

**The Effects of An Anticoagulation Program on Patient compliance following Total Joint  
Replacement**

by

Aisha Stone Corr, RN

TERRI JONES DNP, MSN, BSN, RN, Faculty Mentor and Chair

KATHERINE SHEPPARD, PhD, MA, MSN, RN, Committee Member

MARY BASSEY, RN, Committee Member

Patrick Robinson, PhD, Dean, School of Nursing and Health Sciences

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**Abstract**

Patients undergoing major orthopedic surgery have shown the potential for deep vein thrombosis (DVT) ranging from 46% to 60% postoperatively. To avoid this risk, home rehabilitation is recommended, including nursing and/or physical therapy, proper monitoring of international normalized ratios (INRs), and anticoagulant medication compliance. This quality improvement initiative was done to address the gap in care of inadequate tools for the clinicians to properly manage anticoagulant dependent patients as well as the *inconsistency of anticoagulation therapy management and care*. Applying the five steps of the Iowa model of evidence-based practice, an anticoagulation therapy program was created including an organizational clinician certification. The primary outcome variable involved patients' INR values; secondary outcomes included patient satisfaction scores, evaluation of the number of rehospitalizations and patient adverse events; monthly rating scores from Medicare's Home Health Compare; and collaboration of the organization's root cause analysis team. No significant improvements were observed in the primary outcomes during data collection. However, Press Ganey patient satisfaction ratings related to medication education and disease process teaching showed an improvement. Home Health Compare ratings remained the same. Other quality improvement studies may benefit from the lessons learned, and continued efforts to improve anticoagulation in orthopedic surgery patients are needed.

*Keywords: warfarin, international normalized ratio, deep vein thrombosis, medication barriers, orthopedic surgery patients, medication compliance.*

## **The Effects of An Anticoagulation Program on Patient compliance following Total Joint Replacement**

Patients undergoing major orthopedic surgery face the highest risk for blood clots over other types of surgery; studies have shown that the potential for deep vein thrombosis (DVT) ranges from 46% to 60%. Patients experiencing DVT after major orthopedic surgery have been shown to have a 3.4-day average increase in hospitalization days, coinciding with a \$6,000 average increase in medical charges when assessed 90 days after surgery (Nutescu, Shorr, Farrelly, Horblyuk, & Franklin, 2008). In addition, these patients with DVT have a 22% increase in the average number of outpatient visits and a 74% increase in the average number of emergency department visits (Nutescu et al., 2008). This population also has a tendency to show reduced self-efficacy, motivation, and confidence following discharge from orthopedic surgery (Tung, Cooke, & Moyle, 2013).

Orthopedic patients are routinely discharged home from the hospital requiring home rehabilitation and anticoagulation therapy monitoring. Skilled nurses or physical therapists are scheduled for the initial and ongoing home care services. The visits require standard assessments of laboratory values, medication management, teaching, collaboration and monitoring. Due to the lack of standards of care in this area, the clinician establishes plans of care based on their knowledge, experiences, and expertise. Incongruence of care among the clinicians leaves an opportunity for patients to receive less than the optimal levels of care. This quality project was proposed to provide clinicians with a hands-on equipment refresher course, written reference tools, protocols and standards to adequately monitor and, coordinate care with the follow up physician.

### **Problem Description**

The gap in practice addressed in this project included the need for clinicians who are well versed in anticoagulation therapy to address potential complications and barriers to medication compliance in orthopedic patients, including their emotional and physical recovery. To address many facets of a patient's holistic treatment specialized anticoagulation therapy incorporating organizational and clinician intervention is imperative for organizations treating orthopedic patients. P.J.White (2010) indicated that decades of clinical experience and implementation of anticoagulation care models have contributed considerably to improved patient safety with the use of warfarin.

### **Available Knowledge**

Numerous clinical guidelines recommend anticoagulation therapy for patients after orthopedic surgery. Routine guidelines include medication reconciliation, adherence to prescribed drugs, and continuing the drug unless instructed by the physician to stop (Lenzini et al., 2008; Matthes & Albus, 2014; Schlemmer, 2011; Stewart, Gentry, & Freshour, 2012; White, 2010; Xu, Li, Ye, & Lu, 2014). Prior to the use of oral anticoagulation therapy, clinicians assess for contraindications to anticoagulation therapy, active major bleeding, or DVTs (Maynard, Humber, & Jenkins, 2014). Patients are taught to stay in contact with their surgeon and/or consult with health care providers if there is an increased risk of bleeding (Hasan et al., 2011; Spyropoulos, Hurley, Ciesla, & de Lissovoy, 2002). Additionally, patients are instructed to maintain a log of dosage, INR results, and adjustments (Fitzmaurice & Machin, 2001; Shah & Robinson, 2011; Tung et al., 2013). Both the clinician and patient must be aware that dietary factors such as dark and yellow vegetables and foods high in vitamin K can affect the INR results with warfarin (Friedman, 2012; Friedman et al., 2008; Schlemmer, 2011).

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There is considerable data indicating that improper anticoagulation treatment can lead to major complications; therefore, the goal is to obtain the lowest possible effective INR and to conduct regular monitoring to avoid over anticoagulation. In the study by Blanchard and Ansell (2005), major bleeding occurred in 1.0% to 11.3% of the patients treated with warfarin, and the incidence of bleeding was higher in those older than 70 years of age (Hutten, Lensing, Kraaijenhagen and Prins, 1999). Incidentally, 70 years of age is the average age of the joint replacement patient in this home care agency. The prevalence of major anticoagulation complications is related to poor management, the incidence of adverse drug reactions, the presence of comorbidities, and polypharmacy. However, it is not possible to identify which patients will have clinically significant complications or fatal DVTs (Blanchard & Ansell, 2005).

Patient compliance with anticoagulation therapy is imperative to achieve the benefits of the therapy while avoiding its adverse effects. Compiled research data indicate compliance issues are related to irregular therapeutic INR ranges, improper anticoagulation medication administration, and improper dietary management. Patient teaching guidelines should address taking the anticoagulants the same time each day, noting or logging INR blood levels and changing dosing information, and adhering to strict dietary modifications. Such efforts should provide consistency in blood levels (Alton, March, Mallery, & Fiandt, 2015; Matthes & Albus, 2014; Rice & Walsh, 2001).

Medication errors have been established as a threat to patient safety and compliance. These errors may be related to professional practice, procedures, and organization systems (Xu et al., 2014). Medication errors related to system incongruences may include improper prescriptions, inaccurate dosing communication, untimely administration, inaccurate patient knowledge and education, and incorrect INR monitoring and interpretation of blood levels

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yielding potential adverse events (National Coordinating Council for Medication Error Reporting & Prevention, 2016). Approximately 30% to 50% of people on medications do not take them as prescribed (Schwartz & Smith, 2016). Lack of compliance is usually unintentional, but is related to forgetting, running out of medication, or being careless about the dosing schedule (Schwartz & Smith, 2016).

Many patients take numerous drugs which increases the risk of drug interactions with anticoagulants, particularly warfarin. This can lead to a noncompliance or avoidance barrier for the patient due to adverse effects. Medication reconciliation assessment determines the what, when, and how of medication administration for all medications, including anticoagulants. A medication review should be done on the first clinical visit to aid in the identification of potential interactions and any barriers or red flags (Stewart et al., 2012).

When addressing barriers to effective home administration of anticoagulants, the patient's knowledge of various elements that can influence their INR readings—including drugs, vitamin K, foods, alcohol, and compliance with warfarin—must be considered (Alton et al., 2015; Mattes & Albus, 2014; Nutescu et al., 2008; Rice & Walsh, 2001; Schlemmer, 2011; Schwartz & Smith, 2016; Stafford, van Tienen, Bereznicki, & Peterson, 2010; White, 2010). Those with more education scored significantly better on the knowledge questionnaire than those with less formal education. In addition, patients seen in the pharmacist-run medication adherence clinic had better INR readings than those seen in physician offices, suggesting the need for cooperative efforts among physicians, nurses, and pharmacists to achieve better therapeutic outcomes. Results highlight that lack of education on anticoagulation can be a barrier to appropriate anticoagulation.

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Homebound status is a criterion used to qualify a patient for home care services; being homebound and available when the clinician needs to measure INR levels can be an inconvenience for the patient, presenting a barrier to oral anticoagulation therapy (Alton et al., 2015; Stafford et al., 2012; Vincze & Parthan, 2004). Other key terms used to describe barriers were lack of control over one's own health, frequency of testing, fluctuation of therapeutic levels, cost of home care, result variation between labs and home testing, medication compliance, and communication with the physician (Shah & Robinson, 2011, p. 6).

Addressing language barriers can potentially improve compliance among Spanish-speaking clients (Alton et al., 2015; Bereznicki & Peterson, 2010; Eisenstein, 2012; Stafford et al., 2012). Some Spanish-speaking patients may have difficulty reading and understanding written prescription labels as well as meeting the cost of medications. Providing language-specific patient education written handouts can resolve barriers of misunderstanding and potentially medication errors.

When planning an anticoagulation management program, the use of standardized monitoring guidelines and dosing algorithms that incorporate individual patient factors, comorbid disease states, and potential drug interactions is needed (White, 2010). A five-point systematic management approach is imperative to address the issues of medication errors and patient safety. The five points consist of (a) conducting training programs; (b) optimizing medication policies; (c) refining drug management; (d) enhancing the safety process for medication administration; and (e) supervising the process of medication administration (Xu et al., 2014).

### **Rationale**

The use of the Iowa Model of evidence-based practice theoretical framework contributed to the success of this project. This framework allows for a detail-oriented focus on knowledge, proficiency, and problem-focused research leading staff to question current clinical practices and whether improvements are warranted based on current research (Doody & Doody, 2011). Stakeholders were informed of similar health care settings who found it to be best practice to standardize care to improve quality, which the anticoagulation program would fulfill. Practice recommendations should be based on identifiable benefits and risks to the patients (Doody & Doody). Noted benefits of the anticoagulation program include providing the clinician with a standard of practice to follow when case managing anticoagulation dependent patients.

The agencies' Quality Improvement Performance and Improvement (QAPI) committee was functioning prior to the project and all leaders agreed to attend all meetings and participate as needed. The team was responsible for reviewing the organization's data, determine quality of care issues, research standards of care or best practices to address the issue, implement a quality of care initiative, and evaluate the initiative effectiveness and ongoing monitoring efforts.

### **Specific Aims**

The aim of this project was to determine if removing barriers to anticoagulant medication compliance in postoperative total joint patients would affect their therapeutic blood levels. This project included certification of all clinicians on the CoaguCheck XS System to ensure consistency in anticoagulation management and compliance with Clinical Implementation Laboratory Amendments (CLIA), which is needed for Medicare reimbursement. A specialized anticoagulation therapy program was created to assign one clinician to each patient to provide individualized coaching and monitoring. By addressing the barriers to anticoagulant medication



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compliance, the project potentially reduced avoidable rehospitalizations related to DVT, abnormal bleeding, and/or other complications, improved the quality of care by clinicians, and improved patient satisfaction.

### **Methods**

#### **Intervention**

Following a literature review to determine best practice, a team was formed to implement a staff completion of an anticoagulation certification program as part of the agency's annual skills fair. The quality assurance project improvement team and participating leadership worked collaboratively on the mandatory skills fair to ensure that all clinicians were tested for relevant competencies, including patient anticoagulation management. Anticoagulation monitoring and management procedures, appropriate patient education addressing myths, and INR maintenance were the main areas of focus. Each clinician was given written tools for future reference and patient education. Strategies were discussed for developing appropriate patient plans of care, advocating for and improving patients' involvement and knowledge base, recognizing signs of noncompliance, improving physician and patient communication, and documenting patient compliance with care management. By identifying early noncompliance, as evidenced by instability of INR readings, clinicians were able to reverse INR levels and potentially avert rehospitalization related to DVTs.

#### **Measures**

The primary measurable variable of this project was *patients' INR values*. INR results were tracked for all orthopedic patients treated at this agency over a 4-week period before and after the certification intervention. Tracking blood levels weekly allowed a determination of

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whether barriers to compliance were being addressed and whether interventions were effective in optimizing patients' anticoagulation therapy. When clinicians understand how medications work and medications' interactions with other drugs, dietary factors and diseases, patients will be assessed for barriers to compliance and any issues keeping them from being compliant can be addressed (Stewart et al., 2012)

INR values were retrieved from the institutional documentation software, Kinnser, which is used by all clinicians to document the care given to patients. Typically, patients have their INR checked twice a week. These data provided the ability to compare the readings and determine if medication compliance could effectively impact INR blood levels (stability in blood levels is a good indication of the patient's compliance with medication).

Monthly quality-related data were also collected before and after the intervention and were used in conjunction with INR values to determine the effectiveness of this intervention:

- *Patient satisfaction scores*—from Press Ganey each month
- *The number of rehospitalizations and the number of patient adverse events from Certification and Survey Provider Enhanced Reports (CASPER)*. The report allows comparison to national ratings of home care agencies, as well as ratings from prior reports and current ratings or statistics.
- *Monthly ratings from Home Health Compare*, also from the Centers for Medicare and Medicaid Services. Home Health Compare uses a five-star rating system to compare the quality of all home care agencies certified by Medicare, with five stars indicating the agency is above average. The Centers for Medicare and Medicaid Services (2016) indicated that the rating is drawn from patient surveys and agency state survey reports

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and incorporates a number of changes based on input received from stakeholders as well as ongoing data analysis.

- *Reports from the Root Cause Analysis team.* This team, which comprises the same members as the quality assurance project improvement team, investigates patient adverse events and rehospitalizations reported through CASPER. Qualitative information from the root cause analyses was considered when analyzing the results.

All data collected were used to determine if this agency's patient population benefited from the pilot specialized anticoagulation therapy program

### **Analysis**

To determine whether the primary measurable variables showed an improvement on patient satisfaction scores, a comparison of two means were determined. Measures of central tendency means were utilized when analyzing the patient's INR values pre and post project implementation.

### **Ethical Considerations**

The project was approved by the Institutional Review Board committee of Capella University and by the project site.

### **Results**

Among the 22 nurses and physical therapists employed on the date of the skills fair, 21, or 95%, completed the education and certification process for anticoagulation. A total of 26 orthopedic patient's records were reviewed in the pre-implementation study period to determine relevance of the project and 26 in the post-implementation period to determine effectiveness of the project. As shown in Table 1, these patients had limited knowledge of anticoagulation on their initial visit.

Table 1

*Baseline Anticoagulation Knowledge of the 26 Participants*

<i>n=26</i>	Participants answering yes %
Did your doctor explain the reason for taking Warfarin?	100
Are you aware of the dietary restrictions and frequent INR lab monitoring required when taking Warfarin?	75
Are you aware of the consequences of dietary and medication noncompliance with an anticoagulation regime?	50
Are there any barriers keeping you from taking medication on time, correct dosage, and not adhering to dietary restrictions?	75

The primary outcome variable was patients' INR values over a 4-week timeframe.

Expected INR readings for compliant anticoagulant-dependent patients are between 1.5 and 2.5; out-of-range fluctuations would be indicative of noncompliance. Twenty six patient records were reviewed over a four-week timeframe. In an overall comparison of values of pre versus post implementation period, the ranges were not statistically significant. None of the values exceeded 3.0.

Patient satisfaction scores before and after the anticoagulation program were reviewed by the quality assurance performance improvement committee. As shown in Table 2, before the program, patient scores averaged 5 out of 10. A statistically significant improvement (80%) was seen after the program, with the average score improving to 9 out of 10.

Table 2

*Patient Satisfaction Results Before and After Program Implementation*

Question	Preimplementation score	Postimplementation score
1. Are you satisfied with the communication of your nurse/clinician regarding your plan of care?	4	9
2. Are you satisfied with the communication of your nurse/clinician regarding your disease process and medication administration?	4	10
3. Were you provided with the consistent clinician care?	7	9
4. Do you believe your nurse was well educated and competent to handle all of your medical needs?	5	10
Average	5	10

No rehospitalizations or reported adverse events related to DVTs were noted in the 4-week pre or post-implementation period. As such, there were also no reports to review from the home care agency Root Cause Analysis team.

Medicare Home Health Compare Star ratings are based on reported data from the agency. Since the Medicare website is updated quarterly, the impact of the anticoagulation program on the score was not available at the time of this writing.

## **Discussion**

### **Summary**

DVTs and abnormal bleeding have serious implications for the well-being of anticoagulation-dependent orthopedic patients. Patients who are discharged from the hospital with home care services have the expectation of not returning to the hospital. Pain, wound management, and physical debility hinder their welfare, which can lead to noncompliance and

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complications. The main purpose of the program described here was to equip clinicians with the tools to properly identify medication and disease process noncompliance, thus reducing potential rehospitalizations related to DVTs. The anticoagulation program was created to improve competency among clinicians, determine the effectiveness of the patient knowledge base, and improve clinical disease process management and the agency's quality of care.

### **Interpretation**

No significant improvements in INR values were observed in the 4 weeks of postimplementation patient data records. However, if the process had been over a longer period, improvement in several organization areas would have become evident. Prior to the project implementation, clinicians were not properly trained on use of the CoaguCheck XS anticoagulation machine, blood extraction techniques, and interpretation of machine errors. Due to improper use and training, clinicians were not able to get adequate amounts of blood required for an INR reading; therefore, they used numerous INR strips during several attempts to obtain a sample. Each strip costs \$4 and the patient suffered a finger puncture for each strip use. With the coagulation certification, the company should see improved revenues and patient satisfaction with the INR testing.

In addition, Press Ganey patient satisfaction ratings showed that patients perceived receiving better education from the clinicians, implying that the clinicians were well prepared to share important medication and disease process information with their patients. The certification training equipped clinicians with tools to shift their mindset from just performing INR tests and calling the physician, to taking a broader role in assessing barriers to compliance, educating

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patients, and being proactive in keeping the patient from experiencing the consequences of noncompliance.

The clinicians appreciated the program and its intended purpose with the emphasis on improving the standards of practice related to orthopedic patients' anticoagulation. The author was available at all times for consultative support on clinical critical thinking, deteriorating patient status, alternative medical treatment such as mobile Dopplers, and potential anticoagulation adverse events management. Some clinician comments, when asked about the benefits of the program to their practice, suggest that all relevant staff have this training at orientation, the equipment training made a difference in their confidence in front of the patient and with the physician during coordination of care.

### **Limitations**

Patients who start with home health care may choose to continue their therapy with outpatient services after a week or two, which would mean that home health care, would have to discharge the patient. This would limit the comparative INR data received on the patient and the ability to determine if the barriers addressed made a difference in the stability of the patient's INR blood levels. However, none of the 26 patients were discharged prior to 4 weeks on home care services.

### **Conclusion**

Home health care agencies are graded based on their readmission rate and must be proactive in creating practices to maintain their quality of care and reduce patient readmissions within the first 30 days. This is true even though the responsibility for readmissions also ties back to hospitals. Optimal continuity of care requires interprofessional communication between

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the settings of care with thorough sharing of patients' medical and surgical history and with strong continuity of plans of care (Pinelli, Papp, and Gonzalo, 2015). This project addressed a common factor in readmissions: DVT and bleeding. The outcome measures showed that patients perceived better education from clinicians after the intervention, and education is an important element in patient compliance with anticoagulation regimens.



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**Appendix A. STATEMENT OF ORIGINAL WORK****Academic Honesty Policy**

Capella University's Academic Honesty Policy ([3.01.01](#)) holds learners accountable for the integrity of work they submit, which includes but is not limited to discussion postings, assignments, comprehensive exams, and the dissertation or capstone project.

Established in the Policy are the expectations for original work, rationale for the policy, definition of terms that pertain to academic honesty and original work, and disciplinary consequences of academic dishonesty. Also stated in the Policy is the expectation that learners will follow APA rules for citing another person's ideas or works.

The following standards for original work and definition of *plagiarism* are discussed in the Policy:

Learners are expected to be the sole authors of their work and to acknowledge the authorship of others' work through proper citation and reference. Use of another person's ideas, including another learner's, without proper reference or citation constitutes plagiarism and academic dishonesty and is prohibited conduct. (p. 1)

Plagiarism is one example of academic dishonesty. Plagiarism is presenting someone else's ideas or work as your own. Plagiarism also includes copying verbatim or rephrasing ideas without properly acknowledging the source by author, date, and publication medium. (p. 2)

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Capella University's Research Misconduct Policy ([3.03.06](#)) holds learners accountable for research integrity. What constitutes research misconduct is discussed in the Policy:

Research misconduct includes but is not limited to falsification, fabrication, plagiarism, misappropriation, or other practices that seriously deviate from those that are commonly accepted within the academic community for proposing, conducting, or reviewing research, or in reporting research results. (p. 1)

Learners failing to abide by these policies are subject to consequences, including but not limited to dismissal or revocation of the degree.

**Statement of Original Work and Signature**

I have read, understood, and abided by Capella University's Academic Honesty Policy ([3.01.01](#)) and Research Misconduct Policy ([3.03.06](#)), including the Policy Statements, Rationale, and Definitions.

I attest that this dissertation or capstone project is my own work. Where I have used the ideas or words of others, I have paraphrased, summarized, or used direct quotes following the guidelines set forth in the *APA Publication Manual*.

Learner name

and date Aisha Stone 7/27/17

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Mentor name

and school Dr. Terri Jones Capella University

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