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| Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg — Caring for Health / À l'écoute de notre santé<br><br>**PRIMARY CARE PRACTICE GUIDELINES** | **Practice Guideline:**<br>**ORAL ANTICOAGULATION THERAPY** | **Guideline Number:**<br>**PCPG 9** |
| | **Approved By:**<br>*Community Health Services Management Team* | **Pages:**<br>*1 of 16* |
| | **Approval Date:**<br>*July 2011* | **Supercedes:**<br>*August, 2010* |

## 1. PRACTICE OUTCOME

- To provide direction regarding the standard processes for managing WRHA Primary Care Clinic clients who receive anticoagulation therapy with warfarin.
- To improve safety and reduce risk. A standard regional process will improve the accountability of this process, and the clinics' ability to detect errors and missing information.
- To improve clinical outcomes and develop quality indicators. Coordinated anticoagulation therapy that combines client assessment and management guidelines can improve clinical outcomes.
- To ensure evidence based, best practice standards are implemented.

## 2. DEFINITIONS

**Oral Anticoagulation Therapy**: A method of prescribing and monitoring an anticoagulant medication (warfarin, Coumadin) with a goal of maintaining a target INR in order to prevent embolism.

Common Indications: Venous thrombus, pulmonary embolism, mechanical heart valves, atrial fibrillation.

Contraindications: Active bleeding diathesis, non-adherence, pregnancy, severe liver disease, uncontrolled hypertension; recent surgery involving the nervous system, spine, or eye, known hypersensitivity to oral anticoagulation therapy.

**INR** (International Normalized Ratio): A standardized method of reporting prothrombin time (amount of time it takes for blood to form a clot). Therapeutic INR range is 2-3 for most indications. A therapeutic range of 2.5-3.5 is indicated for many prosthetic mechanical heart valves, thromboembolism when INR already 2-3, patients with antiphospholipid antibody syndrome.

## 3. PRINCIPLES

- To provide the collaborative team (physician, nurse practitioner, primary care nurse, pharmacist) with best practice guidelines to ensure appropriate management of clients receiving oral anti-coagulation therapy.
- The guideline is to be used by health care professionals who have completed the delegation of function. (Appendix D)
- This guideline provides evidence based information that can be used to facilitate INR management; it does not replace clinical judgment. Deviations from the recommendations may be appropriate based on primary care provider's discretion.

## 4. PROCEDURES

The scope of this guideline is explained in the following subsections:
4.1.1 Initiation of Oral Anticoagulation Therapy
4.1.2 Processing of INR Results
4.1.3 Clinical Management of INR Results
4.1.4 Follow-up of Outstanding Results

### 4.1.1. INITIATION OF ORAL ANTICOAGULATION THERAPY

The **CHADS2** criteria can help determine if patient diagnosed with atrial fibrillation's risk for cardioembolic stroke warrants warfarin therapy. A point of risk is assigned for each of the following items: history of **C**ongestive heart failure; **H**ypertension; **A**ge older than 75; and **D**iabetes mellitus. A history of **S**troke or TIA counts as **2** points. If a patient has a CHADS2 score of 2 points or higher, anticoagulation with warfarin should be strongly considered. An online CHADS2 risk calculator, based on the 2001 ATRIA study, can be accessed at http://www.mdcalc.com/chads2.

**HAS-BLED** is a tool to guide assessment of bleeding risk and is useful in decisions about the relative risks of stroke vs. major bleeding with various antithrombotic therapies. It is based on the presence of **h**ypertension, **a**bnormal liver or renal function, history of **s**troke or **b**leeding, **l**abile INRs, **e**lderly, and concomitant use of **d**rugs that promote bleeding or excess alcohol use. See chart below:

| Clinical Characteristic | Score |
|---|---|
| Hypertension | 1 |
| Abnormal renal or liver function (1 point each) | 1 or 2 |
| Stroke | 1 |
| Bleeding | 1 |
| Labile INRs | 1 |
| Elderly (age >65 years) | 1 |
| Drugs or alcohol (1 point each) | 1 or 2 |

| Risk Factor Score | Major Bleeds (% per year) |
|---|---|
| 0 | 1.13 |
| 1 | 1.02 |
| 2 | 1.88 |
| 3 | 3.74 |
| 4 | 8.70 |
| 5 | 12.50 |

Initial warfarin dose recommendation is 5mg/day for most patients. A starting dose of <5mg should be considered for patients >70 years old, those with impaired nutrition, liver disorder, or previously documented sensitivity to warfarin.

If triple therapy (warfarin, ASA, and clopidogrel) is warranted, heightened awareness for bleeding episodes is required. The length of triple therapy treatment will be determined based on the individual clinical scenario considering perceived benefit and bleeding risk. The use of ASA and clopidogrel (Plavix) will not directly affect the management of warfarin. INR targets and frequency of INR monitoring will remain the same regardless of concurrent use of these antiplatlet agents.

When a physician or nurse practitioner prescribes oral anticoagulation therapy, the following must be documented in the client record:

1. Indication for anticoagulation therapy, along with duration of treatment
2. Reference range for INR
3. Name, strength, and initial dose schedule of anticoagulant prescribed
4. The following must be discussed and provided to the client:
    - Coumadin: Patient Information Booklet (Appendix A)
    - Client is provided with a stand-alone requisition for INR marked both "Standing Order" and "Urgent". A "Standing Order" indicates that the client will return to the lab on a routine basis for this test. The lab keeps this requisition on file preventing the need for a new requisition for each test. "Urgent" compresses the time it takes for the result to be returned to the clinic.
    - Schedule for initial blood monitoring
    - Ensure client provides efficient and effective mechanism to communicate lab values Examples: work phone numbers, cell phone numbers along with a Next of Kin contact and phone number, and transcribe these numbers to standing orders req.
    - Advise client that anticoagulation dose is once per day, at the same time every evening, and have their INR test performed in the morning, and early in the week whenever possible, so that results can be received the same day, and by the weekend.

During the induction phase, INR should be monitored every 1-3 days until the INR is in the patient's target range for 2 consecutive values, taken at least 3 days apart.

### 4.1.2. PROCESSING OF INR STANDING ORDERS

All outgoing requisitions for INR standing order lab tests will be tracked by the clinic and all incoming results will be immediately reconciled and treated as critical results when received at the clinic.

All INR results will be acted on and communicated to the client within 24 hours of receipt. Administrative staff is responsible for ensuring that any faxed results are provided to the clinician the same day that they are received.

All INR results must be reviewed on a daily basis, before leaving the clinic for the day; follow up actions may be delayed until the next day, at the Providers discretion.

Final copy of INR result must be signed off by the ordering provider, or designate, and filed in the client's record.

*Note:* Refer to site-specific process for review of results when the ordering provider is away from the office.

### 4.1.3. CLINICAL MANAGEMENT OF INR RESULT

Dosage adjustment is not required for minor fluctuations of INR as long as the results remain within the patient's target range.

Fluctuations of INR beyond the client's target range should always be investigated and corrected where possible. Consider causes such as a change in dosage of anticoagulant, patient compliance, medication profile, diet, and concurrent illness. It is strongly recommended that the client's community pharmacist be consulted regarding medication profile. Micromedix Drug Index can also be referenced, it is available online at http://home.wrha.mb.ca/prog/pharmacy/micromedex.php Additionally, Appendix B and C should be used to guide client assessment and subsequent clinical decision. More frequent INR monitoring may be warranted.

Frequency of INR monitoring is based on the individual patient circumstances, INR value, medication history, and is determined on an individual basis.

Once stable (2-3 consecutive results within therapeutic range), INR may be performed less frequently (every 1- 4 weeks). Four weeks is the longest interval between INR tests.

Client must be notified of any changes to warfarin dose and date of next INR.
This information must be documented on the Anticoagulation/INR Flow Sheet (http://home.wrha.mb.ca/hinfo/chif/files/WCC-00042.pdf) and kept as part of the client's record.

**Any clients receiving anticoagulation therapy and experiencing severe bleeding must go to the nearest emergency room for assessment.**

Parenteral Vitamin K vials should be part of the primary care emergency cart. Parenteral vitamin K can be administered orally to treat supratherapeutic INR as advised in the guidelines.

**INR up to 4.5 (Managed by Nurse)**

| **Target INR 2-3** | ***Adjust warfarin only if INR result is final/verified*** | **Target INR 2.5-3.5** |
|---|---|---|
| <2 | Consider reloading with 1 extra dose of warfarin.<br>Increase warfarin by 0-15% per week | <2.5 |
| 2-3 | No Change | 2.5-3.5 |
| 3.1-3.5 | Decrease warfarin by 0-15% per week | 3.6-4 |
| 3.6-4.5 | Hold 1 dose of warfarin.<br>Decrease warfarin by 0-15% per week | 4.1-4.5 |

**INR 4.6-8.9 (Managed with Physician or Nurse Practitioner Consultation)**

| | |
|---|---|
| INR Result<br>4.6-4.9 | Hold warfarin until INR therapeutic range.<br>Decrease warfarin by 5-15% per week |
| 5-9 and<br>no increased risk<br>of bleeding | Hold 2 doses of warfarin<br>Decrease warfarin by 10-20% per week<br>Recheck INR in 1-2 days. |
| 5-9 and increased risk of bleeding | Hold 1-2 doses of warfarin.<br>Give Vitamin K 1mg- 2.5 mg orally.<br>Decrease warfarin by 10-20% per week |
| 5-9 and Bleeding-<br>rapid reversal required | Hold warfarin.<br>Send client to emergency department of nearest hospital. |

**INR > 9 (Managed by Physician or Nurse Practitioner)**

| | |
|---|---|
| INR Result<br>9-20 and no<br>serious bleeding | Hold warfarin.<br>Give Vitamin K 3-5 mg orally.<br>Monitor INR more frequently and repeat Vitamin K as needed<br>Restart warfarin at lower dose once INR is in therapeutic range. |
| > 20 | Hold warfarin. |

| | |
|---|---|
| | Send client to emergency department of nearest hospital |

### 4.1.4 Perioperative management of warfarin therapy

- The management of chronic warfarin therapy in the perioperative period depends on several factors: the type of surgery, the surgeon's preference and the underlying indication for warfarin therapy.
- Pre-anesthesia clinics generally take responsibility for coordinating the management of warfarin in the preoperative period for elective surgical patients, taking into account the above factors. For most patients the risk of thromboembolic events is deemed low enough that warfarin therapy is usually discontinued about 5 days preoperatively and the INR allowed to normalize, then resumed postoperatively. For some minor surgeries with some surgeons, the operation is performed while warfarin is continued at regular doses. For some patients at high risk of thromboembolic events (prosthetic heart valves, acute deep vein thromboses), bridging therapy with shorter acting anticoagulants is initiated when warfarin is stopped preoperatively. These shorter duration anticoagulants, low molecular weight heparin or intravenous unfractionated heparin, are discontinued for the operation, resumed postoperatively and continued until the INR has returned to the therapeutic range. This bridging therapy minimizes the time that these higher risk patients are without anticoagulant therapy.
- Pre-anesthesia clinics take responsibility for liaising with the surgeon, deciding which management plan is followed, instructing the patient on that plan and coordinating the measurement and reporting of INR's in the perioperative period.

### 4.1.5 FOLLOW UP OF OUTSTANDING RESULTS

- The clinic is responsible for ensuring that all INR results are received by Friday that are ordered during the week (Monday to Thursday).
- Any outstanding items must be investigated by contacting the patient to determine whether tests were complete and where, or to locate the result within the clinic and follow up as required.

## 5. RESOURCES

APPENDIX A: Client Education pamphlet information
Dietary Vitamin K Sources
Potential Herbal-Warfarin Interactions
APPENDIX B: Triage Checklist for Managing Abnormal Results

APPENDIX C: Description of Coumadin/Warfarin tablets
APPENDIX D: Declaration of competency in oral anti-coagulation therapy
APPENDIX E: Guide for Management of INR

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## APPENDIX A

Coumadin: Patient Information Booklet

Bristol-Myers Squibb Company (2008) Montreal: Bristol-Myers Squibb Canada Inc.

Highlight the following topics (from the booklet) with the client:

1. How to safely take anticoagulants
2. Required Blood Tests
3. Do's and Don'ts of anticoagulation therapy
4. Life Style
5. Diet (including Vitamin K)

## Dietary Vitamin K Sources

**Foods high in Vitamin K (more than or equal to 200% DV)**

*Eat no more than 1 serving per day*

| Food | Serving size | % Daily Value |
|---|---|---|
| Kale, fresh, boiled | 1/2 cup | 660 |
| Spinach, fresh, boiled | 1/2 cup | 560 |
| Turnip greens, frozen, boiled | 1/2 cup | 530 |
| Collards, fresh, boiled | 1/2 cup | 520 |
| Swiss chard, fresh, boiled | 1/2 cup | 360 |
| Parsley, raw | 1/4 cup | 300 |
| Mustard greens, fresh, boiled | 1/2 cup | 260 |

**Foods moderately high in Vitamin K (60 to 199% DV)**

*Eat no more than 3 servings per day*

| Food | Serving size | % Daily Value |
|---|---|---|
| Brussels sprouts, frozen, boiled | 1/2 cup | 190 |
| Spinach, raw | 1 cup | 180 |
| Turnip greens, raw, chopped | 1 cup | 170 |
| Green leaf lettuce, shredded | 1 cup | 125 |
| Broccoli, raw, chopped | 1 cup | 110 |
| Endive lettuce, raw | 1 cup | 70 |
| Romaine lettuce, raw | 1 cup | 70 |

Source:

- *Important information to know when you are taking: Coumadin and Vitamin K.* Warren Grant Magnuson Clinical Center, NIH Drug-Nutrient Interaction Task Force
- Also see: http://www.nal.usda.gov/fnic/foodcomp/Data/SR17/wtrank/sr17w430.pdf

## Potential Herbal-Warfarin Interactions

### Herbs That Can Increase Risk of Bleeding

agrimony
alfalfa
aniseed
arnica flower
artemesia
asa foetica
bochu
bogbean
bromelains
capsicum
cassio
celery seed
chamomile
Chinese wolfberry
clove
dandelion
danshen
dihydroepiandrosterone
dong quai
fenugreek
feverfew
fish oil
garlic
ginger
ginkgo
horse chestnut
horseradish
licorice
meadowsweet
melilot
onion
papain
parsley
passionflower
prickly ash
poplar
quassia
red clover
sweet clover
sweet woodruff
tonka beans
turmeric
wild carrot
wild lettuce
willow

### Herbs That Can Increase Risk of Clotting

coenzyme Q10
ginseng
green tea
goldenseal
St. John's Wort
yarrow

Source:

- *Herbal Products: What warfarin (Coumadin) patients need to know.* University of Washington Medical Center, UW Medicine and Seattle Cancer Care Alliance Anticoagulation Clinic

## APPENDIX B

### Triage Checklist for Managing Abnormal Results

1. Verify current anticoagulation medication dose
2. Verify adherence with anticoagulation regimen
3. Verify subjective data:
   - Recent acute illness
   - Diet changes
   - Alcohol use
   - OTC use
   - Herbal Medicines
   - Changes in Rx meds
   - Recent injuries or falls
4. Assess patient for signs and symptoms of bleeding:
   - Spontaneous bruising
   - Bleeding gums
   - Nose bleeds
   - Hematuria
   - Melena
   - Hematemesis
   - Hemoptysis
   - Petechiae
   - Other bleeding
5. Assess patient for signs and symptoms of thromboembolism:
   - Weakness, numbness, tingling
   - Blurred vision
   - Slurred speech
   - Dizziness
   - Leg pain/swelling
   - Dyspnea
   - Chest pain
6. Provide appropriate client education
7. Adjust regimen based on management algorithms
8. Schedule follow-up based on management algorithms

## APPENDIX C

### Description of Coumadin / warfarin tablets

Warfarin, or Coumadin brand, tablets are round and scored, which means they can be broken in half. Each tablet color represents a different strength. The strength of the tablet is measured in milligrams (mg) as follows:

- 1 mg (pink)
- 2 mg (lavender)
- 2.5 mg (green)
- 3 mg (tan)
- 4 mg (blue)
- 5 mg (peach)
- 6 mg (teal or blue-green)
- 7.5 mg (yellow)
- 10 mg (white)

Other brands of warfarin should have the same colors and strengths as the Coumadin brand tablets. However, other brands of warfarin tablets may have a different shape or appearance. For example, they may be oval or square.

## APPENDIX D

Medical Directive: Working collaboratively, Registered Nurses and Physicians provide primary care for primary care clients. For some aspects of their work, RN's work autonomously within their scope of practice as identified in the Registered Nurses Act and by the College of Registered Nurses of Manitoba. Registered Nurses also provide care as prescribed by or directed by a physician. Physicians, through medical directives, give the nurses the authority to carry out other aspects of their practice.

A medical directive is a prescription for a procedure, treatment, of intervention that may be performed for a range of clients who meet certain conditions. It is not client specific. The medical directive identifies a specific treatment or range of treatments, specific conditions that must be met and any specific circumstances that must exist before the directive can be implemented. A medical directive is always in written format. Medical directives are reviewed and authorized annually.

**Responsibilities of the physician issuing a medical directive:**

- Know the risks of performing the procedure/intervention ordered.
- Know the predictability of the outcomes associated with the procedure/intervention.
- Know the degree to which safe management of the possible outcomes require physician involvement or intervention
- Ensure that appropriate resources are available to consult with and/or intervene as required.

**Responsibilities of the nurse implementing a medical directive:**

- Know the risks to the client
- Possess the knowledge, skill, and judgment required to safely implement the procedure/intervention.
- Know the predictability of the outcomes of the procedure.
- Determine if management of possible outcomes is within the scope of his/her practice, whether s/he is competent to provide this management, and whether appropriate resources are available to assist as required.
- Know how to contact the physician responsible for care of the client.

I, the undersigned, have read and agree to follow the medical directive and agree with the conditions and responsibilities as specified in the practice guideline.

Signed_____, Registered Nurse Date_____

Signed_____, Site Medical Director or Designate Date_____

## APPENDIX E

## GUIDE FOR MANAGEMENT OF INR

### INR up to 4.5 (Managed by Nurse)

| Target INR 2-3 | ***Adjust warfarin only if INR result is final/verified*** | Target INR 2.5-3.5 |
|---|---|---|
| <2 | Consider reloading with 1 extra dose of warfarin.<br>Increase warfarin by 0-15% per week | <2.5 |
| 2-3 | No Change | 2.5-3.5 |
| 3.1-3.5 | Decrease warfarin by 0-15% per week | 3.6-4 |
| 3.6-4.5 | Hold 1 dose of warfarin.<br>Decrease warfarin by 0-15% per week | 4.1-4.5 |

### INR 4.6-8.9 (Managed with Physician or Nurse Practitioner Consultation)

| | |
|---|---|
| INR Result<br>4.6-4.9 | Hold warfarin until INR therapeutic range.<br>Decrease warfarin by 5-15% per week |
| 5-9 and<br>no increased risk<br>of bleeding | Hold 2 doses of warfarin<br>Decrease warfarin by 10-20% per week<br>Recheck INR in 1-2 days. |
| 5-9 and increased risk of bleeding | Hold 1-2 doses of warfarin.<br>Give Vitamin K 1mg- 2.5 mg orally.<br>Decrease warfarin by 10-20% per week |
| 5-9 and Bleeding-<br>rapid reversal required | Hold warfarin.<br>Send client to emergency department of nearest hospital. |

### INR > 9 (Managed by Physician or Nurse Practitioner)

| | |
|---|---|
| INR Result<br>9-20 and no<br>serious bleeding | Hold warfarin.<br>Give Vitamin K 3-5 mg orally.<br>Monitor INR more frequently and repeat Vitamin K as needed<br>Restart warfarin at lower dose once INR is in therapeutic range. |
| > 20 | Hold warfarin.<br>Send client to emergency department of nearest hospital |