

# Transition From Venipuncture to Point-of-Care International Normalized Ratio Testing in a VA Anticoagulation Clinic

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Point-of-care testing of patients in the immediate clinic area may increase the workload of the staff and be more costly, but the benefits to patients on long-term oral anticoagulation therapy and the overall improved clinic efficiency outweigh the obstacles.

**P**atients taking oral vitamin K antagonist therapy are constantly balancing the risks of thromboembolism with hemorrhage despite adjustments to achieve therapeutic international normalized ratio (INR) values.<sup>1</sup> Oake and colleagues demonstrated that improvement in anticoagulation control can decrease, by approximately half, all anticoagulant-associated adverse events.<sup>2</sup> Review of published studies also suggests that the quality of dose management of anticoagulation therapy significantly influences frequency and severity of adverse events.<sup>3-5</sup> Addition of a specialized anticoagulation clinic is one way to provide this monitoring, and demonstrates overall improvement in anticoagulation management.<sup>6</sup> Unfortunately, the high volume of patients in these clinics may decrease clinic efficiency.<sup>7</sup> To offer an alternative to laboratory venipuncture, specialized clinics are increasing utilization of point-of-care (POC) testing to test the patient in the immediate clinic area and increase timeliness of results.<sup>8,9</sup> Transitioning to this

technology may improve workflow and patient satisfaction.

## BACKGROUND

The anticoagulation clinic at the Charles George VA Medical Center in Asheville, North Carolina, was established in 1995 and is a pharmacist-managed, nurse-assisted clinic with an enrollment of about 1,100 patients. The current workflow entails a clinical pharmacy specialist (CPS) managing the clinic while overseeing up to 3 registered nurses. Each visit includes a face-to-face encounter between the patient and either the CPS or the nurse. The CPS meets with patients whose most recent INR value is above or below therapeutic range, while the nurses see patients who have an INR value within the designated therapeutic range.

In April 2008, the facility invited employees to participate in *Goal Sharing 2008*. This incentive program was designed to encourage employees from various departments to work together on a project to enhance the level of service provided to patients. As part of this program, the anticoagulation clinic staff designed a proposal to transition from laboratory-drawn venipuncture INR

to POC INR testing in the clinic. This project was selected for several reasons. The facility was experiencing an increase in patient reports of dissatisfaction with the current system, as well as an increase in demand on phlebotomy staff. Anticoagulation clinic staff members were frequently being required to work beyond their designated clinic time due to delays in laboratory INR reports and, therefore, patients were seen after their appointment time. The following is a description of the transition to POC INR testing in a large, pharmacist-managed VA anticoagulation clinic as part of a quality-improvement project.

## EQUIPMENT SELECTION AND TRAINING

Selection of the POC testing equipment was completed by the facility ancillary testing coordinator. The Abbott i-STAT System (Abbott Laboratories, Abbott Park, Illinois) POC machine was selected since it was already employed for other testing within the facility. It also has the ability to communicate with the VA computerized patient record system (CPRS).

Correlation data INR tests were performed between the i-STAT and

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the laboratory INR equipment, Sysmex CA-1500 (Embee Diagnostics, Delhi, India) in November 2007. This was done in preparation for the use of POC INR testing through the home-based primary care (HBPC) program at the facility. The facility ancillary testing coordinator arranged the correlation data analysis and the results were reviewed and approved by the chief of laboratory services. After the POC INR correlation data were approved, they were implemented for the HBPC program. It was determined by laboratory services that no additional correlation studies were required prior to initiating this service in the anticoagulation clinic.

Initial training of operators on the i-STAT instrument was completed by the ancillary testing coordinator. Since INR results with the POC machines are technique dependent, each new operator was trained and evaluated on a minimum of 6 finger sticks. These finger stick results were compared to either an “experienced” operator or to the laboratory INR. The 2 results were compared for reproducibility and technique was evaluated before a new operator was able to begin patient testing.

### **BASELINE DATA—LABORATORY WAIT TIME AND TOTAL VISIT TIME**

Data were gathered regarding the average laboratory wait time for patients using the venipuncture INR system. A sample of patients from the anticoagulation clinic (n = 482) was reviewed over a 2-week period. Each selected patient was assessed from the time the INR was drawn to the time it was reported in the CPRS. The results indicated that most patients’ INR values were reported after approximately 20 to 30 minutes (Figure 1).

Data also were collected to assess the total visit time for patients. Total

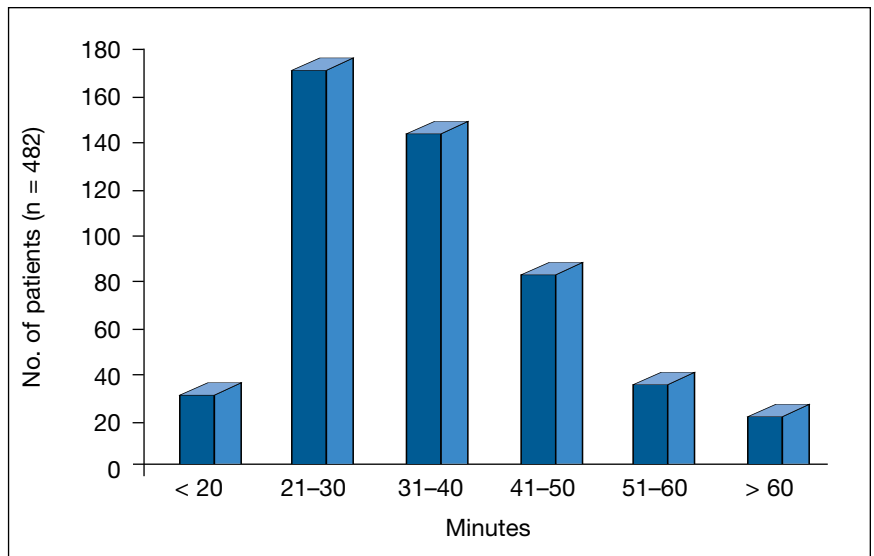


Figure 1. Laboratory wait time for venipuncture INR testing. Laboratory wait time defined as phlebotomy wait time + time from blood draw to INR reported.

visit time was defined as the time the INR was drawn to the time the patient checked out from the clinic visit. A random selection of patients visiting an afternoon anticoagulation clinic (n = 32) was evaluated. The average (SD) total visit time using laboratory venipuncture was 96 (39) minutes.

### **IMPLEMENTATION**

The team surveyed other VA facilities that currently use POC testing. Using this collected information, together with current clinic procedures, a new clinic workflow was designed for the project. Adjustments were made throughout the transition period (weeks 1 through 6) to improve the efficiency of this new clinic workflow. These changes involved optimizing the use of clinic staff, simplifying the clinic process, and eliminating congestion in the clinic area.

Patients completed a questionnaire that obtained such information as current dosage, missed dosages, medication changes, and diet changes. This questionnaire had been used in

the anticoagulation clinic prior to the transition to POC testing. In the final workflow, a room was designated for POC INR testing by a nurse and patients were sent to the waiting room to wait for test results. The next patient could then be called for testing on a second POC machine. The patient questionnaires with INR results were placed in a folder outside the testing room. The questionnaires were taken to the clinic area where the nurse processed patients with therapeutic INR values. The CPS saw patients face to face if their INR results were outside of the therapeutic range. This flow utilized clinic staff appropriately and was not confusing to the patients. The processing time for the POC INR testing was more efficient and the clinic area was not congested. This workflow was used for the duration of the pilot program.

### **FOLLOW-UP DATA**

#### **Patient satisfaction survey**

In order to assess the patients’ levels of satisfaction and receive adequate

**Dear Anticoagulation Clinic Patient,**

**In an effort to continuously improve the quality of care that you receive, we ask that you take 5 minutes to complete this important survey.**

1. How long have you been attending this clinic? \_\_\_\_\_ number of months

**Please circle the score which most represents *your* impression.**

2. The clinic staff is courteous and friendly.

<b>Strongly Disagree</b>		<b>Neutral</b>		<b>Strongly Agree</b>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

3. Compared to previous anticoagulation clinic appointments, today's appointment was faster.

<b>Strongly Disagree</b>		<b>Neutral</b>		<b>Strongly Agree</b>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

4. Compared to previous anticoagulation clinic appointments, today's wait to receive my INR result was reasonable.

<b>Strongly Disagree</b>		<b>Neutral</b>		<b>Strongly Agree</b>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

5. I liked the finger stick compared to the blood draw in the laboratory to get my INR result.

<b>Less Satisfied</b>		<b>Neutral</b>		<b>More Satisfied</b>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

6. Compared to previous anticoagulation clinic appointments, I would rate my overall satisfaction with today's appointment as:

<b>Less Satisfied</b>		<b>Neutral</b>		<b>More Satisfied</b>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

Figure 2. Quantitative survey to assess patient satisfaction.

feedback with the POC process, a locally created quantitative survey was developed (Figure 2). The survey was reviewed and modified by the anticoagulation clinic staff. Patients participating in the project's pilot clinic were asked to complete the survey at the

end of their appointment encounter. If patients returned more than once during the project study period, they were not asked to complete additional surveys.

Periodic evaluations of the surveys were conducted throughout the

project. Variations in responses were noted to correlate with the changes in workflow; however, results were clinically significant for patients favoring POC anticoagulation monitoring.

Based on the surveys, patients' length of time enrolled in the antico-

agulation clinic varied from 2 weeks to 19 years. By week 6 of the pilot project, more than 90% of patients were more satisfied with their clinic experience than they were at previously attended appointments (Table).

A 3-month follow-up patient satisfaction survey was conducted. It included 4 questions that were similar to questions 3 through 6 of the original survey, but asked patients to compare their current clinic experience with the previous anticoagulation clinic system (going to the laboratory before each clinic appointment). The 94 follow-up surveys that were completed revealed that patients remained satisfied with the change from venipuncture to POC testing. The response of “strongly agree” to these survey questions was 83%, 69%, 89%, and 83%, respectively.

### Patient wait times

A follow-up assessment was performed for patients’ total visit time. This time was determined by tracking the check-in time to the check-out time. One of the project’s pilot afternoon anticoagulation clinics was randomly chosen (n = 40). The average (SD) wait time was 34 (20) minutes—a noticeable drop from the 96-minute average wait time found at baseline using the venipuncture INR system (Figure 3).

### Cost analysis

Prior to initiating POC testing, cost analysis was performed to compare the 2 testing methods. Since clerical, clinical, and laboratory personnel remained the same for each testing method, personnel cost was excluded from the analysis. Training of staff was conducted during administrative time by the ancillary testing coordinator and also was excluded from the cost analysis (\$203 POC test supplies utilized in training). The expendi-

**Table. Percentage of patients responding with “strongly agree” or “more satisfied” to survey questions 3 through 6**

Survey question	Week 1, 2, % (n = 57)	Week 3, % (n = 14)	Week 4, 5, 6, % (n = 13)
3	66	50	100
4	73	78	92
5	73	78	100
6	77	78	92

ture for testing INR via venipuncture equaled \$1.76 per patient. This cost included the reagent, control, tube, and needle. The expenditure for testing via the i-STAT was \$3.76 per patient. This cost included the cartridge, lancet, and capillary tube.

### BENEFITS AND LIMITATIONS OF POC TESTING

There are many benefits to the use of POC testing in an anticoagulation clinic. The most significant is improvement in patient satisfaction, which is critical to ensure proper monitoring of a medication to pre-

The decrease in patient traffic to the laboratory potentially decreases workload for laboratory staff. The use of POC testing in the anticoagulation clinic has improved the overall efficiency of the clinic. It has been noted that the clinic is completed during the allotted time more frequently and more patients are arriving at the clinic at their assigned appointment time.

Limitations in using the POC testing include the accuracy and consistency of testing. Technique is user dependent, and with different nurses and pharmacists managing the anticoagulation clinic each day, there is

*The major factor contributing to improved patient satisfaction was decreased overall wait time at the clinic.*

vent adverse events. The major factor contributing to improved patient satisfaction was decreased overall wait time at the clinic. Since patients did not have to report to the laboratory prior to each clinic appointment, laboratory traffic was decreased—presenting a potential for decreased wait time for other patients presenting to the laboratory for blood draws.

In addition to benefits to the patients, there is also benefit to staff.

an inherent variability in the test results over time. An additional limitation is that the POC testing machine cannot verify the accuracy of INR values detected to be greater than 4. Since patients with INR values greater than 4 must be sent to the laboratory for testing, this prolongs the patient visit time. When patients require more intense monitoring, this could affect their adherence in attending appointments.

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# TRANSITION FROM VENIPUNCTURE TO INR TESTING

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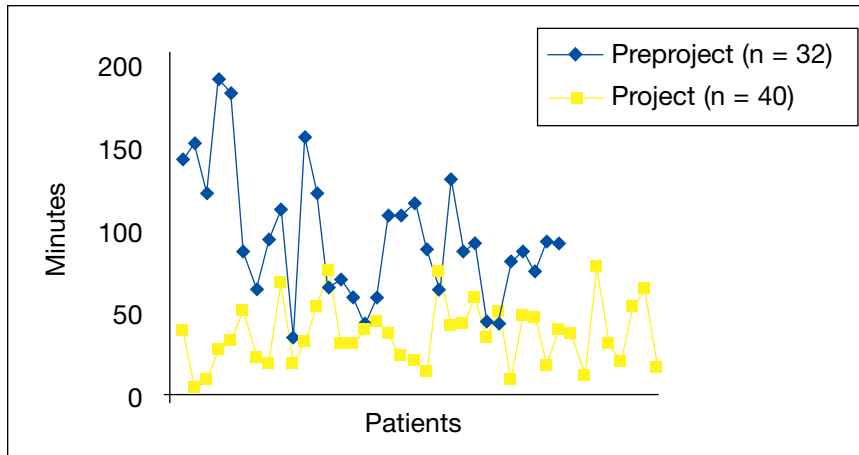


Figure 3. Decrease in patient wait times using POC testing (project) vs baseline data using the venipuncture INR system (preproject).

## QUALITY ASSURANCE

The competency of clinic staff administering POC testing is evaluated regularly. The ancillary testing coordinator is responsible for assessing and documenting the competencies of trained personnel. Quality control checks are completed in the laboratory on each delivery of i-STAT cartridges prior to distribution to the anticoagulation clinic. Equipment maintenance sheets are completed and displayed

and to decrease adverse events. It is important to make management of this therapy as efficient as possible. The improvement in wait times and patient satisfaction should have a positive impact on adherence to appointments. This potentially may increase time in therapeutic range and decrease risk for adverse events.

Although cost was higher for the POC testing procedures, the facility

***The laboratory has at least 40 fewer patients for phlebotomy each day and, therefore, fewer INR tests to complete.***

in the clinic. Currently, all INR results greater than 4 with the i-STAT are reported as “> 4”. These patients are sent to the laboratory for a venipuncture INR to verify the INR result.

## SUMMARY

Patients who require long-term oral anticoagulation therapy must be mon-

determined it was beneficial for patient care to proceed with the conversion to POC testing. The conversion has increased the workload of the anticoagulation clinic staff. One nurse must now be allocated to perform the i-STAT finger sticks each day. The design of an efficient workflow, however, has eliminated the need for

additional staff. Each clinic day, 45 to 60 patients are scheduled for appointments in the anticoagulation clinic. Prior to POC conversion, all of these patients would have had a laboratory INR, but now, only 4 to 6 patients daily require a laboratory INR. The laboratory has at least 40 fewer patients for phlebotomy each day and, therefore, fewer INR tests to complete.

Future considerations to further improve clinic efficiency include expanding current staff by adding a clinical pharmacy technician; increasing the availability of the ancillary testing coordinator to perform quality assurance on POC testing technique; and comparing no-show rates to appointments, both before and after the change to POC testing. Implementing technology, such as POC INR testing, can improve patient satisfaction with long-term management of oral anticoagulation therapy. ●

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## Author disclosures

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*contraindications, warnings, and adverse effects—before administering pharmacologic therapy to patients.*

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