# ANTICOAGULATION CLINIC: A SAFETY NET

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## BACKGROUND

**Oral anticoagulation with Coumadin (warfarin) is becoming more frequent as the US and global population ages and encounters those conditions considered appropriate for anticoagulation therapy.1 Two keys to therapeutic success are education and communication, both of which may be in short supply in a busy clinic or physician's office and which may be shortchanged despite good intentions on the part of both the patient and the physician. While the true incidence of complications from excessive or insufficient warfarin therapy is unknown, it is likely greater in the experience of any one physician or clinic if each physician manages his/her own patients. Complications do occur under the best of circumstances and to those with the best of intentions. The effectiveness and safety of warfarin therapy require maintenance of an international normalized ratio (INR) within a therapeutic range established for a variety of conditions. There are a number of predictors that may trigger a nontherapeutic INR: gender, age, body-mass index, height, weight, ethnicity, tobacco and alcohol abuse, interacting medications, vitamins, herbal supplements, dosage intensity, comorbid conditions, diet, frequency of INR testing and warfarin knowledge, to name a few.2-10**

**There is growing support for the concept of anticoagulation clinics.11-13 Some early evidence suggests therapeutic INR levels are more consistently obtained in clinics monitored by physicians or allied personnel such as nurses, pharmacists and physicians' assistants11-16 and through self-testing as an extension of a clinic setting.11-2° Currently, there is no uniform consensus on whether Coumadin or warfarin is the preferred anticoagulant.21**

## METHODIST DEBAKEY HEART CENTER ANTICOAGULATION CLINIC

Approximately five years ago, the Methodist DeBakey Cardiology Associates inaugurated an anticoagulation clinic to better serve our patients and other physicians who perceived a need for closer supervision of patients on anticoagulation. While initially staffed with a pare-rime nurse, a full-time registered nurse (RN) became necessary as the clinic rapidly evolved. The RN coordinator has 30 years of critical care/clinical nursing experience and is highly skilled in establishing patient rapport, projecting empathy and confidence that enables her to maintain excellent lines of communication. She obtained certification for "anticoagulant therapy managemenc" from the University of Souchern Indiana within che first year of the clinic's opening.

Early enrollment included approximately 150 patients, quickly increased to nearly 400 in the first year and now includes roughly 600 patients. Clinic protocol and guidelines were established according co the Oral Anticoagulation Therapy: Clinical and Operational Guidelines by Ansell et al.1 Each physician ucilizing the clinic agreed co the operational guidelines and signed the protocol and dosing schedule. Depending on the patient's diagnosis, the dosing guidelines provide some leeway for the RN to adjust the warfarin dose to maintain a therapeutic INR. Any corrections deemed necessary chat fall outside these guidelines are discussed with the patient's physician.

New patients meet with the RN for a one-hour educational seminar chat discusses the patient's diagnosis, indication for anticoagulation, warfarin education, interactions with drugs, alcohol and diet and ocher appropriate information. Signs and symptoms of bleeding and ocher potential complications are also reviewed, and the patient is shown an educational video to help clarify the program. After obtaining the initial INR baseline, Coumadin dosage is initiated and the patient is seen within three or four days for follow-up INR testing. Depending on the results, the panenc returns for additional INR within one week. Laboratory testing over che first two months is weekly or until che INR is stable, then bi-weekly for the following month and monthly for the duration of the treatment unless timing alterations are indicated. Patients are instructed co call if they are placed on antibiotics or ocher new drugs, or if invasive procedures are scheduled, so chat che Coumadin may be adjusted accordingly and an INR follow-up scheduled. When patients return for follow-up INR testing, they see the nurse to review the results, make any dose changes and discuss any concerns; a follow-up appointment is also scheduled.

Once established, the patient may have laboratory testing completed at an oucside facility and faxed to the office. The nurse calls the patient with the results, adjusts dosing as needed, discusses any concerns and schedules follow-up testing. If a patient does not have blood tested as scheduled within 15 days and then 30 days, the nurse calls the patient as a reminder. A letter is

mailed co the patient after rwo months, and the process of termination may begin if che patient remains noncompliam. Ac chis point, the physician is notified of "noncompliance" issues and steps are taken to assure the patient's safety during treatment. If a patient is terminated from the program, care of that patient is redirected to a cardiologist or a primary care physician for anticoagulation management.

An overall average of 50 percent of clinic patients maintain therapeutic levels. Ar any one rime, 35 percent of patients have less than therapeutic INR ranges due largely to interventional procedures that require chem to be off Coumadin for a period of time. Alternative methods of anticoagulation are often employed during chis time. Fifteen percent have been tracked with excessive levels, yet thanks co ongoing one-on-one patient/nurse communication, only a few have resulted in hospitalizations for serious bleeds or loss of life. Less than 10 percent of patients are considered noncompliant. The clinic currently has 11 physicians with patients enrolled for anticoagulation therapy management.

INR testing in our clinic is performed with a screening test (the CoaguChek S $S_{y_s}$tem machine) that utilizes a finger stick.[22,24] We regularly compare the results of venous puncture with free-standing laboratories and have found a variance of less than 2 percent. The CoaguChek S System machine cannot give an accurate INR reading for an elevated level over five. Patients who present with an INR greater than five are instructed to withhold the anticoagulant and sent co the commercial lab for a venous puncture to confirm the correct INR and co determine the next approach. If a patient is asymptomatic, chis would include dose adjustment and returning to che office within three days for retesting; the physician is notified for further recommendations. When the patient is symptomatic or the INR level is greater than seven, the physician is notified and the patient is sent to The

Methodist Hospital emergency room for follow-up. If the medication is resumed, the patient will return for INR resting as if they were a new patient.

## SUMMARY

The Methodist DeBakey Cardiology Associates Anticoagulation Clinic has provided all of the participating physicians a peace of mind not previously enjoyed with patients on anticoagulant therapy. Our patients are safer, far better educated in rhe nefarious ways of anticoagulation therapy and enjoy a strong rapport with their physicians. The clinic and its RN coordinator are joint recipients of the Roche Diagnostics' DREAM Award for excellence in anticoagulation management. There are approximately 2,500 anticoagulation clinics throughout the nation, and less than ten percent receive chis award.

We have begun a program of self-testing with a few selected patients. The cost of self-testing remains a problem for many, and chere are additional issues to be addressed for these patients.[20] But when a large volume of patients are to be followed, we believe the concept of an anticoagulant clinic is sound and provides a safer milieu for patients requiring anticoagulant cherapy.21 We are cognizant chat an effective and successful anticoagulation clinic depends upon management skills chat enhance communication with and education of patients. On the horizon are new drugs that may completely alter our current methods of ourpatient anticoagulation and render ancicoagulanc clinics irrelevant. Should that be the case, we trust that the management and communication skills learned here will be applicable to other aspects of our organization.[25]

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