Indian River Medical Center
Policies and Procedures

Policy #: 10.1

Title: ANTICOAGULATION CLINIC

Chapter: Pharmacy
Responsible Person: Director of Pharmacy

Effective Date:
Reviewed Date:
Revised Date:

This policy is intended as a guideline only and failure to follow the policy may or may not be a breach in the current clinical standard of care. It is not intended to replace professional judgment in patient care or administrative matters.

PURPOSE:

GOAL: This document defines the role of the pharmacists and LPNs that staff the Anticoagulation Management Clinic (AMC) at Indian River Medical Center. The goal of participation in the Anticoagulation Management Clinic is to ensure the safety and efficacy of anticoagulation therapy through education and monitoring. For the purpose of this document, the AMC refers to all three of our clinic locations: main hospital campus, Sebastian and Pointe West.

OBJECTIVE: To optimize anticoagulation therapy in patients by; 1) preventing or decreasing thromboembolic events in patients receiving anticoagulation therapy, 2) preventing or decreasing hemorrhagic complications in patients receiving anticoagulation therapy, and 3) providing comprehensive and ongoing education to patients and/or family members about anticoagulants and related therapies.

POLICY: This document will specify exact procedures used in Anticoagulation Management Clinic and define the responsibilities of clinic staff members, patients, and referring physicians.

PROCEDURE:

A. Consultation and referral

Patients may be referred to the AMC at any point in therapy; however, inpatient referral is encouraged to optimize management. Physicians, nurses, or case managers must fax a completed referral form to AMC. Each patient requires a completed physician referral form. The form must include the following: indication for anticoagulation, goal INR range, date of anticoagulation therapy initiation, expected duration of anticoagulation therapy, current dose of anticoagulant medication, and a physician signature. Referrals that are made by hospitalists, surgeons or other physicians who will not have a continued relationship with the patient outside of their hospital stay will be honored for a period of 30 days after discharge. It becomes the responsibility of the patient to maintain a relationship with a physician on a regular basis and the staff of the AMC will obtain a referral from that physician to continue patient's enrollment in AMC. Patients must be a resident of the Indian River County area for >3 months per year to be enrolled in AMC. Special exceptions may be made at the discretion of the clinic pharmacist (e.g. a patient recently discharged from the hospital that will be leaving the area in less than 3 months and has no other management options).

See **Appendix A** – Physician Referral Form

B. Registration

Patients will be pre-registered through the admitting department at IRMC. It is the responsibility of the patient to present new insurance information or change of personal information to clinic staff and registration personnel.

C. Appointment scheduling

A member of the clinic staff will schedule all appointments for the anticoagulation clinic at the specified times/days that the anticoagulation clinic is operating. It is the responsibility of the referring physician, nurse or case manager to obtain the first appointment for new patients being admitted to the anticoagulation clinic directly following hospital stay. Following the initial visit, it is the responsibility of the pharmacist or LPN, in coordination with the patient, to schedule subsequent clinic visits. If an outpatient physician's office is referring a patient, it will be the responsibility of the clinic staff to call patient and schedule appointment in a timely manner. All patients (whether referred by outpatient physician or when discharged from hospital) will be called by the clinic staff to explain location of clinic, given appointment time and instructions regarding what to bring to initial appointment.

D. INR testing procedures

The clinic will utilize point of care INR testing using the CoaguChek® XS Plus system. The accuracy of the testing device will be verified prior to use and will be monitored routinely. The clinic pharmacist will maintain a policy and procedures for the device.

E. Patient database

The clinic will use the CoagClinic® software program to document all patient medical record information, medical history, referral information, initial assessment, progress notes, and follow-up appointments.

F. Initial visit

- The initial visit to AMC will be scheduled no later than 5 days following initiation of therapy, with initial INR check ideally scheduled around day 3-4 of therapy when at all possible.
- Patients who are initiating therapy will be monitored at least 1-2 times per week until therapeutic INR is reached.
- Although 2012 CHEST guidelines suggest an INR testing frequency of up to 12 weeks, due to the advanced age of our AMC clinic population as well as their multiple co-morbidities, the maximum allowable time between visits will be 4 weeks. This may be extended (not more than 8 weeks) in select patients that in the opinion of the pharmacist are very stable as well as competent in identifying changes that could impact INR (including illness, medication changes, side effects etc.)

Step 1 – Clinical Assessment
A member of the clinic staff will interview the patient and obtain a complete medical and medication history and document all findings on patient demographic sheet **Appendix B)**.

Step 2 – Patient Education
New patients and care providers will meet with the pharmacist or LPN for approximately 30 minutes at the initial visit. Counseling will include the following:

- Disease state (indication) and role of anticoagulation therapy
- Name, description, and purpose of the drug
- Basic mechanism of action of the drug and role in therapy
- Time, strength, method of administration, and what to do for missed doses
- Explanation of INR value and the importance of compliance with INR monitoring
- Potential food and drug interactions (prescription, OTC, and herbal products)
- Recognition of excessive anticoagulation and procedures to follow in case of bleeding, excessive bruising, or anticipated surgery or dental procedures
- Recognition of signs and symptoms of thromboembolism and proper procedure if symptoms occur
- Importance of compliance with medication and clinic visits

The patient's understanding of the above will be assessed at each clinic visit and the patient may receive further education. The patient will receive both verbal and written education. See **Appendix C** – Patient Education Materials.

Step 3 – Determination of Dose
After the clinic staff assesses the INR result and overall response to therapy, he/she will determine if any dosage changes are required. Dose adjustments will be made using the following guidelines:

- The dose shall remain the same if the INR falls within the specified therapeutic range, unless otherwise indicated by a change in patient's condition, treatment program, or compliance.
- The dose of warfarin may be increased by approximately 10-20% of the weekly dose if the INR falls below the appropriate range unless otherwise indicated by a change in patient's condition, treatment program, or compliance.
- The dose of warfarin may be decreased by approximately 10-20% of the weekly dose if the INR rises above the appropriate range unless otherwise indicated by a change in patient's condition, treatment program, or compliance.
- The dose of warfarin may be held if the INR is significantly higher than the prescribed range. The physician is to be notified when the patient's condition may be in jeopardy, or if circumstances exist which may be pertinent to the patient's care and treatment plan.
- A clinical pharmacist will review all patient care plans of the LPN and any pharmacy interns that may participate in care as part of their Advanced Pharmacy Practice Experience at IRMC.
- After patient hast 2 consecutive therapeutic INRs on same total weekly dose that are at least 2 weeks apart, monthly monitoring will be initiated.
- Management of extremely high INR's and the administration of oral vitamin K will be based on recommendations from the 2008 and 2012 CHEST guidelines **(Appendix D**

Step 4 – Documentation
The pharmacist or LPN will place all information obtained at the patient visit into the warfarin clinic management software (CoagClinic®). A patient Progress Notes Report will be provided for the patient's medical record as well as the referring physician. See **Appendix E**
– Patient Visit Summary Sheet

Step 5 – Exit Initial Visit
Upon completion of the visit, the pharmacist or LPN will verify that the patient understands the information given to him/her, as well as provide the following written materials:

- Patient education materials
- Written dosage schedule and follow-up clinic appointment date and time.

G. Follow-up visits

Step 1 – Clinical Assessment and Patient Interview
Follow-up visits will take approximately 15 minutes. Any changes in the patient's condition or medications will be documented. The patient will also be assessed for signs/symptoms of bleeding or thromboembolic events. The patient's retention and understanding of important educational materials will be evaluated and re-education will be provided as needed. The patient's compliance with medications and dietary restrictions will also be assessed and documented.

Step 2 – Determination of Dose
The pharmacist or LPN will evaluate the INR result and information obtained from the patient interview and adjust warfarin dose per clinic dosing guidelines (see section F: initial visit) and the patient will receive a new prescription if necessary. A clinical pharmacist will review all patient care plans of LPN and pharmacy interns.

Step 3 – Documentation
The pharmacist will provide a patient Progress Notes Report for the patient's medical record. This form will also be forwarded to the referring physician.

Step 4 – Follow-up Visit
The patient will be given written dosing instructions and a follow-up appointment with the clinic as outlined in Step 2.

H. Discharge

Patients may be discharged from the anticoagulation clinic for any of the following reasons:
1. Completion of the planned duration of therapy.
2. When, in the opinion of the clinic staff, continued noncompliance with prescribed therapy or clinic visits places the patient in significant danger for complications.
3. Staff will notify the referring physician if there are any changes in the patient's status such that the AMC feels that anticoagulation is no longer indicated or that the risks of anticoagulation therapy outweigh any potential benefit.

AMC shall notify the referring physician, and it will then be the responsibility of the referring physician to appropriately follow-up with the patient following discharge.

I. Management of "No Shows"

The clinic staff is responsible for attempting to reschedule all missed appointments. If the clinic makes 1 or more attempt to reschedule a missed appointment and the patient does not return the call, the patient will receive a compliance letter (**Appendix**) by mail and will have 30 days to reply. If the patient does not reply, he or she will be discharged from the clinic and the prescribing physician will be notified. The clinic may notify the referring physician by letter, in the progress note, or verbally. All correspondence to the physician will be documented and provided for placement in the patient's medical record.

J. Physician Contact

The physician may be contacted by phone in the following situations:
1. Actual or suspected signs/symptoms of hemorrhage.
2. Actual or suspected signs/symptoms of thromboembolism.
3. When the duration of therapy has been completed.
4. When the patient consistently misses appointments or continues to be non-compliant with medications.
5. When clinically significant drug interactions that could place the patient at risk for complications are identified.

K. Management of INRs via Phone Consult

The Clinic staff will manage INR results of patients receiving home health services if the situation meets the following requirements:
1. Patient is established with the clinic and has recent history of good compliance at the clinic.
2. Patient will only be requiring home health services temporarily.
3. Please note clinic staff will not manage anticoagulation via phone for any patient requiring long-term home health care.

A clinic pharmacist may provide a patient with an order for a PT/INR to be performed at any US laboratory if patient will be out of town when next due to return to clinic.
1. An order will only be provided for patients that will be out of town for a short period of time such as a vacation or business trip.
2. The pharmacist/LPN will ensure that patient has left a phone number where they can be reached while away so that dosing instructions can be provided in a timely manner. It is the patient's responsibility to ensure they are reachable at provided contact number and to call clinic when they have their blood drawn.
3. It is the patient's responsibility to contact the clinic if they have not received a call from the clinic with dosing instruction within 24 hours of having lab drawn.

L. Management of self-testers

1. Self-testers will be required to test at home once weekly (unless authorized by pharmacist to extend to every 2 weeks or monthly for extremely stable patients).
2. Face-to-face visits will be required every 6-12 months.
3. Patients who have started warfarin within the past 3 months or are currently receiving bridging therapy will not be considered candidates for self-testing.
4. It is the patient's responsibility to call in INR results in a timely manner. Failure to do so will result in the patient being switched back to office visits or discharged from clinic.
5. The clinic reserves the right to switch patients to clinic visits or discharge them if there is concern that patient is not a good candidate for self-testing (e.g. compliance issues, physical impairments, clinic experiences difficulty contacting or communicating with patient by phone.)
6. Consideration for enrollment as a self-tester will be given for patients enrolled by an IRMA physician only. Patients who have non-IRMC staff physicians will not be considered for self-testing through the clinic.

M. Management of patients with orders for INR from an out-of-country physician

1. Clinic will accept an order from an out of country physician for INR and will perform a fingerstick to obtain the INR.
2. No management of anticoagulation dosing will be done for these patients.
3. It is responsibility of patient to contact physician for dosing changes and all therapy-related questions.
4. Patient may provide fax number of physician and results will be faxed to physician as a courtesy.
5. Staff will collect $25 cash from patient.

N. Management of patients receiving bridge therapy with low molecular weight heparin or Arixtra

1. If interruption of warfarin is required due to an upcoming procedure, it is the patient's responsibility to inform AMC in a timely fashion so that a perioperative plan can be coordinated with the referring physician and surgeon.
2. The patient will be assessed for thromboembolic and bleeding risk according to 2012 CHEST guidelines and the 2017 AHA Afib perioperative management position statement. If the patient has not received instructions or the pharmacist is concerned about the appropriateness of the instructions for interruption of their warfarin therapy, the referring physician will be contacted for clarification and final instructions.
3. If bridge therapy is required preoperatively, and the physician requests the clinic to manage, the following protocol will be utilized:
    a. For therapeutic dose SC LWMH Administration:
        i. Hold warfarin x 5 days prior to procedure
        ii. Begin Lovenox 1 mg/kg SC q12 hours if pt is administering Lovenox at home (or 1.5 mg/kg subQ once daily if Lovenox is being administered in the clinic) on day 3 of holding (or when INR subtherapeutic).
        iii. Last dose of Lovenox administered 24 hours prior to procedure at half daily dose
        iv. Resume warfarin when adequate hemostasis is secured and if ok with surgeon (typically evening of procedure or the next morning).
        v. Resume Lovenox 24 hours after procedure if adequate hemostasis is secured and if Ok with surgeon (note: if procedure is high bleeding risk then delay resumption to 48-72 hours later).
        vi. Continue Lovenox 1 mg/kg SC q 12 hours (or Lovenox 1.5 mg/kg subQ once daily) until INR is therapeutic
        vii. Note for CrCl < 30 mL/min: use Lovenox 1 mg/kg SC q 24 hours
    b. For low dose SC LMWH Administration:
        i. Hold warfarin x 5 days
        ii. Begin Lovenox 40 mg SC q24 hours on day 3 of holding (or when INR subtherapeutic)
        iii. Last dose of Lovenox 40 mg SC administered 24 hours before procedure
        iv. Resume warfarin when adequate hemostasis is secured and if ok with surgeon (typically evening of procedure or the next morning)
        v. Resume Lovenox 24 hours after procedure if adequate homostasis is secured and if Ok with surgeon)

vi. Continue Lovenox 40 mg SC q 24 hours until INR is therapeutic

c. Monitoring
    i. PT/INR 24 hours prior to procedure/surgery
        1. Consider administering 1 mg – 2.5 mg phytonadione if INR $\geq$ 1.6
    ii. SrCr within 3 months of procedure, Hgb/HCT, Plts as needed

4. For initiation of warfarin, Arixtra or Lovenox will be used as bridge for at least 5 days or until INR is therapeutic for >24 hours.

O. Clinical Privileges:

The AMC staff is authorized to perform the following functions:

1. Adjust the patient's anticoagulation dosing regimen (including warfarin, LMWH, vitamin K) based on laboratory values and patient assessment.
2. Authorize appropriate medication refills (warfarin) for patients followed in the anticoagulation clinic.
3. Order appropriate laboratory tests (including PT/INR, CBC, CMP, HCG).

P. Responsibilities:

Pharmacist/LPN:

- Providing the patient and caregiver(s) with appropriate education, both written and verbal.
- Adjust the patient's warfarin dose to maintain an INR level within the prescribed range.
- Screen for drug-drug, drug-food, and drug-disease interactions. When a drug interaction requires medical intervention, the pharmacist is responsible for developing an assessment/plan and discussing the recommendation with the physician.
- Notify the referring physician if a patient has any signs of bleeding or thromboembolic event, and may advise the patient to proceed directly to the emergency room if the physician cannot be reached or if the patient's condition is in jeopardy.
- Maintain complete patient records.
- Clinical pharmacist will review all patient care plans of LPN and pharmacy interns.
- Review the anticoagulation clinic protocol yearly and revise as necessary.

Physician:

- Complete the initial clinic referral form instructing the pharmacists what the goal INR should be, the indication for anticoagulation therapy, and expected duration of therapy.
- If medical assistance is required beyond the pharmacist's scope of practice, the patient will be referred to the primary care provider or referring physician as appropriate.

Q. Education

AMC staff will offer presentations on various aspects of anticoagulation therapy to medical, nursing, or other departments as requested. AMC will also serve as an education site for post-doctorate pharmacy residents and doctor of pharmacy students undergoing training in ambulatory care.

R. AMC Staff Education

Each pharmacist or LPN who will be working in the AMC must complete the following criteria prior to working independently:

1. Minimum of PharmD degree or LPN licensure.
2. Successfully complete an instructional module on anticoagulation and be directly supervised in the AMC under the guidance of an experienced pharmacist until supervisor and employee feel confident in abilities to work independently

Appendix A

Indian River Medical Center

Anticoagulation Management Clinic Referral

Please fax this form to: 772-794-1487 or 772-564-6787 (Pointe West)

Patient Name (last, first): _____ **Date:**_____

Phone #:_____ **DOB:**

Referring Physician Signature:_____

Physician Printed Name:_____

MD Phone: _____ **MD Fax:** _____

The following items MUST be completed by physician for enrollment:

1. Indication (Please indicate date of DVT/PE if applicable):

□ DVT I82.91 □ PE I26.99 □ A fib I48.91 □ Other:_____

□ Mitral Valve Replacement I34.8, Z95.2 □ Aortic Valve Replacement I35.9, Z95.2

□ CVA I67.9 □ Hypercoaguable State (please list): _____

2. When Coumadin Started: Current dose:

3. Patient's Last INR: _____ (date:_____) Date Patient due for next INR: _____

4. Desired INR: □ 2-3 □ 2.5-3.5 □ other_____

5. Duration of Therapy: □ 3 months □ 6 months □ Indefinite □ other_____

6. Therapeutic Bridging (optional): Dose is weight based on indication per clinic protocol

□ Arixtra subcutaneously daily until 2 consecutive therapeutic INRs
□ Lovenox subcutaneously daily until 2 consecutive therapeutic INRs
□ Other _____

7. Please indicate location patient would prefer (optional):
□ IRMC Main Campus □ Pointe West □Sebastian

By utilizing this form, it is assumed that you have read and agreed to the AMC Policies and Procedures. Please contact AMC if you have not seen the policies and procedures and would like them faxed to you. A clinical pharmacist can be reached at 772-563-4611 or ext 1773. Pointe West clinic please call 772-226-4260, Sebastian 772-226-3773.

Appendix B

Date_____

Anticoagulation Management Clinic

Name_____ male / female

HPI: _____

Indication:_____Date started:_____Current dose:_____

PMH:

□ Atrial Fibrillation

C – Congestive Heart Failure □ 1 pt
H – Hypertension □ 1 pt
A – Age > 75 years □ 1 pt
D – Diabetes Mellitus □ 1 pt
S – Stroke/TIA (date) □ 2 pt

$CHADS_2$ Score:

□ High Risk (5-6 pts)
*Stroke/TIA w/in 3 mo
*Rheumatic valvular heart disease
□ Moderate Risk (3-4 pts)
□ Low Risk (0-2 pts)
*No prior stroke/TIA

□ Valve Replacement

Type: _____
Location:_____
Implant date: _____

For mechanical:
□ High Risk
*Any Mitral Valve
*Aortic (Caged/Tilting Disk)
*Stroke/TIA w/in 6 mo
□ Moderate Risk
*Aortic Valve and CHADS ≥1 and/or Afib
□ Low Risk
* Aortic Valve and CHADS=0 and no Afib

□ Venous Thromboembolism

Recurrent:_____
Date(s):_____
Hypercoaguable states: _____
_____
Family Hx:_____
_____

□ High Risk
*Recent (3 mo) or severe thrombophilia (Prot C/S def, APLA, homozygous Factor V Leiden, multiple conditions)
□ Moderate Risk
*VTE 3-12 mo, Recurrent VTE, active cancer w/in 6 mo, other thrombophilia (heterozygous Factor V or Factor II mutation)
□ Low Risk
*Single VTE>12 mo ago

Other conditions:_____

Bleeding hx: □ None □ Ulcers year_____ □ PUD □ GERD □ Other:_____

Current RX medications/herbals/otc: (include name, dose, route, frequency, and start date)

_____ _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

Coumadin: AM PM **Tablet strength**: _____ Medication allergies/reaction_____

Alcohol Use (# drinks/week)_____ Tobacco Use (# ppd)_____

Pt counseled on risks with pregnancy and need for contraception? _____ Method _____

Servings of Vit K foods_____

□ Pt uses Pillbox Who fills box or administers medications:_____

PCP:_____Other MD: _____(Cardio Heme/Onc Vascular Other:_____)

Appendix C

Indian River Medical Center
Anticoagulation Management Clinic
Patient Education

Warfarin: Guide for Patients and Families

Why do I have to take warfarin:	• Warfarin is an effective medicine to prevent new blood clots and to keep existing ones from getting bigger. It does not dissolve existing clots. Your body does that naturally
	• A blood clot can slow or stop the flow of blood. Blood clots can cause pain in your legs (known as DVT) or chest (known as PE). Clots can also cause stroke, disability, or death. Prompt treatment is important
	• Warfarin may be used in people who have conditions such as:
	  ○ Atrial fibrillation (irregular heart rhythm)
	  ○ DVT (Deep Vein Thrombosis or a blood clot in a vein)
	  ○ Heart attacks
	  ○ Heart valve replacements
	  ○ Pulmonary embolism (blood clot in your lung)
	  ○ Stroke
	  ○ Valvular heart disease (any problem with one of the four valves in the heart)
	  ○ Pulmonary hypertension (high blood pressure in the arteries that supply the lungs)
	• Warfarin is safe and effective if used carefully, but it's a balancing act. Too much can cause a dangerous amount of bleeding; too little can allow new clots to form.

Get your INR Blood Tests:	• Go for your INR blood tests at least once a month. Many people get tested as often as once a week when first started on warfarin. • At every visit, always ask for your INR number and know what your target range is supposed to be. It may be 2-3; 2.5-3.5; or different depending on your physician's wishes. An INR that's too high shows more risk for bleeding. An INR that's too low shows more risk of clots. • The amount of warfarin you take may change when your INR changes. This will help keep your warfarin at the right level.
Take the right medicines:	• Warfarin has other brand names, Coumadin® and Jantoven™. Do not take Coumadin® or Jantoven™ in addition to warfarin. This will double your dose and can be unsafe. • Warfarin medicines are color-coded by strength. If you get a different color tablet than usual, ask your pharmacist. To simplify the process, it's best to use just one pharmacy. • Try to avoid taking other medicines that can make you bleed more easily. These include Motrin®, Aleve®, ibuprofen or naproxen. • Aspirin can also make you bleed more easily; however, there are many medical conditions that may require you to take aspirin with your warfarin. Talk to your doctor about taking these medications together safely. • Read all new medicine labels to make sure they don't contain aspirin before using them. If you're not sure, ask your doctor or pharmacist. • Tylenol (acetaminophen) is usually OK to take, but check with your doctor first. • If you miss a dose of warfarin, do not take an extra pill to "catch up".

Talk to your doctor:	• Always ask if any new medicine is safe to take with warfarin. This includes prescribed medicines, especially antibiotics and over-the-counter medicines. It also includes vitamins, herbal supplements and nutritional supplements such as Ensure®, Boost®, or Slim-Fast®. • Tell all your healthcare providers that you take warfarin. This includes your physician, nurse, dentist, chiropractor, nautropath and pharmacist. They all need to know. • Stopping or changing the amount of your other medicines can also affect your warfarin.

Alcohol and street drugs:	• Alcohol can make you bleed more easily while taking warfarin
	• If you do drink alcohol, limit your intake. In 24 hours, you should drink no more than:
	  ○ One to two 12-ounce beers
	  ○ One to two 6-ounce glasses of wine
	  ○ One to two mixed drinks
	  ○ One to two shots of hard liquor
	• Binge drinking can significantly increase your INR and your bleeding risk
	• Cocaine, heroin, marijuana and other street drugs can increase your risk of bleeding.

Signs and symptoms of too MUCH warfarin:	• Warfarin makes you bruise easily while taking warfarin. If you bump into something, apply pressure to the spot, or hold ice on it for 2 to 5 minutes. • For a cut, put pressure on the area for 2 to 5 minutes. If you're still bleeding in 20 to 30 minutes, or it's a large cut, go right to the nearest Emergency Department. Tell them you take warfarin. • If you get a nosebleed, do not hold your head back. Instead, hold your head in a normal upright position. Pinch your nose together just below the boney part and squeeze tightly for 2 to 5 minutes. If you're still bleeding in 20 to 30 minutes, go to the nearest Emergency Department. Tell them you take warfarin. • If you get nosebleeds easily, try using a humidifier and a saline nasal spray or gel. This can help keep your nose moist and prevent nosebleeds.
Signs and symptoms of too LITTLE warfarin:	• Sudden weakness in any limb • Numbness or tingling anywhere • Visual changes or loss of sight in either eye • Sudden onset or slurred speech or inability to speak • Dizziness or faintness • New pain, swelling, redness or heat in an extremity • New shortness of breath or chest pain
Go straight to the Emergency Department if you:	• Are in a vehicle accident or have a major fall, especially if you hit your head. • Notice bright red blood in the toilet after you go to the bathroom, or if your urine turns smoky pink or red color • Notice that your stools are black and sticky, like tar. They may also smell unusually bad. • If you are throwing up dark or bloody colored stomach contents. • Get a sudden and extremely painful headache. It might feel worse than any other headache in your life. • Have symptoms similar to the last time you had a blood clot • Briefly black out, cant' move, have trouble talking or become very weak—especially if you're weak on only one side of your face or body. This could be a stroke.

Diet and Exercise:	• Some foods you eat contain vitamin K, which can work against the warfarin. The highest amount of Vitamin K (which helps the blood to clot) is found in foods such as dark green leafy vegetables, and some meats such as beef and pork liver. • Keep your diet consistent in the amount of foods that contain vitamin K. It is important to eat about the same number of servings each **WEEK** of these foods. It is **NOT** necessary to eliminate these foods from your diet completely. • Pay particular attention to foods that are **MODERATE** to **HIGH** in Vitamin K; you do not need to monitor your intake of foods that are **LOW** in vitamin K. • Keep your exercise level regular. • Maintaining regular daily activities including consistent eating and exercise habits will make it less likely to need to change your dose of warfarin.

FOOD	PORTION SIZE	VITAMIN K	FOOD	PORTION SIZE	VITAMIN K
Artichoke, Cooked	1/3 Medium	L	Kale	1 cup	H
Artichoke, Raw	1 Large	L	Kiwi fruit	1 cup	L
Asparagus	7 spears	M	Leeks	1 cup	L
Beans, green	¾ cup	L	Mayonnaise	7 tablespoons	L
Beans, Lima	½ cup	L	Mushrooms	5 pieces	L
Beets	1 cup	L	Okra	½ cup	L
Beet greens	1 cup	H	Onion	2/3 cup	L
Black-eyed peas	1 cup	M	Parsley	1 ½ cup	H
Blackberries	1 cup	L	Parsnip	1 cup	L
Blueberries	1 cup	L	Peas	½ cup	L
Broccoli	½ cup	H	Pepper	1 pepper	L
Brussel Sprouts	1 cup	H	Potato	1 potato	L
Cabbage	1 cup	M	Pumpkin	1 cup	L
Canola/Soybean oil	7 tablespoons	M	Radish	1 cup	L
Cauliflower	½ cup	L	Rhubarb	1 cup	M
Celery	2 ½ stalks	L	Romaine lettuce	1 cup	M
Chard	½ cup	H	Sauerkraut	½ cup	L
Chive	3 tablespoons	L	Spinach	1 cup	H
Coleslaw	¾ cup	H	Squash	1 cup	L
Collards	1 cup	H	Sweet potato	1 cup	L
Corn	½ cup	L	Tofu (soy)	4 oz fried	L
Cucumber	1 cup	L	Tuna	3 oz	L
Dandelion greens	1 cup	H	Tomato	1 tomato	L
Eggplant	1 cup	L	Turnip	3 ½ oz	L
Endive	2 cups	H	Turnip Greens	1 cup	H
Grapes, red/ green	1 cup	L	Watercress	3 cups	H
Iceberg Lettuce	1 cup	L	Mixed vegetables	1 cup	L

KEY: HIGH= 80-1000 ug/serving MEDIUM= 48-80 ug/serving LOW= 0-48 ug/ serving

- Eat as many low vitamin K foods as you like. For foods with medium to high amounts of Vitamin K, don't eat more or less of those than you would normally do in a week.
- Ex: If you usually eat foods high in vitamin K three times a week, don't suddenly change your diet and eat them every day. A steady diet is key. If you have any questions, contact your clinic provider.
- Other foods that are high in Vitamin K include supplement drinks including Boost®, Ensure®, and Slim-Fast®. These should be treated like one serving of a HIGH vitamin K food.
- Other foods may actually INCREASE your INR and increase your risk of bleeding. It is recommended to stay away from eating: grapefruit, cranberries, and mangos. This includes juices and supplements.

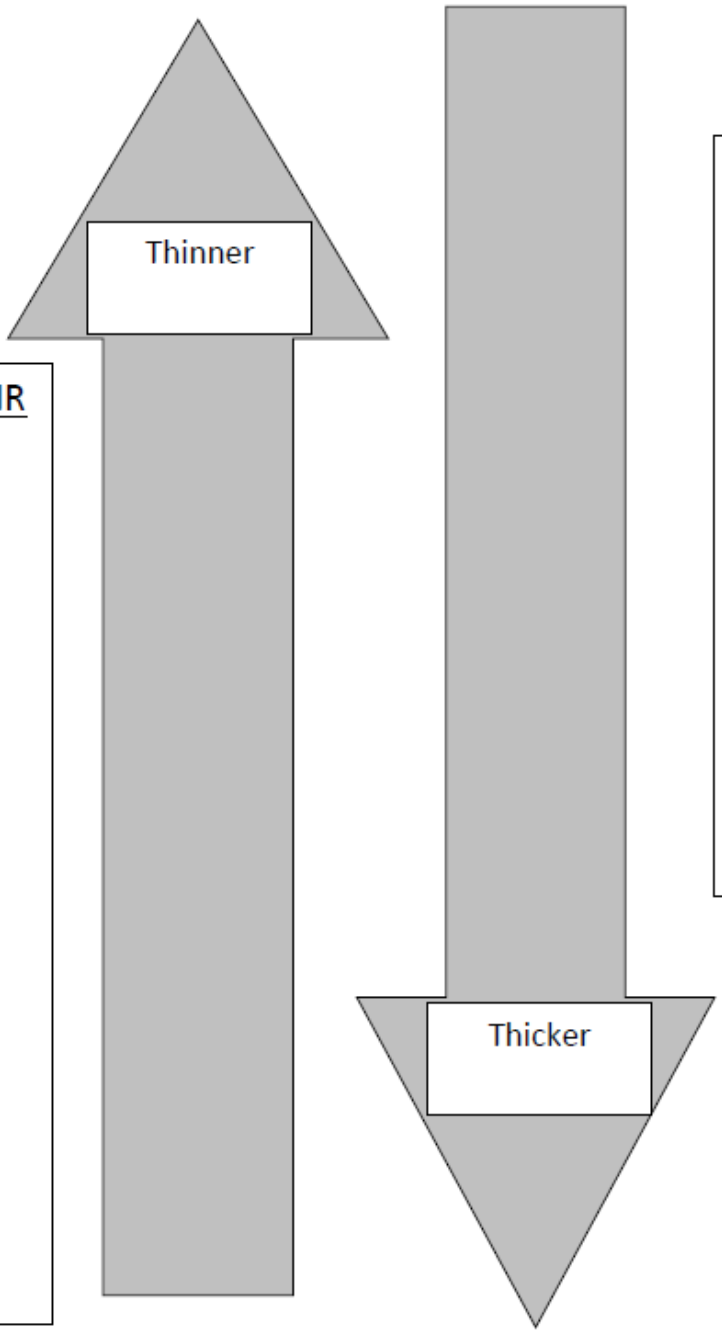
What if I get sick:	• Acute illness will change your body's response to warfarin. • An episode of heart failure, fever, flu, viral/bacterial infection, nausea and vomiting, or diarrhea can cause your INR to fluctuate and increase your bleeding risk. • If you experience any of these, contact your doctor or anticoagulation clinic. • Call the clinic when starting any new medications, even if you won't be taking them for very long. This includes antibiotics, steroids, etc.
What if I get pregnant:	• You should not take warfarin if you are pregnant or actively trying to become pregnant. • There are other, safer options for thinning blood if you want to or already have conceived. • Talk to your OB/GYN about alternatives to prevent harm to developing fetus.

Important Points to Remember:

- Take your warfarin exactly as directed, at the same time each day.
- Your goal INR is most likely between 2-3 or 2.5-3.5. If you are below this range you are at greater risk of forming clots. If you are above this range, you are at greater risk for bleeding.
- Look for signs of bleeding or clotting and report them immediately.
- Notify your doctor or clinic of changes in your dietary vitamin K intake, activity level, or medications (including herbal products, vitamins and over-the-counter medicines).
- Call your doctor or clinic if you have a fever, diarrhea, vomiting, or loss of appetite lasting longer than one day.
- Limit alcohol to 1-2 drinks daily. Drinking 2 or more drinks can greatly increase your INR and increase your risk of bleeding.
- Tell each of your healthcare providers that you are taking warfarin, carry a wallet card, and consider getting an ID bracelet or necklace.
- Keep all appointments or call promptly to reschedule.
- Call the IRMC Coumadin Clinic at 772.563.4611 with any questions you may have. Operating hours are Monday through Friday 8-4. If we do not answer, leave a message and a staff member will return your call shortly.

What will change my INR?

You want to keep your number (INR) in your goal range, and consistency is key.
Here are a few things that may alter your INR.



May Increase INR

Less green leafy vegetables high in Vitamin K

Alcohol

Stress/Pain/Illness

Doubling doses

Certain Antibiotics

Some other Medications

Cranberry

Mango

Grapefruit

May Decrease INR

Extra green leafy vegetables high in Vitamin K

Tobacco

Missing Doses

Green Tea

Liver

Some supplements

If you have any questions about whether your medication is going to change your INR, give us a call and we will be happy to let you know.

Our direct telephone line: 772-563-4611.

Appendix D

Managing Patients with High INR Values

Clinical Situation	Guidelines
INR > therapeutic range but <5, no clinically significant bleeding, rapid reversal not indicated for reasons of surgical intervention	Lower the dose or omit the next dose, monitor more frequently, resume warfarin therapy at a lower dose when INR approaches desired range (if the INR is only minimally above therapeutic range, dose reduction may not be necessary)
INR $\geq$ 5 but < 9, no clinically significant bleeding	Omit next one or two doses, monitor more frequently and resume warfarin therapy at a lower dose when the INR is in the therapeutic range Patients at an increased risk of bleeding: omit the next dose of warfarin and give vitamin K_1 (1 mg - 2.5 mg orally) Patients requiring more rapid reversal before urgent surgery: give 2 to 4 mg oral vitamin K_1; if the INR remains high at 24 hrs, an additional 1 to 2 mg vitamin K_1 may be given
INR $\geq$ 9, no clinically significant bleeding	Hold warfarin; give higher dose of vitamin K_1 (2.5-5 mg orally); closely monitor INR; if the INR is not substantially reduced by 24-48 hrs, use additional vitamin K_1 if necessary; resume warfarin at lower dose when therapeutic INR achieved
Serious bleeding at any elevation of INR	Hold warfarin; administer vitamin K_1 10 mg by slow IV infusion, supplemented with FFP, prothrombin complex concentrate, depending upon urgency; recombinant factor VIIa may be considered as alternative to prothrombin complex concentrate; vitamin K_1 infusion may be repeated q12h
Life-threatening bleeding	Hold warfarin therapy and give prothrombin complex concentrate, with 10 mg slow IV infusion of vitamin K_1; recombinant factor VIIa may be considered as alternative to prothrombin complex concentrate, repeat if necessary, depending on INR
Continuing warfarin therapy	Heparin, until the effects of vitamin K_1 have been indicated after high doses of reversed, and patient is responsive to warfarin vitamin K_1

Appendix E

Patient Progress Notes Report **Indian River Memorial Hospital**

PT Test (CPT85610QW) Encounter No: **Date & Time of Visit**: 6/11/2008 9:50 AM EST

Patient Name	Medical Record / Social Security #	D.O.B / Age	Referring Physician / Supervising Clinician
			Seth Baker Seth Baker

INR Range: 1.9 - 3 **Treatment Start Date:**

Next Visit: 7/14/2008 10:15 AM IRMC **Treatment End Date:**

Diagnosis 1: Atrial Fibrillation / 427.31 **Diagnosis 2:**

Diagnosis 3: **Diagnosis 4:**

Visit Results: **Current INR:** 2 **Current Protime:** **Specimen Coll and Rpt Date/Time:** 6/11/2008 (9:50 AM) EST

Vital Signs: **Pulse** **B/P** **Weight** **Height** 73 **Temp**

Current Dosing Schedule (mg) **Dosage Size(mg):**5 **Additional Pill Size:** 2.5 **Warfarin Type:** Generic

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Total/Wk
7.5	5	7.5	7.5	7.5	5	7.5	47.5

Patient Medication Instruction ☐ Patient Nutritional Counseling ☐ Patient Bruising Instruction ☐

Health Care Provider: Last Education Date:

Previous Visit Information show all visits

Visit Date	INR Goal	INR	Total Weekly Dose (mg)	Daily Dose (mg)						
				Su	Mo	Tu	We	Th	Fr	Sa
6/11/2008	2.45	2	47.5	7.5	5	7.5	7.5	7.5	5	7.5
5/7/2008	2.45	2.1	47.5	7.5	5	7.5	7.5	7.5	5	7.5
4/11/2008	2.45	2.4	47.5	7.5	5	7.5	7.5	7.5	5	7.5
3/4/2008	2.45	2	47.5	7.5	5	7.5	7.5	7.5	5	7.5

Current Medications

Medication	Dose	Units	#	Freq	Route
Acebutolol	200	mg	1	daily	PO
Aspirin	81	mg	1	daily	PO
glucosamine/chondroitin			1	daily	PO
MVI			1	daily	PO
Nifedipine	60	mg	1	daily	PO
Simvastatin	20	mg	1	daily	PO
Vitamin C				daily	PO

Warfarin Interaction Legend

- Could increase INR.
- Could decrease INR.
- Could increase or decrease INR.
- Clinic has reported interaction

Progress Notes

INR 2.0 (Goal 2.0-3.0). Pt properly verbalized warfarin regimen. Pt denies missed/doubled doses. Pt reports no s/sx of bleed, unusual bruising, or thromboembolism. Pt denies any changes in medication, Vit K intake, activity, or use of EtOH/tobacco.

PLAN: Pt is therapeutic. Continue current warfarin regimen of 7.5mg daily except 5mg on Mon and Fri, and RTC in 4 weeks

Appendix F

Indian River Medical Center

Date

Dear Mr. or Ms.:

Coumadin® (warfarin) is an anticoagulant medication used to help prevent your blood from clotting inappropriately. Each person's dose of warfarin is individualized and their blood must be tested routinely to make the necessary adjustments. It is very important to make sure that you are on the right dose, and that we see you regularly. Because so many different factors may affect how likely your blood is to bleed or to clot, the importance of keeping your appointments cannot be overemphasized.

Taking warfarin without having your blood monitored properly places you at an increased risk for having INRs (the lab test we use to measure how likely your blood is to bleed or clot) outside of the desired range. If the INR is too high, this places you at an increased risk for bleeding, which may result in, but is not limited to, death. If the INR is too low, this places you at an increased risk of developing a clot. The clot may then travel to the heart, brain or lungs, and again could result in, but is not limited to, death.

As you can imagine, it takes a great deal of time to telephone and reschedule visits when patients fail to keep their appointments. We have found that when patients understand the serious nature of this medicine, they are more likely to keep their appointments.

Please help us to keep your INRs within range. Our phone number at the Coumadin Clinic is 772.563.4611. If you do not call and reschedule an appointment by (insert date), you will be discharged from the clinic and your referring physician will be notified. If there is anything more we can do to help you understand your therapy or need for these blood tests, please let us know.

Sincerely,

Nikki Brooks, PharmD, BCACP, CACP
Anticoagulation Management Clinic Coordinator