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Establishing a Coumadin Clinic in a Rural Family Medicine Practice

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ESTABLISHING A COUMADIN CLINIC IN A RURAL FAMILY MEDICINE PRACTICE

by

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Abstract

Background. Coumadin is the most commonly prescribed oral anticoagulant worldwide and is safe and effective in the prevention and treatment of stroke and venous thromboembolism (Stoudenmire, DeRemer, & Elewa, 2014). Coumadin is dangerous when poorly managed due to high risk for bleeding and mortality. It is best managed using evidenced-based models of care such as point-of-care (POC) International Normalized Ratio (INR) testing (Garcia et al., 2008; Harrison, Shaw, & Harrison, 2015; Rossiter, Soor, Telner, Aliarzadeh, & Lake, 2013). *Purpose*. Establish a Coumadin Clinic in a rural family medicine practice with POC INR testing to improve anticoagulant management. *Methods*. A quality improvement project was conducted to implement all components of the Coumadin Clinic, to evaluate the time within therapeutic range (TTR) of INR for all patients on Coumadin therapy, and to evaluate patient and staff satisfaction. Components of the Coumadin Clinic were monitored for accomplishment using a checklist at each INR visit. Each patient's pre-intervention TTR was compared to the post-intervention TTR and patient and staff satisfaction were evaluated by questionnaire. *Results*. Results indicate that 50% of patients had improved TTR following implementation of POC INR testing, staff completed each component of a complete Coumadin Clinic visit 84% of the time, and 100% of staff and 87.6% of patients were satisfied with anticoagulant management at the POC. *Conclusions*. A Coumadin Clinic using POC INR testing is an evidence-based model of care that is effective in Coumadin management.

Keywords: Coumadin, Coumadin Clinic, point-of-care, International Normalized Ratio, time within therapeutic range

Millions of people around the world are on anticoagulant therapy (Garcia et al., 2008). Despite the prevalent use and significant contribution of anticoagulant therapy in the prevention and treatment of primary and secondary venous thromboembolism, the prevention of thromboembolism in patients with atrial fibrillation or prosthetic heart valves, and in the prevention of stroke, it is associated with high risk for bleeding and mortality (Garcia et al., 2008; Smith et al., 2008). Consequently, anticoagulants were named the leading cause of death from adverse effects of a medication in 2003 and 2004 (Garcia et al., 2008). The safety considerations of anticoagulation therapy led to its addition in the National Patient Safety Goals of 2008 (Garcia et al., 2008). The stated goal is to "reduce the likelihood of patient harm associated with the use of anticoagulant therapy" (National Patient Safety Goals, 2017). In order to reduce poor patient outcomes, sources suggest anticoagulation management requires a systematic approach to ensure safety and effectiveness of therapy (Gupta, Kogut, & Thompson, 2015). Therefore, to achieve improved patient outcomes, anticoagulants are best managed using evidenced-based models of care including anticoagulation clinics or point-of-care (POC) International Normalized Ratio (INR) testing (Harrison, Shaw, & Harrison, 2015; Rossiter Soor, Telner, Aliarzadeh, & Lake, 2013;).

Statement of the Problem

Coumadin, also known as warfarin or Jantoven, is the most commonly prescribed anticoagulant throughout the world and has been the mainstay of oral anticoagulant therapy for more than 60 years (Stoudenmire, DeRemer, Elewa, 2014). It is well established that Coumadin is safe and effective in the prevention and treatment of thromboembolism. However, it is potentially dangerous if poorly managed due to complex dosing, a narrow therapeutic index, need for frequent INR monitoring, many food and drug interactions, variability of dose response

among patients, and inconsistent patient compliance (Gupta et al., 2015; Smith et al., 2012). Poor patient compliance with anticoagulant therapy and inefficient Coumadin management may lead to serious side effects such as gastrointestinal bleeding or hemorrhagic stroke (Rossiter et al., 2013). Therefore, it is imperative to regularly monitor INR levels of patients on Coumadin therapy, to ensure bleeding time is within therapeutic range and to reduce the incidence of potentially deadly side effects (Rossiter et al., 2013).

Background and Significance

Vitamin K antagonists are oral anticoagulants used for the primary and secondary prevention of thromboembolic events and are effectively used by millions of patients throughout the world (Ageno et al., 2012). Coumadin is the most widely used vitamin K antagonist, although its narrow therapeutic index, food and drug interactions, and variability in dose response present challenges in maintaining optimal dosing (Smith et al., 2012). Despite the significant evidence to support the use of Coumadin in the prevention of thromboembolic events, clinicians are often reluctant to prescribe it due to the uncertainty of patient compliance with treatment and follow-up, dietary implications, and fear of hemorrhagic events (Ageno et al., 2012; Nasser, Mphil, Mullan, & Bajorek, 2012). Non-compliance is often prevalent among low-income populations related to lack of financial assistance, low social support, lack of transportation, and unpredictable housing situations (Smith et al., 2012). The factors contributing to the variability in dose response among patients include age, therapy duration, the target INR range, and the quality of dosing management (Smith et al., 2012). Among these factors, the most important is the target INR range, which indicates the strength of the anticoagulation therapy (Smith et al., 2012). The challenges of maintaining optimal anticoagulation often lead to the underuse of Coumadin and results in suboptimal therapy (Smith et al., 2012). To prevent

complications and optimize anticoagulant therapy, continuous laboratory monitoring is necessary to minimize the risk of bleeding and maximize the antithrombotic effect (Baker, 2013).

Health System Assessment

The health system of interest is a family medicine practice located in Wilson County of South Central Texas. Wilson County is a rural community southeast of the larger metropolis San Antonio, Texas. As of July 1, 2016, the population of Wilson County was estimated at 48,480, a 13% increase since April 2010 (United States Census Bureau (USCB), 2017). Wilson County consists of six small towns, the largest of which is Floresville with approximately 7,495 residents, followed by Poth with 2,213, Stockdale with 1,596, and La Vernia with 1,409 (Texas Association of Counties, 2015). The population is predominantly White, non-Hispanic at 57.8%, followed by Hispanic or Latino at 39.0%, and Black or African American at 1.8% (USCB, 2017). Less than 1% of the population is American Indian or Alaskan Native, Asian, or Native Hawaiian or other Pacific Islander (USCB, 2017). The majority of the population was under the age of 18 at 24.4% and 15.7% was 65 years and older (USCB, 2017). Gender is equally distributed at 49.9% female (USCB, 2017). The median household income from 2011 to 2015 was $68,100, surprisingly higher than the national average of $53,889 (USCB, 2017). Despite the above average household income, the percentage of persons living in poverty was 9.4% and 3.8% are unemployed (County Health Rankings and Roadmaps (CHRR), 2017; USCB, 2017). Lastly, between the years of 2011 to 2015, 85.1% of persons over the age of 25 had a high school diploma, comparable to the national average of 86.7% (USCB, 2017). However, only 19.5% of the population have a Bachelor's degree or higher, 10% less than the national average (USCB, 2017).

According to the U.S. Department of Health and Human Services (2017), Wilson County is a health professional shortage area for primary care and is a medically underserved area. In 2012, the total health care and social assistance revenue equaled $69,544, compared to Bexar County's total revenue of more than 12 million that same year (USCB, 2017). Barriers to healthcare access in Wilson County include socioeconomic demographics such as poverty, low health insurance rates, few providers to patients, and long distances to outside healthcare (CHRR, 2017). Among the population, 18% did not have health insurance, 16% of which were under the age of 65 (CHRR, 2017; USCB, 2017). The ratio of patients to primary care providers in Wilson County is 2,580:1, significantly higher than the Texas average of 1,670:1 (CHRR, 2017). The lack of providers in this region is further complicated by the distance to outside healthcare resources. Wilson County only has one county hospital, located in the county seat of Floresville, and two urgent care facilities. County hospital services are limited to a 10-bed emergency department, surgical, laboratory, and radiology services, in-patient medical and surgical care, a three-bed step-down intensive care unit, and outpatient rehabilitation and home health services (Connally Memorial Medical Center, 2017). The nearest outside hospitals are approximately 30 to 40 miles from Wilson County and approximately 50 miles to the South Texas Medical Center of San Antonio (Google Maps, 2017). Consequently, the lack of providers, distance to outside healthcare services, and poor insurance rates places a heavy burden upon the primary care practices to provide affordable care with reasonable service hours.

A clinical microsystem assessment was performed to examine the purpose, patients, professionals, patterns, and processes of the institution (Walker & Polancich, 2015). The family medicine practice of interest is a certified rural health clinic (RHC) established in the 1990s. The RHC is part of a mesosystem, consisting of three clinics in Wilson County, located in Stockdale,

Floresville, and La Vernia. The microsystem assessment was performed at the Stockdale location, referred to as RHC 1. The Floresville clinic is noted as RHC 2 and the La Vernia clinic is noted as RHC 3. RHC 1 is conveniently located in the downtown area of Stockdale. It is easy to find and has ample parking spaces. Both RHC 2 and RHC 3 are located in the most traveled parts of Floresville and La Vernia. RHC 2 sits in a shopping center housing the local grocery store and RHC 3 sits among several small businesses.

The RHC system is owned and operated by the staff family medicine physician. The physician is the sole proprietor, medical director, and administrator of the clinics. The staff of the RHCs consists of the family medicine physician, four family nurse practitioners (FNPs), one registered nurse, six licensed vocational nurses (LVNs), three receptionists, and one office manager. Each RHC operates daily with one receptionist, one or two LVNs, and one or two providers. The office manager works primarily at RHC 1 and the registered nurse oversees the LVNs, while mainly working from RHC 2.

The purpose of the RHCs is to provide primary health care to the medically underserved population of Wilson County. The RHCs seek to address the needs of indigent patients by providing primary care to patients with family income less than 200% of the poverty level, on a reduced or no-fee basis, and to provide at least 15% of patient care within the indigent care program. The mission of the clinics is to improve access to primary care for Medicare, Medicaid, and indigent patients within the community. According to an FNP in the group, the mesosystem provides the only designated rural health clinics in Wilson County. No patients seeking services offered by the RHCs are turned away and uninsured patients are offered reasonable cash prices for clinic visits and laboratory services.

The RHCs provide primary care medical services to patients of all ages. The services provided include diagnosis, treatment, and follow-up of acute, episodic, and chronic illnesses commonly found in family medicine, on-site diagnosis and treatment of minor trauma such as burns or sprains, routine well-male and well-woman exams, new employment and Department of Transportation physicals, weight loss management, basic laboratory services, referrals to specialists, care of patients at three nursing homes within Wilson County, and occasional home visits for homebound patients. Pediatric services include well-child exams through the Texas Health Steps for Children program, also known as Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) checkups, sports physicals, and vaccines through the Texas Vaccines for Children program. EPSDT checkups are a child health component of Medicaid for children under the age of 21 to receive appropriate preventative, developmental, dental, mental health, and specialty services (Medicaid.gov, n.d.). The Texas Department of State Health Services offers the Texas Vaccines for Children program, which provides low-cost immunizations to eligible children from birth to 18 years of age (Texas Health and Human Services, 2017). Medical services excluded are prenatal and severe trauma care. Patients are referred to nearby hospital facilities for major trauma, radiology, and advanced laboratory services.

Each RHC houses an on-site laboratory and locked medication room. The nursing staff, including the RN and LVNs, operates the on-site laboratories. According to the Centers for Disease Control (2017), facilities that perform tests on human subjects for screening and monitoring of specific medical conditions must have a Clinical Laboratory Improvement Amendment (CLIA) waiver. CLIA waived tests include simple tests with low risk for incorrect results, such as dipstick urinalyses or fecal occult blood tests (Centers for Disease Control, 2017). The RHC system has a current CLIA certificate of waiver and commonly processes

urinalyses, rapid strep tests, blood glucose, urine HCG, and occult blood tests. All other laboratory tests are collected by venipuncture and packaged for processing at a reference lab. Each clinic maintains medications for clinic administration, including sample oral medications, and no separate fee is charged for this benefit. Frequent injectable medications administered include vaccinations, antibiotics, steroids, non-steroidal anti-inflammatories, and vitamin B-12. Vaccinations are only offered through the Texas Vaccines for Children program and cannot be administered to children or adults with private insurance or Medicare, as these insurances do not provide immunization reimbursement for clinics with rural health certification. Therefore, parents and patients are encouraged to keep immunizations up-to-date and asked to bring current vaccination records to clinic visits.

Walk-ins are accepted and seen on a work-in basis depending on medical necessity. The RHCs do not provide after-hours coverage; however, an answering service takes calls when the clinics are closed. Patients calling after hours may leave the on-call provider a voicemail and are instructed to call 911 for emergencies. Patients requiring appointments for Department of Transportation physicals, Medicaid check-ups, well-woman exams, or EPSDT check-ups must be scheduled with an FNP and not the physician. Patients requiring an initial Medicare visit, major suturing or biopsies, evaluation of attention deficit disorder or attention deficit hyperactivity disorder, or evaluation of an injury under a contracted nursing home's Worker's Compensation must be scheduled with the physician. Otherwise, patients may see the provider of personal choice.

The RHCs accept private pay, Medicare, Medicaid, Title V, and some private insurance as forms of payment. The private insurances accepted include Community First, Superior, TriCare, Aetna, United Healthcare, Humana, Humana Military, and Molina Healthcare. Per RHC

standards of operation, the clinics receive a fixed rate of $60.40 for each Medicaid visit. As a courtesy, the RHC offers a $20 discount to all non-insured individuals at each clinic visit. Patients with Title V are not responsible for the charge of any services rendered. Worker's Compensation is only accepted if the patient is an employee of the contracted nursing homes. Lastly, due to the clinic's RHC designation, the clinics receive a set rate of $75 per patient visit, no matter how long the provider spends with the patient, the interventions performed, or how the patient is insured.

All current medical records are maintained in the electronic medical record (EMR). Patient documents from outside sources, including lab results, hospital discharge summaries, imaging, progress notes, immunization records, triplicates, or referrals are scanned into the EMR. The clinic also maintains paper charts for 7 years past the last date of service or until the patient's 21st birthday. The EMR is not capable of running demographic diagnostics of the patient population. Therefore, the office manager obtained demographic data from the outside billing company for this report. The top 10 reasons for clinic visits from January 1, 2016 through December 31, 2016 included primary hypertension, allergic rhinitis, routine child health exams, attention deficit hyperactivity disorder, type II diabetes mellitus, dementia without behavioral disturbance, acute sinusitis, urinary tract infection, hypercholesterolemia, and acute upper respiratory infection. Within this time frame, a total of 26,086 patient visits occurred, 6,318 at RHC 1, 7,642 at RHC 2, 8,547 at RHC 3, and 3,579 nursing home visits. The billing company was also unable to generate demographic data by gender and race or ethnicity, however, as previously noted, the population within this region is predominantly Non-Hispanic White and Hispanic or Latino and equally distributed by gender.

Needs Assessment

After baseline clinical data were collected, the Doctor of Nursing Practice (DNP) student conducted a needs assessment. Organizational needs assessments identify gaps within current processes and performance compared to the organization's desired results. Analyzing gaps within the healthcare setting leads to the identification of gaps in patient care and potential solutions to address those gaps. Ultimately, the needs assessment leads to choosing a course of action and a goal for achieving the desired results (Watkins, Meiers, & Vissser, 2012). The DNP student interviewed the office manager and the DNP student's mentor, a FNP, to identify gaps or needs within the RHC practice. Suggestions received included improving social services access, establishing a Coumadin Clinic, or establishing a protocol for screening of atherosclerotic cardiovascular disease risk.

Upon following the daily work processes of the project mentor and LVNs, the DNP student identified several gaps in care. First of all, older adults were not routinely being screened for fall risk or other geriatric syndromes such as depression, elder abuse, or incontinence. The office manager stated the RHC has received "fall-outs" from Medicare because the providers were not routinely screening for elder fall risk. The clinic has not suffered monetarily for the fall-outs, however, the elder population may suffer serious fall-related injuries from this missed assessment objective. Next, upon completion of clinic visits, patients were not receiving a copy of the treatment plan, known as the visit summary. Lastly, patients were failing to receive the clinic's preventative health screening tool known as We Care About Your Health. The form screens women over the age of 40 for the date of last Papanicolaou smear, mammogram, and post-menopausal dexa scan and screens men over the age of 50 for date of last prostate check. The tool also screens men and women for the date of last colonoscopy, tetanus, pneumonia, or

shingles vaccinations, eye exam, hepatitis C screening, peripheral arterial disease screening if diabetic, and abdominal aorta ultrasound if history of smoking. The form should be used at each annual visit, although the nursing staff reports never remembering to use the screening tool.

After discussing the gaps in care with the project mentor, the FNP agreed all problems were important to the RHC's practice and wanted to include the physician and other staff members in the process of project identification. A simple questionnaire was created with the following project ideas: implementing a geriatric health risk screening tool, developing a protocol for screening atherosclerotic cardiovascular disease risk, establishing regular use of the We Care About Your Health screening tool, providing patients with a visit summary at each visit, or establishing a Coumadin Clinic. The questionnaire was faxed to RHC 2 and 3 and included a letter introducing the DNP student and the student's goal to implement a sustainable, quality improvement project. The questionnaire requested the staff to identify the project ideas that were very important, somewhat important, or not important and offered a section for suggestions. Five staff members responded to the questionnaire, three of whom identified all project ideas as very important. Of the other two staff members, one responded that all topics were very important except for establishing regular use of the We Care About Your Health screening tool and the other responded that the geriatric and atherosclerotic cardiovascular disease risk assessments were most important and all other topics were somewhat important. Project topic suggestions revealed a common theme for the need of more social service access within the community. The DNP student reviewed the results of the questionnaire with the project mentor and determined the top choices for the project were the development of a Coumadin Clinic or implementation of a geriatric fall-risk screening tool. The top project ideas

were presented to the providers at a staff meeting and the providers agreed upon the Coumadin Clinic as the focus for the DNP project.

The DNP student performed a chart review of all patients on Coumadin therapy within the RHC's system from January 1, 2017 through October 4, 2017. The chart review revealed 27 patients on Coumadin therapy, nine of which regularly attended clinic in Stockdale, eight in Floresville, and 10 in La Vernia. The population was predominantly White, non-Hispanic (88.9%), followed by Hispanic/Latino (11.1%). No other race or ethnicity was represented and 100% of the patients were English-speaking. Among this group, 51.8% were female and 66.7% were 65 years of age and older. The youngest patient was 50 years old and the oldest was 95; the median age was 69. Among this population, the reasons for anticoagulant therapy included atrial fibrillation (44.4%), history of thromboembolism, either deep vein or unspecified (26%), history of pulmonary embolism (14.8%), history of cardiovascular accident (18.5%), and the presence of a prosthetic heart valve (14.8%). Common co-morbidities among this group included hyperlipidemia (66.7%), hypertension (70.4%), diabetes mellitus (44.4%), cancer (11.1%), obesity (18.5%), gastroesophageal reflux disease (33.3%), chronic obstructive pulmonary disease (22.2%), seizures (11.1%), hypothyroidism (14.8%), anemia (11.1%), chronic kidney disease (18.5%), and depression (14.8%). The majority of the patients were unemployed or retired (85.1%) and receiving benefits from Medicaid or Medicare Part A (59.3%). Of the remaining patients, only one was private pay and 10 patients (37%) had private insurance including Blue Cross Blue Shield, Humana, Meritain Health, and UnitedHealth group.

The DNP student shadowed nurses and the project mentor to observe the processes for managing patients on Coumadin therapy. This group of patients was seen on a monthly basis or more frequently if INR levels were outside of therapeutic range. Therapeutic range of INR is 2.0

to 3.0 for patients with atrial fibrillation or history of thromboembolism or 2.5 to 3.5 for patients with prosthetic heart valves or pacemakers (Ageno et al., 2012). During INR clinic visits, the nurses assessed the patient's Coumadin dose, if any doses were missed and when, any diet or medication changes, antibiotic therapy and why, and any incidence of bleeding or bruising and documented the findings within the EMR. The providers then assessed the patients and the nurses obtained the blood draw by venipuncture that was processed by an outside laboratory. In some cases, patients came to the clinic for just a nurse visit and blood draw. However, patients that were Medicare recipients were required to also be seen by the provider at every visit.

Once the INR results were received from the outside laboratory, the results were scanned into the EMR. The provider electronically signed the lab report and documented desired changes to the Coumadin dosing and when to return for follow-up. The nurse then called the patient with the lab results, dosing changes, when to follow-up, and provided any pertinent patient education, such as dietary changes. If the nurse was unable to reach the patient by phone, a voicemail was left and an email was sent to the patient through the institution's online patient portal. Messages sent through the patient portal included lab results, plan of care instructions, and a request to call the clinic when the message was received.

The RHCs tracked the up-coming appointments for patients on Coumadin therapy by utilizing a paper calendar tracking system. Each RHC clinic had a designated Coumadin calendar, maintained by the nursing staff, with due dates for each patient's upcoming appointment. The receptionists assisted with tracking the appointments by placing the patients in "recall" in the EMR at the end of each INR visit. The nurse then received a "flag" or notification of when to contact the patient to return for a follow-up INR visit.

The chart review and observation of clinic processes identified problems with Coumadin management including difficulty reporting INR results to patients, missed appointments, incorrect dosing, and lack of patient understanding of anticoagulant therapy. From January 1, 2017 to October 4, 2017, the nurses made approximately 225 phone calls that ended without contact with patients and required leaving a message. Many of these phone calls were not returned by the patient or responsible party. Therefore, the patient did not receive the lab results within a timely manner. There were eight occurrences in which patients were no-shows to scheduled appointments and overdue for an INR check. In addition, the nurses documented various incidences in which patients were not taking Coumadin correctly due to misunderstanding of dosing instructions, missing doses, and failure to report antibiotic therapy, ultimately leading to INR levels out of therapeutic range. A study by Smith et al. (2012) discussed similar findings in an internal medicine clinic managed by a group of medical residents. The residents expressed frustration with managing Coumadin dosing via phone communication, complicating and delaying patient management, with an average of four days passing before lab results and dosing changes were given to the patient. Ultimately, the poor Coumadin management at this institution, led to the establishment of POC INR testing (Smith et al., 2012).

Organization's Readiness for Change

The DNP student evaluated the organization's readiness for change by measuring the staff's willingness or apprehension in establishing a Coumadin clinic. Research supports the need to determine an organization's readiness for change for the successful implementation and maintenance of a new process, policy, or project in healthcare settings (Shea, Jacobs, Esserman, Bruce, & Weiner, 2014). Shea et al. (2014) suggests implementing any type of organizational

change is likely to fail unless sufficient readiness is established. Sufficient readiness among staff members includes mental and behavioral preparation for successful initiation and cooperation with changes. Otherwise, the staff will view the change as undesirable and avoid or even resist the change (Shea et al., 2014). The Organizational Readiness for Change psychometric assessment was given to all staff members of the RHC organization to assess the overall perception of implementing the Coumadin Clinic (Appendix A). The Organizational Readiness for Change uses a five-point ordinal scale ranging from "disagree" to "agree," with a lowest possible score of 12 and highest possible score of 60 (Shea et al., 2014). Of 16 staff members, 13 participated in the assessment. The mean score was 56.4. The average score among the office staff, including the manager, receptionists, and referral coordinator, was 60, the average score of the nurses was 57.2, and the average score of the providers was 53.4. Overall, the scores were high, indicating the staff was anticipating the change and ready for implementation of the Coumadin Clinic. Several of the nurses and providers verbalized excitement for the project and believed it would improve the care processes for patients on Coumadin therapy.

Project Identification

Purpose

The purpose of the project was to establish a Coumadin Clinic in a rural family medicine practice with POC INR testing.

Objectives

The objectives of the project were to:

1. Implement anticoagulation management during set Coumadin Clinic appointments and achieve 95% adherence.

2. Maintain or improve time within therapeutic range (TTR) of INR levels to an overall of 95% for the entire patient population.

Anticipated Outcomes

By May 1, 2018, the anticipated outcomes of the project were to achieve:

- 95% of Coumadin patients will receive full anticoagulant management at appointments.
- 95% of Coumadin patients will maintain or improve TTR.
- 100% of patients will receive individualized dosing instructions at appointment.
- 100% of the staff will be educated on 1) the importance of anticoagulation management at the POC and 2) the roles and responsibilities within the Coumadin Clinic.

Summary and Strength of the Evidence

The Anticoagulation Forum, an evidenced-based practice organization committed to optimizing anticoagulation therapy, published consensus guidelines necessary for successful establishment and maintenance of high-quality anticoagulation clinics (Garcia et al., 2008; Rose et al., 2012). The nine domains of the consensus guidelines are qualifications of personnel, supervision, care management and coordination, documentation, patient education, patient selection and assessment, laboratory monitoring, initiation and stabilization of Coumadin therapy, and maintenance of therapy (Garcia et al., 2008).

According to the Anticoagulation Forum, licensed health professionals including physicians, advanced practice nurses, or pharmacists must manage anticoagulation clinics. Ancillary staff, such as medical assistants or nurses, may assist with technical aspects of anticoagulation management including appointment scheduling and laboratory testing, but should not provide direct patient assessment or therapy management (Garcia et al., 2008; Rose et al., 2012). The Anticoagulation Forum suggests healthcare providers should receive additional

training or competency in Coumadin management related to the risks and complexity of anticoagulation therapy. Training and competencies may be obtained through formal training programs, work experience, or self-study (Garcia et al., 2008). Anticoagulation management services operated by pharmacists or nurses should have a collaborative practice agreement with a responsible or referring healthcare provider (Garcia et al., 2008; Rose et al., 2012).

Anticoagulation management services require written policies and procedures for the optimal delivery of anticoagulation therapy and should be approved by the medical director (Garcia et al., 2008; Rose et al., 2012). Policies and procedures are necessary for quality assurance, to reduce variability in healthcare delivery, and to facilitate the healthcare team's communication of anticoagulation issues. Otherwise, poor communication and variability in management result in suboptimal anticoagulant management and poor patient outcomes (Garcia et al., 2008). According to the Anticoagulation Forum, policies and procedures should include routine dosing, follow-up considerations, common or controversial issues that may occur during therapy, and be available for review at all times (Garcia et al., 2008).

Anticoagulation management services should use efficient tracking and scheduling systems so no patients on anticoagulant therapy are lost to follow-up (Garcia et al., 2008). The use of efficient, computerized documentation systems assists with tracking and scheduling and ensures clinically relevant data is easily accessible (Garcia et al., 2008; Rose et al., 2012). Consideration should be given to adapting computerized charting systems to meet the needs of Anticoagulation management services and facilitate quality assessment (Garcia et al., 2008). Documentation of anticoagulation management should include the percent of TTR, incidences of bleeding or thromboembolic events, and any Coumadin-related deaths (Garcia et al., 2008).

Patient and caregiver education is essential to the delivery of optimal anticoagulation management (Garcia et al., 2008). Sources suggest well-informed patients on anticoagulant therapy have improved understanding of the treatment and are more likely to actively participate and adhere to the plan of care, increasing patient safety and stability of the anticoagulant effect (Garcia et al., 2008). Anticoagulation education is most effective given through face-to-face discussion. Written or audiovisual materials may be used as reinforcement to verbal education (Garcia et al., 2008).

Anticoagulation therapy presents significant, life-threatening risks to patients, such as bleeding and stroke. A systematic approach to anticoagulation management is necessary to reduce these associated risks (Garcia et al., 2008). Rose et al. (2012) suggests anticoagulation management services improve patient outcomes and reduce associated adverse events. For example, a group of medical residents, at a teaching hospital, implemented POC INR testing at an outpatient clinic. The patients on Coumadin therapy at this clinic were poorly managed due to time constraints of the residents and frequent inability to communicate laboratory results to patients. Prior to the implementation of the anticoagulation clinic, the patient's INR levels were within therapeutic range only 25% of the time. After implementation of POC INR testing, the patient's INR levels within therapeutic range increased to 50% (Smith et al., 2012).

Methods

Project Intervention

The project setting was a RHC system in Wilson County, Texas, southeast of San Antonio. The RHC system is a family medicine practice, consisting of three clinics located in Stockdale, Floresville, and La Vernia. The project population included all male and female patients on Coumadin therapy. Patients were not excluded based on age, diagnoses, or reason for

Coumadin therapy. Therefore, patients with history of pulmonary embolism, venous thromboembolism, atrial fibrillation, stroke, and mechanical heart valves were all included in the project sample. The project sample only excluded patients initiated on Coumadin during the project intervention, as there were no data to provide comparison for improvement or failure to improve TTR of INR levels. Components of establishing the Coumadin Clinic included implementation of 1) a new process checklist, the Coumadin Clinic Checklist, 2) POC INR testing, 3) patient-centered dose management, and 4) staff training and education.

Coumadin Clinic checklist. The Coumadin Clinic Checklist is a paper tool designed to assist the staff with implementing the new processes of the Coumadin Clinic and to assist the DNP student with data collection (Appendix B). The checklist is divided into sections based on the care process and various responsibilities of staff and providers throughout each Coumadin Clinic appointment. The first part of the checklist included a section for the receptionist to document the date of the appointment and the patient's medical record number (MRN) at the top of the form. The MRN number was used to longitudinally track each patient's progress towards achieving improvement or maintenance of TTR of INR levels. The next section included checkbox reminders for the nurses to document the previously established Coumadin risk assessment in the EMR, to obtain the INR level at the POC, and to document the INR level on the checklist. At the end of this section, a checkbox reminder was included to prompt the nurses to document the INR result in the EMR, a crucial step in successful establishment of anticoagulation clinics (Garcia et al., 2008).

Next, the providers documented on the checklist if the patient's INR was below goal, at goal, or above goal, also known as subtherapeutic, therapeutic, and supratherapeutic. This is an important step in the process of establishing sound anticoagulation clinic guidelines. Long-

standing guidelines of Coumadin therapy suggest the target INR range is 2.0 to 3.0. During review of Coumadin patients' EMR notes, it was noted that the providers often documented a patient was at goal with INR values as low as 1.7. Therefore, the new process required the providers to indicate the therapeutic goal for each patient. The providers were also prompted to circle "yes" or "no," if the INR result required verification with a reference lab and to check the box indicating a Coumadin dosing sheet was completed and given to the patient. At the end of the clinic visit, the checklist prompted the receptionist to schedule the patient's next INR appointment and to document the appointment date and time on the patient's dosing sheet. All Coumadin Clinic Checklists were kept in a folder at the project mentor's desk for the DNP student's data collection.

In the event a patient was started on Coumadin therapy, a box at the bottom of the checklist was provided to remind the providers to assess for bleeding and stroke risk prior to anticoagulant therapy initiation, to implement the established RHC's Coumadin Contract (an agreement between patient and provider to maintain monthly INR testing), and to provide educational materials. The data from this section was not tracked for purposes of the project, rather it served as a tool for the providers to maintain patient safety and improve patient knowledge upon initiation of Coumadin therapy.

POC INR testing. The process for POC INR testing included the following steps: 1) The nursing staff obtained POC INR levels by fingerstick and analyzed the results with the Coag-Sense device (See the Coumadin Clinic resources section for discussion of the device). 2) The INR value was recorded in the EMR and on the Coumadin Clinic Checklist. 3) The provider reviewed the INR result, determined any necessary dosing changes, and provided appropriate patient education on dosing, diet, and medication safety. If the INR result was equal to or greater

than 5.0, the result was verified with a reference lab. Research suggests INR values obtained with a POC device that are equal to or greater than 5.0 should be verified by a reference lab for patient safety (Johnson, 2017). 4) If lab verification was required, the nurse followed standard operating procedures for obtaining a blood specimen by venipuncture and sent the specimen to the reference lab.

Dose management. A patient dose management sheet (PDMS) was used to facilitate the patient's understanding and adherence to Coumadin therapy (Appendix C). The form is titled: "My Current Coumadin Dose." Patients received a dosing sheet at each visit, even if the provider did not change the Coumadin dose. The PDMS includes a space at the top of the sheet to note the date the form was completed. Noting the date at the top of the PDMS is important for the patient to be able to verify the most current Coumadin dose. Patients on Coumadin therapy are seen on a routine monthly basis but may be seen weekly to monitor INR levels that are out of range. Therefore, to avoid patient confusion of the most current dosing sheet, it is necessary to document the date on the PDMS. Also, the form allows for individualized dosing instructions for each day of the week. Coumadin is frequently not dosed the same each day, therefore, the dosing instructions help the patient to know how much Coumadin to take for each day of the week. As a patient reminder, at the bottom of the page is a fill-in space for the staff to note the date of the next scheduled appointment.

The style of the dosing sheet was created with the reader in mind. Most of the clinic's patients on Coumadin therapy are older than 65. According to the Centers for Disease Control (2016), older adults may suffer from visual challenges inhibiting the ability to read. It is recommended that written materials have a font size of at least 16 with limited text, large spacing between lines, and printed with black lettering on white paper that is not glossy, to prevent any

glare (Centers for Disease Control, 2016). The "My Current Coumadin Dose" sheet is typed in size 26 font with ample spacing between lines and is printed on matte, white paper that does not have a glossy finish.

Coumadin Clinic resources. The POC INR device purchased for the Coumadin Clinic program was the Coag-Sense. Due to the expense of the equipment and ongoing cost of test strips, the RHC system purchased two Coag-Sense machines to share among the three clinics. One device remained at RHC 2 and the second device was moved weekly between RHC 1 and RHC 3. As a result, the Coumadin Clinic was available daily at RHC 2, Mondays through Wednesdays at RHC 3, and Thursdays and Fridays at RHC 1. Clinic stakeholders determined the mobile Coag-Sense would move between RHC 3 and RHC 1 through a process referred to as "out-going." "Out-going" is an established system used to move materials between the clinics, such as office supplies and paperwork. Designated staff members were responsible for this daily task and responsible for moving the Coag-Sense device to the appropriate clinic the day before the scheduled Coumadin Clinic days. Prior to project implementation, the use of the out-going process was an efficient system for this group.

In February 2018, at project rollout, staff began scheduling INR visits on the designated Coumadin Clinic days. Discussion with the DNP student's mentor revealed INR visits prior to project implementation were usually 10 minutes long, unless the nurse had difficulty obtaining a blood specimen by venipuncture. With the addition of dosing changes and patient education occurring at the POC, the in-office process was anticipated to take longer than 10 minutes. The clinic stakeholders were not concerned that the necessary time adjustment would disrupt patient flow, so the scheduling template was not changed. Optimistically, the implementation of all-inclusive anticoagulant management at the POC was expected to improve patient adherence to

Coumadin therapy and decrease the frequency and workload of follow-up calls for the nursing staff.

Update of documentation template in EMR. With the implementation of POC INR testing, the documentation system for charting Coumadin management was updated in the EMR. The RHC system used a Coumadin risk assessment documentation template in the EMR at each INR visit. The template included a set of questions for the nurses to ask the patients, such as current dose, any missed doses since last seen in office and when, any diet or medication changes, antibiotic therapy and why, and any bleeding or bruising. The office manager added a section to record the POC INR results within the Coumadin risk assessment template.

Staff training and education. A staff-training luncheon was organized for all of the nurses and providers to learn staff roles and responsibilities within the Coumadin Clinic. The DNP student provided instructions on the purpose and use of the Coumadin Clinic Checklist and the PDMS and discussed the importance of involvement by all staff members, for optimal achievement of project objectives and anticipated outcomes. Instructional videos on the Coag-Sense device by Coagusense, Inc. were shown during the luncheon for introduction to POC INR testing. A medical device representative provided formal training of the Coag-Sense to the nursing staff at each RHC location at three separate events. Upon completion of the training, each nurse completed a competency checklist to provide evidence of proficient use of the Coag-Sense device. The competency checklists are maintained in the staff training files.

Organizational Barriers and Facilitators

The nurses were excited for the opportunity to implement POC INR testing. The nurses were frustrated with calling patients to discuss INR results and never receiving a response from the patient, along with the increasing workload of more calls and more documentation. The

nurses were also concerned the patients did not understand the Coumadin dosing instructions that were given over the phone. Therefore, the nursing staff was highly motivated to begin POC INR testing to decrease workload and improve patient understanding and adherence to therapy. It was anticipated that patient satisfaction would improve with the use of fingersticks for INR testing instead of venipunctures and receiving all Coumadin management at the POC.

Barriers to project implementation included new staff members, issues with Coumadin Clinic scheduling, and cost of the equipment. At the beginning of the project, the RHC system had a new receptionist in training. The new receptionist was learning clinic processes and might not have recognized the importance of the project. There was a possibility that patients might be unhappy with the scheduled days for the Coumadin Clinic and the limitations of availability of the Coag-Sense device at RHC 1 and RHC 3. Patients might experience difficulties in scheduling appointments due to the limits placed on the available clinic days. In addition, the staff might have difficulty remembering to move the Coag-Sense with out-going materials, causing patients to receive a venipuncture for INR results rather than the intended POC INR test.

Clinic stakeholders were concerned with the associated costs of POC INR testing. Due to RHC regulations, the medical practice cannot receive reimbursement for the POC INR test strips for Medicaid or Medicare recipients. Patients with private insurance or private pay will pay the standard RHC lab fee. Prior to project implementation, 59% of the Coumadin patients were Medicaid or Medicare recipients, 37% had private insurance, and 3.7% were private pay. Therefore, the RHC will not be reimbursed for the majority of the test strips and may not be able to afford POC testing as a continued service. Despite the cost, the office manager hoped POC INR testing would improve care for the Coumadin therapy patients and agreed to support a pilot of the program for at least 6 months.

Ethical Considerations

Potential ethical considerations for this project included patient privacy and risks associated with blood exposure. The Coumadin Clinic Checklist includes the patient's MRN number used to track and analyze program outcomes, particularly INR levels. The MRN is a unique number given to each patient upon entrance into the practice and is documented in the EMR. The MRN is not connected to any personal identification information, such as date of birth or social security number, increasing patient confidentiality and privacy. No other potential patient identifiers were used for the project. All checklists were kept at the project mentor's desk within a private office. Data compilation was done within the private office, away from patient traffic. The checklists were shredded once data was inputted into a secure, password protected dataset.

The nurses performing the POC INR testing were at risk for bloodborne pathogen exposure. However, POC INR testing presented no greater risk than other laboratory procedures already conducted within the practice. To avoid bloodborne pathogen exposure, the nurses maintained universal precautions. The nurses were trained on proper POC testing via fingerstick and showed evidence of competency by performing return demonstration during the formal training with the medical device representative.

Evaluation Plan

The project objectives were evaluated using the Coumadin Clinic Checklist and by comparing pre- and post-intervention TTR of INR levels. The first objective was to implement full anticoagulation management at each appointment. Full anticoagulation management included POC INR testing, the PDMS, and patient education. If the staff failed to utilize the checklist at each appointment, the information was extracted from the EMR. The second

objective of improving TTR of INR levels was evaluated by calculating the patient's TTR after implementation of POC INR testing and comparing this value to the pre-intervention TTR. The goal was to improve or maintain TTR with the implementation of POC INR testing. TTR is expressed as a fraction of the INR levels within therapeutic range, also referred to as the percent of visits in range (Smith et al., 2012). It is calculated by dividing the number of INR values within therapeutic range by the total number of INR values (Smith et al., 2012). According to Smith et al. (2012), there are various methods to calculate TTR, but this method is most commonly used.

Results

The project intervention was implemented and evaluated from January 29, 2018 through April 30, 2018. The timeline provided 3 months of anticoagulation management at the POC and evaluation of TTR of INR levels. During this time, 23 patients were seen for Coumadin management. Among this group, four patients were new to Coumadin therapy and were excluded from data collection. Another two patients were only able to attend one Coumadin Clinic appointment. One of these patients suffered a stroke and was changed from Coumadin to Eliquis therapy, an oral anticoagulant that does not require monitoring of monthly INR levels. The other patient was unable to follow-up on the days the Coumadin Clinic was offered, and received further bloodwork monitoring at an outside laboratory. These two patients were also excluded from data collection. The final sample consisted of 16 patients, all seen at least twice during the project intervention, with a total of 63 Coumadin Clinic visits. The sample was predominantly female (56.3%), of White, non-Hispanic descent (87.5%), over the age of 65 (87.8%), married (56.3%), a recipient of Medicare (62.5%), and 100% English-speaking (Table 1). The population had multiple indications for Coumadin therapy including atrial fibrillation (50%), current or

history of deep vein thromboembolism or pulmonary embolism (31.2%), history of cerebrovascular accident (12.5%), presence of pacemaker (18.6%), and presence of prosthetic heart valve (18.6%).

Twenty-five (40%) of the Coumadin Clinic appointments occurred at RHC 3, followed by 21 visits at RHC 1 (33.3%), and 17 visits at RHC 2 (27%). The FNPs provided the majority of anticoagulation management with a total of 54 INR visits (87.7%).

Each of the components of full anticoagulant management at the POC was evaluated for completion using the Coumadin Clinic Checklist (Figure 1). Of the 63 INR visits, 59 checklists (93.6%) were completed. The data for the remaining four INR visits were extracted from the EMR by the DNP student. During the Coumadin Clinic visits, 100% of the patients received POC INR testing and 100% of the POC INR interventions were documented in the EMR, including the crucial step of documenting the INR level. The PDMS was filled out by the provider and given to the patient at 52 visits (83%), and a follow-up INR appointment was scheduled prior to clinic visit completion at 27 visits (43%).

TTR was evaluated by comparing each patient's pre-intervention TTR to post-intervention TTR (Figure 2). Of the 16 patients, 50% maintained or improved the TTR. Six of these patients (75%) reached therapeutic INR levels 100% of the time.

Table 1

Characteristics of Study Population (*N* = 16)

Characteristic	*n*	%
Gender		
Male	7	43.7
Female	9	56.3
Age		
18-65	2	12.5
65+	14	87.5
Ethnicity		
White/Caucasian	14	87.5
Hispanic/Latino	2	12.5
Primary language		
English	16	100.0
Marital status		
Single	5	31.2
Married	9	56.3
Not specified	2	12.5
Insurance		
Medicare	10	62.5
Medicaid	1	6.3
Commercial	5	31.2
Coumadin indicator		
AFib	8	50.0
DVT/PE	5	31.2
Prosthetic valve	3	18.8
Pacemaker	3	18.8
CVA/TIA	2	12.5

Note. [a]Diagnosis for Coumadin therapy. Afib = Atrial fibrillation, DVT = deep vein thrombosis, VTE = venous thromboembolism, PE = pulmonary embolism, CVA = cerebrovascular accident, TIA = transient ischemic attack, INR = International Normalization Ratio. The reasons for Coumadin indications do not add up to 100% because multiple patients had more than one indication for Coumadin therapy.

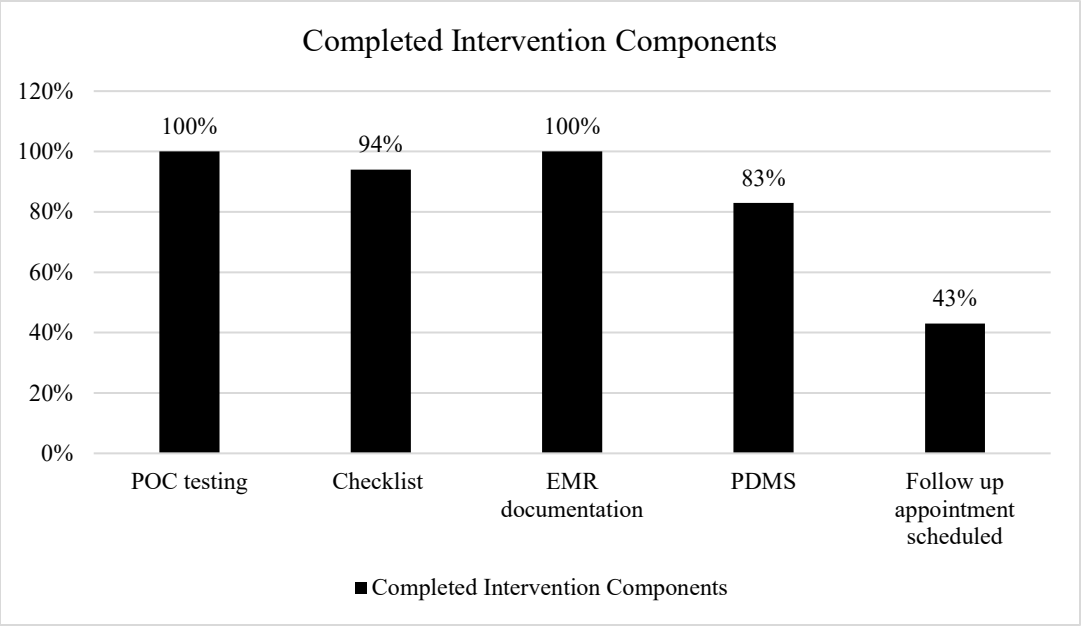

Figure 1. Intervention components with percentage completed.

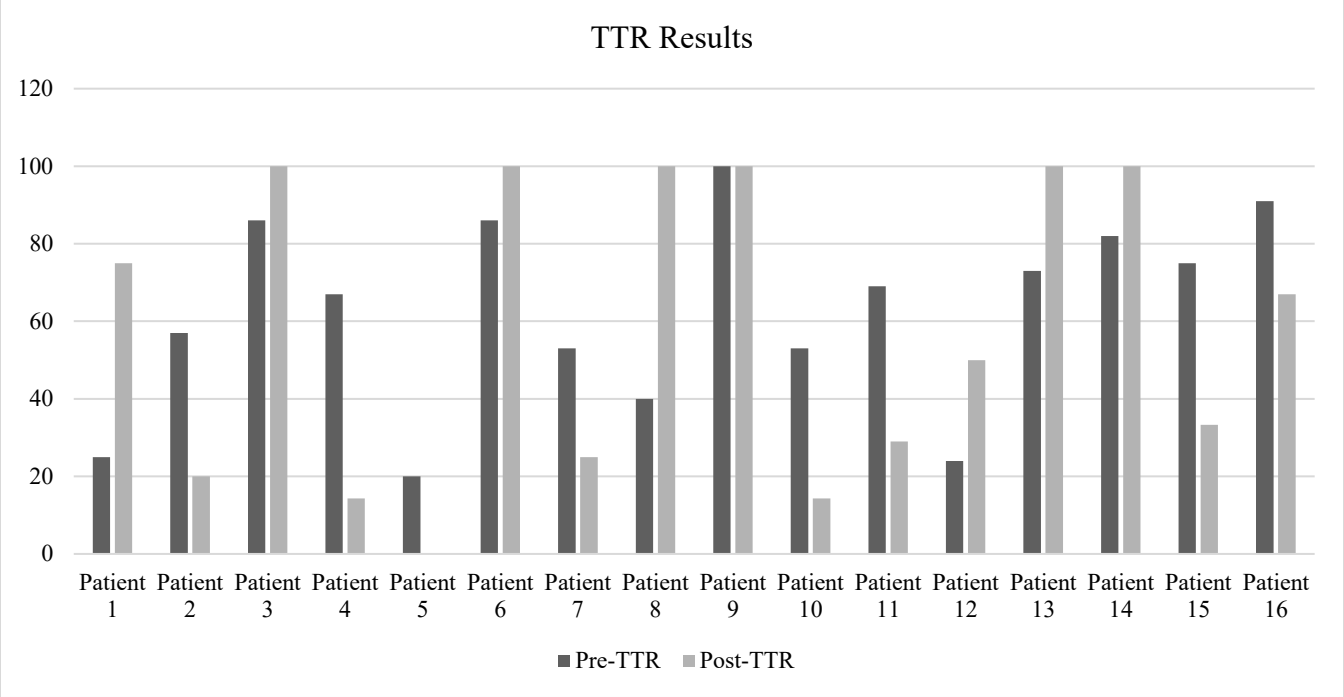

Figure 2. Pre- and post-intervention TTR values for each patient.

Discussion

The purpose of this quality improvement project was to establish a Coumadin Clinic with full anticoagulant management at the POC with aims to improve or maintain TTR of INR levels, and to improve patient understanding and compliance of Coumadin therapy. The clinic staff's performance of implementing full anticoagulant management at the POC was excellent with 100% of patients receiving POC INR testing by fingerstick instead of blood draw by venipuncture. The nursing staff conducted a Coumadin risk assessment and documented the INR level at 100% of POC INR visits. Despite the RHC system's outstanding achievement for implementing POC INR testing, the objective of providing full anticoagulant management at the POC was not met at 95% due to failure of providing the PDMS and scheduling of follow-up appointments at each visit.

The PDMS was given at 83% of the Coumadin Clinic visits. One FNP and one nurse were misinformed about the purpose of the dosing sheet and were only providing the dosing sheet if the Coumadin dose changed. The intention was for the patient to receive the PDMS at each visit, even if a dose change had not occurred, in order for the patient to always have current written instructions. The project mentor provided further education to the staff and upon project completion, three of five providers, provided the PDMS 100% of the time.

Follow-up appointments were only scheduled at 43% of the Coumadin Clinic visits. Prior to project implementation, the DNP student was unaware that the office manager did not allow scheduling of patient appointments for the next month until the provider schedule was determined. Therefore, the receptionists only scheduled a follow-up appointment if the provider wanted the patient to return sooner than a month, or if the provider schedule was ready for the

following month. All patients due to return in a month continued to receive a reminder letter, asking them to call to schedule the next INR appointment.

The goal to maintain or improve TTR of INR levels to an overall of 95% for the entire patient population was not met. Project results revealed only 50% of patients maintained or improved TTR. Of the 63 Coumadin Clinic visits, 29 INR levels (46%) were within therapeutic range. Of the remaining Coumadin Clinic visits, 32 INR levels (51%) were subtherapeutic and 2 INR levels (3%) were supratherapeutic. The results are similar to the outcomes of the study by Smith et al. (2012), which found 50% of 124 INR levels obtained with POC INR testing were within therapeutic range, 33% were subtherapeutic, and 17% were supratherapeutic. There are various possibilities why the project was not successful in achieving the intended objective of maintaining or improving the TTR, including length of project implementation, total number of INR draws, patient co-morbidities, and socioeconomic factors.

First, the project was limited to 3 months for implementation. Pre-intervention data included 10 months of INR draws from the project population. Smith et al. (2012) suggests it is difficult to ascertain if TTR improves with the implementation of POC INR testing, if the pre- and post-intervention periods are not the same length of time, and if the number of pre- and post-INR levels obtained are not the same. During the pre-intervention period, 195 INR clinic visits occurred with 113 INR levels (58%) in therapeutic range, 57 subtherapeutic (29%), and 25 supratherapeutic (13%). Despite the limited number of POC INR levels obtained during project implementation, the 46% of INR levels in therapeutic range were comparative to the 58% in therapeutic range at pre-intervention.

Next, acute illness, co-morbidities, and socioeconomic considerations are all factors that may affect TTR and are not measurable or comparable (Smith et al., 2012). Smith et al. (2012)

suggests poor control of Coumadin management is often the result of poor social support, financial barriers including low-income status and lack of health insurance, unreliable housing, transportation issues, and residing in underserved communities. Residents of the county in which the RHCs reside, experience some if not all of these problems. For example, during the project intervention, one patient reported familial stressors upsetting the living situation and requested assistance with assisted-living placement. Prior to project implementation, this patient's TTR was 53% compared to 29% at post-intervention. Another elderly patient was ill during the intervention with acute bronchitis and influenza and received antibiotic treatment, which is known to increase bleeding time while taken with Coumadin. Prior to project implementation, this patient's TTR was 67% compared to 14.3% at post-intervention. Both patients returned to therapeutic range by the end of project completion.

Research suggests POC INR testing increases patient satisfaction and decreases the length of the laboratory visit (Smith et al., 2012). At the end of the project, patient satisfaction was surveyed by questionnaire. Seven patients responded to the survey, and six of the seven (86%) respondents preferred INR testing via fingerstick. The patient that did not like INR testing via fingerstick complained of pain caused by the fingerstick. Otherwise, the patients were 100% satisfied with the Coumadin Clinic and did not offer any suggestions for improvement. One patient expressed that it was helpful with scheduling conflicts to be able to have the INR checked on Friday, which was previously not available. The nurses and providers were also surveyed by questionnaire to identify satisfaction with establishing the Coumadin Clinic. Three FNPs and four nurses responded to the survey and 100% of the staff believed POC INR testing improved management of Coumadin therapy, increased patient-provider communication, improved patient understanding of dosing using the PDMS, and was more time efficient. All staff denied problems

with the program and denied need for change or improvement to the system. Nurses reported satisfaction with not having the added responsibility of calling patients with INR results and dosing changes, and were thankful to have the Coumadin Clinic in place. In fact, the Coumadin Clinic eliminated nurse-patient calls regarding Coumadin management. Prior to the intervention, the nursing staff documented 225 calls to patients regarding Coumadin management. During the project, only three nurse-patient calls and one email occurred as reminders to return for INR follow-up.

Limitations

The project intervention was limited by small sample size, short project timeframe, and the demand to initially implement the project across all three clinic locations. Prior to project implementation, the RHCs had 27 patients on Coumadin therapy. Among this group, one patient routinely received monthly lab draws at the local hospital and continued this method due to financial constraints limiting the patient's ability to pay for a monthly clinic visit. One patient was unable to attend the Coumadin Clinic during the hours available and another was hospitalized during the intervention and did not return for follow-up. Before the implementation of POC INR testing, two patients suffered a stroke, one resulting in death and the other resulting in a change of anticoagulant therapy that did not require monthly INR monitoring. The remaining five patients not included in the sample, were all dismissed from the RHCs practice prior to the intervention, due to long histories of poor compliance with Coumadin therapy and frequent failure to return for INR monitoring. Unfortunately, these patients were not given the opportunity to participate in the Coumadin Clinic and may have benefited from POC INR testing.

The short timeframe for project implementation limited the amount of POC INR levels obtained. A longer timeframe for project implementation of at least 10 months would have increased the number of INR draws and opportunities for follow-up and counseling patients on Coumadin management, including dietary and medication implications, which would likely increase TTR and patient compliance (Smith et al., 2012).

Due to the small sample size, short project timeline, and cost of POC INR devices and supplies, it was necessary to implement the project across all of the RHCs. Consequently, streamlining the establishment of the new processes across all locations was challenging. This required extra time to train the nursing staff on POC INR testing at each location and assistance from the DNP student to begin the program at each site. The DNP student was not always available to be onsite for every Coumadin Clinic encounter or as a resource for troubleshooting technical issues. Lastly, the differences in work culture and attitudes among various staff members and clinics prevented the Coumadin Clinic processes to be completed in the same manner at each location, including the use of the PDMS. Despite these limitations, project implementation was successful at all three RHCs.

Recommendations

Recommendations for the sustainability of this project intervention include daily use of the Coag-Sense device at RHC 3 and change of the appointment scheduling process. Project results indicate the majority of INR appointments (40%) occurred at RHC 3 and the fewest INR appointments (27%) occurred at RHC 2. Incidentally, the patient that attended the Coumadin Clinic once but was unable to return due to work conflict is a regular patient of RHC 3. Three of the four new patients to Coumadin therapy were also regulars of RHC 3. It is recommended the stationary Coag-Sense at RHC 2 be moved to RHC 3 in order to support the patient load at this

location. The other Coag-Sense will continue to share time between RHC 1 and RHC 2. The other recommendation is to allow the patients to schedule follow-up appointments at the end of each Coumadin Clinic visit. This patient population is seen so frequently that all providers are familiar with these patients and can provide safe, effective Coumadin management. This would eliminate the need to mail monthly reminder letters with instructions to call to schedule an appointment for Coumadin patients and eliminate unnecessary nurse-patient reminder calls.

Implications for Practice

DNP-prepared advanced practice registered nurses (APRNs) have the expertise and leadership abilities to greatly impact patient care delivery systems and patient outcomes (Zaccagnini & White, 2017). The educational foundation of DNP-prepared APRNs includes eight essential components including scientific underpinnings of practice, organizational and systems leadership to establish quality improvement and systems thinking, analysis and clinical application of evidence-based practice, clinical application of information systems and technology, advocacy for health care policy, interprofessional collaboration for improved patient and population health outcomes, health prevention promotion, and advanced practice nursing (American Association of Colleges of Nursing (AACN), 2006). Zaccagnini & White (2017) suggest DNP education of the APRN is necessary to maintain and improve ethical, safe, and quality healthcare practices and systems. The DNP essentials demonstrated in the project are utilizing organizational and systems leadership to establish a quality improvement project and translating technology into practice. Research suggests the use of POC INR testing is an effective tool for managing Coumadin therapy (Smith et al., 2012). Therefore, the DNP student implemented a quality improvement project to establish a Coumadin Clinic with POC INR testing with aims to improve patient care quality and promote patient safety. This required

organizational skills and leadership to coordinate project implementation across three clinics and the proficiency to analyze effectiveness and sustainability of the project. The establishment of POC INR testing also addressed the DNP essential for translating technology into practice by implementing an efficient patient care technology appropriate for outpatient Coumadin monitoring (AACN, 2006).

Summary

A quality improvement project was implemented to establish a Coumadin Clinic in a rural family medicine practice with aims to improve or maintain TTR of INR levels and patient understanding of Coumadin therapy. Coumadin is notoriously difficult to manage and is potentially dangerous due to high risk for bleeding and mortality. Coumadin is best managed using evidenced-based models of care such as POC INR testing (Garcia et al., 2008; Harrison et al., 2015; Rossiter et al., 2013). Results of the study suggest POC INR testing has the potential to improve TTR of INR levels over time and improve patient and staff satisfaction of Coumadin management. Although all objectives were not met, the project established a system valuable to promoting patient care quality and safety.

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Appendix A

Organizational Readiness for Implementing Change (ORIC)

This survey is a tool designed to quantify how well an organization perceives its ability to sustain a practice change. The "change" that each question refers to is the implementation of the Coumadin clinic.

1	2	3	4	5
Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree

1. People who work here feel confident that the organization can get people invested in implementing this change.	1 4	2 5	3	
2. People who work here are committed to implementing this change.	1 4	2 5	3	
3. People who work here feel confident that they can keep track of progress in implementing this change.	1 4	2 5	3	
4. People who work here will do whatever it takes to implement this change.	1 4	2 5	3	
5. People who work here feel confident that the organization can support people as they adjust to this change.	1 4	2 5	3	
6. People who work here want to implement this change.	1 4	2 5	3	
7. People who work here feel confident that they can keep the momentum going in implementing this change.	1 4	2 5	3	
8. People who work here feel confident that they can handle the challenges that might arise in implementing this change.	1 4	2 5	3	
9. People who work here are determined to implement this change.	1 4	2 5	3	
10. People who work here feel confident that they can coordinate tasks so that implementation goes smoothly.	1 4	2 5	3	

11. People who work here are motivated to implement this change.	1 4	2 5	3
12. People who work here feel confident that they can manage the politics of implementing this change.	1 4	2 5	3

Appendix B

Coumadin Clinic Patient Visit Checklist

Receptionist:

Date:

Patient ID #:

Nurse:

Coumadin template charted in EMR ☐

INR lab checked with Coag-Sense ☐

INR result: ☐

INR result documented in EMR ☐

Provider:

INR results are:

Below Goal At Goal Above Goal

Need for INR result verification with lab? Y / N

Coumadin dosing sheet filled out ☐

Receptionist:

Follow-up appt scheduled on appropriate Coumadin Clinic day ☐

Write appointment time/date on patient's dosing sheet & given to patient

PATIENTS RECEIVING INITIAL COUMADIN PRESCRIPTION

CHA2DS2-VASC stroke risk score: ☐

A-fib patients HAS-BLED score: ☐

OR

Acute VTE patients RIETE score: ☐

Patient education materials received ☐

Coumadin Contract received ☐

Appendix C

Patient Dose Management Sheet

My Current Coumadin Dose as of _____

	Dose Instructions
Monday	
Tuesday	
Wednesday	
Thursday	
Friday	
Saturday	
Sunday	

Next appointment:_____

Appendix D

Patient Questionnaire for Coumadin Clinic

Clinic location: Floresville, Stockdale, or La Vernia (Circle one)

Please circle yes or no for each question. If no, please explain.

1. Do you like having your INR checked by fingerstick vs. blood draw? Yes or No

   _____
   _____
   _____

2. Does it help you to get written instructions of your Coumadin dose at each INR check? Yes or No

   _____
   _____
   _____

3. Have you been able to easily schedule appointments for your INR check? Yes or No

   _____
   _____
   _____

4. Is there anything else that we can do to help you manage your Coumadin better?

   _____
   _____
   _____

Appendix E

Nurses and Provider Questionnaire for Coumadin Clinic

For these questions you may answer yes or no, but it would be very helpful if you explained why for each answer. Thank you! ☺

1. Do you think point-of-care (POC) INR testing is helping your patients to better manage their Coumadin?

   _____
   _____
   _____

2. Do you think your patients have a better understanding of their Coumadin dosing using the written handout at each visit?

   _____
   _____
   _____

3. Is POC INR testing more time efficient?

   _____
   _____
   _____

4. **Nurses,** has the Coumadin Clinic decreased the amount of time you are on the phone with patients?

   _____
   _____
   _____

5. What problems have you run into with the Coumadin Clinic?

   _____
   _____
   _____

6. What would you change or improve with the Coumadin Clinic?

   _____
   _____
   _____

Appendix F

Physician Letter of Support

Family Medical Centers
Daryl C. Currier, M.D., P.A.
Stockdale (830) 996-3701 LaVernia (830) 779-3800 Floresville (830)216-7979

October 21, 2017

To whom it may concern,

I am writing to confirm my support of Kathleen Zeledon's Doctor of Nursing Practice (DNP) project. As owner and medical director of the Family Medicine Centers of Floresville, La Vernia, and Stockdale, Texas, I grant permission for Kathleen Zeledon to complete her DNP project at the clinics. The purpose of the project is to establish a Coumadin Clinic at each location with point-of-care testing. The goal is to manage Coumadin at in-office appointments and to increase each patient's time spent with INR levels in therapeutic range. I give Kathleen Zeledon permission to access patient records before and during the project intervention. Cecelia Ann Kothmann, MSN, FNP-BC is overseeing the project and the components of the project have been discussed and agreed upon.

Sincerely,

Daryl C. Currier, M.D., P.A.