Delegation Protocol Number: 7

Delegation Protocol Title:
Initiation and Management of Warfarin – Adult -Ambulatory

Delegation Protocol Applies To:
UW Health Clinics: all adult outpatients with an active order for warfarin

Target Patient Population:
Adult patients initiated or managed on warfarin

Delegation Protocol Champions:
David Ciske, MD – Department of Medicine – Internal Medicine
David Queoff, MD – Department of Family Medicine

Delegation Protocol Reviewers:
Anne Rose, PharmD – Department of Pharmacy
Gina Lanz, RN – Department of Family Medicine
Joan Premo, RN - Internal Medicine, East Towne
Erin Robinson, PharmD, CACP – Department of Pharmacy

Responsible Department:
Department of Pharmacy

Purpose Statement:
To delegate authority from physicians 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 1 of the 2 methods for training
   1.1. Completion of computer-based training program located on the eLearning website. (required)
   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 5 patients requiring warfarin dose adjustments.
   2.2. These cases will be reviewed and approved by either the responsible physician 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 (3 hour live training session) on anticoagulation management.
4. A competency checklist has been created and is listed in Appendix A

Advanced Practice Nurse Practitioners (NP’s), Physicians Assistants (PA’s) and Nurse Midwives may not delegate medical authority. Orders may be pended and routed for signature to these individuals but may not be implemented until signed by the provider.
Guidelines for Implementation:

A. Protocol Initiation
1. All patients receiving warfarin should be managed through the anticoagulation monitoring tool and will require the "Enroll in Anticoagulation" order to both activate this tool and delegate protocol management.
2. 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.
3. The RN or RPH may enter the "Enroll" order for the physician to delegate warfarin management but must send the order to the physician for co-signature per protocol.
4. Within the "Enroll In Anticoagulation" order the responsible pool, target INR range, indication, and anticipated duration of anticoagulation (if known) should be completed.

B. Laboratory Monitoring - Prior to Initiating Warfarin
1. The following labs should be resulted prior to initiating warfarin
   1.1 Within the past 30 days
      • Baseline INR
      • Pregnancy test for women of child bearing age
   1.2 Within the past 90 days
      • Hemoglobin
      • Platelets
      • ALT
      • Serum creatinine
2. If above baseline labs are not available the RN or RPH may enter these laboratory orders and send to the physician for co-signature per protocol and send the patient to lab for venipuncture draw.

C. Warfarin Dosing - Per Protocol
1. The physician 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 7 days of therapy Table 2 is utilized for dose adjustments
4. If the patient is greater than 7 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 < 2.0 bridge therapy with low molecular weight heparin should be considered. The RN or RPH should initiate a discussion with the physician regarding the need for dual anticoagulation coverage.
5. Warfarin doses must not be adjusted without a resulted INR
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 if 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 taken into account before making a dosing change.
   7.1 Appendices C and D show 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 1 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 1-2 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 1 out of range INR requiring an adjustment to their maintenance dose, they can be considered stable after 3 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 both activate the episode
   1.1 The RN may enter the “Enroll in Anticoagulation” order to activate the episode but will select “no” for the delegation question.
   1.2 The RN will send the “Enroll” order for physician, NP/PA 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 taken into account 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 anticoagulation 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
   2.1 For all non-stable patients (defined in Section C) a full patient assessment must be completed and documented in the anticoagulation episode of care (Appendix B)
   2.2 For all stable patients (defined in Section C) a full assessment is preferred but if not possible an abbreviated patient assessment may be substituted for the full assessment and documented in the anticoagulation episode of care (Appendix C)
   2.3 All stable patients must have 1 full assessment completed and documented at least every 6 months.

3. Each encounter for anticoagulation management should be linked to the anticoagulation 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. Patients will be considered unreachable after 3 attempts on separate consecutive 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 3 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 divert back to the physician.
   5.4 The physician may choose to re-initiate the protocol after verbal communication with the RN or RPH
7. Patients should be assessed at least once a year for anticoagulation indication and length of therapy by a physician or mid-level provider

F. Laboratory Monitoring - Maintenance
1. The RN or RPH managing warfarin will instruct the patient on timing of INR monitoring
   1.1 Table 7 for newly initiated patients who have not achieved a stable warfarin dose
   1.2 Table 8 for stable patients with a consistent warfarin dose
2. An INR must be checked at least every 6-8 weeks in a stable patient
4. For clinics utilizing point of care “fingerstick” testing machines, if the reported INR is above the defined accuracy result per machine, a repeat venipuncture is required to verify the INR result. Use the venipuncture INR to determine if a dose change is needed.
5. For patients utilizing home point of care “fingerstick” testing machines
   5.1 Patient reported INR may not be entered into Health Link via enter/edit functionality per Lab Policy 7.98
   5.2 INR should be documented in the “dose description field” of the anticoagulation tracking section as “INR (enter value) per pt home INR machine on date”
   5.3 If the INR is above the specific range for accuracy then a venipuncture INR is required to verify the INR
   5.5 An INR must be drawn at least once a year by an acceptable lab facility (ex. UW Lab)
   5.6 A correlation of the home meter must be done once yearly, a difference of 0.4 is considered acceptable (ex. Comparison of an INR resulted by a clinical lab and by the home meter on the same day)
6. Additional maintenance labs should be ordered at least yearly
   6.1 Hemoglobin
   6.2 Platelet
   6.3 Serum creatinine

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
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
   3.1 Warfarin Patient Education Booklet: Health Facts For You #6900
   3.2 Parenteral Anticoagulation: Health Facts For You #6915
   3.3 Warfarin Patient Education Video: available on 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 UW Health Periprocedural Anticoagulation Guidelines
2. Transitioning patients to an alternative anticoagulant (other than warfarin) requires a providers order.
I. 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 script 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 Warfarin Sensitive Patients

<table>
<thead>
<tr>
<th>Increased Warfarin Sensitivity</th>
<th>Increased Bleeding Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline INR ≥ 1.5</td>
<td>Current antiplatelet therapy</td>
</tr>
<tr>
<td>Age &gt; 65</td>
<td>Thrombocytopenia: platelet &lt;75 K/μL</td>
</tr>
<tr>
<td>Actual body weight &lt; 45 kg or actual &lt; ideal</td>
<td>Significant hepatic disease: cirrhosis or total bilirubin &gt;2.4 mg/dL</td>
</tr>
<tr>
<td>Malnourished/ NPO &gt;3 days</td>
<td>Alcohol abuse history</td>
</tr>
<tr>
<td>Hypoalbuminemia &lt;2 g/dl</td>
<td>End stage renal disease</td>
</tr>
<tr>
<td>Chronic diarrhea</td>
<td>GI bleed within past 30 days</td>
</tr>
<tr>
<td>Significant drug interactions</td>
<td>Surgery within past 2 weeks</td>
</tr>
<tr>
<td>Decompensated heart failure</td>
<td>Intracranial bleed within past 30 days</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Day Therapy</th>
<th>INR Value</th>
<th>Dose Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td></td>
<td>5 mg daily (2.5 mg daily if high sensitivity to warfarin identified)</td>
</tr>
<tr>
<td>In 2-3 days after initiation</td>
<td>&lt; 1.5</td>
<td>5 – 7.5 mg daily</td>
</tr>
<tr>
<td></td>
<td>1.5-1.9</td>
<td>2.5 – 5 mg daily</td>
</tr>
<tr>
<td></td>
<td>2.0-2.5</td>
<td>2.5 mg daily</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.5</td>
<td>Hold and recheck INR next day</td>
</tr>
<tr>
<td>In additional 2-3 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>after last INR check</td>
<td>&lt; 1.5</td>
<td>7.5 – 10 mg daily</td>
</tr>
<tr>
<td></td>
<td>1.5-1.9</td>
<td>5 – 10 mg daily</td>
</tr>
<tr>
<td></td>
<td>2.0-3.0</td>
<td>2.5 – 5 mg daily</td>
</tr>
<tr>
<td></td>
<td>&gt; 3.0</td>
<td>Hold warfarin, recheck in 1-2 days</td>
</tr>
</tbody>
</table>
### Table 3. Warfarin Maintenance Dosing Protocol with INR Goal 1.5 – 2.0

<table>
<thead>
<tr>
<th>INR ≤ 1.2</th>
<th>INR 1.3 - 1.4</th>
<th>INR 1.5 - 2.0</th>
<th>INR 2.1 - 3.0</th>
<th>INR 3.1 - 4.0*</th>
<th>INR 4.1-5.0*</th>
<th>INR 5.1-9.0*</th>
<th>INR &gt; 9.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase weekly dose 10%</td>
<td>Increase weekly dose 5%</td>
<td>No change</td>
<td>Decrease weekly dose 5%</td>
<td>Consider half dose x 1 and Decrease weekly dose 10%</td>
<td>Hold 1 dose Decrease weekly dose by 10-20%</td>
<td><strong>MD order required</strong> Consider: Hold 2 doses Decrease weekly dose 10-20% Check Hct</td>
<td>Contact MD for urgent patient evaluation</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>INR &lt; 1.5</th>
<th>INR 1.5 - 1.9</th>
<th>INR 2.0 - 3.0</th>
<th>INR 3.1- 4.0*</th>
<th>INR 4.1-5.0*</th>
<th>INR 5.1-9.0*</th>
<th>INR &gt; 9.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extra Dose Increase weekly dose 10-20%</td>
<td>Increase weekly dose 5-10%</td>
<td>No change</td>
<td>Decrease weekly dose 5-10%</td>
<td>Hold 1 dose Decrease weekly dose 10%</td>
<td><strong>MD order required</strong> Consider: Hold 2 doses Decrease weekly dose 10-20% Check Hct</td>
<td>Contact MD for urgent patient evaluation</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>INR &lt; 1.9</th>
<th>INR 1.9 - 2.4</th>
<th>INR 2.5 - 3.5</th>
<th>INR 3.6 - 4.5*</th>
<th>INR 4.6-5.0*</th>
<th>INR 5.1-9.0*</th>
<th>INR &gt; 9.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extra Dose Increase weekly dose 10-20%</td>
<td>Increase weekly dose 5-10%</td>
<td>No change</td>
<td>Decrease weekly dose 5-10%</td>
<td>Hold 1 dose Decrease weekly dose 10%</td>
<td><strong>MD order required</strong> Consider: Hold 2 doses Decrease weekly dose 10-20% Check Hct</td>
<td>Contact MD for urgent patient evaluation</td>
</tr>
</tbody>
</table>

* 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

<table>
<thead>
<tr>
<th>INR &lt; 0.5 and previously stable or there is a specific reason for INR to be out of range (ex. missed dose), continue current dose and test INR in 1-2 weeks</th>
<th>INR &lt; 0.5</th>
<th>INR 0.5 - 0.9</th>
<th>INR 1.0 - 1.4</th>
<th>INR 1.5 - 2.0</th>
<th>INR 2.1 - 3.0</th>
<th>INR 3.1 - 4.0</th>
<th>INR 4.1-5.0</th>
<th>INR 5.1-9.0</th>
<th>INR &gt; 9.0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contact MD for urgent patient evaluation</strong></td>
<td><strong>Contact MD for urgent patient evaluation</strong></td>
<td><strong>Contact MD for urgent patient evaluation</strong></td>
<td><strong>Contact MD for urgent patient evaluation</strong></td>
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<td><strong>Contact MD for urgent patient evaluation</strong></td>
</tr>
</tbody>
</table>
MONITORING RECOMMENDATIONS

Table 7. Frequency of INR Monitoring After Initiation of Warfarin

<table>
<thead>
<tr>
<th>INR Check</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Every 2 – 3 days</td>
<td>Until INR within therapeutic range on 2 consecutive INR checks</td>
</tr>
<tr>
<td>Then every week</td>
<td>Until INR within therapeutic range on 2 consecutive INR checks</td>
</tr>
<tr>
<td>Then every 2 weeks</td>
<td>Until INR within therapeutic range on 2 consecutive INR checks</td>
</tr>
<tr>
<td>Then every 4 weeks</td>
<td>When dose is stable check monthly</td>
</tr>
</tbody>
</table>

Table 8. Frequency of INR Monitoring for Maintenance of Warfarin

<table>
<thead>
<tr>
<th>INR Check</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>In 1 week</td>
<td>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</td>
</tr>
<tr>
<td>Every 1-2 weeks</td>
<td>If dose adjusted by 5-10% or if using a home INR meter</td>
</tr>
<tr>
<td>Every 4 weeks</td>
<td>If maintained on same stable dose &lt; than 6 months</td>
</tr>
<tr>
<td>Every 6-8 weeks</td>
<td>If maintained on same stable dose for at least 6 months</td>
</tr>
</tbody>
</table>

*If INR stable every 6 weeks x 2 consecutive checks then may consider every 8 weeks.

Order Mode: Protocol/Policy, Without Cosign


Collateral Documents/Tools:

Deleted: ¶
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: ___________________________________________________________________

<table>
<thead>
<tr>
<th>Employee’s initials</th>
<th>Preceptor’s initials</th>
<th>Date of completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Complete “Anticoagulation Management with Warfarin Guidelines” computer based training program located within the Learning and Development System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Attend live training program on “Anticoagulation Management with Warfarin Guidelines” given quarterly (optional)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Develop warfarin management plans for a minimum of 5 patients requiring dose adjustments – cases must be reviewed and approved by anticoagulation champion or responsible physician

3. Case 1

4. Case 2

5. Case 3

6. Case 4

7. Case 5

Resources:

- Warfarin Management – Adult – Ambulatory – Clinical Practice Guideline
- Ambulatory Initiation and Management of Warfarin for Adults Protocol #7
- [www.uwhealth.org/anticoagulation](http://www.uwhealth.org/anticoagulation)
- HFFY #6900 – Warfarin
- HFFY #6915 – Heparin (Unfractionated and Low Molecular Weight)
- HFFY #6115 - Stopping Anticoagulation and Antiplatelet Therapy For Patients and Providers

Name: _______________________________  Date: ________________

Anticoag 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

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/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. e
   • 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

Appendix D.
Abbreviated Patient Assessment Tool (Stable Patients)
1. Verify patient dose (patient repeats what dose they have been taking)
2. Medication Changes Y/N
3. Upcoming surgery or procedures: Y/N
4. Bruising/bleeding or other concerns Y/N

Approved By:

UW Health Ambulatory Anticoagulation Committee: August 2013, September 2015
UW Health Ambulatory Protocol Committee: August 2013, November 2015
UW Health Laboratory Practices Committee:
UWHC Pharmacy and Therapeutics Committee: September 2013
UWHC Medical Board: October 2013
UW Health Chief Medical Officer:

Effective Date: October 2015

Scheduled for Review: October 2017