Warfarin Therapy Management

Effective Date: October 1, 2010

Scope

This guideline applies to long term management of warfarin therapy in adults, 19 years and over, within the office setting. The guideline describes: 1) warfarin initiation, 2) international normalized ratio (INR) monitoring with optimal ranges, and 3) warfarin dosage adjustment. This guideline assumes the physician has reviewed the indications for warfarin and the duration of therapy as these are not discussed in this guideline. Perioperative management of warfarin is covered in the BC Guideline *Warfarin Therapy – Management During Invasive Procedures and Surgery.*

Initiation of Warfarin

1) Consider Contraindications - Prior to initiating warfarin treatment consider the contraindications below. All contraindications are relative to a patient's risk for thrombosis weighed against the risk for bleeding (Table 2) while on vitamin K antagonist anticoagulation therapy.[1] **For a complete list of contraindications, refer to the product monograph.**

Absolute Contraindications	Some Relative Contraindications
• The presence of a severe or active bleeding diathesis • Non-adherence to medication and INR monitoring • Pregnancy[2] (avoided at least during the first trimester and from about 2 to 4 weeks before delivery) • Allergy or intolerance to warfarin (consider warfarin alternative - Nicoumalone)	• Uncontrolled hypertension (greater than 180/100 mm Hg) • Severe liver disease • Recent surgery and procedures involving the nervous system, spine or eye

2) Establish baseline INR - Should be done in every case and will guide further therapy.

3) Initial Dose - Initial dose of warfarin is typically 5 mg/day in most patients.[3,4] A starting dose of less than 5 mg may be considered for patients greater than 70 years of age, elevated baseline INR greater than 1.1, hypoalbuminemic patients (e.g., malnourished, liver disorders, post-operative), impaired nutrition (weight < 45 kg), heart failure, known to take medications that increase sensitivity of warfarin (Appendix A), or previously documented increased sensitivity to warfarin.[5,6]

Note: Whenever feasible, a single strength warfarin tablet (highly recommend 1 mg only for safety and dose flexibility) should be prescribed such that doses are multiples of one tablet strength. Patients should take their warfarin once a day at the same time in the evening, and have their INR test performed in the morning. This limits diurnal variations and provides the physician with a same day window for dosage adjustment in the event of an unanticipated INR change.

Pharmacogenetics-based therapy has been suggested in the estimation of the therapeutic warfarin dose by genotyping patients for single nucleotide polymorphisms that affect warfarin metabolism or sensitivity. Although Health Canada has updated the label of warfarin to include information on pharmacogenetic testing, there is currently no evidence that genotyping will improve clinically relevant outcomes in individual patients.[6-9]

4) INR Target and Frequency of Monitoring - The optimal maintenance dose for warfarin to enable a therapeutic INR varies from patient to patient and at different times in the same patient.[9-12] There is no maximal or minimal dose to maintain a therapeutic range. Two therapeutic ranges are recommended, depending on the indication for anticoagulation.

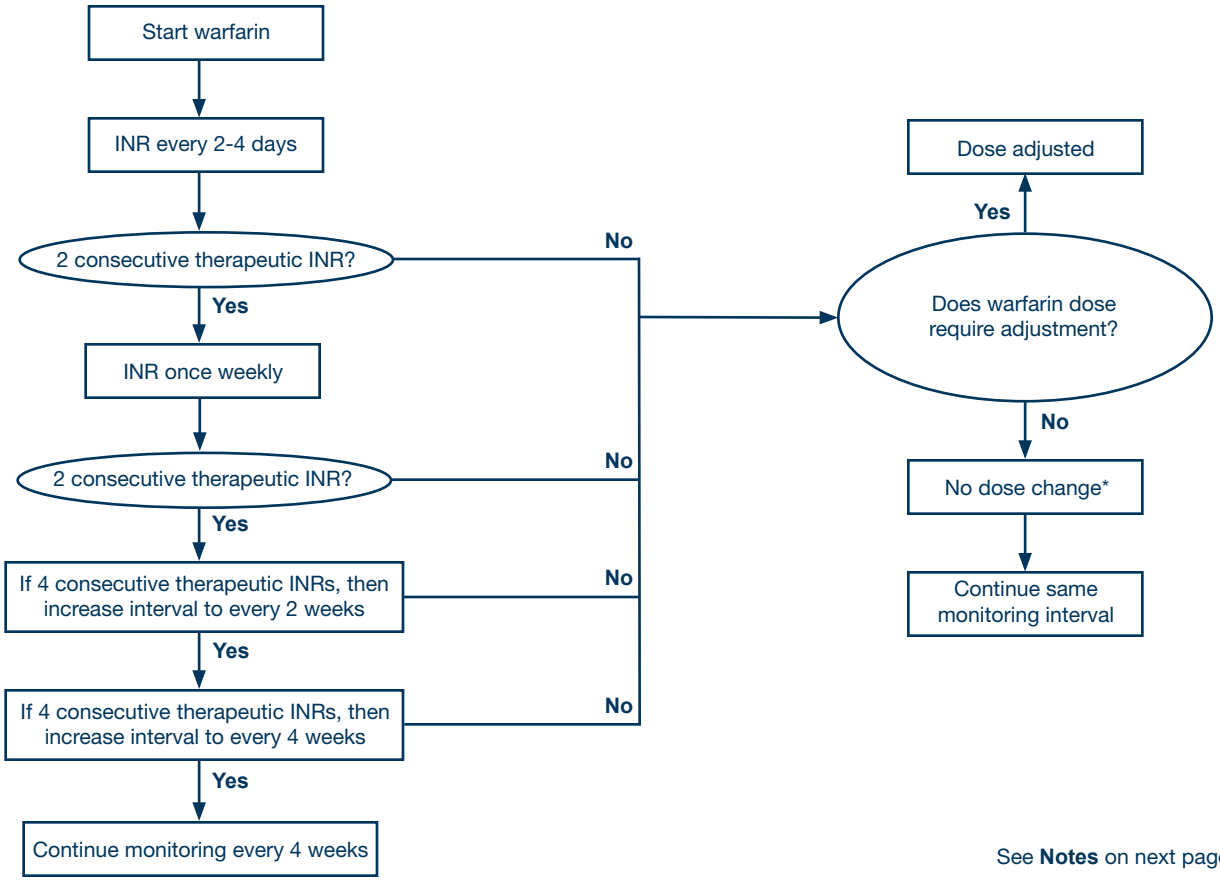
Target INR is 2.5 with a range of 2.0 – 3.0 for most indications for warfarin therapy.[9,10]

Target INR is 3.0 with a range of 2.5 – 3.5 for the following indications[10,13]
- Mechanical heart valves in mitral position
- Non-bileaflet valve in aortic position (establish desired range with a specialist physician)

Under-anticoagulation can result in recurrent venous or arterial thrombosis, while over-anticoagulation can produce minor or major hemorrhagic complications. The narrow therapeutic index and a high risk/benefit ratio necessitate close and long-term monitoring. During the first few days of treatment, the INR rises without concomitant clinical anticoagulant effect. Moreover, during the maintenance phase, dose changes may not be reflected in INR for 4-5 days. For these reasons, **frequent dose changes are not recommended.**

During the induction or initiation phase, it is recommended that INR be monitored every 2-4 days (initially daily if on therapeutic heparin) until the INR is in the patient's target range for two consecutive values. Once the INR is stabilized within the patient's target range, it can be monitored weekly. The interval can be gradually increased up to every 4 weeks if the INR remains stable and within the therapeutic range. Below is a flowchart outlining the recommended INR testing interval.

Recommended INR Testing Interval



See **Notes** on next page →

Notes: Increase frequency of INR (every 2-4 days) if any of the following happens: non-therapeutic INR, intercurrent illness, any medication change (including herbal), or significant diet change.

* Some reasons for NOT changing the dose when the INR is not therapeutic:[14]
  1. Patient noncompliant (forgot doses or took too many doses)
  2. Inadequate number of days before previous dose change to take full effect
  3. Binge alcohol use (will transiently elevate INR)

5) Dosage Adjustment & Maintenance Therapy - 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 patient's target range should always prompt a direct communication with patient to determine cause. Consider causes such as a change in dosage of warfarin, patient compliance, medications including OTCs, dietary changes, unusual alcohol consumption, or intercurrent illness.

The recent trend is to change the total weekly warfarin dose (TWD).[15] For example, if the patient is taking 5mg/day, the weekly dose is 35mg. If the dose must be decreased by 10%, then the weekly dose should be 35 mg - 3.5 mg=31.5 mg and the daily dose becomes 31.5 mg/7=4.5 mg.

Table 1: Dosage Adjustments for Patients on Warfarin Maintenance Therapy
(Target INR 2.0 - 3.0 or 2.5 - 3.5, No Significant Bleeding)

INR	Intervention (Refer to flowchart above for timing of next INR)
≤ 1.5	- Give one time top-up equal to 20% of weekly dose and increase weekly dose by 10-20%
1.5 < INR < therapeutic range	- No change in dose - If two consecutive INRs are low, increase weekly dose by 10-20%
INR in therapeutic range	- No change
INR > therapeutic range but < 5.0	- Lower weekly dose (10-20%) or consider omitting one single dose - Increase the frequency of INR monitoring and resume therapy at 10-20% lower weekly dose when INR therapeutic - Note: If the INR is only minimally elevated (0.1 - 0.4 above upper limit of the therapeutic range), dose reduction may not be necessary[14]
INR 5.0 – 9.0*	- Omit 1 to 2 doses then recheck INR - Increase the frequency of INR monitoring and resume therapy at 10-20% lower weekly dose when INR therapeutic - If the patient is at high risk of serious bleeding, consider administering vitamin K** 1 to 2 mg orally
>9.0; no bleeding	- Discontinue warfarin temporarily, consider administering vitamin K 2-5 mg orally then recheck INR*** - Increase the frequency of INR monitoring and resume therapy at 20% lower weekly dose when INR therapeutic - Give additional vitamin K if INR is not substantially reduced by 24 hrs***

* Bleeding risk increases exponentially from INR 5.0 to 9.0[16] and should be monitored closely.

** If vitamin K is not available in your local pharmacy, it can be obtained from your local ER. Avoid intramuscular injections of vitamin K to prevent local injection site bleeding which also reduces bioavailability.

*** The effect of a single dose of vitamin K on the INR can be expected between 8-24 hours.

Notes:

- If patient's clinical status is compromised due to bleeding, admit to an acute care facility for assessment and management.
- Bleeding with a high potential for complications (e.g. elderly, propensity to fall) requires clinical judgement to determine whether to manage within the office setting or to send to an acute care facility.
- The patient should be followed using the Warfarin Record Sheet (attached) or a similar log sheet and encouraged to keep their own record.
- If patient is to undergo an invasive procedure or surgery, refer to BCGuidelines.ca: *Warfarin Therapy – Management during Invasive Procedures and Surgery.*

Table 2: Risk Factors for Bleeding Complications of Anticoagulation Therapy[1,9,18]

Risk Factor Category	Specific Risk Factors
Age	> 70 years
Time Period	Within first year of warfarin treatment
Cardiac	Uncontrolled hypertension, heart failure
Gastrointestinal	History of gastrointestinal haemorrhage, active peptic ulcer, hepatic insufficiency
Hematologic/Oncologic	Thrombocytopenia, platelet dysfunction, coagulation defect, underlying malignancy
Neurologic	History of stroke, cognitive or psychological impairment
Renal	Renal insufficiency
Trauma	Recent trauma, history of falls
Alcohol	Excessive alcohol intake
Medications	Use of aspirin or other NSAIDs; Discontinuing medications that reduce INR; See Medication Interaction Table

Adapted from: Warfarin Reversal Position Statement, Australasian Society of Thrombosis & Hematosis[19]

The most common sites of serious bleeding are gastrointestinal tract, genitourinary tract, and soft tissues including wounds.[20] An underlying cause should always be sought, especially if the INR is within the therapeutic range or lower.

6) Patient Education - Warfarin is more likely to be used safely by a patient who is aware of the potential for drug and diet interactions, understands the need for monitoring, and can recognize the signs of over- and under- anticoagulation. The effect of warfarin may be inhibited by very high dietary or supplemental vitamin K intake. It is generally recommended that patients on warfarin try to consume the adequate intake for vitamin K (90-120 µg),[21] while avoiding large fluctuations in vitamin K intake that might interfere with the adjustment of their anticoagulant dose . A separate resource guide, including resources with patient information sheets, is available with these guidelines and should be discussed with the patient.

At the initiation of warfarin therapy, it is recommended that the physician discuss the following with the patient and/or other care providers when possible:

- the reason for prescribing warfarin and duration of treatment
- the need to adhere with recommended warfarin dosage
- the importance of monitoring and the patient's target INR

- the need to take their warfarin once a day, preferably at the same time in the evening, and to have their INR test performed in the morning
- side effects, signs of bleeding and potential need for blood products
- set-up an agreed upon system of communication when side effects or changes occur
- when to call the doctor or seek urgent attention at an emergency facility
- strongly encourage to wear Medic Alert bracelets or necklaces to assist with care in an emergency
- review of current medications (prescription & non-prescription), herbal supplements and diet for potential interactions
- the need for caution when initiating or stopping other medications (including ASA), herbs or supplements
- the use of a daily pill box to assist with improving patient compliance with warfarin therapy
- the importance of consistent vitamin K content in the diet
- the need to avoid heavy or variable alcohol consumption
- influence of intercurrent illness
- the importance of avoiding pregnancy while taking warfarin if applicable
- the importance of not changing brands of warfarin
- the need to avoid intramuscular injections (for flu shots – physicians are recommended to apply firm, prolonged pressure for several minutes after a deltoid injection)

Rationale

Warfarin therapy reduces the risk of thromboembolic events. There has been an extraordinary increase in the use of warfarin over the past decade, mainly because of aging of the population, and the demonstration of its benefit in atrial fibrillation.[6,22,23] Studies have shown that warfarin therapy could reduce these patients risk of stroke by about 66%.[23] Unfortunately, approximately a third of the patients who would benefit from warfarin never receive it, and over half of those who do receive warfarin are managed suboptimally because of the complex pharmacology and numerous drug, disease, dietary and herbal interactions.[6,9]

Warfarin is given orally and is absorbed rapidly and completely.[9,26,27] Absorption is not impacted by food. It is almost fully bound to albumin in blood; thus hypoalbuminemic patients (e.g. malnourished, liver disorders, post-operative, etc.) need lower doses. An effect on the INR generally occurs within 24 hours after drug administration; however, the full anticoagulant effect may be delayed for 5 to 7 days due to the half-life of prothrombin.[9]

The major challenge in warfarin therapy is its narrow therapeutic range. Even a mild degree of over-anticoagulation may lead to haemorrhage. Bleeding is the most serious complication of warfarin therapy.[18,20,24,25] The average yearly bleeding rates vary widely depending on study design. Estimated annual incidences are 0.6% for fatal bleeding, 3.0% for major bleeding, and 9.6% for minor bleeding.[24,25] A good warfarin management plan can reduce bleeding risk.

Pregnancy: If possible, warfarin therapy should be avoided during pregnancy.[2] If warfarin therapy is essential, it should be avoided at least during the first trimester (because of teratogenicity) and from about 2 to 4 weeks before delivery to reduce risk of hemorrhagic complications. Unfractionated heparin or low molecular weight heparin could be substituted when appropriate because these agents do not cross the placenta and are considered the anticoagulant drugs of choice during pregnancy. Consider referral to hematologist and obstetrician.

Vitamin K: If required, oral vitamin K therapy is a safe, effective and convenient treatment for overcoagulation.[29,30] Subcutaneous vitamin K should be avoided as it may be absorbed unpredictably. Likewise, intramuscular vitamin K should be avoided as it promotes intramuscular haemorrhage. Intravenous vitamin K is the most predictable,[30] but can cause facial flushing, diaphoresis, chest pain, hypotension, dyspnea, anaphylaxis and cerebral thrombosis, and should be given only in emergency situations and by slow infusion. Some effect of oral vitamin K therapy on INR is usually observed within 24 hours and with intravenous vitamin K in 6-8 hours.[29,30] Patients who have received vitamin K, particularly parenteral doses above 5-10 mg, may be difficult to reanticoagulate. Accordingly, doses of vitamin K should be kept as low as feasible. An oral formulation of vitamin K is no longer available in Canada; most pharmacies administer oral doses of the parenteral preparation in juice or water. Oral vitamin K therapy may not be appropriate for patients with disorders that may affect the absorption of vitamin K such as biliary obstruction, liver insufficiency or other malabsorptive syndromes. If emergency

reversal of warfarin is required for life and limb threatening haemorrhage, plasma or prothrombin complex concentrate (Octaplex®) may be used in consultation with a specialist. For further information on the use of vitamin K in the perioperative period, see the BCGuidelines.ca *Warfarin Therapy – Management during Invasive Procedures and Surgery.*

Alternatives to Warfarin: Nicoumalone (Sintrom®) is a vitamin K antagonist available for patients allergic to warfarin. Several new orally administered alternatives to warfarin are either in clinical trial or approved for limited use in Canada for thromboprophylaxis during joint replacement or for stroke prevention in atrial fibrillation or treatment of thrombosis. It is not within the scope of this guideline on warfarin management to discuss the relative risks and benefits of these agents. Physicians are encouraged to stay abreast of new evidence but exercise caution when using new medications.

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Resources

For local information contact a hematologist at your closest referral centre/ major hospital, or call the following anticoagulation/thrombosis clinics:

- Vancouver Coastal Health – Vancouver General Thrombosis Clinic, Vancouver (604) 875-4111 ext. 69275
- Vancouver Island Health – Royal Jubilee Hospital, Victoria (250) 370-8776
- Fraser Health - Outpatient Anticoagulation Program, Burnaby Hospital, Burnaby (604) 412-6288

List of Abbreviations

INR - international normalized ratio
OTC - over the counter medications
TWD - total weekly warfarin dose

Appendices

Appendix A: Important Interactions with warfarin: medications, foods, herbs and supplements

Associated Documents

- Warfarin Record Sheet
- WARFARIN and Food: Guide for Patients (including *Vitamin K Content of Selected Foods and Resource Guide: Information Sources for Patients*)

This guideline is based on scientific evidence current as of the Effective Date.

The guideline was developed by the Guidelines and Protocols Advisory Committee, approved by the British Columbia Medical Association and adopted by the Medical Services Commision.

The principles of the Guidelines and Protocols Advisory Committee are to:

- encourage appropriate responses to common medical situations
- recommend actions that are sufficient and efficient, neither excessive nor deficient
- permit exceptions when justified by clinical circumstances

Contact Information

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Appendix A: Important Interactions with Warfarin (Medications, Foods, Herbs and Supplements)

- Starting, changing or stopping any drug, herbal product, or supplement can potentially affect the activity of warfarin. Monitoring frequency should be increased.
- The following list includes only commonly used agents and only those with more than two case reports of clinically significant interaction and/or serious adverse effect. For a complete listing refer to the drug monograph.
- Also refer to *WARFARIN and Food: A Guide For Patients at bcguidelines.ca*

Medications

Increased bleeding risk due to increased effect of warfarin: ↑ INR			Decreased effect warfarin: ↓ INR
Analgesics o acetaminophen[1] o aspirin (high dose) o salicylates, topical o tramadol **Antiarrhythmics** o amiodarone o propafenone **Antibiotics e.g.** o amoxicillin o cephalosporins (some) o isoniazid o fluoroquinolones[2] o macrolides[3] o metronidazole o sulfonamides o telithromycin o tetracyclines[4]	**Anticonvulsants e.g.** o phenytoin (early on) o sodium valproate **Antidepressants e.g.** o duloxetine o venlafaxine o SSRI - fluoxetine - fluvoxamine - paroxetine - sertraline - citalopram **Antifungals e.g.** o fluconazole o itraconazole o ketoconazole o miconazole (oral,vaginal) o voriconazole	**Antihyperlipidemics** o ezetimibe o fenofibrate o fluvastatin o gemfibrozil o rosuvastatin **Other** o allopurinol o cimetidine o corticosteroids (oral) o proton pump inhibitors (PPI) – isolated case reports with all PPIs o thyroid supplements	**Antibiotics e.g.** o rifampin **Antidepressants** o trazodone **Antiepileptics e.g.** o carbamazepine o phenobarbitone o primodone o phenytoin (later on) **Other** o antithyroid agents o cholestyramine
Increased bleeding risk due to non-warfarin mechanisms			
Analgestics o aspirin o cox II inhibitors o nonsteroidal anti-inflammatory drugs	**Anticoagulants/Antiplatelet agents** **Antidepressants** o selective serotonin reuptake inhibitors		

Foods, Herbs and Supplements

Increased bleeding risk due to increased effect of warfarin: ↑ INR			Decreased effect warfarin: ↓ INR
Alcohol (binges)[5] Birch Chitosan Cranberry Juice/extract (dose dependent)	Danshen Dong Quai Fish oil Garlic supplements[6]	Glucosamine±chondroitin Grapefruit Mango Papaya extract	Alcohol (chronic)[5] Coenzyme Q10 Ginseng (American,Asian) Smoking St. John's Wort Vitamin C (high dose) Vitamin K
Increased bleeding risk due to non-warfarin mechanisms			
Alcohol (heavy drinkers) Garlic supplements[6]			

1. Randomized controlled trials suggest 2-4 g acetaminophen daily has a clinically significant effect on INR [Parra, 2007; Mahe, 2006].
2. Fluoroquinolones e.g. ciprofloxacin, Levofloxacin, moxifloxacin.
3. Macrolides include azithromycin, erythromycin, clarithromycin.
4. Tetracyclines including tetracycline and doxycycline.
5. Consuming small or moderate amounts of alcohol in patients with normal liver function is unlikely to have an effect.
6. Consuming foods with small amounts of garlic is unlikely to have an effect.

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WARFARIN PATIENT RECORD SHEET

ATTACH PATIENT INFORMATION LABEL HERE

PATIENT INFORMATION

SURNAME OF PATIENT	FIRST NAME (INITIALS)	PHN

Indications:
- ❑ atrial fibrillation
- ❑ DVT/PE
- ❑ thrombophilia
- ❑ prosthetic heart valve
- ❑ intracardiac thrombus
- ❑ Other: ➟

Target INR Range: ❑ 2.0 – 3.0 ❑ 2.5 – 3.5 ❑ Other: ➟ _____

Duration: ❑ 3 mos ❑ lifelong ❑ reassess when: ➟

Oral Anticoagulant: ❑ Warfarin ❑ Other: ➟

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Tablet Strengths: ❑ 1 - pink ❑ 2 - lavender ❑ 2.5 - green ❑ 3 - tan ❑ 4 - blue ❑ 5 - peach ❑ 6 - teal ❑ 7 - yellow ❑ 10 - white

OTHER INFORMATION

NAME OF PRIMARY PHYSICIAN	TELEPHONE NUMBER	FAX
NAME OF SPECIALIST	TELEPHONE NUMBER	FAX
NAME OF SPECIALIST	TELEPHONE NUMBER	FAX
INR RESULTS ALSO COPIED TO:	DATE	FAX

LAB	PHARMACY	OTHER

Specimen Date	HB if done	PLTS if done	INR Result	Dosage Instruction	Weekly mg	Next INR	MD Initials	Date/Status of Patient Notification	Notifier Initials
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