

# ADVANCES IN HEMATOLOGY

Current Developments in the Management of Hematologic Disorders

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## Patient Self-Management of Oral Anticoagulation

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### **H&O** What are the options now available for monitoring oral anticoagulation?

**GR** There are 4 basic models from which to choose for monitoring oral anticoagulation in patients. The oldest model, called “usual care,” refers to physician-managed anticoagulation. The primary physician sees the patient at intervals to draw blood in order to measure the international normalized ratio (INR) and then adjusts the anticoagulation dose based on that result. The patient receives minimal education and information. This model is associated with the highest amount of complications.

A big advance was made 10–20 years ago with the advent of anticoagulation management systems. With this approach, patients come to a clinic for a laboratory test, but receive feedback about the result as well as some education. This systems enabled patients to become more involved in their own care, by realizing how their test results were influenced by diet or other medications, for example. These clinics were the paradigm for anticoagulation monitoring for approximately 10 years.

Over the past 5 years or so, oral anticoagulation monitoring has taken place increasingly in the home setting. With the patient self-testing model, patients receive an outpatient instrument to take a “fingerstick” measurement of their INR. Patients then communicate the measurement to their physician and the physician adjusts the dose of anticoagulant based on that result. The main advantage to this model is more frequent testing, because patients can do this at home, rather than going to a doctor’s office. This model, called patient self-testing, improved outcomes, with patients staying in the therapeutic range for a longer period of time.

The most recent advance has been patient self-management. With this approach, patients not only measure their own INRs at home using an outpatient fingerstick

device, they also have nomograms that instruct them on how to adjust their anticoagulant dose according to the INR measurement. Patient self-management appears to be more effective than any of the prior models.

### **H&O** Why is patient self-management such an effective approach?

**GR** Most likely, the improvements are a result of patient education and involvement with their own care. With the usual care model, there is very little impetus for the patient to be involved with their care. More distance between physicians and patients meant less communication about why the INR level might not be in the normal range and how to improve it for subsequent measurements, and thus the approach was associated with more complications. With the anticoagulation clinics, patients began to be educated. Now, patients can be completely involved with their care, not only testing themselves, but also being involved with decision-making in regard to their dose.

### **H&O** Has there been a formal study comparing the outcomes with the various approaches?

**GR** Yes. Just recently, the results of the largest such study that has been conducted as of yet were published in the *Annals of Internal Medicine*. This Spanish study enrolled 700 patients and compared patient self-management with an anticoagulation clinic model, thought to be a reasonable standard for anticoagulation monitoring. The study found a dramatic reduction in complications in the self-management group compared with the clinic group, and conclusively proved that patient self-management is the most effective approach.

### **H&O** What types of cautions must be kept in mind in regard to patient self-management of anticoagulation?

**GR** The main concern when discussing options with patients is to ensure that self-management is the appropriate approach. In Europe, where this approach has been studied more than in the United States, only 50–60% of patients are candidates for self-management or self-testing.

## **H&O** How does one determine whether a patient is an appropriate candidate for self-management?

**GR** The patient must be interviewed in order to determine whether he/she, or a caregiver, is willing and able to do the at-home tests. The patient must be able to record the test results in a logbook, and must occasionally attend a clinic in order for quality-control (QC) studies to be performed on their home instrument. In these clinics, the patient must demonstrate competence and receive retraining to ensure that the skills necessary for obtaining reliable results are maintained. There must be no history of patient noncompliance with similar types of treatment.

## **H&O** What is the exact process by which this assessment would be made?

**GR** In the Spanish study, patients underwent 2 2-hour sessions with a nurse educator to review the goals of self-testing, how to use the instrument, etc. The nurses observed the patients to ensure they could use the equipment properly, and reviewed how to complete their logbooks and use the nomograms. Over this 4-hour period, the nurse educators were able to make this assessment.

The process is similar to that used for selecting patients for outpatient treatment of deep vein thrombosis, where a nurse will observe a patient or their at-home caregiver self-inject low molecular weight heparin. The nurse assesses their ability, willingness, and history of compliance to determine whether the self-management approach is appropriate. Some patients are not able to master the skills, or will not follow instructions. Usually, the nurse educators can assess which patients are right for self-management and which are not.

## **H&O** What instruments are used for at-home oral anticoagulant monitoring, and what improvements are needed, if any?

**GR** There are 4 such devices available in the United States. CoaguCheck (Roche) is one of the oldest. The others are Harmony INR (LifeScan), INRatio (HemoSense), and the ProTime Microcoagulation System (New Line Medical). All of these are approved by the US Food and Drug Administration (FDA) and are widely available.

Continued education and training to ensure patients don't lose their skills in collecting blood samples and running the instruments are of primary concern. The instruments need to be validated against a traditionally drawn venipuncture sample 2–3 times per year, or more frequently if there is some suspicion that the instrument is not working correctly. There must be QC checks done with the instruments, so there is some limitation. However, many QC features are built into the instruments. For

example, whenever a patient runs their own sample, a QC sample is being done simultaneously, so that the patient can be reassured that the result is valid.

## **H&O** Do you expect the use of patient self-management to increase over the coming years?

**GR** I think so. The devices are FDA-approved for monitoring patients with prosthetic valves and anticoagulation only. Most likely, they will be more widely approved, since current data indicate that they are safe and effective. Right now, the largest study is the one from Spain. It would be useful to have more data from the United States. If a US study demonstrated similar benefits from patient self-management compared with the standard anticoagulation clinic model, that would likely result in wider FDA approval of this anticoagulation monitoring model.

## **H&O** Does at-home monitoring have economic advantages?

**GR** Yes. Several cost-effectiveness studies have shown an advantage for self-management. However, the savings do not come from doing the test at home. In fact, the devices cost \$1,000–\$2,000. Rather, self-management lowers the complication rate, and thus cost. Bleeding events with an anticoagulant, for example, usually require a hospital stay, with transfusion in the majority of cases and sometimes surgery. Preventing adverse hemorrhagic events in just a few out of 100 patients is enough to make at-home testing and management very cost effective.

## **H&O** Are older patients suitable for self-management?

**GR** Age should not be a barrier to using this approach. Because older patients generally have more bleeding complications, they are ideal candidates for more frequent testing, in order to avoid those complications. The Spanish study included a large number of older patients and is therefore representative of real-world experience.

## **Suggested Reading**

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