Duquesne University Academic Center for Pharmacy Care		
	Policy Name	Anticoagulation Management Service (AMS)
	Policy Number	
	Effective Date	July 2014
	Responsible for Content	All CPC Staff

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1. INTRODUCTION

Purpose of the Anticoagulation Management Service (AMS):

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

b. Education: To provide patient education regarding the safe use of anticoagulant medications. This includes but is not limited to dietary considerations, drug-drug and drug-disease interactions, self-monitoring parameters for sign and symptoms of bleeding, bruising, and thromboembolism, as well as compliance to medication and follow-up appointments.

c. Follow-up: To ensure continuity of care for all patients in order to optimize anticoagulation therapy while minimizing hemorrhagic and/or thromboembolc complications.

Applicability:

This manual is applicable to all patients consulted to the AMS and should be followed by all credentialed pharmacists. The clinical coordinator will exercise oversight over the AMS to ensure the protocol is followed correctly. Patients will be managed according to the protocol enclosed. The protocol will be reviewed annually by the clinical coordinator and the department and updated with current practices.

Team Members:

Clinical Coordinator: Director of the Center for Pharmacy Care and oversight of all clinical programs (Suzanne Higginbotham, B.S., Pharm.D., BCACP)
AMS Pharmacist: Pharmacist trained by the clinical coordinator, or other authorized personnel to perform AMS functions (Brandon Herk, Pharm.D.)
Referring Physician: Physician authorizing anticoagulation management of their patient to AMS provider. The AMS pharmacist will be in constant contact with the referring physician regarding any issues or concerns with anticoagulation management
Collaborative Practice Physician: Physician responsible for oversight of AMS pharmacist's clinical practice and review of laboratory values (Michael Essig, MD)

Office Hours/Location:

The Center for Pharmacy Care (CPC) is currently open Monday through Friday from 9:00 – 4:00. AMS services will be provided while the CPC is open. The CPC is located at the Muldoon Building, 1000 5th Avenue Pittsburgh, PA 15282. Phone: 412-396-2155. Fax: 412-396-2161.

2. POLICY AND PROCEDURES

Referral:

a. A completed physician referral form is needed for the CPC pharmacist to engage in anticoagulation management ***(Appendix T)***. Both the referring physician and CPC pharmacist must sign the Delegation of Duties agreement in order for the patient to be managed under the CPC AMS agreement. Information in the referral should include:
   i. Patient name, date of birth, age, past medical history
   ii. Patient anticoagulation diagnosis, INR goal, duration of therapy, current or previous warfarin dosage if applicable, pertinent labs, exams or anticoagulation history
   iii. Appropriate indications for anticoagulant therapy

Pharmacist Responsibilities:

The AMS pharmacist is responsible to the referring physician for the safe, efficient, and effective anticoagulation therapy management of assigned patients. Each AMS pharmacist will be responsible for the following:

i. Ensure all patients (including patients with prior history of warfarin therapy and education) receive an initial education session at their first visit.
ii. Ensure all patients are given pertinent patient education materials at their first visit and additional copies at subsequent visits if deemed necessary.
iii. Review the need for ongoing anticoagulation therapy on all patient visits.
iv. Adjust medications and manage therapy according to the approved AMS protocol.
v. Refer patients to emergency room or hospital if patient has dangerously high INR, active bleeding, serious bleeding, suspected bleeding, or if further testing is required. Tests and/or referrals made will be made known to the patient's referring physician in a timely manner.
vi. Ensure that before each visit is complete, each patient is given a patient medication action plan that describes any dosing changes as well as the date of the next visit.

Referring Physician Responsibilities:

The referring physician is ultimately responsible for overseeing the care of the referred patients. Collaboration with the AMS pharmacist is essential in facilitating the quality and continuity of care for the patient. The referring physician **must** fill out the referral form (***Appendix T***) for their patient to be seen by the AMS pharmacist. The provider should notify the pharmacist if any of the below listed items occur:

iv. Patient is hospitalized and/or discharged
ii. Patient is released from care or anticoagulation therapy is no longer necessary

Collaborative Practice Physician Responsibilities:

The collaborative practice physician will review monthly reports for the program including patient's INR and warfarin dose change based on INR obtained during the visit and patient's INR goal range.

Patient Visit Procedures:

1. Each patient will be seen in clinic during normal clinic hours Monday through Friday 9:00am to 4:00pm.
2. All encounters with patients (including counseling and point of care testing) will occur in a one-on-one setting in a patient exam room in the CPC.
3. During their initial visit, new patients will be provided with a Patient Education Booklet (***Appendix A***) which contains information concerning dietary considerations, drug-drug and drug-disease interactions, self-monitoring parameters for symptoms of bleeding/bruising and thromboembolism, medication compliance, and follow-up appointments via verbal instruction and written handouts. The patient will be made aware of clinic hours and contact information. The need to contact the clinic should any changes in their medication and disease states occur will be stressed.
4. During their initial visit, patients will also complete an initial intake form (***Appendix B***). The CPC staff may aid the patient in completing the form if necessary. Initial consults will take 1 hour. Follow up appointments will take 20-30 minutes.
5. During each clinic visit, the patient will be evaluated for the following using the monitoring form (***Appendix C***):
    a. Adherence (missed/extra doses, taking as prescribed, etc.)
    b. Diet (vitamin K foods, caffeine intake, etc.) and alcohol use
    c. Medication changes
    d. Signs/symptoms of bleeding and/or thromboembolism
    e. Changes in health status (fever, illness, diarrhea, dehydration, poor nutrition, etc.)
    f. Appropriateness of switching from warfarin to a novel anticoagulant
6. These variables will be assessed with current PT/INR results (***Appendix K***) and an appropriate follow up appointment will be made.
7. Any additional patient education reinforcement will be provided.
8. After each visit, the patient will be given a patient medication action plan (***Appendix D***) reminding the patient of the date of their next visit as well as any changes made to their treatment regimen.
9. After the visit, patients will be instructed to check out with the front desk to confirm their next appointment date.
10. For every new patient seen for AMS, an Introductory Letter to Physician (***Appendix E***) describing our service and CPC will be faxed to the referring physician in charge of managing the patient's anticoagulation.
11. After every patient visit, a Physician Communication Form (***Appendix F***) will be filled and faxed to patient's referring physician and CPC's Clinical Intervention Policy will be followed to follow-up with the communication.
12. A report to the collaborative practice physician (Dr. Michael Essig) will be generated and sent for every patient monthly (***Appendix G***).
13. Log patient's allergy, medical history, lab values, medications changes, SOAP note, and any other pertinent information into MedicationPathfinder according to the CPC patient visit protocol.
14. Properly bill for the visit under MedicationPathFinder.

Patient Education:

Initial Visit:
Patient education during the initial visit will be typically 30-45 minutes long and will start with a thorough documentation of past medical history, social and family history, diet, exercise, and a current medication list.

The pharmacist will then comprehensively discuss the following topics concerning warfarin therapy with the patient:

1. Warfarin indication
2. Mechanism of action
3. Duration
4. Dosing
5. Available tablet strengths
6. Generic vs. brand
7. INR monitoring (purpose, goals, frequency)
8. Potential complications (bleeding, etc.) and what to do if they occur
9. Factors that can affect INR (diet, medication changes, alcohol, illness, OTC's/herbals)
10. Clinic procedures, expectations, missed appointments

Follow-up visits:
At follow up visits, the pharmacist will continue to monitor for signs/symptoms of bleeding (significant amount of blood in urine, stool, sputum, or emesis) and thromboembolism (pain, swelling, redness, heat in the lower extremities, chest pain, shortness of breath, sweating, increased heart rate, coughing up blood, one sided weakness, slurred speech, and vision changes) as well as PT/INR levels using the monitoring form (***Appendix C***). Patient education regarding previously discussed topics or ongoing problems the patient is having will always be addressed.

Educational materials:

- Patients will be given a "Patient Education Booklet" (***Appendix A***) at their initial visit. This booklet includes tables describing vitamin K content in foods (***Appendix H***) and drug interaction table (***Appendix N***).
- At their initial visit and any follow-up visits, patients will receive the "Medication Action Plan" (***Appendix D***), a document informing them of the interventions that were discussed (dose changes, diet changes, recommendations, etc.) and date of the next appointment. This same information will be disseminated to the referring physician via the physician fax form (***Appendix F***)
- Additional patient education materials are available from the following web sites:
    - www.coumadin.com
    - www.clotconnect.org
    - www.clotcare.com
    - www.ahrq.gov/patients-consumers/diagnosis-reatment/treatments/btpills/index.html
    - www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/A-Patients-Guide-to-Taking-Warfarin_UCM_444996_Article.jsp
    - www.nlm.nih.gov/medlineplus/ency/patientinstructions/000292.htm

Missed/Canceled Appointments:

At the first appointment, every patient will be given a copy of CPC's "Cancellation, Missed Appointments, Late Arrival Policy" to read and sign the form.

If a patient misses a scheduled clinic visit, the following steps will insure adequate follow-up:

i. If a patient fails to attend an appointment, we will attempt to contact them promptly and reschedule them for the next available appointment after the missed appointment.

ii. Missed appointments will be documented in the patient's profile.

iii. In regards to cancelled appointments, the patient is responsible for informing the CPC within 24 hours before their appointment if they are unable to attend. We will then reschedule the clinic visit with the patient. Patients must reschedule missed appointments within 24 hours of a missed appointment and be seen at the CPC within one week of the missed appointment. Failure to do so may results in dismissal from the program.

iv. If a patient is more than 10 minutes late to the appointment, the patient will be rescheduled for the next available time slot that day.

v. If a patient misses an appointment without notifying the CPC a letter will be sent to their home informing them of the risks of taking warfarin without monitoring. If a patient fails to show a second time, a second letter will be sent. If a patient misses three appointments they will be dismissed from the service and the referring physician will be notified (***Appendix O, P, Q***)

3. ANTICOAGULATION MANAGEMENT

INR Range:

Most warfarin indications recommend an INR range of 2-3 (exceptions include mechanical mitral valves and caged ball or caged disk valves) (***Table 1***). Our goal is to maintain the patient in their therapeutic INR range.

Table 1. Warfarin Indication and Associated INR Ranges and Treatment Durations

Indication	Duration
INR Range 2-3	
Atrial fibrillation	Indefinite
Prophylaxis of venous thrombosis (high-risk surgery)	10-35 days
Treatment of venous thrombosis	3 months to indefinite
Treatment of pulmonary embolism	3 months to indefinite
Prevention of systemic embolism	Indefinite
Cardioembolic stroke or TIA (with cerebral venous sinus thrombosis)	3-6 months
Pre and post cardioversion	3-4 weeks
Valvular heart disease	Indefinite
Acute myocardial infarction	At least 3 months
Bioprosthetic mitral valve	3 months
Mechanical aortic valve	Indefinite
Antiphospholipid syndrome	Indefinite
Homozygous Factor V Leiden	Indefinite
Deficiency of Protein C, S or Anti-Thrombin	Indefinite

INR Range 2.5-3.5	
Mechanical mitral valve	Indefinite
Caged ball or caged disk valves	Indefinite

Warfarin Initiation:

Starting dose:
The standard starting dose is 5 mg by mouth daily.

- Consider starting at a lower dose (2mg- 5mg daily) in patients likely to be sensitive to warfarin (elderly, frail, liver-diseased, malnourished patients, congestive heart failure)
- Consider a higher starting dose in patients that are younger (<50 years old) and/or obese (BMI >30.0)

Monitoring:
Table 2 contains a warfarin initiation dosing algorithm in which the dose is adjusted according to INRs with the goal of achieving a therapeutic and stable INR. This table is a guideline and should not be substituted for clinical judgment. It is important to remember that a baseline INR must be reported prior to the first dose of warfarin. Additionally, female patients of child bearing age are required to have a negative pregnancy test prior to starting warfarin. Warfarin is teratogenic (category X).

Table 2. Warfarin Initiation INR Goal 2-3		
Day of Therapy	***INR***	***Dose Adjustment***
Day 1	Reference	
2-3 days after initiation	<1.5 1.5-1.9 2.0-2.5 2.5-3.0 >3.0	5-7.5 mg daily 2.5-5 mg daily 2.5 mg daily 0-2.5 mg daily Hold and recheck INR next day
Additional 2-3 days after last INR check	<1.5 1.5-1.9 2.0-3.0 >3.0	7.5-10 mg daily 5-10 mg daily 2.5-5 mg daily Hold warfarin, recheck in 1-2 days

Bridging during Warfarin Initiation:
Warfarin takes 5-7 days to reach full therapeutic effect and is also associated with an initial procoagulant state. Accordingly, overlapping warfarin treatment with a parenteral anticoagulant medication is a reasonable approach in many instances and is especially indicated for patients being treated for acute DVT/PE.

At the time of warfarin initiation, it is recommended to overlap a parenteral anticoagulant (warfarin and parenteral start same day) for *at least 5 days* until INR reaches therapeutic range (>2.0) and maintained for *at least 24 hours*, then discontinue parenteral therapy.

Warfarin Maintenance:

Monitoring:
Monitoring is critical to successful management of anticoagulated patients on warfarin. The narrow therapeutic range, long half-life, and the seriousness of the potential complications require diligent monitoring of their anticoagulant state. Patients will be monitored using INR values. The following monitoring schedule in ***Table 3*** will be used unless otherwise specified by the consulting physician.

Table 3. Warfarin Monitoring	
INR Check	**Notes**
INR Monitoring After Initiation of Warfarin	
Initially every 2-3 days	Until INR within therapeutic range on 2 consecutive INRs
Then every week	Until INR within therapeutic range on 2 consecutive INRs
Then every 2 weeks	Until INR within therapeutic range on 2 consecutive INRs
Then every 4 weeks	Check monthly when dose is stable
INR Monitoring for Maintenance of Warfarin	
After 1 week	If start/stop interacting medication, change in diet, change in activity level or other change that could affect INR
Every 4-6 days	If dose adjusted by >10%
Every 1-2 weeks	If dose adjusted by <10%
Every 4 weeks	If patient maintained on same stable dose <6 months
Every 6-8 weeks	If patient maintained on same stable dose >6 months
INR Monitoring for Critical lab values (<1.5 or >4.5)	
Every 2-3 days	Extra doses or held doses will be initiated for critical lab values in the absence of serious active bleeding

Drug-Drug Interactions:
Please see (***Appendix N***) for the list of pertinent warfarin drug interactions. With few exceptions (amiodarone, fluconazole, metronidazole, sulfamethoxazole, rifampin), most drug interactions do not require a prophylactic dose adjustment. Most interactions with warfarin will start to have an effect within 3-5 days of concomitant therapy. Exceptions include amiodarone, levothyroxine, carbamezapine, and rifampin which will start to have an effect within 7-14 days of therapy.

Disease-Drug Interactions:
Many various patient-factors and disease states (***Table 5***) influence the response to warfarin treatment. It is important to account for these factors when seeking to explain fluctuations in INR or dose variances. Additionally, (***Table 6***) includes additional factors that are associated with an increased bleeding risk for warfarin users.

Table 5. Drug-Disease Interactions	
Factors that *Increase* Warfarin Sensitivity	**Factors that *Decrease* Warfarin Sensitivity**
Baseline INR ≥1.5	Diet high in vitamin K
Age >65	Age <50
Actual body weight <45 kg or actual < ideal	Obesity
Malnourished/NPO >3 days	Edema
Hypoalbuminemia <2 g/dl	Hypothyroidism
Chronic diarrhea	Hyperlipidemia
Significant drug interactions	Hereditary warfarin resistance
Decompensated heart failure	Smoking cessation
Liver disease	
Hyperthyroidism	
Cancer	
Hereditary warfarin sensitivity	
Fever	

Table 6. Factors Associated with Increased Bleeding Risk	
Patient Factors	***Medication and Diet Factors***
Increased age History bleeding Genetics Female sex Uncontrolled hypertension Hepatic dysfunction Renal insufficiency Previous stroke Anemia Malignancy Thrombocytopenia Excessive fall risk	Warfarin naïve Poor adherence Higher anticoagulation intensity Low time in therapeutic range Decrease in dietary vitamin K Concomitant medications Medications that increase bleeding risk (antiplatelets, NSAIDs) Excessive alcohol

Diet Interactions:
Warfarin is a vitamin K antagonist and therefore its therapeutic effect is negated by vitamin K obtained from our diet. Changes in vitamin K intake can lead to variable INRs as well as INRs outside therapeutic range. Accordingly, it is important that patients keep their vitamin K intake *consistent*. There are many foods that contain vitamin K ranging from high to low content. Please see the attached document "Vitamin K Content in Foods" (***Appendix H***) which will be used as a resource for AMS clinicians when managing patients.

Management of Non-therapeutic INRs:
Management of anticoagulation is a patient-specific and highly variable process. Published guidelines for managing anticoagulated patients as well as clinical judgment based upon patient's presentation will be utilized. Decision-making will incorporate recommendations from the 2008 and 2012 American College of Chest Physicians guidelines. The aggressiveness of INR correction is also determined by the patient's thromboembolism (***Tables 7 and 8***) and bleeding risk (***Tables 6 and 8***).

That being said, the protocols below are to help guide decision-making. Guidelines are intended for general information only and do not replace sound clinical judgment. No clinician should attempt to apply these recommendations in a blanket fashion, especially in cases with extenuating circumstances.

Table 7. Assessing Patient Thromboembolism Risk		
Mechanical Heart Valve	*Atrial Fibrillation*	*History of VTE*
Low TE Risk	**Low TE Risk**	**Low TE Risk**
Bileaflet aortic valve without a stroke risk factor (atrial fibrillation, prior stroke or transient ischemic attack, hypertension, diabetes, congestive heart failure, age >75 years)	$CHADS_2$-VAS_c score = 0	Prior VTE >12 months ago and no other risk factors
Moderate TE Risk	**Moderate TE Risk**	**Moderate TE Risk**
Bileaflet aortic valve and at least one risk factor for stroke (atrial fibrillation, prior stroke or transient ischemic attack, hypertension, diabetes, congestive heart failure, age >75 years) A history of an embolic event while subtherapeutically or therapeutically anticoagulated	$CHADS_2$-VAS_c score = 1* A history of an embolic event while subtherapeutically or therapeutically anticoagulated *$CHADS_2$-VAS_c score of 1 due to gender along does not constitute moderate risk	VTE within the past 3-12 months Non-severe thrombophilia (eg, heterozygous factor V mutation) Recurrent VTE A history of an embolic event while subtherapeutically or therapeutically anticoagulated
High TE Risk	**High TE Risk**	**High TE Risk**
Any mitral valve prosthesis Older (caged-ball or tilting disc) aortic valve prosthesis Recent (within 6 months) stroke or TIA	$CHADS_2$-VAS_c score ≥ 2 Recent (within 3 months) stroke or TIA Rheumatic valvular heart disease	Recent VTE (<3 months ago) Severe thrombophilia (eg, antiphospholipid antibodies) Active cancer (treated within 6 months or palliative)

Table 8. Thromboembolism and Bleeding Risk for Atrial Fibrillation

Thrombotic Risk – Atrial Fibrillation
CHA_2DS_2 –VASc

Risk Factors

□ CHF (1 pt) □ HTN (1 pt) □ Age (≥75 (2 pts) □ DM (1 pt) □ Hx CVA/TIA/TE (2 pts)
□ CAD/MI/PAD aortic plaque (1 pt)
□ Age 65-74 (1 pt) □ Female (1 pt) Total points: _____

Adjusted Stroke Rate (%/year)

Low (0 pts)	Moderate (1 pt)	High (≥ 2 pts)
0%	1.3%	2 pts = 2.2% 3 pts = 3.2% 4 pts = 4.0% 5 pts = 6.7% 6 pts = 9.8% 7 pts = 9.6% 8 pts = 6.7% 9 pts = 15.2%

Thrombotic Risk – Atrial Fibrillation
$CHADS_2$

Risk Factors

□ CHF (1 pt) □ HTN (1 pt) □ Age (≥75 (1 pt)
□ DM (1 pt)
□ Hx CVA/TIA/TE (2 pts) Total points: _____

Adjusted Stroke Rate (%/year)

Low (0 pts)	Moderate (1 pt)	High (≥ 2 pts)
1.9%	2.8%	2 = 4.0% 3 = 5.9% 4 = 8.5% 5 = 12.5% 6 = 18.2%

Bleeding Risk – Atrial Fibrillation
HAS-BLED

Risk Factors

□ HTN (1 pt)
□ Renal Impairment (1 pt)
□ Hepatic Impairment (1 pt)
□ Hx CVA (1 pt)
□ Bleeding Hx/Predisposition (1 pt)
□ Age (>65 (1 pt)
□ DM (1 pt)
□ Drugs that increase bleeding (1 pt)
□ INR in range <60% of time (1 pt)
□ Alcohol abuse (1 pt)
Total points: _____

Risk Classification
(bleeds per 100 patient years, % major bleed risk)

0 = 1.13, 0.9%	3 = 3.74, 5.8%
1 = 1.02, 3.4%	4 = 8.7, 8.9%
2=1.88, 4.1%	5= 12.5, 9.1%

6 or greater (too few events to determine risk)

Subtherapeutic INRs:

- In patients with previously stable therapeutic INRs who present with a single out-of-range INR of <0.5 below therapeutic range, we will continue the current dose and test the INR within 1 week. If two consecutive INRs are <0.5 below range, a permanent dose change is logical.
- A temporary dose increase (for one day) may be necessary if presenting with a single INR value >0.5 below range.
- Given the individual patient dose response with warfarin, permanent dosing changes will be made in small increments of ~10-15% of weekly dose.
- For those patients who remain subtherapeutic despite repeated small dose increases, a larger permanent change of ~15-25% of the weekly dose may be necessary given the thromboembolic risk of continued subtherapeutic INRs.
- ***Table 9*** is included in this protocol for suggested management of sub/supratherapeutic INRs

Supratherapeutic INRs:

- INR correction is highly variable and in addition to the type of reversal treatment employed (holding warfarin, administering vitamin K, etc.), additional patient-specific factors may contribute to the rate and extent of INR reversal (***Table 10***). It is important to consider these factors when correcting elevated INRs as they may contribute to delayed INR correction and/or overcorrecting the INR and predisposing the patient to risk for thromboembolism.
- For all INRs > 4.5 (critical value), notification to medical personnel will be made first to the referring physician. If the referring physician is unavailable, on call back up physician will be consulted. INRs >4.5 ***must be*** followed with a venous blood draw.
- All patients with elevated INRs will receive additional counseling regarding the risk for and self-monitoring parameters of bleeding and avoidance of high-risk activities.
- The following approaches may be used in regards to supratherapeutic INRs. These guidelines should never substitute for clinical judgment.
    - <u>INRs greater than the recommended goal but < 4.5 without significant bleeding</u>
      a. Reduce the current day's dose or omit a dose of warfarin and resume therapy at a lower dose. If INR is only minimally above therapeutic range (<0.5) or if elevated INR was due to time-related and reversible variable(s), no dosage reduction may be necessary.
    - <u>INRs 4.5 to 8 without significant bleeding</u>
      a. Omit the next 1 or 2 warfarin doses, monitor the INR more frequently, and resume therapy at a lower dose when the INR has fallen back into therapeutic levels.
      b. Recheck INR in 1-2 days
      c. Alternatively, omit the next dose and administer vitamin K 1.0-2.5 mg orally (especially if the patient has increased risk for bleeding).
    - <u>INRs >8</u>
      a. Without significant bleeding: patients will be instructed to hold doses and recheck INR within 1-2 days
      b. With significant bleeding: patients will be referred to the emergency room
- Patients with serious/life-threatening bleeding (regardless of INR) will be referred to emergency personnel

Table 9. Warfarin Dosing Algorithm					
Target INR 2-3					
INR <1.5	INR 1.5-1.9	INR 2.0-3.0	INR 3.1-4.0	INR 4.1-5.0	INR 5.1-9.0
Consider extra dose Increase weekly dose 10-20%	Increase weekly dose 5-10%	No change	Decrease weekly dose 5-10%	Hold 1 dose Decrease weekly dose 10%	Consider: Hold 2 doses Decrease weekly dose 10-20%
Target INR 2.5-3.5					
INR <1.9	INR 1.9-2.4	INR 2.5-3.5	INR 3.6-4.5	INR 4.6-5.0	INR 5.1-9.0
Extra dose Increase weekly dose 10%	Increase weekly dose 5-10%	No change	Consider holding one dose Decrease weekly dose 5-10%	Hold 1 dose Decrease weekly dose 10%	Consider: Hold 2 doses Decrease weekly dose 10-20%

Table 10. Factors Associated with Rate of INR Correction	
Delayed Correction	***Rapid Correction***
Advanced age Lower maintenance dosage of warfarin High baseline INR Decompensated congestive heart failure Active cancer Recent use of a medication known to potentiate warfarin's effects	Younger patients Higher maintenance dosage of warfarin Low baseline INR

Management of Patients Undergoing Procedures/Surgeries:

Below are recommendations regarding when to continue or discontinue warfarin treatment in anticipation of a procedure/surgery. These recommendations are simply a guide. In these instances, it is critical that a plan for anticoagulation management is developed by the patient's healthcare team (physicians, pharmacists, nurses) and that it is then clearly expressed to the patient. Our recommendations regarding bridging therapy will derive from 2012 ACCP guidelines. ***Figure 1*** is provided as a guide to perioperative management for the AMS pharmacist. Clinical judgment should always be used when bridging patients.

In general, the decision of whether to bridge anticoagulant therapy is based on the patient's thromboembolism risk (***Tables 7 and 8***), and the bleeding risk of the procedure bleeding risk.

- In ***high-risk patients***, the need to prevent TE will dominate management irrespective of bleeding risk; the potential consequences of TE may justify bridging.
- In ***moderate-risk patients***, a single perioperative strategy is not dominant and management will depend on individual patient TE risk assessment.
- In ***low-risk patients***, the need to prevent TE will be less dominant and bridging may be avoided.

Additional Notes:

- In patients who require temporary interruption of a VKA before surgery, it is recommended to discontinue warfarin approximately 5 days before surgery rather than discontinuing closer to the procedure
- In patients who require temporary interruption of a warfarin before surgery, it is recommended to resume warfarin approximately 12 to 24 hours after surgery (evening of or next morning) and when there is adequate hemostasis instead of later resumption of warfarin.
- In patients who are receiving bridging anticoagulation with therapeutic-dose SC LMWH, it is suggested to administer the last preoperative dose of LMWH approximately 24 hours before surgery instead of 12 hours before surgery.
- In patients who are receiving bridging anticoagulation with therapeutic-dose SC LMWH and are undergoing high-bleeding-risk surgery, it is suggested to resume therapeutic-dose LMWH 48 to 72 hours after surgery instead of resuming LMWH within 24 hours after surgery.
- The AMS pharmacist will contact the patient's surgeon to discuss invasiveness of surgery
- The AMS pharmacist will also contact the patient's referring physician to discuss plans for stopping warfarin and bridging with LMWH if needed
- The AMS pharmacist will provide the patient with a bridging calendar (***Appendix S***) prior to the procedure and the start date of holding warfarin if needed

Low bleeding-risk surgeries/procedures include:

- Simple dental extraction and endodontic procedures
- Skin biopsy
- Cataract surgery
- Colonoscopy without biopsy or polypectomy

Recommendations: In patients who are undergoing minor surgical or invasive procedure (dental, skin, or cataract), interruption of antithrombotic therapy may not be required.

Minor dental procedure: continue warfarin with coadministration of an oral prohemostatic agent *OR* stop warfarin 2 to 3 days before the procedure.

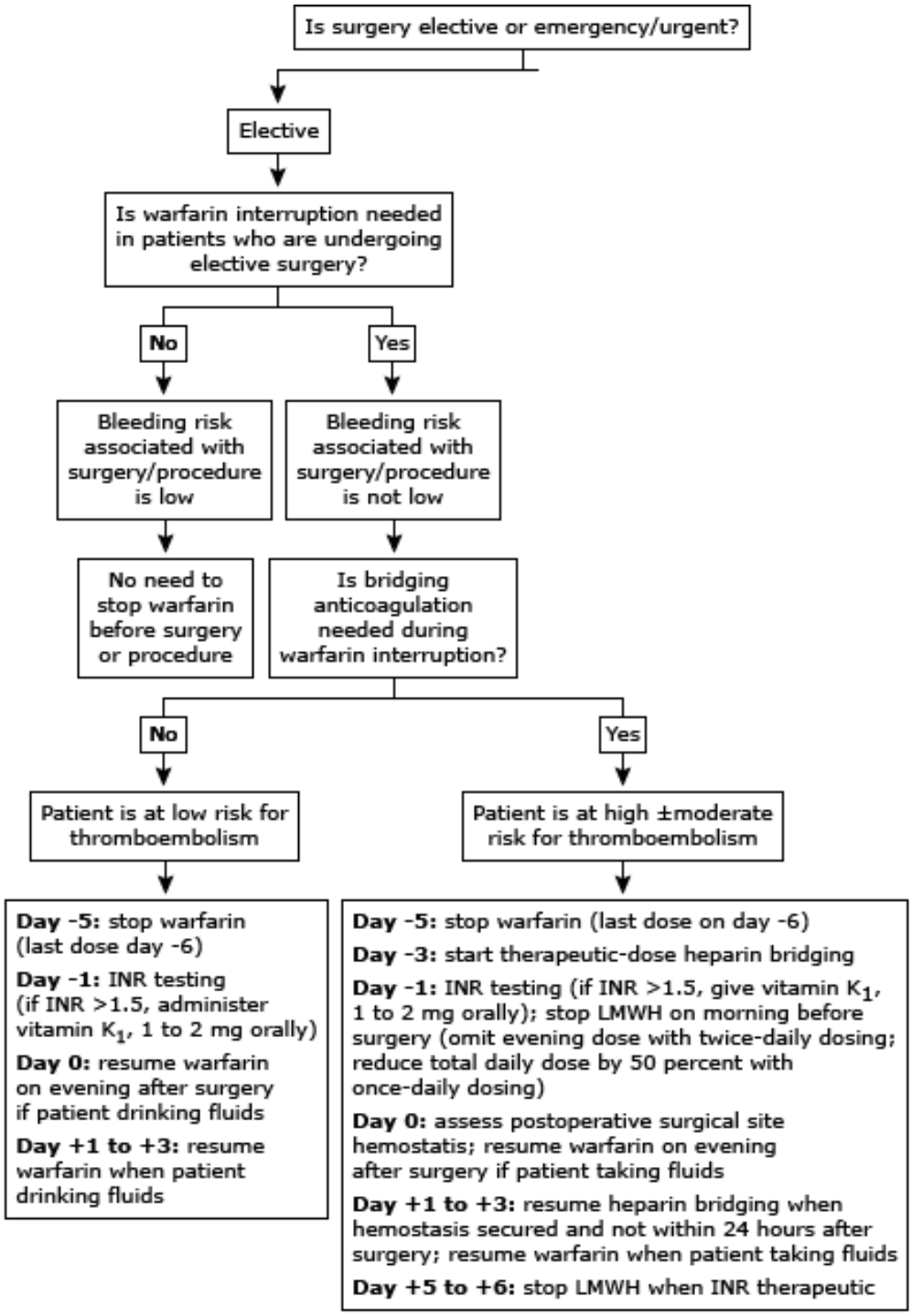
Minor dermatologic procedures: continue warfarin and optimize local hemostasis.

Cataract surgery: continue warfarin around the time of the surgery.

High bleeding-risk surgeries/procedures include:

- Urologic surgery/procedures (TURP, bladder resection/ablation, nephrectomy/kidney biopsy)
- Pacemaker or ICD implantation
- Colonic polyp resection, especially >1-2 cm sessile polyps
- Vascular organ surgery (thyroid, liver, spleen)
- Bowel resection (bleeding may occur at anastomosis site)
- Major surgery involving considerable tissue injury (cancer surgery, joint arthroplasty, reconstructive plastic surgery)
- Cardiac, intracranial or spinal surgery
- Dental (multiple tooth extraction, extensive surgery)

Figure 1. Perioperative Management of Warfarin Therapy



This research was originally published in Blood. Douketis JD. Perioperative management of patients who are receiving warfarin therapy: an evidence-based and practical approach. Blood 2011; 117:5044. Copyright © 2011 American Society of Hematology.

4. PROGRAM EVALUATION

The AMS will be evaluated quarterly. The clinical coordinator will be responsible for assessing whether pharmacists are abiding by the treatment and procedure protocols and outcomes relative to the practice.

Outcomes to evaluate include:

1. Patient, provider and pharmacist satisfaction
2. Workload volume (number of patient visits and number of patients)
3. Physician time saved
4. Number of no-shows or missed appointments
5. % of INR's within goal (time in therapeutic range)
6. % of INR's > 4.5 or < 1.5
7. Deviation from INR goal
8. Identifiable causes of INR's out of goal
9. Number adverse events (minor/major bleeds, thromboembolisms)

5. TRAINING

Pharmacists providing service for the AMS will be required to:

1. Complete a clinic approved anticoagulation certification course entitled "Anticoagulation Therapy Management for Pharmacists". This course was developed by Laura Annis, Pharm.D., R.Ph., Douglas F. Covey, Pharm.D., F.C.C.P., M.H.A., and Michele Weizer-Simon, Pharm.D., R.Ph. from the University of Florida. It is a 40.5 CE ACPE accredited course. A certificate is rewarded upon completion.
2. Receive approval to practice by the pharmacy clinical coordinator. This includes but is not limited to:
    a. Training on site with the clinical director
    b. Complete the case-management of 5 patients according to the AMS protocol. Provided recommendations align with those of the clinic coordinator and the AMS protocol.
3. Satisfy competency training for CoaguChek XS.
4. Complete 2 hours of CE credit per year related to outpatient anticoagulation management.
5. Pharmacists must keep up to date annually with ongoing changes in anticoagulation management.
6. Quarterly evaluations of patient therapeutic management will be completed by the clinical coordinator for all credentialed clinic pharmacists to ensure the protocol is adhered to.

Anticoagulation certification courses will be covered by the CPC and costs $795 per course. Additional educational opportunities (CE credit) may be covered and will be discussed on a case by case basis.

Training for CoaguChek XS:
Each pharmacist that is responsible for patient care under the AMS will receive training for the point of care testing device, CoaguChek XS. This includes on-site training with a representative from Roche diagnostics or a well established AMS pharmacist practicing in the clinic. The training pharmacist must also review and complete the Competency Assessment ***(Appendix I)***. The clinic coordinator will work with each applicant and verify that he/she has read and reviewed the "Policy and Procedure Manual" and that he/she has completed the "Operator Evaluation Checklist", "Operator Certification Test", and "Operator Certification Checklist" ***(Appendix J)***.

Training video: https://www.poc.roche.com/

6. COAGUCHEK XS POINT OF CARE TESTING

Please see the attached materials "Getting Started Guide", "Evaluation of the Accuracy and Precision of the CoaguChek XS System", "Package Insert" and "User Manual" regarding upkeep, testing, and maintenance of the CoaguChek XS point of care testing device. The attached "Policy and Procedure Manual" concerns quality assurance, competency, and training.

The CoaguChek XS System uses exclusive technology to help ensure accurate results, and offers the flexibility and control that healthcare professionals need to confidently manage a wide range of anticoagulated patients.

Accurate and flexible technology

- Accurate, precise results in about one minute
- System performs onboard quality control and determines patient results in a single test chamber
- Neutralizes therapeutic levels of heparin and LMWH
- INR corrected for hematocrit within specified range - manage a broad array of patients with one device

Easy and convenient to use

- Small sample size (8µl) for easy dosing
- Strip allows dosing from either top or side for simple blood application
- 21-month strip shelf life from date of manufacture– no refrigeration needed
- Outside meter blood application – minimizes potential for cross-contamination
- Small, battery-powered, handheld meter for portability and efficiency
- 300 test memory

Efficient and cost-effective

- Onboard controls – no external QC necessary
- Auto-on with strip insertion and auto-off capabilities
- Testing, treatment and potential revenue capture in one appointment
- Fingerstick test that patients prefer

Additional education materials:
Available at: https://www.poc.roche.com/

- CoaguChek XS Manual
- CoaguChek XS Getting Started Guide

- CoaguChek XS Package Insert
- CoaguChek XS Policy and Procedure Manual
- CoaguChek Systems Medicare Reimbursement Handbook for Healthcare Professionals
- How to Apply for a CLIA Certificate
- CoaguChek LOINC Code Listing

Case Studies / White Papers

- CoaguChek XS Precision White Paper
- Heparin Sensitivity White paper
- CoaguChek XS Onboard controls white paper
- CoaguChek Comparison White Paper

7. REFERENCES

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Reviewed/ Approved by

CPC Director _____

Original Policy Date Approval and Revisions:

Revision #	Date
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