

# Coumadin Clinic Protocols (adopted after Sacramento Heart Anticoagulation Clinic protocols)

# **Purpose:**

To improve patient outcomes through education, patient assessment, monitoring of anticoagulation, dosage adjustment and follow-up care of those patients receiving anticoagulation therapy.

# **Role of Physician:**

- 1.) Order and prescribe the initial dose of Coumadin/Warfarin.
- 2.) Determine INR range and duration of therapy.
- 3.) Inform coumadin clinic supervisor of patient's name, start date, dose, diagnosis, duration of therapy, and co-existing conditions or bleeding risks.
- 4.) Report changes to coumadin clinic supervisor on patient status and/or medication changes.
- 5.) Be readily available to coumadin clinic supervisor for consultation and questions.
- 6.) Review dosing changes outside of established protocols.
- 7.) Review and update protocols annually.

#### **Role of Coumadin Clinic Supervisor:**

- 1.) Make contact with the patient upon entry into Coumadin clinic and review the following items:
  - a. Indication for Coumadin/Warfarin therapy
  - b. Action of medication
  - c. Monitoring process with lab testing
  - d. Adverse reactions/signs of bleeding
  - e. Common interactions with foods and medications
  - f. Instructions to call the clinic with any potential symptom or initiation of any new medications including prescription and OTC.
  - g. Review safety issues
- 2.) Document, date and sign that the above items were discussed with the patient and/or family.
- 3.) Obtain patient signature on Patient Consent/Contract form for all new patients.
- 4.) Provide patient with helpful informational handouts about Coumadin/Warfarin therapy, side effects and interactions.
- 5.) Notify physician when adverse reactions or excessive anticoagulation occur.
- 6.) Adjust Coumadin/Warfarin dose per physician's order.
- 7.) Schedule patients for office visits to address issues of compliance, bleeding, adverse reactions, communication problems or other problems that are difficult to manage over the telephone.
- 8.) Consult with the physician when changes outside of established protocols are necessary.
- 9.) Track delinquent patients weekly and provide reminders via telephone or letter as needed.
- 10.) Inform physician regarding patients demonstrating repeated problems with noncompliance.
- 11.) Document all problems with compliance or delinquency of blood tests in the patient's medical record.
- 12.) Ongoing education and teaching with patients receiving Coumadin/Warfarin therapy.
- 13.) Review and update protocols annually with physician.
- 14.) Perform related work as required.

#### ANTICOAGULATION CLINIC MANAGEMENT PROTOCOLS

# **INITIATION OF COUMADIN/WARFARIN THERAPY**

- 1.) Start therapy with 2-5mg daily taken in the evening. Lower initiation doses are recommended for elderly patients or patients with a potential increased INR response to Coumadin/Warfarin therapy.
- 2.) Follow-up PT/INR will be obtained 3-5 days after initiation of therapy.
- 3.) A minimum of a weekly PT/INR will be done for the first 3-4 weeks of therapy to ensure proper dosing.
- 4.) Once stable anticoagulation is achieved, maintenance therapy will be managed per the following protocols.

### **SCHEDULING FOLLOW-UP PROTIMES**

### TARGET INR 2.0-3.0

RANGE	ADJUSTMENT	FOLLOW-UP
<2.0	Per protocol	1-2 weeks
2.0-3.0	No change	4-6 weeks
3.1-4.0	Per protocol	1-2 weeks
4.1-6.0	Per protocol	3-7 days
>6.0	Notify M.D.	Per protocol

### TARGET INR 2.5-3.5

RANGE	ADJUSTMENT	FOLLOW-UP
<2.5	Per protocol	1-2 weeks
2.5-3.5	No change	4-6 weeks
3.6-4.5	Per protocol	1-2 weeks
4.6-6.0	Per protocol	3-7 days
>6.0	Notify M.D.	Per protocol

# OPTIMAL THERAPEUTIC RANGES FOR ORAL ANITCOAGULATION

Indication Target INR Atria fibrillation: in valvular/nonvalvular heart disease 2.0-3.0 (chronic) lone atrial fibrillation if age >60 2.0-3.0 (chronic) precardioversion (for AFIB >48hr) 2.0-3.0 (3 weeks) postcardioversion 2.0-3.0 (4 weeks) Cardioembolic stroke: large stroke 2.0-3.0 (chronic) (delayed 5-14 days) 2.0-3.0 (chronic) (delayed 48 hours) small stroke following embolic event despite anticoagulation 2.5-3.5 (chronic (or 2.0-3.0 plus ASA, 160mg/day) Left ventricular dysfunction: ejection fraction <30% 2.0-3.0 (chronic) transient following myocardial infarction 2.0-3.0 (1-3 months) following embolic event despite anticoagulation 2.5-3.5 (chronic) (or 2.0-3.0 plus ASA, 160mg/day) Myocardial Infarction: following myocardial infarction 2.5-3.5 Thromboembolism (DVT, PE): treatment/prevention of recurrence 2.0-3.0 (6 weeks-3 months) (transient risk factors) treatment/prevention of recurrence 2.0-3.0 (3-6 months) (chronic risk factors) recurrence despite anticoagulation 2.5-3.5 (indefinite) recurrence off anticoagulation 2.0-3.0 (3-6 months) ongoing hypercoagulable state 2.0-3.0 (chronic) (AT-III, protein C or S deficiency, malignancy) Valvular disease: aortic valve disease -with concurrent mitral valve disease 2.0-3.0 (chronic) -with associated AFIB 2.0-3.0 (chronic) -with hx systemic embolism 2.0-3.0 (chronic) mitral annular calcification -with associated AFIB 2.0-3.0 (chronic) -with hx systemic embolism 2.0-3.0 (chronic) mitral valve prolapse -with associated AFIB 2.0-3.0 (chronic) -with hx systemic embolism 2.0-3.0 (chronic) -with hx TIA despite ASA treatment 2.0-3.0 (chronic) -S/P embolic event despite anticoagulation 2.5-3.5 (chronic) (or 2.0-3.0 plus ASA) rheumatic mitral valve disease -with associated AFIB 2.0-3.0 (chronic) -with hx systemic embolism 2.0-3.0 (chronic) -S/P embolic event despite anticoagulation 2.5-3.5 (chronic) (or 2.0-3.0 plus ASA) Indication Target INR

Valve replacement:

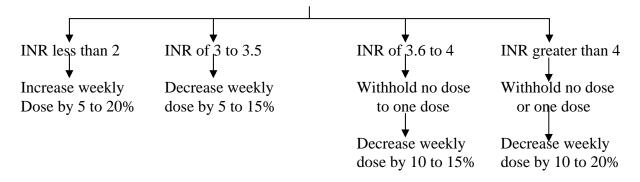
mechanical valve prosthesis mechanical valve following systemic embolization tissue valve prosthesis tissue valve with hx systemic embolization 2.5-3.5 (chronic) 2.5-3.5 (chronic) plus ASA 2.0-3.0 (3 months) 2.0-3.0 (chronic)

*Key:* AFIB, atrial fibrillation; ASA, acetylsalicyclic acid; AT-III, antithrombin III; DVT, deep venous thrombosis; hr, hour; hx, history; INR, International Normalized Ratio; PE, pulmonary embolism; S/P, status post; TIA, transient ischemic attack.

# ADJUSTMENT OF COUMADIN/WARFARIN DOSE

Altering Coumadin/Warfarin Dosage to Achieve INR of 2 to 3

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**FIGURE 2.** Algorithm for establishing a percentage change in the weekly Coumadin/Warfarin dosage to achieve an INR of 2 to 3. (INR=International Normalized Ratio)

#### Altering Coumadin/Warfarin Dosage to Achieve INR of 2.5 to 3.5 INR of 2 to 2.4 INR of 3.6 to 4.6 INR less than 2 INR of 4.6 to 5.2 INR greater than 5.2 Give additional dose Increase weekly Decrease weekly Withhold no dose Withhold no dose dose by 5 to 15% dose by 5 to 15% and increase weekly or one dose to two doses dose by 10 to 20% Decrease weekly Decrease weekly dose by 10 to 20% dose by 10 to 20%

FIGURE 3. Algorithm for establishing a percentage change in the weekly Coumadin/Warfarin dosage to achieve an INR of 2.5 to 3.5. (INR=International Normalized Ratio)

<sup>1</sup> Source: Horton, Bushwick, Warfrain Therapy: Evolving Strategies in Anticoagulation, American Family Physician, Feb 1, 1999

# Adjustment of Coumadin/Warfarin dose continued...

Dosing adjustment using 2mg tab

1

		r -						
SUN	MON	TUES	WED	THUR	FRI	SAT	Total	%

							Weekly	change
1 tab	½ tab	1 tab	½ tab	1 tab	½ tab	1 tab	11mg	-20%
1 tab	½ tab	1 tab	1 tab	1 tab	½ tab	1 tab	12mg	-15%
1 tab	½ tab	1 tab	1 tab	1 tab	1 tab	1 tab	13mg	-5%
1 tab	1 tab	1 tab	1 tab	1 tab	1 tab	1 tab	14mg	0%
1 tab	1 ½ tab	1 tab	1 tab	1 tab	1 tab	1 tab	15mg	+5%
1 tab	1 ½ tab	1 tab	1 tab	1 tab	1 ½ tab	1 tab	16mg	+15%
1 tab	1 ½ tab	1 tab	1 ½ tab	1 tab	1 ½ tab	1 tab	17mg	+20%

Dosing adjustment using 2.5mg tab

SUN	MON	TUES	WED	THUR	FRI	SAT	Total	%
							Weekly	change
1 tab	½ tab	1 tab	½ tab	1 tab	½ tab	1 tab	13.75mg	-20%
1 tab	½ tab	1 tab	1 tab	1 tab	½ tab	1 tab	15mg	-15%
1 tab	½ tab	1 tab	1 tab	1 tab	1 tab	1 tab	15.75mg	-5%
1 tab	1 tab	1 tab	1 tab	1 tab	1 tab	1 tab	17.5mg	0%
1 tab	1 ½ tab	1 tab	1 tab	1 tab	1 tab	1 tab	18.75mg	+5%
1 tab	1 ½ tab	1 tab	1 tab	1 tab	1 ½ tab	1 tab	20mg	+15%
1 tab	1 ½ tab	1 tab	1 ½ tab	1 tab	1 ½ tab	1 tab	23.75mg	+20%

Dosing adjustment using 5mg tab

SUN	MON	TUES	WED	THUR	FRI	SAT	Total	%
							Weekly	change
1 tab	½ tab	1 tab	½ tab	1 tab	½ tab	1 tab	27.5mg	-20%
1 tab	½ tab	1 tab	1 tab	1 tab	½ tab	1 tab	30mg	-15%
1 tab	½ tab	1 tab	1 tab	1 tab	1 tab	1 tab	32.5mg	-5%
1 tab	1 tab	1 tab	1 tab	1 tab	1 tab	1 tab	35mg	0%
1 tab	1 ½ tab	1 tab	1 tab	1 tab	1 tab	1 tab	37.5mg	+5%
1 tab	1 ½ tab	1 tab	1 tab	1 tab	1 ½ tab	1 tab	40mg	+15%
1 tab	1 ½ tab	1 tab	1 ½ tab	1 tab	1 ½ tab	1 tab	42.5mg	+20%

Dosing Adjustment using 7.5mg tab

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SUN	MON	TUES	WED	THUR	FRI	SAT	Total	%
							Weekly	change
1 tab	½ tab	1 tab	½ tab	1 tab	½ tab	1 tab	41.25mg	-20%
1 tab	½ tab	1 tab	1 tab	1 tab	½ tab	1 tab	45mg	-15%
1 tab	½ tab	1 tab	1 tab	1 tab	1 tab	1 tab	48.75mg	-5%
1 tab	1 tab	1 tab	1 tab	1 tab	1 tab	1 tab	52.5mg	0%
1 tab	1 ½ tab	1 tab	1 tab	1 tab	1 tab	1 tab	56.25mg	+5%
1 tab	1 ½ tab	1 tab	1 tab	1 tab	1 ½ tab	1 tab	60mg	+15%
1 tab	1 ½ tab	1 tab	1 ½ tab	1 tab	1 ½ tab	1 tab	63.75mg	+20%

# MANAGEMENT OF EXCESSIVE ORAL ANTICOAGULATION OR BLEEDING

**Table 4B-5.1** Recommendations for the Management of Excessive Oral Anticoagulation or Bleeding from the American College of Chest Physicians.

INR Intervention

Above therapeutic range but <6.0; no bleeding	Hold Coumadin/Warfarin until INR declines to therapeutic range, Resume at a lower dose.
6.0-10.0; no bleeding	Vitamin K <sup>1</sup> , 1-2mg subcutaneously, then resume at lower dose when INR declines to normal range.
>10.0; no bleeding and	Vitamin K <sup>1</sup> , 3mg subcutaneously; check INR in about 6 hours, repeat Vitamin K if needed.
>20.0 or serious bleeding	Vitamin K <sup>1</sup> , 10mg subcutaneously or slow IV* infusion (20-30 minutes). Supplement with fresh-frozen plasma or prothrombin complex concentrates. Check INR every 6 hours.
Life-threatening bleeding or serious Coumadin/ Warfarin overdose	Vitamin K <sup>1</sup> , 10mg slow IV infusion. Supplement with prothrombin complex concentrates

<sup>\*</sup>Because of concern for anaphylactic reactions, dilute IV vitamin K¹ and give by slow infusion during a period of several minutes (5-15). *Source:* Reprinted with permission from Hirsh, Dalen, Deykin, Poller, and Bussey. Oral Anticoagulants: Mechanism of Action, Clinical Effectiveness, and Optimal Therapeutic Range, Chest, 108(suppl) 231S-246S, ©1995, American College of Chest Physicians.

- 1. The Coumadin clinic supervisor will always notify the patient's physician and cardiologist if excessive anticoagulation occurs.
- 2. The above guidelines will be followed unless otherwise indicated by the patient's cardiologist. If other interventions are ordered, it will be documented in the patient's medical record.
- 3. Review for signs and symptoms of bleeding will be done on each patient found to have an INR greater than 4.5.
- 4. If signs or symptoms of bleeding are present, the patient's cardiologist and physician will be notified immediately and orders other than the stated protocols will be obtained.
- 5. If it is not possible to obtain an INR at 6hrs. post Vitamin K injection, an INR will be obtained as soon as possible without exceeding 18hrs. post injection.
- 6. With INR ranges of 6.0-10.0, it would be acceptable to hold Coumadin/Warfarin until INR declines to a therapeutic range, then resume at lower dose if there are no signs of bleeding and the patient is at very low risk for bleeding or injury.
- 7. INR values greater than 6 will always be checked with repeat analysis prior to administration of Vitamin K.
- 8. Any INR value obtained via fingerstick that is found to be greater than 8 will be repeated using a venous sample prior to administration of Vitamin K.

# MANAGEMENT FOR SCHEDULED INTERRUPTION OF COUMADIN/WARFARIN NOT REQUIRING ALTERNATE TREATMENT

- 1. Simple dental appointments such as cleanings or routine check ups do not require an interruption in Coumadin/Warfarin unless the patient's dentist prefers it. If desired by the dentist, a two-day interruption of Coumadin/Warfarin can be advised.
- 2. Dental or GI procedures that may result in bleeding such as extractions, invasive deep scaling, upper or lower endoscopy, would require a 2-3 day interruption of Coumadin/Warfarin therapy. For atrial fibrillation or MVR, a 2-day interruption, and for AVR, a 3-day interruption will be advised unless otherwise indicated by the patient's cardiologist.
- 3. Patients scheduled for coronary angiography will be advised to hold Coumadin/Warfarin 3 days prior to the procedure.
- 4. Dental, GI or other surgical procedures requiring an interruption of Coumadin/Warfarin for greater than 3 days is subject to physician review.
- 5. Coumadin/Warfarin will be restarted on the evening of the completed procedure at 1 ½ times the usual daily dose for two days followed by the patient's regular weekly dose.
- 6. A protime will be checked at 1 week after restarting Coumadin/Warfarin after a scheduled interruption.
- 7. Further adjustments will be made using the dosage adjustment protocols.

# MANAGEMENT FOR SCHEDULED INTERRUPTION OF COUMADIN/WARFARIN REQUIRING ALTERNATE TREATMENT WITH LOVENOX

- 1. Patients who are considered at high risk for embolic events may require Lovenox SQ during Coumadin/Warfarin interruption.
- 2. Collaboration between physician performing procedure and patient's cardiologist will determine the number of days prior to the procedure that Coumadin/Warfarin will be stopped.
- 3. As the INR falls (+/- 2 days), Lovenox will be started at 1mg/kg SQ every 12 hours.
- 4. Upon completion of the procedure, Coumadin/Warfarin will be restarted and Lovenox continued until INR is in therapeutic range.
- 5. An INR will be done 3 days after restarting Coumadin/Warfarin.

# MANAGEMENT FOR SCHEDULED INTERRUPTION OF COUMADIN/WARFARIN REQUIRING ALTERNATE TREATMENT WITH HEPARIN

- 1. Patients who are considered at high risk for embolic events and cannot use Lovenox may require heparin SQ during Coumadin/Warfarin interruption.
- 2. Collaboration between physician performing procedure and patient's cardiologist will determine the number of days prior to the procedure that Coumadin/Warfarin will be stopped.
- 3. On the day that Coumadin/Warfarin is stopped, heparin will be initiated subcutaneous using the following algorithm:

<50kg: 12,500U s/c</li>
50-70kg: 15,000U s/c
>70kg: 17,5000U s/c

- 4. Daily aPTT will be assessed and heparin will be adjusted in a step fashion based on aPTT value. Steps for heparin dosing are: 10,000-12,500-15,000-17,500-21,250-25,000-30,000.
- 5. The following will be used to make dose adjustments:
  - aPTT 50-120s: no adjustment of heparin dose: repeat aPTT within 24hrs
  - aPTT <50s: heparin dose-one step up: repeat aPTT in 6hrs\* and adjust as follows:
    - o aPTT 50-90s: heparin dose-same step: repeat APTT in 6hrs\*.
    - o aPTT 91-120s: heparin dose-one step down: repeat APTT in 6hrs.\*
  - aPTT>120s: heparin dose-withhold heparin: repeat aPTT in 3hrs and adjust as follows:
    - o aPTT<50s: heparin dose-same step: repeat aPTT in 6hrs\*
    - o aPTT 50-90s: heparin dose-one step down: repeat aPTT in 6hrs\*

- o aPTT 91-120s: heparin dose-two steps down: repeat APTT in 6hrs\*
- o aPTT >120s: withhold heparin: repeat aPTT in 3hrs
- 6. Upon completion of the procedure, Coumadin/Warfarin will be restarted and heparin continued until INR is in therapeutic range.
- 7. An INR will be done 3 days after restarting Coumadin/Warfarin.

\*if it is feasible to complete aPTT in 6hrs the following may occur after review with the physician:

• heparin dose may be repeated at the same step in 12hrs with a repeat APTT within 24hrs.

### MANAGEMENT DURING AMIODARONE LOADING

- 1. Physicians will notify the Coumadin Clinic Supervisor when a patient receiving Coumadin/Warfarin is started on Amiodarone.
- 2. Unless otherwise instructed by the physician, the patient will be adivised to reduce their Coumadin/Warfarin dose by 25%.
- 3. A protime will be obtained every 3-4 days during Amiodarone loading and weekly until maintenance dose of Amiodarone is achieved.
- 4. Further adjustments will be done using dosage adjustment protocols.

### MANAGEMENT DURING EXTENDED TRAVEL

- 1. Advise patient of importance for continuing Coumadin/Warfarin regimen and scheduled blood tests while traveling for extended periods of time.
- 2. Give patient lab requisition forms for PT/INR with instructions to fax results to the clinic.
- 3. Set up system for patient to call our office 24hrs. after completion of INR to obtain Coumadin/Warfarin dose instructions.
- 4. Obtain an emergency number or contact that is able to get in touch with the patient if needed.

### ANTICOAGULATION FOR ELECTIVE CARDIOVERSION

- 1. Patients with duration of atrial fibrillation greater than 2 days will be initiated on Coumadin/Warfarin per initiation protocol.
- 2. Patients with duration of atrial fibrillation confidently known to be less than 2 days can be considered to forego anticoagulation at the physician's discretion.
- 3. INR will be checked weekly until 3 consecutive INR values fall within range of 2.0-3.0 before cardioversion is performed.
- 4. Anticoagulation will be maintained with an INR range of 2.0-3.0 for 3 weeks prior to cardioversion and 4 weeks after sinus rhythm is established.

#### MANAGEMENT DURING EECP THERAPY

- 1. Patients who take Coumadin/Warfarin that are referred for EECP treatment will be maintained on Coumadin/Warfarin with an increased frequency of INR levels.
- 2. INR will be checked the first day of treatment and biweekly during the course of EECP therapy.

<ul><li>3. If at anytime the patient has an INR of greater than 3.0, EECP therapy will be held and not resumed until the INR has dropped below 3.0.</li><li>4. All dosage adjustments will be made according to the guidelines outlined in this protocol.</li></ul>					
4. An dosage adjustments will be made according to the guidelines outlined in this protocol.					
References: 1. Fifth ACCP Consensus Conference on Antithrombotic Therapy, CHEST, Volume 114, Number 5, November 1998					
2. Sixth ACCP Consensus Conference on Antithrombotic Therapy, CHEST, Volume 119/1, January 2001					

- 3. Tiede, et al. Modern Management of Prosthetic Valve Anticoagulation. Mayo Clinic Proc 1998; 73:665-680
- 4. Horton J, Bushwick B. Warfarin Therapy: Evolving Strategies in Anticoagulation. American Family Physician, Feb 1, 1999
- 5. Ansell J, Oertel L, Wittdowsky A. Managing Oral Anitcoagulation Therapy: Clinical and Operational Guidelines. Aspen Publishers, Inc. 1997
- 6. Prandoni P, Bagatella P, Bernardi E, et al: Use of an algorithm for administering subcutaneous heparin in the treatment of deep venous thrombosis. Annals of Internal Medicine 1998, 129 (4): 299-302

### STATEMENT OF APPROVAL AND AGREEMENT

This document was developed based on the Sacramento Heart Anticoagulation Clinic's protocols with their permission. By signing this Statement of Approval and Agreement we, the below signed,

- approve of the policies and protocols contained in this document.
- agree to maintain a collaborative and collegial relationship.
- Agree to abide by the policies and protocols presented within this document.

David Katz, M.D. Medical Director, CCHC	Date
Jason Auriemma, M.D. Physician/CCHC Peterson Clinic	Date
Tony Lichwa, M.D. Physician/CCHC Peterson Clinic	Date
Daniel J. Albano, LVN Patient Services Director	Date
Michele Ackerman, RMA CCHC Care Coordinator /Coumadin Clinic	Date