PT/INR Point-of-Care Testing Clinical Tool

ONTARIO PHARMACISTS ASSOCIATION
Advocating Excellence in Practice and Care

Type of Interaction

Patient asks about the PT/INR POCT

I am glad you want to know more about the PT/INR POCT.

- A PT/INR test is used to measure how long it takes the blood to clot.
- If you are taking warfarin, the results of this test can be used to determine how well your medication is working to prevent clots as well as help to avoid any adverse effects from the drug, such as bleeding.[iv]
- Amongst patients on chronic warfarin, annually, 1-2% experience a major bleeding event, while 10-20% experience minor bleeding events.[i]
- If your PT/INR POCT result is out of your personalized target range, the pharmacist may be able to make immediate adjustments to your medication regimen.

Refer to box on Target Populations for more information on who should receive testing.

Pharmacist screens for eligible patients

TARGET POPULATIONS[i,ii]

Population	Testing Frequency
Starting warfarin therapy *or* Undergoing warfarin dose change	2-3 days after the first dose or dose change until stable INR achieved
On warfarin, stable INR	Usually at least once a month (some patients may require more frequent monitoring while others (e.g., INR in therapeutic range and dose has not changed for ≥3 months) may be tested every 12 weeks)
On warfarin, changes to other medications (Rx, nonRx, or herbal/natural products) *or* On warfarin, new illness (e.g., acute infections, heart failure, diarrhea, vomiting)	Increase frequency of INR testing (e.g., obtain INR 3-4 days after starting a new drug that affects warfarin metabolism or clearance)

Special Considerations[iii]

- PT/INR POCTs are less accurate if the INR is >3.5
- Refer the following patients to an anticoagulation clinic or thrombosis specialist for PT/INR testing (POCTs may be inaccurate):
  - Severe anemia or polycythemia (hematocrit approximately <25% or >55%, respectively)
  - On other anticoagulants in addition to warfarin (e.g., low molecular-weight heparin)
  - Antiphospholipid antibody positivity

For more information, refer to the Clinical Guides from Thrombosis Canada.

***Note:** Prior to proceeding with the POCT, pharmacists are encouraged to review the patient's historical laboratory results via one of the provincial clinical viewers, where applicable.*

Are you interested in receiving a PT/INR POCT today/booking an appointment?

Based on your profile, it appears that you may benefit from a PT/INR POCT. Would you like to know more about it?

YES → Patient asks about the PT/INR POCT
NO → Patient Response

Patient Response

- **Yes, I would like to get it today/book an appointment. (Receptive)**
- **I'm not really sure I need that. (Hesitant)** → Address any concerns
- **No, thank you. (Unreceptive)** → Is there any more information I can give you to address your concerns?
  - YES → Address any concerns
  - NO → **No problem.** If you change your mind and decide you would like to get a POCT in the future or have any additional questions, please feel free to contact us.

POINTS FOR DISCUSSION

- Associated costs (refer to the OPA Point-of-Care Testing Suggested Fee Guide for more information)
  - Point-of-care testing is an uninsured service but may be covered by the patient's private plan (e.g., Health Spending Account)
  - Patient may be eligible to have this test completed and covered by OHIP at a public health laboratory with a requisition order from an authorized practitioner[v]
- Overview of the service (e.g., specimen collection, real-time testing, interpretation of results, provision of results, pharmacist consultation, etc.)

FREQUENTLY ASKED QUESTIONS

Q: What is a POCT?[vi]
A: A POCT is a type of test that is completed start to finish at the site of patient care (e.g., at the pharmacy) and does not require sending the sample to be tested at a laboratory. The results of the test are typically available within a few minutes, allowing the healthcare professional (e.g., pharmacist) to act immediately on the results and work with you to make informed changes or recommendations to your care plan as necessary.

Q: Why should I get a POCT at the pharmacy over a test done at a public health laboratory through my doctor?[vii]
A: Some of the advantages of point-of-care testing at the pharmacy compared to tests completed by public health laboratories are that less time is required, a smaller volume of blood is required (typically only a few drops) from a prick on the tip of one of the fingers, and there is immediate application of the test result, i.e., the pharmacist will interpret and discuss the results with you and provide any additional education, information, or adjustments to therapy as needed to help you reach your health goals without delay.

Q: Is point-of-care testing safe and effective?[viii]
A: Yes. Devices used for point-of-care testing in Ontario must be licensed for use by Health Canada. The licensing process includes a thorough evaluation of the safety, effectiveness, and quality of these testing devices. Furthermore, the safety and effectiveness continue to be monitored by Health Canada after approval. Your POCT at the pharmacy will be conducted by trained pharmacy professionals who have the knowledge and expertise to perform the test and interpret the results.

Q: How accurate is a PT/INR POCT?[iii]
A: When comparing PT/INR results from a POCT to a lab-based test, it has been found that the differences are usually within 15% of each other, which is similar to the difference seen in INR results between different laboratories. These differences, when assessed by experienced anticoagulation clinicians, have not been found to lead to different dosing instructions provided to patients to manage their condition. However, there are some situations where a POCT may not be preferred. The pharmacist can help to determine if the POCT is appropriate in your situation prior to proceeding. *(Refer to box on Target Populations for more information on who should receive testing)*

Patient Decision

- **Proceed with POCT today**
- **Book an appointment**
- **Refer to primary care provider/No longer interested**

Obtain informed consent and perform POCT

Pharmacist interprets the results and provides patient consultation

TARGET RANGES[i]

Population	Target INR
Most patients on warfarin	2.0-3.0
Most patients on warfarin with mechanical mitral valves	2.5-3.5

For more information about INR targets for mechanical and bioprosthetic heart valves, refer to the guideline from Thrombosis Canada.

MANAGEMENT[ix]

General Tips for Managing Out-of-Range INRs

- Try to determine the cause (*see tables on Out-of-Range INRs – Common Causes*). Questions to consider asking may include:
  - Can you tell me what warfarin doses you've taken in the past 2 weeks?
  - In the past week, have you missed any doses and if so, how many? How do you make sure you've taken all your doses, e.g., do you use a pill box, calendar, etc.?
  - Have you recently started or stopped taking any medications (Rx and nonRx, e.g., antibiotics, acetaminophen) or supplements? Have there been any dose changes to any of your medications?
  - How has your appetite been lately and are you eating regularly? Any recent changes to your diet?
  - Do you drink alcohol and if so, how often and how much do you drink?
  - How has your health been overall, i.e., any infections, fever, diarrhea, cold/flu, etc.?
- Consider therapy adjustments as necessary
  - **One-time change:** to address a transient cause
  - **Maintenance dose change:** for patients who have at least two consecutive out-of-range INRs in the same direction with no identifiable transient cause and who had stable, in-range INRs previously
  - Both one-time and maintenance dose changes: as applicable

Out-of-Range INRs – Common Causes

High INRs~	Suggested Management†
DOSING – non-compliance or dosing errors (e.g., patient took a higher dose than prescribed)	• Review the actual doses of warfarin the patient has taken over the last several weeks • Simplify the regimen if possible (e.g., adjust the dosage to minimize the number of different tablets the patient needs to take) • Consider use of adherence aids (e.g., blister packs, warfarin dosing calendar)
DRUG INTERACTIONS (e.g., amoxicillin, macrolides, quinolones, metronidazole, TMP/SMX, fluconazole, amiodarone, some statins, fenofibrate, acetaminophen >1 g/day)	• Avoidance of drugs that interact with warfarin is generally not necessary • Temporary drug interactions: temporarily hold or decrease the dose of warfarin • Chronic drug interactions: decrease warfarin maintenance dose and measure INR more frequently until stable
MALNUTRITION (e.g., resulting in Vitamin K deficiency)	• Encourage a regular and consistent diet • Consider addition of meal replacement beverages as needed • Decrease warfarin maintenance dose and measure INR more frequently until stable
ALCOHOL CONSUMPTION	• Can continue usual warfarin maintenance dose if the INR increase is transient (i.e., caused by a one-time ingestion of a moderate to large amount of alcohol (>2 drinks))
HEALTH STATUS CHANGES (e.g., acute illness, fever, diarrhea, uncontrolled hyperthyroidism, CHF exacerbation; reduction in food intake)	• Decrease the warfarin dose temporarily and measure INR more frequently until the patient's health is stabilized

~ Concomitant use of warfarin with antiplatelet agents (e.g., acetylsalicylic acid, clopidogrel, prasugrel, ticagrelor) and NSAIDs typically do not result in INR changes, however, the risk of bleeding is significantly increased. Therefore, the risks and benefits of concomitant use should be considered based on the indication for use, clinical necessity, and bleeding risk. Unless specifically indicated, concomitant use with warfarin should be avoided.
† Use as applicable. This is not a complete list and pharmacists should use professional judgement to determine the most appropriate management approach for each patient.

Low INRs	Suggested Management‡
DOSING - missed doses, non-compliance, dosing errors (e.g., patient took a lower dose than prescribed)	• Review the actual doses of warfarin taken over the last several weeks • Simplify the regimen if possible (e.g., adjust the dosage to minimize the number of different tablets the patient needs to take) • Consider use of adherence aids (e.g., blister packs, warfarin dosing calendar, reminder alarms)
UNDERDOSING	• Aim to achieve an INR of 2.5 to decrease the chances of underdosing • An INR of 1.5-2.0 carries a similar risk of bleeding as an INR of 2.0-3.0 but INRs <2.0 increase the risk of thrombosis
DRUG INTERACTIONS – Rx medications (e.g., phenytoin, carbamazepine, barbiturates, rifampin, azathioprine, trazodone); nonRx (e.g., green tea, ginseng, St. John's Wort)	• Rx drug interactions: › INR change usually observed within 2 weeks of drug initiation › Incrementally increase warfarin maintenance dose until stable • NonRx drug interactions: › Avoid herbal supplements if possible • Encourage consistency
LIFESTYLE CHANGES – dietary changes (e.g., increased intake in Vitamin K rich foods such as green leafy vegetables, soy, avocado, seaweed, meal replacement beverages that have Vitamin K); increased exercise	• Patients do not need to eat less of foods rich in Vitamin K even though dietary intake of Vitamin K causes INR variability • Encourage a regular and consistent lifestyle and diet • Adjust warfarin if lifestyle and/or diet changes are long-term

‡ Use as applicable. This is not a complete list and pharmacists should use professional judgement to determine the most appropriate management approach for each patient.

Single Out-of-Range INR

The specific approach to managing a single slightly out-of-range INR (e.g., INR 0.5 above or below target) in a patient who was previously in-range should take into consideration how much the value is out-of-range, the patient's past experience with out-of-range INRs and the patient's risk of thrombosis/stroke or bleeding. Two possible management options are:

Option	Repeat INR
Continue current maintenance dose	In 1-2 weeks
Make a one-time dosage change (increase or hold by ½ to 1 single dose) then resume current maintenance dose	

Example of a Maintenance Dosing Algorithm for Non-bleeding Patients on Warfarin (Assuming Target INR 2.0-3.0)^

INR	Dosage Change of Warfarin*	Repeat INR
<2.0	Increase by 10-15% (Consider a 15% increase if INR ≤1.5 with no explanation)	Within 1 week
3.1-3.5	Decrease by 0-10%	Within 2 weeks
3.6-4.0	Hold 0-1 dose, decrease by 10-15%	Within 1 week
4.1-8.9#	Hold 0-2 doses, decrease by 10-15%	In 2 days
>9.0#	Hold 2 doses, decrease by 15-20%	Next day

^ This is to be used as a guide only and does not replace professional judgement. Other warfarin dosing algorithms are available.
* Dose change percentage is based on the total weekly dose.
# For INRs >4.5 but <10 in the absence of clinically relevant bleeding, the usual recommendation is to temporarily hold the warfarin and not give Vitamin K. However, even in the absence of bleeding, if INR >10, depending on patient-specific factors such as bleeding risk factors, thrombosis risk if INR is over-corrected, and ability to repeat INR testing, Vitamin K may be given.

EXAMPLES OF ADDITIONAL SERVICES THAT MAY BE OFFERED

- Medication review/MedsCheck Annual
- Follow-up medication review/MedsCheck Follow-up
- Pharmaceutical Opinion
- Prescription adaptation/renewal
- Adherence packaging (e.g., dosette, blister packing)

(Refer to the OPA Suggested Fee Guide for Uninsured Clinical and Professional Pharmacy Services for more information as required)

Document and notify patient's primary care provider

Schedule follow up as required

(Refer to box on Target Populations for testing frequencies)

ABBREVIATIONS:

CHF: congestive heart failure; **NSAIDs:** non-steroidal anti-inflammatory drugs; **OHIP:** Ontario Health Insurance Plan; **POCT:** point-of-care test; **PT/INR:** prothrombin time/international normalized ratio; **Rx:** prescription; **TMP/SMX:** trimethoprim/sulfamethoxazole

DISCLAIMER:

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