

POINT-OF-CARE ANTICOAGULATION MONITORING DEVICES: A BETTER ALTERNATIVE?

RESEARCH HIGHLIGHTS - FEBRUARY 2007

This document highlights key findings from a CADTH health technology assessment report on the clinical and cost effectiveness of point-of-care monitoring devices for long-term anticoagulation therapy.

Oral anticoagulation therapy (OAT) is common in Canada for the prevention of thromboembolic events for those at increased risk of forming blood clots.

Frequent monitoring of these patients is crucial to ensuring an appropriate level of anticoagulation therapy. Too high can lead to bleeding; too low may lead to clots.

Traditionally, monitoring is achieved through regular visits to a laboratory or hospital where blood is taken and tested to determine the international normalized ratio (INR).

This can be inconvenient and time-consuming for patients – especially those in rural and remote areas, or those wishing to travel for extended periods.

Alternatives to usual care for the monitoring of anticoagulation therapy exist in the form of portable point-of-care (POC) testing devices.

But how well do POC anticoagulation monitoring devices work? Do they offer value-for-money or cost savings to the health care system? Are there factors, such as convenience, that should be considered?

KEY FINDINGS

- POC monitoring devices can improve health outcomes:
 - Fewer deaths
 - Fewer thromboembolic events
 - Better INR control.
- POC monitoring devices can reduce costs:
 - Cost savings for health care payers when used in a clinical setting.
- Additional resources would be required to implement the use of POC devices in anticoagulation clinics or for patients eligible for self-testing at home.

POC Devices

- Portable, point-of-care technology
- A drop of blood from a fingertip is used for testing to provide INR results
- Results are available almost immediately
- Devices in Canada include ProTime® and CoaguChek®



FOR HEALTH CARE PROVIDERS

Comparing laboratory and point-of-care testing – a clinical perspective

	Usual Care (Laboratory Testing)	Point-of-Care Monitoring
Sample for Testing	Venipuncture	Blood drop from fingertip
Location	Hospital or outpatient laboratory	Clinical setting, patient care setting or patients' homes
Test Frequency (per year)	20	23 (clinic) 52 (self-testing)
Timing	Delay between testing and availability of results	Results available immediately
Results	INR	INR
Health Outcomes Compared to Usual Care	N/A	<ul style="list-style-type: none">• ↓ deaths• ↓ thromboembolic events• ↑ INR control• = hemorrhagic events

INR=international normalized ratio; N/A=not applicable

MORE OPTIONS WITH POC DEVICES

OAT management with traditional laboratory testing:

- Patients are usually sent to a lab for testing.
- Once results are available, they are sent to the patient's doctor.
- Any necessary changes in therapy are then ordered by the physician.

OAT management options with POC devices:

- *Location:* The device may be used in an anticoagulation clinic, a nursing home, a doctor's office or a patient's home (self-testing).
- *Self-testing:* Patients can self-test and then inform their doctor of the results; doctors can then make any necessary changes in therapy.

- *Self-management:* Patients could self-manage their OAT, by testing and then self-adjusting their dose as necessary.

Limitations of POC Devices

For self-testing, patients must have reasonable:

- *Visual acuity*
- *Manual dexterity*
- *Cognitive ability.*

This limits self-testing to about 25% of OAT patients.

Up to half of OAT patients who self-test will require caregiver assistance.

Education is key for patients, caregivers and health care providers.



FOR POLICY MAKERS AND ADMINISTRATORS

- An estimated 209,000 patients on long-term OAT are in publicly funded drug programs in Canada.
- Over 50,000 (about 25%) of these patients could be eligible for POC self-testing and monitoring at home.
- The use of POC devices in clinical settings is cost saving and cost effective.
- Patient self-testing has not been shown to be cost effective for Canada's publicly funded system – but it is for society if patient and caregiver time and travel costs are considered.
- Evidence suggests that in anticoagulation clinics, patients prefer POC testing to usual care.
- Patients who continue self-testing and self-management with POC devices prefer it to usual care.
- The implementation of POC testing in clinics would require additional resources – an estimated \$84,000 in capital costs and \$8 million per year in consumable costs.
- The implementation of POC self-testing for the ~50,000 eligible patients would require \$50 million in capital costs and \$18 million per year in consumable costs.

Comparing laboratory and point-of-care testing – a cost perspective

Monitoring Option	Annual Monitoring Costs Per Patient			Comparison With Usual Care (Health Care Cost Per QALY)		
	Health Care System	Patients and Caregivers	Total	Health Care Providers (Excludes Nursing Homes)	Health Care Providers (Includes Nursing Homes)	Societal*
Usual Care (Laboratory)	\$322	\$686	\$1,008	N/A	N/A	N/A
Anticoagulation Clinic With CoaguChek®	\$361	\$862	\$1,223	cost saving	cost saving	\$10,808
Self-testing With CoaguChek®	\$807	\$274	\$1,081	\$72,955	\$57,595	cost saving
Anticoagulation Clinic With ProTime®	\$392	\$862	\$1,254	\$2,437	cost saving	\$15,966

*Includes costs to patients and their caregivers; N/A=not applicable; QALY=quality-adjusted life-year (an extra year of healthy life expectancy)



What is a thromboembolic event?

A **thromboembolism** is the formation of a clot in a blood vessel.

A **thromboembolic event** occurs when a blood clot forms or when complications arise from a blood clot. These events include a pulmonary embolism (a clot in the lung), a stroke (a clot in the brain), a heart attack (a clot in the heart) – as well as clots in the legs, kidneys, or gastrointestinal tract.

GLOSSARY OF IMPORTANT TERMS

INR – international normalized ratio, a unit that is used to indicate the intensity or degree of anticoagulation

OAT – oral anticoagulation therapy

Long-term OAT – oral anticoagulation therapy for more than three months (often for life)

POC – point-of-care (testing where the patient is located, rather than the patient traveling to a laboratory for testing)

QALY (Quality Adjusted Life Year) – an extra year of healthy life expectancy

Warfarin – the most common medication used for OAT in North America

PROJECT INFORMATION

Despite the availability over the last decade of POC monitoring devices for OAT, questions remained about the utility of these devices. CADTH initiated a review of the clinical and cost effectiveness of POC devices in May 2005 to provide evidence to help answer these questions.

The research lead for the project was Allan Brown, BSc MBA MA, a health economist with CADTH. The clinical lead for the report was Phil Wells, MD FRCPC, Professor and Chief, Division of Hematology, and Director of Clinical Research at The Ottawa Hospital, who also holds a Canada Research Chair in thromboembolic disease.

CADTH's full-length Technology Report, *Point-of-Care Monitoring Devices for Long-Term Oral Anticoagulation Therapy: Clinical and Cost Effectiveness*, as well as a Technology Overview and this Research Highlights tool, are available at www.cadth.ca.

ABOUT CADTH

The Canadian Agency for Drugs and Technologies in Health (CADTH) is a national body that provides Canada's federal, provincial and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies.

NEED MORE INFORMATION?

kt@cadth.ca

NEED PRINTED COPIES?

pubs@cadth.ca

