# POINT-OF-CARE INR MONITORING OF WARFARIN THERAPY

**TARGET AUDIENCE:** All Canadian health care professionals.

## **OBJECTIVE:**

To provide an overview of point-of-care (POC) home international normalized ratio (INR) monitoring.

#### **ABBREVIATIONS:**

INR	international normalized ratio
POC	point-of-care
PT	prothrombin time

## **BACKGROUND:**

A POC device is a small portable instrument that measures clotting time from a fingerstick whole blood sample. Most POC devices report the result as either a prothrombin time (PT) or as an INR.

## HOW ARE POC DEVICES USED?

For both adults and children, use of a POC INR device provides a simple way to improve warfarin anticoagulation management in both the office setting and at home. The POC INR device requires a small blood sample in order to produce an INR result within one minute, enable timely drug dose adjustments and allow prompt attention to INR values that fall substantially outside the therapeutic range. INR measurements can be performed at a patient's convenience and eliminate the need for laboratory visits. This convenience facilitates more frequent INR testing. Furthermore, in randomized trials comparing POC with laboratory-based INR monitoring, POC-based monitoring has been shown to improve the quality of anticoagulation control (i.e. time in the therapeutic range) and to reduce thromboembolic and hemorrhagic events. POC INR devices vary in their ease of use due to: differences in blood sample volume required, the technique of application of blood sample to meter, the need for external quality control testing, refrigeration of test strips, and meter portability.

Three different modes of POC INR monitoring and management have been utilized:

- 1) POC INR testing within a health care facility (hospital or clinic) where patients receive immediate INR results and instructions on drug dosage.
- 2) POC INR testing in the home with results phoned to an anticoagulation clinic or physician followed by instructions on drug dosing (self-testing).

3) POC INR testing in the home with patients undertaking self-dosing using a predetermined dosing nomogram combined with their own experience (self-testing and self-monitoring).

## WHAT IS THE ACCURACY AND PRECISION OF POC INR DEVICES?

Numerous studies have assessed the accuracy and precision of POC INR devices in both adults and children. The accuracy and precision of POC devices are inconsistent and less accurate when an INR is above the therapeutic range (i.e. INR > 3.5). In general, when comparisons are made between laboratory-based and POC-based INR measurements, the difference between values is generally within 15%. Such a difference is acceptable as it is similar to that of INR results done in different laboratories using anticoagulated plasmas that are simultaneously compared using different instrument and/or thromboplastin reagents.

# HOW DOES ONE DEFINE CLINICALLY-IMPORTANT DIFFERENCES IN INR BETWEEN POC AND LABORATORY-BASED MEASUREMENTS?

Although there may be numeric differences in INR results between POC- and laboratory-based INR measurements, the INR values should be either within 0.5 of each other, or both fall within or outside the target range.

## WHAT ARE SOME CONSIDERATIONS PRIOR TO POC INR DEVICE USE?

Before a POC INR device can be recommended for clinical use, we suggest the following to ensure proper use and optimal patient safety:

- 1) Patients must demonstrate good adherence to treatment.
- 2) At least three comparisons between POC-based and laboratory-based INR measurements should be done to evaluate the accuracy of the POC INR device in a given patient.
- 3) Patients should participate in a standardized educational program to ensure proficiency in testing technique. A standardized validated educational tool is available entitled KIDCLOT<sup>©</sup> POC (contact www.TIGC.org). This tool describes CoaguChek XS meter (Roche Diagnostics, Basil, Switzerland). Although this tool is designed for children, it can also be used successfully in adults.
- 4) A relationship with an anticoagulation clinic or family doctor familiar with POC INR testing is essential so that the patient may access this professional for advice or trouble-shooting, if needed.
- 5) Ongoing quality assurance (i.e. laboratory-meter comparisons) should be performed every 6-12 months or if an INR is inconsistent with clinical expectations.

## **PATIENT SELF-MANAGEMENT:**

Self-management empowers the patient to participate in and manage their therapy in a manner similar to glucose self-monitoring and management of diabetes. Self-managed care assumes that patients can be taught to accurately self-test using a POC INR device and will be able to successfully manage their warfarin therapy. In clinical trials of adults who required long-term warfarin therapy, self-management using a POC INR device was associated with cost-savings to the health care system as well as to the patient. Self-management of anticoagulation also confers moderate improvement in the time within the therapeutic range, and improvements in patients' quality of life. Patient self-testing and self-management of warfarin therapy was also evaluated in children and it demonstrated an improved time in therapeutic range and health-related quality of life.

## REFERENCES:

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