

A Tool to Assess Compliance in Anticoagulation Management

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Abstract

Compliance with any medication can be quite variable and difficult to assess. Assessment becomes particularly important in the case of a medication, such as warfarin, that has multiple interactions and requires frequent laboratory monitoring. Good compliance with medication dosage and blood test monitoring are necessary to safely manage warfarin patients. The Community Anticoagulation Therapy (CAT) Clinic, established in 2005 through a grant from the Agency for Healthcare Research and Quality (AHRQ), Partnerships in Implementing Patient Safety (PIPS), measures compliance with warfarin therapy. The Clinic developed a tool called the “Warfarin Compliance Assessment Scale,” which assigns points to categories. The assessment scale provides the CAT Clinic with an objective way to measure an individual patient’s compliance in using warfarin. It is important to note that the scores of patients enrolled to date indicate an increase in their compliance over time. This paper describes the function and benefit of the compliance tool in the management of anticoagulation therapy.

Background

In 2005, the Agency for Healthcare Research and Quality (AHRQ) awarded a 2-year grant (Award No. 5 U18 HS015830) to Kirkwood Community College and Physicians’ Clinic of Iowa (PCI). The grant supported the creation of the Community Anticoagulation Therapy (CAT) Clinic and the Cedar Rapids Healthcare Alliance (CRHA), a nonprofit corporation established to oversee the CAT Clinic. The project’s broad coalition of stakeholders included provider organizations, hospitals, payers, employers, educational institutions, and patients. Another important project partner was Rockwell Collins, a large local employer that designs and manufactures aircraft avionics systems and has extensive experience in Lean, Six Sigma[®], and ISO 9000[™] quality systems. These stakeholders realized that working together on a community level was a positive way to improve patient care and safety.

In writing the grant, project investigators determined that anticoagulation management was a safety issue within the community. At that time, January through December 2004, there was no dedicated anticoagulation service in the area, and adverse drug events (ADEs) related to anticoagulation accounted for 25 percent of all ADEs at each of the two 400-bed community hospitals. It was estimated that 3,000 to 4,000 patients in our community of 150,000 were taking warfarin (Coumadin[®]), and that approximately 60 admissions related to bleeding and clotting events occurred annually at each hospital.

At the time the grant application was submitted, the National Quality Forum listed anticoagulation management utilizing a dedicated anticoagulation service as one of the 30 National Patient Safety Practices.¹ Warfarin was also included on the Institute of Safe Medication Practices (ISMP) list of high-alert medications.² In 2004, the Joint Commission listed to “improve the safety of using medications”³ as a requirement for their National Patient Safety Goals.

The Problem

The Cedar Rapids provider community serves a growing elderly population. The Cedar Rapids Chamber of Commerce reported that in 2005 and 2006, within three area counties (Benton, Jones, and Linn), there were 15,370 adults aged 65 to 74 and an additional 15,320 over age 75. Combined, this represents 13 percent of the population of these three counties.⁴ The fastest-growing segment of the population is adults over age 80; patients in this group frequently make mistakes in taking their medications. In a 2004 Information Technology Association of America Teleconference titled *Using a Patient-Based Information Technology Approach for Solving Prescription Medication Non-Compliance*, it was reported that (1) up to 60 percent of all medications prescribed are taken incorrectly or not at all, (2) up to 90 percent of elderly patients make some medication errors, and (3) up to 35 percent of the elderly make potentially serious errors when taking their prescribed medications.⁵

Since anticoagulation therapy is particularly risky, patients need to be aware of the risks and must closely follow established treatment protocols. Health care providers must also make appropriate treatment decisions by monitoring patients regularly and following established protocols. However, because many variables can affect an individual’s anticoagulation levels and compliance is difficult to assess, it can be quite challenging for clinicians to consistently monitor outpatients on anticoagulation medication. In order to meet these challenges, many health care facilities have established outpatient anticoagulation clinics for their patients receiving warfarin.

The purposes of the CAT Clinic include:

- Provide consistent monitoring of patients taking warfarin.
- Ensure that the international normalized ratio (INR) levels are within target range.
- Decrease adverse drug events (ADEs).

Although the structure of anticoagulation clinics varies among institutions, most clinics share some of the following policies and work-related procedures:

- Identify the roles and duties of clinic staff and personnel.
- Identify which patients are viable anticoagulation clinic enrollees.
- Develop electronic systems to track patients due for lab tests, document results of lab tests, and document successful patient management.
- Develop protocols for managing patient results and for timely reporting of results to physicians and health care professionals.
- Develop and update resources for ongoing patient education.

The Solution: A Compliance-Assessment Tool

Many different factors can affect how warfarin affects patients and their INR levels, which are used to adjust the required warfarin medication dosage. Quite early in our experience, it became apparent that there was no established method to measure patient compliance with anticoagulation management. For this reason, the CAT Clinic staff designed and developed a compliance tool, the Warfarin Compliance Assessment Scale (WCAS), that assigns points to the following categories (see Table 1):

- Medication use, such as the addition/discontinuance of antibiotics.
- Amiodarone.
- Herbal supplements, aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs).
- Dietary intake of foods high in vitamin K.
- Alcohol intake.
- Missed/extra doses.

Use of the WCAS assists the CAT clinic nurses when making dosage decisions and provides a simple way to monitor the effectiveness of overall warfarin management.

The Rockwell Collins improvement specialists provided guidance in the project team's use of Lean and Six Sigma concepts in their analysis of the current anticoagulation system in two busy cardiology practices in Cedar Rapids. Their analysis produced valuable objective advice on ways to improve the warfarin management system.

Under their expert leadership, the CAT Clinic designed and developed a Web-based database to precisely document individual patient visits. Each patient is specifically identified in the database, which incorporates the WCAS compliance tool, assigning points to each item on the compliance assessment scale. After a CAT Clinic patient's blood draw is completed and the CAT Clinic nurse has received the INR level results, the nurse can contact the patient and assess the patient's compliance with each of the items on the WCAS. If the patient reports a change in any of the items, the nurse can easily update the patient's individual record by clicking on the drop-down list and choosing the most appropriate item (Figure 1).

The database then calculates a score for the individual patient based on the number of visits and the total for each item selected from the compliance assessment. For instance, if a patient reported missing two doses of warfarin since the last INR, 2 points are assigned. If the patient had two INRs that month and a score of 2.0, the compliance score is calculated as 2.0 points divided by two visits, or 1.0.

Clinic nurses can use this information to help educate patients about certain important aspects of their medication compliance. In cases where patients may be consistently missing warfarin doses, the nurse and patient can work together to plan ways to improve compliance. In addition, patients' compliance scores can be reviewed in aggregate. The patient's score is tallied each month and plotted graphically. Figure 2 documents a decrease (i.e., improvement) in average compliance score over time, as patients become more educated about their individual dosing requirements, illustrating an increase in patients' understanding and compliance with their warfarin therapy.

Table 1. Warfarin compliance-assessment scale

Compliance categories	Points	Patient score
Missed doses (not prescribed)		
Missed 1 dose in a week	1	
Missed 2 doses in a week	2	
Missed 3 or more doses	3	
Additional doses (not prescribed)		
Took 1 extra dose	1	
Took 2 extra doses	2	
Took 3 or more doses	3	
Diet: How has your diet changed over the past week?		
Ate 1-2 <u>more</u> servings than usual of vitamin K foods	1	
Ate 3-4 <u>more</u> servings than usual of vitamin K foods	2	
Ate 4 or <u>more</u> servings than usual of vitamin K foods	3	
Ate 1-2 <u>less</u> servings than usual of vitamin K foods	1	
Ate 3-4 <u>less</u> servings than usual of vitamin K foods	2	
Ate 4 or <u>less</u> servings than usual of vitamin K foods	3	
Alcohol consumption		
Drank the usual amount of alcohol in the past week	0	
Drank more than your usual amount of alcohol this past week	1	
Binged (drank excessive amounts of alcohol) 1 or more times this past week	2	
Medications		
Started or stopped an antibiotic in the past week	Yes - 1 No - 0	
Started or stopped an herbal supplement in the past week	Yes - 1 No - 0	
Started or stopped an aspirin-containing product or an NSAID in the past week	Yes - 1 No - 0	
Started or stopped amiodarone or another medication this week	Yes - 1 No - 0	
Total Score		

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The CAT Clinic has successfully implemented several interventions that might affect patients' compliance scores. Each patient referred to the clinic receives comprehensive warfarin education, and the nurse conducts a "brown-bag" review of all their current medications. During this educational session, the nurse and patient review a booklet entitled, "*My Guide to Warfarin Therapy*," which was developed by several nursing faculty members at Kirkwood Community College who were studying the issue of health literacy.⁶

If INR too high or low, patient reason :

CAT Score Visit Assessment

Any missed doses (not prescribed)? :	<input type="text" value="No missed doses since last reading (0 pts)"/>
Any extra doses (not prescribed)? :	<input type="text" value="No extra doses since last reading (0 pts)"/>
More <u>Vitamin K</u> in diet? :	<input type="text" value="No additional Vitamin K taken since last reading (0 pts)"/>
Less <u>Vitamin K</u> in diet? :	<input type="text" value="No additional Vitamin K taken since last reading (0 pts)"/>
Alcohol Consumption :	<input type="text" value="Drank the usual amount of alcohol since last reading (0 pts)"/>
Started/Stopped an Antibiotic:	<input type="text" value="No (0 pts)"/>
Started/Stopped an herbal supplement:	<input type="text" value="No (0 pts)"/>
Started/Stopped an aspirin or NSAID:	<input type="text" value="No (0 pts)"/>
Started/Stopped an Amiodarone:	<input type="text" value="No (0 pts)"/>

Figure 1. INRPro[®] database WCAS page.

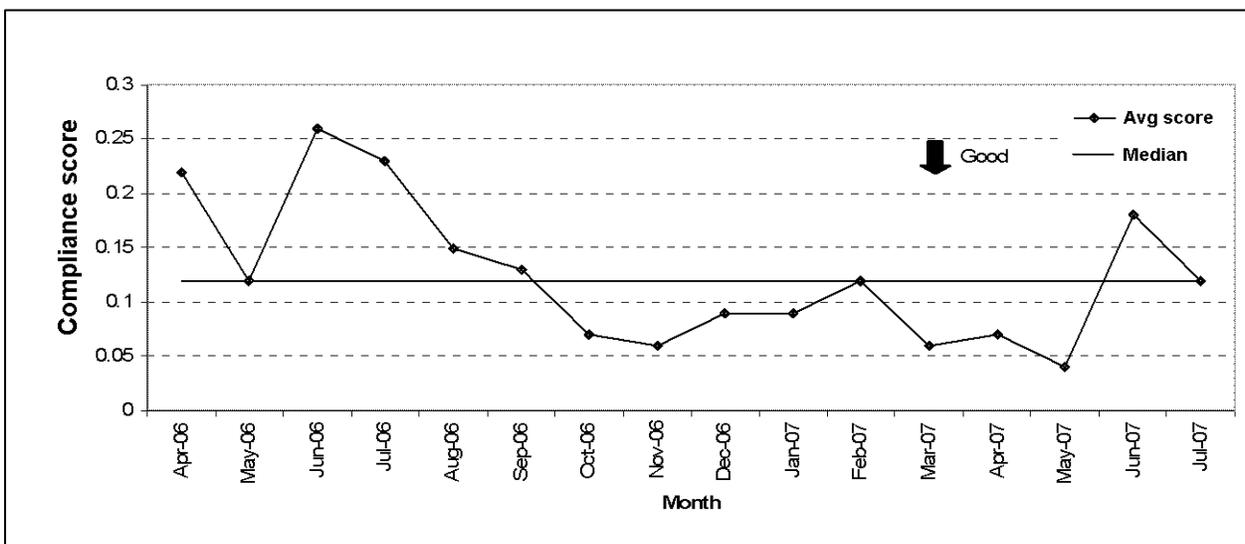


Figure 2. Average CAT compliance score, from April 2006 to July 2007.

Health literacy concerns are compounded by the high number of older adults living in the Cedar Rapids community who are taking warfarin. Many of these adults require intensive guidance in order to help them comply with their unique medication requirements. While this guide was in development, a group of participants at a local Cedar Rapids senior center reviewed the contents and provided valuable feedback that served to strengthen the guide. The nursing instructors reviewed the existing warfarin patient education materials and found that they were too difficult for patients to understand because they:

- Were written using medical language that was too technical.
- Were printed in a color other than black ink on white paper.
- Used too small a font and contained too few pictures (e.g., not enough “white space”).

The new guide is written at a fifth-to-sixth grade level and is printed in black ink on white paper using a larger size font. The guide uses numerous pictures and bullet points to explain important aspects of warfarin therapy.

During the “brown-bag” medication review, patients bring in their actual prescription pill bottles and all of their over-the-counter medications, as well as a list of medications they are currently taking. CAT Clinic nurses review each medication name, indication, dose, and frequency with the patient. If the patient has a question or does not understand something, the nurse uses this as an opportunity to educate the patient about his or her medication. If there is a discrepancy between the medication listed and the medication taken by the patient, the nurse contacts the patient’s primary care physician for clarification and confirms the correct medication and dosage with the patient.

Another intervention found to be useful in monitoring patient medication compliance and making dosage decisions is the control chart (Figure 3), which provides a statistical signal that a process might have gone awry, allowing the operator to make the necessary adjustments to bring the process back into control.⁷ The CAT Clinic utilizes the database mentioned above which displays a control chart of each patient’s historical INR values along with a histogram. This information allows the CAT Clinic nurse to make statistically based decisions on whether the patient needs a dose change, instead of basing decisions solely on the most recent readings. The compliance assessments, along with the use of the control chart, are simple techniques for making objective dosage decisions for the CAT Clinic patient.

Conclusion

Good compliance with medication and blood test monitoring are necessary for safely managing patients taking warfarin. In our community, and in most others, there usually is no established method to actually measure patient compliance with anticoagulation therapy. The AHRQ PIPS grant provided the necessary support to enable a community-wide group of health care professionals and manufacturing quality engineers to join forces to find solutions to this problem. The CAT Clinic staff and the quality engineers worked together to develop a compliance tool that assigns points to various aspects of medication use, diet, and alcohol use.

In addition to assisting clinicians in making warfarin dosage decisions, the WCAS score has become useful for assessing and updating patients' plans of care. The tool can be customized to review an individual patient's compliance, and it can be aggregated to provide accurate data on all patients in an anticoagulation clinic. The tool is easy to use, provides an objective measure of patient compliance with warfarin therapy, and has made a positive impact on patients seen in the CAT Clinic.

Acknowledgments

This manuscript is the result of work supported by a grant from the Agency for Healthcare Research and Quality (AHRQ) and The Wellmark Foundation. The grant was awarded to Kirkwood Community College and Physicians' Clinic of Iowa, Partnerships in Implementing Patient Safety grant project Award No: 5 U18 HS015830.

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References

1. Safe practices for better healthcare: A consensus report. Washington, DC: The National Quality Forum; 2003. Available at: www.qualityforum.org/pdf/reports/safe_practices.pdf. Accessed March 16, 2008.
2. Survey on high-alert medications: Differences between nursing and pharmacy perspectives revealed. ISMP medication safety alert. Huntingdon Valley, PA: Institute for Safe Medication Practices; 2003. Available at: www.ismp.org/Newsletters/acutecare/articles/20031016.asp. Accessed March 16, 2008.
3. National patient safety goals 2008. Oakbrook Terrace, IL: Joint Commission; 2008. Available at: www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals. Accessed March 16, 2008.
4. Demographic information for the Greater Cedar Rapids area, 2005-2006. A project of Priority ONE. Cedar Rapids, IA: Economic Development Division, Cedar Rapids Chamber of Commerce.
5. Using a patient-based information technology approach for solving prescription medication non-compliance. Arlington, VA: Information Technology Association of America; 2004. Available at: www.itaa.org/isecevents/presentations/1154.ppt#356,9,How%20Much%20Does%20Noncompliance%20Cost. Accessed March 16, 2008.
6. My guide to warfarin therapy. Cedar Rapids, IA: Cedar Rapids Healthcare Alliance; 2006. Available at: <http://faculty.kirkwood.edu/kumsche/My%20Guide%20to%20Warfarin%20Therapy.pdf>. Accessed June 12, 2008.
7. Statistical quality control handbook. Indianapolis, IN: Western Electric Corporation; 1956.