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The Effect of an Educational Intervention on Oral Anticoagulation Therapy Knowledge in Primary Care

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THE EFFECT OF AN EDUCATIONAL INTERVENTION ON ORAL ANTICOAGULATION THERAPY KNOWLEDGE IN PRIMARY CARE

by

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DEDICATION

To my husband, Greg, and children, Jon and Kate, who believed the DNP could be accomplished and encouraged me the entire time.

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PREFACE

“Interdependent relationships involve the willingness and ability to give to others and accept from them aspects of all that one has to offer such as love, respect, value, nurturing, knowledge, skills, commitments, material possessions, time and talents”. (Roy & Andrews, 1999, p. 111).

TABLE OF CONTENTS

LIST OF TABLES

Table **Page**

LIST OF FIGURES

Figure **Page**

ABSTRACT

It is estimated that three million people in the United States are on oral anticoagulation therapy (warfarin). Populations studied have been found in therapeutic range 64% of the time (Pernod, Labarere, & Bosson, 2008). The low percentage of therapeutic range is attributable to (a) adherence, (b) monitoring infrequency, (c) Vitamin K antagonists, and (d) the effects of aging and comorbidities. The purpose of this evidence-based practice (EBP) project was to examine whether an educational intervention would improve the knowledge of patients receiving warfarin therapy. Roy's model for patient adaptation and the Stetler Model for EBP were used as frameworks for the project. A pretest/posttest design was used over a 2-week period that included 38 patients aged 42 through 90 (M = 74.7, SD = 10.1). An educational intervention done by the project manager using a booklet, video, and food models on warfarin therapy was completed after the pretest. Patients' INR (International Normalized Ratio) values were tracked at pretest, posttest, and every two weeks for twelve weeks. A paired sample t test found a statistically significant difference between the pre- and posttest scores. The mean pretest score was 11.11; SD = 2.35 compared to the posttest mean score of 12.48; SD = 1.45; (t (37) = -4.215, p < .001). No significant difference from pretest INR to posttest INR was found (t (26) = -2.002, p > .056). A Cochran's Q test showed INR results from 4 to 12 weeks were not statistically significant ($x^2(4) = 4$, p > .406). Results demonstrated that an educational intervention improved patient knowledge, but the intervention did not improve the patients' INR values over two weeks, or over the four to 12 week time frame. There were no trends over time, other than to support the literature of a low percentage of the population in therapeutic range. Replication of this EBP project has been patterned by the project manager's institution.

CHAPTER 1

INTRODUCTION

One of the roles of the advanced practice nurse (APN) is to implement evidence-based practice (EBP) in the clinical setting. Evidence-based clinical decision making leads to improved patient health and safety outcomes. EBP also decreases patient morbidity and mortality while reducing healthcare costs. Finally, EBP minimizes geographic differences in patient care delivery (Melnyk & Fineout-Overholt, 2011).

Interpreting EBP involves multiple steps. These steps include (a) formulating the urgency of inquiry, (b) presenting the clinical question through current practice and patient welfare, (c) locating the most relevant and best evidence in the medical literature, (d) incorporating clinical practice and patient preferences with best evidence to influence a change in practice, (e) evaluating the outcomes based on the evidence, and (f) sharing the outcomes so that more may have the knowledge of best practice results for both patients and providers. The clinical question is then answered (Melnyk & Fineout-Overholt, 2011). Each of these steps is addressed throughout this project.

Oral anticoagulation therapy (OAT) is patient use of generic warfarin or its brand name, Coumadin® by prescription for the purpose of prevention of stroke for patients with thromboembolic heart disease. Examples of thromboembolic heart disease include atrial fibrillation or flutter, cardiomyopathy, valvular heart disease, mechanical heart valve replacement, coronary artery disease, or myocardial infarction (Engelke, 2012). In addition, OAT is used in clinical practice for the purpose of dissolving emboli and emboli prevention for patients with pulmonary emboli, deep vein thrombosis or ischemic stroke (Engelke, 2012; Wilson, Racine, Tekieli, & Williams, 2003). In summary, OAT is used to help prevent blood clots, dissolve current clots or prevent clots from occurring in cardiovascular disease. The physiology of OAT is a Vitamin K antagonist. OAT

suppresses the Vitamin K coagulation in the liver, causing the blood to be thinner (Wilson, et al., 2003).

It is estimated that two million patients each year begin OAT world-wide (Banerjee & Lip, 2011). There are approximately three million people taking OAT in the United States (Kirsch, 2011). However, only 50% of the population in the United States is in the therapeutic INR (International Normalized Ratio) range (Kirsch, 2011). The low percentage of patients on OAT in the therapeutic range is attributable to inconsistency of the INR laboratory value of these patients (Banerjee & Lip, 2011). Inconsistent INR can be due to (a) failure of patients to dose OAT as prescribed, (b) lack of patient participation in medical monitoring, (c) inconsistent intake of Vitamin K antagonist by the patient in consumed food, beverage or medications, or (d) the effects of patient aging and comorbidities (Banerjee & Lip, 2011). The majority of these factors can be related to the patient's understanding of OAT. An understanding of what influences these factors is essential in providing safe and effective care.

The patient's knowledge of OAT, specifically warfarin or the name brand, Coumadin®, was assessed in the APN's clinical agency in order to achieve improved patient outcomes. Improving outcomes also facilitated patient satisfaction by (a) having more INR tests in the therapeutic range, (b) increasing the time between INR testing by 1, 2 or 3 weeks, (c) avoiding patient emergency room visits from excessive bleeding or embolic symptoms, and (d) reducing hospitalizations related to bleeding or embolic formation. Keeping patient INR values in the therapeutic range assisted the clinic to be more efficient. More INR values in therapeutic range also provided greater professional staff job satisfaction implementing and maintaining an effective patient education program. Patient adherence with medication dosing and laboratory monitoring was necessary to safely manage OAT patients.

Background

Patient education regarding OAT contributes to the patient's knowledge and safety. Inadequate patient education, poor understanding of the medication's action or non-adherence with OAT can lead to adverse events. Patients who have a poor understanding of OAT and its adverse effects are more likely to be non-adherent than those who receive education (Ryan, Byrne, & O'Shea, 2008). For example, it is noted that patients stating they had no education relative to warfarin therapy spent only 20% of their time in a therapeutic range during laboratory surveillance (Ryan et al., 2008).

For high risk groups such as the older adult, the lack of understanding of OAT can be a major barrier to effective health care. The older adult is at greater risk due to multiple comorbidities such as hypertension and obesity. In addition, due to diminished cognitive functions such as concentration, word recognition or adequate vision, the older adult may not display adequate knowledge of OAT (Wilson et al., 2003). Much of OAT information is written at a higher educational level than the patient's comprehension (Clarkesmith, Pattison, Lip, & Lane, 2013). This learning barrier puts the older adult, or any patient who does not comprehend the information, at greater risk for adverse medication reactions. Furthermore, learning barriers place the patient at a generally higher health risk and increase the likelihood of hospitalization (Cook-Campbell & Sefton, 2010).

The participating group for the OAT project was 38 clinic outpatients on OAT ranging in age from 42 to 90 who have thromboembolic heart disease. These diseases include atrial fibrillation or flutter, cardiomyopathy, valvular heart disease, heart valve replacement or coronary artery disease. Patients on OAT who have chronic deep vein thrombosis, pulmonary emboli or ischemic stroke were also in the participating group.

The educational intervention was applied to patients on OAT in this project. Patient information for the educational intervention included how the OAT interferes with

the body's blood clotting abilities, particularly preventing formation of a blood clot, disrupting an existing clot or treating conditions that cause blood clots. Within this blood thinning mechanism, patients needed to understand OAT's purpose, administration, laboratory values, dietary guidelines, safety precautions and adherence. In addition, patients had necessary close medical surveillance to help avoid complications of bleeding or clot formation (Holbrook et al., 2012).

History of Warfarin

Warfarin's pharmacologic potency was originally found in plants. In the 1920's, cattle in the Canada and the Northern United States were discovered to have ingested moldy silage made from sweet clover (*Melilotus alba* and *Melilotus officinalis*) (Pirmohamed, 2006). A researcher located in North Dakota, L. M. Roderick, found the silage contained a hemorrhagic property that reduced the activity of prothrombin, which is a blood clotting factor (Engelke, 2012; Pirmohamed, 2006). In 1940, Karl Link and his student, Harold Campbell, discovered the anticoagulant in the sweet clover in Wisconsin was 3.3'-methylenebis (4-hydroxy coumarin) (Pirmohamed, 2006). Continued work by Link lead to the synthesis of warfarin in 1948. Warfarin was approved in 1952 as a rodenticide in the United States. It was approved for human use in 1954 to prevent stroke (Engelke, 2012). The name warfarin is derived from the Wisconsin Alumni Research Foundation *(WARF*) and from the chemical name, coumarin *(-arin*). (Agnesian HealthCare, 2011; Pirmohamed, 2006).

Why OAT Education is Important

As the first oral thrombin inhibitor, warfarin is the most widely prescribed anticoagulant. Warfarin is the most cost-effective and physiologically-effective medication world-wide for preventing embolic strokes in patients with atrial fibrillation (Pirmohamed, 2006). Warfarin education should start when the medication is prescribed. OAT education can begin in the hospital, clinic office, or home setting. This education

should include the purpose of OAT, its risks and benefits, and the name, dose, route, schedule, and side effects of the medication. Dosing directions also include what to do if a dose is missed. The patient learns about safe blood monitoring called International Normalized Ratio (INR) with the warfarin education (Holbrook et al., 2012). The INR numerical range conveys information and education to the patient of current OAT control. Food and drug interactions plus self-care safety such as wearing gloves when gardening or avoiding situations that could cause injury are important information for patients on OAT. Patients also need to know whom to call if they have questions or concerns (Engelke, 2012).

Assessing OAT Adherence

Objective ways of assessing OAT patient adherence is performed with various assessment tools. Assessment of patient adherence is necessary for a variety of reasons. Such reasons include inquiring if the patient is using other medications that interfere with the action of OAT. Dosing OAT can be affected by the patient's alcohol intake, taking extra or omitting doses, or the addition or discontinuance of antibiotics (Huber, Levett, & Atkinson, 2008). Seasonal foods can also affect the patient's compliance with OAT. For example, fresh green vegetables seem a healthy alternative to many food choices; however, green vegetables contain Vitamin K antagonists which contribute to the ineffectiveness of OAT (Engelke, 2012).

Medical literature described the use of assessment questionnaires to determine patient adherence with OAT (Huber et al., 2008; Palareti et al., 2005; Wilson et al., 2003; Zeolla, Brodeur, Dominelli, Haines, & Allie, 2006). These questionnaires include the Warfarin Compliance-Assessment Scale (Huber et al., 2008) and the Questionnaire on Comprehension of Oral Anticoagulant Treatment (QCOAT) (Palareti et al., 2005). Additional OAT assessment questionnaires include the 20-question Knowledge Information Profile (Wilson et al., 2003), the 14-question Knowledge Information Profile-

Coumadin® (Nordstrom, Wilson, Templin, & DiNardo, 2009) and the Oral Anticoagulation Knowledge test (Zeolla et al., 2006).

Patient assessment questionnaires measure the patient's comprehension. Assessment questionnaires can also serve as part of the teaching intervention. Such questionnaires can measure how the education needs to be tailored to each patient producing improved outcomes for the patient. The questionnaires serve as a reminder to the patient of OAT adherence. As the patient's learning needs are evaluated by an assessment questionnaire, responses to the questionnaire can provide documentation of the patient's comprehension and be scored numerically. Improved patient adherence to diet and medication knowledge practices leads to more INR laboratory values in the therapeutic range. Determination of the patient's safety with OAT and adherence is consistently required throughout the patient's lifetime dosing (Mazor et al., 2007). This EBP project used the Knowledge Information Profile-Coumadin® scale (KIP-C) for the assessment questionnaire (Nordstrom, et al., 2009).

Statement of the Problem

Patients failing to take OAT as prescribed may do so for a variety of reasons (Engelke, 2012). Failure to take the OAT may result from the inability to refill the prescription due to a lower socioeconomic status or no health insurance. If the patient has a lower educational background, the patient on OAT may be unable to read the label or write down directions for dosing (Engelke, 2012; Wilson et al., 2003). Dosing errors include forgetting the dose or taking an extra dose. Patients may believe that OAT caused a previous stroke or trans-ischemic attack. In addition, patients may attribute an adverse reaction to OAT, such as blood loss through the mouth, nose, ear, stool, or urine (Engelke, 2012).

Patients may miss INR checks due to cost concerns or inconvenience of getting to the lab or clinic for blood draws. Frustration of not achieving a therapeutic INR can be

a cause of non-adherence (Engelke, 2012; Woten, 2013). Individual lifestyle patterns of work or family commitments may interfere with getting to the lab or clinic. The INR check may not be considered a priority or its importance not known to the patient (Clarkesmith, Pattison, & Lane, 2013; Engelke, 2012).

Patients on OAT can be unaware of food and beverage changes which impact anticoagulation. Patients can be unsure of food sources of vitamin K. Food sources of vitamin K are not only in green leafy vegetables but also in grapefruit, pomegranate, cranberry, oils, margarine, and salad dressings (Huber et al., 2005). The food listing may not be logical or easy for the patient to remember. Beverages such as green tea contain Vitamin K. More than two drinks per day of alcohol interfere with the effectiveness of OAT (Tom, 2005). High protein diets have an anticoagulation lowering effect (Huber et al, 2005). Individuals on OAT who consume a high protein diet have an increased albumin which causes an increase in protein-binding warfarin. This binding causes less free warfarin available for an anticoagulant effect, thus causing a lower INR (Tom, 2005).

Cold medications, stomach remedies, pain relievers, and dietary supplements interfere with OAT (Smith et al., 2010). Over-the-counter medications such as ibuprofen and naproxen are classified as non-steroidal anti-inflammatory drugs (NSAIDS) and have their own anticoagulation effect. With 20% of the population of the United States using a supplemental product, patients have a lack of awareness of the pharmacologic properties of vitamins and supplements (Smith et al., 2010). Many supplements increase the bleeding risk by interacting with OAT.

The final problem of inconsistent INR results is that the patient's knowledge of OAT can vary with age and comorbidities. Older patients often demonstrate poor knowledge of OAT which places patients at increased risk for bleeding, poor compliance, and poor control (Hu, Chow, Dao, Errett, & Keith, 2006). In a previous study, Hu et al. (2006) described older patients who have a limited income, reported a lower educational

level, and did not work outside the home scored lower on OAT knowledge tests. In addition, medication interactions, appetite changes, and poor medication compliance are risk factors for older patients. Inadequate teaching or using teaching tools above the patient's reading ability may also lead to poor patient outcomes (Wilson et al., 2003).

In summary, multiple factors can attribute to the INR not being in the therapeutic range. Patients may demonstrate (a) a lower educational level, (b) poor knowledge base of OAT, (c) a lack of education on OAT, and (d) medication non-adherence. Health beliefs regarding OAT are a barrier. Consistent food, beverage, and medication intake are not well understood by patients on OAT (Hu et al., 2006). Additional factors placing the patient at greater risk for bleeding include multiple comorbidities and effects of the aging process (Hu et al., 2006).

Data Included from the Literature Supporting the Need for the Project

Studies in the current literature stated that patient education is needed to promote adherence and prevent complications in the population on OAT. However, this education is often lacking. Lowthian et al. (2009) interviewed 40 patients on OAT and their physicians. These physicians consisted of 35 general practitioners and one specialist. Of the 36 physicians who were interviewed, 12 were unaware their patients on OAT had multiple problems, such as depression and medication non-adherence. Only five of the 36 physicians in this study believed they had responsibility for their patient's education of OAT; 15 physicians believed it was up to the laboratory services to do the OAT teaching; and 16 physicians acted only to refer the patient to another provider who treated the patient's pathology and ordered the OAT. Of the 36 physicians interviewed, only 14 reported conducting any patient education at the beginning of the patient's OAT (Lowthian el al., 2009). The authors stressed the importance of the patient's knowledge of OAT should be assessed when OAT was initiated. Ongoing OAT education was addressed as very important to maintain sustained INR values. The ongoing education

was directed by the primary physician during regular office visits. Another solution was to direct an advanced practice nurse for high-risk patients to assess the patient and provide OAT education during regular office visits (Lowthian et al., 2009).

Palareti et al. (2005) studied risk factors for highly unstable response to OAT. Insufficient knowledge of OAT's action was a risk factor. Patients not knowing or following the rules of treatment nor monitoring were added risk factors. The authors recommended standardized criteria for patients with great variability in their unstable INR values.

A case-control study by Palareti et al. (2005) included matched cases (77) and stable controls (80) that were followed over four months. The primary goal of the study was to determine patient factors for INR stability. The second aim of the study was to examine how anticoagulation clinics evaluated the INR stability in comparison to standardized criteria. Palareti et al. (2005) found a larger number of unstable cases were unaware of why they were prescribed OAT. The patients in the matched cases group did not understand the action of OAT and its side effects. A scored questionnaire and patient interviews were completed during this case control study to discover these facts. An interview was conducted with a physician who focused on correcting the wrong answers to the questionnaire and used the interview as an educational intervention. Palareti et al. (2005) found that participating in the study had a positive educational effect on the patients in the uncontrolled group. The INR stability improved over the next four months. In addition, the patient education also reduced the risk of major bleeding in the unstable cases cohort.

Patient knowledge through education of OAT therapy and its management from the OAT clinic was attributed to improved INR control (Palareti et al., 2005). The percentage of time spent within the therapeutic range improved (61.6% vs. 38.8%, p = 0.0001) over the four months following the intervention. Time spent below the

therapeutic range improved significantly (33% vs. 17%, $p = 0.013$). INR control improved above the therapeutic range also improved significantly (25% vs. 12%, $p = 0.0002$). The researchers further concluded good OAT clinic management includes (a) assessment of the patient, (b) an intervention such as the questionnaire, (c) knowledgeable dosing, (d) continued education by assessment, and (e) an interview as a teaching intervention for patients who are uncontrolled (Palareti et al., 2005).

Literature indicated that patient knowledge of OAT varies with age. Elderly patients (>75 years) generally demonstrate poorer knowledge of OAT (Clarkesmith, Pattison, and Lane, 2013). Patients in this age group on OAT should attend the clinical agency every three months for surveillance in weight, for determination of medication tolerance, and for review of consulting physician findings. In addition, conversation during the appointment should address any unreported bleeding incidents, laboratory values, and general well-being. With surveillance of the older adult patient's weight, discussion leads to appetite and eating habits. A change in eating habits including a decline in appetite can cause the INR to decrease below therapeutic levels due to the body's absorption pathways (Woten, 2013). Time spent with patients measuring their knowledge base and discussion during their office appointments can help improve their knowledge, attitudes and practices.

Data Included from the Clinical Agency Supporting the Need for the Project

The clinical agency was a satellite clinic of a regional medical center. The medical center is located in a Midwestern city which has a population of 113,040. Licensed for 325-beds, the not-for-profit medical center serves a six county area.

The clinical agency was a primary care office located seven miles north of the medical center where 3500 patients are registered. The patients are all adults and geriatric patients. Sixty-five patients with indications for OAT related to their cardiovascular conditions were patients at the clinic. These patients ranged in age from

42 to 90. Of the patients on OAT, 50 had their OAT managed in primary care, while the additional 15 OAT patients had another consulting provider manage their OAT.

The clinical agency used dosing guidelines from the Dosage Adjustment Algorithms of the Point of Care Guides, based from the American College of Chest Physicians clinical guidelines (Ebell, 2005; Holbrook et al., 2012). Patients are tracked from one INR to the next ordered INR. The clinical guidelines recommend healthcare providers who conduct anticoagulation therapy conduct this in a systematic manner (Holbrook et al., 2012). Recommendations include baseline INR, plus tracking in four days as a therapeutic INR level can be achieved in 96 hours (Ludwig, 2008). For a target INR of 2.0 to 3.0, the dose is increased by 10% with the next INR check in four to eight days if the INR is less than 1.5. Another increase of the dose by 10% is given with the next INR check in seven days if the INR is 1.5 to 1.9. Patients whose INR is 2.0 to 3.0 have no change in their dosing. The next INR is requested as the number of consecutive in-range INR's increase in one week increments, the maximum time between testing is four weeks (Ebell, 2005; Holbrook et al., 2012).

One difficulty experienced by the clinic is that concomitant disease processes may take the clinic's patient to the emergency room for treatment. When patients are later seen in the clinical agency, the patient on OAT is often found to have been prescribed a medication that affects the action of OAT by emergency room staff. The clinical agency corrects this prescription error, facilitating the patient back to a safer and therapeutic INR without adverse bleeding or clotting events.

Another difficulty is attempting successful call-backs for patient questions regarding OAT. One full-time physician, one full-time nurse practitioner, and one part-time nurse practitioner work in the clinical agency. In addition to scheduled patient visits, the providers return over 40 patient calls daily to help trouble-shoot various patient

problems and concerns. Five to ten phone calls daily are patient-related calls to OAT (agency nurse practitioner, personal communication, April 3, 2013).

Still another difficulty for the clinical agency is patients on OAT who are prescribed medications by other providers that interfere with OAT therapy. Examples of this documentation included two-week antibiotic therapy from infectious disease physicians or nine-month antibiotic therapy from urology practices. Orthopedic groups use non-steroidal anti-inflammatory drugs (NSAIDS) which also interfere with OAT. Clinical agency experience also included patients having chemotherapy prescribed by oncology practices with resulting INR values out of the therapeutic range (agency nurse practitioner, personal communication, April 17, 2013).

The clinical agency's patients on OAT also presented with new over-the-counter medications that were not previously on the office medication list for that patient. Examples of these were ginseng, garlic, green tea, ginkgo biloba, and St. John's Wort which have the potential to interact adversely with OAT (Agnesian Healthcare, 2011). Patients often announced they were taking an over-the-counter medication to self-medicate another healthcare issue, only to find this was not part of OAT adherence.

In addition, three or 6% of the clinic's patients on OAT were in the emergency room with bleeding and lacerations during the period from August, 2013 through September, 2013. One of the emergency room visits included a fatality (agency nurse practitioner, personal communication, August 21, 2013).

Current practice for inpatient or outpatient education throughout the medical center and its clinics is to utilize patient education materials specific to disease-oriented diagnoses (Dugdale, 2013).These are generic computer-based information sheets of patient education information written on the ninth grade reading level in two-point font (Dugdale, 2013). The generic computer-based information sheet does not contain any pictures. There is also an eight-page booklet on warfarin therapy. The booklet is written

on the ninth-grade reading level with twelve-point font and used in the outpatient setting (Ludwig, 2008). It does not contain pictures for easier patient recall (Ludwig, 2008). The booklet does not contain safety measures for the patient to help prevent indoor or outdoor injury (Ludwig, 2008). The booklet does not address diet changes or a weight loss plan, seeing other providers, or address specific medical conditions for taking OAT (Ludwig, 2008).

The medical center currently has 459 policies and procedures mentioning OAT. Within the 459 policies and procedures, general medication teaching about initiation of any new drug is addressed regarding indication for use, dosing and side effects. Policies and procedures indicate that general drug education should be reviewed with the patient upon discharge, in hospital-based specialty clinics, and during home care (Cook-Campbell & Sefton, 2010). However, there are no specific policies and procedures on OAT initial or continuing education in the clinical agency or medical center. There is also no current measurement of patient knowledge or follow up intervention to promote OAT education performed consistently in the clinical agency or at the medical center.

Purpose of the EBP Project

The purpose of this EBP project was to provide an educational intervention for the clinical agency's patients using warfarin or Coumadin® in an effort to improve their basic knowledge of OAT safety and the efficacy of OAT for the patient. Patients participating in the project increased their knowledge after the educational intervention. The Knowledge Information Profile-Coumadin® (KIP-C) (Nordstrom et al., 2009) assessment questionnaire was measured by posttest scores. Additional factors measured included the patient's level of education, gender, indications for OAT, if the patient had ever had education previously on OAT, and how long ago the patient had previous education on OAT. Further demographics included the patient's duration of therapy using OAT and whether the patient had a spouse or significant other listening to

the instruction. Finally, the project measured the impact of food selections, beverage interactions, and interactive medications.

Identification of the Compelling Clinical Question

The compelling question is: What is the effect of an educational intervention on oral anticoagulation therapy knowledge for adult patients on OAT in primary care?

PICOT format. EBP involved developing the clinical question using the PICOT format. PICOT is an acronym of (P), patient population, (I), intervention of interest, (C), comparison of the intervention, (O), outcome, and (T), time frame. The acronym is based on clinical question components from Melnyk and Fineout-Overholt (2011). Applying PICOT, the compelling question becomes: Among clinic patients taking warfarin or Coumadin® in primary care (P), what is the effect of an educational intervention with one follow up contact two weeks after the intervention (I), compared to pre-intervention oral anticoagulation therapy knowledge (C) affecting the INR consistency in the narrow therapeutic range (O) within two weeks (T)? Two weeks will be used to allow sufficient lag time for the INR to change based on patient behavior. The lag time allows for a more valid measure, that is, did the tool measure what it was intended to measure (Stiggins, 1987)? In addition, did the patient's behavior change due to the intervention (Stiggins, 1987)? It is not realistic to expect significant change of behavior in a shorter time frame because the patient needs time to implement the changes in foods, beverages, or medications that were learned during the intervention. In addition, it takes approximately three to five days for the INR to adjust to changes to anticoagulation dosing or diet sources (Ebell, 2005). Patients who implement the behavior changes would facilitate an improvement in the INR in the therapeutic range (Stiggins, 1987). Further psychometric evaluation of the KIP-C will be discussed in Chapter 2.

Significance of the EBP Project

The Joint Commission identified anticoagulants as one of the top five drugs associated with patient safety issues in the United States (Engelke, 2012). Major bleeding occurs in >2% of the patients using OAT. OAT-associated cerebral hemorrhage can recur in 22% of patients after restarting OAT (Engelke, 2012; Palareti & Cosmi, 2009). In patients over age 80, risk factors for major bleeding include insufficient patient education and polypharmacy (Engelke, 2012). Less than 50% of patients on OAT are able to maintain the stability of their target INR (Kirsch, 2011). Being out of therapeutic range puts patients using warfarin or Coumadin® at risk for either bleeding or embolism.

Because teaching the patient on OAT is time-consuming for clinicians and overwhelming for patients, OAT education is often omitted. Strategies to find the most effective and consistent patient education methods for patients were located in the literature for this EBP project. Teaching approaches for the clinician are also identified in the literature. Clarkesmith, Pattison, and Lane (2013) cited patients on OAT may have very little knowledge or comprehension of their medication as well as the disease for which the OAT is prescribed. The patient may not understand the scope of the disease, nor understand the risks and benefits of OAT therapy. This project addressed these issues from the literature and within this clinical agency.

CHAPTER 2

FRAMEWORKS AND REVIEW

The frameworks guiding this project included the Roy Adaptation model addressing patient characteristics and behaviors of adaptation. The Stetler model of EBP was utilized for problem-solving by the clinician.

Roy's Adaptation Model

Theoretical framework description. The theoretical nursing model used to guide this project was Sister Callista Roy's Adaptation model. Roy's model originated when she worked as a pediatric nurse (Phillips, 2010). As a pediatric nurse, she noted the resiliency of children and their ability to adapt to psychological and physical changes when hospitalized. Later in her graduate studies, Roy utilized adaptation as the foundation for her conceptual framework (Phillips, 2010).

The adaptation framework focused on three effects of stimuli encountered by the individual (Roy, 2011). These effects included focal stimuli, contextual stimuli, and residual stimuli (Roy, 2011). Within adaptation, focal stimuli described the immediate stimuli facing the individual (Phillips, 2010). The contextual stimuli translated to the multiple factors or circumstances that add to the impact of the immediate or focal stimuli (Roy, 2011). Residual stimuli encompassed characteristics of the environment, which may or may not influence the individual's circumstance (Phillips, 2010).

The three effects of stimuli within adaptation fit well with the patient using OAT. The focal stimulus for the patient was learning the disease process which included the need for OAT. Contextual stimuli combined the impact of the cardiovascular process requiring OAT plus utilizing OAT and its side effects. Residual stimuli for the patient on OAT were environmental factors such as the interaction of lifestyle, foods, or other medication. As the patient learned how to manage the effects of residual stimuli by

incorporating foods, lifestyle and prescribed medications, the INR's therapeutic range was achieved by the patient. The therapeutic INR range promoted disease process stability with less likelihood of clot formation or bleeding.

Roy's (2011) four adaptation modes of physiological, self-concept, role function and interdependence integrated well with the patient using OAT. The patient on OAT found physiological integrity compromised with an illness or disease process requiring OAT. Self-concept was challenged as the patient learned new skills and the importance of adherence to a new medication therapy. The patient entered into a new role function of integrating the disease process with the medication for OAT to improve or sustain life. Adaptation continued as the patient identified physiological integrity, improvement in self-concept and OAT adherence. Interdependence in patients on OAT allowed the patient to acquire knowledge and skills through providers. Interdependence disclosed relationships with family and friends, and demonstrated significant behaviors that contributed to the patient's health using OAT. The patient flowed through these modes which are perceived as adaptation (Phillips, 2010).

Application of theoretical framework to EBP project. Roy's theoretical framework was effectively applied in this project of determining the educational intervention of OAT. Patients understood their cardiovascular condition put their health at risk. Poor patient understanding surrounding the cardiovascular condition and its treatment contributed to the patient's likelihood of not adhering to recommendations. The project on OAT assisted the patient with understanding both the disease process and its treatment. In addition, the project facilitated the patient's adaptation with multiple health issues.

Clinic patients using OAT who participated in the project took the standardized pretest including eight questions of demographics to assess their knowledge of OAT. The eight questions of demographics were age range, gender, level of education

achieved, if the patient ever had education on OAT, how long ago was the OAT education, length of time using OAT, indication, and was there a significant other also listening to the education. The teaching intervention consisted individually discussing the pictorial handout *Blood Thinner Pills: Your Guide to Using Them Safely* (Huber, 2005) with the patient plus showing food models during the discussion. In addition, the teaching intervention included answering all questions which the patient may have about the pretest, the pictorial booklet and the food models. The patient then watched a 12-minute video on OAT. Both the pictorial booklet as well as the video was sent home with the patient. As described in Roy's Adaptation model, patient integrity improved as patients learned of their cardiovascular condition and why OAT was prescribed. Self-concept expanded as the patient comprehended the impact of OAT by consuming consistent daily food and beverages containing Vitamin K. Role function of the patient on OAT was enhanced as the patient experienced INR testing with more consistent therapeutic values. Interdependence between nursing and the patient was fostered by the educational intervention, the need for monitoring surveillance, and INR stability.

Since Roy's theory of adaptation applied to outcomes, the patient took the standardized posttest two weeks after the educational intervention. A two-week time period provided validity since it provided enough time to measure significant changes in patient behavior and the INR within therapeutic range (Ebell, 2005). Consistency of the INR can be found after four days (Holbrook, et al., 2012). INR therapeutic range, which differs from consistency, can be found in one week and also at two weeks (Ebell, 2005). Posttest knowledge was determined two weeks after the intervention was implemented. The posttest functioned as a diagnostic tool since it was able to identify the patient who did not have knowledge of OAT (Speros, 2009). The post-test showed information the patient had learned or information the patient already knew (Speros, 2009). It also identified the topics the patient did not know and evaluated the topics the patient had not

learned (Speros, 2009). More effective teaching assisted the patient on OAT through Roy's adaptive process.

Teaching about OAT therapy is generally done and documented when the patient begins the medication. Whether the patient has taken OAT or is new to OAT, the pretest provided an evaluation of the patient's current knowledge. The OAT pictorial booklet *Blood Thinner Pills: Your Guide to Using Them Safely* (Huber, 2005) as well as the educational intervention promoted patient recognition of coordinating a healthy lifestyle with medication. The booklet and intervention indicated OAT therapy as being critically important to the patient's care, as well as fostered the patient's personal understanding of their OAT.

Roy stressed that adaptation is a continuum (Phillips, 2010). The APN should therefore examine the adaptation continuum for patients on OAT. Various patient adaptations with INR values not in therapeutic range triggered the APN to begin investigating OAT as an EBP project. Ongoing evaluation of patients assists nursing with interventions to facilitate patient outcomes. Adaptation occurs after the patient displays an environmental response. The adaptation response may be effective or ineffective. Nursing has a unique goal to effectively assist the patient's environmental adaptation process with the patient utilizing OAT. As nursing guides the patient on OAT to manage the environment, the result is an attainable goal of optimum wellness by the patient.

Strengths and limitations of the Roy theoretical framework for the OAT project. Strengths of the Roy model include its ability to be experienced by the patient and observed by nursing (Phillips, 2010). The Roy model is a practice theory that outlines nursing assessment as it relates to the patient's self-concept (Roy, 2011). Nursing assessment draws conclusions about appropriate nursing interventions, addresses multiple patient variables, and facilitates patient adaptation (Phillips, 2010).

The Roy model focuses on the patient and the patient's adaptation (Roy, 2011). The patient is the active participant and the nurse is the guide (Roy, 2011). As a framework, the model serves to facilitate the project manager's thinking of patients' problems of adaptation with OAT. The model can evaluate the patient's food source adaptation. Roy's model assisted the project manager to distinguish between effective and non-effective adaptation by patients on OAT and their families. Adaptation helped the patient put his or her energy into improving health. Finally, the Roy model provided a framework to affect knowledge development of adaptation in the patient on OAT (Phillips, 2010).

Four modes of adaptation named in the Roy model are considered a weakness of the model. As adaptation is considered a process, Roy's model was weak when a quick decision has to be made, such as in sudden bleeding from OAT, with emergent treatment options (Phillips, 2010). However, the model affected knowledge development assisting the patient on OAT with information about problem solving, such as stopping the sudden bleeding and what to do for emergent treatment options. Another weakness of the model was implied direction for the nurse if the patient does not choose to actively participate in adaptation (Roy, 2011). The model was considered limited because it primarily addressed the concept of patient adaptation and focused on the patient (Roy, 2011). Finally, the information on the nurse or nursing assessment and intervention was implied (Phillips, 2010).

The EBP Model of Implementation

The Stetler model for EBP. The EBP model for this project was the Stetler model. The Stetler model allows individual nurses to use critical thinking skills as well as evidence to implement change in daily practice pattern (Romp & Kiehl, 2009). Analyzing current practice patterns with opportunities to improve practice also promotes the Stetler model for individual use (Stetler, 2001).

In addition to critical thinking and reflecting practice patterns, the Stetler model EBP provides the clinician with phases or steps to follow. Ciliska et al. (2011) summarized the order of these phases:

1. Naming the clinical issue or problem
2. Finding the change agent(s) who will champion the cause to facilitate a change in practice
3. Looking for research based on levels of evidence to support the problem
4. Naming the barriers to the practice change and communicating how to address the barriers
5. Clarifying ways to disseminate the information depicting the change in practice
6. Proceeding with the change in practice
7. Examining the impact of the change in practice on structure, function and overall outcomes
8. Finding ways to keep the change in practice current and applicable

The Stetler model defined evidence in healthcare information that is able to be reproduced, observed, and remains dependable through time (Ciliska et al., 2011). In addition, evidence is able to be verified and supported within the literature (Stetler, 2001). Furthermore, evidence in the Stetler model can come from a variety of resources (Ciliska et al., 2011). There are two types of evidence in the Stetler model (Stetler, 2001). Evidence may be described as *external evidence* (Ciliska et al., 2001). External evidence comes from outside research that is able to be reproduced, observed, and supported for practitioner use (Stetler, 2001). *Internal evidence* includes local facts, figures, quality measures, outcomes and evaluations as well as collected data (Stetler, 2001). In addition, EBP adds patient preferences or patient wishes which adds to additional internal evidence (Ciliska et al., 2011).

Application of the Stetler model to the OAT project. This EBP project included an individual patient assessment of OAT knowledge, followed by a teaching intervention. A second patient assessment followed in two weeks to determine the effectiveness of the educational intervention. Implementing the Stetler model in this project provided a step-by–step framework for an individual clinician to incorporate theory, literature, and include patient preferences to promote a change in practice.

The five phases of the Stetler model which facilitate EBP are (a) preparation, (b) validation, (c) comparative evaluation/decision making, (d) translation/application, and (e) evaluation. Each of these phases is discussed.

Phase I: Preparation. The first phase is described as a time to identify the problem and acknowledge any less-than-best practice relative to it. In this project, the clinical problem was "What were the best approaches to facilitate the adult patient who is using OAT and maintain the INR in therapeutic range?" As part of the preparation, relevant evidence was found in the literature related to the clinical problem. External evidence revealed patient education in a one-on-one setting, that included safety issues the patient could understand, written in large print with pictures that increased learning (Clarkesmith, Pattison, & Lane, 2013; Nasser, Mullen, & Bajorek, 2011; Wofford, Wells, & Singh, 2008). Literature explained that a take-home video on OAT further reinforced the interventions and provided periodic "refreshers" for the patient and family (Clarkesmith, Pattison, Lip, & Lane, 2013; Mazor et al., 2007; Nasser et al., 2011; Wofford et al., 2008). Additional external evidence showed a patient questionnaire to evaluate learning was also a valuable tool for facilitate patient knowledge (Clarkesmith et al., 2013; Lane, Ponsford, Shelley, Sirpal, & Lip, 2005). Still further, external evidence described if patients had a poor understanding of food choices, a non-therapeutic INR can result (Clarkesmith, Pattison, and Lane, 2013; Wofford et al., 2008; and Cook-Campbell & Sefton, 2010). In addition, patients on OAT were asked their opinion why

the INR was unstable. This question added internal evidence. Clinic data revealed instances when the patient's OAT dose was changed to achieve the therapeutic INR, but not accomplishing a therapeutic INR provided additional internal evidence. Other clinic patients on OAT had a therapeutic INR dosing regimen but failed to maintain it. Finally, groundwork for project resources within the clinical agency as well as project time frames were deliberated during the preparation phase.

Phase II: Validation. In the second phase, evidence in the literature related to the clinical question was reviewed and analyzed for its validity, reliability, and applicability to the clinical question (Melnyk & Fineout-Overholt, 2011). Literature was evaluated according to the level of evidence table from Melnyk and Fineout-Overholt (2011) rating system for the hierarchy of evidence. The rating system for the literature pertaining to the clinical question was located in systematic reviews, randomized control trials (RCT's), and additional levels of evidence. All levels of evidence were ranked according to their quality from higher to lower levels of evidence on a validation scale. Non-credible resources were discarded when the level of evidence could not be measured, or there was no reproducible study within the literature. Stetler (2001) cited if no credible literature is found, the EBP project would end.

To conclude the validation phase, current evidence found in the literature was combined with clinical practice to determine the project's purpose and measureable outcomes. This analysis revealed that both the literature and clinical practice drive the need for the project. The project becomes a priority in evidence-based clinical decision making for the project leader (Stetler, 2001).

Phase III: Comparative evaluation/decision making. Phase III began with making a comparative evaluation of the information already gathered and a decision about the project. This phase was a breakdown and compilation of Phase I and Phase II. The breakdown and compilation influenced decisions or recommendations which apply

to practice. Decisions regarding practice recommendations were incorporated in Phase III. The findings were a problem-solving fit and accurately reflect current practice (Stetler, 2001). Nasser et al. (2011) did find in their systematic review that educational interventions regarding OAT did make a difference and resulted in better anticoagulation control.

Phase IV: Translation/application. The EBP was translated and applied to current practice in Phase IV (Romp & Keihl, 2009). In this project, the project manager introduced the patient on OAT to the educational intervention. The educational intervention focused on understanding the patient's condition and experiences with OAT. Patient responses facilitated this project manager's appreciation of why the intervention was important. The educational intervention augmented the interdependence between patient and nursing. The translation or application to practice was the consistent evaluation and knowledge exchange between each patient on OAT and nursing in primary care. Such a change in practice also facilitated the office staff understanding of the patient's knowledge of OAT. The educational intervention showed itself beneficial to patients who have OAT prescribed for their cardiovascular conditions. Measuring the patient's knowledge of OAT and implementing a teaching intervention emphasized patient knowledge acquisition and led to better outcomes. The outcome data were utilized to promote continued informative patient education. The patient assessment and educational intervention translated into new practice for the current primary care office.

Phase V: Evaluation. In Phase V, outcomes were presented with a formative evaluation done by the project manager on the actual implementation and goal progress for the practice change. In addition, Phase V included a summative evaluation of Phase I outcomes and goal results that reflected OAT patient outcomes. The project manager conducted an evaluation of all the outcomes.

Identified strengths and limitations of the Stetler model for the OAT project. Strengths of the Stetler model included more direction for the project manager to examine EBP (Stetler, 2001). The OAT project had one project manager. Another strength detailed appropriate application of existing research-based knowledge into practice (Ciliska et al., 2011). For this project, literature regarding educational interventions in patients using OAT were located and applied to the OAT project. The phases of the Stetler model further helped prevent the project manager from using research inaccurately (Romp & Kiehl, (2009). The Stetler model supported and recreated critical thinking among providers who worked with the project manager. The project manager also utilized the model's use of both research utilization (RU) and EBP. The Stetler model facilitated programs and practice methods which improved nurse satisfaction, increased the commitment of nurses to the practice and reduced the turnover rate (Romp & Kiehl, 2009).

A limitation of the Stetler model was found in the overlapping of phases which could have caused the project manager to go back to a previous phase (Stetler, 2001). As an example, a decision to use evidence was found in Phase III, such as whether to use the intervention of an individual class or group classes with OAT intervention. The project manager then went back to Phase II to see if the evidence applied to the project. As the project manager then moved forward to Phase III, the project could have stopped at Phase III if the strength of the decision was not sufficient to support the practice change (Romp & Kiehl, 2009). The project manager's awareness of the overlapping phases avoided this situation. Another limitation for the project manager was in Phase IV, in the application of the evidence. The EBP evidence may not provide details for a complete procedure change, based on the different levels of evidence (Stetler, 2001). Strong, highly ranked evidence and current practice pattern of utilizing questionnaires with educational interventions with other disease processes avoided this limitation.

Another limitation was in Phase IV, the evidence in the project findings implied or encouraged its users to *fill in the blanks* with their own information or judgment and make a conclusion (Stetler, 2001). Statistical evidence found in this project addressed the previous limitation. Phase IV, as an application phase, suggested the levels of evidence within a set of actions are reported as findings (Romp & Kiehl, 2009). This cites another limitation as the findings can be *adapted* rather than adopted into practice (Romp & Kiehl, 2009). Again, strong, highly ranked evidence supports an improved APN practice pattern.

Combining both the Roy model of adaptation with the Stetler model guide for EBP. To combine the two theories, Roy's Adaptation model showed patient adaptation to change and facilitated adaptation through nursing care. Nursing influenced environmental stimuli for the patient's benefit. Patients were able to see their own personal dignity and self-esteem improve by being recognized first as patients on OAT. Confirming or increasing the patient's knowledge base of their medical condition utilizing OAT increased their self-worth. The patient's adaptation and hands-on involvement in their care motivated patient to focus on consistent meals, beverages and medications for optimal outcomes, therapeutic INR's, and fewer adverse events.

The Stetler model was a framework for nursing to guide the project manager from research utilization to outcomes with EBP. This approach relied on internal evidence which was the process of gathering current patient outcomes, preferences, and clinical expertise (Stetler, 2001). The internal evidence combined with external evidence or project outcomes to facilitate EBP for the patient using OAT. Literature citing the problems of OAT had been found in systematic reviews, RCT's and other levels of external evidence. The levels of evidence provided a framework to illustrate best practice. Clinic and medical center data emphasized a need to change practice. As an APN, the project manager's plan was to use both RU and EBP to plan change and

evaluate this change both in formative as well as summative data using the Stetler model (Stetler, 2001).

Current practice and proposed change. As part of current practice in the medical center system, patients new to OAT have medication teaching done at the hospital or outpatient clinic setting. Patients in either setting receive *A Patient's Guide to using Coumadin®/Warfarin* (Ludwig, 2008). This is an eight-page booklet which is given to patients who begin OAT in the hospital or outpatient setting. The booklet is written on a ninth-grade reading level and printed in 12-point font. There are no pictures in the booklet to facilitate patient comprehension.

Prescribing and dosing OAT was done by clinical practice guidelines, either by itself or concomitantly with antiplatelet medication such as aspirin or clopidogrel (Holbrook et al., 2012). For example, patients with atrial fibrillation began OAT therapy at either two or five milligrams daily (Ebells, 2005). Other patients utilizing OAT who had deep vein thrombosis (DVT) had the adjunct of injectable enoxaparin along with five milligrams of OAT to help them achieve therapeutic INR with a faster response. The patient obtained a baseline INR and complete blood count (CBC) on day one. Another INR and CBC were drawn in four days. A subsequent INR was drawn in seven days. The enoxaparin or heparin was discontinued when the INR is between 2.0 to 3.0 for DVT patients; the OAT was continued daily (Holbrook et al., 2012). Patients who had atrial fibrillation continued taking OAT daily. Patients who used multiple cardiac medications had their dose adjusted which influenced Vitamin K synthesis.

Nursing staff in primary care telephoned patients with their INR value and directions for the next dosing. The staff informed patients to write down directions for dosing. Current clinical guidelines showed INR testing to be subsequently drawn every one, two, three, or four weeks based on the number of consecutive in-range INR's within those intervals (Ebells, 2005). An example of this was a patient who had an INR result

between 2.0 to 3.0. The next test was requested in one week, subsequent tests were requested in two weeks, then three weeks, and next in four weeks as long as results were within 2.0 and 3.0. There was a maximum of four weeks between INR testing (Ebells, 2005).

Literature Search

Search engines and key words. The search for current literature pertaining to OAT in the primary care setting included the databases from (a) Cumulative Index to Nursing and Allied Health Literature (CINAHL), (b) Medline, (c) ProQuest, (d) Johanna Briggs Institute (JBI), (e) Cochrane Database of Systematic Reviews, (f) Nursing Reference Center, and (g) the National Guideline Clearinghouse. The search also included a hand search from available literature. In addition, one article was located doing a citation search from the literature references used in the levels of evidence. The following search terms were used: *warfarin or Coumadin, oral anticoagulation therapy, educate, teach and train, knowledge, self-administration,* and *educational strategies.* The terms were used in various combinations to obtain maximum results from the databases. After the initial search was completed, abstracts were reviewed after a hard copy of the literature was created and reviewed for correct inclusion criteria. See Summary of Evidence, Figure 2.1.

Inclusion/exclusion criteria. Inclusion and exclusion criteria were used to determine the most relevant evidence as it relates to the PICOT question. Inclusion criteria limiters included (a) published literature in the English language, (b) involved adult populations of age 45 through over 80 years of age, and (c) dated from January, 2005 through July, 2013. The inclusion criteria were chosen based on the characteristics of the population for the project. Further analysis of inclusion criteria examined improving clinical outcomes through education and educational interventions for stable

maintenance dosing of OAT. Additional criteria included literature noting challenges in the patient's knowledge of OAT.

Exclusion criteria established were articles published prior to 2005 and those that did not include the search terms of *warfarin or Coumadin, oral anticoagulation therapy*, *educate, teach and train, knowledge, self-administration, and educational strategies*. Exclusion criteria also included literature of patients on OAT who were self-managed, that is, patients who dosed their own OAT at home with prompt directions. Literature entirely based on patients who were cared for by stand-alone OAT clinics without hospital affiliation was also omitted. Children and adolescents were omitted from inclusion criteria as well as long-term care patients who did not dose their own medications. Published works describing best control practices of OAT but not including any education in OAT were also deleted. Literature on educational interventions solely for hospitalized patients on OAT was discarded. However, educational opportunities comparing post-hospitalized patients continuing outpatient educational interventions were included. Literature was examined and considered based on evidence-based practice, clinical guidelines, systematic reviews, qualitative or quantitative studies, and descriptive studies.

Figure 2.1

Summary of Evidence

Database	Hits	Articles Found	Initial Review	Duplicates	Full text review	Included in analysis
CINAHL	32	18	14	0	12	1
Medline	80	47	18	3	15	4
JBI	2	2	2	0	1	0
Cochrane	31	31	4	0	2	1
ProQuest	9	1	1	0	0	0
Nursing Reference Center	258	168	30	6	8	1
National Guideline Clearinghouse	48	48	2	2	2	1
Hand Search	1250	1040	32	5	26	2
Citation Search	14	14	14	0	1	1
Total	1724	1369	117	17	67	11

Summary of evidence. See Figure 2.1. The initial search of CINAHL found 32 hits, 18 articles were located by title, and 14 articles were initially reviewed by abstract. Full text review was completed on 12 articles. This resulted in one article which met inclusion criteria in the analysis. The one article consisted of one well-designed RCT.

The Medline database first located 80 hits and 47 articles by title. Of these articles, 18 were initially reviewed by title and abstract, and three were duplicates from the CINAHL database. Medline full text review was completed with 15 articles, with four of them included in the analysis. The four Medline articles included one RCT, and three were single descriptive studies.

Johanna Briggs Institute database yielded two hits and two articles were found by title. These two articles were initially reviewed by abstract, but neither article met inclusion criteria.

The Cochrane database found 31 hits and 31 articles by title. There were four articles initially reviewed by abstract. Full text review was completed on two articles. The one article included in the analysis was a systematic review.

ProQuest yielded nine hits and one article was located by title and abstract. However, this article did not meet inclusion criteria and was not in full text review.

Nursing Reference Center's database found 258 hits, with 168 articles located by title, and 30 were initially reviewed by abstract. There were six duplicates located in the CINAHL, Medline, and Nursing Reference Center databases. Full text was reviewed in eight articles. The one article included in the analysis was a systematic review which met inclusion criteria.

The National Guideline Clearinghouse was searched as well. There were 48 hits with 48 clinical guidelines found by title; two met initial review by abstract. One clinical guideline for OAT was selected. The second clinical guideline on OAT was not selected

as these were clinical guidelines for Great Britain and did not list the same INR therapeutic range as the United States.

A hand search of the literature was also performed for the project. There were 1040 articles located, adding the search term *educational strategies* narrowed the articles to 32 articles that were initially reviewed by title. The articles which were reviewed by abstract included five duplicates in CINAHL, Medline, and Nursing Reference Center databases. Full text review was done on 26 articles and two articles were selected for the project. The literature selected was one systematic review and one cohort study based on inclusion criteria.

A citation search was done over the previously selected articles for the project. One article was selected based on inclusion criteria and this was a single descriptive study. A second literature search was done over all the data bases previously listed. There were no additional articles retrieved.

All literature included in the summary of evidence on OAT was reviewed for level of evidence, sample size, method of evaluation of the evidence, conclusions drawn from the evidence, and number of sites used. The 11 pieces of evidence yielded by the literature search provide the framework for the interventions listed in this EBP project.

Levels of evidence. Levels of evidence for this project were evaluated by the rating system for the hierarchy of evidence for intervention/treatment questions by Melnyk and Fineout-Overholt (2011). Level I evidence is evidence from a systematic review or meta-analysis of all relevant RCT's and is considered the highest level of evidence on this scale. Level II evidence is retrieved from well-designed RCT's. Level III is evidence from well-designed control trials that do not have randomizations. Level IV is evidence from well-designed cohort or case-control studies that are well designed. Evidence found in Level V comes from systematic reviews of descriptive and qualitative studies. Level VI is evidence from single descriptive or qualitative studies. Level VII is

evidence from expert committees or opinions of authorities (Melnyk and Fineout-Overholt, 2011).

There were three systematic reviews of Level I evidence and one clinical guideline of Level I evidence found for this project. Level II evidence located for this project was two randomized control trials. There was no Level III evidence found. Level IV evidence included one case-control article. There was no Level V evidence located for this project. Level VI evidence was found in four articles. No Level VII evidence was found for this project.

Evidence Appraisal

Specific questions related to critical appraisal were used from Critical Appraisal Skills Programme (CASP) (2014). Evidence studies were chosen for their validity, reliability, and applicability to the project and to answer the clinical question. The literature in the review was all evaluated by the CASP method. Rating scale for the literature was scored with a threshold of 7 out of 10 detailed points for validity, reliability, and applicability in the CASP rating scale to be considered for this project. The AGREE II tool was used to score the clinical guidelines.

Level I evidence. Clarkesmith, Pattison, and Lane (2013) provided a systematic review of eight trials with a total of 1,215 patients with atrial fibrillation (AF). The authors showed a specific population of newly diagnosed patients with atrial fibrillation to those with permanent AF and accepted as the *normal* heart rhythm. RCT's of educational or behavioral interventions with any length of follow-up were studied. Any language was included in these trials which were held in six different countries. Databases searched included Cochrane, Medline, EMBASE, and CINAHL.

Educational interventions included educational booklets, videos, decision aids, and talking interventions. The studies also included behavioral interventions designed to

modify the patients' response toward treatment and symptoms. These interventions included cognitive behavioral therapy, motivational interviewing, and biofeedback. It was reasonable to combine the reviews as the primary outcome measure was the percentage of time spent within therapeutic range. Overall results did not favor self-monitoring plus education in improving time in therapeutic range, with a mean difference of 6.31 (95% CI -5.63 to 18.25). Secondary outcomes measured were increased knowledge with regard to AF and anticoagulation therapy, patient satisfaction, and acceptability of OAT. Secondary outcomes also included quality of life, changes in perception toward AF and INR control. Additional secondary outcomes included changes in the patient's illness beliefs and illness representations. Further secondary outcomes included self-reported adherence to treatment, cost-effectiveness of the intervention, and a change in the patient's beliefs about medications. Secondary outcomes favored usual care over decision aids for reducing decision conflict, with a mean difference of -0.1 (95% CI -0.2 to -0.02).

These outcomes applied to the population in this project as those who self-monitor (but not self-dose) do not have any more time in therapeutic range than those patients who have laboratory testing. Also, patients in usual care (no education but initial instruction when warfarin initiated) reflect the project population with their INR stability versus patients who have decision aids from another healthcare source and have INR instability. An outcome not considered in this article was the psychological impact for the patient. Although the researchers concluded that more trials are needed to impact education and behaviors of the patient on OAT, the benefits outweigh the harm and cost due to the secondary outcomes noted. This Level I evidence received a CASP score of nine.

Nasser et al. (2011) reviewed 62 articles and focused on the challenges for adults over 65 years for patient knowledge of OAT, access to OAT education, and

educational resources. Their literature review was done in Medline, EMBASE, CINAHL, International Pharmaceutical Abstracts, Meditext, and Google Scholar. The researchers compiled a comprehensive literature search over a 20-year time span. However, the literature retrieved was only in English. Results of the studies were reasonable to combine as their primary endpoints included improved knowledge in older patients improved their anticoagulation control. Overall results of the studies were expressed by statistical significance.

The researchers noted that between 50-80% of older patients had inadequate knowledge about basic aspects of warfarin therapy. These knowledge deficits included OAT's action, benefits and risks, and interactions with food or drugs. Demographic factors such as advancing age, lower family income, and limited health literacy were found to inversely affect patients' warfarin knowledge. In addition, access to warfarin education was often suboptimal in different practice settings. Major barriers to patient education included lack of provider time to teach as well as a lack of a multidisciplinary approach to teaching in busy outpatient healthcare settings. Educational strategies and resources such as providing the patient with information at their cognitive skill level, videos for home use, and group classes improved outcomes. Providing individual classes for patients as well as including a patient knowledge assessment of OAT improved outcomes. All important outcomes were considered as the educational knowledge testing also assisted with cognitive assessment. The Nasser et al. (2011) Level I evidence received a CASP score of nine.

The populations and outcomes discussed by Nasser et al. (2011) were applied to the OAT project. The adult patients on OAT in this project with multiple comorbidities were reflective of the Nasser et al. (2011) study. It was estimated that 40 patients in the project population had inadequate knowledge of foods, beverages and other medication

interaction with OAT. A knowledge assessment was done with the project population that determines their learning needs and what the patients learned.

Holbrook et al. (2012) provided a set of 2012 clinical practice guidelines for patients on OAT in a rigorous review. Melnyk and Fineout-Overholt (2011) noted that clinical guidelines are specific practice recommendations resulting from rigorous reviews of the best evidence on the topic and therefore are Level I evidence. Guidelines provide answers for clinical practice. Guidelines function as tools to improve the quality and process of care. In addition, the guidelines also function to improve patient outcomes, reduce the variation in care, and help avoid unnecessary expenditures (Melnyk & Fineout-Overholt, 2011).

The 2012 clinical guidelines from the American College of Chest Physicians specifically addressed evidence-based management of anticoagulant therapy (Holbrook et al., 2012). The focus of these guidelines is antithrombotic therapy and prevention of thrombosis. The guidelines are in its ninth edition and replaced a previous version from 2008. The American College of Chest Physicians evidence-based clinical practice guidelines include 216 references. Guideline objectives were to (a) update EBP recommendations for the use of anticoagulant therapy for the management of thromboembolic conditions, (b) offer guidance for many common problems related to OAT, and (c) optimize patient health outcomes and the processes of care for patients who have experienced or are at risk for thrombotic events (Holbrook et al., 2012).

Evidence for the clinical practice guidelines for this study was selected from systematic reviews and randomized control trials. Observational studies were also included where there was insufficient RCT data addressing an intervention and for questions of risk assessment. The guidelines focused on vitamin K antagonists (warfarin/Coumadin®) and unfractionated heparin or low-molecular-weight heparin

(LMWH) such as injectable enoxaparin sodium (Lovenox), which is available in the United States.

The clinical guidelines were analyzed on an outcome basis using criteria from the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to rating quality of the evidence. Expert consensus was the method used to formulate the recommendations (Holbrook et al., 2012). The rating scheme for the strength of the recommendations ranged from strong recommendation, high quality evidence, Grade 1A to weak recommendation, low quality evidence, and a grade of 2C. There were six grades of recommendation in all. All grades included RCT's and observational studies. Implications for patients were given for each grade of recommendations.

The AGREE II instrument (Appraisal of Guidelines for Research & Evaluation II) (Brouwers et al., 2010) was also used to evaluate the set of clinical guidelines of Holbrook et al. (2012) (Level I evidence). The AGREE II 23-item evaluation tool measures six domains for quality in order to guard against potential biases of guideline development. The recommendations were also considered internally and externally valid and were usable for practice. Scoring is from 1 of strongly disagree through 7, strongly agree.

The first domain explained the scope and purpose for quality of the guideline. The overall objectives of the guideline are specifically described and found in guideline objectives and target population *Agree Score:* 7 (*AS*: 7).The health questions covered by the guideline were specifically described (*AS*: 6) as well as the population for whom the guideline was intended (*AS*: 7) and found in the target population section.

Stakeholder involvement was the focus of the second domain. All committee members were medical doctors or doctors of philosophy (*AS*: 4).Other stakeholder views and preferences from the target population, such as the patients who were sought but

not clarified in the guidelines (*AS*: 1). Target uses of the guidelines were clearly defined and listed under intended users for OAT (*AS*: 7).

The rigor of development was completed systematically and found under the description of methods used to collect/select the evidence (*AS*: 7). In rigor of development, the criteria for selecting the evidence were clearly described and found in defining the clinical questions of population, intervention, comparator, and outcome (*AS*: 7). The strength and limitations of the body of evidence were clearly described and found in assessing studies and summarizing evidence (*AS*: 7). The methods for formulating the recommendations were clearly described. The group met as a Consensus Development Conference (*AS*: 7). The health benefits, side effects, and risks considered in formulating the recommendations was done by using the GRADE rating scale mentioned previously (*AS*:6). There was an explicit link between the recommendations and the supporting evidence to ensure consistency across articles (*AS*: 6). Clinical guidelines have been externally reviewed by experts prior to its publication and located in method of guideline validation (*AS*: 6). Updating the guideline procedures were not provided (*AS*: 1).

Guidelines were clear in language, structure and format; the recommendations were specific and unambiguous (*AS*: 7). Clinical guidelines for different options in management of OAT (*AS*: 7) as well as key recommendations were easily identifiable and located in recommendations (*AS*: 7).

For applicability of presentation, the guidelines described facilitators and barriers to its application and improvement. These methods of improvement were located in the guideline recommendation section describing the benefits/harms of implementation (*AS*: 7).The guideline provided advice and/or tools placing the recommendations into practice. Advice was found in evidence supporting the recommendations (*AS*: 7). Potential resource implications of applying the recommendations were considered and found in

the benefits/harms section of implementing the guideline recommendations (*AS*: 6). Clinical guidelines presented monitoring and/or auditing criteria and this criteria was found in qualifying statements (*AS*: 7).

Under editorial independence, the views of the funding body did not influence the content of the guidelines and listed under source of funding (*AS*: 5).The final criteria asked for competing interests of guideline development. There was a complete listing of group members with their financial disclosures and conflicts of interest. (*AS*: 7).

Applying the AGREE II evaluation tool (Brouwers et al., 2010) to this EBP project resulted in a total score was 139 out of 161. The CASP score was nine. These scores were found to be acceptable for the project.

Wofford, Wells, and Singh (2008) identified best strategies for patient education about OAT in a systematic review. The researchers' background noted teaching OAT is often ignored since it is time consuming for clinicians and overwhelming for patients. To identify the best education strategies, the Wofford et al. (2008) initial search of 206 citations decreased to 32 for data extraction in Medline and Google Scholar and was found only in English. Authors searched literature matching their population based on clinical setting, study design, group size, personnel involved, educational strategy, and patient's knowledge retention. Results of the reviews were not listed numerically but given in priority for topics required for knowledge of OAT as well as the assessment tools available to measure patient knowledge. Delivery of the content of OAT was reinforced with handouts and videos to use at home for "refreshers". Outpatient clinic setting and size applied to the project on OAT this systematic review, as well as prioritizing patient topics and the need to measure outcomes with a validated instrument. The CASP score was seven.

Level II evidence. Mazor, et al. (2007) reported on three approaches to communicating with patients about safe warfarin use. The approaches in this

randomized clinical trial included patient education incorporating narrative evidence such as patient anecdotes, statistical evidence, and narrative and statistical evidence combined. These three approaches were compared to a usual-care control group. Patients received a baseline questionnaire. Three weeks after the baseline questionnaire was received, a second set of study materials was sent, including a video on all three approaches. The control group did not receive a video. The posttest was included for all groups. Six hundred patients met inclusion criteria and were randomized in a Massachusetts anticoagulation clinic by clinic staff. Groups were similar at the start of the trial. There was no blinding to randomization. A total of 317 completed the study. Patients randomized to video intervention versus control did not differ significantly with respect to variables. Comparison of scores on baseline knowledge and beliefs did not vary between groups. The group who watched the video showed higher scores with increased knowledge than the control group ($p < .001$). This group also showed higher scores in the knowledge of laboratory testing ($p = .010$). In addition, this video-viewing group better understood taking OAT was beneficial ($p = .012$). Baseline knowledge used as a covariate showed patients who saw a video plus had a narrative showed greater knowledge gains ($p = .006$). The groups which were sent information of patient anecdotes and video instruction were found to be the most effective in patient education.

Results from Mazor et al. (2007) can be related to the pre- and posttest questionnaire. The questionnaire provided an assessment for the population as well as providing a narrative during the patient intervention. The RCT also included the individual patient's warfarin-related beliefs regarding benefits, worry, dosing confusion or difficulty, and importance of testing on the questionnaire as a section of reported outcomes. Benefits were worth the RCT related to patients' behavior changes from improved patient knowledge. The Mazor et al. (2007) RCT received a CASP score of nine.

Clarkesmith, Pattison, Lip, and Lane (2013) discussed the TREAT (**Tr**ial of an **E**ducational Intervention on patients' knowledge of **A**trial fibrillation and anticoagulant therapy, INR control, and outcome of **T**reatment with warfarin) study. The researchers hypothesized that poor patient understanding of atrial fibrillation and the medications to help avoid cardiovascular complications may add to the patients' unwillingness to comply with OAT. Patients were randomized with published registered protocol in Current Control Trials. Groups were similar at the start and end of the trial with a total of 97 patients participated in the study. There were 46 who were randomized in the intervention group and 51 who were in the usual care group. The patients were stratified as to age, sex, and location of recruitment in two locations in Birmingham, United Kingdom. The patient intervention was a DVD program, handout, self-monitoring diary, and worksheet. The usual care group received the same handout only. The patients were followed at intervals of one, two, six, and twelve months.

The primary endpoint was time in therapeutic range. The intervention group had significantly higher time in therapeutic range than the usual care group at six months (76.2% vs. 71.3%; $p = 0.035$). Surprisingly, at 12 months the differences were not significant (76.0% vs. 70.0%; $p = 0.44$). Secondary endpoints were knowledge, quality of life, depression, and anxiety. Medication beliefs such as considering OAT harmful and the patients' understanding of their cardiovascular condition were also secondary endpoints. Knowledge was found to increase over time ($p = 0.01$) but there was no difference between the two groups ($p = 0.07$). Knowledge scores predicted time in therapeutic range at six months after the intervention. The differences in knowledge scores were not significant at 12 months. The authors believed these results demonstrated that the intervention allowed the patient time to make behavioral changes and implement the changes to maintain their INR over time. Since the authors found the

intervention did not result in statistically significant differences at the 12-month interval, they concluded that a periodic intervention be implemented to help maintain adherence.

Clarkesmith, Pattison, Lip, and Lane (2013) concluded that an educational intervention improved time in therapeutic range by atrial fibrillation patients using OAT during the first six months after the intervention. The authors added that adverse outcomes may be decreased by improving the patients' knowledge and comprehension of OAT. Finally, the authors concluded education for patients with atrial fibrillation is necessary for effective dosing and patient safety. The TREAT RCT can be applied to the OAT project as it used a questionnaire to determine patient knowledge of OAT. The TREAT RCT also utilized an educational intervention with a pictorial booklet and video to improve the patient's lack of knowledge as well as to address barriers to treatment and compliance. CASP score for the RCT was nine.

There was no Level III evidence located for this project.

Level IV evidence. Pernod, Labarere, and Bosson (2008) evaluated the effect of an oral anticoagulation program to improve knowledge and reduce complications from both bleeding and clotting. There were a total of 302 patients, 135 women and 167 men who were randomized among 15 physician practices and 26 hospital departments in Grenoble, France, over 24 months. The cohort was representative of the population representing diagnosis of deep vein thrombosis or pulmonary embolism diagnosed by radiography from the physician groups in private practices and hospital departments. The patients were randomized with a one-to-one ratio to either the control or experimental group by inpatient or outpatient, annual volume of patients, and surgical versus medical specialty for hospital departments. The study group received a one-on-one tailored educational intervention of an approximately 30-minute teaching session. Each patient received a picture book describing the disease and treatment according to the patient's cognitive level. The control group received the usual unstructured

information about Vitamin K antagonist therapy and a standard teaching booklet published by the French Heart Association. Both groups were assessed after three months with a standardized 18-item questionnaire which addressed Vitamin K antagonist therapy, optimal therapeutic range, and practical management of bleeding or non-therapeutic INR. The questionnaire was objectively scored from zero to 20 and *p* values of less than 0.05 were considered statistically significant. The mean knowledge score was higher in the experimental group (13.9 +/- 4.5) than in the control group (12.4 +/- 4.9), $p = 0.08$). Knowledge scores were higher in younger patients under age 70 (14.3 +/- 4.6 versus 11.2 +/- 4.4; $p < 0.01$) than those who were over 70 years. Patients who graduated from high school had a higher knowledge score than those who did not graduate from high school which was statistically significant (15.4 +/- 3.7 versus 11.5 +/- 4.5, $p < 0.01$).

Another objective outcome during the three month follow-up was that the main criteria outcome of bleeding events was observed 15 times in the control group (10.6% of the patients) and 5 (3.1%) times in the experimental group. The cumulative risk reduction in the experimental group was statistically significant (OR 0.25%, 95% CI 0.1-0.7, $p < 0.01$). The researchers objectively reported the educational program helped patients demonstrate a better knowledge of OAT as well as decrease the incidence of adverse bleeding by threefold in the experimental group compared to the control group (Pernod et al., 2008). Since the researchers focused on the reduction of adverse events of clotting or bleeding, they did not control how effective the educational program was based on the patient's INR control. This may be a bias because more frequent INR reports were associated with fewer adverse events of bleeding (Pernod et al., 2008). This case control study supported the project with its educational intervention and knowledge of INR testing. It was given as CASP score of nine.

There was no Level V evidence located for this project.

Level VI evidence. Cook-Campbell and Sefton (2010) examined outpatients on OAT with a telephone survey of homecare patients to determine the level of knowledge regarding the patient's management of OAT. The researchers found basic knowledge of food and medication interactions significantly decreased the adverse events of bleeding or clot formation. A total of 36 patients qualified for the study based on inclusion criteria of no cognitive limitations and access to a telephone. Additional inclusion criteria included speaking and understanding English, management of their own medications, and the use of long-standing anticoagulation therapy of three months or longer. Content validity was supported through a panel of nurses and pharmacists. The questionnaire was given a pilot test by four rehabilitation patients following those patients' education of OAT. Questions were validated by a certified gerontological nurse. Reliability of the survey was conducted by five patients currently using OAT in a test/retest method that was found to be 91% in agreement. Data collection was done by the home care nurse within two weeks of hospital discharge.

Percentages of correct responses of the 14 individual survey questions were described by the researchers. The question with the most correct responses pertained to knowledge for rationale for warfarin therapies with 94% correct (Cook-Campbell & Sefton, 2010). The least correct response was the question about using the Medic-Alert bracelet or identification cards with 28% correct (Cook-Campbell & Sefton, 2010).

Results answered the research question. A *t* test of p =.01 was significant for patient's knowing one food type containing Vitamin K, t (33.1) = -2.98. Knowledge of foods to be aware of interaction showed significance at $p < .01$, t (34) = -2.77. Identification of three foods high in Vitamin K was found significant between men and women of $p < .05$, t (34) = -2.16. The term *blood thinner* knowledge was found significant at $p < .10$, t (19) = 1.83. The knowledge of complication awareness was found significant between men and women at $p < .10$, t (33.6) = 1.87. Over-the-counter

medication interaction knowledge of patients in this group was found significant at $p < .10$, t (33.6) = -1.88. Limitations of the study were the small sample size of 36 patients. In addition, the education of OAT was not given by any consistent providers but conducted by nurses, pharmacists, and physicians.

Survey questions revealed the overall knowledge about warfarin was poor, with a mean score of 56%. The majority of the participants were adults aged 81 or older (n = 20). Registered nurses provided patient education on OAT during the first 24 months of therapy. Based upon their findings, the researchers concluded there is value to a comprehensive education program which follows patients across the continuum of care. The authors further indicated an education program with a questionnaire to document knowledge would also validate whether or not the patient understood the teaching and be able to safely manage their warfarin.

Findings from Campbell and Sefton (2010) study transferred well to the project on OAT. The age of the patients, size of the sample, a lower literacy teaching intervention, a 14-item survey, and patient diagnosis for OAT were all similar characteristics to the project on OAT. The CASP score for the knowledge retention home care survey was 10.

Smith et al. (2010) surveyed 100 patients on OAT and measured their **C**ongestive Heart Failure, **H**ypertension, **A**ge, **D**iabetes and **S**troke, second revision (CHADS2) score. The targeted age group was 68 +/- 10 years. A 52-item questionnaire was given to each of the 100 CHADS2 patients on OAT. Sampling strategies were clearly defined and justified as data were stratified by educational level, CHADS2 score, and duration of warfarin use. Comparisons between groups were based on a two-sample t test. Group comparisons were based on Fisher's exact test and $p < 0.05$ was considered significant.

Survey questions were compiled based on the five categories of general warfarin knowledge, compliance, drug interactions, herbal and vitamin interactions, and diet. Warfarin knowledge stratified by duration of warfarin use showed none were statistically significant. The group using warfarin greater than five years had a higher score for more knowledge but was not statistically significant ($p = 0.281$). The group using warfarin less than one year showed more compliance but was not statistically significant ($p = .453$). There was essentially no statistically significant difference in the three groups showing knowledge in drug-drug interactions ($p = 0.869$). There was no statistically significant difference in the three groups' knowledge of drug-vitamin supplement knowledge ($p = 0.148$). The group using warfarin over five years showed more knowledge of diet, but it was not statistically significant ($p = 0.686$).

Warfarin knowledge was also stratified by CHADS2 score. General knowledge ($p = 0.301$) and compliance ($p = 0.1777$) were not found to be statistically significant among the three groups. Drug-drug interaction knowledge was not found statistically significant among the three groups ($p = 0.329$), nor was drug-vitamin supplement knowledge ($p = 0.366$). In addition, diet knowledge was not found statistically significant among the groups ($p = 0.534$).

The researchers worked to understand how educational levels influenced survey scores favorably or unfavorably. There were no significant differences between groups in any category with respect to maximum educational level achieved or duration of therapy. Results also reflected knowledge of CHADS2 risk scores. Patients with higher CHADS2 scores had no significant difference in their knowledge, compliance, drug-drug interactions, or drug-vitamin supplement knowledge, but did score higher on their knowledge of diet. There was also no significant difference in knowledge for patients on OAT under 75 years versus those over 75 years.

The researchers concluded the negative impact that knowledge deficit has on warfarin therapy. They concluded that drug education, if provided at all, is often delivered at the beginning of therapy. The researchers emphasized the need for ongoing knowledge assessment with educational approaches to improve patient outcomes.

Results can be transferred to the project on OAT. The subjects in the Smith et al. (2010) study were similar to the population for the project on OAT related to their age and educational levels. Scores for the project on OAT showed patients at highest risk score the lowest in knowledge of OAT. Researchers in the Smith et al. (2010) study noted the negative impact of the knowledge deficit of OAT and the potential for educational strategies to improve treatment outcomes as well as effectiveness of OAT. The educational strategies, improved treatment outcomes, and effectiveness of OAT were all parts of this project on OAT. The CASP score was seven.

Lane, Ponsford, Shelley, Sirpal, and Lip (2005) studied patients with atrial fibrillation using OAT in the United Kingdom. The study was designed to test patient knowledge of OAT and atrial fibrillation both before and after an educational intervention. The sample consisted of 93 patients who finished a questionnaire to determine their knowledge of atrial fibrillation (AF) and its multiple treatment options related to OAT. All the patients were given an informational booklet explaining atrial fibrillation. The booklet contained information about the symptoms, causes and side effects, treatment possibilities, and the risks and benefits of atrial fibrillation. A follow-up questionnaire was completed by 33 of the 93 original patients to reassess their knowledge of atrial fibrillation and OAT. At baseline, only 49% of the original 93 patients could name their heart condition. Half the patients were aware of the risk of embolism. After the educational intervention, there was a non-significant increase in patient knowledge of the risks of atrial fibrillation. In patients who completed both questionnaires, just over half (52% or 18 patients) understood that anticoagulants reduce blood clots. This increased

to 70% or 26 patients after the intervention. The educational intervention also improved the patient's knowledge of INR and factors affecting INR. The researchers concluded that patients with atrial fibrillation may have little knowledge of their heart conditions and OAT. The authors also noted that a brief educational intervention utilizing an information booklet can help the patient's basic knowledge about OAT used to treat atrial fibrillation.

Data were analyzed by 2-tailed statistical testing. Results addressed the research question; however, there may have been selection bias as the researchers stated that those who attend their appointments may be more educated about their underlying condition, that of AF. CASP score for the Lane et al. (2006) educational intervention with questionnaire research study was nine.

The study by Lane et al. (2006) corresponds well to the project on OAT as information regarding cardiovascular conditions was included in the educational intervention. Knowledge of the INR as well as the questionnaire supplemented the intervention.

Hu et al. (2006) conducted a cross-sectional observational study with 100 patients who had mechanical heart valves and life-long OAT. The researchers surveyed 100 patients over 13 months in a cardiac network database in Toronto, Ontario, with a validated Knowledge Information Profile (Wilson et al., 2003), a 20-item questionnaire used to measure the patients' knowledge of warfarin, its side effects, and vitamin K food sources. This was the same questionnaire the OAT study used, before the KIP-C (Nordstrom et al., 2009) was reduced to 14 questions to lower the literacy level of the questionnaire. Results of the KIP showed 61% of the patients had scores showing insufficient knowledge of warfarin therapy (score </= 80%). Age was negatively related to warfarin knowledge score (r = 0.27, p = .007). Community counseling on OAT was done and included a brochure written by a pharmaceutical company. Patients with family incomes greater than $25,000, who had greater than an eighth grade education, and

who were employed or self-employed had higher warfarin knowledge scores (p =0.007, p = .002, and p = .001, respectively). Gender, ethnicity, and warfarin therapy before mechanical heart valve surgery were not related to warfarin knowledge scores.

Results of the Hu et al. (2006) study addressed their research question, which were factors influencing patient knowledge of warfarin therapy after mechanical valve replacement. Multivariate regression analysis showed understanding the concept of INR, knowing what INR means, age, and receiving the patient education were the strongest predictors of warfarin knowledge. Having community counseling resulted in significantly improved warfarin scores.

The Hu et al. (2006) study transferred well to the project on OAT. The same Knowledge Information Profile questionnaire was used, with six questions omitted to lower the literacy level of the questionnaire. In addition, patient education on OAT in the community as well as addressing demographic variables of the patient on OAT made this study similar to the clinical agency of the project on OAT. The Hu et al. (2006) study received a CASP score of nine.

Table 2.1

Levels of Evidence from the Appraisal of Literature

Author, Year, Study Design, Level of Evidence	Sample/Intervention/Findings	Strengths /Weaknesses
Clarkesmith, Pattison, and Lane (2013) Systematic Review Level I	8 trials with 1,215 patients in 6 countries, interventions impact more time in therapeutic range, using educational booklets, videos, decision aids, patient teaching, and questionnaires. 2 trials reported impact on patient knowledge, but this returned to pre-intervention levels after 6 months. 2 trials reported improved impact on patient knowledge but returned to pre-intervention level after 3 months. 2 trials did not find self-monitoring plus usual care or education improved time in therapeutic range. There was a mean difference of 6.31 (95% CI -5.63 to 18.25). The secondary outcome of patients having a conflict with their decision-making favored usual care over decision aids. The mean difference was 0.1 (95% CI -0.2 to -0.02).	Strengths included a trial in patient satisfaction, education improving INR over 3 months, and percentage of time in therapeutic range improved. Weaknesses included 4 trials had mixed indication cohorts as patients have different INR ranges with valve replacements, 5 studies did not report the patient's level of education which may impact knowledge uptake and treatment control.

Table 2.1

Levels of Evidence from the Appraisal of Literature

Author, Year, Study Design, Level of Evidence	Sample/ Intervention/Findings	Strengths and Weaknesses
Nasser et al. (2011) Systematic Review Level I	14,541 older adult patients using OAT 50-80% of older adults have inadequate knowledge of anticoagulation. Assessment instruments or questionnaires were used to measure knowledge. Face-to-face, group sessions, written educational resources and videos on OAT improved patient knowledge and time in therapeutic range.	Strengths: Study found improved patient knowledge resulted in better anticoagulation control. Mean knowledge scores were higher in face-to-face group than control ($p = 0.08$). Statistically significant ($p < 0.01$) cumulative risk reduction in major bleeding events Weaknesses: assessment instruments or questionnaires were not validated; lacked consistent educational tools

Table 2.1

Levels of Evidence from the Appraisal of Literature

Author, Year, Study Design, Level of Evidence	Sample/ Intervention/Findings	Strengths and Weaknesses
Holbrook et al. (2012) Clinical Practice Guidelines Level I	The 2012 American College of Chest Physicians, 9th edition 13 management criteria including patient education, used for adult patients Relevant evidence was found in systematic reviews, RCT's, and prospective cohort studies. 137 members were in the American College of Chest Physician's Antithrombotic Therapy and Prevention of Thrombosis Panel	Strengths: Guidelines given for warfarin as the oral anticoagulant Guideline authors graded the evidence through GRADE work group for strength of evidence, gave disclosure by name of entire review panel Weaknesses: No specific patient resources were listed for teaching; no tools were listed for patient assessment of knowledge.
Wofford et al. (2008) Systematic Review Level I	32 articles related to OAT vary in strategy, patient testing via questionnaires for adult patients. Prioritizing educational domains, standardizing patient content and consistency of delivering the content efficiently will be necessary to improve the quality of OAT for the patient.	Strengths: 13 articles discuss specific educational strategies, such as 1-on-1 classes with handouts. 12 articles address main objectives of the educational content. Weaknesses: no direction to determine the patient's literacy level in the questionnaires listed No specific guidance given as what patient education handout to use for content or literacy level.

Table 2.1

Levels of Evidence from the Appraisal of Literature

Author, Year, Study Design, Level of Evidence	Sample/Intervention/Findings	Strengths and Weaknesses
Clarkesmith, Pattison, Lip, and Lane (2013) RCT Level II	**TREAT** trial showing the intervention group of 46 patients had significantly more time in the therapeutic range than the usual care group at 6 months (76.2% vs. 71.3%; *p* = 0.035), but not at 12 months (76.0% vs 70.0%; *p* = 0.44). The study was done with 97 adult patients in 2 locations as a RCT. The intervention was a DVD program, handout, diary and worksheet. The usual care group of 51 patients received only a handout. Patients were followed at 1,2,6, and 12 months	Strengths: TREAT intervention gives patients a framework to make behavior changes and strategies to maintain a therapeutic INR over time. The teaching intervention is listed that needs to be done every 6 months to maintain levels of adherence to warfarin therapy. Weaknesses: Atrial fibrillation often seen predominantly in white populations; 234 eligible patients declined to participate due to questionnaire burden

Table 2.1

Levels of Evidence from the Appraisal of Literature

Author, Year, Study Design, Level of Evidence	Sample/Intervention/Findings	Strengths and Weaknesses
Mazor et al. (2007) RCT Level II	Patients on OAT may benefit from periodic (every 6 months) educational efforts reinforcing key medication safety information, even after initial education and ongoing monitoring. 600 patients randomly assigned to one of three groups who received warfarin education including videos and handouts, or usual care. 317 patients completed both baseline and post-test questionnaires. Patients who had education showed greater gains on the questionnaire than those in control group ($p <$ .001); they also showed greater positive results in their beliefs in the importance of INR ($p = .010$), and believed that taking warfarin was beneficial ($p = .012$).	Strengths: The questionnaire demonstrated many patients to have dangerous beliefs and gaps in their warfarin knowledge Study found non-adherence a great concern, leading to risky behaviors and life-threatening adverse events Weaknesses: patients responding to the questionnaire were not supervised and minorities were not represented. The educational strategies had no longer term impact than 6 months.

Table 2.1

Levels of Evidence from the Appraisal of Literature

Author, Year, Study Design, Level of Evidence	Sample/Intervention/Findings	Strengths and Weaknesses
Pernod et al. (2008) Case-Control Open Randomized Study Level IV	Study showed insufficient patient education is associated with adverse thromboembolic event rates in adult patients. Cumulative risk reduction in experimental group versus control group was statistically significant (OR 0.25, 95%; CI 0.1, <0.01) in multivariate analysis. Patient knowledge was assessed with an 18-item questionnaire, patients received picture booklets.	Strengths: Experimental group had 3 times decreased adverse events than control group, regardless of patient's age or economic level. Weaknesses: The researchers did not control the efficacy of the educational program based on frequent INR testing; researchers thought physicians biased toward experimental group.
Cook-Campbell and Sefton, (2010). Descriptive Study Level IV	36 home care patients (mean age was 79 years) were given a survey of 14 questions related to OAT Basic knowledge of food and medication interventions can make a significant impact on reduction of adverse effects of bleeding or clot formation. Older adults may have different needs which may hinder their OAT education. 6 out of 14 questions were found statistically significant for knowledge gained after the educational intervention.	Strengths: Study showed knowledge deficit among patients >65 years now home after hospitalization, citing mental capacity of elderly may be a factor and older adults may have different needs that hinder warfarin education. Home care developed educational program based on survey results of OAT. Weaknesses: small sample size; there was no established reliability or validity to questionnaire used in the survey. The teaching was done by either nurses or physicians, or literature was provided, there were no teaching guidelines.

Table 2.1

Levels of Evidence from the Appraisal of Literature

Author, Year, Study Design, Level of Evidence	Sample/Intervention/Findings	Strengths and Weaknesses
Hu et al. (2006) Descriptive Study Level IV	100 patients with mechanical heart valves using OAT were tested with the 20-item questionnaire, the Knowledge Information Profile (KIP). 61% of patients had scores showing insufficient knowledge of warfarin, multivariate regression analysis showed understanding INR, knowing the acronym, age, were the strongest predictors of knowledge of OAT. Patients who received community counseling did have significantly higher knowledge of OAT compared to those who did not receive any knowledge (p = .001).	Strengths: The study used the Knowledge Information Profile, a previously validated questionnaire. KIP was translated into different languages and accommodated socioeconomic status. Weaknesses: Patients who received more than 1 teaching tool may be a confounding factor. Study was unable to tract INR values for correlation to INR control.
Lane et al. (2005) Descriptive Study Level IV	2 hospital clinics in the UK had 93 patients with atrial fibrillation complete a baseline questionnaire followed by an educational intervention on OAT. 33 of the 93 clinic patients completed a follow-up questionnaire. The educational intervention significantly improved the patient's knowledge of the therapeutic INR range and conditions that may affect INR levels (p = 0.001 and p = 0.014) for patients who finished both assessments.	Strengths: Patients improved their knowledge of atrial fibrillation and its treatment. Weaknesses: The patient education handout was not measured with regard to literacy level; the study did not assess the usefulness of the handout.

Table 2.1

Levels of Evidence from the Appraisal of Literature

Author, Year, Study Design, Level of Evidence	Sample/Intervention/Findings	Strengths and Weaknesses
Smith et al. (2010) Descriptive study Level IV	100 patients were given a 52-item questionnaire of Coumadin knowledge, compliance, drug interactions, herbal or vitamin interactions and diet. Patients were stratified according to their educational level. No knowledge difference related to diet (p = 0.686) or drug-drug (p = 0.869) or drug-supplement interaction (p = .148). Data was attributed to high variability in effectiveness of OAT and highlight the need for innovative educational approaches.	Strengths: The study had patients reading a food label on the questionnaire and found the ineffectiveness of the education to be at too high a literacy level. The questionnaire revealed the patient's lack of knowledge regarding vitamins and minerals with OAT. Weaknesses: The questionnaire was not validated, the questionnaire was based on current practices in education of OAT, and patient responses were self-reported.

Construct EBP

Literature Synthesis to Support EBP Recommendations

Level I evidence summary and synthesis. Level I evidence from three systematic reviews and the one clinical practice guideline showed the evidence to be strong for patient educational interventions of OAT. As Nasser et al. (2011) indicated, there are multiple challenges of older patients' knowledge of OAT. These multiple challenges help direct how to assess the patient's current knowledge. The recommendations from these researchers included utilizing a validated questionnaire to measure patient knowledge. Providing various patient accesses to education of OAT in different practice settings was another recommendation.

The clinical practice guidelines from Holbrook et al. (2012) agreed with Nasser et al. (2011) that patient education for OAT should be done in a systematic and coordinated manner with INR testing and tracking. Wofford et al. (2008) agreed with patient education assessment by questionnaire as a systematic and coordinated manner to determine education required for OAT, as well as measuring what the patient learned.

Nasser et al. (2011) addressed the barrier of older patient's cognitive functional decline as an additional challenge for OAT. Particularly, the assessment review by Wofford et al. (2008) discussed the provider's need to recognize the patient's reading and literacy level related to cognitive function. However, Clarkesmith, Pattison, and Lane (2013) examined patient uncertainty about making decisions as a knowledge deficit rather than cognitive decline for the older patient. These researchers also discussed emotional barriers of OAT, utilized educational booklets at the patient's reading level, and implemented INR testing interventions to facilitate working through these barriers.

Clarkesmith, Pattison, and Lane (2013) and Nasser et al. (2011) recommended one-on-one or face- to-face patient interactions regarding the questionnaire and patient

education on OAT. The information can then be customized for patient need without patient embarrassment if lack of knowledge is determined.

Wofford et al. (2008) acknowledged the provider to be experienced in OAT and names *physician extenders* who are knowledgeable in OAT to do the patient education. The researcher's endpoints revealed the educational content of education of OAT should be that of safety by topic and not include extraneous points of anticoagulation. Wofford et al. (2008) also recommended office efficiency to be maximized with the utilization of physician extenders, who are knowledgeable using validated instruments with patient visits.

Clarksmith, Pattison, and Lane (2013), Nasser et al. (2011), and Wofford et al. (2008) all acknowledged videos on OAT to augment the educational intervention. In addition to the pictorial handout, the video was a take-home reminder of the importance of OAT. The video provided reinforcement, convenience, and flexibility for the patient.

Level II evidence summary and synthesis. The two RCT's recommended clinicians utilize patient narratives with examples of information on OAT during patient interviews. Specifically, education of OAT using educational booklets and measuring what patients learned with questionnaires was endorsed to measure effective patient education of OAT. Both RCT's found gaps in the patient's knowledge regarding OAT before patient education began. The two RCT's showed the importance of monitoring as a learning tool for OAT, and looked at monitoring as well as time in therapeutic range as teaching tools. Clarkesmith, Pattison, Lip, and Lane (2013) as well as Mazor et al. (2008) encouraged patient updates of OAT done by face-to-face educational interventions or videos. Specifically, Clarkesmith, Pattison, Lip, and Lane et al. (2013) found no difference between the interventional group and the control group with knowledge of OAT after six months.

Level IV evidence summary and synthesis. Pernod et al. (2008) recommended an educational intervention for patients on OAT to decrease complications of hemorrhage or thromboembolic events. The researchers found the impact of an educational program utilizing an 18-item questionnaire and a picture book on OAT on clinical adverse event rates were clinically significant no matter the age or sociocultural level of the patient. Their best practice recommendations focused on greater awareness of the need for education as well as regular INR values monitored every one, two, three, or four weeks to lower adverse rates of thrombotic or hemorrhagic complications of OAT.

Level VI evidence summary and synthesis. Consistencies within all four descriptive studies for the project on OAT included that education to accommodate the patient's literacy level on OAT was needed prior to therapy. Another consistency was utilizing a validated tool such as a questionnaire or pretest/posttest to evaluate patient knowledge of OAT. Hu et al. (2006) used the same assessment questionnaire as the project on OAT will be using. However, the Knowledge Information Profile was 20 questions in 2006. It has been decreased to 14 questions by its authors and its literacy level measured to that of a sixth grade reading level (Nordstrom et al., 2009).

Further consistencies within all four descriptive studies concerned the patient's knowledge deficit and why the patient had the knowledge deficit. Hu et al. (2006) noted patients who had incomes less than $25,000 and less than an eighth grade education had literacy barriers to knowledge of OAT. Smith et al. (2010) found the patients at highest risk with multiple comorbidities had the lowest knowledge scores. Cook-Campbell and Sefton (2010) and Lane et al. (2006) discovered patient knowledge deficits of over-the-counter medications which were not included in the patient's medication list that affected OAT. The patient did not know the over-the-counter medications were important and could make a difference in the INR. Cook-Campbell and

Sefton (2010) and Hu et al. (2006) found the patients had knowledge deficits of food items containing Vitamin K that affect the INR and the need to reinforce the information through written patient education. The researchers listed reasons why the patient may have forgotten the information or it was originally poorly understood.

Hu et al. (2006) and Lane et al. (2006) agreed that understanding the concept of INR and ongoing monitoring of the INR to be strong predictors of improved knowledge as well as longer time in therapeutic range.

Finally, all four descriptive studies were consistent with recommendations of on-going community counseling with educational handouts written at a lower literacy level to improve patient knowledge about taking OAT. None of these four descriptive studies found an increased knowledge of OAT with duration of therapy.

Best Practice Model Recommendation

Based on the most current and relevant evidence from the literature, the project manager identified similarities within the evidence. These similarities indicate that the best practice model recommendation for the project included the following:

1. An experienced APN in the management of OAT for patient assessment, education implementation and dosing of OAT (Wofford et al., 2008).
2. A questionnaire or validated tool in the form of a pretest/posttest which determined patient baseline knowledge of OAT (Clarkesmith, Pattison, & Lane, 2013; Cook-Campbell & Sefton, 2010; Hu et al., 2006; Lane et al., 2005; Smith et al., 2010; and Wofford et al., 2008).
3. The questionnaire was written on a sixth grade reading level (Hu et al., 2006).
4. A large-print written booklet with pictures was used for the educational intervention (Clarkesmith, Pattison, & Lane, 2013; Cook-Campbell & Sefton, 2010; Holbrook et al., 2012; Hu et al., 2006; Lane et al., 2005; Mazor et al., 2007; Nasser et al., 2011; Smith et al., 2010; and Wofford et al., 2008).

5. The large-print written booklet with pictures on a sixth grade reading level was used for the teaching intervention (Hu, et al., 2006; Mazor et al., 2007).
6. One-on-one educational interventions were provided to the patients (Clarksmith, Pattison, & Lane 2013; Cook-Campbell & Sefton, 2010; Holbrook et al., 2012; Hu et al., 2006; Lane et al., 2005; Nasser et al., 2011; and Smith et al., 2010).
7. A 12-minute video on OAT was used to augment the educational intervention and provided a reinforcement for home use (Clarkesmith et al., 2013; Lane et al., 2006; Nasser et al., 2011; Wofford et al., 2008)
8. Continued INR monitoring in accordance with American College of Chest Physicians (ACCP) EBP clinical guidelines was implemented to answer the clinical question (Holbrook et al., 2012; Mazor et al., 2007; Pernod et al., 2008; Wofford et al., 2008)

The 2012 ACCP EBP clinical guidelines for OAT used in this project do not specify that a questionnaire or pretest/posttest be utilized to measure learning. However, the 2012 ACCP EBP clinical guidelines do indicate that patient education be conducted in a systematic and coordinated manner. The ACCP recommendations included INR testing, tracking, follow-up, and good patient communication of results and dosing decisions in patient education.

Best Practice Recommendation

The project manager utilized the eight best practice recommendations found in the best evidence regarding the effect of an educational intervention on OAT in a primary care setting. Roy's (2001) Adaptation model for patients and nursing's role in redirecting stimuli facilitated the patient's adaptation behaviors. The Stetler model (2001) identified five phases of project development that promoted critical thinking and guided the project.

Permission was obtained to utilize the KIP-C by one of its authors, Feletta L. Wilson, PhD. RN, see Appendix A. Patients on OAT were asked to take part in a 14-question true/false pretest, the KIP-C (Nordstrom et al., 2009), see Appendix B. These patients then had a 25-minute educational intervention using a professionally written and illustrated handout constructed on the sixth grade reading level. The illustrated handout is located in Appendix C.

Key elements of the handout included basics of anticoagulation, risk-benefit of OAT and adherence. Patients had their questions addressed on accessing healthcare professionals, diet and lab monitoring. Medication interactions and self-care issues had precedence. The narrative to the educational handout is located in Chapter 3.

The patient viewed a 12-minute video to reinforce OAT and took home both the handout and the video. Questions the patient had were answered during the patient's educational intervention. The patient returned to the primary care office in two weeks for their follow up appointment and completed the posttest.

Answering the Clinical Question with the Best Practice Recommendation

Effective patient education interventions were utilized in this project. The PICOT question was: *"Is an oral anticoagulation therapy educational intervention given to adult outpatients in primary care effective in increasing the patient's knowledge two weeks after the intervention?"* The project leader administered the pretest prior to the intervention, provided the educational intervention, and administered the posttest two weeks later. The effectiveness of the intervention was graded by the testing scores.

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CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

Setting and Participants

The setting for this EBP project was an adult and geriatric outpatient clinic office of three providers with approximately 3500 patients. The nurse practitioner who works full time was the project manager for this EBP project .Originally a one physician-owned practice since 2005, the full-time nurse practitioner joined the practice October 1, 2007, and the part-time nurse practitioner joined the practice in 2013. The practice was sold to a local community medical center in a Midwestern city on April 1, 2013. Located seven miles from the hospital on its own campus, the practice was renamed as part of a medical group. The medical center is an affiliate of a larger health system in Chicago and has received Magnet status.

The participants for the EBP project were adult and geriatric outpatients who were prescribed Coumadin® or warfarin, named in this project as OAT. The participants had English as their written and spoken language. They did not reside in long-term care and did not have dementia as a diagnosis on their health problem list. The project was implemented from September 9, 2014 through January 31, 2015.There were 65 patients on OAT in the clinic. There were 38 patients in the project.

Outcomes

The primary outcome was knowledge gained of OAT after an educational intervention by the project manager. Permission was obtained by the author (see Appendix A) to use a validated 14-item questionnaire, the Knowledge Information Profile-Coumadin, (see Appendix B) as the data collection tool to measure intervention effectiveness in knowledge gained of OAT. The project manager then used a large-print pictorial booklet for the intervention and discussed each topic with the patient. Food

models were used during the intervention to create a visual and tactile application of foods or beverages which interact with OAT. The patient also viewed a 12-minute video on OAT and took both the booklet and the video home for continued reference.

Intervention

The project manager implemented the educational intervention in the clinic. The project did not require any financial hardship for the organization or the patient as the patient attended the clinic for an appointment, a follow up appointment, or a scheduled INR monitoring. The project manager did not receive scholastic reimbursement for the project. The project manager spent face-to-face time with the medical center's IRB attorney for the project proposal, consent, authorization form, data collection tool, educational tool, and protocol. Nursing Research Council from the medical center approved the same forms. Consent was provided by the Valparaiso University's IRB for the project prior to implementation.

The project was implemented in the office during routine office visits, a follow up visit, a walk-in visit, or a scheduled INR monitoring. These four patient encounters showcased the Stetler model (2001). The model identified affirming perceived problems with internal evidence. The desired measureable outcomes were attained with the educational intervention. Roy's perception of individual adaptation congruently found the patient in a position for learning with the APN who evaluated the patient's adaptation on a continuum.

As the evidence illustrated, a questionnaire should be used to measure the direction of the education (Clarkesmith et al. 2013; Cook-Campbell & Sefton 2010; Hu et al. 2006; Lane et al. 2006; Mazor et al. 2007; Smith et al. 2010; Wofford et al. 2008). The KIP-C true/false questionnaire was given to the patient at this time and alphabetically coded for protection of human subjects and HIPPA privacy. The questionnaire was stored in a locked drawer of a locked office until data retrieval. The

KIP-C was written on a sixth grade reading level. Current evidence supported recognizing literacy issues of the adult patient (Hu et al., 2006; Mazor et al., 2007).

Face-to-face or individual patient interaction was addressed in the evidence as best practice (Clarkesmith et al., 2013; Nasser et al., 2011; Smith et al, 2010). The project manager used a 25-minute face-to-face anticoagulation therapy educational intervention utilized the booklet, *Blood Thinner Pills: Your Guide to Using Them Safely* (Huber, 2005) (see Appendix C). The 12-page, large-print pictorial booklet covered the following topics:

1. The name of my blood thinner
2. About your blood thinner
3. How to take your blood thinner
4. Check your medicine
5. Using other medicines
6. Possible side effects
7. Stay safe while taking your blood thinner
8. Food and your blood thinner
9. Talk to your other doctors
10. Blood tests
11. Common medical conditions

The educational intervention was clarified in each page of the handout and allowed the patient to write a note or mark important points to remember. The evidence supported written materials for patient use (Clarkesmith et al., 2013; Cook-Campbell and Sefton, 2010; Holbrook et al., 2012; Hu et al.,2006; Lane et al., 2006; Mazor et al., 2007; Nasser et al., 2011; Smith et al., 2010; and Wofford et al., 2008). Within the intervention, the project manager followed a regular pattern of questions and answers pertaining to each of the subjects listed above and located in the handout. Clinical guidelines (Holbrook et

al., 2012) addressed a systematic and coordinated approach, good patient communication of results and dosing decisions in patient education. The project manager noted the patient's response to each topic based on his or her current knowledge of OAT. Evidence of provider knowledge was included in best practice (Wofford et al., 2008).

The patient returned to clinic two weeks later to take the questionnaire as the posttest, which was also the KIP-C. It was coded and stored in the same manner as the pretest.

Planning

Planning well in advance of implementation was required before the project was developed. The project manager met with the physician and other nurse practitioner for guidance and suggestions for implementation. The methods of implementation were adjusted for the older adult, such as a slower-paced, large-print booklet on a lower-literacy level, the use of food models and reinforcement of the information with a video. Permission had been granted to use the KIP-C tool from the author (see Appendix A). The patient booklet was cited in the references of this project (see Appendix C) and is in public domain; it may be used and reprinted without permission.

Recruiting Participants

Patients were identified using the clinic's EMR. A listing of patients was also available. The listing was only known to the project manager as patients are tracked for timeliness of INR monitoring. As patients who reside in long-term care and with dementia were omitted, the remaining patients were offered the OAT educational intervention. Patients came to the office for a routine office visit, a follow-up visit, walk-in visit, or for monitoring their INR, so there was not a hardship coming to the clinic for either the questionnaire or the intervention. Patients who agreed to take part in the

intervention signed a consent form (see Appendix D) and an authorization form (see Appendix E).

Data

Reliability and validity

Two-thirds of the patients eligible for this study were over 70 years old. Literature indicated (Hu et al., 2006; and Nasser et al., 2011) that older adults may not use medication correctly and have poor adherence as a result of lack of understanding. In OAT, poor adherence occurs with 10-26% of patients, but is more pronounced in the older population (Wilson et al., 2003). The older adult may not be able to process or remember the information about OAT due to (a) poor understanding, (b) polypharmacy, (c) impaired reasoning from the effects of cardiovascular diseases or medication side effects, (d) multiple sensory impairment, e) difficulty with word recognition, and (f) lack of concentration (Wilson et al., 2003).

One of the authors of the KIP-C, Feleta Wilson, PhD, MPH, BSN, RN, FAAN, is an associate professor in the College of Nursing at Wayne State University, Detroit, Michigan. Dr. Wilson has championed health literacy and patient education for the past 20 years. Originally named “KIP”, the Knowledge Information Profile was a 20-item true/false questionnaire that was used in 2003 in a study of 60 patients at an oral anticoagulation clinic. Content validity of the KIP was confirmed by a group of six professionals in anticoagulation therapy and gerontology. In addition, other validity characteristics included:

1. KIP provided a definite purpose of defining knowledge of medication action, drug interaction and food sources of Vitamin K
2. Food, beverage or medication characteristics were common among patients in age groups, English speaking, and African American

3. The subjects were determined to be physically and mentally able to participate in the study
4. The questionnaire measured patient knowledge using true and false answers
5. The questionnaire captured culturally-based scenarios that were realistic to the patient
6. The KIP was compared to the REALM (Rapid Estimate of Adult Literacy in Medicine) evaluation during the study, which is a word recognition test to help assess adult learning capacity (Wilson et al., 2003; Stiggins, 1987)

KIP reliability for this study was 0.80. In addition, reliability was demonstrated as the pharmacist, APN's, and physicians were trained in OAT and assessed for consistency (Wilson et al., 2003). Rater bias was minimized through training and cultural awareness in the anticoagulation clinic (Wilson et al., 2003). This provided a common environment for both the patient and professionals (Wilson et al., 2003).

Results of the KIP study showed a significant relationship between literacy and education ($p < 0.01$). An inverse relationship was found between age and literacy ($p < 0.01$). The study found literacy levels decreased as age increased. In addition, as age increased, knowledge about food and medicine decreased ($p < 0.01$) (Wilson et al., 2003).

In 2009, Dr. Wilson and colleagues modified the assessment tool to the current KIP-C, which was shortened from 20 to 14 questions (Nordstrom et al., 2009). Dr. Wilson and colleagues studied 192 patients with similar backgrounds and the same clinic site as the first study. The researchers tested psychometric properties of test-retest score reliability. They also correlated the patient's length of OAT therapy with knowledge scores for construct validity. Dr. Wilson and colleagues hypothesized that more patient knowledge would be related with more literacy (Nordstrom, et al., 2009). The REALM

and demographic profiles were again used. The posttest was completed two weeks later. This period of time was selected because this was sufficient time to detect a change in knowledge between pre-/posttests and to measure INR consistency in therapeutic range (Nordstrom, et al., 2009).

The KIP-C correlated with pre-/posttests ($p < .0001$) suggesting test-retest reliability. The KIP-C pretest correlated with the REALM ($p = .005$). The posttest follow-up correlated with the REALM ($p < .0001$) as well as the patient's time using Coumadin ($p = .01$) supporting construct validity.

Data Collection

The 14-question KIP-C took the patient less than ten minutes to complete. The questions represented Vitamin K foods and knowledge, side effects of OAT and other foods, beverages and medications related to OAT. The eight points of demographics for each patient included (a) age range, (b) gender, (c) level of education, (d) indications for OAT, (e) if the patient ever had previous teaching on OAT, (f) how long ago the teaching was, (g) duration of OAT, (h) and was a partner listening to the intervention.

After explanations of the consent and authorization forms and signatures of the same, the patient took the pretest. Any questions the patient had after the pretest were answered. The educational intervention was done after the pretest. Two weeks later, the patient returned to clinic for a follow up to their office visit, or for an INR check and completed the post-test. The entire project was done by the project manager.

Management and analysis

Pretest and posttest questionnaires were placed in a participant folder. The folder was labeled alphabetically and corresponded to a list of patient names for reference. Only the project manager had access to this information. The folder was placed in a locked desk drawer which was only accessible to the project manager. The desk was inside a locked office.

Descriptive data were calculated. Scores of the pretest/posttest were calculated with 78% as the passing grade to show competency and mastery of the topic. An analysis was run to see where any teaching topic was missed or the patient failed to learn the material. The number of questions correct was expressed in percentages. Paired *t* tests were be used to assess differences in pretest/posttest scores. The scores were correlated in all eight demographic points.

Protection of Human Subjects

The project manager received a certificate of completion from the National Institutes of Health (NIH) Office of Extramural Research. This was achieved by completing the NIH Web-based training course "Protecting Human Research Participants". The project manager also completed the Collaborative Institutional Training Initiative (CITI) for social and behavioral research, also via a web-based training course. The project was approved by expedited review by the Valparaiso IRB, and was be approved by the medical center's IRB.

CHAPTER 4

FINDINGS

The purpose of the OAT project was to answer the PICOT question *"Is an oral anticoagulation therapy educational intervention given to adult outpatients in primary care effective in increasing the patient's knowledge two weeks after the intervention?"* Patients who participated in the OAT project completed pretest/posttest questionnaires and submitted INR data, or were knowledgeable of their INR data utilized in the project. Data were analyzed using the SPSS statistical program. Information identifying patients was not included and the program was double password protected. Patient test scores, INR data, and demographic variables were entered and a descriptive analysis was conducted. The data were analyzed using descriptive statistics in (a) measures of central tendency, (b) prediction and association, (c) parametric inferential statistics, and (d) nonparametric inferential statistics.

Sample

Forty patients began the project and 38 completed the project. The participation rate was 95% (*N* = 38). The intervention was given over a 16-week period from September 9, 2015 to January 31, 2015. The two patients (5%) who did not complete the project became ill prior to their posttest and did not complete the posttest. Both of these patients were male, had atrial fibrillation, were age 79 and 80 respectively.

For the 38 patients who were in the project, the pretest provided information about their knowledge of OAT through 14 true/false questions. Eight demographics were assessed, including (a) age, (b) last completed grade in school, (c) gender, (d) if the participant had education on OAT in the past, (e) how long ago the patient received education on OAT, (f) duration of OAT, (g) indication for OAT, and (h) if a spouse or partner had also heard the intervention (see Table 4.1 and Figures 4.1 to 4.5). Ten

(26.3%) of the 38 patients denied having any previous education of oral anticoagulation therapy.

An independent *t* test was calculated comparing the mean score of patients who had a spouse or significant other listen to the educational intervention and the mean scores of patients who did not have a spouse or significant other listen to the intervention. The mean score of the patient who had a spouse or significant other listen to the intervention (*M* = 12.00, *SD* = 4.24) was not statistically different from the mean score of the patients who did not have a spouse or significant other listen to the intervention (M = 11.78, *SD* = 2.84) (*t* (10) = .169, *p* > .87).

Table 4.1

Patient Characteristics

	n (%)	*M (SD)*	*Range/Years*
Age	38 (100)	74.7 (10.1)	48
Highest Grade Completed in School		13.4 (2.6)	
Less than 12th grade	4 (10)		
High School	15 (39)		
Trade School or College	19 (50)		
Gender			
Male	18 (47.4)		
Female	20 (52.6)		
Educational History of OAT			
Yes	28 (73.7)		
No	10 (26.3)		
How Long Ago was the OAT Education? (years)		5.13 (5.2)	21
Duration of OAT Therapy (years)		6.50 (4.8)	20
Reason for OAT Therapy			
Atrial Fibrillation	26 (68.4)		
Valve Replacement	2 (5.3)		
Embolus	7 (18.4)		
Stroke	2 (5.3)		
Other	1 (2.6)		
Did Spouse/Partner Hear the Teaching Intervention?			
Yes	10 (26.3)		
No	20 (52.6)		
Not Applicable	8 (21.0)		

Figure 4.1

Age Distribution of OAT Project

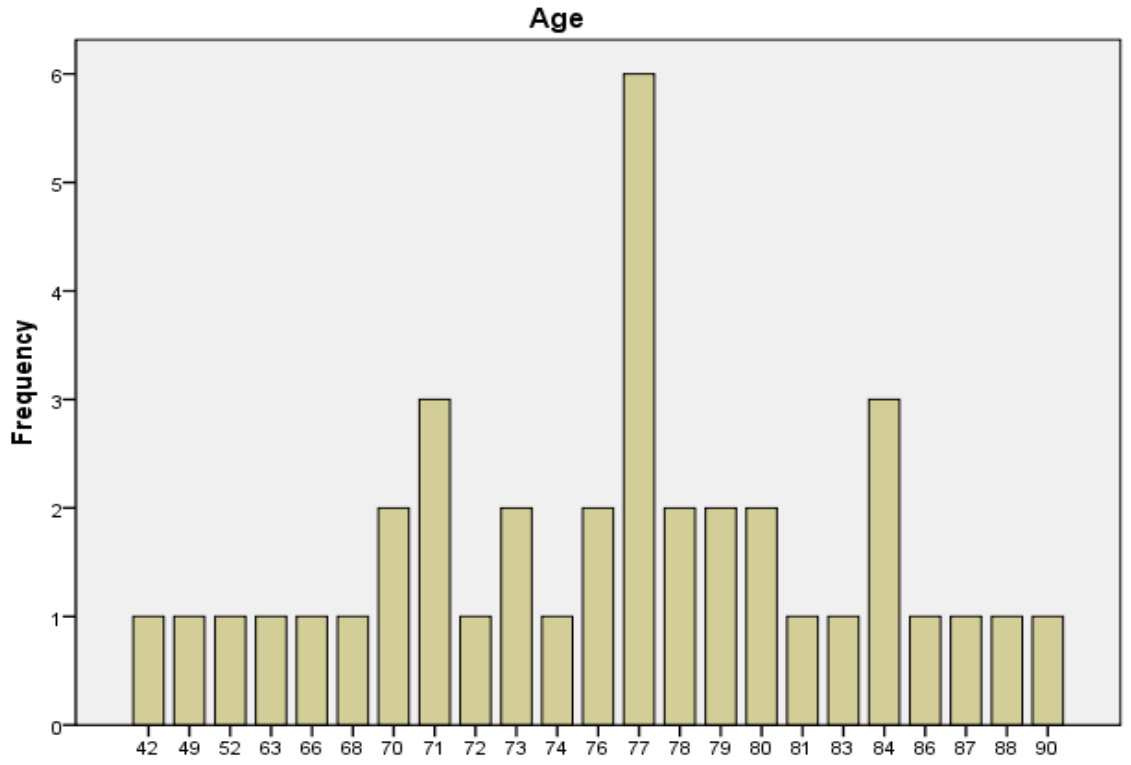

Figure 4.1 Age distribution of the population who participated in OAT project. The range in age was 48 years.

Figure 4.2

Indications or Reasons for Oral Anticoagulation Therapy

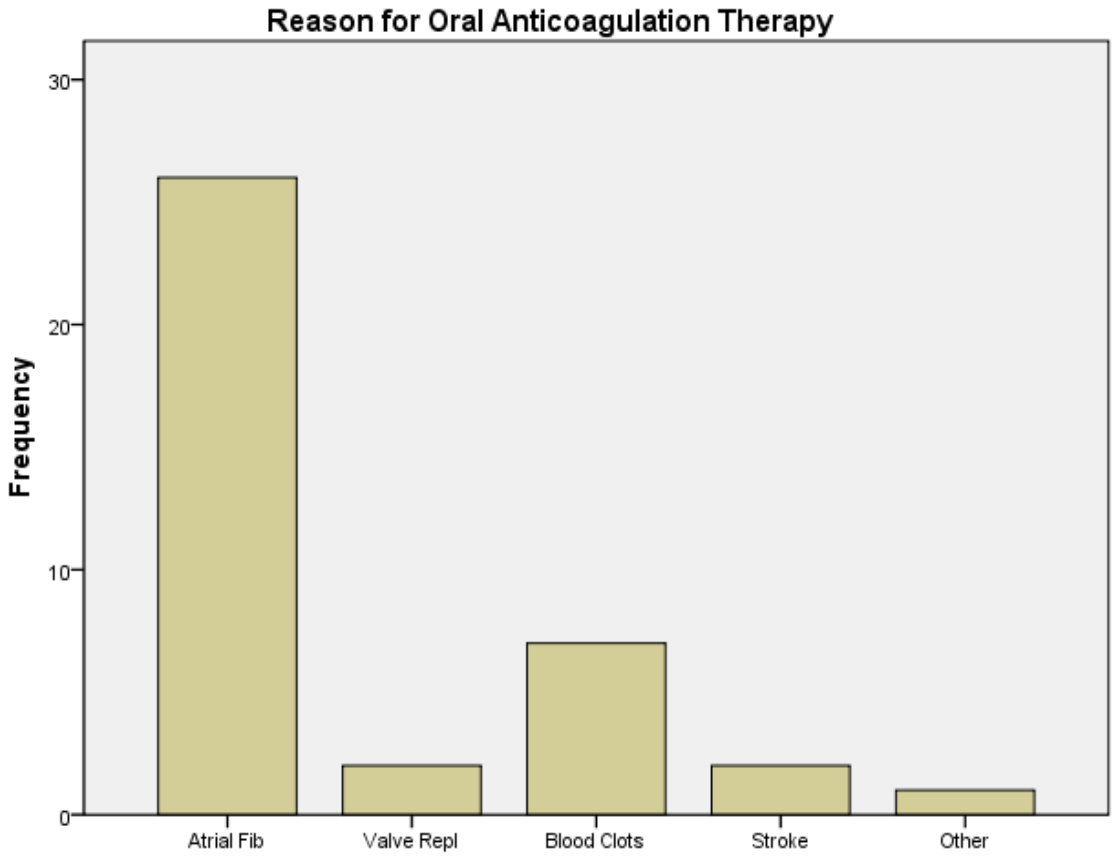

Figure 4.2 Indications or reasons patients listed as why they were using OAT.

Figure 4.3

Previous Education of OAT

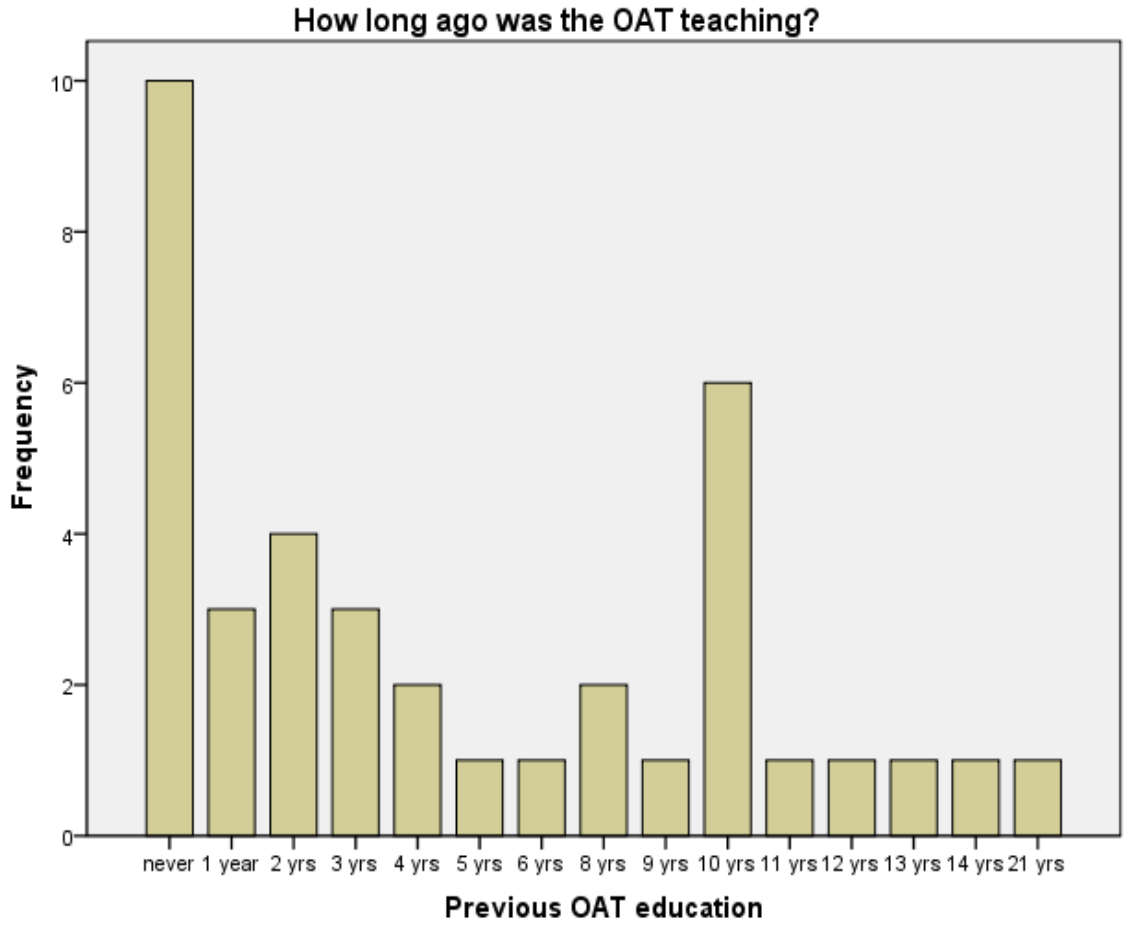

Figure 4.3 Participants were asked how many years ago they had received oral anticoagulant therapy teaching. Ten participants listed they had never had oral anticoagulation teaching.

Figure 4.4

Duration of Oral Anticoagulation Therapy

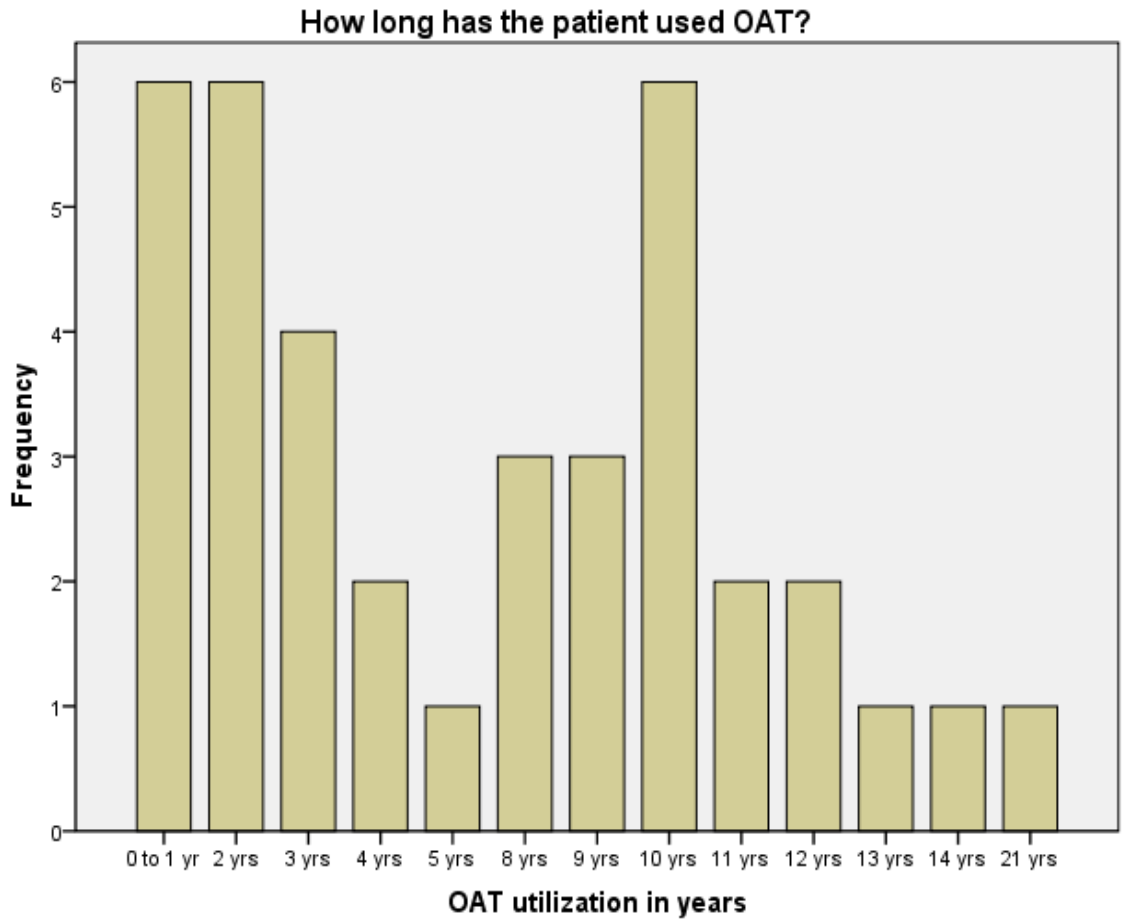

Figure 4.4 Number of years the participants had used oral anticoagulation therapy.

Figure 4.5

Spouse/partner Participation during the Intervention

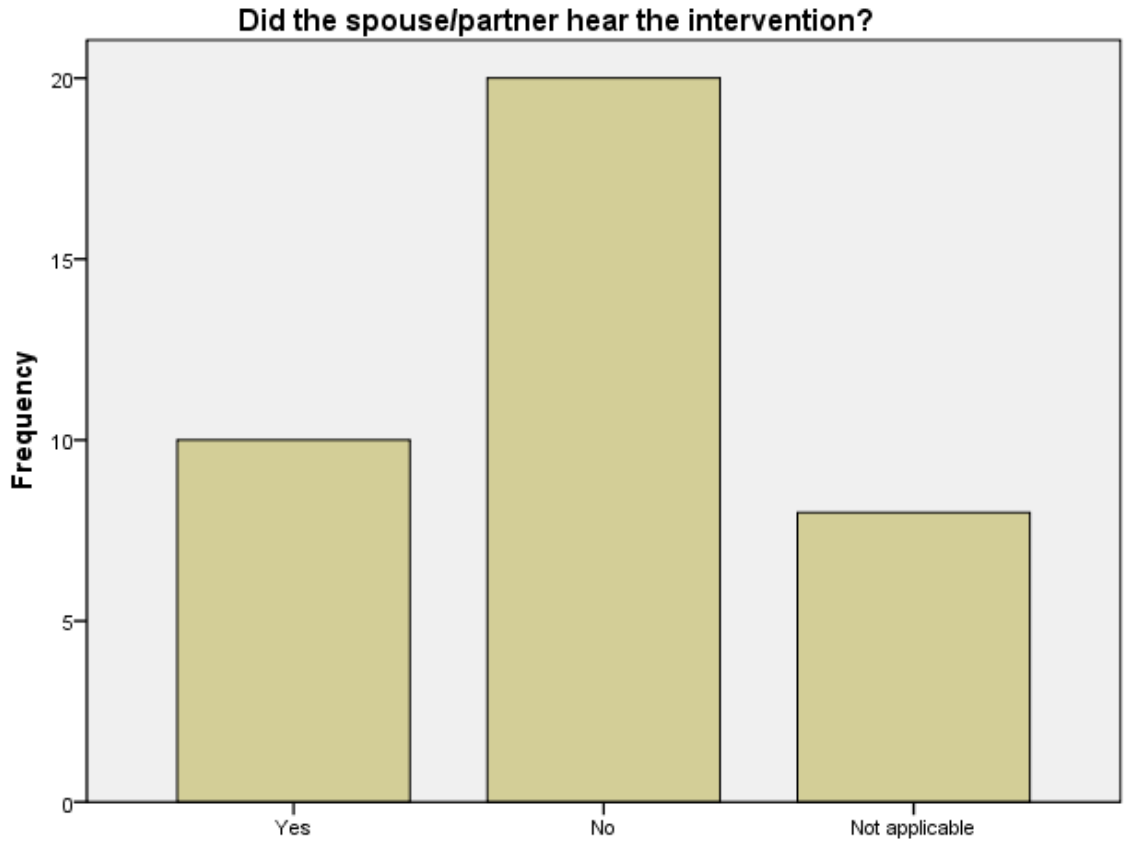

Figure 4.5 The eight patients who responded "not applicable" did not have a spouse or partner to hear the intervention. Those who replied "no" did have a spouse or partner, but that person was not present for the intervention.

Outcomes

Statistical testing. SPSS Base 18 statistical program was used to analyze the data. Information identifying the subjects in the project was not included and the program was double password protected.

Significance. Pretest scores on the KIP-C ranged from three correct (21%) to all 14 (100%) of the questions correct. A passing score was 78%. A total of 26 (68%) patients passed the pretest and 35 (92%) patients passed the posttest. The same two patients scored 100% on both the pretest and the posttest. There were two (5%) patients who did not pass either the pretest or posttest; one was over age 80. Four (10%) patients scored more incorrect answers on the posttest than the pretest. There were nine (23%) patients between the ages of 80-89, and one (2.5%) was aged 90. Of the 10 patients who were over 80, six (15%) of them scored more correct answers on the posttest than the pretest.

To answer the PICOT question, a paired samples *t* test was calculated to compare the mean pretest score to the mean posttest score. The mean pretest was 11.16 (*SD*= 2.24), and the mean posttest score was 12.58 (*SD*= 1.44). A statistically significant increase from pretest mean score to posttest mean score was found *(t* (37) = -4.651, $p < .001$).

Overall benefits of the educational program included patients' renewed interest in foods, beverages, and medications, both prescription and over-the-counter, which would interfere with OAT. Patients mentioned their booklet or video as reference in subsequent office visits when asked about any bleeding from OAT. Another reported benefit included several patients who verbalized an exact dose of OAT made their INR more stable from week to week.

Secondary outcomes were also analyzed. A paired samples *t* test was calculated to compare the mean pretest INR to the mean posttest INR, which was done two weeks

after the pretest. Not all of the 38 patients had their INR value drawn at the time of posttest. Eleven participants were scheduled to recheck INR values at three or four weeks. At two weeks, 27 of the 38 patients had a mean pretest INR of 2.07 (*SD* = .66) and the mean posttest was 2.83 (*SD* = 1.88). No significant difference from pretest INR to posttest INR was found (t (26) = -2.002, $p > .056$). However, these INR differences did show clinical changes approaching a significant change.

Pearson Correlation coefficients were calculated for the relationships among the patient's age, highest grade achieved in school, how long ago their education was on OAT, and duration of warfarin therapy (see Table 4.2). A strong positive correlation was found (r (36) = .889, $p < .001$), indicating a significant linear relationship between the two variables of how long ago the participant had education on OAT with their duration of warfarin therapy.

A Cochran's Q test was conducted to assess for differences in the patient's INR results at four, six, eight, ten, and twelve weeks. No significant differences were found ($X^2(4) = 4$, $p > .406$). On the average, there were changes to patients' INR's, which included INR values above, within, and below therapeutic range (see Table 4.3). Follow-up INR values ranged from 1.1 to 5.7 (*M* = 2.50, *SD* = 1.02). By week 4, the majority of patients were within the therapeutic range; however, the number within therapeutic range continued to decline following week 4. For week 10, the fewest number of patients returned for an INR and these patients had the fewest members within therapeutic range.

Cronbach's Alpha is a measure of internal consistency and tests for reliability of test construction (Cronk, 2012). For the project on OAT, Cronbach's Alpha was used to determine the degree to which all the items in the pretest and posttest measured the patient's knowledge of OAT. The reliability coefficient was 0.720, for each testing period which represented good internal consistency.

Test-retest reliability (Cronk, 2012) is a measurement of temporal stability that tells whether or not the instrument is consistent over time or over multiple administrations. Pearson Correlation coefficients were completed on pretest/posttest total scores. The test-retest reliability of the KIP-C was .56, showing moderate test-retest reliability.

Table 4.2

Correlation Matrix

Correlations

		Age	Highest grade completed in school	How long ago was OAT teaching?	Duration of OAT
Age	Pearson Correlation		-.066	.047	.034
	Sig. (2-tailed)		.695	.778	.842
	N		38	38	38
Highest grade completed in school	Pearson Correlation			.166	.131
	Sig. (2-tailed)			.319	.433
	N			38	38
How long ago was OAT teaching?	Pearson Correlation				.889**
	Sig. (2-tailed)				.000
	N				38
Duration of OAT	Pearson Correlation				
	Sig. (2-tailed)				
	N				

**. Correlation is significant at the 0.01 level (2-tailed).

Table 4.3

INR Follow-up Results

Patient	Baseline INR *n* = 38	2 weeks *n* = 27	4 weeks *n* = 21	6 weeks *n* = 16	8 weeks *n* = 21	10 weeks *n* = 12	12 weeks *n* = 19
A-1	1.0	2.5					
B-2	3.0	1.9					
C-3	2.8	2.9	3.0.	2.7			
D-4	1.3	7.2	3.2				
E-5	2.2	2.4	2.9	2.4	2.9		
F-6	2.2	1.9	1.8	2.4	2.0		
G-7	2.7	3.4	3.5	2.5	2.3	2.7	
H-8	3.5				2.1		
I-9	2.0	2.0					
J-10	2.2	1.9		2.3			
K-11	3.1	2.6		2.7			
L-12	1.6	1.7	1.7	1.5	1.5	1.3	
M-13	2.2	2.3		2.3		2.7	1.7
N-14	2.1	2.2		3.0	2.4	3.5	
O-15	1.7	2.9		1.5	2.5		
P-16	1.2	1.9		1.6	2.1	1.7	
Q-17	1.2	2.4	3.4		1.3	1.1	1.5
R-18	1.5	2.6	2.7		1.8		2.3
S-19	2.7	4.1	2.3		2.1		4.3
T-20	2.4		2.1		2.9		2.2

Table 4.3
INR Follow-up Results

Patient	Baseline INR *n* = 38	2 weeks *n* = 27	4 weeks *n* = 21	6 weeks *n* = 16	8 weeks *n* = 21	10 weeks *n* = 12	12 weeks *n* = 19
-21	2.2		2.3		1.6		5.7
V-22	1.9		2.0		2.0		2.1
W-23	1.4	2.0		1.8	2.3	1.3	2.2
X-24	3.1						2.8
Y-25	2.7		2.7		3.6	2.6	3.0
Z-26	1.8	2.8				1.6	1.8
AA-27	1.1	3.0	2.0	2.1	1.9	2.0	1.8
BB-28	1.7	1.9	2.6				2.4
CC-29	2.5		2.3		2.9		2.4
DD-30	3.2	1.6					
EE-31	2.0		2.0		1.8		1.8
FF-32	2.3		2.8				2.3
GG-33	2.7	10.5	1.3		1.8		1.2
HH-34	2.0	1.9		2.2		2.8	
II-35	2.7		1.4	3.5		3.0	2.4
JJ-36	3.1		2.3		2.0		2.5
KK-37	2.6	1.7		3.3			
LL-38	2.7	2.1					
% of patients in 2.0-3.0	50%	52%	67%	60%	62%	29%	58%
INR (*M*),	2.22	2.83	2.40	2.32	2.20	2.17	2.50
(*SD*)	.652	1.88	.608	.611	.546	.756	1.02

Note: Red values = Indicate INR within therapeutic range

CHAPTER 5

DISCUSSION

This EBP project was implemented to determine if an educational intervention given to outpatients in a clinic setting who used OAT resulted in knowledge gained two weeks after the intervention. Analyses were conducted for the 38 patients who participated in the project. Results of the patients' educational intervention scores, the patients' demographic data, and their INR data over 12 weeks of the project were analyzed and tabulated. The outcomes of this project demonstrated that implementation of an educational intervention can improve knowledge of OAT. However, the effect of education on patients' INR values demonstrated inconsistent changes over time.

Explanation of Findings

Patients mean scores demonstrated a statistically significant difference (-4.651; $p < .001$) from the pretest to the posttest. In comparing this project with the levels of evidence cited, the systematic review by Clarkesmith et al. (2013) noted two trials of patients who had inadequate knowledge of control of OAT improved their knowledge with a questionnaire and an educational intervention. Nasser et al. (2011) noted that 50 - 80% of older patients using OAT who completed a questionnaire had inadequate knowledge of anticoagulation control. Nasser et al. (2011) also found significantly higher questionnaire scores in patients who were taught face-to-face (13.9 out of 20 compared to 12.4; $p = 0.08$). All the patients in this project were taught face- to-face, and 92% passed the posttest. The RCT by Mazor et al. (2007) found that patients who had teaching showed a statistically significant (56 pretest/70 posttest; $p < .001$) knowledge improvement with pretest and posttest questionnaire. The descriptive study by Hu et al. (2006) also showed 61% of the patients had insufficient knowledge of OAT, and added that patients who had counseling showed a statistically significant higher knowledge

scores (-2.65 (-3.8 to -1.5; p = .001) than patients who did not receive any counseling. Another descriptive study by Lane et al. (2005) showed questionnaire scores to be statistically significant in improved patient knowledge (22 out of 33; p = 0.001).

Patients in the study by Lane et al. (2005) were also knowledgeable about conditions affecting their INR level (19 out of 33; p = 0.014) One descriptive study by Smith et al. (2010) cited patients who were not found to have any knowledge difference related to diet or medications with a questionnaire were given educational materials at too high a literacy level. The literacy level of the questionnaire as well as the large print educational booklet used in the EBP project was on the 6th grade level, the mean educational level of patients in the EBP project was 13 years. The lower educational level of the questionnaire likely enabled more patients in the project on OAT to pass the pretest/posttest.

The EBP project was also done to see if the teaching intervention also improved patient INR stability. There were no statistically significant results obtained in either the pretest to posttest INR values (t (26) = -.2.002, p > .056) or the INR values achieved in weeks 4 through 12 (x^2(4) = 4, p > .406). However, the INR values from pretest to posttest were approaching statistical significance and did reach clinical significance. In addition, there were trends in the INR values over the 12 weeks. In this project, the patients' INR results were in therapeutic range approximately 29% to 62% of the time over three months. Initially, the percent of patients with INR values in the therapeutic range increased, but then the percent decreased over time.

The findings from this EBP project may be due to the irregular method of INR checking done the patients in this project. Many patients are directed to recheck their INR but do not do so when asked and get their INR checked when they remember or when their scheduled allows. The INR instability results also may be attributed to the variability of the OAT itself. For example, the populations studied by Pernod et al. (2008)

were found in range approximately 64% of the time. The INR instability also may be related to patients not taking OAT as prescribed or utilizing medications, foods, or beverages that interfere with synthesis of OAT. One SR by Clarkesmith, Pattison, and Lane (2013) found two trials that reported improved patient INR control over three months with patients who had an educational intervention and improved the percentage of time spent in therapeutic range. The same SR by Clarkesmith, Pattison, and Lane (2013) noted INR value improvement over three months with patient education and the percentage of time spent in therapeutic range improved. The RCT by Clarkesmith, Pattison, Lip, and Lane (2013) found the group who had the educational intervention spent statistically significant more time in the INR therapeutic range than the usual care group (76.2% vs. 71.3%; $p = 0.035$), but this only occurred for a six month period of time. Due to this statistic, the researchers recommended the educational intervention to be done every three to six months to maintain patient levels of adherence (Clarkesmith, Pattison, Lip, and Lane, 2013). Mazor et al. (2007) also noted that patients on OAT may benefit from educational efforts every 6 months even after initial education and ongoing monitoring related to non-adherence.

Atrial fibrillation was listed as the major reason for OAT use (68%) among the patients in this EBP project. Atrial fibrillation is seen predominantly in white populations as noted in the RCT by Clarkesmith, Pattison, Lip, and Lane (2013). The entire population of this EBP project was white. The SR by Clarkesmith, Pattison, and Lane (2013) and the descriptive studies by Lane et al. (2005) and Smith et al. (2010) discussed populations with atrial fibrillation but did not specify the white population with a higher percentage of atrial fibrillation.

The descriptive study by Cook-Campbell and Sefton (2010) noted the mean age of the population surveyed was 79 years. The mean age of the EBP project patients was 74 years. Cook-Campbell and Sefton (201) noted patients who were older than 65 had

knowledge deficits about warfarin and cited the mental capacity of the older adult may be a factor. The findings from this EBP project did not show mental capacity to be a factor as 68% passed the pretest and 92% passed the posttest. The pretest and posttest were written on a 6th grade level which may have contributed to a higher percentage of patients who passed both the pre- and posttest. The project population showed a higher literacy level as their average last completed grade in school was 13.

In reference to the pretest/posttest, Cronbach's Alpha (Cronk, 2012) was used as a measure of internal test consistency and reliability. The reliability coefficient was 0.720 for both the pretest and the posttest. This represented good internal consistency. Pearson correlation coefficients were completed on pretest/posttest total scores. The test-retest reliability of the KIP-C was .56, showing moderate test-retest reliability. Using a tool that showed reliability supports the findings in this EBP project, and the reliability results in this project mirrored findings in the literature (Hu et al., 2006).

Although the EBP project did not find the low percentage of therapeutic range to be attributable to the effects of aging and comorbidities, the low percentage of patients within therapeutic range could be related to adherence as well as monitoring infrequency. Patients who knew they have used Vitamin K antagonist foods, beverages, and medications which interfere with therapeutic INR values may have not done their INR value when requested and therefore contributed to monitoring infrequency.

Evaluation of the Theoretical Framework

Roy's Adaptation model. Sister Callista Roy developed the theoretical framework used to guide the EBP project which described adaptation in life's responses and illustrated the effects of focal stimuli, contextual stimuli, and residual stimuli upon adaptation (Phillips, 2010). Focal stimuli were the immediate responses facing the individual. In this project, it was the patients' need to understand their cardiovascular processes and realize the need for OAT. Contextual stimuli added many factors which

increased the impact of the focal stimuli, that being the cardiovascular processes which require OAT and learning how the medication works as well as its side effects. Residual stimuli are numerous environmental factors such as the interaction of lifestyle, foods, medications, or beverages that patients on OAT may choose to use in moderation or omit from their intake. Although residual stimuli may be unclear to the patient, the patient constantly is in a pattern of coping and adapting to a changing environment with responses that promote integrity as well as responses that are ineffective (Phillips, 2010). The educational intervention of this project on OAT was integrated into the patients' coping and adapting to their changing environment, thus promoting more responses which facilitate medication therapy using OAT.

Roy (2011) further explains adaptation modes of physiological, self-concept, role function, and interdependence that was apparent in this EBP project. Patients often questioned their body's physiological response in cardiovascular or hematological wellbeing. Patients were challenged with self-concept when they agreed to take both the pretest and posttest questionnaire to determine what they understood about OAT. Role function was realistic and pragmatic as the patients admitted their understanding of day-to-day life utilizing OAT.

Role function in adaptation was revealed for 10 patients who had a spouse or significant other listen to the educational intervention. These 10 patients expressed not only their knowledge of OAT but also their interdependent relationships with their spouse or significant other. They uncovered their compliance or lack of compliance of OAT to their spouse or significant other during the educational intervention. Patients also verbalized their appreciation when taking part in the EBP project as well as their gratitude for the education they had received. This was particularly expressed by another 10 patients who listed they had never had education on OAT.

Roy's Adaptation model was a good fit for this EBP project as it allowed the project manager to continuously observe the patients' self-concepts in their role while using OAT. The Roy Adaptation model also allowed the project manager to address individual patient variables related to the patient's OAT dosing, day-to-day use, and any side effects, thus facilitating patient adaptation. Non-effective patient adaptation was identified by the Roy Adaptation model so that the project manager could bring to the patient's attention his/her needs. The Roy Adaptation model allowed the project manager to redirect the patient to pragmatic knowledge development with OAT.

Strengths of the Roy Adaptation model included ease of assessment in appropriate and necessary nursing interventions which helped the patient flow through the focal, contextual, and residual stimuli. In applying this concept, the patients quickly understood that OAT may be easier to control, they could succeed in this project with questionnaire participation, and that the project was being done for their benefit so they could learn about OAT. The project also disclosed that 10 patients (27%) of the patients who participated never had previous teaching of OAT.

Patient adaptation was also evident through the teaching intervention with the booklet as well as the video, some patients liked the booklet better and others preferred the video format. Patients' coping skills were examined through their preferred method of learning. Patients took home both the booklet as well as the video to promote further adaptive responses and increase awareness of their ineffective coping responses while utilizing OAT.

Weaknesses of the Roy Adaptation model included the four modes of adaptation; all the modes were considered a process and may be considered weak when a quick decision needed to be made. However, quick decisions were made by patients for emergent bleeding during this EBP project's time frame. One patient went to the emergency room for sudden bleeding related to a medication interaction. Another

weakness of the Roy Adaptation model implied that the patient would learn to problem solve as the patient learned what was taught. Four (10%) patients scored more questions incorrect on the posttest than the pretest, which inferred they did not learn. The four patients who scored more incorrect responses on the posttest than the pretest could suggest poor problem solving, guessing the answers, or maladaptive learning behaviors. A third weakness was implied nursing assessment or intervention. Although cited as a weakness, this was considered a strong point of the Roy Adaptation model (Phillips, 2010) as nursing assessment and intervention were actively pursued with each patient.

Evaluation of the EBP Framework

The Stetler model for EBP. The Stetler model (2001) for individual use allowed the project manager to engage in critical thinking, actively analyze current practice patterns, and provided opportunities to reflect and improve practice. The Stetler model (2001) had five phases to facilitate EBP that included (a) preparation, (b), validation, (c) comparative evaluation/decision making, (d) translation/application, and (e) evaluation.

Naming the problem and the change agent were a part of preparation phase. Included in the preparation phase was locating *internal evidence* within the clinic which found patients using OAT not in therapeutic range related to knowledge deficits, monitoring infrequency, Vitamin K antagonist use, and adherence. During the preparation phase, e*xternal evidence* was found in the literature related to the clinical problem and presented plausible solutions in RU and EBP. Ranking the studies by levels of evidence was completed in the validation phase. Locating the barriers to the practice change and addressing the barriers were in the comparative evaluation/decision making phase. Synthesizing what the studies were conveying and finding common threads related to the strength of the evidence was found in the comparative evaluation/decision making phase. The translation/application phase included cognitive application of

validating current practice and experiencing an increased awareness of what the patients did not understand. The cognitive application provided a method to develop the multiple-method teaching intervention for the project on OAT. The evaluation phase allowed an ongoing formative evaluation which looked at both the patient and provider experiences of the educational intervention. Clarifications of the information to depict the change in practice and progressing with the change in practice were within in the translation/application phase. Proceeding with the change in practice as well as finding ways to keep the change in practice current and applicable was in the evaluation phase.

The Stetler model was a good fit as it revealed both *internal* and *external evidence* to be exposed and continuously reassessed. Both types of evidence provided convincing reasons to pursue the project. The Stetler model included patient preference or wishes which added to internal evidence. The comparative evaluation/decision making phase also allowed an individual project manager to look at the project feasibility, risk, resources, and readiness. This project examination endorsed a pragmatic fit and flowed well in current clinical practice with present and upcoming quality measures.

Strengths of the Stetler model included more direction for one project manager to examine EBP as well as the use of RU. The phases of the Stetler model helped prevent the project manager from using research inaccurately (Romp & Kiehl, 2009). Other providers who worked with the project manager also developed and verbalized critical thinking skills and named this project as a high priority. The practice method provided by the Stetler model facilitated the program's development for OAT. It can also serve as an exemplary model for future program and practice development.

Weaknesses of the Stetler model included overlapping phases which caused the project manager to go back to a previous phase, such as whether to use group or individual classes to teach patients regarding OAT. Strength of the evidence did support

individual classes, and in this case, overlapping phases was not a hardship. Applying the evidence in Phase IV was not as detailed for the project manager as outlined in the literature. The lack of detail in Phase IV was another weakness. A final weakness included adapting the findings into practice instead of adopting the findings into practice. The findings will not be adapted into practice instead of adopted into practice as the project manager's has utilized the questionnaire, booklet, and video for anticoagulation teaching as was completed in the project. The questionnaire will be part of the EMR and used as a quality indicator in documentation for reimbursement.

There were no modifications to the project. If the EBP project was repeated, electronic access would be needed for the questionnaire as documentation of a quality measure for the patient on OAT. If the large-print educational booklet on OAT was needed in Spanish for the educational intervention, a Spanish language version is located at the same web site as the English version. Currently the teaching booklet for warfarin therapy at the medical center is written at the ninth grade reading level. The large-print picture booklet used in this project is written on the 6th grade reading level and has received the approval from the director of pharmacy. Next, the booklet will need to be approved by the Pharmacy and Therapeutics Committee for its utilization throughout the medical center. Several of the levels of evidence have already been used by a committee to form a Coumadin® Clinic for the medical center and community.

Strengths and Weaknesses of the EBP Project

Strengths of the EBP project included the high-quality levels of evidence that were located to construct the plan and the educational intervention. Multiple learning strategies were found in the evidence, thus facilitating patient learning through questionnaires, large-print picture booklets, food models, and audiovisuals. Assessing patient demographics was highly emphasized in the evidence to learn about population characteristics. Additional strengths included (a) the evidence had statistical significance

which supported the project's analysis, (b) the KIP-C questionnaire still showed consistency and reliability, (c) the questionnaire promoted patient learning, (d) the questionnaire was used as tool to measure patient outcomes, and (e) the educational intervention started or revisited patient teaching on OAT.

Further strengths included the need to do the project for a population who admitted not having education on the medication they were taking or not having any refresher information on utilization of OAT for many years. Also, the project was conducted in the outpatient arena where the patient could put what was learned into practice as well as having the teaching materials available for continued reference. The attitudes of the patients who took part in the project were of particular benefit for the project manager as well as a major strength. Patients verbalized that they were extremely pleased to take part in the project for their own edification. A final strength of the project was that there is now an educational intervention in place for patients who are new to OAT. Since the completion of the project, the educational intervention has already been used six times for new patients starting on OAT; none have been hospitalized with side effects.

A weakness of the EBP project was the small size of the population who participated. A number of patients were found to have dementia or already had dementia on their EMR and did not qualify for the project. Another reason for the smaller sample size was the number of patients who only saw the physician and not the project manager for their office visit. Patients who only saw the physician left the office before the project manager could approach them about participation. Another weakness was the entire population of the project was Caucasian and 68.4% had atrial fibrillation for a diagnosis in this project. Atrial fibrillation does primarily affect the Caucasian population (Clarkesmith, Pattison, Lip, & Lane, 2013). A further weakness was the attrition rate; it is unknown whether or not questionnaire scores as well as INR values over 12 weeks

would have been different than the population in the project; however, the attrition rate was only two patients.

The time it took to implement the project was a factor; the educational intervention was done during the patient's office visit. Often the project manager was 45 minutes late seeing subsequent patients on the daily office visit schedule. Educational interventions do take more time but there is a quality measure obtained for the time spent doing the intervention. A proposed solution to better time utilization would be scheduling the patient as the last patient of the morning or the afternoon schedule. The extra time used would not interfere with the next patient and allow for an educational intervention without being rushed. Current and future quality measures include necessary medication educational documentation and a questionnaire which can be interfaced into the EMR. All of these measures currently are and will continue to be a product for reimbursement.

Implications for the Future

Practice. For the APN as well as the RN, Lane et al (2006) as well as Cook-Campbell and Sefton (2010) discussed whether the patient was really taught what they needed to know about OAT. Hu et al. (2006) discussed insufficient patient knowledge of OAT. When reflecting on the log for this project, all of these points vividly show the need for initial and ongoing assessment and education on OAT. Charts and graphs in this EBP project showed monitoring infrequency of OAT with concern for patient adherence; both of these issues offer implications for practice. Pretest/posttest scores showed improvement and were statistically significant for learning measured. However, ongoing INR values did not consistently improve. INR values traced over 12 weeks showed the patient in therapeutic range approximately 29-67% of the time.

This EBP project reflected the study done by Pernod et al. (2006) which showed the population in that study to be in range approximately 64% of the time. One of the

reasons for patients not to be in therapeutic INR range was found by both the APN as well as the RN in the project manager's outpatient office. Patients' need to write down directions for dosing after the most recent INR value has been obtained. The APN and the RN found patients who acknowledged the phone call but not the dosage change, and patients continued their former dose without any change to the next INR value. Further questioning of the patients determined they did not know how to interpret new dosing directions. Phone calls to family members discovered many patients did not understand their new directions for OAT were to be done immediately and the next INR to be obtained in the time frame directed.

Theory. The Roy Adaptation model facilitated patients' adaptation responses and promoted patient coping strategies. Patients note many physiological changes when taking OAT, and understand their functional integrity has been challenged with a medication which can cause bleeding. The Roy model provides the patient with a self-concept which promotes body image as well as expectations within relationships and culture. Particularly for the APN and RN, theory can identify patient problems, facilitate change, and provide a guide for direction to improve patient outcomes with a greater understanding of application to practice. Using theory enhances the credibility of both the RN and APN when results of the problem as well as the solution are found in the literature. Findings from this EBP project can influence future theory development in (a) practice change related to polypharmacy or reimbursement, (b) increased staff awareness to assist patients who need to overcome obstacles, (c) support readiness for change by patients, or (d) increase awareness of strategies for time-consuming office and patient care issues.

Research. The project on OAT has implications for both the APN and the RN as they both care for the patients with atrial fibrillation, stroke, clotting disorders, and valve replacements in the outpatient setting. Further research can be done specifically with

these populations, just as Hu et al. (2006) reported on patients with mechanical valves and used the 20-question KIP to assess patient knowledge. With 68% of the population having atrial fibrillation in the EBP project, further research should be conducted with this population and then have expansion to other populations.

The six new patients mentioned previously who started warfarin since the project closed were on a new anticoagulant with their atrial fibrillation onset, but none of the patients could afford the new medication or did their insurance have any of the new anticoagulants on their formulary. Future research could examine cardiology prescribing efforts in patient anticoagulation and safety related to insurance formulary practices. If patients are not able to afford their medications, they will not comply with OAT.

Education. Education on OAT in the outpatient clinic setting provided timely feedback of patient needs when using questionnaires and a direct one-on-one educational intervention. Future implications for education from this study show the need for ongoing OAT education, suggesting a refresher every three months as did the work by Clarkesmith, Pattison, Lip, and Lane (2013). Ongoing education will be recommended with policies and procedures in place upon the start of the new Coumadin® clinic among the medical center providers and community.

There is also no standard for education in questionnaires used to determine patient knowledge. Many questionnaires previously used in the literature contained 38 - 56 items and the literacy levels of these questionnaires were not determined (Smith et al., 2010). Evidence supports using questionnaires that are consistent and reliable. Direct implications for future research can advise standardization of questionnaires, and measure the literacy level of not only the questionnaire but also the educational materials to better accommodate the population studied.

Conclusion

The primary outcome of this EBP project was that an educational intervention did make a significant difference in oral anticoagulation therapy knowledge in primary care. Overall, 26 of the 38 patients (68%) passed the pretest and 35 of the 38 (92%) patients passed the posttest. The educational intervention showed statistical significance which mirrored findings in the literature. The educational intervention facilitated the patients as they moved through the phases of adaptation in a positive manner when confronted with environmental stimuli. The educational intervention made the patients' learning skills manageable as well as attainable. Patients also had information about OAT in a large print booklet as well as in multimedia format to use for a refresher at home as a result of the educational intervention.

Secondary outcomes of the EBP project revealed the patients' INR values did not show a statistically significant change in improved stability nor control in therapeutic range from pretest and in two weeks at the post-test. However, the results did demonstrate an initial clinical improvement in INR values and a general trend to early improvement. However, outcomes in INR values also did not show continued stability or control toward the end of the 12 weeks. These findings support the studies by Smith et al. (2010) which expressed a high variability in effectiveness with warfarin therapy. Related to these outcomes, data from this EBP project also supports the need for (a) continued patient education every three months (Clarkesmith, Pattison, & Lane, 2013), (b) controlled efficacy of the educational program (Hu et al., 2006), (c) evaluating the literacy level of the educational materials (Lane et al., 2005), and (d) more frequent INR testing (Pernod et al., 2008).

Secondary outcomes also revealed that 10 patients admitted never having any prior educational intervention on OAT. Again, patients were able to face environmental

stimuli and successfully process new learning skills with an educationally-leveled questionnaire and booklet. Patients in this EBP project had positive outcomes in their questionnaire scores. Having the spouse or significant other in the room during the educational intervention did not make a statistically significant difference in the patients' questionnaire scores. However, the majority of patients were able to achieve passing scores on both their pretest and posttest questionnaires related to the lower educational level of the teaching tools as well as questionnaire.

Cook-Campbell and Sefton (2010) sited that older adults may have different learning needs related to the aging process and comorbidities and that their mental capacity may be a barrier. Their study did not use a questionnaire that had established reliability or validity. In this EBP project, mental capacity of the older adult due to age, comorbidities, or mental capacity was not a factor when using a lower literacy level questionnaire to measure patient knowledge. This EBP project also showed the questionnaire, the KIP-C, as stable over time, and constant over multiple administrations as did previous literature (Hu et al., 2006; Wilson et al., 2003; Wilson et al., 2014).

Education with health promotion is a privilege as well as a duty of nursing to foster the best of all possible outcomes in patient care. As nursing becomes more aware of patient risk with the ever-present use of polypharmacy, the patients' longer life span, and multiple chronic disease comorbidities, education in the outpatient arena is and will continue to be a quality measure in cost-savings for the patients as well as the healthcare system. Consistently striving for positive outcomes in an unpredictable environment of patient decisions and modifiable risk, patient education will continue to be goal-driven in nursing.

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BIOGRAPHICAL MATERIAL

Ms. Deck graduated with a nursing diploma from Graham Hospital School of Nursing, Canton, Illinois, in 1974. She received a BSN from Coe College in Cedar Rapids, Iowa, in 1978. Ms. Deck worked in various ICU settings before directing her focus toward patients with diabetes. She began a hospital outpatient diabetes program in 1986 and became a certified diabetes educator in 1989. Ms. Deck has been a member of the American Association of Diabetes Educators and its Chicago chapter since 1989. In 1995, she wrote an insulin pump flip chart which was published by a diabetes technology company. Ms. Deck has presented insulin pump management at both local and national conferences. She reviewed manuscripts for *The Diabetes Educator* magazine from 1995 to 2005. In 1988, she was inducted into Kappa Sigma Chapter of Sigma Theta Tau International and received the Kappa Sigma Nurse Excellence Award in 1998 and 2012. She received a grant for diabetes education in 1992 as a principal investigator, and she participated as a secondary investigator for a female urinary incontinence study from 2005 to 2011. Ms. Deck pursued parish nursing and completed the PN program in 1998 at Concordia University, Mequon, Wisconsin, developing programs for church and community involvement. Ms. Deck received her master's degree as a family nurse practitioner from Ball State University in 2003, and is certified by ANCC. She was called to do international nursing in Palestine, and has supported five mission trips to Honduras. Currently practicing in adult medicine, Ms. Deck has served as a clinical faculty advisor for nurse practitioner students from 2006 to the present, as well as for parish nurse candidates. She is currently attending Valparaiso University, earning a DNP in 2015.

ACRONYM LIST

ACCP: American College of Chest Physicians

AF: Atrial Fibrillation

AKA: Anticoagulant Knowledge Assessment

APN: Advanced Practice Nurse

AHRQ: Agency for Healthcare Research and Quality

AS: AGREE II score

CBC: Complete Blood Count

CHADS2: Congestive heart failure, Hypertension, Diabetes, Stroke, 2nd revision

DVD: Digital Video Disc

DVT: Deep Vein Thrombosis

EBP: Evidence-Based Practice

HIPPA: Health Insurance Portability and Accountability Act

INR: International Normalized Ratio blood test

IRB: Institutional Review Board

KIP: Knowledge Information Profile

KIP-C: Knowledge Information Profile-Coumadin®

NSAIDS: Non-Steroidal Anti-Inflammatory Drugs

OAT: Oral Anticoagulation Therapy

PICOT: Patient population, Intervention or Issue of interest, Comparison, Outcome, and Time frame

PT: Prothrombin Time (blood test)

REALM: Rapid Estimate of Adult Literacy in Medicine

RU: Research Utilization

SPSS: Statistical Package for the Social Sciences

TREAT: **TR**ial of an **E**ducational intervention on patients' knowledge of **A**trial fibrillation and anticoagulation therapy, INR control and outcome of **T**reatment with warfarin study

TTR: Time in Therapeutic Range

APPENDIX A

Valparaiso University

Elizabeth Deck < elizabeth.deck@valpo.edu>

RE: permission to use KIP-C
4 messages

Feleta Louise Wilson < aa3107@wayne.edu> Sat, Jul 20, 2013 at 7:28 AM
Reply-To: aa3107 <aa3107@wayne.edu>
To: elizabeth.deck@valpo.edu

Yes you have my permission

Sent from my Galaxy S3®

-------- Original message --------
From: Elizabeth Deck <elizabeth.deck@valpo.edu>
Date: 07/19/2013 10:15 PM (GMT-06:00)
To: feleta@wayne.edu
Subject: permission to use KIP-C

Dear Dr. Wilson,

May I please have permission to use your 14 item KIP-C for my evidence-based practice project at Valparaiso University? I am a post-graduate DNP student and have worked as a nurse practitioner for the last 10 years.

The title of the EBP project is "The Effect of an Educational Intervention on Coumadin Surveillance in Primary Care". I would like to use the tool as a pre-test/post-test and show a short video for the teaching intervention.

I work with an internal medicine physician in a small office in Bourbonnais, IL, we are one hour south of Chicago. Our population is adults and geriatrics. The 14 item true/false is best suited for the population of interest. We have approximately 50 patients of our own on Coumadin and run our own Coumadin clinic. I have looked at the Anticoagulation Knowledge Assessment (AKA) and a 52 item questionnaire out of Utah, and these tools seem to be extensive for my project.

I have no monetary gain for this EBP project and would not use it for any other purpose. I am bound to the IRB at Riverside Medical Center for EBP work and also to the IRB at Valparaiso University. I would send you a copy of my poster session upon project completion.

Thank you for your time. I hope to hear from you soon.

Elizabeth Deck, FNP, BC, CDE
DNP student, Valparaiso University

Elizabeth Deck < elizabeth.deck@valpo.edu> Sat, Jul 20, 2013 at 11:00 AM
To: aa3107 <aa3107@wayne.edu>

Thank you.

Elizabeth Deck

Sent from my iPhone
[Quoted text hidden]

Elizabeth Deck < elizabeth.deck@valpo.edu> Sat, Jul 20, 2013 at 12:08 PM
To: Dee Nesius <Dee.Nesius@valpo.edu>

See enclosed, I have received permission to use the true/false tool from Dr. Feleta Wilson at Wayne State U.
[Quoted text hidden]

Elizabeth Deck < elizabeth.deck@valpo.edu> Thu, Jul 25, 2013 at 9:22 AM
To: eddeck@comcast.net

---------- Forwarded message ----------
From: **Feleta Louise Wilson** <aa3107@wayne.edu>
Date: Sat, Jul 20, 2013 at 7:28 AM
Subject: RE: permission to use KIP-C
To: elizabeth.deck@valpo.edu

[Quoted text hidden]

APPENDIX B

Knowledge Information Profile-Coumadin® (KIP-C®)

Directions: Circle either True or False

1. True or False The medicine will make my blood clot.
2. True or False I can take over-the-counter medicines like aspirin while I am taking Coumadin®.
3. True or False Coumadin® is an anticoagulant medication.
4. True or False If I want to go on a diet, now would be a good time while I am taking Coumadin®.
5. True or False I can take any amount of laxatives and aspirin while taking Coumadin®.
6. True or False Lots of Vitamin K is good for me while taking Coumadin®.
7. True or False Vitamin K helps Coumadin® prevent blood clots.
8. True or False It is not safe to drink liquor while on this medicine, but I can have as much beer or wine as I want.
9. True or False Foods like fish, mineral water and tomatoes are high in Vitamin K.
10. True or False I can eat any amount of collard greens as I want while taking Coumadin®.
11. True or False Indigestion is a side-effect of Coumadin®.
12. True or False Bleeding from the gum after brushing my teeth in a side-effect of Coumadin®.
13. True or False Swelling of the hand and feet is a side-effect of Coumadin®.

14. True or False I can take any kind of vitamins I want while I am on Coumadin®

Demographics: Circle one answer

Age: _____years

Last grade of school completed: _____

Gender: Male or Female

Have you ever had patient information of warfarin or Coumadin® in the past?

Yes No

How long ago did you receive patient information on Coumadin® ?_____

How long have you used Coumadin® ?_____

Reason for Coumadin®/warfarin therapy:
Atrial fibrillation
Valve replacement
Blood clots
Stroke
Other

If this is your first visit for the pretest, will your spouse/partner also hear the teaching session?

_____yes _____no _____not applicable

APPENDIX C

Blood Thinner Pills: Your Guide to Using Them Safely

U.S. Department of Health and Human Services

Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

AHRQ
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • **www.ahrq.gov**

AHRQ Pub. No. 09-0086-C
Revised August 2010

The name of my blood thinner is: _____

Reminders:

Call your doctor or pharmacy if you have questions about your blood thinner.

- My doctor's phone number is: _____
- My pharmacist's phone number is: _____

Notes:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

About Your Blood Thinner

Your doctor has prescribed a medicine called a blood thinner to prevent blood clots. Blood clots can put you at risk for heart attack, stroke, and other serious medical problems. A blood thinner is a kind of drug called an anticoagulant (*an te-ko-AG-u-lent*). "Anti" means against and "coagulant" means to thicken into a gel or solid.

Blood thinner drugs work well when they are used correctly. To help you learn about your medicine, your doctor has given you this booklet to read. Depending on where you receive care, you may be seen by a doctor, nurse, physician's assistant, nurse practitioner, pharmacist, or other health care professional. The term "doctor" is used in this booklet to refer to the person who helps you manage your blood thinner medicine.

You and your doctor will work together as a team to make sure that taking your blood thinner does not stop you from living well and safely. The information in this booklet will help you understand why you are taking a blood thinner and how to keep yourself healthy. Please take time to read all of the information in this booklet.

Warning!

Tell your doctor if you are pregnant or plan to get pregnant. Many blood thinners can cause birth defects or bleeding that may harm your unborn child.

1

How to Take Your Blood Thinner

Always take your blood thinner as directed. For example, some blood thinners need to be taken at the same time of day, every day.

Never skip a dose, and never take a double dose.

If you miss a dose, take it as soon as you remember. If you don't remember until the next day, call your doctor for instructions. If this happens when your doctor is not available, skip the missed dose and start again the next day. Mark the missed dose in a diary or on a calendar.

A pillbox with a slot for each day may help you keep track of your medicines.

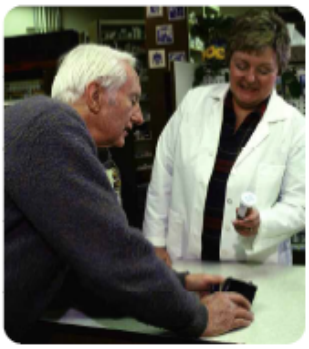
Check Your Medicine

Check your medicine when you get it from the pharmacy.

- Does the medicine seem different from what your doctor prescribed or look different from what you expected?
- Does your pill look different from what you used before?
- Are the color, shape, and markings on the pill the same as what you were previously given?

If something seems different, ask the pharmacist to double check it. Many medication errors are found by patients.

2



Using Other Medicines

Tell your doctor about every medicine you take. The doctor needs to know about all your medicines, including medicines you were taking before you started taking a blood thinner.

Other medicines can change the way your blood thinner works. Your blood thinner can also change the way your other medicines work.

It is very important to talk with your doctor about all the medicines that you take, including other prescription medicines, over-the-counter medicines, vitamins, and herbal products.

Products that contain aspirin may lessen the blood's ability to form clots and may increase your risk of bleeding when you also are taking a blood thinner. Talk with your doctor about whether or not you should take aspirin and which dose is right for you.

Medicines you get over the counter may also interact with your blood thinner. Following is a list of some common medicines that you should talk with your doctor or pharmacist about before using.

Pain relievers, cold medicines, or stomach remedies, such as:

- Advil®
- Aleve®
- Alka-Seltzer®
- Excedrin®
- ex-lax®
- Midol®
- Motrin®
- Nuprin®
- Pamprin HB®
- Pepto Bismol®
- Sine-Off®
- Tagamet HB®
- Tylenol®

Vitamins and herbal products, such as:

- Centrum®, One a Day®, or other multivitamins
- Garlic
- Ginkgo biloba
- Green tea

3

Tell your doctor about all your medicines.

Always tell your doctor about all the medicines you are taking. Tell your doctor when you start taking new medicine, when you stop taking a medicine, and if the amount of medicine you are taking changes. When you visit your doctor, bring a list of current medicines, over-the-counter drugs—such as aspirin—and any vitamins and herbal products you take.

Possible Side Effects

When taking a blood thinner it is important to be aware of its possible side effects. Bleeding is the most common side effect.

Call your doctor immediately if you have any of the following signs of serious bleeding:

- Menstrual bleeding that is much heavier than normal.
- Red or brown urine.
- Bowel movements that are red or look like tar.
- Bleeding from the gums or nose that does not stop quickly.
- Vomit that is brown or bright red.
- Anything red in color that you cough up.
- Severe pain, such as a headache or stomachache.
- Unusual bruising.
- A cut that does not stop bleeding.
- A serious fall or bump on the head.
- Dizziness or weakness.

Some people who take a blood thinner may experience hair loss or skin rashes, but this is rare.

4

Stay Safe While Taking Your Blood Thinner

Call your doctor and go to the hospital immediately if you have had a bad fall or a hard bump, even if you are not bleeding. You can be bleeding but not see any blood. For example, if you fall and hit your head, bleeding can occur inside your skull. Or, if you hurt your arm during a fall and then notice a large purple bruise, this means you are bleeding under your skin.

Because you are taking a blood thinner, you should try not to hurt yourself and cause bleeding. You need to be careful when you use knives, scissors, razors, or any sharp object that can make you bleed.

You also need to avoid activities and sports that could cause injury. Swimming and walking are safe activities. If you would like to start a new activity that will increase the amount of exercise you get every day, talk to your doctor.

You can still do many things that you enjoy. If you like to work in the yard, you still can. Just be sure to wear sturdy shoes and gloves to protect yourself. Or, if you like to ride your bike, be sure you wear a helmet.

5

Tell others.

Keep a current list of all the medicines you take. Ask your doctor about whether you should wear a medical alert bracelet or necklace. If you are badly injured and unable to speak, the bracelet lets health care workers know that you are taking a blood thinner.

To prevent injury indoors:

- Be very careful using knives and scissors.
- Use an electric razor.
- Use a soft toothbrush.
- Use waxed dental floss.
- Do not use toothpicks.
- Wear shoes or non-skid slippers in the house.
- Be careful when you trim your toenails.
- Do not trim corns or calluses yourself.

To prevent injury outdoors:

- Always wear shoes.
- Wear gloves when using sharp tools.
- Avoid activities and sports that can easily hurt you.
- Wear gardening gloves when doing yard work.

Food and Your Blood Thinner

The foods you eat can affect how well your blood thinner works for you. High amounts of vitamin K might work against some blood thinners, like warfarin (Coumadin®, *COU-ma-din*). Other blood thinners are not affected by vitamin K. Ask your doctor if you need to pay attention to the amount of vitamin K you eat.

Examples of some foods that contain medium to high levels of vitamin K:

- Asparagus
- Broccoli
- Brussels sprouts
- Cabbage
- Endive
- Green onions
- Kale
- Lettuce
- Parsley
- Soybean oil
- Soybeans
- Spinach
- Turnip, collard, and mustard greens

Cranberries. You should talk with your doctor about whether you should avoid drinking cranberry juice or taking other cranberry products.

Alcohol. If you are taking a blood thinner, you should avoid drinking alcohol.

Call your doctor if you are unable to eat for several days, for whatever reason. Also call if you have stomach problems, vomiting, or diarrhea that lasts more than 1 day. These problems could affect your blood thinner dose.

Keep your diet the same.

Do not make any major changes in your diet or start a weight loss plan before calling your doctor first.

Talk to Your Other Doctors

Because you take a blood thinner, you will be seen regularly by the doctor who prescribed the medicine. You may also see other doctors for different problems. When you see other doctors, it is very important that you tell them you are taking a blood thinner. You should also tell your dentist and the person who cleans your teeth.

If you use different pharmacies, make sure each pharmacist knows that you take a blood thinner.

Blood thinners can interact with medicines and treatments that other doctors might prescribe for you. If another doctor orders a new medicine for you, tell the doctor who ordered your blood thinner because dose changes for your blood thinner may be needed.

7

Blood Tests

You might have to have your blood tested often if you are taking a blood thinner. The blood test helps your doctor decide how much medicine you need.

The International Normalized Ratio (INR) blood test measures how fast your blood clots and lets the doctor know if your dose needs to be changed. Testing your blood helps your doctor keep you in a safe range. If there is too much blood thinner in your body, you could bleed too much. If there is not enough, you could get a blood clot.

Too Little	Best Range	Too Much
May cause a blood clot		*May cause bleeding*

Once the blood test is in the target range and the correct dose is reached, this test is done less often. Because your dose is based on the INR blood test, it is very important that you get your blood tested on the date and at the time that you are told.

8

Illness can affect your INR blood test and your blood thinner dose. If you become sick with a fever, the flu, or an infection, call your doctor. Also call if you have diarrhea or vomiting lasting more than 1 day.

Important reminders:

- ☐ Take your blood thinner as directed by your doctor.
- ☐ Go for blood tests as directed.
- ☐ Never skip a dose.
- ☐ Never take a double dose.

My INR blood test range is: _____

I should get my blood tested at: _____

Phone: _____

Common Medical Conditions

If you have any of the following medical conditions or are at risk for having them, your doctor may have given you a prescription for a blood thinner. A blood thinner helps your blood flow more easily and lowers your risk for developing blood clots in your body.

Atrial fibrillation. Atrial fibrillation (*A-tre-al fi-bri-LA-shun*), a type of irregular heartbeat, is a fairly common heart disorder that you may or may not feel. Sometimes your heart will beat too fast or out of rhythm and may cause blood clots. Sometimes atrial fibrillation is also called A-fib.

Blood clots in the lung. A blood clot that forms in another part of your body, such as in your leg, can break loose and move through the blood to your lungs. The clot then gets stuck within a blood vessel that brings blood to the lungs (called a pulmonary embolism, *PULL-mun-ary EM-bo-lizm*). If the lungs cannot get enough blood, they will be damaged, and you could stop breathing.

Blood clots. Blood clots (DVT, deep vein thrombosis, *throm-BO-sis*) form in a vein. The veins deep inside your leg, especially the calf and thigh, are the most common areas where clots occur. Blood clots can lead to damage of the blood vessels in your leg and break loose and cause other organ damage.

Family history. Some people are more likely to get blood clots because of a family history. You may have a genetic condition that causes your blood to form potentially dangerous clots.

Heart attack. A heart attack is caused by a lack of blood supply to the heart. The lack of blood happens when one or more of the blood vessels pumping blood to the heart are blocked.

Heart valve disease. Heart valve disease is any problem in one or more of the four valves in the heart. Heart valves keep blood flowing in one direction. They act as a door that swings open, allowing blood to flow through the sections of the heart.

9

Heart valve replacement. There are many types of artificial valves that are used to replace your own heart valve. The material used to make these valves may cause blood to stick and form clots.

Stroke. A stroke is caused by a blood clot that blocks a blood vessel in the brain. This blockage cuts off the blood flow to a part of the brain and can cause problems with your speech, swallowing, or movement of different parts of your body. You may be at a higher risk for a stroke if you've had a heart attack.

This booklet is based on a product developed by Carla Huber, A.R.N.P., M.S., Cedar Rapids Community Anticoagulation Clinic, Cedar Rapids, Iowa (chuber@pcofiowa.com), under Agency for Healthcare Research and Quality (AHRQ) Grant No. 1 U18 HSO15830-01 to Kirkwood Community College.

AHRQ would like to thank Stephen E. Kimmel, M.D., M.S.C.E., from AHRQ's Center for Education & Research on Therapeutics at the University of Pennsylvania School of Medicine for his expert review of this document.

How to Order AHRQ Booklets

For more copies of this booklet, e-mail the AHRQ Publications Clearinghouse at AHRQPubs@ahrq.hhs.gov or call the toll-free number: 1-800-358-9295. This booklet and a video on blood thinner pills are available at www.ahrq.gov/btpills.htm. For other consumer and patient materials, go to the AHRQ Web site at: www.ahrq.gov/consumer.

Appendix D

Written Informed Consent

Title of Project: "The Effect of an Educational Intervention on Oral Anticoagulation Therapy Knowledge in Primary Care"

Principal Investigator: Elizabeth Deck, FNP-BC, CDE

IRB #164

1. **Purpose of the Study:** You are invited to participate in a study involving research. The purpose of this study is to determine if knowledge is gained using the pre-test/post-test Knowledge Information Profile-Coumadin®, (KIP-C®), a 14-question true/false tool. The KIP-C® measures what you know about Vitamin K foods, side effects, and other foods, liquids to drink, and medications related to Coumadin® or warfarin. You will make choices of eight facts including your age range, how much schooling you have had, gender, if you have had Coumadin®/warfarin teaching in the past, range of time using Coumadin®/warfarin therapy, how long ago you had the teaching, reasons for using Coumadin®/warfarin and if your spouse/partner will also hear the teaching intervention. The principal investigator will show you the handout on Coumadin/warfarin, plus use food models to show food servings that may help you gain more knowledge about using this medication. Besides the eight facts about you, the pre-test/post-test scores will be used in this study. The duration of the study is 12 weeks. About 40 patients will be in this study if they consent. The study will only be in this office. .
2. **The procedures to be followed include:** You will read and sign a consent form from Riverside Medical Center. You will then take the Knowledge Information Profile-Coumadin® in the office, 300 Riverside Drive, Suite 2400, Bourbonnais, Illinois. The principal investigator will give you a handout called: "Blood Thinner Pills: Your Guide to Using Them Safely", a handout available to the public from Agency for Healthcare Research and Quality (AHRQ). The principal investigator will also show you the handout and food models as examples of foods and drinks to show the same use of these foods each week. In two weeks you will come back to the office and take the post-test.

   Reason to Participate/Benefits: The benefits you may receive include more knowledge about Coumadin® or warfarin including foods, beverages, and medication side effects. Coumadin® or warfarin is a pill that helps you keep your blood thinner to help stop problems of your heart or blood vessels. Sometimes food, drinks or other pills may pose a problem that you do not know.
3. **Participation is voluntary**. Your becoming a subject in this study is entirely by your own free choice. You may also drop out of this study by your own free will,

after having agreed to become a subject. You may refuse to enroll in this study or drop out of the study at any time without any problem; by doing so, you will not lose any benefits that you may be entitled. The principal investigator in this study may have to end your taking part in the study as a subject if you become ill during the pre-test/post-test or showing you the food models and cannot finish the office visit. Anything the principal investigator finds during the course of the study which may relate to your agreeing to continue doing the study will be provided to you.

4. **Procedures to be followed**: If you participate in the study, you will be asked true/false questions about what you know of Coumadin® or warfarin therapy. This is the pre-test. You will also be asked 8 questions of facts about yourself. The blood thinner handout and the food model demonstration will be done over 25 minutes; this will include a 12-minute video on Coumadin/warfarin therapy. You will be able to take the handout and the video home with you. You will then return to the office in two weeks and take the post-test. This completes the study for you. You do not have to use these resources in any way. Any harm or discomfort thought to happen with your help in this study is not greater than what you do during the day or for a routine office visit, blood pressure check or blood check for your Coumadin®/warfarin.
5. **Potential risks, discomfort, and inconveniences**: Any risks, discomfort, or burden if you choose to take part in the study will not be greater than those experienced in daily life or during an exam in the office. The chances for harm for completing the study are not greater than those that may happen during an office visit. This is considered no more than minimal risk. If you experience discomfort or are injured during the study you are to contact the office administrator at 815-935-2784 during office hours within 24 hours of your appointment.
6. **Statement of confidentiality**: All of your records will be in a password-protected electronic medical record and be kept confidential. Signed copies of your consents authorizations will be kept in a locked office file cabinet for three years and then destroyed. We shall put the information collected about you during the study into a research record. This research record will not show your name, but will have a code entered in it, that will allow the information to be linked to you. However, we shall keep your research record confidential, to the extent provided by federal, state and local law. No one other than the principal investigator will be allowed to see the information, subject to legally proscribed exceptions. You will not be identified in any reports on this study. The primary physician will be contacted if project investigator in the course of this project learns of a medical condition that requires immediate attention.
7. **Personal benefits**: Personal benefits include learning food, drug and medication side effects of Coumadin®/warfarin therapy. The overall benefit includes helping

you know more about Coumadin®/warfarin therapy. You may notice you benefit from the study, or what you learned may help others who also are on Coumadin®/warfarin.

8. C**ompensation for taking part in the study**: You will not get paid for taking part in the study.
9. **Health insurance bills**: The insurance will not be billed for any extra time spent with you. If you do the pre-test/post-test during the regular routine office visit, the insurance will only be billed for the routine office visit information. There is no fee for the high blood pressure monitoring visit if you take your test during that visit. The blood test (INR) is ordered by the doctor and the patient's insurance pays for this test. No additional fees will be added to your insurance bill or the pre-test/post-test or food model demonstration.
10. **New risks uncovered**: If any new risks are found during the course of the research-based practice study which may show the risks of harm have increased, the investigator will let you know so that you may reconsider your willingness to stay in the study. To find out any aspect of this study you may contact: Elizabeth Deck, FNP-BC, CDE, 300 Riverside Drive, Suite 2400, Bourbonnais, Illinois, 60914, office phone 815-935-2784 during business hours. If you have any questions or concerns about your rights as a study subject or grievances, you may contact Karen Block, Riverside's HIPPA Privacy Officer at 815-933-1671.
11. **Alternative procedures/treatment**: You may choose not to participate in this study. Alternatives to the study include the regular office visit, the blood pressure check or the blood check for your medication tracking.
12. **Principal Investigator's participation/payment**: The principal investigator will not get paid for doing this from Riverside or Valparaiso University.
13. **Where copies of documents are kept**: One copy of the informed consent will be kept locked with the principal investigator's research records. A second copy will be given to you to keep. A third copy will be placed into your record at Riverside Medical Center. Data will be maintained for three years in a locked office file cabinet then destroyed.
14. **Study subjects' statement of consent to participate in the study**: I have read the information given above. The investigator has personally discussed with me and told me more about the study, and answered my questions. I understand the meaning of this information. I am aware that, like in any research-based practice study, the investigator cannot always predict what may happen or possibly go wrong. I have been given enough time to consider if I should join this study. I hereby consent by my own free choice to take part in the study as a study subject. I am not waiving any of my legal rights by signing this form. I understand I will receive a copy of this consent form.

15. Signatures required on the informed consent document:

_____Printed Name

_____Signature

_____Date

_____Time

_____Person completing the consent

_____Investigator

Appendix E

Authorization Form

The Privacy Law, Health Insurance Portability & Accountability ACT (HIPPA), protects my individually identifiable health information (protected health information). The Privacy Law requires me to sign an authorization (or agreement) so researchers can use or disclose my protected health information for research purposes. My protected health information will be used/disclosed for the following research study: The Effect of an Educational Intervention on Oral Anticoagulation Therapy Knowledge in Primary Care.
I authorize Elizabeth Deck, FNP-BC, CDE, to create, access, use and disclose my protected health information for the purposes described below.

My protected health information that may be used/or and disclosed includes:
*Age group, educational level, gender, length of time using Coumadin®/warfarin, and indication for Coumadin®/warfarin, and score on the pre-test/post-test, which is coded alphabetically and not disclosed to anyone but primary researcher.

My protected health information will be used for:
*The purpose the study is to determine if knowledge is gained using the pre-test/post-test Knowledge Information Profile-Coumadin® (KIP-C®), a 14-question true/false tool or questionnaire. The KIP-C® assesses patients' knowledge of Vitamin K foods, side effects, and other foods, liquids to drink, and medications related to Coumadin or warfarin. Eight areas of facts including age group, how much education you have had, gender, if you have had patient information on Coumadin®/warfarin, length of time using Coumadin®/warfarin, reasons for Coumadin®/warfarin therapy, and if your spouse/partner will also hear the educational intervention will be used in this study. The principal investigator will give you a handout on Coumadin®/warfarin, plus use food models to show possible food, drinks and medication side effects to taking Coumadin®/warfarin on a daily basis. The PHI (protected health information) is necessary to conduct the research and meet legal, institutional and accreditation requirements.

The Researchers may use and share my health information with:
*Representatives of Riverside Medical Center or Riverside Medical Center's Institutional Review Board
*My primary physician will be contacted if researcher in the course of the project learns of a medical condition that needs immediate attention

Should my health information be disclosed to anyone outside of the study, the information may no longer be protected by HIPPA and this authorization; however, the use of my health information would still be regulated by applicable federal and state laws.

I do not have to sign this Authorization. If I decide to sign the Authorization:
It will not affect my treatment, payment or enrollment in any health plans or affect my eligibility for benefits. I will still be able to ask my doctor questions about my Coumadin® or warfarin treatment.
I may not be allowed to participate in the research study.

After signing the Authorization, I can change my mind and:

*Not let the researcher disclose or use my protected health information (revoke the Authorization).
*If I revoke the Authorization, I will send a written letter to: Elizabeth Deck, FNP-BC, CDE, 300 Riverside Drive, Suite 2400, Bourbonnais, Illinois, 60914, to inform her of my decision.
*If I revoke the Authorization, the researcher may only use and disclose the protected health information **already** collected for this research study.
*If I revoke this Authorization, my protected health information may still be used and disclosed should I have any adverse event (a bad effect).
*If I change my mind and withdraw the Authorization, I may not be allowed to participate in the study.
This authorization does not have an expiration date but can be terminated if I decide to withdraw my permission.
If I have not already received a copy of the Privacy Notice, I may request one from Elizabeth Deck, FNP-BC; CDE at 815-935-2784. If I have questions or concerns about my privacy rights, I should contact Karen Block, Riverside's HIPPA privacy officer at 350 N. Wall Street, Kankakee, IL 60901, 815-933-1671.
I have read this information, and I will receive a copy of this form after it is signed. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction.

_____ _____
Signature of subject Date

_____
Printed name of subject