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## Warfarin Management

### International Normalized Ratio Self-Testing and Warfarin Self-Dosing

Henry I. Bussey, PharmD; Marie Bussey, BBA

Until recently, most patients taking warfarin (brand name Coumadin) had to visit a laboratory and/or clinic every few weeks for an international normalized ratio (INR) blood test and adjustment of their warfarin dose. It is now possible for a patient to measure his/her INR (self-testing) with a finger-stick drop of blood with use of a small, portable, battery-powered device. Some self-testing patients adjust their dose of warfarin (self-dosing) based on a set of instructions. Even more recently, online systems have been developed to facilitate and improve self-testing and self-dosing. Patients who use self-testing have described it as life changing. A video on the ease and benefits of self-testing by a physician-patient named Dr Michael Schwartz can be viewed on ClotCare at [www.clotcare.org/inrselftestingvideo.aspx](http://www.clotcare.org/inrselftestingvideo.aspx).

#### Does Self-Testing Offer Benefits Beyond Ease and Convenience?

Yes. The additional benefits are why Medicare and other insurance companies started paying for self-testing for

most patients in March 2008. To understand the other potential benefits, however, one needs some background information. Warfarin is used to prevent blood clots that cause strokes, heart attacks, or other life-threatening conditions. If the dose of warfarin is too small, the INR will be low, and a patient may get a blood clot. If the dose is too large, the INR will be high, and a patient may develop a bleeding problem. In most cases, an INR between 2 and 3 indicates that the warfarin dose is about right. In one large study,<sup>1</sup> the risk of stroke caused by a blood clot increased 3 to 4 times when the INR was between 1.4 and 1.7 (not enough warfarin). In the same study, the risk of stroke caused by bleeding increased  $\approx 12$  times when the INR was  $>4.5$  (too much warfarin). Therefore, it is critical to avoid such extreme INRs. We must work together to keep the INR within the target range.

A review of self-testing and self-dosing studies found several potential benefits.<sup>2</sup> In addition to the ease of testing at home or while traveling, self-testing reduced the stress of man-

agement and improved quality of life. The review also found a 26% lower risk of death and a 42% lower rate of major blood clotting events. One interesting study<sup>3</sup> divided  $>700$  patients into 2 groups. One group did weekly self-dosing, and the other group was managed at an anticoagulation clinic. Although both groups had their INRs in range about the same amount of time, the self-dosing group had a 61% lower death rate and a 70% lower rate of major blood clots and major bleeding. This study did not report the time spent at extremely low and extremely high INRs, but some experts suspect that the better outcomes in the self-management group may be due to patients in that group staying closer to the target range.

#### What Factors Besides the INR Are Important for Self-Testing or Self-Management?

More frequent (weekly) INR testing helps keep INR values closer to the target range and prevents extremely low or high values. In some self-

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**Table 1. You Should Let Your Clinician Know If You Have**


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Missed or taken extra doses of warfarin
Changed your other prescription or nonprescription medications, or their doses
Had changes in your diet, vitamins, or food supplements; alcohol consumption or tobacco use; or physical activity
Been ill, had a fever, or received any injections
Had a change in bowel habits (such as diarrhea or constipation)
Noticed evidence of bleeding, such as bruising, pink or brown urine, red or black bowel movements, nose bleeds, gum bleeds, blood in your eye, coughing up blood, or heavy vaginal bleeding
Noticed any new symptoms that might suggest a mild stroke such as a change in vision, problems with balance or speaking, unusual headaches, numbness, tingling, or weakness
Noticed possible symptoms or signs of blood clots, such as a new pain, swelling, or tenderness in the leg, difficulty breathing, chest pain, or shortness of breath
Been to an emergency department, been hospitalized, or received instructions from another doctor

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testing systems, the clinician is only notified when a patient's INR is out of range. In such systems, the clinician must try to address the problem after the INR is already out of range. Self-testing systems that give the clinician all INRs, both in range or out, and other pertinent information may allow the clinician to prevent the INR from moving out of range. Table 1 lists information that may be useful to the clinician when managing warfarin therapy. Last, patients who are well educated about their condition and therapy have better treatment outcomes. Patients who self-test or self-dose usually receive additional patient education.

### Are INR Results With the Self-Testing Devices Reliable?

The short answer is yes, but there are some considerations. Several factors

can cause the INR test to be inaccurate, regardless of whether a self-testing device or laboratory is used. It is always reasonable to repeat the test if the results are different than expected. A repeat test may be done by using a fresh fingerstick and a point-of-care device, or the repeat value may be measured by the traditional laboratory method. In general, the 2 methods of INR determination usually agree fairly well when the INR is within the usual therapeutic range. Regardless of the method used, however, the INR test result becomes more variable at higher levels, so that repeat tests are likely to be somewhat different if the true INR is well above the usual therapeutic range. Results of routine INR self-testing results appear to be as reliable as laboratory results in most patients, and in 1 report of 2 studies, self-testing INR results were more reliable and more reproducible than the laboratory results.<sup>4</sup>

### Can Internet Use Improve Self-Testing or Self-Management?

Yes. At least 4 small studies have reported on the use of Internet-based systems to improve self-testing and self-dosing. These systems, which allow the patient to test from anywhere with Internet access, facilitate documentation and communication between the patient and clinician. Each study showed a significant improvement in INR control, and 2 of the trials achieved an exceptionally high 80% time in the therapeutic INR range, while virtually eliminating extreme INRs.<sup>5</sup> Further studies are needed to determine what impact this improved control will have on rates of blood clots and bleeding.

### Conclusion

Self-testing and self-dosing improve warfarin management, while reducing patient

**Table 2. Tips When Doing INR Self-Testing**


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Follow all of the manufacturer's instructions for use of the device and storage of the test strips.
Keep the device on a level surface that is free from vibration throughout the testing process.
Consider using methods to obtain a large enough drop of blood. These measures include
Hold the hand down and swing it back and forth to force blood into the finger.
Soak the hand in warm water or use a heating pad to increase blood flow (note: if warm water is used, be sure to completely dry the finger to avoid diluting the drop of blood).
Squeeze the base of the finger to trap blood in the finger.
Stand up to get the heart as high as possible above the finger to increase the blood flow.
Apply the drop of blood to the test strip as soon as possible. Excessive time delay may result in an inaccurately low INR.
Do not squeeze the finger excessively because this may cause an inaccurately low INR.
If someone other than the patient is performing the finger puncture, that person should reach across the patient and use the patient's far hand. This allows more flexibility of movement when positioning the hand over the test strip.

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INR indicates international normalized ratio.

stress and improving quality of life. Major blood clotting events and deaths can be greatly reduced while keeping the bleeding risk low. Recent studies in which Internet-based systems were combined with self-testing or self-dosing showed even better INR control, suggesting that even better outcomes are possible. For patients who are starting self-testing, Table 2 provides some helpful tips for achieving a good INR test result.

### Disclosures

Dr Bussey received the 3-year Distinguished Scholar in Thrombosis Award in 2008 from the Chest Foundation of the American College of Chest Physicians for a proposal to

develop and test an online automated monitoring and management system (ClotFree) for warfarin patients who perform self-testing. This project received additional support from Roche Diagnostics, Indianapolis, IN (makers of the CoaguChek XS INR testing device). M. Bussey's company developed and owns the ClotFree system.

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