

Delegation Protocol Number: 7

Delegation Protocol Title:

Initiation and Management of Warfarin - Adult - Ambulatory

Delegation Protocol Applies To:

UW Health Clinics

Target Patient Population:

Adult patients initiated or managed on warfarin

Delegation Protocol Champions:

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Delegation Protocol Reviewers:

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Responsible Department:

Department of Pharmacy

Purpose Statement:

To delegate authority from physicians or advanced practice providers (e.g. nurse practitioners, physician assistants) to Registered Nurses (RNs) and Pharmacists (RPhs) the initiation, assessment, dose adjustment, and monitoring of warfarin therapy.

Who May Carry Out This Delegation Protocol:

Registered Nurses and Pharmacists licensed in their respective fields in the state of Wisconsin who have documented completion of warfarin training and passed competency.

1. Warfarin training – each RN and RPH will be required to complete one of the two methods for training
 - 1.1. Completion of computer-based training program located on the eLearning website; OR
 - 1.2. Attendance of the live training program by Anticoagulation Program Coordinator. (optional)
2. Competency – each RN and RPH will be required to achieve competency in the protocol as defined by the following:
 - 2.1. Development of a management plan for a minimum of five patients requiring warfarin dose adjustments.
 - 2.2. These cases will be reviewed and approved by either the responsible provider or clinic anticoagulation champion.
3. The clinic anticoagulation champion has either been identified based on their experience and expertise in the area of anticoagulation or has received intensive training (three-hour live training session) on anticoagulation management.
4. A competency checklist is listed in Appendix A.

Guidelines for Implementation:

A. Protocol Initiation

1. The protocol is initiated in one of two ways:
 - 1.1. Ordering “Consult to Anticoagulation Clinic”

- 1.2. Verbal/Inbox Messaging/Progress Note Documentation to the RN from the Provider
2. All patients receiving warfarin should be managed through the warfarin episode of care. To activate the episode of care, the “enroll in anticoagulation” order is required
 - 2.1.1. The “enroll in anticoagulation” order should be entered by a RN, RPH or pharmacy technician associated with the clinic being delegated the task of warfarin management.
 - 2.2. Within the "Enroll In Anticoagulation" order the responsible pool, target INR range, indication, and anticipated duration of anticoagulation (if known) should be completed. This information will be obtained via the “Consult to Anticoagulation” order or from the authorizing provider verbally or through Inbox Messaging/Progress Note Documentation.
 - 2.3. Within the “Enroll In Anticoagulation” order there is a question regarding the delegation of warfarin management to an RN or RPH. Selecting “YES” confirms delegation. The order must be sent to the authorizing provider associated with 1.0 above for co-signature.
 - 2.4. Upon entering the enroll order an inbasket message is sent to the responsible pool. This inbasket message should be used to double check the patient has a plan for warfarin dosing and next INR date scheduled.

B. Laboratory Monitoring - Prior to Initiating Warfarin

1. The following labs should be resultated prior to initiating warfarin:
 - 1.1 Within the past 30 days
 - Baseline INR
 - Pregnancy test for women unless:
 1. Are postmenopausal (12 months of amenorrhea in a woman over age 45 years old in the absence of other biological or physiological causes)
 2. Had a hysterectomy or bilateral salpingo-oophorectomy
 3. Have ovarian failure
 4. Had a bilateral tubal ligation or another surgical sterilization procedure
 5. Are known to be pregnant
 6. Have had a miscarriage or abortion within the last 7 days
 7. Have given birth within the past 4 weeks
 - 1.2 Within the past 90 days
 - Hemoglobin
 - Platelet count
 - ALT
 - Creatinine
2. If above baseline labs are not available, the RN or RPH may enter these laboratory orders and send to the provider for co-signature per protocol and send the patient to lab for venipuncture draw.

C. Warfarin Dosing - Per Protocol

1. The provider will provide the initial warfarin dose, indication, and target INR goal before delegating management to the RN or RPH.
2. Table 1 may be utilized to identify patients who may be potentially sensitive to warfarin.
3. If the patient is within the first seven days of therapy, Table 2 is utilized for dose adjustments.
4. If the patient is greater than seven days after initiating warfarin therapy, Tables 3-6 is utilized for dose adjustments depending on the target INR range.

- 4.1 For INR ranges that do not have corresponding dosing tables the same principles of adjusting the weekly dose by approximately 10% for an INR not in goal should be used.
- 4.2 Patients with mechanical mitral valves and INR goal of 2.5-3.5, if the INR below 2.0 bridge therapy with low molecular weight heparin (LMWH) should be considered. The RN or RPH should initiate a discussion with the provider regarding the need for dual anticoagulation coverage.
- 4.3 Patients with ventricular assist devices (VADs), if the INR falls below the following thresholds, bridging with LMWH should be considered. the RN or RPH should initiate a discussion with the provider regarding the need for dual anticoagulation coverage.
 - INR < 1.4 (for VAD patients with INR goal 1.8-2.5)
 - INR < 1.6 (for VAD patients with INR goal 2.0-3.0)
 - INR < 2.0 (for VAD patients with INR goal 2.5-3.5)
5. Warfarin doses must not be adjusted without a resulted INR, except in the case of significant drug interactions.
6. Patients utilizing home point of care “fingerstick” testing machines may be followed per protocol.
 - 6.1 Appendix B outlines recommended criteria that should be used to determine is a patient is a good candidate for home INR testing.
7. Missed doses, recent INR trends, changes in diet and/or activity, changes to medications, and symptoms of bleeding or clotting will be considered before making a dosing change.
 - 7.1 Appendix C provides a complete list of patient assessment questions.
 - 7.2 Clinical judgment may be used when completing the patient assessment to tailor the depth of questioning based on patient response and/or INR result.
8. A stable warfarin patient is defined as a patient maintained on the same warfarin dose for at least 6 months.
 - 8.1 If a previously stable patient has one out of range INR and is maintained on the same dose, they may still be considered stable if their next INR is back within target range.
 - 8.2 If a previously stable patient has one to two out of range INRs due to a specified event (e.g., drug interaction, missed dose) and required a temporary dose change due to the event, they may be considered stable once the previously stable dose is resumed.
 - 8.3 If a previously stable patient has one out of range INR requiring an adjustment to their maintenance dose, they can be considered stable after three months on the same warfarin dose.

D. Warfarin Dosing - NOT on Protocol

1. All patients receiving warfarin should be managed through the anticoagulation monitoring tool and will require the “Enroll in Anticoagulation” order to activate the episode of care.
 - 1.1. The RN may enter the “Enroll in Anticoagulation” order to active the episode but will select “no” for the delegation question.
 - 1.2. The RN will send the “Enroll” order for provider signature.
2. When evaluating an INR result it is recommended that missed doses, recent INR trends, changes in diet and/or activity, changes to medications, and symptoms of bleeding or clotting should be considered before making a dosing change.
 - 2.1. The RN may still complete the patient assessment on each resulted INR for warfarin management, but all findings must be sent to the provider.
3. The RN, LPN, or MA may instruct the patient with warfarin dosing instructions from their provider.

E. Documentation

1. For all patients on warfarin the following should be documented in the warfarin episode of care in the electronic medical record:
 - 1.1 Indication for anticoagulation
 - 1.2 Target INR range
 - 1.3 Current warfarin dose
 - 1.4 Current INR
 - 1.5 Return INR date
 - 1.6 Warfarin tablet strength
 - 1.7 Telephone contact for the patient
2. At each patient encounter for INR monitoring, patients must be assessed for changes that could affect warfarin dosing (Appendix C).
3. Each encounter for anticoagulation management should be linked to the warfarin episode of care within the electronic medical record.
4. Follow up on INRs for warfarin management may be completed via telephone conversation or scheduled clinic visit and will occur no later than the next business day of the reported INR result.
5. If the clinician is not able to reach the patient a message should be left (if able) and documentation of the call entered in the medical record.
 - 5.1 Additional attempts to reach the patient should occur every 24-72 hours based on clinic schedule.
 6. Patients will be considered unreachable after three attempts on separate business days have been unsuccessful in contacting the patient.
 - 5.1 Documentation of all contact attempts and messages will be included in the progress note.
 - 5.2 After three telephone attempts to contact the patient have been unsuccessful a letter will be sent to the patient's home address or electronically if available (via My Chart).
 - 5.3 After the letter has been sent to the patient, the protocol will end, and warfarin management will revert back to the provider.
 - 5.3.1 The RN or RPH must contact the provider informing them of the patient non-compliance and end of protocol management
 - 5.3.2 The provider may choose to re-initiate the protocol after verbal communication with the RN or RPH.
 7. If the clinic is notified of an inpatient admission, emergency department visit or death, the RN or RPH will determine if the event was due to a thrombotic or bleeding event. If yes:
 - 7.1 Documentation of the event should occur in the warfarin episode of care under "anticoagulation related adverse events."
 - 7.2 The episode of care should be resolved for deceased patients.
 8. Patients should be assessed at least once a year for anticoagulation indication and length of therapy by a physician or advanced practice provider.

F. Laboratory Monitoring - Maintenance

1. The RN or RPH will instruct the patient on timing of INR monitoring.
 - 1.1 Table 7 is for newly initiated patients who have not achieved a stable warfarin dose.
 - 1.2 Table 8 is for stable patients with a consistent warfarin dose.
2. An INR must be checked at least every eight to twelve weeks in a stable patient.
3. For clinics utilizing point of care "fingerstick" testing machines, if the reported INR is above the defined accuracy per machine, a repeat venipuncture is required to verify the INR result. Use the venipuncture INR to determine if a dose change is needed.

4. For patients utilizing home point of care “fingerstick” testing machines:
 - 4.1. Patient reported INR results maybe entered into Health Link via enter/edit functionality using the result type “INR – PATIENT REPORTED” and resulting lab name “HOME INR MONITOR”.
 - 4.2. If the INR is above the specific range for accuracy then a venipuncture INR is required to verify the INR.
5. Additional maintenance labs should be ordered at least yearly:
 - 5.1. Hemoglobin
 - 5.2. Platelet count
 - 5.3. Creatinine
6. Critical INR results for patients followed by Anticoagulation Clinic:
 - 6.1. Upon notification of a critical INR result, the anticoagulation clinic RN or RPH will develop a plan based on patient assessment (appendix C) and the dosing tables listed in the protocol
 - 6.2. A physician order is not required for INRs between 5.1-9.0 in a patient with a negative assessment or noted minor bleeding (e.g. nosebleed)
 - 6.3. A physician must be contacted if the resulting INR is > 9.0 or INR 5.1-9.0 with a positive finding of bleeding in the urine, stool, sputum, or emesis during patient assessment (appendix C)

G. Patient Education

1. For all patients started on warfarin, patient education that highlights the importance of the following should be completed:
 - 1.1 Follow-up
 - 1.2 Monitoring
 - 1.3 Compliance
 - 1.4 Dietary restrictions
 - 1.5 Potential for drug interactions
 - 1.6 Potential adverse reactions
 - 1.7 Pregnancy: contact provider immediately if patient becomes pregnant or suspects pregnancy; educate patient to utilize contraception to prevent pregnancy while using warfarin (unless patient is postmenopausal [12 months of amenorrhea in a woman over age 45 years old in the absence of other biological or physiological causes]; has had a hysterectomy or bilateral salpingo-oophorectomy; has ovarian failure; has had a bilateral tubal ligation or another surgical sterilization procedure).
2. Documentation of patient education will occur in the electronic medical record.
3. Educational materials for warfarin and parenteral anticoagulants have been created for use:
 - [Warfarin: Health Facts For You #6900](#)
 - [Heparin \(Unfractionated and Low Molecular Weight\): Health Facts For You #6915](#)
 - Warfarin Patient Education Video available at www.uwhealth.org/anticoagulation

H. Periprocedural and Transitioning Therapy

1. Periprocedural anticoagulation should be individualized for each patient depending on bleeding risk of procedure and risk factors for thromboembolism.
 - 1.1. Periprocedural plans may be developed for patients based on the recommendations provided in the [Periprocedural Management with Antithrombotic Therapy UW Health Guideline](#).
2. Transitioning patients to an alternative anticoagulant (other than warfarin) requires a provider order.

I. Identifying Patients Overdue for INRs

1. The episode of care will send an inbasket message for patients who are overdue for INRs based on their return INR date.
2. The warfarin patient registry (workbench report) should be run twice per month to catch patients who may have missed their INR follow up
 - 2.1. The report is titled " Anticoagulation Responsible Pool." It will pull all patients with an active anticoagulation episode of care associated with the inbasket pool entered. It identifies last INR date and how many days overdue a patient is for an INR check.

J. Medication Prescribing and Renewal

1. For patients followed per the warfarin management protocol, the UW Administrative Policy 8.91 Prescription Renewal will be utilized.
2. In addition to Policy 8.91, patients followed per protocol may have the following prescriptions prescribed or renewed by the RN or RPH:
 - 2.1. Warfarin (Coumadin®)
 - 2.2. Low Molecular Weight Heparins
 - 2.3. Fondaparinux (Arixtra®)
 - 2.4. Phytonadione/Vitamin K (Mephyton®)
3. For all new warfarin prescription or renewals:
 - 3.1 Instructions should read "Take as directed based on INR. RPh: *** tablets = *** day supply."
 - 3.2 The number of tablets per 30- or 90-day supply must be entered in the prescription for outpatient pharmacies to bill through insurance.
4. Clinic staff may take messages/faxes from patients and pharmacies regarding the anticoagulation prescription renewal and will forward these requests to the RN or RPH for completion.
5. Clinic RN or RPH will complete the requested prescription renewal during normal clinic hours and within 48 hours, unless marked as urgent.

Table 1. Factors for Identifying Patients with Increased Warfarin Sensitivity

Table 1. Warfarin sensitivity factors	
Increases sensitivity (usually require lower doses)	
<ul style="list-style-type: none"> • Baseline (pre-warfarin) PT/INR (e.g., greater than 1.4) • Advanced age (e.g., 60 years of age or older) • Underweight (e.g., BMI less than 18kg/m²) • Nutritional status (e.g., malnourished, low vitamin K intake/stores) • Genetic factors (e.g., CYP2C9, VKORC1 phenotypes) • Drug-drug interactions • Hypoalbuminemia • Ethnicity (Asian) • Liver disease • Thyroid Disease (e.g., hyperthyroidism, Graves' disease) • Heart Failure • Febrile illness • Prolonged vomiting and diarrhea • Surgery and blood loss • Cannabinoids • Alcohol • Drug interactions 	
Decrease warfarin sensitivity (may require higher doses)	
<ul style="list-style-type: none"> • Enteral feedings • High-vitamin K intake • Estrogens • Chewing tobacco 	

Table 2. Warfarin Initiation Dosing Protocol (Week 1) with INR Goal 2-3

Day Therapy	INR Value	Dose Adjustment
Day 1		5 mg daily (2.5 mg daily if high sensitivity to warfarin identified)
In 2-3 days after initiation	<1.5	5-7.5 mg daily
	1.5-1.9	2.5-5 mg daily
	2.0-2.5	2.5 mg daily
	>2.5	Hold and recheck INR next day
In additional 2-3 days after last INR check	<1.5	7.5-10 mg daily
	1.5-1.9	5-10 mg daily
	2.0-3.0	2.5-5 mg daily
	>3.0	Hold warfarin, recheck in 1-2 days

Table 3. Warfarin Maintenance Dosing Protocol with INR Goal 1.5-2.0

INR less than 1.5	INR 1.5-2.0	INR 2.1-3.0 [‡]	INR 3.1-4.0*	INR 4.1-5.0*	INR 5.1-9.0*	INR greater than 9.0
Increase weekly dose 5%	No change	Decrease weekly dose 5%	Consider half dose x 1 and decrease weekly dose 10%	Hold 1 dose and decrease weekly dose by 10-20%	Order required Consider: Hold 2 doses and decrease weekly dose 10-20%; check hematocrit	Contact provider for urgent patient evaluation

*If the INR is above the specified range for accuracy per POC device, a repeat venipuncture is required to verify INR
‡See Table 6.

Table 4. Warfarin Maintenance Dosing Protocol with INR Goal 2-3

INR less than 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*	INR greater than 9.0
Extra dose and increase weekly dose 10-20%	Increase weekly dose 5-10%	No change	Decrease weekly dose 5-10%	Hold 1 dose and decrease weekly dose 10%	Order required Consider: Hold 2 doses and decrease weekly dose 10-20%; check hematocrit	Contact provider for urgent patient evaluation

*If the INR is above the specified range for accuracy per POC device, a repeat venipuncture is required to verify INR
‡See Table 6.

Table 5. Warfarin Maintenance Dosing Protocol with INR Goal 2.5-3.5

INR less than 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*	INR greater than 9.0
Extra dose and increase weekly dose 10-20%	Increase weekly dose 5-10%	No change	Decrease weekly dose 5-10%	Hold 1 dose and decrease weekly dose 10%	Order required Consider: Hold 2 doses and decrease weekly dose 10-20%; check hematocrit	Contact provider for urgent patient evaluation

*If the INR is above the specified range for accuracy per POC device, a repeat venipuncture is required to verify INR
‡See Table 6.

Table 6. All INR Ranges

If INR is above or below therapeutic range ≤ 0.5 and previously stable or there is a specific reason for INR to be out of range (example missed dose), continue current dose and test INR in 1-2 weeks

Table 7. Frequency of INR Monitoring After Initiation of Warfarin

INR Check	
Every 2-3 days	Until INR within therapeutic range on two consecutive INR checks
Then every week	Until INR within therapeutic range on two consecutive INR checks
Then every 2 weeks	Until INR within therapeutic range on two consecutive INR checks
Then every 4 weeks	When dose is stable check monthly

Table 8. Frequency of INR Monitoring for Maintenance of Warfarin

INR Check	
In 1 week	If dose adjusted by 10-20%, starting or stopping an interacting medication, change in diet, change in activity level, or other change that could affect INR
Every 1-2 weeks	If dose adjusted by 5-10% or if using a home INR meter
Every 4 weeks	If maintained on same stable dose fewer than 3 months
Every 8-12 weeks	If maintained on same stable dose for at least 3 months

*If INR stable every 8 weeks x 2 consecutive checks then may consider every 12 weeks.

Order Mode:

Cosign Required Protocol/Policy

References:

1. Ageno W, Gallus AS, Wittkowsky A, Crowther M, Hylek EM, Palareti G. Oral anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012;141(2 Suppl):e44S-e88S.
2. Garcia DA, Witt DM, Hylek E, et al. Delivery of optimized anticoagulant therapy: consensus statement from the Anticoagulation Forum. *Ann Pharmacother*. 2008;42(7):979-88.
3. Holbrook A, Schulman S, Witt D, Vandvik P, et al. Evidence-based Management of Anticoagulant Therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012;141(2 Suppl):e152s-e184s.
4. Holbrook AM, Pereira JA, Labiris R, et al. Systematic overview of warfarin and its drug and food interactions. *Arch Intern Med*. 2005;165(10):1095-1106.
5. Wittkowsky AK. Drug interactions update: drug, herbs, and oral anticoagulation. *J Thromb Thrombolysis*. 2001; 12(1):67-71.
6. Wittkowsky AK, Boccuzzi SJ, Wogen J, et al. Frequency of concurrent use of warfarin with potentially interacting drugs. *Pharmacotherapy*. 2004;24(12):1668-1674.
7. Barnes GD, Kong X, Cole D, et al. Extended international normalized ratio testing intervals for warfarin-treated patients. *J Thromb Haemost*. 2018;16(7):1307-1312.
8. Margolis AR, Porter AL, Staresinic CE, Ray CA. Impact of an extended International Normalized Ratio follow-up interval on healthcare use among veteran patients on stable warfarin doses. *Am J Health Syst Pharm*. 2019;76(22):1848-1852.
9. Rose AE, Robinson EN, Premo JA, Hauschild LJ, Trapskin PJ, McBride AM. Improving Warfarin Management Within the Medical Home: A Health-System Approach. *Am J Med*. 2017;130(3):365 e367-365 e312

Collateral Documents/Tools:

1. [Periprocedural Management with Antithrombotic Therapy UW Health Guideline](#)
2. [Warfarin: Health Facts For You #6900](#)
3. [Heparin \(Unfractionated and Low Molecular Weight\): Health Facts For You #6915](#)
4. UW Administrative Policy 8.91 Prescription Renewal

Approved By:

UW Health Ambulatory Anticoagulation Committee: July 2021

UWHC Pharmacy and Therapeutics Committee: September 2021

UWHC Medical Board: October 2021

UW Health Chief Clinical Officer: October 2021

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Appendix A. UW Health Warfarin Protocol Skills Training Checklist

1. Develop warfarin management plan for patients followed in clinic based on standardized protocol/practices

Name _____ Employee # _____

Clinic: _____

	Employee's initials	Preceptor's initials	Date of completion
1. Complete "Anticoagulation Management with Warfarin Guidelines" computer based training program located within the Learning and Development System			
2. Attend live training program on "Anticoagulation Management with Warfarin Guidelines" given quarterly (optional)			
Develop warfarin management plans for a minimum of 5 patients requiring dose adjustments – cases must be reviewed and approved by anticoagulation champion or responsible provider			
3. Case 1			
4. Case 2			
5. Case 3			
6. Case 4			
7. Case 5			

Resources:

- [UW Health Anticoagulation](#)
- [Warfarin Management – Adult – Ambulatory Clinical Practice Guideline](#)
- [Initiation and Management of Warfarin - Adult - Ambulatory Delegation Protocol \[7\]](#)
- [Warfarin: Health Facts For You #6900](#)
- [Heparin \(Unfractionated and Low Molecular Weight\): Health Facts For You #6915](#)

Name: _____ Date: _____

Anticoagulation Champion/Nursing Supervisor/Clinic Manager

Name: _____ Date: _____

Physician Lead

Appendix B. Recommended Criteria for Home Point of Care INR Testing

The patient has:

1. Good compliance with anticoagulation management and the ability to follow directions
2. Manual and visual dexterity to perform testing or has a committed support person to assist with testing
3. A chronic condition that would require long term anticoagulation (ex. atrial fibrillation, valve replacement)
4. Completed training on self-testing and demonstrated competency on the device
5. Been on at least 6 months of warfarin therapy

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Appendix C

Full Patient Assessment Tool

1. Verify patient dose
 - patient repeats what dose they have been taking
2. Missed doses
 - Y/N
3. Medication or OTC Changes
 - Y/N
4. Changes in diet/alcohol
 - Y/N
5. Recent Illness
 - Y/N (*If yes identify symptoms*)
 - Diarrhea
 - Nausea/Vomiting
 - Hospitalization
 - Upcoming surgery or procedure
 - New Diagnosis
6. Signs of bleeding
 - Y/N (*If yes identify symptoms*)
 - Nose
 - Sputum/Emesis
 - Urine/Stool
 - Bruising
 - Other
7. Falls/Injuries
 - Y/N
8. Clotting Symptoms
 - Y/N (*If yes identify site*)
 - Chest pain
 - Shortness of breath
 - Leg/Calf pain
 - Leg/Calf redness or swelling
9. Stroke Symptoms
 - Y/N (*If yes identify symptoms*)
 - Headache
 - Numbness/Weakness one sided
 - Vision changes
 - Confusion/Slurred speech