with the UIHC methods, then the company of the machine will be contacted.
- 7.4. Patients testing INRs on home monitors will be assessed and regarded as having a local laboratory and thus will follow the procedures outlined above in Section 6.
- 7.5. The ACMS will follow set guidelines by the POC device's company for individual patients.

- 7.5.1. In the event of a high INR on the home POC monitor (INR value to be determined by the company of the machine), the patient will be asked to come to UIHC or go to a local laboratory for a venipuncture INR.
- 7.5.2. Once the venipuncture result is received by the ACMS the patient will be contacted to further assess their anticoagulation.

8. Process for Missed ACMS UIHC/Local Visits

- 8.1. If the patient has missed their appointment either at UIHC or the local lab, the ACMS clerk contacts the patient and reminds them of the missed appointment.
- 8.2. No-Show Letters (Attachment VII)
 - 8.2.1. A copy of all patient No-Show letters will be documented in the UIHC IPR medical record which will be signed final by the clinical pharmacist.
 - 8.2.2. If the patient does not respond after phoned within 24 hours, the patient will be sent the 1st No-Show letter in 3-5 days after the scheduled follow-up date.
 - 8.2.3. If still no response, a 2nd No-Show letter sent one week after 1st letter.
- 8.3. Lost to Follow-Up Letter (Attachment VIII)
 - 8.3.1. If the patient fails to respond after 2 No-Show letters are sent, he/she will be contacted again by telephone 4 weeks after the Anticoagulation appointment is missed. The patient will also be sent a Lost to Follow-Up letter, the 3rd and final letter, by certified mail discussing their possible dismissal from the ACMS.
 - 8.3.2. If the patient fails to reply to the ACMS in one week after the certified Lost to Follow-up letter is sent out, the patient will be considered lost to follow-up. The patient will then be discharged from the ACMS at that time.
 - 8.3.3. Documentation regarding lost to follow-up will be placed in IPR and the Family Care Center Primary Care Provider will be assigned as the final reviewer.
 - 8.3.4. If a patient who has been considered lost to follow-up comes to a visit at UIHC to see their Primary Care Provider, they may be re-enrolled into the ACMS. The patient's enrollment will follow set procedures for consulting ACMS as previously outlined in Section 2.
 - 8.3.5. If the ACMS receives notification of an INR on a patient that is currently considered lost to follow-up, an attempt will be made to contact the patient.
 - 8.3.5.1. If the patient is contacted and they have not been getting their INRs routinely monitored, then the INR result will be forwarded to the previous primary care provider in the FCC.
 - 8.3.5.2. If the patient is being managed by a local provider, the INR result will be referred to their local provider.
 - 8.3.5.3. If the patient is unable to be contacted, the lab where the result was drawn will be contacted to inform them that the ACMS is no longer managing the patient's warfarin therapy.

9. Documentation and Record Keeping

- 9.1. As above, every care plan note for visits, no-shows, etc. is documented into IPR following an ACMS visit at UIHC or a local laboratory.

- 9.2. Each patient followed by the ACMS will have an Anticoagulation Patient Profile (Attachment IX) and International Normalized Ratio (INR) flow sheet on IPR. The Anticoagulation patient profile includes demographic information and is located under the Alert section of the Working Problem List tab in the Contact Summary of IPR. The anticoagulation flow sheet in IPR includes INR values and warfarin doses which are located under Profiles and Results → Data Profiler → Anticoagulation Clinic Profile.
- 9.3. All patients will be entered into an ACCESS[®] database.
- 9.3.1. The daily ACCESS[®] database includes patient name, hospital number, follow-up date and location, last primary care provider appointment date and a notes section for communication between the pharmacists and the clerk regarding pertinent patient information. The database will be updated daily. This separate database is used to help keep track of patients that no show.
- 9.3.2. The master ACCESS[®] database includes other pertinent information including the date of enrollment into the service, the date discharged from the service and the reason for discharge from the service for each patient.

10. Protocol for Bridging with Unfractionated Heparin (UFH) or Low Molecular Weight Heparin (LMWH)

- 10.1. If a patient is planning to undergo a procedure where stopping warfarin therapy is possible, the patient's FCC primary care provider will be contacted for further guidance on anticoagulation interruption and the need for bridging with either UFH or LMWH.
- 10.2. The primary care provider and the ACMS may refer to recommended guidelines on peri-procedural bridging for invasive surgical procedures and dental procedures in individual patients (Attachment X and XI).
- 10.3. If it is decided to bridge with LMWH as an outpatient, education will be provided to teach the patient on subcutaneous injection technique and the patient will be provided with an instruction sheet with explicit directions for the interruption of warfarin therapy (Attachment XII).

B. CLINICS OUTSIDE OF THE FAMILY CARE CENTER

1. Other clinics located within UIHC that have a dedicated pharmacist and overseeing LIP may also establish their own ACMS.
2. Policies and procedures similar to the FCC guidelines (section A above) should be drafted to address patient eligibility, enrollment, monitoring, and documentation.

ATTACHMENT I: ACMS CONSULT FORM

Order: Family Care Center -- Anticoagulation Case Management Service (ACMS)

To accept the Anticoagulation consult, the patient **MUST** have established care with a primary care provider in the Family Care Center (FCC) and have been seen at least once by that provider within the last year. If the patient does not have established care within the FCC, the patient will **only be enrolled** into ACMS once the patient has the first visit with the primary care provider.

Please contact the **ACMS Consult Pager #7700 Monday through Friday 8am to 5pm** for assistance with determining if they already have a FCC PCP or need to establish care. Also, the clerk will help arrange the first available date and time to have the patient enrolled into the ACMS.

*NOTE: As the consulting physician, you **MUST assume responsibility** or will arrange appropriate anticoagulation monitoring until the patient is able to be enrolled into the FCC Anticoagulation Case Management Service.*

Please complete ALL of the following:

INDICATION FOR ANTICOAGULATION THERAPY (please check all of the appropriate boxes)

Atrial fibrillation/flutter (recommended INR goal 2.0-3.0) – MUST complete the following:

- CHADS2 score for annual risk of stroke* (Gage JAMA.2001; 285: 2864-2870)
 - Congestive Heart Failure (recent) Y/N
 - Hypertension Y/N
 - Age _____
 - Diabetes Y/N
 - Stroke or TIA history Y/N

Annual Risk of Stroke _____% (to be calculated in IPR)
*High Risk = _____, Moderate Risk = _____, Low Risk = _____

Aortic valve replacement (recommended INR goal 2.0-3.0 if a St. Jude Medical bileaflet valve OR CarboMedics bileaflet or Medtronic Hall tilting disk with normal left atrium size and in sinus rhythm, otherwise target range of 2.5-3.5)

- mechanical (type: _____)
- bioprosthetic

Mitral valve replacement (recommended INR goal 2.5-3.5)

- mechanical (type: _____)
- bioprosthetic]

Treatment of DVT (recommended INR goal 2.0-3.0)

Treatment of calf DVT* (recommended INR goal 2.0-3.0)

*Note: 6-12 weeks duration or serial Dopplers over 10-14 days recommend

Treatment of PE (recommended INR goal 2.0-3.0)

H/O recurrent DVT/PE (recommended INR goal 2.0-3.0)

Date(s) of Thrombotic event(s) _____

Thrombophilia: _____
Confirmatory laboratory testing and date _____

Other Indication: _____

ATTACHMENT I (CONT.)

TARGET INR RANGE:

- 2.0 – 3.0
- 2.5 – 3.5
- Other: _____

ANTICIPATED DURATION OF THERAPY:

- 6 weeks
- 3 months
- 6 months
- 12 months
- Indefinitely
- Other: _____

THE OUTPATIENT BLEEDING RISK INDEX

**1.) Risk factors present:
(1 point for each box)**

- Age ≥ 65 years
- History of stroke
- History of GI bleed
- Patient has one or more of the following:
 - Recent MI
 - Hematocrit < 30%
 - SrCr > 1.5 mg/dl
 - Diabetes mellitus

2.) Sum of risk factors:

- Zero
- One
- Two
- Three
- Four

3.) Classification:

- Low risk (0 risk factors)
- Intermediate risk (1-2 risk factors)
- High risk (3-4 risk factors)

REASON FOR CONSULTATION AND PERTINENT INFORMATION: *(box to document additional information below)*

Ordering CLP:

Pager #:

ATTACHMENT II: PATIENT-PROVIDER AGREEMENT

**ANTICOAGULATION CASE MANAGEMENT SERVICE (ACMS)
FAMILY CARE CENTER, UNIVERSITY OF IOWA HOSPITALS AND CLINICS
Patient-Provider Agreement for Anticoagulation Therapy**

Coumadin® (warfarin) is a life saving drug. When used correctly and under close management, warfarin can prevent blood clots from forming in your blood stream. Harmful blood clots can result in a stroke or damage to very important organs.

Warfarin is a potentially dangerous medication. When used incorrectly or without regular blood tests, warfarin can cause serious side effects, which could include internal bleeding or a blood clot and can lead to death in some cases.

When used carefully and in the right dose, warfarin can be a very safe and helpful medication for you. The best dose of warfarin for you can be determined if you allow us to work closely with you. Every person is different and the dose of warfarin you will need will change from time to time. For these reasons, it is very important that we see you every few weeks and perform blood test.

This document is an agreement formed between _____ (Patient Name) _____, the Anticoagulation Clinic, and the patient's Primary Care Physician. The purpose of this agreement is to provide the best care and help you get the most benefit from this medication through the consistent use of warfarin and recommended clinic visits.

To accomplish this goal, the following promises have been made to the Anticoagulation Clinic:

- I must have a Primary Care Physician in the Family Care Center.
- I agree to provide the Clinic with my phone number and an alternate phone number where I can be contacted.
- I agree to provide the Clinic with the name and phone number of the pharmacy I will use.
- I will take my warfarin exactly as prescribed by the Clinic.
- I will NOT let outside physicians adjust my warfarin dose unless I discuss the change with the Clinic FIRST. An exception would be during emergency situations, but I understand that I should still notify the Clinic of my dosage change.
- I will inform the Clinic of any time that my warfarin therapy needs to be stopped for a procedure or other reason.
- I will discuss any prescription, herbal/alternative, or over-the-counter medication changes with a provider in the Clinic.
- I agree to use alcohol in moderation and with consistency and report any changes in consumption to the Clinic.

ATTACHMENT II (CONT.)

- Female Patients: I understand taking warfarin during pregnancy can be harmful to developing babies. I am not currently pregnant.

- I will contact the Clinic if I have problems such as:
 - Bleeding from the gums or nose that does not stop
 - Red or brown urine; Red or black (look like tar) stools
 - Throwing up blood or anything that looks like “old coffee grounds”
 - Cuts that do not stop bleeding or bruises that grow bigger
 - Very heavy menstrual flow or other vaginal bleeding
 - Severe headaches or feeling unusually lightheaded, dizzy or weak
 - Pain or swelling in your stomach

- I understand that if I get my INR drawn at a non-UIHC lab, I must come to the Anticoagulation Clinic at least 4 times per year and see my FCC Primary Care Physician at least once per year.

- I will call the Clinic if I do not get instructions 48 hours after an INR/PT blood test.

- I will show up for my scheduled appointments and arrive on time. If an appointment must be cancelled due to an emergency, I will contact the clinic at 319-384-8084 to cancel and reschedule that same day.

- I will be released from the clinic if I have ignored all attempted contacts from the Clinic to reschedule my appointment for an INR for three weeks in a row.

Prescription Policy

- If there are no refills left on my warfarin, I understand that I must call 72-hours in advance. After notification, we will notify your physician and/or pharmacy to renew the warfarin as soon as possible.

- Prescriptions for refills will only be issued Monday through Friday during business hours. Requests made on Friday will be issued on the following Monday. If a refill is needed on a Saturday or Sunday and it can not wait until the following Monday, please contact your physician and/or pharmacy.

I understand that failure to follow these guidelines may result in stopping of my warfarin or possible removal of my patient status in the Anticoagulation Clinic.

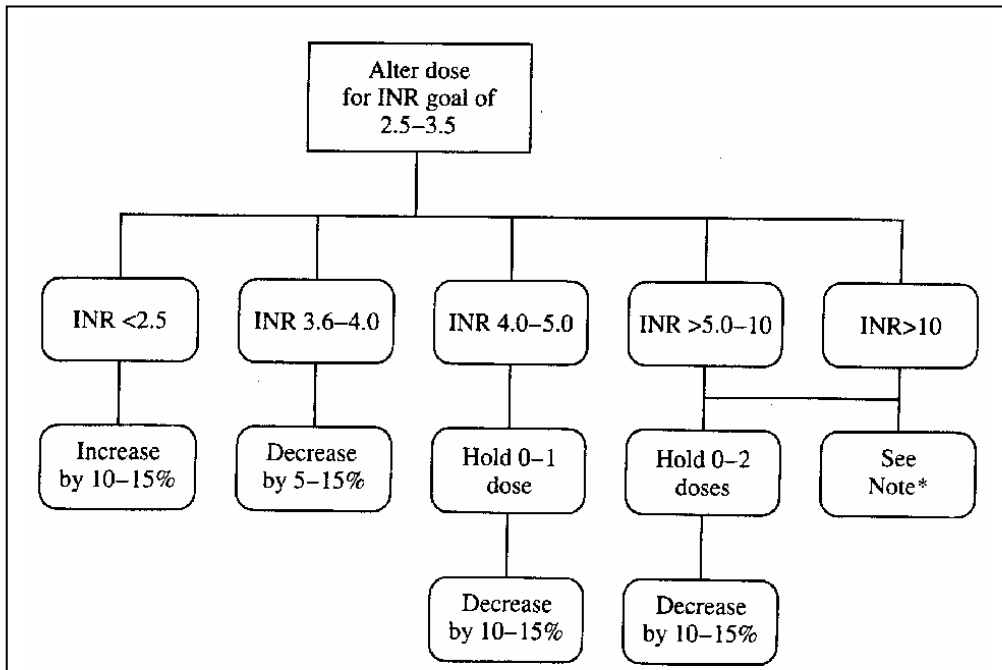
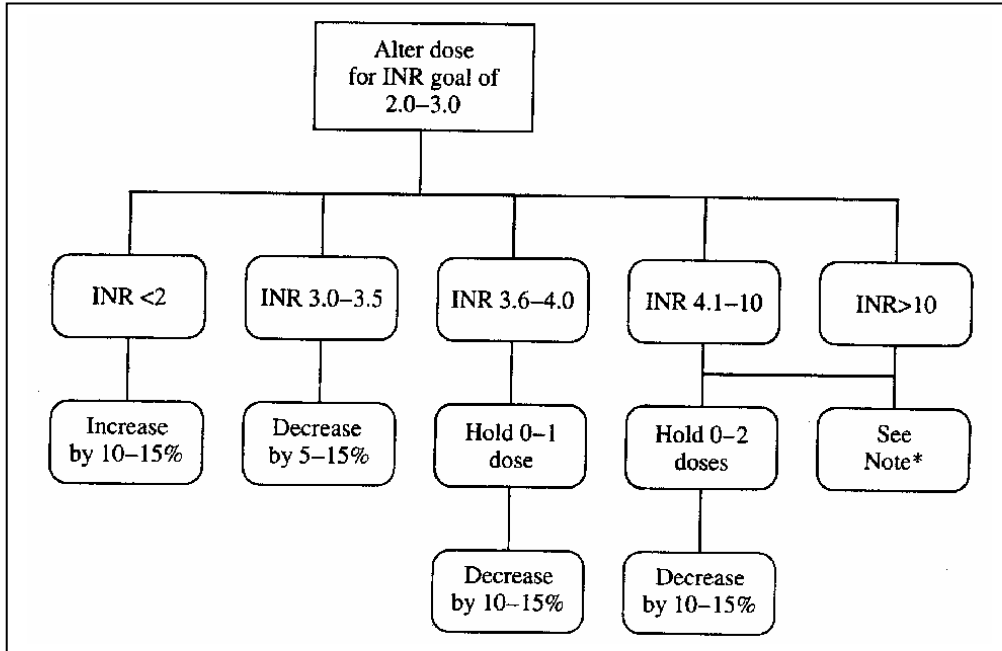
My signature below confirms that I have had the opportunity to review the terms of the agreement, have had any questions answered to my satisfaction and agree to ALL of the above requirements to obtain anticoagulation management for my warfarin within the Family Care Center.

Patient’s Signature _____ Date _____

Pharmacist’s Signature _____ Date _____

ATTACHMENT IV: EXAMPLE WARFARIN DOSING PROTOCOL

Reference: Ansell JE, Oertel LB, Wittkowsky AK, eds. *Managing Oral Anticoagulation Therapy: Clinical and Operational Guidelines*. 2nd ed. St. Louis, Missouri: Wolters Kluwer Health, Inc. Facts and Comparisons. 2003.



ATTACHMENT V: EXAMPLE SPECIFIC WARFARIN DOSING ADJUSTMENT PROTOCOL

Reference: Adapted from the Southwest Medical Associates, Inc. Anticoagulation Clinic Policies and Procedures

Goal INR: 2.0-3.0 (all indications except mechanical valves, or other as specified by referring provider). Clinical judgment may be used in place of the protocol with clear documentation of rationale.

<u>INR</u>	<u>Dosage Adjustment</u>
<1.3	Increase weekly dose approximately 15-20%, recheck PT/INR in 1 week or sooner as needed.
1.4-1.7	Increase weekly dose approximately 10%, recheck PT/INR in 1-2 weeks or sooner as needed.
1.8-1.9	Assessment to determine need for dosage adjustment by AC Nurse or Pharmacist. Recheck PT/INR in 2 weeks or sooner as needed.
2.0-3.0	No change to dose, recheck PT/INR in 4 weeks or sooner as needed.
3.1-3.2	Assessment to determine need for dosage adjustment by AC Nurse or Pharmacist. Recheck PT/INR in 2 weeks or sooner as needed.
3.3-3.4	Decrease weekly dose approximately 5%, recheck PT/INR in 2 weeks or sooner as needed.
3.5-4.9	Lower or omit next dose. Recheck PT/INR on 4 th day; resume at a 10-15% weekly dose reduction once PT/INR back in therapeutic range.
≥5.0	Refer to Guidelines for the Management of High INR's (next page). Contact referring physician to communicate situation.

Goal INR: 2.5-3.5 (mechanical valve, or as specified by referring provider)

<u>INR</u>	<u>Dosage Adjustment</u>
<1.8	Increase weekly dose approximately 15-20%, recheck PT/INR in 1 week or sooner as needed. Continue or start Heparin/LMWH as needed.
1.8-2.3	Increase weekly dose by approximately 10%, recheck PT/INR in 1 week or sooner as needed. Continue or start Heparin/LMWH as needed.
2.4	Assessment to determine need for dosage adjustment by AC Nurse or Pharmacist. Recheck PT/INR in 2 weeks or sooner as needed.
2.5-3.5	No change. Recheck PT/INR in 4 weeks or sooner if needed.
3.6-3.7	Assessment to determine need for dosage adjustment by AC Nurse or Pharmacist. Recheck PT/INR in 2 weeks or sooner as needed.
3.8-3.9	Decrease weekly dose approximately 5%, recheck PT/INR in 2 weeks or sooner as needed.
4.0-4.9	Lower or omit next dose. Recheck PT/INR on 4 th day; resume at a 10-15% weekly dose reduction once PT/INR back in therapeutic range.
≥5.0	Refer to Guidelines for the Management of High INR's

ATTACHMENT V: WARFARIN DOSING ADJUSTMENTS (CONT.)

Reference (cont.): Adapted from the Southwest Medical Associates, Inc. Anticoagulation Clinic Policies and Procedures

Guidelines for the Management of High INR's

INR	Recommendation
INR > therapeutic range but < 5.0 No significant bleeding	Refer to Anticoagulation Clinic Treatment Protocol for dosage adjustment recommendations
INR ≥5.0 but < 9.0 No significant bleeding	<ul style="list-style-type: none"> - If INR >8.0, recheck PT/INR to assure accuracy of results - Omit 1-2 doses - Recheck PT/INR on 4th day, resume at a 10-15% weekly dose reduction once PT/INR back in therapeutic range. - Alternate (if increased risk of bleeding): omit 1 dose, give Vitamin K (preferably 1-2.5mg po, but up to 5 mg).
INR ≥5.0 but < 9.0 No significant bleeding Requires urgent surgery	<ul style="list-style-type: none"> - If INR > 8.0, recheck PT/INR to assure accuracy of results - Omit 1-2 doses - Vitamin K (preferably 2-4mg po, but up to 5 mg). - Expect reduction in INR in 24 hr. - If still high at 24 hrs, may give additional Vitamin K (1-2mg po).
INR >9.0 No significant bleeding	<ul style="list-style-type: none"> - Patient should be referred to Urgent Care or, if necessary, the Emergency Room. - Hold warfarin and give higher dose of vitamin K (5-10mg po). - Expect reduction in INR in 24-48h. - Monitor more frequently (i.e. every three to four days) and use additional vitamin K if necessary. - Resume at a 10-15% weekly dose reduction once PT/INR back in therapeutic range.
Serious bleeding (at any elevation of INR)	<ul style="list-style-type: none"> - Patient should be referred to Urgent Care or the Emergency Room - Hold warfarin and give vitamin K (10mg IV). - Supplement with FFP or prothrombin complex concentrate, depending on the urgency of the situation. - Recombinant factor VIIa may be considered as alternative to prothrombin complex concentrate. - May repeat vitamin K every 12 hours.
Life-threatening bleeding	<ul style="list-style-type: none"> - Patient should be referred to Urgent Care or the Emergency Room - Hold warfarin and give prothrombin complex concentrate supplemented with vitamin K (10mg IV); recombinant factor VIIa may be considered as alternative. - Repeat if necessary.

ATTACHMENT VI: PATIENT THERAPEUTIC INR LETTER

Date:

Name:

Hospital #

Address

Dear (patient name):

The purpose of this letter is to inform you of your laboratory results. Your INR was (patient INR result) on **/**/**. This value is within your target INR range of (patient INR range).

I was unable to reach you by phone after several attempts. Our records indicate that your current warfarin (Coumadin) dose is (patient dose).

Please continue taking the same dose and have your blood drawn on **/**/** at (UIHC or your local lab).

It is very important to monitor your blood while taking warfarin therapy because you could be at risk for bleeding or developing a blood clot.

Please do not hesitate to call us at (319) 384-8084 or 800-777-8442 if you have any questions or problems regarding your warfarin therapy.

Sincerely,

ACMS Provider Name
Anticoagulation Case Management Service

ATTACHMENT VII: PATIENT NO-SHOW LETTER

Date

Name

Hospital #

Address

Dear (patient name):

Our records show that you were scheduled to have your blood drawn to monitor your warfarin (Coumadin[®]) therapy on **/**/**. We have attempted to reach you by telephone several times and have been unsuccessful. It is very important to monitor your blood while taking warfarin therapy because you could be at risk for bleeding or developing a blood clot. Please call as soon as possible to reschedule your next INR.

If you have already had your blood drawn, please contact us as soon as possible so we can obtain the results from your lab. Please do not hesitate to call us at (319) 384-8084 if you have any questions or problems regarding your warfarin therapy.

Sincerely,

ACMS Provider Name

Anticoagulation Case Management Service

ATTACHMENT VIII: PATIENT LOST TO FOLLOW-UP LETTER

Date

Name

Hospital #

Address

Dear (patient name):

Our records show that you have not had an INR/Protime check to monitor your warfarin (Coumadin[®]) therapy within the last month. We have attempted to reach you by telephone and by mail several times and have been unsuccessful. Please let us know if there is another number that we can use to contact you. It is very important to monitor your blood while taking warfarin therapy because you could be at risk for bleeding or developing a blood clot. Please call as soon as possible to reschedule your next INR.

If you wish to have your warfarin therapy managed by our ACMS clinic you must call 319-384-8084 immediately to schedule an appointment with the anticoagulation clinic. If we do not hear from you, you will be discharged from our service and considered lost to follow-up. You will then be responsible for setting up management of your warfarin with your Primary Care Provider. Please do not hesitate to call us at (319) 384-8084 if you have any questions or problems regarding your warfarin therapy.

Sincerely,

Provider Name

Anticoagulation Case Management Service

ATTACHMENT IX: ANTICOAGULATION PATIENT PROFILE

ANTICOAGULATION PROFILE:

Primary Number:
Work Phone Number:
Mobile Phone Number:
Other Phone:

PHYSICIAN:

pager:
CLP:

Pharmacy:

LOCAL LAB:

Name:
Phone:
Fax:

CARE FACILITY:

Name:
Phone:
Fax:

Visiting Nurse:

Indication for Warfarin:
Target INR Range:
Duration of Warfarin Therapy:
Date Warfarin Initiated:

Alcohol use:

Anticoagulation Comments:

Anticoagulation Agreement Signed:

ATTACHMENT X: RECOMMENDED GUIDELINES FOR WARFARIN MANAGEMENT IN PATIENTS UNDERGOING INVASIVE PROCEDURES

Reference: Adapted from the Southwest Medical Associates, Inc. Anticoagulation Clinic Policies and Procedures, Disease-a-Month 2005;51:183-93 and Cleveland Clinic Journal of Medicine 2003;70(11):973-84.

Introduction

The following are guidelines for the management of anticoagulation therapy in patients undergoing invasive procedures. These guidelines can be used to help stratify the risk for the patient in regards to the thromboembolic risk of individual patients and bleeding risk of the procedure. It may also help provide recommendations regarding holding warfarin dosing and instituting bridge-therapy. However, the decision on how to manage patients receiving long-term anticoagulation therapy who require an invasive procedure is based on the perceived risks of continuing or stopping therapy and on the cost of alternative options.

I. Thromboembolic Risk of the Patient

- a. Annualized risk of thrombotic complications in the absence of anticoagulant therapy for selected conditions:

Condition	Thrombosis Risk (%/yr)
Lone atrial fibrillation	1
Average risk atrial fibrillation	5
High-risk atrial fibrillation	12
Dual-leaflet (St. Jude) aortic valve prosthesis	10-12
VTE >3mo ago*	15
Single-leaflet (Bjork-Shiley) aortic valve prosthesis	23
Dual-leaflet (St. Jude) mitral valve prosthesis	22
Multiple St. Jude prosthesis	91

*Risk for recurrent VTW is 40% in the 1st month from acute VTE event and 10% in the 2-3 months following the VTE event.

- b. The CHADS₂ score determines the risk of stroke in an individual patient. The higher the score, the greater the chance of having a stroke. Patients receive points based on the following factors of their medical history:

Condition	Points
Congestive heart failure (any history)	1
Hypertension (prior history)	1
Age >75	1
Diabetes mellitus	1
Secondary prevention in patients with prior ischemic stroke or TIA; most experts also include patients with a systemic embolic event.	2

ATTACHMENT X: RECOMMENDED GUIDELINES FOR WARFARIN MANAGEMENT IN INVASIVE PROCEDURES (CONT.)

c. Risk stratification by thromboembolic risk:

Thromboembolic risk when discontinuing oral anticoagulation		
High-Bridging advised (annual ATE risk >10%; 1-month VTE risk >10%)	Intermediate-Bridging on case-by-case basis (annual ATE risk 5-10%; 1-month VTE risk 2-10%)	Low-Bridging not advised (annual ATE risk <5%; 1-month VTE risk <2%)
•VTE or ATE within preceding 1-3 months	•VTE >3 but <6 months	•remote VTE >6 months ago
•NVAf CHADS ₂ score 4-6 or AF with MHV or stroke	•Older MHV model at aortic position without risk factors	•NVAf CHADS ₂ score 0-1
•NVAf with clinically apparent rheumatic heart disease	•AF without a history of cardiac embolism but with multiple risks for cardiac embolism (NVAf CHADS ₂ score 2-3)	•Newer MHV model at aortic position
•Prosthetic heart valve with other risk factors (prior TE, AF, severe left ventricular dysfunction, or known hypercoagulable state) or recently placed (<3 months)	•Cerebrovascular disease with recurrent stroke/TIAs without risk factors for cardiac embolism	•Intrinsic cerebrovascular disease w/o risk factors for cardioembolism (recurrent strokes or TIAs)
•Older MHV model at mitral position (caged-ball; tilting-disc)	•Newer MHV model at mitral position (St. Jude)	
•Intracardiac thrombus		
•TE event with known hypercoagulable state (Protein S or C deficiency, antithrombin deficiency, homozygous factor V Leiden mutation, antiphospholipid syndrome, active cancer) or recurrent idiopathic TE		

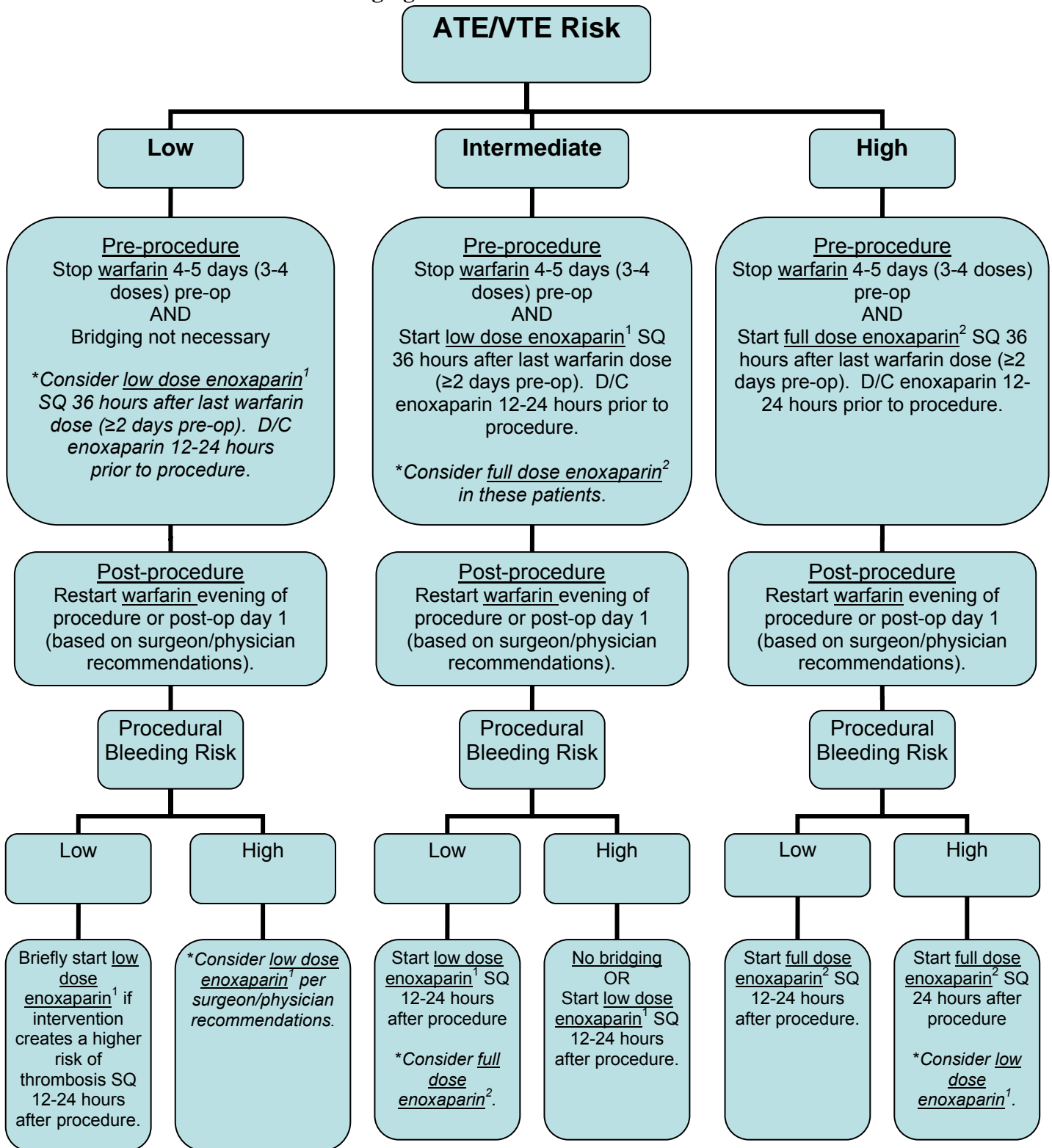
Abbreviations: AF, atrial fibrillation; ATE, arterial thromboembolism; CHADS₂, estimation of risk of stroke; MHV, mechanical heart valve; NVAf, nonvalvular atrial fibrillation; TE, thromboembolism; TIA, transient ischemic attack; VTE, venous thromboembolism.

Disease-a-Month 2005;51:183-93 and Cleveland Clinic Journal of Medicine 2003;70(11):973-84.

II. Bleeding Risk of the Procedure (*Disease-a-Month 2005;51:183-93; Cleveland Clinic Journal of Medicine 2003;70(11):973-84.*)

Procedural Bleeding Risk	
High (2-day risk of major bleed 2-4%)	Low (2-day risk of major bleed 0-2%)
•Heart Valve replacement	•Cholecystectomy
•Coronary artery bypass	•Abdominal hysterectomy
•Abdominal aortic aneurysm repair	•Simple dental extractions
•Neurosurgical/urologic/head and neck/abdominal/breast cancer surgery	•Gastrointestinal endoscopy ± biopsy, enteroscopy, biliary/pancreatic stent w/o sphincterotomy, endonosonography w/o fine-needle aspiration
•Bilateral knee replacement	•Carpal tunnel repair
•Laminectomy	•Dilation and curettage
•Transurethral prostate resection	•Skin cancer excision
•Kidney biopsy	•Abdominal hernia repair
•Polypectomy, variceal treatment, biliary sphincterectomy, pneumatic dilation	•Knee/hip replacement and shoulder/foot/hand surgery and arthroscopy
•PEG placement	•Hemorrhoidal surgery
•Endoscopically guided fine-needle aspiration	•Axillary node dissection
•Multiple tooth extractions	•Hydrocele repair
•Vascular and general surgery	•Cataract and noncataract eye surgery
•Any major operation (procedure duration >45 minutes)	•Noncoronary angiography
	•Pacemaker and cardiac defibrillator insertion and electrophysiologic testing
	•Bronchoscopy ± biopsy
	•Central venous catheter removal
	•Cutaneous and bladder/prostate/thyroid/breast/lymph node biopsies

III. Recommendations for Bridging Once Risk is Assessed



1- low dose enoxaparin 30mg SQ BID or 40mg SQ daily

2- full dose enoxaparin 1mg/kg SQ BID or 1.5mg/kg SQ daily

*- Surgeon/physician should be contacted in these circumstances as there is no clearly defined recommendations per CHEST in these scenarios.

IV. Dosing of UFH and LMWH

- No studies compare LMWH to UFH or to no bridging, so the optimal management of patients on warfarin in the perioperative setting remains to be determined.
- a. Unfractionated Heparin (UFH)
 - i. Full dose: 80units/kg loading dose followed by 18mg/kg/hr infusion; monitor PTT and adjust dose according to goal
 - ii. Low-dose: 5000 units subcutaneously every 8 to 12 hours

b. Low-Molecular Weight Heparin (LMWH)

Treatment	Prophylactic Dose	Full-Dose or Treatment Dose	Renal adjustment for ClCr <30ml/min (prophylactic dose)	Renal adjustment for ClCr <30ml/min (treatment dose)
Enoxaparin (Lovenox)	30mg SC every 12 hours or 40mg SC once daily	1 mg/kg SC every 12 hours or 1.5mg/kg once daily	30mg SC daily	1mg/kg SC once daily

V. Bridging Protocol:

- Approximately 5 days is needed for the INR to be <1.5 if goal on warfarin is 2-3. With neurosurgical procedures and certain major noncardiac surgeries, near-normal INRs (<1.2) may be desirable.
- Preoperative protocol
 - If preoperative INR 2-3, stop warfarin 4-5 days before surgery (3-4 doses).
 - If preoperative INR 3-4.5, stop warfarin 6 days before surgery (5 doses).
 - Start enoxaparin 1mg/kg SQ q12 hours OR 1.5mg/kg SQ daily (therapeutic dose), or 30mg SQ BID OR 40mg SQ daily (prophylactic dose) 36 hours after last warfarin dose at least 2 days prior to surgery.
 - Last dose of enoxaparin 12-24 hours prior to procedure
 - OPTION: Check INR 1 day prior to surgery
 - If INR <1.5, proceed with surgery
 - If INR 1.5-1.8, consider low-level reversal with Vitamin K
 - If INR >1.8, recommend reversal with Vit K (either 1mg SQ or 2.5mg PO)
 - Check INR day of procedure to ensure <1.5
- Postoperative protocol
 - Restart enoxaparin 12-24 hours post-procedure at 1mg/kg SQ q12 hours or 1.5mg/kg SQ daily; consider 30mg SQ q 12 hours if patient is high risk for bleeding.
 - Discuss plan with surgeon
 - Start warfarin 5mg daily or patients’ preoperative dose on evening of surgery or postoperative day 1.
 - Check daily PT/INR until patient is discharged and periodically thereafter until INR is in therapeutic range.
 - CBC with platelets at day 3 and day 7 (HIT screening).
 - Discontinue enoxaparin when INR is 2-3 for 2 consecutive days.

VIII. Alternate Recommendations for Bridging: (*Southwest Medical Associates, Inc. Anticoagulation Clinic Policies and Procedures*)

Condition	Description
Low risk of thromboembolism	<p><u>4 days prior to surgery</u>, stop warfarin to allow INR to return to near normal</p> <p><u>Post-op</u>: If procedure increases risk of thromboembolism, may start low-dose UFH or prophylactic dose LMWH until INR is therapeutic.</p>
Intermediate risk of thromboembolism	<p><u>4 days prior to surgery</u>, stop warfarin to allow INR to fall.</p> <p><u>2 days prior to surgery</u>, begin low-dose UFH or prophylactic dose LMWH.</p> <p><u>Post-op</u> continue low-dose UFH or prophylactic dose LMWH until INR is therapeutic</p>
High risk of thromboembolism	<p><u>4 days prior to surgery</u>, stop warfarin to allow INR to return to normal</p> <p><u>2 days prior to surgery</u>, begin full dose UFH or LMWH (discontinue 12-24 hrs prior to surgery)</p> <p><u>Post-op</u> start low-dose UFH or LMWH until INR is therapeutic</p>
Low risk of bleeding	<p><u>4-5 days prior to surgery</u>, lower dose to reach INR 1.3-1.5</p>
An alternate approach	<p><u>2 days prior to surgery</u>, stop warfarin</p> <p><u>24 hours prior to surgery</u>, give low-dose oral vitamin K along with LMWH or UFH</p> <p><u>Post-op</u>, continue LMWH or UFH if risk stratification indicates until INR therapeutic</p>

ATTACHMENT XI: RECOMMENDED GUIDELINES FOR DENTAL PROCEDURES

Reference: Adapted from the Southwest Medical Associates, Inc. Anticoagulation Clinic Policies and Procedures

Introduction: This policy provides guidelines for the management of anticoagulation therapy in patients undergoing dental procedures.

Discussion: In the case of dental procedures, case reports and studies have indicated the risk of serious bleeding problems is minimal in patients receiving warfarin. However, serious embolic complications have been reported in patients in whom warfarin therapy has been stopped for a dental procedure. Below is a chart detailing specific dental procedures and the INR ranges through which they are thought to be safe.

Procedure	INR Range
Exams, x-rays, models, simple restorations, supragingival prophylaxis	Safe throughout the range of <1.5-3.5
Complex restorations, scaling and root planing, and endodontics	Safe <1.5-3.0, probably safe to 3.5
Simple extractions, curettage, gingivoplasty	Safe <1.5-2.5, probably safe through 3.5 but use local measures to limit bleeding when >2.5
Multiple extractions, removal of bony impaction	Safe <1.5-2.0, probably safe through 3.5 but use local measures to limit bleeding when >2.0
Gingivectomy, apicoectomy, minor periodontal flap surgery, placement of single implant	Probably safe <1.5-2.5, not advised when >2.5
Full mouth/full arch extractions	Probably safe <1.5-2.0, but use local measures to limit bleeding when >2.0. Not advised when >2.0
Extensive flap surgery, extraction of multiple bony impactions, multiple implant placements	Probably safe <1.5, not advised when >1.5
Open-fracture reduction, orthognathic surgery	Not advised when anticoagulated

Topical Measures

1.1 Local measures

- Application of pressure (biting on gauze), suturing, biting on tea bags (containing tannic acid), topical thrombin

1.2 Antifibrinolytic mouthwashes

- Tranexamic acid (Cyklokapron): available as IV solutions which can be prepared as a mouthwash
 - Using a 4.8% solution, have patient hold 10ml of the solution in their mouth at the time of surgery and four times daily for seven days. Patient should hold the solution in the mouth for about two minutes and then expectorate. Avoid swishing or using a drinking straw to avoid dislodging the forming clot
- Aminocaproic acid (Amicar): available as intravenous solution which can be prepared as a mouthwash, as well as an oral syrup
 - Prepare 5 gram solution and make a total volume of 100 ml
 - Hold 10mL of the solution in their mouth for 2 minutes starting 30 minutes prior to the procedure and continuing every one to two hours after the procedure until the solution is gone and the bleeding has stopped. Avoid swishing or using a drinking straw to avoid dislodging the forming clot

ATTACHMENT XII: PATIENT HANDOUT FOR PERI-PROCEDURAL BRIDGING WITH LMWH

INSTRUCTIONS FOR STOPPING WARFARIN PRIOR TO YOUR PROCEDURE

1. You will take your last dose of warfarin (Coumadin®) on: _____
2. Start enoxaparin (Lovenox®) injections the morning/evening of: _____
3. Your enoxaparin (Lovenox®) dose will be:
_____ twice daily (every 12 hours)
_____ once daily in the morning/evening
4. Your last dose of enoxaparin (Lovenox®) will be the morning/evening of: _____

INSTRUCTIONS FOR RESTARTING WARFARIN AFTER YOUR PROCEDURE

1. Restart your previous warfarin dose and enoxaparin (Lovenox®) injections the same night of your procedure, unless directed otherwise by your physician.
2. Continue warfarin and enoxaparin (Lovenox®) and have your blood drawn on: _____