Effects of follow up calls on patient compliance in Anticoagulant Management

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Abstract

A patient once discharged with warfarin, receives a follow-up educational phone call within the pre-specified time frame of discharge and first follow-up post-hospitalization visit. After that, the burden is on the patient to remember the risk factors, do's and don'ts associated with warfarin, and when to call their providers to discuss any changes in current diagnosis or medication regimen or diet/lifestyle changes that can alter the warfarin management. The purpose of this project was to increase patients' awareness regarding barriers for effective OAC therapy management through weekly follow-up phone calls. The development of a comprehensive outline for follow-up phone calls and training to assist providers in conducting proper anticoagulant management to keep INR values within the therapeutic range to avoid ADEs. The paired t-test was used to determine if the means of the two sets of observations differed when the same groups of individuals were tested before and after the educational follow-up phone calls. Evaluation of the pre- and post- educational survey questionnaire surveys revealed that the participant had gained more knowledge and a better understanding of the warfarin AOC therapy management; this helped the participant in managing their INR values within the therapeutic range (2.0 to 3.0). The results did show statistically significant differences; however, they were also clinically significant from pre- to post-intervention. The results of this project can be used as a valuable resource for future research conducted using larger sample sizes, and the sustainability of this project can be accomplished by repeating the project on a larger scale with funding from interested stakeholders, in coordination with the health care team members.

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Effects of follow up calls on patient compliance in anticoagulant management

Chapter I

The direct vitamin K inhibitor, Warfarin, prevents systemic embolism in patients with prosthetic heart valves, atrial fibrillation (AF), venous thromboembolism (VTE), inherited or acquired thrombophilic disorders, and is used as a prophylactic treatment after myocardial infarction (MI) (Garcia & Schwartz, 2011). Warfarin was the only oral anticoagulant (OAC) available in the USA until 2010, and about four million Americans are on long-term OAC therapy with warfarin. This drug has a very narrow therapeutic range and has multiple drug interactions that make adjusting the dose very challenging and risky (Garcia & Schwartz, 2011). Warfarin is used for the treatment of VTE but carries a high risk of causing bleeding or clot formation if not appropriately managed. Bleeding episodes are estimated to be 15% to 20% per year, with fatal bleeding episodes of 1% to 3% per year (Zareh, Davis & Henderson, 2011). Patients on warfarin require close, frequent, and diligent monitoring and drug dose adjustments to avoid an adverse reaction. The International Normalized Ratio (INR) levels are the lab test used to measure the anticoagulation status of patients on warfarin. INR range of 2.0 to 3.0 is generally an effective therapeutic range for people taking warfarin. When the INR is higher than the recommended range, it means that blood clots more slowly than desired and can cause a risk of bleeding. Lower INR means blood clots quicker than desired, causing the risk of clot formation. To avoid adverse drug effects (ADEs), patients must be aware of the factors that can affect their INR while taking the prescribed warfarin.

Preventing bleeding with warfarin therapy takes proper monitoring of frequent blood work, keeping the INR levels in the therapeutic range, multiple-dose adjustments based on INR levels, patient education on factors affecting INR values, and their compliance with the regimen.

This process is quite challenging for health care providers, and this is where weekly follow-up phone calls can be a crucial factor for meeting those challenges for outpatient OAC management (Huber, Levett & Atkinson, 2008).

Background and Significance

VTE includes both deep vein thrombosis (DVT) and pulmonary embolism (PE). About nine hundred thousand people could be affected with DVT/PE yearly in the United States (CDC. 2019). An estimated average of 548,000 hospitalizations with VTE occurs each year among US residents older than 18 years of age. Of these, three hundred forty-nine thousand were DVTs, and two hundred seventy-six thousand were PEs. About 20% of patients are at risk for a second episode of DVT within ten years after the first one (Heit, Spencer & White, 2016). VTEs are considered one of the most common silent killers. AF is also a common arrhythmia affecting the aging population and is a significant life-changing risk factor for cardioembolic stroke (Stanford Health Care, 2017). Annual VTE events cost the US health care system $7–10 billion each year (Grosse et al., 2016).

OACs are the mainline therapy for long-term treatment and prevention of various thromboembolic disorders, including VTE and strokes. In addition to warfarin, direct thrombin inhibitor (dabigatran) and factor Xa inhibitors (rivaroxaban and apixaban) are available OACs. However, warfarin is commonly chosen over these products because of its low cost and is the most common OAC utilized in the outpatient setting (Nutescu et al., 2013).

Thirty million warfarin prescriptions are written annually (Raji et al., 2013), and the total expenditure for warfarin has been estimated around $158 million per quarter (Kirley et al., 2012). Bleeding is the primary complication of OACs. The rate of bleeding depends on the kind of anticoagulant agent, dosing, duration of therapy, and population. The use of warfarin increases

the risk of persistent bleeding by five times (Zareh, Davis & Henderson, 2011). Adults over 65 years of age are more vulnerable to ADEs compared to younger adults (Zareh et al., 2011). Annually, 17% of emergency department (ED) visits and 33% of hospital admissions due to warfarin-related ADEs happen within the older adult population (Zareh et al., 2011). Even with routine testing, therapeutic INR values are prone to fluctuate outside their narrow therapeutic range leading to severe outcomes such as thrombosis and bleeding (Ikeda et al., 2018).

While OAC therapy has relatively reduced the risk of fatal PEs, symptomatic DVTs, and ischemic stroke caused by AF, there is evidence that shows that OAC therapy is not well managed, costing many dollars to the health care system associated with strokes and VTEs that could have been prevented through better OAC management (Guyatt et al., 2012).

Most common anticoagulant ADEs result from overdosed medication errors causing prolonged INR or bleeding events, many of which are preventable, and pose high costs to the healthcare system due to the increased nursing and pharmacy costs (Zareh et al., 2011). Factors contributing to mismanagement of anticoagulant therapy include lack of understanding the importance of anticoagulant therapy by patients, difficulties endured in proper follow-up and lab monitoring, low socioeconomic status, low health literacy, diverse cultural backgrounds, physical disabilities, and comorbid conditions of patients (Kirley et al., 2012). Any changes in lifestyle due to a traumatic event (death or divorce, etc.) in the patient's life, or primary infection or new diagnosis can also cause risk factors that need to be addressed immediately for better OAC management. It is of utmost importance to have a thorough knowledge of how to avoid the complications of OAC therapy (Stanford Health Care, 2017).

Despite health information technology resources like computerized data (safety reporting system), drug algorithms, and clinical decision protocols, healthcare providers face significant

challenges in proper warfarin management (Piazza et al., 2011). Providers must take a thorough patient history and avoid factors contributing to OAC mismanagement such as the variation of OAC management between inpatient and outpatient settings, the transition between different anticoagulant drugs, their related pharmacokinetics and pharmacodynamics, external factors affecting the efficacy of the drug, lack of frequent monitoring, and dose adjustment (Piazza et al., 2011).

Huber et al. (2008) reported that 60% of all medications prescribed are taken incorrectly or not at all. The fastest-growing segment of the population is adults over age 80 years, and patients in this group make frequent mistakes in taking their medications. Up to 90% of elderly patients made some medication errors, and up to 35% elderly made potentially serious errors with prescribed medications (Huber et al., 2008). Proper follow-up phone calls by providers can prevent this from happening.

Proper anticoagulant management education, dose adjustment, and continued interaction between the patient and the provider is a labor-intensive process but has shown positive outcomes in patient care with fewer hospitalizations, ER visits, and less associated costs for thromboembolic and hemorrhagic episodes (Nutescu et al., 2013). Patient education for proper OAC management involves potential drug to drug and drug to herb interactions, understanding signs and symptoms of thromboembolism and bleeding, medication administration instructions, and changes in diet (Nutescu et al., 2013). Implementing evidence-based strategies to implement a detailed action plan to prevent ADEs of warfarin therapy will increase patient adherence and safety, thus creating a healthier community.

Needs Assessment

The project was conducted at an outpatient clinic, where a vulnerable population of older adults receives their care. This clinic sees approximately 2000 patients each year, 20% of whom are prescribed warfarin. The mean age of those served is 80 years. Approximately 15% of the warfarin patients at this clinic have had INR values out of therapeutic range, putting them at risk for bleeding or clot formation as presented by the team care coordinator. Challenges seen with OAC therapy include lack of frequent monitoring and follow-up care causing late dose adjustments. These late dose adjustments put patients at risk for bleeding. Sixty percent of the clinic population is not capable of safely accessing standard public or community health resources because of low socioeconomic status, low health literacy, sensory impairment, physical limitations, and comorbid conditions.

These elderly patients who have multiple medical conditions, often face challenges with transportation. They are dependent on others for transportation to and from the clinic. These patients are generally not technologically advanced. Most do not own or use computers. Therefore, telephone calls are the best means to reach them (HealthyPeople2020, 2017).

Patients and their caregivers' lack of knowledge of the proper evaluation criteria involving drug interactions, dietary changes, procedures, lifestyle changes, and comorbid conditions can increase warfarin-related ADEs. The difference in inpatient and outpatient warfarin therapy, recognition of signs and symptoms of bleeding and clot formation, the impact of alcohol intake on INR, and the importance of dose compliance are factors that need to be part of ongoing warfarin management education.

Knowing the risk factors involved in the management of the disease can help guide patients into the appropriate actions, including changing behaviors and proper self-management

of the disease (Savage et al., 2016). Continuing education can be provided to patients with consistent follow-up phone calls from nurses or providers. Regular screening for any change in the current regimen, for example, a change in diet that can alter the amount of vitamin K intake, weight changes, start of new medications or supplements, any recent surgeries, or diagnostic procedures that require a transition management of anticoagulants from inpatient to outpatient status, can help the provider to monitor for new risk factors and better manage their health.

Assessment tools such as SWOT analysis used to estimate the effectiveness of the project exposed the need to address the following in-depth: limited knowledge, noncompliance, and dosing errors by the patient. HealthyPeople2020 (2017) objectives included "Access to Health Services," which means "the timely use of personal health services to achieve the best health outcomes" and can be achieved by providing proper follow-up care in a timely fashion by health care providers. Follow-up care is critical in the management of thromboembolic disorders so that patients can avoid further complications and the costs associated with ER visits (HealthyPeople2020, 2017). Health promotion, health protection, and risk reduction can decrease the occurrence, severity, and will also help to achieve optimum health for patients (Savage, Kub, & Groves, 2016).

Problem Statement

A patient at this clinic once discharged with warfarin, receives a follow-up educational phone call within the pre-specified time frame of discharge and first follow-up post-hospitalization visit. After that, the burden is on the patient to remember the risk factors, do's and don'ts associated with warfarin, and when to call their providers to discuss any changes in current diagnosis or medication regimen or diet/lifestyle changes that can alter the warfarin management. Patients have limited knowledge regarding the risk factors/barriers in effective

OAC therapy, such as non-compliance, dosing regimen, drug interaction, diet changes, recent changes in comorbid conditions, new procedures, and any changes in lifestyle. Not knowing these barriers can affect a patient's self-efficacy, health outcomes, and increase morbidity and mortality related to warfarin therapy. Lack of timely follow up with OAC therapy can cause unnecessary ER visits, undue financial burdens on the patients and community, as well as additional strain on caregivers.

Project Aims

Following were the objectives of this research project:

- Increase patients' awareness regarding barriers for effective OAC therapy through weekly follow-up phone calls. The development of a comprehensive outline for follow-up phone calls and training to assist providers in conducting proper anticoagulant management to keep INR values within the therapeutic range to avoid ADEs.
- Use of interprofessional team (educators, health care professionals, pharmacists) to address patients' barriers related to OAC therapy and implement educational strategies for the betterment of anticoagulant management during the project
- Reducing ADEs, with closer monitoring and frequent follow-ups with anticoagulant patients, thus improving the well-being and safety of the individual and the community at large during and after the project is conducted.
- An educational session for patients to improve their self-management of warfarin to reduce the complications of anticoagulant therapy on the same day of initiation of warfarin management.

Clinical Question/PICOT

In elderly patients on warfarin, does weekly educational phone call addressing barriers to OAC therapy adherence, compared to the one-time initial educational session, help bring the INR values within a therapeutic range in six weeks of project implementation?

Congruence with Organizational Strategic Plan

The outpatient clinic is in South Florida and is mostly comprised of the older adult population and serves patients regardless of race, color, national origin, gender, or disability. The mission of this organization is to provide patient-centered, proactive, personalized, team-based care with a focus on disease prevention resulting in patient satisfaction, thus improving healthcare outcomes and health care costs.

The purpose of this Evidence-Based Research Project is to provide an ongoing frequent educational intervention that can be adapted in the outpatient clinic for better management of warfarin therapy. Warfarin is an oral medication used to prevent blood clots (oral anticoagulant (OAC) therapy). The most significant ADE of warfarin treatment is bleeding, and the main cause for this is due to drug interaction, changes in diet, and alcohol use (Garcia & Schwartz, 2011). Consistent follow-up calls and ongoing education for patients and their family members about the factors that can affect their INR levels can improve their self-management of OAC therapy. Coordinated care among interdisciplinary team members makes delivery of care more efficient and time-effective, as well as improving patient's quality of life (Wynia, Von Kohorn, & Mitchell, 2012).

Health care providers of clinics/hospitals should use a proactive approach for prevention and health promotion instead of only addressing acute care needs. Comprehensive care includes early detection, screening, preventive care services, lifestyle coaching, and technology to care for

patients. Further, patients establish bonding and mutual trust with team members over time, resulting in more open communication and adherence. The quality improvement project aims to improve patients' awareness of risk factors and barriers and improve their self-management with ongoing support from their health care team.

Open communication without hesitation, between multidisciplinary team members (i.e., social worker, dietitian, pharmacist, primary providers, and nurses, etc.), about the challenges and limitations related to ADEs with the OAC therapy, facilitates the team to coordinate resources. This project's vision focuses on providing patient-centered care through a practical multidisciplinary approach, ultimately reducing the related ADEs with the OAC therapy of a vulnerable population.

Support for this project included input from patient care team members, clinicians, nurses, pharmacists, and dietitians for proper follow-up with patient care. The healthcare team members reviewed and edited the comprehensive follow-up Educational Intervention Flowchart used by the DNP student to educate the patients about the risk factors that can cause ADEs related to OAC therapy. The managerial team helped allocate the resources to implement the project. The mentor, nutritionists, and pharmacists provided support to the development of the follow-up care plan for proper OAC management.

Evidence

Search process. Literature research for this project was conducted using several databases, criteria, and keywords. The databases used to gather the research articles included: Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus with full text, ERIC (Educational Library), PubMed @ Bradley, Google Scholar and Cochrane library. The search criteria included systematic reviews and cohort studies using the keywords: warfarin,

anticoagulant, INR, vitamin K, heparin, NSAIDs, AMS, DVT, AFIB, thromboembolism, telemedicine, and patient care. In total, 53 articles were selected, including evidence-based studies, critical appraisals, professional opinions, government databases, and articles from published journals.

Appraisal of evidence. Using a level of evidence pyramid as a guideline, 30 articles were selected and included in the evidence evaluation table with the level of evidence ranging from 2 to 5. The articles were analyzed to gather a deeper understanding of the presenting problem with OAC management, its challenges, and practical solutions.

Synthesis of Evidence

Thromboembolism affects circulation causing VTE of the leg or pelvis, AF, and its related complications. PE or stroke, especially in older age, is associated with reduced survival, additional health care costs, and a high rate of recurrence. These potential complications require health care providers to monitor patients' INR, CBC, LFTs, and increased d-dimer levels closely before stopping prophylactic OAC therapy, once the patient is stable (Piazza et al., 2011; Wigle et al., 2013; Garcia &Schwartz, 2011; Jaffer & Bragg, 2003).

Patients' INR levels are the predictors of recurrence of clot formation after the idiopathic incidence of AF, VTE, and also for signs of post-thrombotic syndrome (Heit et al., 2016). Patients choose warfarin management because of the low cost, despite its narrow therapeutic window and the associated risk of bleeding (Ikeda et al., 2018). Patients know that the warfarin antidote, vitamin K, is available in the market, which makes them feel safe. Better compliance and timely blood test monitoring are critical for safely managing patients on warfarin. INR value monitoring by clinicians should be done more frequently during the dose adjustment periods, and

patients with self-testing and proper education showed comparable clinical outcomes to a clinic-based anticoagulant management outcome (Garcia & Schwartz, 2011).

The most significant side effect of warfarin treatment is bleeding, and the leading cause for it is the INR fluctuation due to drug interaction, changes in diet, and alcohol use that change warfarin metabolism, thus causing over-coagulation or under-coagulation. INR fluctuation can be life-threatening, and clinicians need to know the detailed guidelines for managing specific INR ranges (Garcia & Schwartz, 2011).

The INR value greater than nine had 20 times higher risk of bleeding than the patients with INR value lower than nine. Holding warfarin or giving vitamin K treatment was ineffective in bringing the INR levels down within 24 hours, whereas plasma infusion helped immediately to reduce the INR value to 2.4 (Pagano & Chandler, 2012). The bleeding related to warfarin is treated with the administration of vitamin K, which overpowers the anticoagulation system and activates the endogenous coagulation factors. Both oral and intravenous (IV) administered vitamin K is effective. The IV vitamin K corrects the INR within 4 to 6 hours. The associated risk is severe anaphylactic reactions. Because of this, the American College of Chest Physicians, the American Heart Association, the American College of Cardiology, the Australasian Society of Thrombosis and Hemostasis, and the American Society of Hematology have suggested the use of IV vitamin K be limited to life-threatening situations only (Zareh et al., 2011).

Routine monitoring with blood work is required for warfarin management. INR monitoring at home with self-testing devices and telemedicine are suitable for patients with prolonged use of warfarin. Barcellona, Fenu, Cornacchini, and Marongiu (2013) also found that self-testing can decrease thromboembolic episodes compared to general management through the clinic without increasing major bleeding.

Providers must constantly balance the risk of bleeding and clotting with patients on warfarin. Warfarin is usually started at a dose of five milligrams per day, while ten milligrams can cause supratherapeutic INRs (Jaffer & Bragg, 2003).

Patients with non-valvular atrial fibrillation are at higher risk of embolism and stroke, and anticoagulation intensity with an INR of 2 to 2.5 provides optimal protection for them (Oden, Fahlen & Hart, 2004). A substantial increase in the risk of intracranial hemorrhage is seen when the INR increases from 2.5 to 4. Patients with diseases of the vessels in the brain increase their risk of mortality by 2.3 times per one unit increase in INR and 1.7 times for events in the vessels of the brain (Oden, Fahlen & Hart, 2004).

Even with the risk of bleeding and constant monitoring, prophylactic therapy with anticoagulants is effective for the prevention of VTE and the benefit-risk analysis done by the provider (based on different surgical procedures and their characteristics) justifies use in patients who are at elevated risk (Gurwitz et al., 2007). Warfarin plays a vital role in reducing morbidity and mortality associated with AF and other conditions. Safety and effectiveness are closely related to the intricate management of the therapeutic range and require ongoing monitoring. A new group of drugs called DOACS (for example, dabigatran), is now available and more adaptable in ambulatory practice, but extremely costly compared to warfarin with less researched data (Kirley et al., 2012).

The approach to better management of this population must be multidisciplinary; including nurses, providers, a nutritionist, and pharmacists. Pharmacist intervention for medication adherence includes medication review with patients, medication management, and patient counseling. Pharmacists come in direct contact with patients before taking medicines, enabling them to influence patient expectations with treatment being effective, the importance of

monitoring blood work, medication adherence, patients' strengths and weaknesses with diagnosis, dexterity, vision, and cognition (Laven & Arnet, 2018). Nutritionists provide support by helping patients in choosing the proper diet and ingredients in their diet that would maintain a consistent intake of vitamin K to maintain their INR values within therapeutic range while considering their likes and dislikes and other comorbid conditions. Nurses and providers support patients with ongoing education based on any changes in their current medication regimen, lifestyle, new medical conditions, and current blood work to help maintain the anticoagulant effects within the therapeutic range and avoid any OAC related ADEs.

Efforts to improve quality to reduce anticoagulant-associated medication errors will improve patient safety and decrease associated health care costs (Piazza et al., 2011). Gurwitz et al. (2007) completed a cohort study of long-term care residents of 25 nursing homes in Connecticut. The results showed that the adverse warfarin-related events were at high risk for this population. Using strategies that target educational efforts concerning the safe use of warfarin in the nursing home setting improved the OAC management resulting in this population, reducing the number of ADEs.

Monitoring errors were related to inadequate laboratory monitoring of warfarin therapy or delayed response by the staff, or a failure to respond to laboratory results (INR values). Prescribing errors included the wrong dose and known interaction (Guyatt et al., 2012). Other barriers that were mentioned in the literature search were: lack of control over one's own health, frequency of testing, fluctuation of therapeutic INR levels, cost of skilled nursing home care, variation in INR results between clinic labs and home testing, medication compliance, and limited communication with providers (Shah & Robinson, 2011; Pizza et al., 2011; Gurwitz et al., 2007).

Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC), pointed out quality indicators relevant to inpatient/transition anticoagulation management since rising health care cost is putting pressure on healthcare facilities to evaluate their practices by reporting findings and implementing ways to improve performance (Nutescu et al., 2013). Indicators for transition care included appropriate referral to outpatient anticoagulation clinic, patients receiving a follow-up phone call within the specified time period, documented communication between inpatient and outpatient providers, patients with discharge instructions and discharge summary sent to receiving provider, documented follow-up educational phone call within pre-specified time frame of discharge, and first follow-up visit post-hospitalization (Nutescu et al., 2013).

Educational guidelines/tools for OAC therapy. Several resources have been developed to guide nurses and practitioners in the management and education of patients on OACs. Wigle, Hein, Bloomfield, Tubb & Doherty (2013) focused on the evidence-based clinical practice guidelines recommended by the American College of Chest Physicians (ACCP) for the goal and duration of anticoagulation therapy, methods of initiating therapy, and monitoring for reducing the ADEs. Witt et al., (2018) reviewed, evidence-based guidelines of the American Society of Hematology (ASH) that provide support to clinicians and other health care professionals in their decision-making process about the use of anticoagulants in the management of VTE. Kano et al. (2017) developed warfarin management algorithms “Recommendations for the use of warfarin in anticoagulation therapy” and “Recommendations for the use of warfarin in anticoagulation therapy: dose adjustment and bleeding control” based on the Delphi method for therapeutic drug monitoring.

A community-based anticoagulation therapy clinic implemented a patient safety tool called 'Warfarin Compliance Assessment Scale' (WCAS), to measure patient compliance with warfarin therapy (Huber et al., 2008). This clinic was established in 2005 with the help of funding from the Agency of Health Research and Quality as well as a partnership with Kirkwood Community College of Iowa and Physician's Clinic of Iowa (Huber et al., 2008). The WCAS included assigned points for new medications, herbal supplements, dietary changes, alcohol intake, missed or extra dose. The clinic also developed a booklet titled "My Guide to Warfarin Therapy" as an educational intervention flowchart. Developing WCAS with help from the community stakeholders helped in better management and patient safety (Huber et al., 2008). For patients on warfarin, the following information should be included in the teaching: why patient is on warfarin and for how long; frequency of INR labs; signs and symptoms of bleeding and clot formation; influence of diet and alcohol on warfarin; drug interactions; specific needs for women of childbearing age; informing all care providers that patient is on warfarin; ensuring notification prior to scheduling any surgeries or procedures; informing of missed dose or overdosing; and carrying a medical bracelet that states they are on blood thinner (Jaffer & Bragg, 2003).

Xu, Li, Ye, & Lu (2014) established a five-point warfarin management intervention strategy that improved medication safety, reduced medication errors, and patient satisfaction included training programs that increased nurses' awareness on medication safety, optimizing medication management criteria, proper administration, nursing management, and increasing medication safety.

In conclusion, optimization of the warfarin therapy is challenging, but proper follow-up from clinicians and comprehensive education regarding patients' possible barriers in effective management is imperative to avoid ADEs and costly emergency hospitalizations. There is a need

to establish a proactive approach that would allow healthcare providers to address the management of warfarin related adverse effects in time.

Conceptual or Theoretical Framework

The Iowa model used for evidence-based practice incorporates research evidence with the needs of the organization. This model leads the healthcare providers to question the effectiveness of current practice and how practice can be improved for better healthcare outcomes (Doody & Doody, 2011). The main steps involved in the process are selecting a topic, forming a team, researching evidence, implementing an evidence-based practice standard, and evaluating it (Doody & Doody, 2011).

This project used the core concepts in the Iowa model in execution, by first selecting the topic that needed to be addressed using a needs assessment of the clinical site. With the help of the mentor, this DNP student has performed a literature review, developed an educational flowchart, and designed the project. The second step of the Iowa model involved forming a team to execute the project. The project care team members include the nurse, clinician, medical assistant, pharmacist, nutritionist, and DNP student. In the third step of the model, the DNP student presented the patient care team members with project outcome results. Patient care team members provided ongoing support to the DNP student by helping with patient selection based on the criteria, pre- and post-survey, selected patient data for analysis, and necessary patient care and referrals based on patient needs to be recognized through the weekly phone calls.

The patient care team members agreed to use the model as mentioned above in developing a project plan to help selected patients identify risk factors and reasons for non-compliance. The committee recognizes this project, to align with their mission, as one of the continuing efforts for improving patient care and satisfaction.

Chapter II: Methodology

Project Design

This quality improvement project was guided by the Iowa model used for evidence-based practice. The patient care team included (clinician, nurse, and medical assistant), as well as interprofessional team members (nutritionist and pharmacist). The synthesis of evidence has identified vital information to include in the assessment and education. The project design focused on developing accomplishable educational strategies that could be easily adapted to an outpatient environment. Selected patients on OAC medication with the help of patient care team members were evaluated after six weeks of educational intervention. The principal focus was to measure the change in patient compliance with OAC therapy, with the implementation of an educational intervention flowchart for weekly follow up phone calls.

Setting

This quality improvement project was conducted in a small outpatient adult clinic setting, located in South Florida. Facility approval was obtained from the clinic administration (see Appendix C). This clinic serves approximately 2000 patients each year, and 15% of them were on anticoagulant therapy. Of the 15%, 10% (30 patients) were on OAC therapy with subtherapeutic INR values. There are three patient care teams, each including primary care providers, nurses, and medical assistants. A dietician and pharmacists are also on the team via telehealth. One of the three patient care teams agreed to be part of the project. The clinic has an electronic health record (EHR) system to track the patient's labs and progress notes. The clinic provides patient-centered, personalized, team-based care with a focus on disease prevention and patient satisfaction. The clinic culture encompasses teamwork, low staff turnover, and positive leadership that makes an excellent site for this research project.

Population

Participants were selected by the patient, health care team nurse based on their age of 65 years and older, and who have sub-therapeutic INR value within one week of project implementation. These participants were included irrespective of their socio-economic, race, or cultural background. For this project, at least ten patients were selected and were followed through the project for six consecutive weeks. Per clinic protocol, biweekly INR levels are drawn on patients with sub-therapeutic INR value, until they have three consecutive INR levels within the therapeutic range to ensure compliance with OAC therapy and avoid ADEs. The EHR was utilized by the patient care team nurse to apply the above criteria in the patient selection process. The elderly population of the clinic was chosen because they are more vulnerable to ADEs related to warfarin management, thus requiring more education (Huber et al., 2008)

Instruments/Tools

The first tool was the "Pre-Educational Survey Questionnaire" (see Appendix B). This tool would help the DNP student to assess patients' current knowledge about their OAC management, including risk factors, possible ADEs related to OAC therapy, and their barriers to their therapy. It included questions such as, "do you know why you are taking warfarin?; are you aware of the dietary restrictions and frequent INR lab monitoring required when taking warfarin?; are you aware of the consequences of dietary and medication noncompliance with an anticoagulation regime? We also explored any barriers that keep patients from taking medication on time, correct dosage, and not adhering to dietary restrictions. The Pre-Educational Survey Questionnaire was implemented to identify medication noncompliance, pill burden, and level of educational support needed for self-motivation and proper compliance to avoid the possible ADEs, the questionnaire was developed based on concepts/ideas adopted from Garcia &

Schwartz (2011), Huber et al. (2008), Jaffer & Bragg (2003), Kano et al. (2017), Thrombosis Canada (2015), and Witt et al. (2018), and modified to fulfill the need for this project. This questionnaire provided a better understanding of patients' current knowledge base and barriers towards compliance.

Pre-Educational Survey Questionnaire was used as the basis for the "Educational Intervention Flowchart" (see Appendix D & E), also developed by this DNP student. The literature review of warfarin management guidelines heavily informed its development (Garcia & Schwartz, 2011, Huber et al., 2008; Jaffer & Bragg, 2003; Kano et al., 2017; Thrombosis Canada, 2015; Witt et al., 2018). As it was being developed, the patient care team was consulted to edit the comprehensive Educational Intervention Flowchart and was used by the DNP student during the weekly educational phone calls with project participants. The focus of the phone calls was to provide educational support to the patients to overcome the barriers and be more compliant to avoid the risk factors that can bring the INR levels in the subtherapeutic range.

The third tool the DNP student-developed was the "Post-Educational Survey Questionaire" (see Appendix F). This tool started with questions based on the Pre-Educational Survey, and it also included questions to assess the satisfaction of the patients with weekly phone calls and awareness of the barriers through education provided by the Educational Intervention Flowchart over six weeks. It also accessed any reduction in the fluctuation of the INR levels and improving their self-management with more confidence to approach their provider with open communication.

Project Plan

The fifteen participants were selected based on their age of 65 years and older, and who had a sub-therapeutic International Normalized Ratio (INR) within one-week of project

implementation. A sub-therapeutic INR was defined as less than 2.0 or higher than 3.0, patients' INR levels are drawn on Monday and Tuesday from 8:00 AM to 12:00. The DNP student was at the clinic during those times to recruit participants.

The patient team care nurse approached the selected patients as they came into the clinic for regularly scheduled blood work appointments and informed the patient about the project plan. The basic invitation script used by the nurse to recruit patients included:

> "There is a research project ongoing within the clinic that you might find beneficial. The researcher is a Doctor of Nursing Practice (DNP) family nurse practitioner student finishing her education. She wants to educate patients about warfarin therapy. We invite you to participate in this education because you are prescribed warfarin, the blood thinner, and your recent lab that measures warfarin is not in the therapeutic range. We want to find ways to keep your levels within the therapeutic range. The researcher, Vanita, is here in the conference room if you would like to speak with her about possibly joining this education project. Vanita does not want to know your private health information, so for this project, may we please call you [ ](e.g., "Sam100")?

After recruitment, the patient was introduced to the DNP with his new identity given by the nurse to further explain and complete the procedure related to consent form (see Appendix A) and Pre-Educational Survey Questionnaire (see Appendix B).

The Doctor of Nursing Practice (DNP) student investigator is not an employee of the clinic. Thus, as per the "safe harbor" protocol, the following steps were taken not to reveal the patient's phone number to the researcher, to protect the patient's identity.

The nurse called the participants from the clinic to initiate the weekly educational phone call, on the previously agreed date and time, provided by the participants. Once the participant is

on the line, then the researcher was called into the room to speak with the participant utilizing the Educational Intervention Flowchart. During the phone calls, the caller ID was covered to safeguard the phone number of the participants. The nurse and DNP student repeated this call process on the participants' selected date and time for six weeks. The phone calls lasted anywhere from 15 to 30 minutes.

During follow-up phone calls, any critical findings of the participant were communicated by the DNP student to the health care team nurse for proper follow-ups. Additionally, the DNP investigator monitored INR laboratory blood levels. Biweekly INR levels were drawn on participants with sub-therapeutic INR values following the clinic protocol. Participants' INR values were provided by the nurse to the DNP student to be saved in a password protected "Data Collection Worksheet" Excel file on her password-protected personal computer.

The DNP student-led the weekly huddle with patient team care members as follow up after the educational phone calls had been made to ensure continuity of care of selected participants. During the huddle, participant anonymity was maintained by using the participant's pseudo name only.

The data collection worksheet was stored in the DNP student's password-protected personal computer and is accessed by the DNP student only. At the end of six weeks, with the last follow up phone call, the participant was asked to provide self-assessment on the Post-Educational Survey Questionnaire and was thanked for their time and participation.

The patients' health care team nurse selected patients whose EHR had INR values less than 2.0 or higher than 3.0 within one week prior to project implementation. When these selected patients came for blood work, the lab would notify the nurse. The DNP student then presented the project plan to the patient in person, and if the patient agreed to participate, he/she was asked

to complete the Pre-Educational Survey Questionnaire and sign the consent form. The patient was given an assigned pseudo name for the de-identification and security of patient data. Consent forms with the patient's pseudo name were scanned into the EHR and can only be accessed by the patient's health care team members. The pseudo name was provided to the DNP student for use during weekly follow-up phone calls. The final selection included fifteen participants with consent to participate in the project.

The INR values of the patients are one of the main measurable variables of this project tracked for patients who were in the sub-therapeutic range. Per clinic protocol, biweekly labs were drawn on patients whose INR values are in the sub-therapeutic range, till they get three consecutive INR levels within the therapeutic range. Selected patients would have three biweekly INR blood draws in the next six weeks of project implementation.

The selected information was transferred by the nurse to the DNP student via email as a limited data set in a password protected Excel spreadsheet format, then the data from the Excel spreadsheet was added to the data collection worksheet, saved on a personal computer. Access to this file was protected by a password, ensuring the safety of patient' data. The Excel spreadsheet provided the DNP student with only those patients' data who have consented to the project. During phone calls, patients identified themselves with a previously assigned pseudo name. The Pre-Educational Survey Questionnaire was created to provide insightful information about dosing errors, whether patient informed their provider about their scheduled procedures or surgery, whether they maintain the diet without changing the intake of vitamin K, their current knowledge about factors affecting INR levels, signs of bleeding or clot formation, risk with subtherapeutic levels of INR, motivational factors, perceived vulnerability, and personal barriers.

The survey also determined the level of educational support needed to motivate the patient to improve compliance with the regimen and to avoid the possible ADEs with better management.

Data gathered in the Pre-Educational Survey Questionnaire was used to prepare the Educational Intervention Flowchart for individualized follow-up phone calls rather than a "one size fits all" approach. Patients were provided with two phone call schedule choices to choose from, Monday or Tuesday. Patients were called weekly on their selected choices (date and time) for the six weeks. The phone calls lasted anywhere from 15 to 30 minutes. Regular screening through weekly phone calls kept patients motivated to stay on track and be compliant with medication regimens. Inquiring about diet changes, weight change, new medications, upcoming procedures, new illnesses or diagnosis, recent hospitalizations or recent travels can give the team insight during the huddle, to determine if any changes in the dosage or change in the frequency of blood work are needed to keep the INR values in the therapeutic range. Weekly phone calls also helped the team to recognize, intervene, and implement individualized care plans for patients and prevent regression and fluctuation in INR levels. The DNP student alerted the team of any critical follow-ups or referrals to a dietician or pharmacist. At the end of six weeks, on the last follow up phone call, the Post-Educational Survey Questionnaire was completed.

All team members have agreed to contribute to the project voluntarily. The clinic manager was consulted regarding the protection of patient privacy and have health insurance portability and accountability act (HIPPA) form signed before starting the project. Patients' personal information and analyzed data will remain anonymous and protected through the implementation of the "Safe Harbor" method of de-identification of medical records which will provide a safeguard to the identification of participating patients from people outside the health care team (Arwood & Paniker 2017; USDHHS, 2019).

Outcome Assessment

At the end of six weeks, the pre- and post-interventional INR values were compared to see if weekly educational follow-up phone calls showed an improvement in keeping the INR values within the therapeutic range, thus reducing the episodes of any ADEs related to OAC management like the formation of blood clots or bleeding and ER visits. INR values of before and after the implementation of the Educational Intervention Flowchart were compared using a paired *t*-test with the significance set at $p < 0.05$.

Comparison of individual scores given by the patient for each question in the Pre- and Post-Educational Survey Questionnaires were done to identify changes in the score to highlight any improvement or regression in patient awareness to self-management, barriers, education, and confidence in warfarin management and better relationship with their health care team members.

During week six, patients completed the post-educational survey questionnaire. Patients were informed that this is the last phone call related to the project and were thanked for their time and participation.

Evaluation and Sustainability Plan

The goal of this quality improvement project is to increase patients' awareness regarding risk factors and barriers to self-management of OAC therapy, through educational weekly follow-up phone calls using the Educational Intervention Flowchart. The aim is for follow-up phone calls to reduce OAC related ADEs and rehospitalization by addressing noncompliance, dosing errors, and risk factors in a timely fashion.

This quality improvement project can contribute to long-term outcomes beyond the period of the project, based on the success of this project. Once the program has proven to be effective in reducing the INR fluctuations, increasing patients' confidence in self-management

and their barriers to avoid OAC related ADEs and rehospitalization, the clinic will have a choice to implement the finding of this DNP project as an integral part of future patient care along with cost-effective analysis. The sustainability of this project will be accomplished by repeating the project on a larger scale with funding from interested stakeholders, in coordination with the health care team members.

Strategies and recommendations from patient care team members can be further discussed to recognize any foreseen challenges, barriers, or boundaries with implementation on a larger scale before changing the present protocol. Cooperation with other patient care teams, patients, interdisciplinary team members, and, later, with health organizations and government bodies will allow this project to meet long-term goals of expanding not only in this clinic but to other clinics as well.

Timeline

The project officially received Institutional Review Board (IRB) approval on May 20, 2019, and was fully launched on June 3, 2019 (See Appendix G). The duration of the project, including recruitment, was seven-weeks. During this time, participants returned to the clinic for their INR bloodwork, and the DNP student made weekly follow-up phone calls to them after their appointment. During huddles, the clinic team members were briefed, and adjustments to each participant's regimen took place if needed. The final analysis of the impact of these services was evaluated at the end of the eight weeks.

Institutional Review Board

Project approval was approved through submissions from the Bradley University Committee on the Utilization of Human Subjects in Research (CUHSR) at Bradley University (see Appendix H).

Ethical issues. Informed was obtained from the patients to participate in the project voluntarily. Subjects were informed about the purpose, goals, risks, and benefits involved in the project. They were encouraged to ask questions to understand the scope of the project entirely. Full confidentiality was maintained throughout the project involving their identity, health data, and personal information. Patient care team members were the only ones accessing patient information from the EHR. Participation in the project was entirely voluntary and can be withdrawn at any time without any questions or repercussions. The selection of patients was fair and not discriminate against any social, racial, or ethnic group. No recruitment criteria applied for the selection of interprofessional team members for participation in the project. Personal beliefs, preferences, cultural values will be given the utmost respect during the project implementation. Subjects and health care team members involved in this project will be requested not to share information with other subjects or with anyone outside the research team and not to use personal identifiers at any time. The personal identifier was used as a pseudo name (e.g., Sam100) to de-identify the patient data and to honor the confidentiality of the patients. The Post-Educational Survey Questionnaires were done via phone calls using assigned pseudo names to maintain confidentiality. Any recommendation in the huddle by interprofessional team members was kept confidential.

The risks/constraints of this project are very minimal. The privacy of participants was protected by de-identifying their identity and any link between their personal information with collected data; this resulted in minimal risk of probability and magnitude of harm. The participant was never forced to answer any question that may cause any emotional setback. The DNP student asked questions in a very supportive manner and will respond to subjects' reactions appropriately. The data were restructured to have no direct identifier a.k.a. de-identification

process. The new code comprised of alphanumeric characters. The clinic nurse assigned a new identification code, after which data was passed on to the DNP student in an aggregate format. The Microsoft Excel spreadsheet was password protected. The procedures mentioned above provided a needed safeguard for the data (Arwood & Paniker 2017).

The “Safe Harbor” method of de-identification of medical records was utilized for safeguarding the identity of participating patients (USDHHS, 2019). The clinic is already being covered entity under the HIPAA privacy rule.

Chapter III: Organizational Assessment & Cost-Effectiveness Analysis

Organizational Assessment

The clinic is proactive in the search for innovative ideas/approaches to serve patients with quality, safe care, which includes reducing ADEs related to anticoagulation management with optimal satisfaction. This research is strongly supported by clinical management, clinicians, nurses, a dietician, and the DNP student's mentor to implement this project with enthusiasm. The research project abides by the mission of the clinic. The team members were provided with a brief description of the research and time commitment required to carry out this research project. The team sees this project as sustainable for future ongoing patient care with positive outcomes. Ongoing preventive education for patient safety and cost-effective care as the primary intervention is part of the clinic mission. Involving the patient's family and caretakers provided the added support patient needs for better self-management of warfarin therapy along with improved open communication with other providers involved in patient care.

Readiness for Change

The clinical management and patient care team members are ready and excited to support this research project in June 2019. The research outline and its objectives were discussed during the prescheduled lunch meeting with team members involved in the project. The project complemented the present preexisting follow-up protocol for warfarin management in the clinic. The staff is supportive and practice teamwork to enhance efficacy in patient care. The clinic administration provided the DNP student access to all team members, equipment, printers, a copier, and a conference room for meetings with clients. The project is a perfect opportunity to enhance ongoing support and care, along with preventive education for elderly warfarin patients. The patient care team members agreed that this project did improve the patient's self-management and provide timely follow-up care involving their family members and caregivers.

Barriers and Facilitators to Implementation

There are several barriers to consider, as the project is implemented. However, the anticipated barriers for patients can be their unwillingness to participate, or they may consider weekly phone calls too much intrusion into their privacy, frustration, mental fatigue, or embarrassment. Social and personal factors may hinder the patient's desire to participate, such as age, educational level, marital status, and socioeconomic status. Patients were adequately informed about the purpose, goals, risks, and benefits involved in the project, which helped eliminate some of the above barriers.

Each team member has been working for more than five years and, hence, the chances of any member leaving the team are very low. Standby members were also being recruited as part of project team selection in case any team members have to leave for unavoidable personal reasons. As such, the research project was completed within the intended time frame.

The Role of Interprofessional Collaboration

Interprofessional collaboration among team members had been active in assisting the DNP student in brainstorming steps for successful implementation of the project and continued throughout the project duration. The research mentor guided the DNP student in research and data analysis. Once the project team members were finalized, the roles and responsibilities of each team member were further established at the start of the project during the initial meeting. The patient team care nurse assisted in providing de-identified pre and post-interventional biweekly INR values to the DNP student for project use. The DNP student prepared an individualized Educational Interventional Flow Chart (Appendix D & E) based on the Pre-Educational Survey Questionnaire data to make biweekly phone calls. The DNP student alerted the team immediately of any critical follow-ups or referrals to a dietician or pharmacist, identified during the weekly phone calls for proper patient care. DNP student-led the huddle on

previously agreed meeting day of each week by the team members (doctor, nurse, and medical assistant) for the next six weeks as follow up after the educational phone calls have been made for continuity of care of selected patients. Provider, nurse, nutritionist, and pharmacist provided ongoing support with their expertise to manage patient's identified barriers by the DNP student during the weekly phone calls and huddles to manage OAC therapy and reduce ADEs. The medical assistant took responsibility for making sure that the resources (office supplies, meeting room, etc.) are available to complete the project tasks effectively and efficiently. The needed data and human resources, including office facilities, were available for the DNP student to use for the duration of the project.

Cost Factors

Budgetary needs. The EHR system available at the clinic was used to monitor the INR values of the selected patients. The cost of this project was minimal because supplies, including paper for the charts, binders, pens, copy paper, photocopies, and access to the EHR, were provided by the clinic. Also, the team members volunteered their services. The project was free for participants and was an extra service to them. The DNP student and clinic staff had access to Microsoft Word, Excel and PowerPoint software and phones to utilize at no additional cost to the clinic. The participating patient care team members working at the clinic have agreed to volunteer their time for the project. The individualized approaches and interviewing was done during regular office hours to avoid overtime staffing cost. The research team members' roles and responsibilities were discussed during an hour-long lunch break on a pre-assigned date within the office based on everyone's availability. Additional dates were reserved for team

members who could attend the meeting on the pre-assigned date. Research and reference materials were obtained from Bradley University's Cullom-Davis Library web portal.

Cost avoidance or savings associated with implementation. The project has built-in cost avoidance strategies such as volunteering time from the patient care team members and the use of available resources within the clinic for research, implementation, and analysis of the project. After an anticoagulant-associated ADR, most hospitalization expenditures average $33,189 per ADR for nursing care and $7,451 in pharmacy care (Piazza et al., 2011). Readmission for recurrent VTE was generally more costly than the initial index event admission (Fernandez, et al., 2015). The implementation of a quality improvement project would result in fewer doctor visits, reduce anticoagulant-associated medication errors, and reduce health care expenditures. The time saved can be used for the treatment of other patients, providing greater patient satisfaction. However, patients' satisfaction will outweigh the weekly cost of sustaining the project findings.

It takes approximately 30 minutes to make a phone call and go through all the questions in the educational intervention flowcharts, this will take five hours for ten participants to complete all the questions, and add one hour of a provider to evaluate the outcome weekly phone calls, if needed; this results in total six hours of clinic time per week.

The approximate cost of sustaining this project can be calculated using the following:

Average weekly cost ($) = (0.5 HR/participant) X (number of participants) X (hourly salary of a medical staff)

Chapter IV: Results

Analysis of Implementation Process

Upon receiving the approval of the Human Subjects in Research application from the university's Committee on the Use of Human Subjects in Research (CUSHR), the first step was to provide the clinic manager and health care team members with the approval letter via email. The DNP student called for a huddle to discuss the date(s) for recruiting participants and the timeline at the clinic.

The bloodwork for INR values is done on Mondays and Tuesdays at the clinic. As a participant came to the clinic for the bloodwork, the health care team nurse introduced selected participant (based on inclusion criteria), to the project. Once agreed, participants were provided pseudo names for project purposes and were introduced to the DNP student in the conference room, the details of the project, risks, and benefits, consent form, the pre-interventional questionnaire was explained. They were also advised that the questions may be somewhat personal to pinpoint their challenges regarding warfarin management. Through the next two weeks of the implementation process, four participants were lost due to unscheduled surgeries/travel and family emergencies. The final participant count was ten.

The Data Collection Worksheet and the Pre-Educational Survey were entered for each participant. Participants' pseudo names were placed in front of their electronic charts within the DNP student's password-protected computer. The nurse called the participants from the clinic to initiate the weekly educational phone call starting week one, on the previously agreed upon date and time provided by the participants. Once the participant was on the line, the researcher was called into the conference room to speak with the participant, utilizing the Educational Intervention Flowchart. During the phone calls, the caller ID was covered to safeguard the phone

number of the participants. The nurse and DNP student repeated this call process for each participant for the next six weeks. The average phone call lasted for 45 minutes. At the end of six weeks, with the last follow up phone call, Post Intervention Survey Questionnaire scores were collected and entered into the computer. Participants were thanked for their time and participation.

Data collection worksheet, pre- and post-questionnaires, and weekly educational phone call flowcharts were password protected and accessed by the DNP student only. Six months after data analysis is completed, all electronic data files will be deleted, as discussed with the participant during the consent process. Participants were advised that any publication or presentation of this information will use de-identified data only.

Analysis of Project Outcome Data

Quantitative data were collected from the data collection worksheet as well as qualitative data from pre- and post-educational survey questionnaires to be analyzed and to identify the impact of the educational follow-up phone calls utilizing the Educational Intervention Flowchart. The paired *t*-test was used to determine if the mean of the two conditions differed when the same groups of the individual tested twice (before and after educational follow-up phone calls were implemented).

The descriptive statistics of their INR score, pre- and post-interventional INR value from six weeks, the pre- and post- range of INR values, the standard deviation of INR value as appeared in table 1.

Table 1

Descriptive Statistics of INR Values for project participants.

Variable	Minimum INR value	Maximum INR value	Mean	SD
Pre-intervention INR value	1.57	3.63	2.36	0.75
Post-intervention INR value	2.33	3.80	2.81	0.45

Note. (N=10)

The statistical analysis shows that the post-interventional INR scores ranged from 2.33 to 3.8, with a mean of 2.81 (SD =0.45) is less than the pre-intervention INR scores ranged from 1.57 to 3.63 with the mean of 2,36 (SD = 0.75). This comparison helped determine that addressing the barriers during the educational phone calls resulted in improvement in patients' warfarin self-management efficacy.

Paired *t*-test. A paired t-test was used to examine the difference between pre and post-intervention INR values. The mean pre-intervention INR score was 2.36 (SD = 0.75), and the mean post-intervention INR score was 2.75 (SD = 0.45), indicating a mean difference of 0.38. The difference between the scores was statistically significant ($t(9)= 2.312$, $p < 0.05$). This analysis confirms that although the difference in score is statistically significant, it is relatively small. The intervention elicited an increase of 0.38 (95% CI, 0.00 to 0.76) in scores from pre- to post-intervention, which is a large effect size (d=9), see Table 2.

Table 2

Paired Samples T-Test comparing Pre-Intervention and Post-Intervention Values

				95% confidence interval of the difference				
Pair	Mean	SD	S.E. Mean	Lower	Upper	t	df	p
Pre-Intervention Values	2.36	0.75	0.24	0.76	0.008	2.31	9	0.046
Post-Intervention Values	2.75	0.45	0.14					
Paired Differences								
	Mean	SD	S.E. Mean	Lower	Upper	t	df	p
Pre - Post	0.38	0.53	0.166	0.76	0.008	2.31	9	0.046

(N =10)

There was a statistically significant difference between the mean as evidenced by the P-value of 0.046 (< 0.05); therefore, we can answer the PICOT question and conclude that the education interventional phone call can reduce the INR fluctuation in six weeks.

Analysis of Pre- and Post-Intervention Questionnaires

The participant's responses, poor, good, and excellent, were assigned numeric values of one (poor), two (good), and three (excellent), respectively, in Pre- and Post-Educational Survey Questionnaires (Figure 1), this figure present most significant changes in responses.

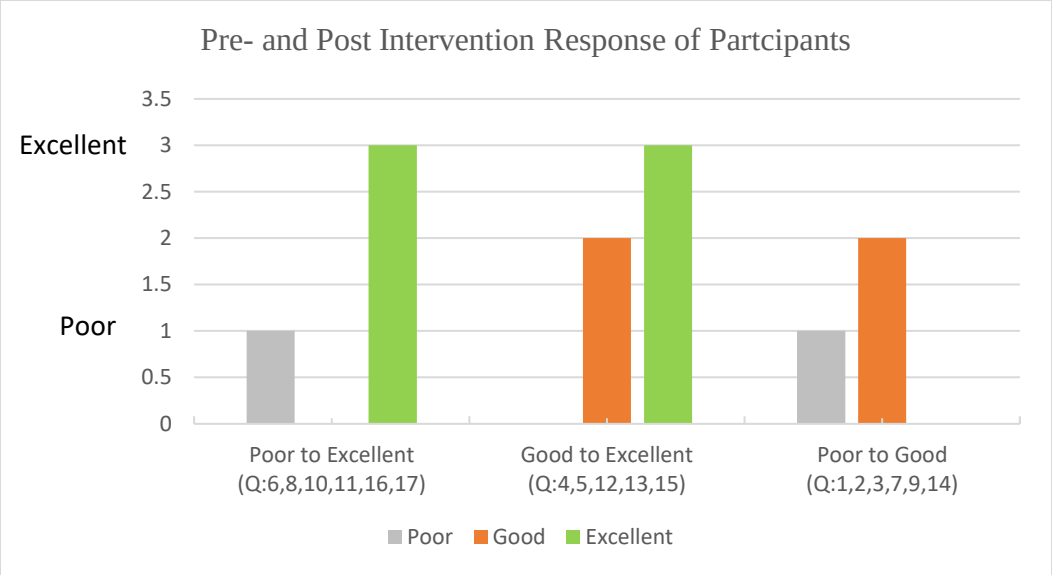

Figure 1. Pre- and Post-Educational Survey Questionnaire response of participants

Participants stated that the weekly phone calls have increased their knowledge from poor to excellent on how changes in the daily diet intake (Q 6), alcohol intake (Q 8), and interaction with other medications (Q 11) affect their INR values, and their current level of knowledge of "factors that can change your PT/INR values (Q 16), along with the importance of updating their providers about any ongoing or new diagnosis (Q 10).

The Q4 (What is your current level of knowledge about "common signs/symptoms of unusual bleeding"?) and Q5 (What is your current level of knowledge about "common signs/symptoms of possible blood clot formation"?) helped participants to understand common signs/symptoms of unusual bleeding and possible blood clot formation, thus changing their knowledge level from good to excellent (Q 4 & 5). Participants were more aware of the importance of informing all their providers about the blood thinners that they are currently on. They were more aware of the barriers and challenges that hindered their compliance with warfarin therapy (Q 15; What is your current level of knowledge about "your barriers to compliance with warfarin therapy"?).

The following table 3 and figure 2 shows that the majority of the post-interventional spread of INR values remains within the therapeutic INR range, and also reveals that, on average, the participants have improved their knowledge, compliance, and self-efficacy of warfarin therapy management, thus reducing fluctuation in their biweekly INR values.

Table 3

Pre- and Post-Interventional Spread of Average INR Values of Participants

Patient Pseudo Name	Pre-intervention Average INR value	Post-intervention Average INR value
Sam100	3.07	3.2
Peter150	1.87	2.4
Bob200	1.57	2.33
Jon300	1.77	2.53
Don400	3.47	2.63
Juan500	2.3	2.43
Rick600	1.9	2.63
Dan700	2.1	2.57
Sean800	1.97	2.97
Julia900	3.63	3.8

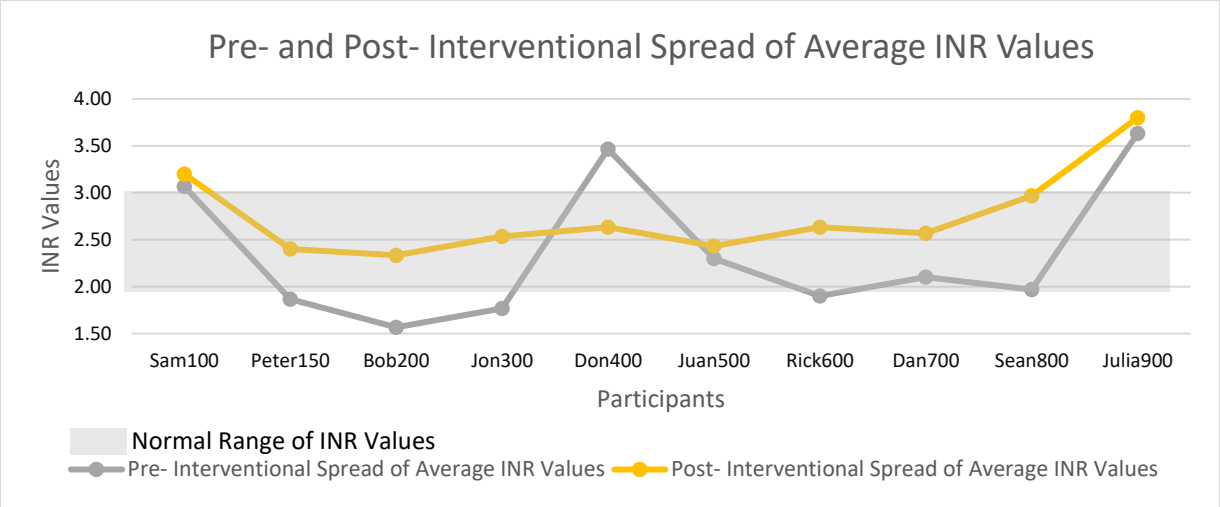

Figure 2. Pre- and Post-Interventional Spread of Average INR Values of Participants

The weekly phone calls have boosted the patients' morale and confidence in the understanding of their on-going warfarin treatment. The participants wanted to continue in this program; they said that this program has made their life more comfortable and were always excited and waited for the next phone call. Based on the participants' responses, it can be assumed that the chances of a severe complication due to warfarin can be minimized because they have a better understanding of *to do* and *not to do* things. Some participants who forgot to take medication due to factors like other doctor's visits, dining out, travel, or unforeseen sickness, now had (somewhat) a better understanding of keeping track of their medication regimen by writing down on the calendar or instructional sheets provided by their nurse. Patients have improved their knowledge of warfarin management through more education and awareness.

The post educational survey questionnaire showed four participant scores improved from poor to excellent on Q 6, 8, 10, 11, 16, and 17, four participant score improved from good to excellent Q4, 5, 12 13 and 15, and all participants improved from poor to good in Q1, 2, 3, 7, 9, and 14.

Chapter V: Discussion

The findings of this project suggest that through the weekly follow-up educational phone calls with participants who had subtherapeutic INR values, the DNP student was able to address barriers and motivate them to manage their warfarin therapy more effectively. Participants' average post-interventional INR range was closer to the therapeutic range (2 to 3), indicating less fluctuation in their INR values and less possibility of warfarin-related complications, which is resulted due to increasing awareness regarding barriers for effective OAC therapy through weekly follow-up phone calls.

An interprofessional team comprised of educators, health care professionals, pharmacists helped address patients' barriers related to OAC therapy and implement educational strategies for the betterment of anticoagulant management during the project. This approach provided closer monitoring and frequent follow-ups with anticoagulant patients, thus improving the well-being and safety of the individual and the community at large during and after the project is conducted.

The project implementation did not override existing health care policies within the clinic but instead complemented existing standards of care. The project magnifies the challenges with warfarin management and addresses them with a meaningful solution for the individual patient through individualized educational flow charts and addressing individual barriers. The motivational and educational approach did not cost anything extra because it complements existing policies of follow-up phone calls to warfarin patients after the labs were drawn as well as did not require extra personnel or training. However, only the frequency of phone calls was increased. These weekly educational phone calls can be considered mandatory protocols for warfarin patients to avoid related ADEs. The clinic can also color-code their current warfarin

patient charts so that when providers call the patient for different issues, they can also address warfarin compliance.

Limitations or Deviations from Project Plan

A significant deviation in this project was a delay in the approval of the IRB for three weeks, which was followed by a major holiday during which the clinic was closed. The holiday was a hurdle in planning because continuous six weeks of follow-up phone calls and bi-weekly lab monitoring was essential to see the effects of the interventional phone calls on the INR values.

An unexpected loss of five participants due to upcoming surgery and other unavoidable circumstances (travel and family emergencies), which resulted in the final sample size of ten participants. Limited participants, single outpatient clinic, limited project duration and involvement of only current warfarin patients were some of the limitations encountered that could have skewed the project outcome data. Other outliers in the outcome included participants who were noncompliant with dosage and one patient falling sick requiring the use of antibiotic therapy during the project in Figure 2 (Julia900, an INR of 3.8). Due to ongoing education regarding the factors that can affect the efficacy of warfarin management, patient Julia900 was able to recognize and inform the DNP student about her being on the antibiotic therapy due to sickness, was able to receive required intervention from the nurse to monitor the INR levels closely, thus avoiding the possible ADEs and hospitalization or the use of antidote. Another patient who started the Atkins diet acknowledges it as a risk factor and informed the DNP student during the follow-up phone call to confirm if this will require any further intervention as far as warfarin management. Both examples, exemplify the effect of education provided through the weekly phone call by recognizing the risk factors as well informing their providers for proper

follow-up as needed to avoid any ADEs related to warfarin usage. Participants forgot to take medication due to medical provider visits, dining out, travel, an increase in alcohol intake, or unforeseen sickness.

Providing education to patients through a phone call was challenging because of the distractions, and some participants were hard to communicate with due to hearing loss and unclear verbalization of sentences. Phone calls were also rewarding because none of the participants felt nagged or annoyed with personal questions; rather, they felt genuine concern from the DNP student and appreciated the weekly follow up phone calls. Even though participants were provided interventions like pill container, placing it on the dining table, marking the calendar, some still forgot to take the medications. The intervention that seemed to help most was the support system through family members in reminding them to take pills on time and keeping consistency in daily routine.

Implications

The importance of providing education to participants in a phone call setting is intuitive and exciting. The weekly phone calls demonstrated that weekly educational phone calls alone could impact a participants' future health outcomes was a challenge. Numerous studies on warfarin management in the literature guided the project to a successful conclusion. This project proves that ongoing education and support to improve patients' self-efficacy in warfarin management, as invaluable tools for health care providers to be implemented as part of ongoing care to reduce ADRs, as well as the average cost of warfarin patients, care on the health care system. Further research on the subject of implementing innovative ways as weekly phone calls can be used to effectively manage warfarin patients and reduce the frequent ER visits as well as the life span of patients.

The analysis of Pre- and Post-Intervention Questionnaires have revealed that, on average, the participants have improved their knowledge, compliance, and self-efficacy of warfarin therapy management, thus reducing fluctuation in their biweekly INR values.

Chapter VI: Conclusion

Value of the Project

Providing educational guidance for those with subtherapeutic INR values appears to have improved participant's outlook on their future health and wellbeing, as well as updated their current medication regimens through ongoing communication with providers. As future providers, NPs need to integrate ongoing reminders for their patients' medication management to avoid complications as well as polypharmacy, which are two significant issues with the elderly population due to their limitation of sense and physical and emotional dependency on others. Frequent checks, ongoing education, and reminders to our warfarin patients can prevent frequent hospitalizations and ER visits by avoiding adverse effects. Involving family and friends through education about the medication, community resources, as well as the needs of the patients can provide them with an ongoing support system when health care providers are not there for them. The duration of the project was only six weeks, which creates uncertainty about whether patients will continue to follow the educational guidance that was given to them through educational phone calls and maintain their self-efficacy, as well as avoid risk factors that can reduce the effectiveness of warfarin.

DNP Essentials

This evidence-based project allowed this DNP student to meet the DNP Essential outcomes I, II, III, VI, VII, and VIII. Educating patients about warfarin-related risk factors, follow-up care, and close communication with providers met the DNP Essential II "Organizational and systems leadership emphasizes promoting patient health outcomes and eliminates health care disparities"(AACN, 2006). The DNP essential III, clinical scholarship, and analytical methods for evidence-based practice ensure that up to date evidence-based research is applied during the evaluation of results. The DNP essential VI, inter-professional collaboration

for improving patient and population healthcare outcomes, prepares the DNP student for collaboration and leadership within an interdisciplinary health care team. The DNP essential VII, clinical prevention, and population health for improving the nation's health promote health maintenance and disease prevention (AACN, 2006).

Providing educational phone calls to volunteering participants, identifying their needs, and working in sync with other health care professionals and provide up-to-date education utilizes DNP essential II and VI. This evidence-based project promoted a reduction in the INR fluctuation through structured and consistent educational phone calls geared towards the need of the individual participant, which falls within the DNP III essentials description. The DNP essential VII was met by the weekly educational phone calls utilizing Educational Intervention Flowchart, which added to the nation's effort to reduce warfarin related ADRs.

Plan for Dissemination

The DNP student plans to disseminate this evidence-based project to the students, faculties, administration, and community members through an online video presentation hosted by Bradley University, Peoria, IL. Within one week of oral presentation, Bradley University Public Notice of Defense will be submitted to the graduate school. The final paper will be submitted through the Doctor of Nursing Practice Doctoral Project Repository after a successful presentation. A complete final status report of the project will be submitted to the CUHSR.

Attainment of Personal and Professional Goals

The project was put together to improve follow-up and knowledge of risk factors related to warfarin management in patients. The goal of this project was to highlight the role of educational support in improving patient self-efficacy, multidisciplinary care, and communication between patients and providers for better health outcomes. The project helped

the student's understanding of the importance and utilization of research-based evidence evaluation of current healthcare policies, including health care delivery with ongoing patient education and comprehensive care through the use of the multidisciplinary health care team. The DNP student was able to use the DNP essentials and learn proper implementation of a project. The level of guidance from the mentor and project advisor helped the DNP student to reach the level of confidence needed to develop during this research project, best clinical judgment, and understanding of diverse populations, human behavior, self-beliefs, and perception of susceptibility needed towards preserving the optimum level of functioning. Heath care team members, project team members, and clinic administration contributed significantly to success in reaching the goals of the project.

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Appendix A

Informed Consent

Project Title: Effects of follow up calls on patient compliance in Anticoagulant Management

An invitation to be part of a research project

I am inviting you to be a part of a research project for my Doctor of Nursing Practice (DNP) Family Nurse Practitioner degree program. To qualify, you must be a volunteer who is 65 years or older, prescribed the blood thinner warfarin, and have a recent lab that measures warfarin, not in the therapeutic range.

Key information regarding the project

This project is an evidence-based research project. The purpose of this project is to educate patients on anticoagulant therapy management. We want to find ways to keep INR levels within the therapeutic range, which, if left unmanaged, would significantly increase adverse drug events (ADEs) like bleeding or clot formation. Your participation will allow us to develop an efficient method that can help educate patients on how to better manage their warfarin therapy.

After signing the consent form, the DNP student will assist you in completing a pre-educational survey questionnaire. Completing the survey may take about 10 minutes. The nature of this survey is to assess your current knowledge about several topics affecting your warfarin therapy. You will be ranking your knowledge for each question as “poor, good, or excellent.”

Your DNP student will call you weekly for the next six weeks on the previously agreed date and time as per your comfort. Each phone call will last about 15 - 30 minutes. During the phone call, the DNP student will ask questions regarding warfarin therapy, educate you on your

current risk factors, assess any changes in your current health condition, and review your upcoming warfarin blood work appointments. She will also inform your health care team nurse if she identifies any need to follow-up on any critical information. The DNP student will be tracking your INR values to monitor changes in your INR values. During the last phone call, she will assist you in completing the post-educational survey questionnaire by again ranking your knowledge for each question about warfarin therapy as "poor, good or excellent."

There are no known risks for participating in this project. You may benefit by learning more about managing your warfarin therapy. You may stop your participation in the project at any time, and it will not interfere with your regular clinic appointments. You are not required to answer any question if you do not want to answer during the project. You will not be penalized or face any consequences if you decide not to participate in this project at any time from your participation is entirely voluntary. We will honor and respect your decision. However, your participation in this project will be highly regarded.

How will your information be protected?

You will be identified by this unique pseudo name during the phone calls and any communication taken between the DNP student and the patient from now till the end of the project. The nurse will call you from the clinic to initiate the weekly phone call, and then the researcher will come on the line to complete that education session.

Your health care team medical assistant will scan the signed consent form, place it in your record at the clinic, and will shred the hard copy. You will be given a copy of the consent form for a personal record. Only your health care team members will have access to your records. Your nurse will provide your INR values to the DNP student for research purposes

during the project duration. All the project related data will be saved digitally, password-protected, and accessed only by the DNP student investigator. After data analysis is completed, all electronic data files will be deleted. Any publication or presentation of this information will use anonymous data only.

Whom should I contact with questions about my rights as a research participant?

Questions about this project may be directed to Vanita Verma (the DNP student) (954) 304-7545 vverma@mail.bradley.edu or Dr. Judy Walloch, who is in charge of this project at (309) 677-2528**.** If you have general questions about being a research participant, you may contact the Committee on the Use of Human Subjects office at (309) 677-3877.

Your informed consent

You are voluntarily deciding to participate in this project. Your signature means that you have read and understood the information presented and have decided to participate. Your signature also means that the information on this consent form has been fully explained to you, and all your questions have been answered to your satisfaction. If you think of any additional questions during the project, you should contact the researcher(s).

I agree to participate in this project.

_____ _____

Signature of Participant Date

I authorize Associated Family Physicians of Boca Raton to release my INR laboratory results to Vanita Verma for purposes of this research. Understanding that this data will not be reused or disclosed to any other person or entity, except (a) as required by law, (b) for authorized

oversight of the research project, or (c) for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule.

_____ _____

Signature of Participant Date

Patient pseudo name: _____.

Office staff: keep this page. Scan it, place in the patient's electronic health record (EHR) along with a copy of the first three pages. Shred the signature page after scanning.

Appendix B

Pre-Educational Survey Questionnaire

Q	**Patient Pseudo Name: …….**	**Scale**		
		Poor	Good	Excellent
1	What is your current level of knowledge of “how warfarin works”?			
2	What is your current level of knowledge on “what to do when you have missed/taken an extra dose of warfarin”?			
3	What is your current level of knowledge about your “therapeutic INR range”?			
4	What is your current level of knowledge about “common signs/symptoms of unusual bleeding”?			
5	What is your current level of knowledge about “common signs/symptoms of possible blood clot formation”?			
6	What is your current level of knowledge about the “effects of change in diet on warfarin effectiveness”?			
7	What is your current level of knowledge of “how smoking changes the effectiveness of warfarin”?			
8	What is your current level of knowledge of “how alcohol affects warfarin effectiveness”?			
9	What is your current level of knowledge of “which lifestyle factors to consider when on warfarin therapy”?			
10	What is your current level of knowledge on “informing your doctor who manages warfarin about the new illness/diagnosis”?			
11	What is your current level of knowledge of “medications that can affect warfarin effectiveness”?			
12	What is your current level of knowledge of “the importance of telling your doctor about other blood			

	thinners you might be on like Plavix, aspirin, NSAIDs"?			
13	What is your current level of knowledge about "informing all your health care providers about your warfarin intake"?			
14	What is your current level of knowledge about "the importance of informing your doctor about upcoming dental or other invasive procedures"?			
15	What is your current level of knowledge about "your barriers to compliance with warfarin therapy"?			
16	What is your current level of knowledge of "factors that can change your PT/INR values"?			
17	What is your current level of knowledge on "how you can reduce the risk of bleeding"?			

(Adopted and modified from Garcia & Schwartz, 2011, Huber et al., 2008; Jaffer & Bragg, 2003; Kano et al., 2017; Thrombosis Canada, 2015; Witt et al., 2018).

Appendix C

March 1, 2019

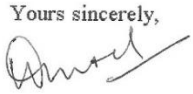
To Whom It May Concern

I, Dr. Dushyant Utamsingh, allow and accept the DNP student Ms. Vanita Verma for using IRB at Bradly University "CUHSR" for the project requirements.

Project title: "Effects of follow up calls on patient compliance in Anticoagulant Management"

Clinic site: Associated Family Physicians of Boca Raton, P.L. located at 9910 Sandalfoot Plaza Dr # 1, Boca Raton, FL 33428.

Yours sincerely,



Dr. Dushyant Utamsingh

Appendix D

Educational Intervention Flowchart

Patient Pseudo Name: ……

Educational Intervention Flowchart questions		wk #1	wk #2	wk #3	wk #4	wk #5	wk #6
What is warfarin?	Your liver makes the proteins that require vitamin K to clot the blood. Warfarin reduces your liver's ability to use vitamin K to make these blood clotting proteins, which makes it harder for your blood to clot. Warfarin does not make your blood thinner. Warfarin interferes with the body's ability to make a blood clot.						
What is your current dose of warfarin?	NO; Ask your doctor to write on the instruction sheet in bold. Different days can have different dosages, so make sure you know exactly how to take until you return for blood work. Based on the blood work, your warfarin dosage can change.						
Do you have enough supply of warfarin till the next renewal?	No; call your nurse/doctor						
When is your next blood work?	Mark on the calendar with red letters						

What does the therapeutic INR range mean?	(PT) Also, it measures how many seconds it takes for your blood to form a clot. It is measured in seconds. The only accurate way to report the PT results is in INR. Therapeutic range means that your warfarin levels in your blood do not pose any risk to your health (bleeding or clot formation).						
Do you take any other blood thinner (Aspirin/Plavix/NSAIDs)?	Yes; inform your nurse/doctor						
Have you missed or taken the extra dose within the last week?	Yes. Need to call your doctor. Tell them the size of the pill and date when it happened if you can recall. This information may be critical for your clinician to interpret the dosage based on the blood work appropriately. If it is close to 12 hours or less since you were supposed to have taken the dose, then go ahead and take it. If it is more than 12 hours, either wait until your next dose is due or follow the instructions of your clinician.						

	Sometimes your doctor might tell you to skip a dose or take an extra dose to adjust the warfarin level in your blood, but you should not attempt to adjust your dose on your own.						
Any unusual bleeding/bruising (gums/stool/urine)	Yes, call your provider. It is an early warning sign for the need for better management of warfarin. Unusual bruising means bruises that develop without a cause or bruises that tend to grow or expand. Signs of bleeding - nose bleeds, bleeding gums, pink or brown urine, red or black stools, coughing up blood, vomiting blood, or "coffee ground" colored material. Symptoms for serious bleeding include a severe headache, dizziness, fatigue, or weakness. You should contact your clinician immediately. With severe bleeding symptoms, you should						

	go to an emergency department.						
Any recent falls or trauma?	Yes; did you bleed or bruise; yes, call your provider						
Any new Rx medication added, stopped, or changed (NSAID, ABT, Herbal, and Amiodarone)?	Yes; inform your nurse/doctor immediately						
Any new over the counter medication/Herbal products added stopped or changed?	Yes; give details to your provider						
Drug interactions with warfarin.	Prescription medications, medications you can buy without a prescription, vitamins, dietary supplements, and herbal preparations can cause a dangerous change in the effect of warfarin-like increasing your risk of blood clot formation or bleeding; this can mean severe harm or even death. Keep your anticoagulation clinician up to date on any such product(s) you are taking. You should not start, stop, or change the dosage of any such product without the approval of your						

	anticoagulation clinician. Do NOT presume that other clinicians will notify your anticoagulation clinician of the change in medication or if the change is safe for you. You should immediately notify your anticoagulation clinician of the change.						
Do you currently take alcohol/ any changes in the amount?	Yes, how much? Inform your doctor of any change in the amount and frequency you drink. Alcohol affects your liver and irritates the lining of your intestine, which can cause internal bleeding. Abstinence is best. If you can not then limit your consumption to only 1 or 2 drinks a day						
Do you smoke? How much/any changes in the amount of intake?	Yes, how much? Inform your doctor of any change in the amount and frequency you smoke because smoking tends to increase how fast your body metabolizes warfarin.						
Other lifestyle factors/travel.	Yes; inform your doctor						

	Rough sports, roller-coaster rides, sharp objects, razors, outdoor gardening tools, a construction job. Be aware of your environment and practice precaution from injury/bleeding.						
Any recent infection or illness?	Yes, were you placed on any new medication; yes, then call your doctor to inform.						
Any dental, surgical or invasive procedure?	Yes, do you need to hold warfarin, yes then call your doctor to inform for transition management of warfarin?						
Any change in diet (vitamin K intake)?	Vitamin K helps to clot hospitalizations blood. You get vitamin K from green vegetables, vitamins, herbs, and certain oils. If your intake of vitamin K increases, warfarin dose needs to be increased to keep significant blood from clotting. If your intake of vitamin K is reduced, warfarin dose needs to be reduced to prevent bleeding. The level of vitamin K and warfarin to rise and fall in the blood						

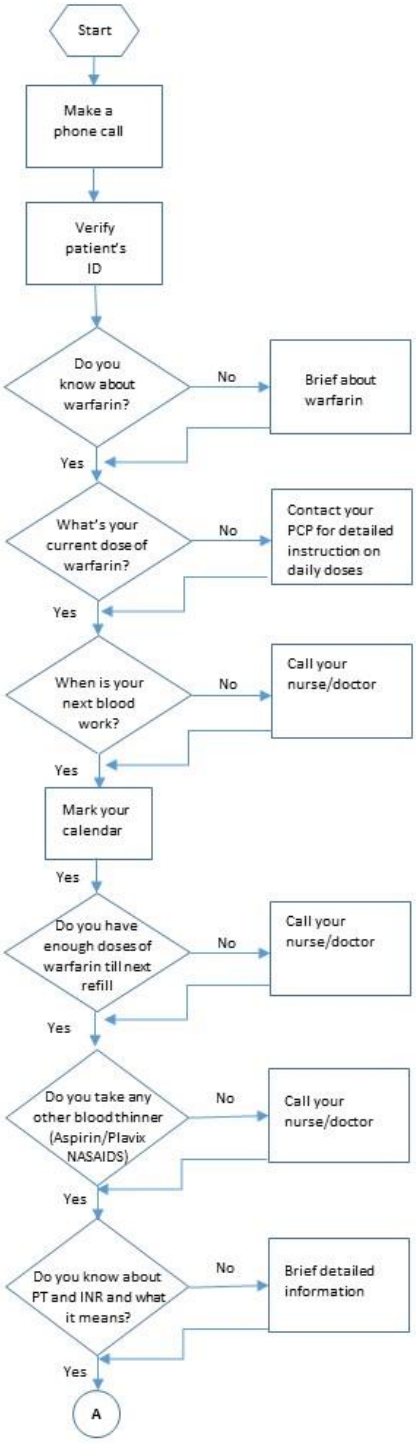
	takes several days, so the effect of each other is monitored every week rather than daily. It can take days to bring warfarin levels back in the therapeutic range. So, consistency is the key.						
Other things that can change your INR.	Diet, vitamins, food supplements, herbal preparations, other medications (either prescription or those bought "over the counter"), change in your level of exercise, getting sick, smoking, and consuming alcohol. A change in the INR may cause a substantial change in your risk of bleeding or blood clot formation. You must tell your doctor about any changes. Discuss in advance if you are planning: going on a trip, starting an exercise program, trying to stop smoking, going on a new diet, taking an herbal preparation, etc.						
How can you reduce the risk of bleeding/clotting?	In addition to keeping your clinician informed of changes that may alter your						

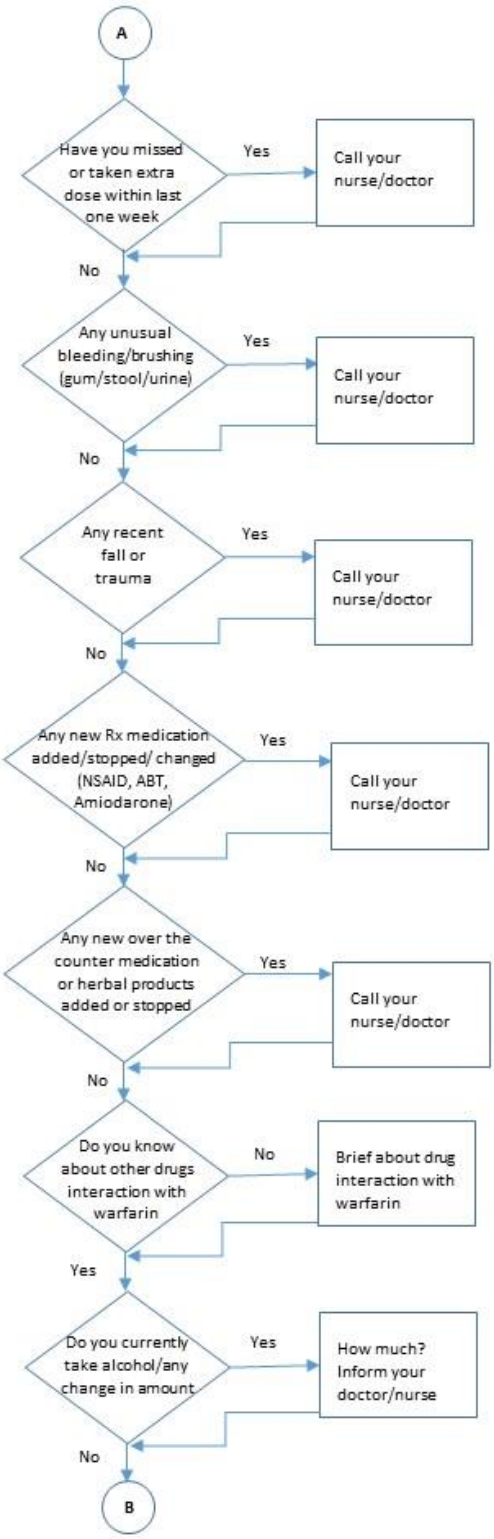
	response to warfarin, you can also reduce your risk of severe bleeding by monitoring yourself for signs and symptoms of bleeding like blood in urine or stool, tarry stool, or signs of severe headache, dizziness, fatigue or weakness						

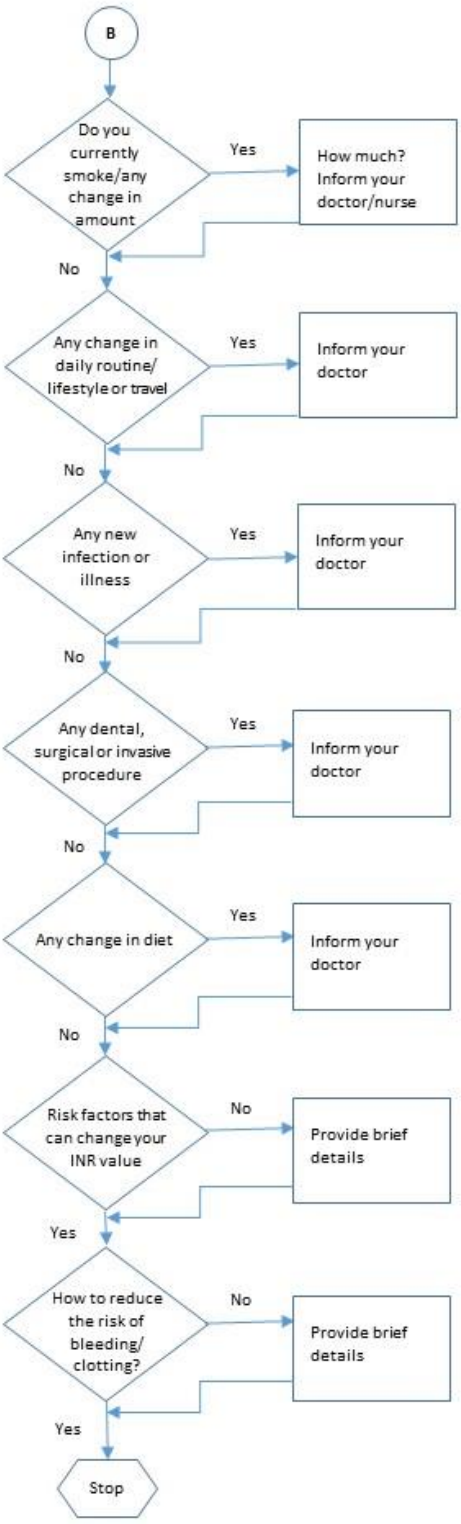
(Adopted and modified from Garcia & Schwartz, 2011, Huber et al., 2008; Jaffer & Bragg, 2003; Kano et al., 2017; Thrombosis Canada, 2015; Witt et al., 2018).

Appendix E

Educational Intervention Flowchart




A
Have you missed or taken extra dose within last one week
Yes
Call your nurse/doctor
No
Any unusual bleeding/brushing (gum/stool/urine)
Yes
Call your nurse/doctor
No
Any recent fall or trauma
Yes
Call your nurse/doctor
No
Any new Rx medication added/stopped/ changed (NSAID, ABT, Amiodarone)
Yes
Call your nurse/doctor
No
Any new over the counter medication or herbal products added or stopped
Yes
Call your nurse/doctor
No
Do you know about other drugs interaction with warfarin
No
Brief about drug interaction with warfarin
Yes
Do you currently take alcohol/any change in amount
Yes
How much? Inform your doctor/nurse
No
B


B
Do you currently smoke/any change in amount
Yes
How much? Inform your doctor/nurse
No
Any change in daily routine/ lifestyle or travel
Yes
Inform your doctor
No
Any new infection or illness
Yes
Inform your doctor
No
Any dental, surgical or invasive procedure
Yes
Inform your doctor
No
Any change in diet
Yes
Inform your doctor
No
Risk factors that can change your INR value
No
Provide brief details
Yes
How to reduce the risk of bleeding/ clotting?
No
Provide brief details
Yes
Stop

Appendix F

Post Educational Survey Questionnaire

Patient Pseudo Name: ……..	**Scale**		
	Poor	Good	Excellent
What is your current level of knowledge of “how warfarin works” post educational follow-up phone calls?			
What is your current level of knowledge on “what to do when you have missed/taken an extra dose of warfarin” post educational follow-up phone calls?			
What is your current level of knowledge about your “therapeutic INR range” post educational follow-up phone calls?			
What is your current level of knowledge about “common signs/symptoms of unusual bleeding” post educational follow-up phone calls?			
What is your current level of knowledge about “common signs/symptoms of possible blood clot formation” post educational follow-up phone calls?			
What is your current level of knowledge about the “effects of change in diet on warfarin effectiveness” post educational follow-up phone calls?			
What is your current level of knowledge of “how smoking changes the effectiveness of warfarin” post educational follow-up phone calls?			
What is your current level of knowledge of “how alcohol affects warfarin effectiveness” post educational follow-up phone calls?			
What is your current level of knowledge of “which lifestyle factors to consider when on warfarin therapy” post educational follow-up phone calls?			
What is your current level of knowledge on “informing your doctor who manages warfarin about the new illness/diagnosis” post educational follow-up phone calls?			

What is your current level of knowledge of “medications that can affect warfarin effectiveness” post educational follow-up phone calls?			
What is your current level of knowledge of “the importance of telling your doctor about other blood thinners you might be on like Plavix, aspirin, NSAIDs” post educational follow-up phone calls?			
What is your current level of knowledge about “informing all your health care providers about your warfarin intake” post educational follow-up phone calls?			
What is your current level of knowledge about “the importance of informing your doctor about upcoming dental or other invasive procedures” post educational follow-up phone calls?			
What is your current level of knowledge about “your barriers to compliance with warfarin therapy” post educational follow-up phone calls?			
What is your current level of knowledge of “factors that can change your PT/INR values” post educational follow-up phone calls?			
What is your current level of knowledge on “how you can reduce the risk of bleeding” post educational follow-up phone calls?			

(Adopted and modified from Garcia & Schwartz, 2011, Huber et al., 2008; Jaffer & Bragg, 2003; Kano et al., 2017; Thrombosis Canada, 2015; Witt et al., 2018; Ruffalo, 2018).

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Appendix G

Project Timeline

Date	**Activities**
June 3 and 4	Consent form sign up
June 12 and 14	1st Weekly phone call
June 17 and 18	1st INR
June 19 and 21	2nd Weekly phone call
June 26 and 28	3rd Weekly phone call
July 1 and 2	2nd INR
July 3 and 5	4th Weekly phone call
July 10 and 12	5th Weekly phone call
July 15 and 16	3rd INR
July 17 and 19	6th Weekly phone call

Appendix H

CUHSR Letter

April 1, 2019

Committee on the Use of Human Subjects in Research
Bradley University
1501 W Bradley Avenue
Peoria, IL 61625

Dear CUHSR Committee,

As a requirement for the Doctor of Nursing Practice Degree at Bradley University, I am submitting the following quality improvement project for CUHSR approval: In elderly patients on warfarin, does weekly educational phone call addressing barriers to oral anticoagulant therapy adherence, compared to one-time initial educational session, would help bring the International Normalized Ratio (INR) values within therapeutic range in six weeks of project implementation.

Concerns over keeping the INR value within the therapeutic range has been growing among health care professionals and patients.

Through an interprofessional collaboration with health care team members and DNP student, this quality improvement project seeks to establish an enhanced role for healthcare professionals. The pilot project will enable healthcare professionals to develop awareness and preparedness to provide needed support and identifying patients who are having a challenging time in managing their INR values.

Thank you and the committee for your time and consideration of our request.

We look forward to your response.

Very Respectfully,

Vanita Verma, BSN RN

Appendix I

IRB Approval

BRADLEY University

DATE: 20 May 2019

TO: Vanita Verma, Judy Walloch
FROM: Bradley University Committee on the Use of Human Subjects in Research

STUDY TITLE: Effects of follow-up calls and patient compliance an anticoagulant management
CUHSR #: #30-10
SUBMISSION TYPE: Initial Review

ACTION: Approved
APPROVAL DATE: 20 May 2019
REVIEW TYPE: Expedited

Thank you for the opportunity to review the above referenced proposal. The Bradley University Committee on the Use of Human Subject in Research has reviewed your study and approval has been granted pursuant to 45 CFR 46.110(a) [expeditable under Category 5 Research involving materials (data, documents, records, or specimens) that have been collected for any reason or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis) and Category 7 Research on group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs, or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies].

This research meets the regulatory requirements for approval as specified in 45 CFR 45. 111. Specifically, the risks to subjects are minimized and reasonable in relation to anticipated benefits to subjects and the importance of the knowledge that may reasonable be expected to result, and that written informed consent and HIPAA authorization will be sought from each prospective subject or the subjects legally authorized representative. The informed consent document meets the regulatory requirements as outlined in 45 CFR 46.116. Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the consent document. Additionally, the authorization for the use/disclosure of PHI within the consent form documentation meets the regulatory requirements.

All vita and ethics certificate are on file.

Please Note: Research must be conducted according to the proposal that was approved. Any revisions to the protocol must first be approved by the Committee on the Use of Human Subjects in Research (CUHSR) prior to implementation and that substantial changes may result in the need for further review. Please submit a Request for Minor Modification of a Current Protocol found on our website at https://www.bradley.edu/academic/cio/osp/studies/cuhsr/forms/ should a need for a change arise.

Committee on the Use of Human Subjects in Research – 100 Kauffman
1501 W Bradley Ave.
Peoria, IL 61625