

The Model Matters Point-of-Care Pro-Time Testing

An Oregon hospital recently had an adverse event triggered by the use of a point-of-care testing device for monitoring anticoagulant therapy. These devices measure the prothrombin time/international normalized ratio (PT/INR) and are typically used for patients taking Coumadin, an anticoagulant medication (“blood thinner”) to decrease the risk of blood clots in patients with atrial fibrillation, recurrent venous or arterial thrombosis, and other conditions. Below are images of three common hand held devices for home usage.



Why we are sharing this information: Handheld devices for monitoring INR are widely used in anticoagulation clinics and outpatient settings. Also, they are increasingly being used by patients in the home to make certain that they are receiving the correct amount of medication to decrease the risk of a blood clot while not increasing the risk of bleeding. Managing the dose of Coumadin requires that INR measurements be held to a narrow range. Out of range INRs are associated with significant adverse events, including bleeding and blood clots, both of which may result in a stroke. The various models used in monitoring INRs have different requirements for accurate readings. Some that give accurate readings when used in patients on Coumadin, will give inaccurate readings if used in patients getting a different anticoagulant medication such as low molecular weight heparin (LMWH), i.e. Lovenox, etc.

What happened: A regular patient at this facility on Coumadin and Lovenox came in to the clinic for monitoring and any necessary adjustment of his anticoagulant. He had been recently discharged from the hospital and was being closely monitored to stabilize the medication regimen needed for maintaining his target INR. Despite several increases in medication to decrease the risk of a blood clot, the INR (as measured by the device in question) remained below the target value. On the evening of his last appointment the patient called the facility to say that he was unable to stop bleeding from his nose. He

was told to immediately come to the ED for evaluation. In the ED a venous sample showed a very high INR. He was treated and discharged without significant harm.

Findings:

- ◆ On the day in question, staff was using a different hand held device that had recently replaced the previous device used.
- ◆ The RN was knowledgeable and experienced in caring for patients on anticoagulants.
- ◆ Staff followed clinic procedures for using the handheld device
- ◆ Device controls to verify the calibration are built into the test strips and had been checked with each use.

Additional Information:

Current practice in many clinics using a handheld device to monitor PT/INR involves drawing concurrent venous samples the first 3-4 visits. The necessity for this practice however is currently being reexamined, according to Elizabeth Goldstein, Executive Director of the [Anticoagulation Forum](#), which provides networking and educational resources for health professionals. More information for patients and providers is also available online with [ClotCare](#) and the [National Alliance for Thrombosis and Thrombophilia](#), a national organization for patients.

Recommendations:

- ◆ Review specifications for all current INR devices in use. Explicitly check whether or not device will give accurate readings with LMW heparin and what type of blood sample should be used.
- ◆ Any new equipment, whether a newer model, different model, or replacement of existing model should prompt review of the equipment's capabilities and cautions.
- ◆ Initiate staff briefings on current equipment to assure understanding regarding the handheld device's limitations and cautions for use.
- ◆ Since handheld devices are standardized for use with capillary (finger stick) blood samples, they should not be used with venous blood.

Contact us!

If your hospital has observations, or lessons to improve patient safety associated with this type of event, please call Leslie Ray at 503.224.9227. We want to encourage a discussion. In addition, we can connect you to other experts willing to analyze your particular situation. All information will be kept confidential.