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Patient education and Coumadin (warfarin) therapy: Readmission rates pre/post Coumadin team initiation

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Patient Education and Coumadin (warfarin) Therapy:

Readmission Rates Pre/Post Coumadin Team Initiation

by

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Abstract

As a response to the 2011 National Patient Safety Goals (NPSG), a Coumadin Team, consisting of a Physician Chair, Pharmacists, and Registered Nurses, was formed at Mission Health System to focus on International Normalized Ratio (INR) testing, Coumadin dosing, and patient education. The goal of this team has been to identify and eliminate barriers that prevent the stabilization of INRs within the prescribed goal range, and to ensure that all patients receive education about Coumadin therapy in order to prevent harm and reduce readmission rates related to Coumadin therapy. The purpose of this study is to compare readmission rates within the same timeframe in consecutive years, before and after the Coumadin Team was initiated, to determine if these measures have in fact been an effective avenue to reaching the 2011 NPSG. In a retrospective chart review 556 patients with active Coumadin orders from July 1 – July 31, 2010 were compared to 417 patients with active Coumadin orders from July 1 – July 31, 2011 to determine if readmission rates in the 90 days following hospitalization were in fact lower as a result of one-to-one Coumadin therapy education by a Registered Nurse. Research results have confirmed that in 2010 Coumadin related readmissions occurred at a rate of 7.2% of the total patient group, while in 2011 Coumadin related readmission occurred at a rate of 1.4% of the total patient group, giving a net reduction of Coumadin readmission rates of 5.8% after the initiation of the Coumadin Team.

Acknowledgements

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Chapter I

Introduction

Anticoagulant therapy can be a lifesaver for many patients with health problems ranging from atrial fibrillation, deep vein thrombosis, pulmonary embolism, and mechanical heart valve implants to more complicated and lifelong issues with genetic clotting disorders (U.S. Department of Veterans Affairs, 2009). Patients now have the ability to live full and healthier lives – all while living with disease processes that would have led to loss of life at an early age, as recently as two generations ago. Anticoagulant therapy, like many therapies, is a blessing but also a curse, if not managed properly. Anticoagulant medications are more likely to cause harm to patients than other therapies because of complex dosing issues related to lifestyle, prescription and over the counter medication interactions, and dietary restrictions (Joint Commission, 2010). Literature reviews show that very little research has been done in this area, so research is vital if the National Patient Safety Goals (NPSG) are going to be met. The requirements are defined, and now the best way to meet those requirements must be determined.

Background

Originally identified in 1939, and first used on human subjects in 1941 by the Mayo Clinic, Coumadin (warfarin) was not commonly used to treat the public until after it was used successfully to treat President Dwight D. Eisenhower after he suffered a heart attack in the mid-1950s (Ansell, Oertel, & Wittkowsky, 2005). Since that time, Coumadin has become the predominant oral anticoagulant used in the United States and North America (Ansell et al., 2005). Since those early beginnings, little else has been

discovered about this compound. Instead, scientists have focused on the role of vitamin K in Coumadin therapy, as well as patient education.

In 2010 the Joint Commission issued the 2011 National Patient Safety Goals and listed among them was the need for more effective patient education related to anticoagulant therapy. NPSG.03.05.01 specifically defines the expectations for anticoagulant education in the following excerpt:

> To achieve better patient outcomes, patient education is a vital component of an anticoagulation therapy program. Effective anticoagulation patient education includes face-to-face interaction with a trained professional who works closely with patients to be sure that they understand the risks involved with anticoagulation therapy, the precautions they need to take, and the need for regular International Normalized Ratio (INR) monitoring. The use of standardized practices for anticoagulation therapy that include patient involvement can reduce the risk of adverse drug events associated with… warfarin (NPSG).

Purpose

The purpose of this study is to determine if one-to-one education regarding Coumadin therapy performed by a Registered Nurse can increase post-hospitalization compliance. With a therapeutic INR goal of 2.0-3.0 and an intense therapeutic INR goal of 2.5-3.5, it is imperative patients be compliant with their diet and laboratory testing schedules to prevent complications from sub-therapeutic or critically high INR levels (Barber, 2011). Completion of this study will show that one-to-one education performed

by a Registered Nurse regarding Coumadin therapy can increase compliance and decrease readmission rates and sentinel events related to Coumadin therapy.

Research Questions

The ultimate questions behind this research are two-fold. First, will one-to-one Coumadin therapy education by a Registered Nurse be more relatable to the patient, and therefore better understood? Secondly, will patients be able to put that information to better use in relation to dietary compliance and adherence to INR testing schedules as dictated by their primary care provider?

Hypothesis

The researcher hypothesizes this study will show that one-to-one Coumadin therapy education performed by a Registered Nurse can increase compliance and decrease readmission rates and sentinel events related to Coumadin therapy.

Significance

The significance of this research is evident in the fact that The Joint Commission (TJC) is requesting interventions to reduce patient morbidity and mortality related to anticoagulant therapy. In addition to the dangers that Coumadin therapy can present for patients, adverse events also contribute to the increasing cost of healthcare for patients and the institutes that serve them. Given an estimated inpatient cost of major anticoagulant-related bleeding of $7,500, Ansell et al. (2005) report that retained annual savings by preventing five major events would be $37,500 per 100 patients.

The National Institutes of Health Drug-Nutrient Interaction Task Force (2003) reports the average intake of vitamin K for most adults in the U.S is 70 to 80 micrograms (mcg) daily. The recommended daily value for vitamin K is 80 mcg, which is an estimate

of daily need (National Institute of Health, 2003). Because vitamin K is a vital part in the creation of functioning prothrombin, it acts as an antidote to Coumadin (Ansell et al., 2005). It is therefore recommended that adults on Coumadin therapy limit the intake of vitamin K rich vegetables that provide more than 60% of the daily value for vitamin K (National Institute of Health, 2003).

The ultimate goal of this study is to ascertain whether or not one-to-one Coumadin therapy education provided by a Registered Nurse will result in lower readmission rates and decreased sentinel events related to Coumadin therapy. While there is no completely accurate method of measuring compliance, Ansell et al. (2005) report that compliance issues with Coumadin therapy are the same as other disease processes, with the exception of the fear of bleeding. Compliance must then be measured by the frequency of poor outcomes that are the result of non-compliance. For Coumadin patients, poor outcomes are defined as those outcomes that lead to a major bleeding event or a newly diagnosed clotting disorder.

Theoretical Framework

Nola Pender's Health Promotion Model (HPM) will be used as the theoretical framework for this study (see Figure 1). The HPM acknowledges the cognitive-perceptual factors and the modifying factors that can influence a patient's participation in health-promoting behaviors. Understanding patient barriers can assist the nurse in helping the patient to understand their own perceived barriers to action and boost their belief in their own perceived self-efficacy. Ultimately patients will be away from health care facilities and must have a plan in effect to overcome their own barriers and to focus

on the perceived benefits of action that will result from optimal compliance (Tomey & Alligood, 2006).

The HPM begins by acknowledging prior related behaviors that led to less than optimal outcomes for the patient. Personal factors for the patient that encompasses biological, psychological, and sociocultural factors are then included as variables that may or may not be changeable. Perceived benefits and barriers to action are then explored with the patient to determine the most effective plan to achieve compliance (Tomey & Alligood, 2006).

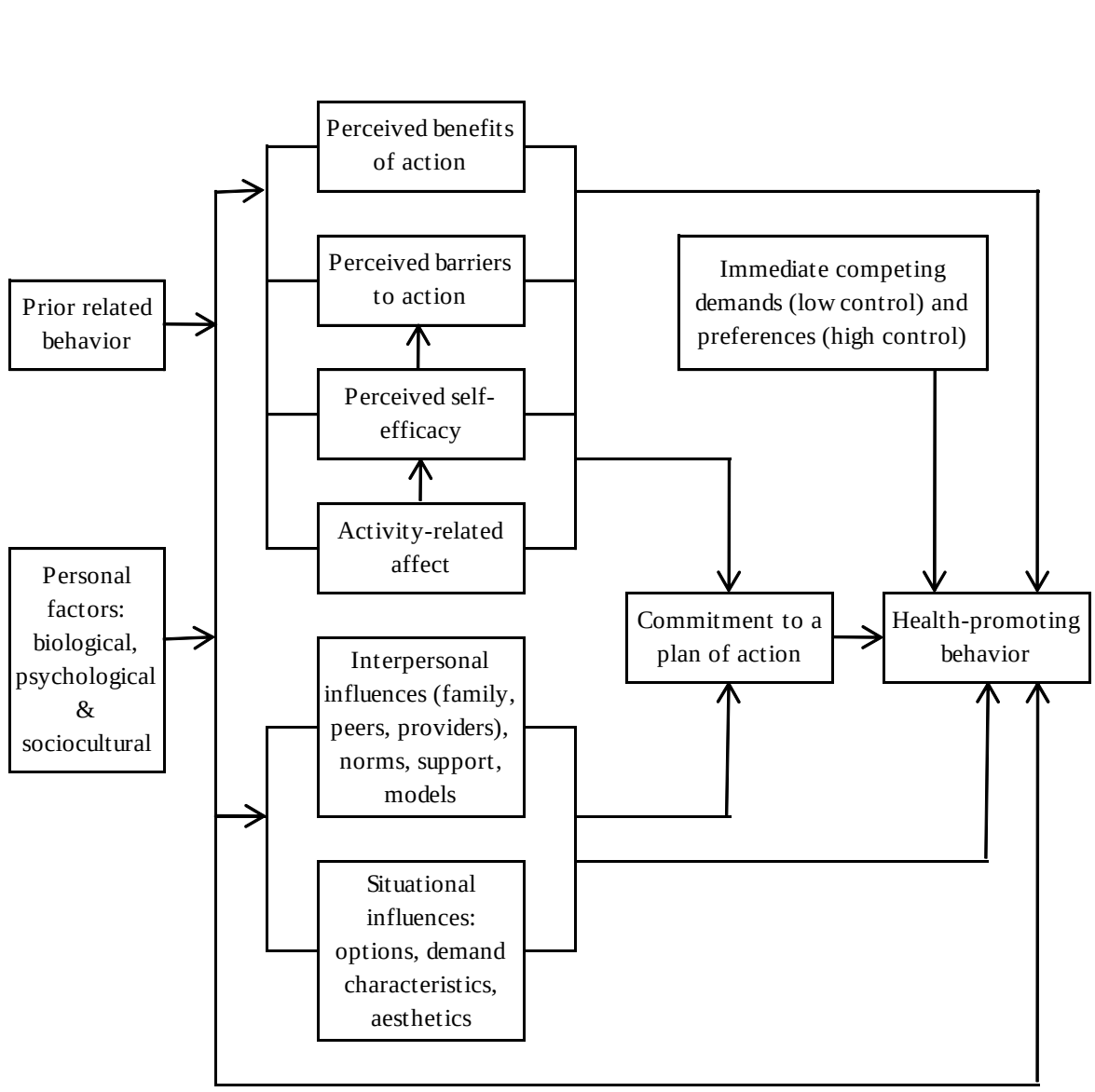

Figure 1. Revised Health Promotion Model. (From Pender, N.J., Murdaugh, C.L. & Parsons, M.A. [2002], *Health promotion in nursing practice* [4th ed., p. 60]. Upper Saddle River, NJ: Prentice-Hall.

Table 1 and Table 2 identify how the concepts shown in the HPM will be utilized in the educational process to increase patient knowledge regarding Coumadin therapy, and which health promoting behaviors will be encouraged in the quest for compliance.

Table 1

Description of the Coumadin Education Plan Integrated with the HPM.

BEHAVIOR SPECIFIC COGNITIONS AND AFFECT	
Perceived Benefits of Action	INR within goal range for catalyst diagnosis
Perceived Barriers of Action	Knowledge deficit related to Vitamin K Lack of transportation for lab work
Perceived Self-Efficacy	Judgment of personal capability to limit Vitamin K intake, find solutions to transportation issues, and incorporate safety precautions into lifestyle
Activity-Related Affect	Subjective feelings, be they positive or negative surrounding the behaviors necessary to achieve goal INR, and work within a safe environment
Interpersonal Influences	Expectations of family or friends, level of social support, education provided, and modeling of other people living with Coumadin therapy
Situational Influences	Perceptions of options available, the demands that Coumadin therapy places on personal lifestyle, and the aesthetic features of the environment from which a patient must pursue health-promoting behaviors

Table 2

Description of Behavioral Outcomes Based on Patient Controlled Events

BEHAVIORAL OUTCOME	
Immediate competing demands (low control) and preferences (high control)	Low Control – Timing of Coumadin administration, frequency of INR lab work, limiting Vitamin K in diet High Control – Diet choices with respect to types of foods available, time of evening/night to take Coumadin dose, where and how INR testing takes place
Commitment to a plan of action	Plan of action should be determined with the patient and their family (if requested), tools to support compliance should be available (such as dietary serving information, cost of Coumadin and pharmacy information, location of Coumadin clinics and style of testing [blood draw vs. finger stick])

In this study, Pender's concept of interpersonal influences was synonymous with one-to-one education regarding Coumadin therapy. This education will provide the best foundation for patients to begin to make the changes necessary to obtain all of the benefits of anticoagulant therapy, while minimizing the risks involved. One-to-one education would include: (a) instructions on dosing of Coumadin, (b) INR testing and patient goals, (c) signs and symptoms of bleeding and/or blood clots, (d) tips to help prevent cuts and bleeding, (e) possible drug interactions, (f) Coumadin storage instructions, (g) dietary restrictions, and (h) vitamin and nutritional supplement precautions (Mission Hospital, 2010).

Pender's concept of perceived self-efficacy was considered to be dietary compliance. Dietary compliance was determined by confirmation by the patient that they have limited intake of foods high in vitamin K, limited cranberry and grapefruit juice to eight ounces daily, eliminated liver from their diet, avoided all herbal teas, and avoided

or limited soybeans and soy products from their diet (Mission Hospital, 2010). This confirmation came via chart review to identify the presence of health promoting behaviors.

Pender's concept of health promoting behavior was considered to be the absence of readmission within the first 90 days of hospital discharge for reasons related to Coumadin therapy. According to Tomey and Alligood (2006), the movement to greater responsibility and accountability for successful personal health practices requires the support of the nursing profession through development of evidence-based practice, (p.462). This study was performed to determine if the educational support of Registered Nurses could influence patient responsibility and accountability and therefore reduce readmission rates and sentinel events related to Coumadin therapy.

Chapter II

Literature Review

The study of the effects of one-to-one patient education on Coumadin (warfarin) self-medication by a Registered Nurse has the potential to increase patient compliance and decrease readmission rates and sentinel events. While this study measured readmission rates, many areas need to be evaluated to understand what these rates represent when patients are given standard educational materials. The complexity of Coumadin therapy requires a broad review of patient compliance as it relates to medication dosing, INR monitoring, and dietary intake. There is simply no one factor that often leads to an adverse event, but more of a series of factors that lead to a cascade effect that cause the adverse event. This literature review looked at many of these areas in an attempt to isolate the education component in understanding patient compliance.

Education and Health Literacy

A prospective, multicenter, open randomized study was performed by Pernod et al. (2008) to evaluate the effectiveness of an oral anticoagulation patient education program in reducing adverse events in Coumadin patients. Both hemorrhagic and recurrent thrombotic complications were evaluated to determine the effectiveness of the educational program. The sample included 302 patients, over the age of 18, diagnosed with deep vein thrombosis or pulmonary emboli requiring Coumadin therapy for a minimum of three months. Research nurses, blinded to the study groups, interviewed the study sample 90 days after enrollment to identify episodes of bleeding and symptomatic recurrence of venous thromboembolism (Pernod et al., 2008)

Participants either received standard care alone, or participated in a tailored educational intervention lasting 20-30 minutes. These educational sessions consisted of a one-to-one teaching session. Thrombotic or hemorrhagic complications were not shown to be decreased, as the results were similar to previous data. The significant findings of this study were the fact that the educational intervention group did have a threefold reduction of adverse events. The authors report that this *"supports a significant and independent impact of our* educational *program on the reduction in risk of events"* (Pernod et al., 2008).

Limited health literacy is but one of the factors that lead to difficulty following medication instructions, and can often lead to poor health outcomes. Fang, Machtinger, Wang, and Schillinger (2006) conducted a study using bivariate analysis comparisons to determine the effect of limited health literacy on Coumadin knowledge, adherence, and control. Medications that are known to be potentially dangerous require that patients' understanding and participation during therapy are obtained (Fang et al., 2006).

During this study, patients were asked to complete a Test of Functional Health Literacy in Adults (s-TOFHLA) to determine their level of health literacy, and then to answer questions about their Coumadin therapy. One hundred seventy-nine patients participated in this study, which ultimately determined that limited health literacy was not associated with missing Coumadin doses, but did correlate with incorrect answers on the mechanism of Coumadin, medication interactions, and frequency of monitoring. Limited health literacy was not found to be associated with the percentage of time that a patient was in therapeutic INR range (Fang et al., 2006).

St. Louis and Robichaud-Ekstrand (2003) conducted a descriptive and correlational study to determine if knowledge level and coping strategies correlated with INR levels. They report that anywhere from 20 to 70% of patients are non-compliant because of a lack of knowledge or an incorrect interpretation of physician instructions. Interestingly, they also report that Coumadin has been found to be one of the three medications for which geriatric patients are the least compliant. Documented reasons for non-compliance include frequent blood tests, travel costs, diet modifications, and a belief that the treatment is useless (St. Louis & Robichaud-Ekstrand, 2003).

This study included 100 subjects and sought to answer two questions. The first was to identify the knowledge that older persons with atrial fibrillation had about anticoagulant therapy and the coping strategies they used. The second was to establish relationships between knowledge level, coping strategies, and INR levels. Researchers found a correlation between knowledge level and coping strategies, but coping strategies did not correlate to therapeutic INR levels (St. Louis & Robichaud-Ekstrand, 2003).

Compliance and Perceived Barriers

Parker et al. (2007) performed a prospective cohort study to assess and quantify patient compliance of medication administration times. This study used the electronic medication event monitoring system (MEMS) cap measurements to verify the claims of both self-report and clinician assessment of patient adherence. One hundred forty- five participants who were newly started on Coumadin (less than two months) were given MEMS caps for their warfarin pill bottles, which records the time and date the bottles were opened. Results showed that patients may benefit from adherence counseling even when they claim to be taking their warfarin, as patient reported compliance and physician

assessment of compliance did not often correlate with the data retrieved from the MEMS caps. The first six months of monitoring showed worsening compliance, which was followed by improvement beyond the six month date (Parker et al., 2007).

Woo, Chang, Ewing, and Bauer (2008) conducted research using secondary analysis of data from a prospective cohort study to determine if Coumadin use increased the risk of osteoporosis in older men. Medications that cause further health complications can often result in non-compliance, as the patient may view that the risks outweighed the benefits of that medication therapy. Bone mineral density at the hip and spine were used as a baseline for 5533 community dwelling ambulatory men. Follow-up at 5.1 years found that the risk of non-spine fracture was similar in warfarin user and nonusers. Final results found that warfarin use was not associated with lower bone mineral density, accelerated bone less, or higher non-spine fracture risk (Woo et al., 2008).

A qualitative study using a semi-structured group interview of 11 nurses of the Northern Sydney Area Health Service was performed by Bajorek, Krass, Ogle, Duguid, and Shenfield (2006) to explore the barriers to Coumadin use from the nursing perspective while working with geriatric patients. Investigators reveal that Australian studies indicate that Coumadin therapy is underutilized in the geriatric population, even when contraindications are absent. Lack of support services for elderly patients is cited as one of the reasons for this underutilization (Bajorek et al., 2006).

Data from 11 nurses was collected during a group interview in order to assess the attitudes, feelings, beliefs, experiences, and reactions that nurses had in relation to Coumadin use. Sessions were tape recorded and notes were also taken by a scribe to

ensure accuracy. The researchers found that nurses are a potentially underutilized resource for prescribers and patients, which is unfortunate, as nurses maintain a unique relationship with patients (Bajorek et al., 2006).

Safety and INR Monitoring

An open-label, three-treatment, randomized crossover clinical trial was conducted by Mohammed Abdul et al. (2008) to determine if cranberry or garlic intake would have a pharmacodynamic interaction with Coumadin. Intake of either cranberry or garlic would result in patients appearing to have international normalized ratio (INR) levels that would indicate non-compliance. A single 25mg dose of Coumadin was given to 12 healthy males alone or after two weeks of pre-treatment with either cranberry or garlic. Both herbal medicines showed some evidence of VKORC1 genotype-dependent interactions with warfarin, which researchers noted is worthy of further investigation because this interaction indicates that the effects of Coumadin can be increased significantly as a result. However, only cranberry was shown to increase the area under the INR time curve (by 30%). Based on these results, the researchers recommended careful monitoring of the co-administration of cranberry and warfarin (Mohammed Abdul et al., 2008).

Lazo-Langer, Monkman, and Kovacs, (2009) performed a retrospective cohort study of consecutive ambulatory patients treated at a thrombosis clinic in a tertiary care hospital. The purpose of the study was to determine if a model that incorporated genetic testing for determining warfarin dosing would be better than the nomogram currently in use. It was thought that isolating genetic factors known to correlate with an individual's clotting response would enable practitioners to achieve stable maintenance doses more

rapidly. Three hundred and sixty-three outpatients with acute venous thromboembolism were started on treatment using a standardized Coumadin nomogram until stable, then linear regression was used to determine if the dosing requirements would have changed if genetic models were used. The researchers concluded that costly genetic testing was not necessary, and that maintenance Coumadin dosing can be accurately predicted using individual response to a standard warfarin initiation nomogram (Lazo-Langner et al., 2009).

Researchers Rose, Ozonoff, Berlowitz, Henault, and Hylek (2009) conceded that many factors can contribute to suboptimal INR control: non-compliance with adherence to Coumadin therapy or dietary restrictions, interactions with other medications, and genetic differences between patient populations. After exclusions of patients with INR target ranges other than 2.0-3.0 and patients new to warfarin, 3961 patients were chosen to participate in this observational study (Rose et al., 2009).

INR levels showed that a shorter follow-up interval predicted a higher likelihood of dose change. The study also showed that a dose change in one direction at a previous visit was predictive of a dose change in the opposite direction at the current visit. This observational study suggests that warfarin dose changes when the INR is lower than 1.7 or higher than 3.3 could improve control, as Coumadin dose changes any closer to the 2.0 – 3.0 target range would ultimately result in a dose change in the opposite direction at the next visit. Researchers also noted that this theory should be confirmed by a randomized trial (Rose et al., 2009).

In order to retain the benefits of Coumadin home treatment for deep vein thrombosis, researchers Harper, Monahan, and Baker, (2005) initiated a treatment

program that provided 5 mg of Coumadin for the first 6 days of treatment along with INR testing on day four and six. Standard treatment consists of using a loading dose given over several days along with daily INR testing (Harper et al., 2005).

Using a retrospective audit after the induction of their low-dose Coumadin loading regimen, researchers evaluated 248 patients to determine if the new protocol was safe and effective. The new treatment protocol also included the administration of low molecular weight heparin subcutaneously for at least five days. Coumadin was given in 5 mg doses daily with the first INR measurement taken on day four. Daily INR measurements were then taken beginning on day six until the INR measurement reached 2.0 or higher for two consecutive measurements (Harper et al., 2005).

While this method of low dose Coumadin initiation was deemed safe by the researchers due to the fact that of the 248 patients only eight had an INR greater than 3.0 on day four, and only one had an INR greater than 4.0 on day four; it is noted that it does take longer for patients to reach the therapeutic level of 2.0 to 3.0. This extended time for reaching therapeutic levels means that patients will need to take subcutaneous low molecular weight heparin longer, as most patients required six to ten days to reach a stable INR (Harper et al., 2005).

As more patients enter the healthcare market, researchers are trying to find ways to meet the needs of these populations by determining if expanding the developing role of nurses can meet those needs. Connor, Wright, and Fegan, (2002) conducted a nonexperimental design study to determine if nurse-led anticoagulation services would be as safe and as effective as those led by hematologists. Effectiveness was defined as

maintaining a patient between their INR target ranges for 70% of their visits (Connor et al., 2002).

Using a retrospective chart review, data was collected from patients who had undergone 18 months of continuous management from the hematologist consultants versus those who had undergone 18 months of continuous management by nurses. The sample of patients consisted of 197 patients from 27 to 91 years of age. Results indicated that that the anticoagulant nurses are equally as safe as the consultant hematologist in managing the anticoagulant therapy of clinic patients (Connor et al., 2002).

This study, like the previous one, was designed to test the effectiveness of a nurse-led anticoagulation service. What makes this one unique is that the researchers are testing this theory in England, where patients had been traveling to their local hospital for testing. This new service not only uses nurses, but does so in clinics that are located in local areas or using home health nurses. The nurses are also utilizing a computer based decision support system, which was not being used by hospital doctors (Lusignan, Singleton, & Wells, 2004).

While patients overall liked the service because of the greater ease of testing, the computerized decision support system proved to be challenging. Eighteen nurses participated in this program, all of whom were experienced in anticoagulation monitoring. The difficulty lay in situations where the computer program recommended a particular dose and retesting date that the nurse did not agree with. Because of these complications, nurses were reporting as never giving more Coumadin than recommended, but they did show an increased rate of arranging follow-up dates sooner than the program recommended. Overall, the nurses operated on the side of caution. The researchers

concluded that while the nurses acted cautiously, technological solutions based on hospital practice are difficult to implement in primary care (Lusignan et al., 2004).

Researchers Rose, Ozonoff, Henault, and Hylek (2008) performed a study in order to describe the management of patients with atrial fibrillation in the community based setting. The effectiveness of lower INR target ranges (1.5-2.5) and (2.0-2.5), intended to prevent bleeding risk, were questioned in relation to their effectiveness of preventing stroke. Previous studies were reported that had suggested that lower INR levels may increase the risk of stroke without actually reducing bleeding risk. In this community based study of 3396 patients from 101 community based practices, the reports of hemorrhage and stroke were low, but the risk versus benefit of lower INR ranges remains uncertain. It is interesting to note that patients who had lower INR target ranges had more incidences of thromboembolic events and hemorrhagic events (Rose et al., 2008).

Along with education, the second component that the Coumadin Team addresses is the necessary follow-up that patients require upon discharge. The requirement set forth by the team dictates that patients must have a follow-up INR check within 48-72 hours of discharge. Research completed by Jackson, Peterson, Vial, and Jupe (2004) also addresses this component and gives insight into the validity and efficacy of this practice.

A total of 128 patients were studied after they had been initiated on Coumadin in the hospital. The group was randomly divided into two smaller groups, one of which received the usual care Coumadin patients had been receiving, which consisted of not only the usual care that their general practitioner would provide but also a visit from a pharmacist on day eight of therapy. Their general practitioner was also contacted after

this visit to alert them if an adverse trend was identified or if the patients INR was not in the therapeutic range that was expected (Jackson et al., 2004).

The second group, known as the home care group, received home visits by a pharmacist on four occasions, beginning on the second day after discharge. In addition to earlier INR checks by this pharmacist, the patients also received education at that first visit, consisting of information about anticoagulant therapy, possible adverse events, and medication interactions (Jackson et al., 2004).

This study reflects an increase in positive outcomes within the home care group. While both groups showed nearly the same percentage of patients had therapeutic INRs at discharge, by day number eight, only 4% of the home care group proved to have a supratherapeutic INR compared to 26% of the usual care group. In addition, when compared at the three month mark, only 15% of the home care group had sustained a bleeding event, while 36% of the usual care group had sustained such an event. This study shows a marked level of improvement in patient care and safety for the home care group (Jackson et al., 2004).

Sampling Quality

The aim of this cross-section comparison study, conducted by researchers Zengin and Enc (2006), was to determine if concurrent blood samples taken from venipuncture and via peripheral venous catheter showed a clinically significant difference in prothrombin time (PT) and activated partial thromboplastin time (aPTT) in patients currently undergoing anticoagulant therapy. While the traditional method for testing Coumadin effectiveness is the INR, many hospitals utilize the PT/INR which does fall under the scope of this testing (Zengin & Enc, 2006).

A sample population was taken of 120 patients who were undergoing anticoagulation therapy, while patients who were undergoing thrombolytic therapy were excluded. Each type of blood sample was drawn simultaneously from the patient. Blood collected via venipuncture was labeled as the reference sample, while blood from the peripheral venous catheter was labeled as the experimental sample. This method allowed each case to serve as their own control. The results of this study ultimately concluded that it is safe practice to collect blood sample from peripheral venous catheters for use in PT and aPTT testing (Zengin & Enc, 2006).

Throughout the literature, many areas have been studied in order to ascertain the precise reason for adverse reactions and sentinel events related to Coumadin therapy. The key behind all of these studies would, by all accounts, be linked to the lack of patient knowledge regarding their therapy. This common link is evident behind the NPSG.03.05.01 requirements as reiterated below:

> To achieve better patient outcomes, patient education is a vital component of an anticoagulation therapy program. Effective anticoagulation patient education includes face-to-face interaction with a trained professional who works closely with patients to be sure that they understand the risks involved with anticoagulation therapy, the precautions they need to take, and the need for regular International Normalized Ratio (INR) monitoring. The use of standardized practices for anticoagulation therapy that include patient involvement can reduce the risk of adverse drug events associated with…warfarin (NPSG).

The strengths of the research contained in this literature review are the various ways that researchers are attempting to isolate the components that lead to readmissions and sentinel events related to Coumadin therapy. Like working through a maze, the correct path can only be discovered by revealing the failures of the other paths available. Literature review has then outlined that genetic testing, reduced INR goals, and low dose Coumadin initiation are not valid paths to reducing readmission rates and sentinel events related to Coumadin therapy.

Conclusion

This literature review found many studies on the various types of barriers to effective INR goals, however, specific studies to determine if one-to-one education by a Registered Nurse would result in increased compliance and decreased readmission rates, and sentinel events were scarce to non-existent. By all appearances, this is an area with a need for research in the future.

Chapter III

Methodology

With a therapeutic International Normalized Ratio (INR) goal of 2-3, and an intense therapeutic INR goal of 2.5-3.5, it is imperative that patients be compliant with their diet and laboratory testing schedules to prevent complications from sub-therapeutic or critically high INR levels. The purpose of this research study was to ascertain whether or not one-to-one education by a Registered Nurse about Coumadin (warfarin) therapy could increase compliance and decrease readmission rates and sentinel events related to Coumadin therapy (Barber, 2011).

Implementation

Quantitative data was obtained using a retrospective chart review process. Each patient record was reviewed to determine if the patient was new to Coumadin or continuing Coumadin therapy, what the diagnostic catalyst was for the initiation of Coumadin therapy, and whether or not they had been readmitted to the hospital within 90 days of the research period. It was also determined if the readmissions were related or unrelated to their Coumadin therapy. Specifically, readmissions related to Coumadin therapy would include all cases where patients were admitted because of bleeding, and/or cases where the patient was diagnosed with any form of a blood clot.

Setting

This research was conducted at a hospital in the Southeastern United States. This health care facility is a designated Level II Trauma Center with over 800 inpatient beds. Patient care units selected for this study were diverse, including Medical Surgical Units, Progressive Care Units, Intensive Care Units, and Psychiatric Care Units. Emergency

Care, Labor and Delivery, Pediatrics, and 24 hour observation units were not included in the study setting.

Sample

Patient samples were obtained from the information technology department at the health care facility. A total of 973 patients with active Coumadin orders were selected for this study. The pre-intervention group consisted of 556 patients which were selected from July 1, 2010 to July 31, 2010. The pre-intervention group were all patients at the facility before the initiation of the Coumadin Team. The post-intervention group consisted of 417 patients which were selected from July 1, 2011 to July 31, 2011. The post-intervention group was all patients at the facility after the initiation of the Coumadin Team. Due to the strict dietary requirements to maintain a stable INR, it was felt that testing groups from consecutive years during the same month would eliminate variations that could potentially exist simply because of the unavailability of some green leafy vegetables in the other months.

All patients selected for both groups were receiving Coumadin therapy for a history of deep vein thrombosis, pulmonary emboli, orthopedic surgery, atrial fibrillation, atrial flutter, heart valve disease or replacement, cardiovascular disease, cerebrovascular disease, factor V Leiden deficiencies, port-a-cath placement, or other diagnostic catalyst as defined by their physician.

Research Design

A quasi-experimental design has been chosen to complete a retrospective chart review for 973 patients within the selected healthcare facility. Comparisons looked at the readmission rates of 556 Coumadin patients from July 1, 2010 to July 31, 2010, who

were admitted before their Coumadin Team was formed, and 417 patients from July 1, 2011 to July 31, 2011, who were admitted after their Coumadin Team was formed in January 2011. The purpose of using a quasi-experimental research design is to examine the cause-and-effect relationship between one-to-one Coumadin education provided by a Registered Nurse and patient compliance (Burns & Grove, 2009).

Protection of Human Subjects

Prior to conducting the chart reviews, the researcher obtained permission from the Internal Review Board (IRB) for Gardner-Webb University in Boiling Springs, NC as well as from the IRB for a Level II Trauma health care facility in the Southeastern United States. As this study consisted of a retrospective chart review, informed consent was waived by the Gardner-Webb University IRB, as well as the health care facility's IRB.

Instruments

A data collection tool was used by the researcher to organize data obtained from the retrospective chart review (Appendix A). This tool was designed to record the implementation status of the patients Coumadin therapy, the diagnostic catalyst for that therapy, and their readmission dates in the 90 days following their original admission. The tool also recorded the number of Coumadin related readmissions, as well as the unrelated readmissions during that same time period.

Data Collection

Data collected from the participants included their original admission date, and whether or not they were already taking Coumadin upon admission, or were prescribed Coumadin for the first time. Data regarding their diagnostic catalyst for Coumadin, if they were readmitted within 90 days of the original admission, and whether or not the

diagnosis given to them during that admission was related in any way to their Coumadin therapy was also obtained.

Data Analysis

All data, including statistical data, was entered into the Statistical Software for the Social Sciences, version 20 (SPSS v. 20, 2010) as well as into Microsoft Excel 2010. From these software platforms, the researcher was able to compare the percentage of occasions that each participant was readmitted to the hospital within the 90 day period following their original admittance. The researcher was also able to compare the occurrence rates of the diagnostic catalysts which prompted the physician order for Coumadin therapy.

Summary

The need for patient education regarding Coumadin therapy is clearly needed in order to ensure patient safety. This research project was designed to ascertain the effectiveness of Coumadin education when provided on a one-to-one basis by a Registered Nurse. All processes in this research project were designed to eliminate variances that have the potential to skew the results, such as performing data collection in the same month of the year for two consecutive years. This eliminated variations that may occur due to the decreased availability of fresh vegetables in the winter months. Data was also eliminated from surgeons known to prescribe Coumadin for their patients while they were in the hospital, but discontinued it in favor of aspirin upon discharge. The ultimate goal was to determine the effectiveness of the Coumadin Team educational process.

Chapter IV

Results

This research project had a clear goal. With a therapeutic International Normalized Ratio (INR) goal of 2-3, and an intense therapeutic INR goal of 2.5-3.5, it is imperative that patients be compliant with their diet and laboratory testing schedules to prevent complications from sub-therapeutic or critically high INR levels. Once completed, this study will ascertain whether or not one-to-one education by a Registered Nurse about Coumadin (warfarin) therapy can increase compliance and decrease readmission rates, and sentinel events related to Coumadin therapy (Barber, 2011).

Sample Characteristics

Two different samples were clearly defined in order to ascertain the effectiveness of patient education as it relates to Coumadin therapy at the chosen healthcare facility. The pre-intervention group was a total of 556 patients that had active Coumadin orders between July 1 and July 31 of 2010. This sample was taken before the initiation of the Coumadin Team. The post-intervention group was a total of 417 patients that had active Coumadin (warfarin) orders between July 1 and July 31 of 2011. This sample was taken after the initiation of the Coumadin Team.

The pre-intervention group from 2010 had 556 total patients; 234 patients who were new to Coumadin therapy and 322 patients who were continuing Coumadin therapy during their admission. The post-intervention group from 2011 had 417 total patients; 197 who were new to Coumadin therapy and 220 who were continuing Coumadin therapy during their admission. The numbers of patients which fell in each diagnostic category are outlined in Table 3.

Table 3

Patient Diagnosis Rates by Year

	July 1 – July 31, 2010	July 1 – July 31, 2011
Treatment or secondary prevention of venous thromboembolism or pulmonary emboli	107	64
Prophylaxis of thromboembolism associated with surgery or trauma	111	118
Prophylaxis of thromboembolism associated with atrial fibrillation or flutter	210	141
Prophylaxis of thromboembolism associated with valvular heart disease or prosthetic heart valves	41	16
Prophylaxis of thromboembolism associated with heart disease	21	13
Prophylaxis of thromboembolism associated with cerebrovascular disease	15	8
Treatment of heparin-induced thrombocytopenia	0	1
Diagnosis of Factor V Leiden	1	1
Protein C or S deficiency	0	0
Antiphospholipid antibody syndrome	1	0
Other Diagnosis requiring Coumadin therapy	17	8
Treatment for multiple diagnoses requiring Coumadin therapy	32	47

The last data collected during this process was the number of readmissions each patient had in the 90 days following their initial admission within the defined dates. Once a readmission was found, it was then researched to discover if the readmission was related to the patient's Coumadin therapy, or unrelated to their Coumadin therapy. The diagnoses that were considered as related to Coumadin therapy, include any new type of blood clot, which included but were not limited to: (a)deep vein thrombosis, (b)pulmonary embolism, and (c) stroke due to emboli, as well as any type of bleeding disorder, which included but were not limited to: (a)gastrointestinal bleeding and (b) hemorrhagic stroke.

The number of readmissions related to Coumadin therapy in the 2010 group was 40, while the number of readmissions unrelated to Coumadin therapy was 135. The number of readmissions related to Coumadin therapy in the 2011 group was 6, while the number of readmissions unrelated to Coumadin therapy was 121. The major findings of these results will be discussed in Chapter V. Visual representations of the sample statistics can be found in Figures 2 through 4.

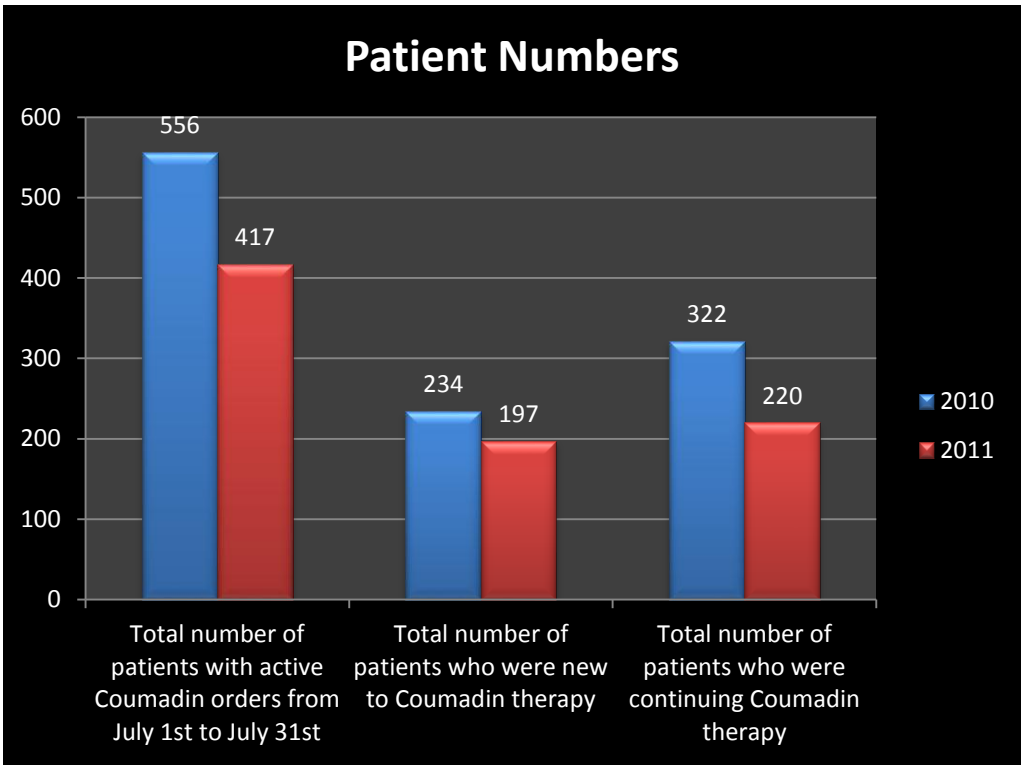

Figure 2. Patients Numbers by Sample Year

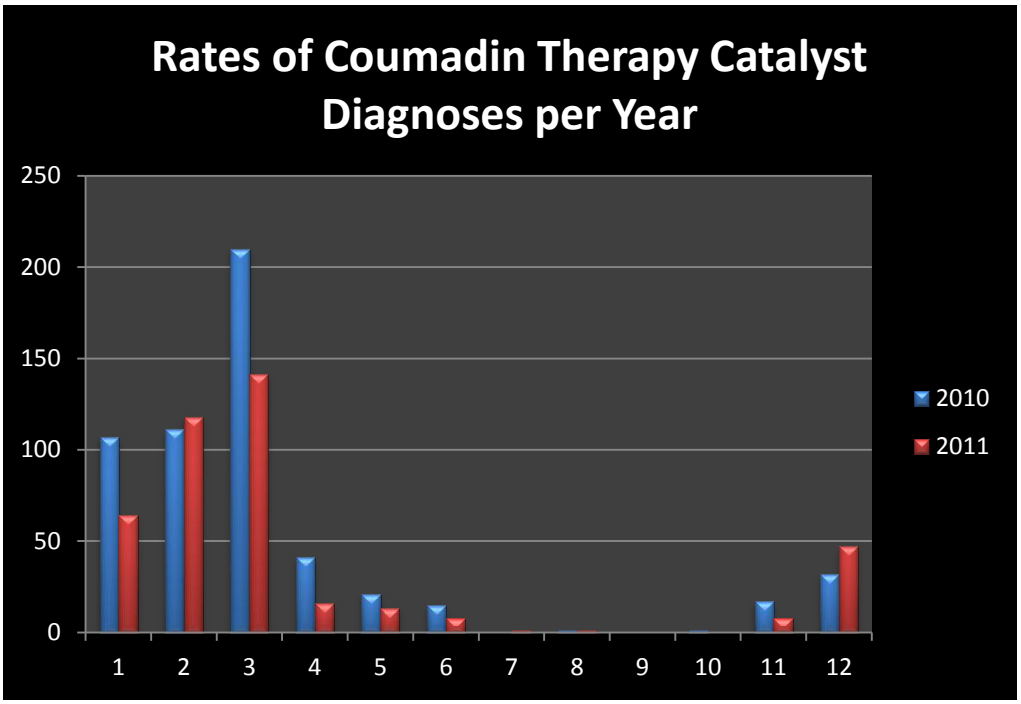

Figure 3. Rates of Coumadin Therapy Catalyst Diagnoses per Year

Key: (1) Deep vein thrombosis/Pulmonary emboli (2) Surgery/Trauma (3) Atrial fibrillation (4) Valve disease/replacement (5) Cardiovascular disease (6) Cerebrovascular disease (7) Heparin-induced thrombocytopenia (8) Factor V Leiden (9) Protein C or S deficiency (10) Antiphospholipid antibody syndrome (11) Other diagnoses requiring Coumadin therapy (12) Treatment for multiple diagnoses requiring Coumadin therapy

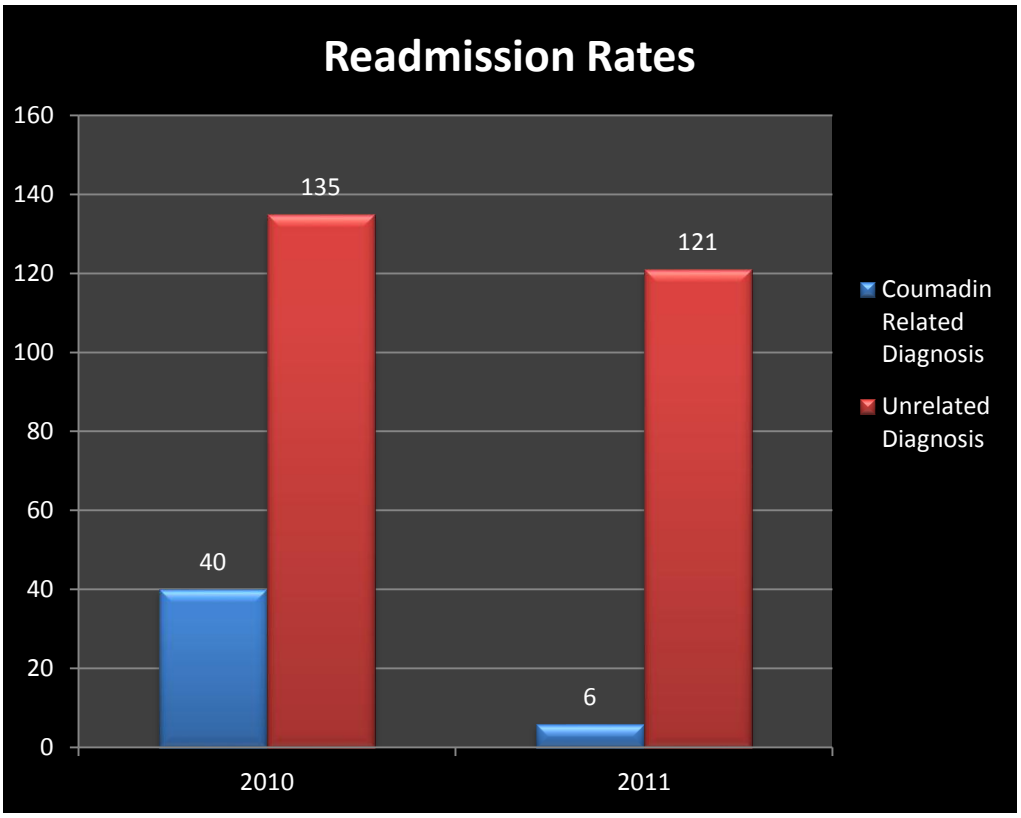

Figure 4. Readmission Rates per Year

Major Findings

In 2010 Coumadin related readmissions were 7.2% of the total number of patients, while in 2011 Coumadin related readmissions were 1.4% of the total number of patients. This represents a reduction in Coumadin related readmissions of 5.8% from 2010 (pre-intervention) to 2011 (post-intervention).

When the total number of readmissions versus the total number of patients from the 2010 and the 2011 post-intervention group were compared, the significance in a two-tailed T test showed a p value of 0.072 which when divided showed a one tail p value of 0.036, (See Table 4-6).

Table 4

Paired Sample Statistics for the Pre and Post-Intervention Groups (Coumadin Related)

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Total Number of Admissions	486.50	2	98.288	69.500
	Number of Coumadin Related Readmissions	23.00	2	24.042	17.000

Table 5

Paired Samples Correlations for the Pre and Post-Intervention Groups (Coumadin Related)

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Total Number of Admissions & Number of Coumadin Related Readmissions	2	1.000	.000

Table 6

Paired Samples Test for the Pre and Post-Intervention Groups (Coumadin Related)

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Total Number of Admissions - Number of Coumadin Related Readmissions	463.500	74.246	52.500	-203.576	1130.576	8.829	1	.072

The two groups were also compared for readmission unrelated to Coumadin therapy. This two-tailed T test had a p value of 0.055, (See Table 7-9).

Table 7

Paired Sample Statistics for the Pre and Post-Intervention Groups (Coumadin Unrelated)

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Total Number of Admissions	486.50	2	98.288	69.500
	Number of Unrelated Admissions	128.00	2	9.899	7.000

Table 8

Paired Samples Correlations for the Pre and Post-Intervention Groups (Coumadin Unrelated)

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Total Number of Admissions & Number of Unrelated Admissions	2	1.000	.000

Table 9

Paired Samples Test for the Pre and Post-Intervention Groups (Coumadin Unrelated)

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Total Number of Admissions - Number of Unrelated Admissions	358.500	88.388	62.500	-435.638	1152.638	5.736	1	.110

This study found a 5.8% decrease in readmission rates between the pre-intervention group in 2010 and the post-intervention group in 2011. It also produced a one-tail p value of 0.036. In multivariate analysis statistical significance was obtainable if $p < 0.05$.

Chapter V

Discussion

The most important task for any new team within the hospital setting must be to do what it set out to do, and to prove those measures are working with research and quantifiable data. This research study was set forth to do just that. The purpose of this research study was to look at the work being done, and ascertain whether or not Coumadin (warfarin) therapy education by a Registered Nurse was in fact reducing readmission rates.

Implications of Findings

In 2010 Coumadin related readmissions were 7.2% of the total number of patients, while in 2011 Coumadin related readmissions were 1.4% of the total number of patients. This represents a reduction in Coumadin related readmissions of 5.8% from 2010 (pre-intervention) to 2011 (post-intervention). The implications of these findings are profound. A 5.8% reduction in the number of Coumadin related admissions in a single month translate to more than just numbers. It translates into greater patient safety and a reduction in health care expenditures for the individual as well as the facility.

Descriptive statistics revealed that when the total number of readmissions versus the total number of patients from the 2010 and the 2011 post-intervention group were compared, the significance in a two-tailed T test showed a p value of 0.072, which when divided showed a one tail p value of 0.036. Therefore the data shows that the reduction is statistically significant because $p < 0.05$, (See Tables 4-6).

The second set of descriptive statistics for the unrelated readmissions is further proof that the decrease in readmission rates were related to the Coumadin education

provided to patients and not because of other factors. If other factors were influencing readmission rates, then the unrelated rates should have also proven to be statistically significant and they were not. This two-tailed T test did not show statistical significance as $p = 0.055$, which is higher than the statistically significant value of $p < 0.05$, (See Tables 7-9).

As previously stated, Ansell et al., 2005) reported that the average cost for readmission related to Coumadin therapy was $7,500, and that if one uses the average cost, then the reduction of readmissions by five events then translated into $37,500 saved in healthcare expenditures. This study saw a reduction in Coumadin related readmissions of 34 events in a single month. This translates into a total savings of $255,000 in healthcare expenditures. This benefits not only the patient, but also the healthcare facilities which serve them.

Application to Theoretical Framework

The application to Nola Pender's Health Promotion Model (HPM) was appropriate for this study because it outlines the partnership that must take place between patient and care provider to achieve an optimal outcome. Through education, the Registered Nurse can help patients to understand which factors they can control, and which factors they cannot control. Perceived benefits and barriers to actions can then be explored together as a team to produce an environment with greater safety and control.

By understanding that dietary compliance and proper INR monitoring can vastly affect their own outcomes in relation to morbidity and mortality; patients can come to understand that they hold the key to a safe and happy future. With the proper education,

patients then feel more equipped to handle Coumadin therapy and adjust their lifestyles to achieve the best outcomes.

Limitations

Limitations were largely removed at the onset of this research project by careful planning; however there was one specific limitation that was beyond the researcher's control. This limitation is that several patients had been prescribed Coumadin therapy, but no clear indication could be found in the history and physical as to why. On more than one chart, the hospitalist assigned to the patient, specifically noted in the history and physical that neither they nor the patient knew why they were taking Coumadin.

Implications for Nursing

The implication for nursing is clear. Even if the facility, where the nurse is employed, does not have a team dedicated to patient education about Coumadin, nurses must find a way to ensure that patients receive Coumadin education before discharge, and ensure that patients have a follow-up INR appointment at discharge. This research further confirms that the 2011 NPSG are valid, and that complying with those goals does increase patient safety.

Conclusion

In 1933, when a Wisconsin farmer named Ed Carlson brought a milk bottle full of cows blood that would not coagulate to researchers at the University of Wisconsin-Madison's Wisconsin Alumni Research Foundation (WARF) to find out why his cows had been dying after eating spoiled sweet clover, no one could have expected that the research that came out of this discovery would become the most widely prescribed blood thinner in the world. Warfarin (trademarked Coumadin) took its' name from these

modest beginnings at WARF, and is truly a miracle drug to the thousands whose lives it has saved (Jordan, 2011). It is not, however, a drug to be taken lightly. With frequent lab work to be completed, and a list of dietary and other drug interactions, patients must be presented with the best education possible so that they may pursue therapy while minimizing the risks of the harmful and potentially fatal side effects of this medication.

One-to-one education provided by a Registered Nurse about Coumadin therapy can increase compliance and decrease readmission rates and sentinel events related to Coumadin therapy. Patient education must become the cornerstone of any medication therapy regimen to provide the best outcome for our patients.

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Appendix

Appendix A

Data Collection Tool

Target period admit date: _____ # Coumadin related readmissions _____

Non-related readmissions _____

☐ This patient was initiated on therapy during this hospitalization

☐ This patient was receiving warfarin prior to admission, and therapy is being continued during hospitalization.

Indication for warfarin:

☐ Treatment or secondary prevention of venousthromboembolism or pulmonary embolism

☐ Prophylaxis of thromboembolism associated with surgery or trauma

☐ Prophylaxis of thromboembolism associated with atrial fibrillation/flutter

☐ Prophylaxis of thromboembolism associated with valvular heart disease or prosthetic heart valves

☐ Prophylaxis of thromboembolism associated with cardiovascular disease

☐ Prophylaxis of thromboembolism associated with cerebrovascular disease

☐ Treatment of heparin-induced thrombocytopenia

☐ Factor V Leiden

☐ Protein C or protein S deficiency

☐ Antiphospholipid antibody syndrome

☐ Other: _____

Readmission Date:	Admit diagnosis:	Coumadin Related?