CADTH Evidence Driven.

Point-of-Care INR Testing Compared with Lab INR Testing: **What Does the Evidence Say?**

Patients take oral anticoagulation therapy (OAT) with warfarin or other vitamin K antagonists to prevent blood clots. When taking these drugs, patients must be monitored to ensure that they are getting the right amount of the medication and are not at risk for bleeding or blood clots.

The usual method for monitoring drug therapy is laboratory testing of blood obtained by venipuncture to measure the INR. Point-of-care (POC) testing – testing at or near where a patient is located – is another way of monitoring the INR. POC INR testing is similar to the way patients with diabetes test their blood sugar. A small sample of blood is obtained by pricking the fingertip. The blood is placed on a test strip and inserted into a device called a coagulometer, which analyzes the blood and displays the INR result.

Three Ways POC INR Testing Can Be Used

1 PATIENT SELF-MANAGEMENT (PSM)

The patient self-tests the INR using a POC device, and also self-adjusts the dose of the anticoagulant medication based on the results using a predetermined algorithm or protocol.

2 PATIENT SELF-TESTING (PST)

The patient self-tests the INR using a POC device and a clinician adjusts the dose of anticoagulant medication based on the results.

3 CLINIC-BASED POC INR TESTING

POC testing is performed in a clinical setting such as a physician's office or anticoagulation clinic.

The CADTH project on POC INR testing included a review of the clinical evidence and a health economic analysis to compare POC INR testing with standard laboratory testing. Feedback from interested stakeholders was sought and an advisory committee comprised of experts from across Canada was established to help CADTH provide guidance on this topic. The results of the research are summarized in the following quick reference table.

Lab INR and POC INR: A Comparison

	LAB INR	POC INR PATIENT SELF-MANAGEMENT (PSM)	POC INR PATIENT SELF-TESTING (PST)	POC INR CLINICAL SETTING
RESULTS	INR	INR	INR	INR
PATIENTS	All patients taking OAT	Patients taking OAT (or their caregivers) with necessary: • cognitive capacity • manual dexterity • visual acuity • willingness to self-manage	Patients taking OAT (or their caregivers) with adequate: • cognitive capacity • manual dexterity • visual acuity • willingness to self-test	Patients taking OAT who can present to a clinic or doctor's office
SAMPLE FOR TESTING	Venipuncture (blood draw)	Blood drop from fingertip	Blood drop from fingertip	Blood drop from fingertip
LOCATION	Hospital or community lab	Wherever the patient is	Wherever the patient is	At a clinic or doctor's office
AVERAGE TEST FREQUENCY (ONCE STABLE)	~ Monthly but may vary by patient and health care provider	Weekly* or biweekly but may vary	Weekly or biweekly but may vary	~ Monthly but will vary depending on clinic and patient
HEALTH CARE PROFESSIONAL REQUIRED	For taking the blood sample, analyzing the blood sample, and making dose adjustments	For initial training and ongoing education Quality assurance role?	For initial training, ongoing support and dose adjustment Quality assurance role?	For testing and dose adjustment Quality assurance
PATIENT (OR CAREGIVER) TRAINING REQUIRED	No	Yes	Yes	No
ACCURATE COMPARED WITH LAB	–	Yes	Yes	Yes
TIMELINESS OF RESULTS	Delay between testing and availability of results	Results available immediately with immediate dose adjustment (if required)	Results available immediately – but potential delay between availability of results and dose adjustments	Results available immediately with immediate dose adjustment (if required)
TIME IN THERAPEUTIC RANGE (TTR) COMPARED WITH LAB TESTING	–	↑↑	↑	↑
PATIENT SATISFACTION/ QUALITY OF LIFE		↑ Based on limited patient preference data	↑ Based on limited patient preference data	↑ Based on limited patient preference data
HEALTH OUTCOMES COMPARED WITH LAB	–	=	=	=
ESTIMATED COST/PATIENT/YEAR Cost includes: equipment/device, testing strips, health care provider costs, and cost of warfarin therapy	$7,033 (12 tests/patient/year)	$7,266 (26 tests/patient/year)	$8,234 (26 tests/patient/year)	$7,841 (23 tests/patient/year)
ICER OR COST/QALY GAINED		$13,028	$325,283	$127,315
COST-EFFECTIVE	–	Yes *but if testing > 42x/year, clinic-based testing may be more cost-effective	?	?
QUESTIONS OR CONSIDERATIONS FOR THE IMPLEMENTATION OF POC INR	• Since per-test lab costs for INR measurement are modest, savings in lab costs or reductions in lab workload may not be significant • POC INR testing is not appropriate for all patients. Therefore, lab infrastructure and staffing to conduct INR testing will need to be maintained for those patients not being tested by POC INR devices	• Who will pay for the device? • Who will pay for test strips, lancets, and test solutions? • What percentage of patients will be able to perform PSM or PST? • Which patients will be eligible for PSM or PST? How will that be determined? Who will determine this? • Who will educate and train patients and/or caregivers? • Who will monitor patient/caregiver skill and capacity on a regular basis? • Who will be responsible for quality control of the POC INR devices? • For PSM, which nomogram or software program will patients follow for OAT dose adjustments? • How will INR results and dose adjustments be recorded?		• Patient population • Access of patient population to lab facilities • Other contextual issues for your clinic • Staff training and resource use • Comparison of costs using POC INR in your clinic setting versus lab testing • Quality control of the POC INR device

ICER
Incremental Cost-Effectiveness Ratio

INR
International Normalized Ratio

OAT
Oral Anticoagulation Therapy

POC
Point of Care

PSM
Patient Self-Management

PST
Patient Self-Testing

QALY
Quality Adjusted Life Years

TTR
Time in Therapeutic Range

Other Considerations

- POC INR testing may be helpful for patients in rural or remote settings or those who may be isolated for other reasons (e.g., elderly patients confined to their homes), particularly if laboratory services are not easily accessible or INR results cannot be obtained in a timely manner. However, there was no evidence available regarding the impact of POC INR testing in these settings, and further research is required.
- There was no evidence identified regarding the use of POC INR testing in long-term care settings.

The Bottom Line

- **POC INR testing with any currently available POC INR device is an accurate alternative to lab INR testing.**
- **Patient self-management (POC INR testing + dose adjustment) may be the most cost-effective option, when feasible.**
- **Patient self-testing with health care provider dose adjustment may be an option when lab INR testing is difficult.**
- **Clinic-based POC INR testing requires careful consideration of context and costs.**

Questions or comments about CADTH, our POC INR project, or this tool?

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ABOUT CADTH

CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.