Quality Improvement: Perioperative Management Protocol for Anticoagulant Therapy in Primary Care Settings

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Anticoagulant therapy (ACT) has become progressively common as more need for anticoagulation such as coronary artery stent placements have arisen (Huisa & Fisher, 2017). Moreover, newer anticoagulant therapies have improved management and dosing of anticoagulants. Patients receiving anticoagulant therapy are at increased risk for perioperative complications including epidural hematoma formation after placement or removal of epidural or spinal catheters (Huisa & Fisher, 2017). Unlike thrombolytics, anticoagulants do not break up clots, rather, they prevent thrombus formation and proliferation by reduction of fibrin formation. Anticoagulants act on different steps of the intrinsic and extrinsic coagulation pathways (Furnish & Wallace, 2014).

When evidence-based precautionary measures are implemented prior to surgery, issues which can cause serious complications during and after elective surgeries can be greatly reduced (Michota, 2013). Prior to surgery, there is a need for preoperative management of cardiac patients receiving anticoagulants prior to surgery to reduce the incidents of complications and re-hospitalization after surgery (Michota, 2013). The goal of perioperative medicine is to provide complete organ protection without complications (Butcher & Richards, 2017). An interdisciplinary approach has been proven to be an effective method for improving patient outcomes and system results.

ACT continues to play a dominant role in the prevention of stroke and heart attacks. The perioperative management of anticoagulation in cardiac patients can be a challenging one (Pereira & Pinheiro, 2013). However, for patients with a history of cardiovascular disease, or those who are receiving anticoagulants, it is imperative to overcome the challenges. Piereira &

Pinheiro (2013) noted that for cardiac patients with a low hemorrhagic risk, it is possible to resume non-vitamin K antagonist oral anticoagulants (NOACs) six to eight hours after the surgery. In cardiac patients with low thromboembolic risk, NOACs may be resumed 48 to 72 hours after the procedure (Pereira & Pinheiro, 2013).

Background

Many of the pre-surgical precautionary measures are centered on the preparation of the surgical team, and the surgery (De Haan, Calsbeek, & Wolf, 2016). However, the importance of providing patient education prior to surgery has demonstrated effectiveness in ensuring the patient knows and understands their role in the success of the surgery as well as post-surgery (De Haan, Calsbeek, & Wolf,). There is a need for preoperative management for cardiac patients receiving anticoagulants prior to surgery to reduce the incidents of complications, re-hospitalizations after surgery and surgery cancellations.

The management of anticoagulants in the perioperative environment is still a challenge for the medical profession. Spyropoulos and Douketis (2012) noted that there is a dilemma in deciding on the management of anticoagulation in patients who are preparing for surgery. There is the issue of clots, and there is the issue of bleeding risks. On one hand, if the anticoagulant therapy is interrupted for a surgical procedure, the risk of thromboembolism increases. On the other hand, surgeries are associated with bleeding risks, that are increased by the anticoagulants which are given to prevent thromboembolism (Spyropoulos and Douketis, 2012). The solution therefore, lies in finding a balance.

According to Spyropoulos and Douketis (2012), there are novel oral anticoagulants (dabigatran, rivaroxaban, and apixaban) that are emerging. There is also new evidence that recommends new modes of therapy to the popular warfarin. The American College of Chest

Physicians (2016) now recommends non-vitamin K antagonist oral anticoagulants (NOACs) over warfarin for initial and long-term treatment of venous thromboembolism (VTE) in all patients who do not have cancer. They have found new evidence that indicates that NOACs are as effective as vitamin K antagonists (VKA) therapy with reduced risk of bleeding and increased convenience for patients and health-care providers.

There are some options for cardiac patients receiving ACT in regards to perioperative procedures, most of whom take Coumadin (Warfarin) which helps to reduce the risk of stroke and heart attacks. The options are to continue warfarin therapy, withhold warfarin therapy for a period of time before and after the procedure, or temporarily withhold warfarin therapy and also provide a "heparin bridge" during the perioperative period (Daley, 2016). Cardiac specific therapy indicates that if the annual risk for thromboembolism is low, warfarin therapy can be withheld for four to five days before the procedure without bridging. A few prospective studies recommend that cardiac patients on long-term warfarin therapy who undergo minor invasive procedures, and who are taken off their oral anticoagulation for a maximum of 5 days have a less than 1% risk of experiencing a thromboembolic event (Daley 2016, Spyropoulos, 2012).

Problem Statement

Despite research supporting standardized a care approach in the perioperative management of patients receiving ACTs, inconsistency in management of patients is common (Spyropoulos & Douketis, 2012). A proposed standardized care approach based on current literature, utilizing the new protocol called the *Patient Anticoagulant Management* (PAM) (Appendix A) for cardiac patients would improve healthcare outcomes for patients at the practice site. Under *PAM*, patients with a history of cardiovascular disease, and who are receiving ACT

would have less cancellations of their elective surgeries due to lack of patient education regarding when to stop their ACT therapy prior to surgery.

Presently, at the practice site, each provider has a different directive for patients receiving ACT. The perioperative preparation for patients receiving ACT varies from physician to physician. Some patients receiving ACT are advised to stop use three days prior to surgery, some are told five days, and some seven days. This creates ambiguity for the nurse practitioners, confusion, and cancellation of surgeries for the patients, many of whom are receiving ACT, and are referred for medical or cardiac clearance two days prior to the surgery. The surgeries are sometimes postponed up to seven days, as a result. The change in practice is needed because the practice site hosting this DNP project does not have a standardized monitoring approach for patients receiving ACT prior to surgery. This has at times cause complications after surgery, many of which has led to re-admission into the hospital and surgical cancellation.

In primary care settings where there is a standardized management of ACT, patient outcomes are much better than places where there is none (Spyropoulos & Douketis, 2012). This is a result of strict reporting standards by the Centers for Medicare and Medicaid (CMS) in order to be reimbursed. CMS monitors the rate at which patient's status post-surgery are discharged to acute hospital settings. The research shows the numbers are extremely small, as small as 1/1000 (Fox, Vashi, Ross, & Gross, 2014). Due to the need for quality control in hospitals and outpatient surgical centers, it is to their advantage to have perioperative systems in place to reduce penalties from the federal government.

Purpose Statement

The purpose of this DNP project is to improve the management of perioperative warfarin therapy through the implementation of the PAM protocol for cardiac patients over the age of 18.

The aim is to decrease surgery cancellation, intraoperative and postoperative complications such as, hemorrhaging and thromboembolism through the implementation of the PAM protocol which is founded in evidence-based research and collaborative efforts in primary care settings. According to Spyropoulos and Douketis (2012), patients need an aggressive perioperative strategy, including the use of heparin bridging therapy, to minimize the time they are off ACT.

Project Question

In preoperative cardiac patients, does the implementation of a cardiac specific PAM protocol reduce the risk of complications and surgical cancellations in comparison to current practice in primary care over a span of 4-6 weeks?

Project Objectives

At the conclusion of this DNP Project the following objectives should be achieved:

1. Utilize evidence-based research and clinical nursing expertise to assess the current prescreening protocols for cardiac patients on anticoagulation medications prior to surgery.
2. Collaborate with medical and inter-professional healthcare personnel to plan and implement, PAM protocol for cardiac patients undergoing surgery.
3. Evaluate the PAM protocol to determine its success or failure over 4-6 weeks. Through comparative analysis of the period pre-intervention and 4 weeks post implementations of protocol.

Search Terms

A systematic review was conducted by searching the databases of CINAHL, EBSCOT, Medline, Google Scholar, Jay Sexter Library, Up to Date, and PubMed for articles with a five-year time limit and for articles concerning standard protocols for perioperative procedures for patients receiving ACT. Inclusion criteria were peer-reviewed articles from 2012 to present.

Searches were inclusive of articles from the US and other developed countries. This was important for the sake of reducing biases in the research, relevance, reliability, and validity. The references used from earlier formal searches for background and topic proposal were also reviewed for additional information. Searches for clinical practice guidelines were also conducted using government websites such as National Guideline Clearinghouse, and the US Department of Health and Human Services. Searches were conducted using key terms: preoperative cardiac patients, surgical centers, NOAC, anticoagulant therapy and perioperative surgery, ambulatory surgical centers, cancellations. Literature reviewed examined randomized control trials, retrospective cross-sectional descriptive studies, meta-analysis, and cohort studies. The included studies were analyzed for intervention types, safety outcomes, quality and effects on patients. There were 30 studies that met the inclusion criteria and will be used as evidence for the DNP project.

Review of Literature

The purpose of this literature review is to provide an objective account through synthesis and analysis of existing evidence relating to the management of anticoagulants, in cardiac patients within perioperative environments such as primary care settings.

Impact of the Problem

According to Eisenstein (2015), approximately 250,000 people who are receiving warfarin for long-term ACT will require interruption of their therapy for surgical or other invasive procedures. Continuation of ACT during surgical or invasive procedures predisposes such patients to increased bleeding risks because of warfarin's long half-life (two to three days). That is why some recommendations include cessation of ACT three to five days prior to surgery (Douketis et al., 2015). Another study indicates that approximately 10% to 20% of patients

undergoing treatment with anticoagulants will be exposed to surgery or invasive procedures in either an emergency setting or other sometime in their lives (Pernod, et al., 2013).

There are many studies regarding anticoagulant therapies and their impact on surgery. For patients who must cease their ACT therapy before surgery, there needs to be a standardized protocol to ensure continuity of care and consistency in practice (Douketis et al, 2015; Spyropoulos, 2012). This position coincides with this DNP project, as empirical studies and interviews with peers at the practice site found that there is still a lack of consensus amongst physicians, surgeons, and other healthcare specialists regarding the most appropriate time to cease and to resume ACT.

The importance of preoperative management for patients receiving anticoagulants for atrial fibrillation has been underscored in many studies. The incidence of arterial thromboembolism was 0.4% in the no-bridging group and 0.3% in the bridging group (risk difference, 0.1 percentage points; 95% confidence interval [CI], −0.6 to 0.8; P = 0.01 for noninferiority). The incidence of major bleeding was 1.3% in the no-bridging group and 3.2% in the bridging group (relative risk, 0.41; 95% CI, 0.20 to 0.78; p=0.005 for superiority (Douketis, et al., 2015).

In a retrospective cross-sectional descriptive study conducted at a metropolitan hospital in over a four-year period, the reasons for cancellations of elective surgeries were examined. There were 12,500 patients who attended the out-patient clinic during the study period. The patients (67%) were seen by an anesthesiologist, and 37% by an assistant anesthesiologist. Nearly 60% of surgeries were cancelled on the day of surgery for anesthetic reasons. The most common reason was due to patients' nonadherence to medication such as anticoagulant and fasting guidelines (Emanuel & McPherson, 2013). In instances where the surgeries were

performed, there was a mean of five days from the assessment to time of surgery (Emanuel, McPherson, 2013).

Addressing the Problem with Current Evidence

Current management. Currently, the recommendation for cardiac patients taking warfarin is that it should be discontinued approximately three to five days before surgery or a procedure (Ortel, 2013). For cardiac patients at low risk for thromboembolic complications, it is recommended that warfarin be stopped five days before the procedure, and then be resumed once the procedure has been completed. Perioperative data with the novel oral anticoagulants, such as dabigatran, rivaroxaban, and apixaban, are emerging, but their relatively short half-life, rapid onset of action, and predictable pharmacokinetics should simplify perioperative use. Three to five days has been the most common recommendation (Ortel, 2013; Douketis et al., 2015; Eisenstein, 2015).

Current recommendations. According to the American College of Chest Physicians (2016) in their Evidence-Based Clinical Practice Guidelines (8th Edition), in patients requiring vitamin K antagonist (VKA) interruption before surgery, stopping VKAs five days before surgery instead of a shorter time before surgery (Grade 1B evidence) is recommended.

In patients with a mechanical heart valve, atrial fibrillation, or venous thromboembolism (VTE) at high risk for thromboembolism, they suggest bridging anticoagulation instead of no bridging during VKA interruption (Grade 2C); in patients at low risk, there should be no bridging (Grade 2C). In moderate-to high-risk patients who are receiving acetylsalicylic acid (ASA) and require non-cardiac surgery, the recommendation is continuing ASA around the time of surgery instead of stopping ASA seven to ten days

before surgery (Grade 2C). (American College of Chest Physicians, 2012; Ortel, 2013; Douketis et al., 2015).

In patients with a coronary stent who require surgery, the recommendation is to defer surgery six weeks after bare-metal stent placement and six months after drug-eluting stent placement (Grade 1C); in patients requiring surgery within six weeks of bare-metal stent placement or within six months of drug-eluting stent placement, continuing antiplatelet therapy preoperatively instead of stopping therapy seven to ten days before surgery (Grade 2C) is recommended.

Based on the literature reviewed there are some variations in recommendations based on the type of surgery (American College of Chest Physicians, 2012; Spyropoulos and Douketis, 2012). This is relevant in terms of showing the need for holding ACT therapy regardless of the surgery. This is the case at the practice site, where a number of providers operate under one roof. Therefore, there has to be a standard for ACT cessation prior to all surgeries.

Implications for Practice

One of the more common ways of treating patients with cardiovascular disease is to prescribe ACT such as coumadin. According to Chow & Kim (2013), this oral anticoagulant is commonly prescribed for preventing complications such as thromboembolism in patients with prosthetic heart valves, congestive heart failure, and valvular defects. However, when cardiac patients need surgery (regardless of the type of surgery, for example dental or hip replacement), the risk of bleeding is always a concern, therefore, the anticoagulant therapy, if not stopped or bridged, could cause complications during surgery as well as after the surgery.

Prichard (2012) stated that the National Institute for Clinical Evidence (NICE) has stressed the need for detecting and treating any new conditions identified such as cardiac

arrhythmias, cardiac murmur, or blood disorders, during pre-operative assessment. According to Prichard (2012), drugs such as Warfarin increase the risk of bleeding post-operatively and must be stopped prior to surgery. When this pre-operative assessment is not done in a timely manner, patients lack the necessary information, and often have their surgeries cancelled or delayed (Pritchard, 2012). Cardiac patients on ACT can benefit from patient education on when to stop their ACT therapy prior to surgery.

Needs Further Investigation

In instances where patients receiving ACT need surgery, the big concern is determining when is it safe to perform surgery without increasing the risk of hemorrhage or increasing the risk of thromboembolism (venous, arterial) after discontinuing treatment. The literature under review by various authors indicate that three to five days is acceptable, depending on the level of risk. (Daley, 2016; DeBiase, 2014).

A study conducted by the National Heart, Lung, and Blood Institute (NHLBI) revealed that a periprocedural bridging strategy with low-molecular-weight heparin (LMWH) offered no clinical advantages compared with interrupting warfarin treatment (Daley, 2016). Yet, a 2014 randomized study by DiBiase showed that performing catheter ablation of atrial fibrillation (AF) without warfarin discontinuation reduces the occurrence of periprocedural stroke and minor bleeding complications compared with bridging with low-molecular-weight heparin (Daley, 2016). More research is needed regarding perioperative strategies specific to cardiac patients receiving ACT who, according to the research will need either emergency or elective surgery at some time in their life (Pereira, Pinheiro, 2013). There is therefore the need to determine whether continue warfarin therapy, stop warfarin therapy for a period of time before and after the

procedure, or temporarily withhold warfarin therapy and also provide a heparin bridge during the perioperative period (Daley, 2016).

Barriers to Practice and Controversies

The management of anticoagulants in the perioperative environment is still a challenge for the medical profession. There is a dilemma in deciding how to manage anticoagulation in patients who are preparing for surgery (Spyropoulos and Douketis, 2012). There is the issue of clots, and there is the issue of bleeding risks. If the anticoagulant therapy is interrupted for a surgical procedure, there is an increased risk of thromboembolism. On the other hand, bleeding risks are associated with surgeries because of the anticoagulants which are given to prevent thromboembolism (Spyropoulos and Douketis, 2012). One way to avoid this is to have a standardized protocol for patients who are receiving ACT prior to surgery.

The Agency for Healthcare Research Quality [AHRQ], (2017) has an ambulatory surgery center checklist that includes pre-operation, during, and post-operation as a safety measure and one of the items to be checked is whether there is a risk of venous thromboembolism and if there is a risk, compression boots and/or anticoagulants should be considered postoperative. The goal of perioperative medicine is to provide complete organ protection without complications.

According to Eisenstein (2015), approximately 250,000 people who are receiving warfarin for long-term ACT will require interruption of their therapy for surgical or other invasive procedures. Continuation of ACT during surgical or invasive procedures predisposes patients to increased bleeding risks because of warfarin's long half-life (two to three days). Other recommendations found in the literature review from (Douketis *et al*, 2012; Keeling, Tait, Watson, British Committee of Standards for Hematology, 2016) cautioned that Warfarin needs to be stopped five days before elective surgery to ensure hemostasis has returned to normal. This

differs for other vitamin K antagonists with different half-lives (for example, fluindione, three days; phenprocoumon, five days). If possible, the International Normalized Ratio (INR) should be determined the day before surgery to allow the administration of phytomenadione if the INR is ≥1·5, so reducing the risk of cancellation. Due to its slow onset of action warfarin can be resumed, at the normal maintenance dose (Douketis *et al*, 2012), or with two initial days of double maintenance dose the evening of surgery (or the next day) if there is adequate hemostasis (Keeling, Tait, Watson, British Committee of Standards for Hematology, 2016).

Despite the guidelines, the literature suggests that adherence to the recommendations and guidelines are not adequate (Chow & Kim, 2013; Douketis et al, 2015). This means ambulatory surgery centers and primary care settings need to be closely monitored to ensure they are also using standardized patient anticoagulant management protocol. Management of ACT by a nurse practitioner may improve compliance and safety in primary care settings and ambulatory surgery centers. This PAM is to implement a pre-operative management protocol for cardiac patients receiving anticoagulants to prevent surgical cancellation, as well as intraoperative and post-operative complications.

Theoretical Framework

Theory Identification and Historical Development

Interdisciplinary collaboration among clinicians and the utilization of evidence based research is imperative in order to achieve high quality care, improve patient outcomes and patient satisfaction. In 1966, Avedis Donabedian, then a physician and health service researcher at the University of Michigan, established the Donabedian Model, a conceptualized framework used to investigate health services and evaluating quality of care. This model focuses on three key elements: structure, process, and outcome (Thomson, Gorospe, & Cooke, 2015). There is a

relationship between the three concepts. The first concept is structure which is defined as the physical and organizational aspects of care setting, the second concept is process which focuses on what is performed and how it will be delivered in order to improve patient health. The final concept is outcome which determines the effect of healthcare on the status of patients and populations (McDonald, Sundaram, & Bravata 2007).

This conceptual framework is broadly utilized in nursing literature. Nurses are becoming more involved in healthcare policy and advocacy and have the potential to affect the delivery of healthcare across all settings (Chism, 2013). The Donabedian model can be very useful when conducting nursing research, implementing policies and procedures to improve patient care, and healthcare outcomes. Patient experiences and quality of life has been proven to improve through various research studies that incorporated the Donabedian conceptual framework (Kobayashi, Takemura, & Kanda, 2011). This model is considered to have sufficient generality to apply patient inquiries across multiple regions of nursing. Integrating this approach allows nursing professionals and policy makers to identify problems, causes, and effect in healthcare which will subsequently lead to quality improvement (Kobayashi, et al., 2011).

Major Tenets of the Theory

The major tenets of the theory are structure, process and outcome.

Structure. Structure of healthcare is described as the physical and organizational characteristics of care settings. For example, facilities, personnel, financial processes and equipment (McDonald, Sundaram, & Bravata 2007).

Processes. Processes lies in the middle of the triadic conceptual framework since they depend on the structures to provide resources and mechanisms for providers to conduct patient care activities. Furthermore, processes are performed to subsequently enhance quality of care,

healthcare, promoting recovery, survival, functional restoration and patient satisfaction (McDonald, Sundaram, & Bravata 2007).

Outcomes. Outcomes are driven by the process. The process determines what will be measured, evaluated, and reassessed (McDonald, Sundaram, & Bravata 2007). All three tenets are interconnected to examine health services and evaluate quality of healthcare.

Applicability of Theory to Current Practice

The Donabedian model can be easily applied to healthcare research and clinical practice. Multiple research studies reviewed have proven the efficacy of this model. A study was conducted in Michigan, which incorporated four hospitals to examine the unique contribution of call light response time to total fall rates and injurious fall rates among adult patients (Tzeng, Titler, & Ronis, 2012). The Donabedian conceptual framework was selected to determine the relationship between call light response time and fall rates along with injurious fall rates. It was noted in the study that shorter call light response time was associated with lower total fall rates and lowered the rates in injurious falls, hence quality improvement was observed, (Tzeng, Titler, & Ronis, 2012).

Wu, Kinsinger & Provenzale (2014), described how the Veterans Health Administration (VHA) organized key stakeholders, healthcare delivery and research to develop a more systematic and comprehensive proposal to collaborate more effectively to generate and evaluate a clinical program for lung cancer screening. The Donabedian triad was used to establish the required characteristics of a quality lung cancer screening program. Standardized protocols and ongoing monitoring of data collection were developed which subsequently helped to measure and identify quality of care and care delivery.

A cross sectional study was conducted in Northeast South Africa in seven primary healthcare facilities to research patients and healthcare providers' satisfaction with the dimensions of ICDM services and to evaluate the quality of care (Ameh, Gómez-Olivé, & Kahn, 2017). Donabedians model was utilized to determine the quality of care in patients with chronic diseases such as Human Immunodeficiency Virus, Acquired Immunodeficiency Deficiency Syndrome, diabetes, hypertension, and chronic obstructive pulmonary diseases. It was noted that healthcare providers and patients' satisfaction increased more than 50% (Ameh, et al., 2017).

An empirical study conducted by Kajonius and Kazemi, (2016) to evaluate the relative importance of Donabedian conceptual framework for quality of care from the perspective of the elderly population using nursing home care and home care services. It was observed that patients living at home were more satisfied with nursing home care because they felt more respected and experienced a relatively high degree of autonomy when receiving care in their own home oppose to patients receiving care in nursing home (Kajonius, & Kazemi, 2016). These results highlight the positive impact the Donabedian model had on the quality of care provided to nursing home care patients.

McKay and Wieck, (2014) evaluated how a collaborative care model approach impacted the survival rate of hospitalized patients. The purpose of this study was to investigate if there was a difference in survival, length of stay and cost per case for congestive heart failure population in facilities using the clinical integration model compared to those using a traditional care delivery model (McKay & Wieck, 2014). The Donabedian conceptual framework was utilized to provide a comprehensive structure to change the environment in which care is provided through the process of care delivery to optimize patient outcome. Due to the integration of this new approach, it was found that when healthcare providers coordinate and

collaborate patient length of stay in hospitals were decreased with lower cost to the healthcare institutions (McKay, & Wieck, 2014).

A study conducted by Lee & Wan (2002) investigated the relationship between the magnitude of structural clinical integration of a hospital, mean per discharge and surgical complication ratio in hospital death ratio. The conceptual framework of the study was based on Donabedian's triadic model. It was determined that increase in the average total cost had a positive effect on surgical complications, and an increase surgical complication ratio certainly related to in hospital mortality ratio (Lee & Wan, 2002). Patient outcome is influenced by the care that is provided by healthcare professionals.

Application of Theory to DNP Project

Interdisciplinary collaboration is needed to reduce fragmentation of patient care delivery in the United States. Collaboration among health care providers is imperative to provide high quality care and meeting patients expectations (McKay, & Wieck, 2014). Standardized protocols and constant scrutinization of data collection and delivery of care, coupled with intense evaluation and analysis can assist with defining and measuring delivery of care and quality of patient care (Wu, Kinsinger & Provenzale, 2014).

The Donabedian conceptual framework is applied for this project to examine the relationship between perioperative management of cardiac patients receiving warfarin therapy with surgical cancellation rates, and intraoperative and postoperative complications.

Structure

This DNP project will be conducted at a primary care practice in Long Island, New York. The practice site which is comprised of primary care providers, cardiologists, nurse practitioners and physician assistants will be conceptualized as the system structure indicators.

Process

The implementation of patient anticoagulant management (PAM) protocol for cardiac patients receiving coumadin/warfarin and interdisciplinary collaboration will be conceptualized as a staff centered process. A standardized PAM protocol will be implemented and serve as a guide for physicians, nurse practitioners, physician assistants, and registered nurses who are involved in coumadin/warfarin management for the cardiac patient undergoing surgical procedures. Interdisciplinary team meetings will be used to facilitate and coordinate collaborative efforts among providers to effectively implement the PAM protocol.

Outcome

Outcomes will be determined by the effect of collaborative care and the effectiveness of the PAM protocol for cardiac patients receiving coumadin/warfarin. Through a collaborative team approach, the goal is to reduce surgical cancellations, intraoperative and postoperative complications, while improving patients' quality of life, surgical outcomes, satisfaction and quality of healthcare.

The adaptation of theoretical framework that is well established and has proven to be effective is imperative to help guide development, implementation, and evaluation of care coordination interventions (McDonald, Sundaram, & Bravata 2007). Donabedian's conceptual framework was selected to guide this DNP project. Perioperative management of cardiac patients on coumadin/warfarin has been a challenge at the practice site. To combat this problem, the plan is to make structural changes at the practice site where this DNP project will be conducted. The process will be modified through a standardize PAM Protocol and enhancing interdisciplinary collaboration to guide perioperative management of cardiac patient on coumadin/warfarin. The clinical integration of these processes is designed to change patient

surgical screening process and will also change the attitudes of providers in the care process. These changes will subsequently influence quality of care, improve patient outcomes and patient satisfaction. Based on the fact that a good structure should promote a good process and a good process should in turn promote a good outcome, this DNP project will be a great contribution to healthcare (Ameh, et al., 2017).

Project Design

An evidence based quality improvement (QI) project design will be utilized for this DNP project. This design was chosen because the overall goal of this project is to improve processes and outcomes in healthcare, specifically improving the management of perioperative anticoagulant therapy in cardiac patients. According to Moron et al, (2017), the Health Resources and Services Administration (HRSA) (2011) defines quality improvement as a systematic and continuous process that leads to measurable improvement in healthcare services and the health status of targeted groups. The Donabedian model will provide the framework during the planning, implementation and analysis stages of the project.

Stage 1 (Structure) - Recruitment and identification of participants will be selected based on providers that manage warfarin therapy. During this stage the DNP project will be presented and all questions from participants will be addressed.

Stage 2 (Process) - To assess the providers' knowledge, a pre and post-test questionnaire (Appendix B) will be administered. All participants will be educated and trained on the PAM protocol. A Power Point presentation will be presented to all participants based on evidence-based research and clinical nursing guidelines. Participants will be educated and trained on utilizing and administering the PAM protocol. Providers will implement the PAM protocol for patients on warfarin therapy undergoing surgical procedures.

Stage 3 (Outcome) - Data collection and analysis will be done via chart review before and after implementation for comparison of data. A total of 45 chart reviews will be conducted pre-op and 45 chart reviews post-op. Patient data will consist of two different patient groups. Data will then be recorded onto an excel spreadsheet and imported into SPSS software. Patient data will be analyzed to determine the reduction rate in surgical cancellations and surgical complications such as hemorrhaging and thromboembolism pre and post implementation of the PAM protocol.

Variables

This project will consist of both independent and dependent variables. The independent variable is perioperative management of warfarin therapy, the PAM protocol, and the dependent variables are the impact on post-operative complication rates and surgical cancellation rates.

Population of Interest & Stakeholders

The population of interest is healthcare providers that manage warfarin therapy at the practice site. The healthcare providers will consist of four registered nurses, five nurse practitioners, five physician assistants, two medical doctors and one cardiologist. These providers were selected because they all participate in the management of warfarin therapy and surgical clearance. The PAM Protocol will be utilized and administered by the healthcare providers for patients over the age of 18 that are on warfarin therapy and are reporting for medical or cardiac clearance prior to any type of surgical procedures. According to Wu et al, (2014) in order to achieve proven quality care, collaboration is vital between health care providers, evidence based research policies and guidelines.

In order to formulate a successful scholarly DNP project it is crucial to establish a rapport with stakeholders within the practice. One of the most important components of a successful

DNP project is ensuring stakeholder support (Moran, et al., 2017). The key stakeholders identified for this DNP project is the Medical Director, Registered Nurses, Nurse Practitioners, Physician Assistants, Medical Doctors and Cardiologist. Developing a strong relationship with stakeholders will be beneficial in executing a successful project. A formal meeting will be held with key stakeholders to introduce the objectives and outcomes of this DNP project, address any issues or questions and solicit stakeholders' feedback. To foster and strengthen this rapport regular meetings will be scheduled to inform stakeholders of project progress and challenges. The ultimate goal of patient-centered outcomes research is to enhance quality of care and improve patient health outcomes by incorporating stakeholders and patients throughout the research process, beginning with the research question formulation and extending to the dissemination of the findings (Chi, et al., 2018).

Setting

The setting for this DNP project is at a family medical practice located in Long Island, NY. The practice consists of two clerical staff members, three medical assistants, four nurses, five nurse practitioners, five physician assistants, two medical doctors, one cardiologist and the director of patient services. The practice provides services to patients from all socio-economic background and accepts most insurances and private pay. On a daily basis the practice provides services to over 100 patients and offers a full range of medical and cardiac services. These services include general healthcare, diabetes management, cardiac management, neurological testing, allergy testing, perioperative evaluation, smoking cessation and nutritional counseling including weight management.

Recruitment Methods

An affiliation agreement and approval to conduct this DNP project was obtained from the director of patient services at the practice site. The providers responsible for warfarin management and surgical clearances will be recruited to implement the PAM protocol. This QI project will need full participation from the providers within the practice. On a regular basis, training and education will be provided based on evidence-based research and clinical guidelines. Project updates and questions will be addressed via email when the project leader is not present on site. Information and feedback received from all healthcare providers that are participating in the project will be kept confidential. Inclusion criteria are all the healthcare providers that manages warfarin therapy and provide cardiac and medical surgical clearances. Exclusion criteria are staff members that do not provide warfarin therapy management, medical clearances, or cardiac clearances.

Tools and Instruments

According to Yu et al., (2014), clinical pathways have been originated from clinical guidelines. In recent years, clinical pathways have become increasingly essential and are commonly utilized in the health care industry to improve quality of care by disseminating evidence-based research more effectively. One of the tools that will be utilized for this project is the 2017 periprocedural management of anticoagulation pathway (PMAC) decision algorithm (Appendix C). The goal of this pathway decision algorithm is to provide guidance to providers in the complex decision making of perioperative management of anticoagulation. The recommendations of withholding and resuming vitamin K antagonist (VKA) therapy refer specifically to warfarin (Doherty et al., 2017). Even though the PMAC algorithm is fairly new, the clinical practice guidelines and recommendations by the American College of Cardiology

(ACC) are not new. In an attempt to strengthen the effect of ACC policies on patient care, an ACC Presidential Task Force was established in 2014 to analyze the ACC clinical documents. The key recommendation of the Presidential Task Force was to create new succinct decision pathways in lieu of traditional longer documents, thus the PMAC pathway decision algorithm was developed (Doherty et al., 2017).

Since it is recommended by the PMAC pathway decision algorithm to evaluate bleeding and thrombotic risk, the other tools that will be utilized are the CHA2DS2-VASc (Appendix D) scoring system and the HAS-BLED (Appendix E). The CHA2DS2-VASc scoring system is a tool that is used to calculate thromboembolic risk. The HAS-BLED scoring system is utilized to assess patients risk for bleeding (Boutsikou, et al., 2014). The CHA2DS2-VASc calculated score is usually used to determine if patients require anticoagulant therapy. The HAS-BLED scoring system is a tool that is used to assess bleeding risk in patients taking anticoagulants (Ruff, 2014). The HAS-BLED bleeding risk scoring system was utilized in a cohort study for patients who were treated with anticoagulation therapy and were undergoing surgical procedures to evaluate its effectiveness. It was noted that the predictive accuracy of the HAS-BLED system was an effective tool to determine bleeding risk in the overall population, particularly when patients were only treated with antiplatelet agents or no antithrombotic therapy (Lip, et al., 2011). Since atrial flutter is strongly correlated with an increased risk for thromboembolism a study was done among patients undergoing cardiac catheter ablation and the CHA2DS2-VASc scoring system was utilized to predict the risk of a thromboembolic event after the procedure. It was observed that the CHA2DS2-VASc was useful and effective in predicting the risk for thrombosis (Jin, et al., 2018). The PAM protocol (Appendix A) will be developed by the project

leader and implemented by providers over a period of 4-6 weeks. A power point presentation based on evidence-based research and nursing expertise will be presented to the providers.

Data Collection

Once the recruitment process has been completed, collection of data will begin. A retrospective review of 45 charts pre-implementation will determine surgical cancellation rates and post-operative surgical complications such as hemorrhaging and thromboembolism prior to implementation of the PAM protocol. Once the PAM protocol is implemented a systematic sampling will be completed on every 3rd patient chart on a daily basis. A total of 45 chart reviews will be conducted to determine surgical cancellation rates and postoperative complications. Data will be collected onto an excel spreadsheet and then be imported into SPSS software for comparative analysis of pre and post implementation of the PAM protocol.
All charts and paperwork will be locked in a cabinet at the practice site to maintain privacy. There will be no identifying patient information collected. Data collected electronically will be protected by an encrypted password that will only be utilized by the project leader. Patient privacy and confidentiality will be maintained according to the Institutional Review Board (IRB) and the Health Insurance Portability and Accountability Act (HIPAA) guidelines.

Intervention/Project Timeline

The implementation for this DNP project will be approximately five weeks. The proposed timeline is as follows:

Week 1

Meetings will be conducted at the practice site with key stakeholders, physicians, cardiologist, physician assistants and nurse practitioners to begin the implementation process. Training sessions will be held with healthcare providers implementing the PAM protocol.

Following the training sessions, the implementation process will be monitored on a daily basis during morning huddles which will last approximately five minutes. Huddles are extremely important and valuable, and it is imperative to identify the best time of day for conducting them in order to obtain effectiveness. During huddles important patient information is discussed and critical information is communicated to improve quality of care and achieve goals (Brady, 2018). At the conclusion of the day data will be collected and entered onto an excel spreadsheet. Chart audits will also be conducted on a daily basis.

Week 2-4

The DNP project implementation process will continue and be monitored on a daily basis. Morning huddles with healthcare providers will be executed daily to address any questions, concerns and to obtain feedback on the implementation process. Continuation of data collection and entry onto excel spreadsheet will be done daily. Chart audits will be performed daily. Collaboration with project mentor and content expert will be conducted for guidance and feedback.

Week 5

Results from 45 chart reviews pre-implementation and 45 chart reviews post implementation of the PAM protocol will be organized and entered onto an excel spreadsheet. During this phase privacy and confidentiality will be maintained. The data that is collected on the excel spreadsheet will be imported into SPSS software for comparative analysis pre and post-implementation of the PAM protocol. Findings from the DNP project will be disseminated to practice site stakeholders.

Ethics/Human Subjects Protection

Due to unethical practices in research, laws has been established to protect human subjects from harm. In 1979, the Belmont report was published. This report outlines three important ethical principles; respect for persons, beneficence and justice. These are three key elements that should be respected when conducting research with Human subjects (Robinson-Bailey, 2014). It is the responsibility of the project leader to treat each patient in an ethical manner by protecting their privacy, keeping them safe from harm and respecting their decisions. Throughout this project, patients' information will remain confidential, private and protected by using encrypted passwords with chart reviews completed in a private area. Information obtained from patients' chart will not contain patient identifiers to ensure compliance with HIPAA Guidelines.

The purpose of an IRB committee is to safeguard the rights and welfare of human research subjects. The initial phase in determining whether a project requires to be reviewed by the IRB board is to determine if it meets the definition of research with human subjects (Hicks, 2018). For this DNP project an IRB approval will not be required by the practice site. This project is a QI project and there is minimal risk to the participants. The IRB process at Touro University will be followed. This is a QI project and will likely not require a full IRB review. This QI project will be submitted to the Touro University of Nevada (TUN) IRB Committee, to determine if it requires a full IRB review or if it will be exempt and fall into the category of a TUN QI. Participants will not be compensated for their contribution to this project. In this DNP project, patients will not be exposed to any form of treatment. The population of interest are the healthcare providers who are implementing the screening protocol.

Plan for Analysis/Evaluation

Data collection will begin during week one of the implementation phase. At the conclusion of each day, data will be collected and chart audits will be conducted through week four. The data collected and entered onto the excel spreadsheet will be imported into the statistical package for social sciences (SPSS) software for comparative analysis of pre and post-implementation of the PAM protocol. This will determine the effectiveness of the protocol in decreasing post-operative complications and patient surgical cancellation.

SPSS software version 20 (IBM, 2011) will be used to analyze the data at an alpha (α) significance level of $p<.05$. Three chi square tests of independence will be utilized to determine if there are differences in three patient outcomes before and after the implementation of the PAM protocol: surgical cancellation, hemorrhaging, and thromboembolism. A chi square test will be utilized because the groups of patients before and after implementation are different. Hence, a paired test would be inappropriate. The chi square test has assumptions (McHugh, 2013). These include the following:

1. The data must be in the form of frequencies or counts. This assumption is met because each of the outcomes are measuring incidence (occurred versus did not occur).
2. The categories of each variable included in the analysis must be mutually exclusive. This means that a subject could not fall into both categories. This assumption is met because the two patient groups before and after the implementation did not contain the same patients. Likewise, in terms of patient outcomes, a patient could not have their surgery cancelled and also have it take place.
3. The data cannot be from a paired or a repeated measures design (the groups must be independent). This assumption is met because the design of the collection of patient data was

not paired, nor repeated measures.

4. The data must be measured (or coded) at the nominal or ordinal level. This assumption is met because each of the outcomes are dichotomous (occurred versus did not occur). Likewise, the patient groups are coded as before and after implementation.
5. Within the cross tabulation, no cell should have an expected frequency less than one. Likewise, 80% of the cells should have an expected frequency of five or more. This assumption is usually met with an adequate sample size. McHugh (2013) recommends a minimum sample size of the number of cells multiplied by five. For these analyses this minimum sample size would be 20 (four cells multiplied by five). The achieved sample size of 90 vastly exceeds this minimum.

A sample size analysis was performed using G*Power 3.1 statistical software (Faul et al., 2007). G*Power 3.1 uses Cohen's *w* as an effect size measure for the chi square test. Cohen's *w* was set at 0.30 (a medium effect size), the desired power to 0.80, the degrees of freedom to 1, and the alpha significance (α) level to .05 (indicating the rate of making a Type 1 error is 5%). The required sample size with these parameters is 88. Hence, the total sample size of 90 should be sufficient to obtain 80% power.

A pre and post-test (Appendix B) will be administered to providers to determine knowledge level of perioperative management of warfarin therapy. A paired samples *t*-test will be utilized to compare providers test scores before and after the educational training sessions on the use of the PAM protocol and the PMAC algorithm. A paired samples *t*-test compares two sample means from the same population concerning the same variable at two different times (Pallant, 2016). The paired samples *t*-test is appropriate for this comparison because the

independent variable is time and the dependent variable is a continuous ratio level variable (percentage correct).

Given that the sample size was limited to the number of providers within the practice, a power analysis was conducted to determine what the power would be with the restricted sample size of 13. A power analysis was performed using G*Power 3.1 statistical software (Faul et al., 2007). G*Power 3.1 uses Cohen's *dz* as an effect size measure for the paired samples *t*-test. Cohen's *dz* was set at 0.50 (a medium effect size) and the alpha significance (α) level to .05. A one-tailed test was estimated given that it was expected that test scores would stay the same or increase (not decrease). The achieved power with these parameters is 52%.

The statistical testing is necessary to confirm the assumption that, providers who completed the PAM protocol for cardiac patients over the age of 18 and are undergoing surgical procedures, will avoid surgical cancellation and complications. Providers who will be implementing the protocol will be provided with a PAM Protocol Compliance Checklist (Appendix F), to indicate whether or not the protocol was utilized. This checklist was designed to validate the providers' adherence to the protocol. It will remain in the patients chart and will be evaluated during random chart auditing post implementation.

Analysis

Providers Data

A paired samples *t*-test was conducted to evaluate providers test scores before and after the educational training sessions on the use of the PAM protocol and the PMAC algorithm. The paired samples *t*-test was statistically significant, $t(12) = -7.04$, $p < .001$, $\underline{d_z} = -1.95$. Provider test scores significantly increased from the pre-test ($M = 74.62\%$, $SD = 13.91\%$) to the post-test ($M = 97.69\%$, $SD = 4.39\%$).

Table 1
Paired samples t-test comparing mean differences in provider test scores

Paired Differences				*t*	*df*	*p*
M	*SD*	95% CI of Difference				
		L	U			
-23.08	11.82	-30.22	-15.93	-7.04	12	< .001

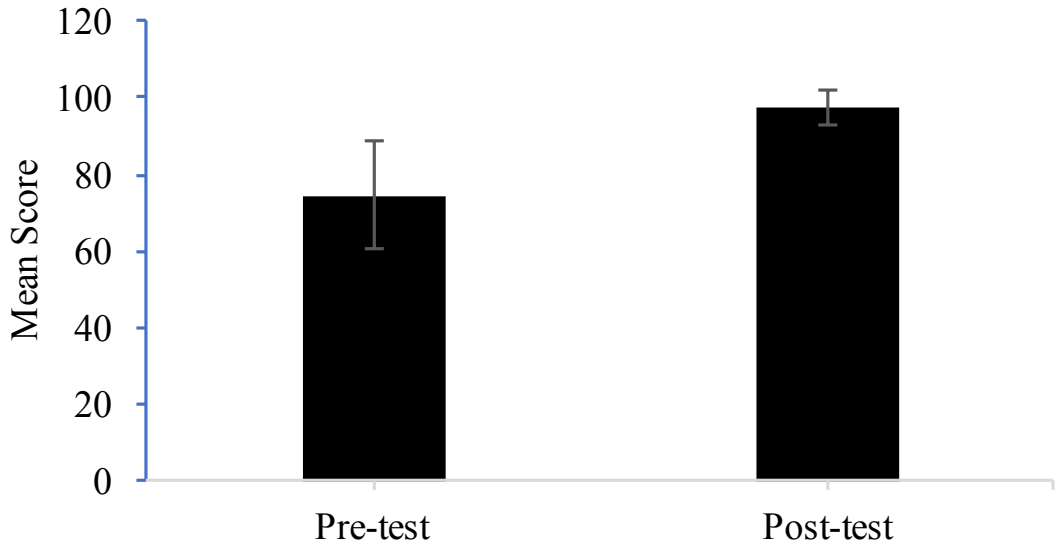

Figure 1. Provider mean test scores pre and post intervention, $t(12) = -7.04$, $p < .001$, $\underline{d_z} = -1.95$

Patient Data

Data from 90 patients was included in the analysis. A retrospective review of 45 charts pre-implementation was used to determine surgical cancellation rates and post-operative surgical complications, hemorrhaging and thromboembolism prior to implementation of the PAM protocol. Once the PAM protocol was implemented a systematic sampling was done on every 3rd patient chart on a daily basis. A total of 45 chart reviews was conducted to determine surgical cancellation rates and postoperative complications. Chi square tests of independence was utilized to determine if there were differences in three patient outcomes before and after the

implementation of the PAM protocol: surgical cancellation, hemorrhaging, and thromboembolism.

Surgical cancellations. The chi square test for independence indicated that a significant difference in surgical cancellations existed between time points, $X^2(1) = 12.53$, $p < .001$. The number of surgical cancellations significantly decreased from 24.4% before the intervention to 0% after the intervention. Likewise, the number of surgeries not cancelled significantly increased from 75.6% to 100%. No expected cell counts were less than one. All expected cell counts were greater than five. All assumptions were met for this analysis.

Table 2

Incidence of surgical cancellations pre and post intervention, $X^2(1) = 12.53$, $p < .001$

			Pre	Post	Total
Surgical Cancellation	No	*N*	34	45	79
		%	75.6%	100.0%	87.8%
	Yes	*N*	11	0	11
		%	24.4%	0.0%	12.2%

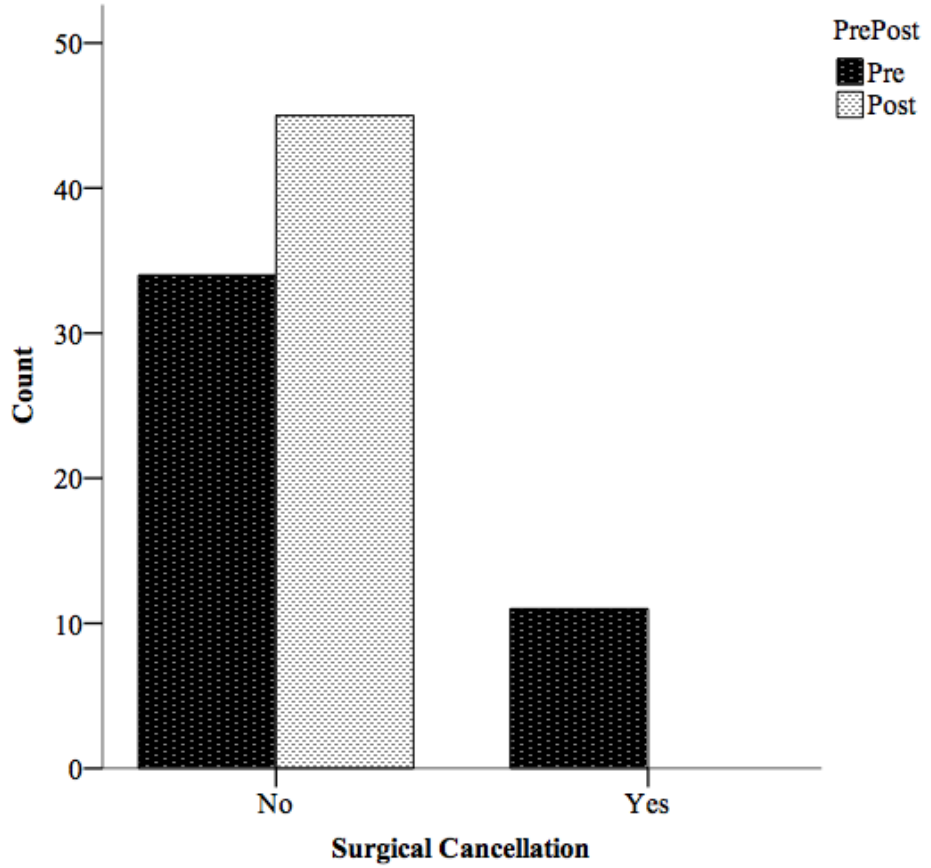

Figure 2. Incidence of surgical cancellations pre and post intervention, $X^2(1) = 12.53$, $p < .001$

Hemorrhaging. The chi square test for independence indicated that there was not a significant difference in hemorrhaging between time points, $X^2(1) = 0.71$, $p = .398$. The incidence of hemorrhaging decreased from 8.9% before the intervention to 4.4% after the intervention, but this was not a statistically significant difference. No expected cell counts were less than one. Fifty-percent of the expected cell counts were greater than five. The other expected cell counts were three. Hence, the final assumption for this analysis was not fully met.

Table 3

Incidence of hemorrhaging pre and post intervention, $X^2(1) = 0.71$, $p = .398$

			Pre	Post	Total
Hemorrhaging	No	*N*	41	43	84
		%	91.1%	95.6%	93.3%

	Yes	*N*	4	2	6
		%	8.9%	4.4%	6.7%

Thromboembolism. The chi square test for independence indicated that there was not a significant difference in thromboembolism between time points, $X^2(1) = 2.86$, $p = .091$. The incidence of thromboembolism decreased from 11.1% before the intervention to 2.2% after the intervention, but this was not a statistically significant difference. No expected cell counts were less than one. Fifty-percent of the expected cell counts were greater than five. The other expected cell counts were three. Hence, the final assumption for this analysis was not fully met.

Table 4

Incidence of thromboembolism pre and post intervention, $X^2(1) = 2.86$, $p = .091$

			Pre	Post	Total
Thromboembolism	No	*N*	40	44	84
		%	88.9%	97.8%	93.3%
	Yes	*N*	5	1	6
		%	11.1%	2.2%	6.7%

Discussion of Findings

The aim of this DNP project was to, develop and implement a protocol for patients over the age of 18 that are on warfarin therapy and undergoing surgical procedures. The purpose of this protocol is to effectively manage a patient's anticoagulant therapy to prevent post-operative complications and surgical cancellations.

The results of the current project reflected that education on the use of the PAM protocol and the PMAC algorithm was effective in increasing provider knowledge. The effect of this education was large according to the effect size.

Over the time span of 4-6 weeks, the implementation of PAM protocol was effective in reducing the incidences of surgical cancellations in cardiac patients over the age of 18 on

warfarin therapy. Although the incidence of hemorrhaging and thromboembolism did decrease after the PAM protocol, the results were not significantly different. While the overall sample size was sufficient according to the priori sample size analysis, there were very few cases of hemorrhaging and thromboembolism both before and after the intervention. More data collection would likely be necessary to witness an effect.

This DNP project was effective in preventing surgical cancellations for patients over the age of 18 that are on warfarin therapy and undergoing surgical procedures. Prior to the implementation of the PAM protocol there were high incidences of surgical cancellations, however, after the implementation of the project there were no surgical cancellations. Even though, there were decrease incidences of postoperative complications such as, hemorrhaging and thromboembolism, the results were not significantly different prior to the implementation of the DNP project.

Significance/Implications for Nursing

The significance of this project to the nursing profession is to enhance and improve patient care, safety, outcomes and healthcare delivery. Even though, standardized evidence-based protocols have demonstrated improvement of patient outcomes they are rarely utilized (Doherty et al., 2017). By creating this protocol based on evidence it will serve as a guide to clinicians in the complex decision making of perioperative warfarin management. In spite of a significant amount of patients that are treated chronically with warfarin therapy, some providers do not utilize standardized protocols to guide perioperative management of anticoagulant management (Skeith, et al., 2012).

Due to the small amount of available guidance for the complex decision making of warfarin therapy management for patients undergoing surgical procedures, this protocol has the

potential to be beneficial if utilized in similar settings. Since excessive bleeding and thrombotic risk factors are known surgical complications, related to inadequate management of perioperative management of warfarin therapy (Nutescu, et al., 2013), the PAM protocol can have a positive impact on patient's surgical outcomes. Furthermore, in a study done by Emanuel & McPherson, (2013) one of the most common reasons for surgical cancellation is mismanagement of anticoagulant therapy prior to surgical procedures. The authors concluded that if patients who are on anticoagulant therapy are assessed and evaluated at least five days prior to surgical procedures they had a greater chance of not having their surgical procedures cancelled (Emanuel & McPherson, 2013). Hence, it is vital to manage warfarin therapy preoperatively to decrease surgical complications and cancellations.

Based on the results from the statistical analysis of this project, the PAM protocol can be beneficial for providers that are responsible for medically clearing patients who are on warfarin therapy for surgical procedures. Ambulatory care centers can also benefit from the PAM protocol to aid in the management of ACT which will subsequently improve compliance and safety. The nursing profession is one of the largest sectors in healthcare, which gives them the ability to make changes in healthcare nationally and globally, through evidence-based research and clinical practice. Perioperative management of anticoagulation is a common clinical challenge that includes a multidisciplinary team approach. Nurses plays a vital role in influencing healthcare polices, leadership, research, and discovery, which will subsequently improve health care outcomes and delivery (Chism, 2017). To be influential advance practice nurse's ought to view themselves as leaders, who has the ability to influence polices, patient safety, healthcare outcomes and delivery.

Limitations of the Project

The low incidences of hemorrhaging and thromboembolism pre and post implementation is a limitation of this project. The project would benefit from a larger sample size and a longer time frame for implementation, to ensure meaningful results for hemorrhaging and thromboembolism. Given the project was conducted at one site and there is no information about patient demographics, the results of this project may not generalize to other sites. Likewise, the lack of random assignment of the intervention as well as the lack of random selection of medical records is also a limitation and may bias the results.

Future projects would benefit implementing this intervention at multiple sites with random assignment of the intervention. This would improve generalization. Likewise, future projects could benefit from a larger sample size of medical records. Demographic information as well as other patient factors related to hemorrhaging and thromboembolism should be obtained from the medical record to control for factors that may affect these outcomes.

Areas for Dissemination

This DNP project is a quality improvement project to improve the management of perioperative anticoagulation, with the intent to disseminate to the targeted audience. Dissemination is vital aspect of any scholarly project (Chism, 2016). The outcomes of this project was presented to the stakeholders and providers who are responsible for perioperative management of anticoagulation at the practice site. The outcomes from this project will be disseminated via power point presentation to the faculty at Touro University of Nevada and to the staff at a Pre-Surgical testing unit located in local hospital in Long Island, New York. This project will be submitted to the Doctoral Project Repository. This will enable others to gain insights on the, success and challenges of the project and will subsequently provide a platform

for future projects to build upon to improve quality of care. An abstract of this project will be submitted to the, 2020 13th National Doctors of Nursing Practice Conference. This will provide an opportunity collaborate with others across the nursing profession and also afford the ability to explore strategies to sustain the project much further than implementation.

Sustainability

In order to sustain this quality improvement project, the outcomes and additional recommendations following the implementation was provided to the main stakeholders at the practice site. "Sustainability refers to locking in the progress made by an improvement initiative and replication occurs when best practices and knowledge about successful interventions are actively disseminated to every available care center" (Moran, et al, 2017). The PAM protocol was developed based on evidence based research and clinical practice, it can be transferrable to ambulatory surgical centers and other primary care settings that are responsible for management of anticoagulant therapy in cardiac patients undergoing surgical procedures. It is vital to keep abreast with evidence based research and clinical practice, to ensure that the guidelines utilized in this project remains best clinical practice. Through dissemination of this DNP project, surgical cancellation can be prevented by utilizing the PAM protocol. On the other hand, this project can be expanded on to decrease postoperative complications such as hemorrhaging and thromboembolism. Furthermore, there are no cost associated with the sustainability of this project, and it has the ability to increase patient satisfaction, improve quality of care, decrease healthcare cost and surgical cancellations.

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Appendix A

Patient Anticoagulation Management (PAM) Protocol

PATIENT ANTICOAGULANT MANAGEMENT (PAM) PROTOCOL FOR CARDIAC PATIENTS ON /WARFARIN AND ARE UNDERGOING SURGICAL PROCEDURES

Providers:

- Physicians, nurse practitioners, and physician assistants familiar with the protocol and are involved in the care of patients that are on warfarin may implement protocol.

Initiate Protocol:

1. Has the patient been diagnosed with any cardiovascular conditions?
   - ☐ Yes
   - ☐ No

2. Has the patient been anticoagulated with warfarin?
   - ☐ Yes
   - ☐ No (Exit protocol)

3. Schedule patient for medical clearance 10-14 days prior to surgical procedure.

4. Use the HAS-BLED scoring system to identify if patient is at risk for bleeding complications.

5. Use the CHA2DS2-VASc to identify if patient is at risk for thrombotic event.

6. Obtain PT/INR to evaluate the extrinsic pathway of coagulation.

7. Based on results of the HAS-BLED, CHA2DS2-VASc, PT/INR and clinical judgement determine whether to bridge or to interrupt anticoagulant therapy.

8. Educate patient on anticoagulant management and inform patient when to discontinue warfarin therapy or how to bridge anticoagulant therapy.

9. Assess patients understanding of warfarin therapy management for surgery and provide clarification if needed.

10. Inform patient of when to return for follow up visit status post-surgery.

Appendix B

Providers Knowledge Pre and Post-Test Questionnaire

1. Have you had previous training on perioperative management of warfarin therapy?
a) yes
b) some training
c) no

2. A 50-year-old male presents for medical clearance with a history of deep venous thrombosis (DVT) and is being treated with warfarin therapy based on current guidelines by the American College of Cardiology (ACC), which of the following should be assessed?
a) risk for bleeding
b) risk for thrombotic event
c) PT/INR to evaluate the extrinsic pathway of coagulation
d) all the above

Answer: **D**

3. A nurse practitioner is medically clearing a patient who is being treated with warfarin 5mg due to cerebrovascular accident (CVA). Which of the following tools should the nurse practitioner utilize to determine bleeding and thrombotic risk?
a) CHA2DS2-VASc
b) HAS-BLED
c) TLR signaling pathway
d) Both A & B

Answer: **D**

4. Which of the following scoring system identify patient at risk for bleeding complications?
a) CHA2DS2-VASc
b) HAS-BLED
c) Both A & B
d) none of the above

Answer: **B**

5. Which of the following scoring system identify patient at risk for thrombotic event?
a) CHA2DS2-VASc
b) HAS-BLED
c) Both A & B
d) None of the above

Answer: **A**
6. The physician is providing education to a patient on warfarin management prior to surgery. Which of the following should the physician do?

a) Instruct and educate patient when to discontinue warfarin therapy or how to bridge anticoagulant therapy
b) Assess patients understanding of warfarin therapy management prior to surgery
c) Provide clarification if needed on perioperative management of warfarin
d) All of the above

Answer: **D**

7. What results would the provider use to determine whether to bridge or to interrupt anticoagulant therapy? Select all that apply

- PT/INR
- Clinical judgment
- HAS-BLED
- CHA2DS2-VASc
- TLR signaling pathway

Answer:
PT/INR
Clinical judgment
HAS-BLED
CHA2DS2-VASc

8. What is the goal level of INR measurement 5-7 days prior to surgical procedure?
a) 1.0 to 1.5 or 1.5 to 2.0
b) 2.0 to 2.5 or 2.0 to 3.0
c) 3.5 to 4.0 or 4.0 to 4.5
d) None of the above

Answer: **B**

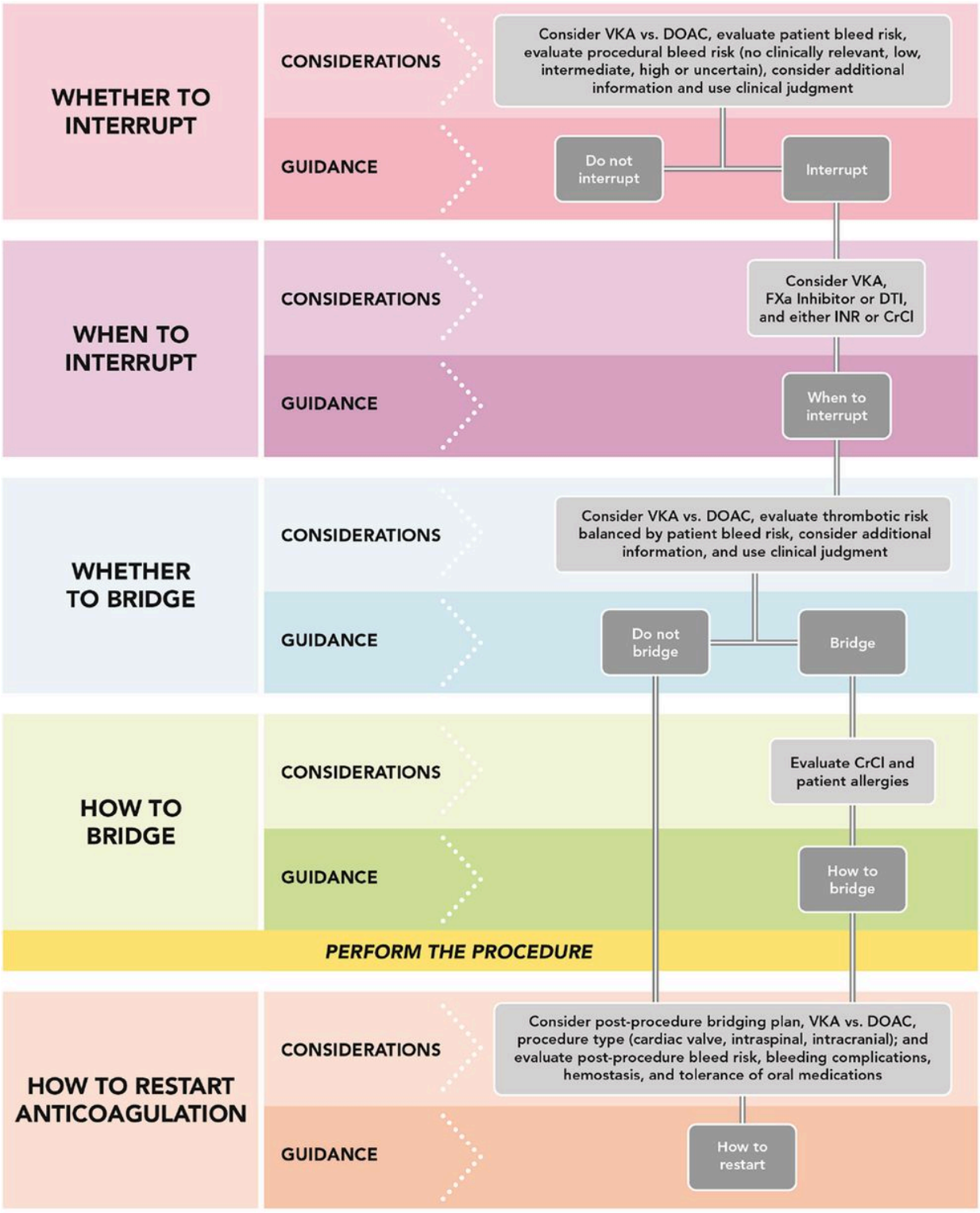
9. Which of the following factors may increase a patient bleeding risk?
a) Hypertension
b) Prior stroke
c) greater than age 65
d) all the above

Answer: **D**

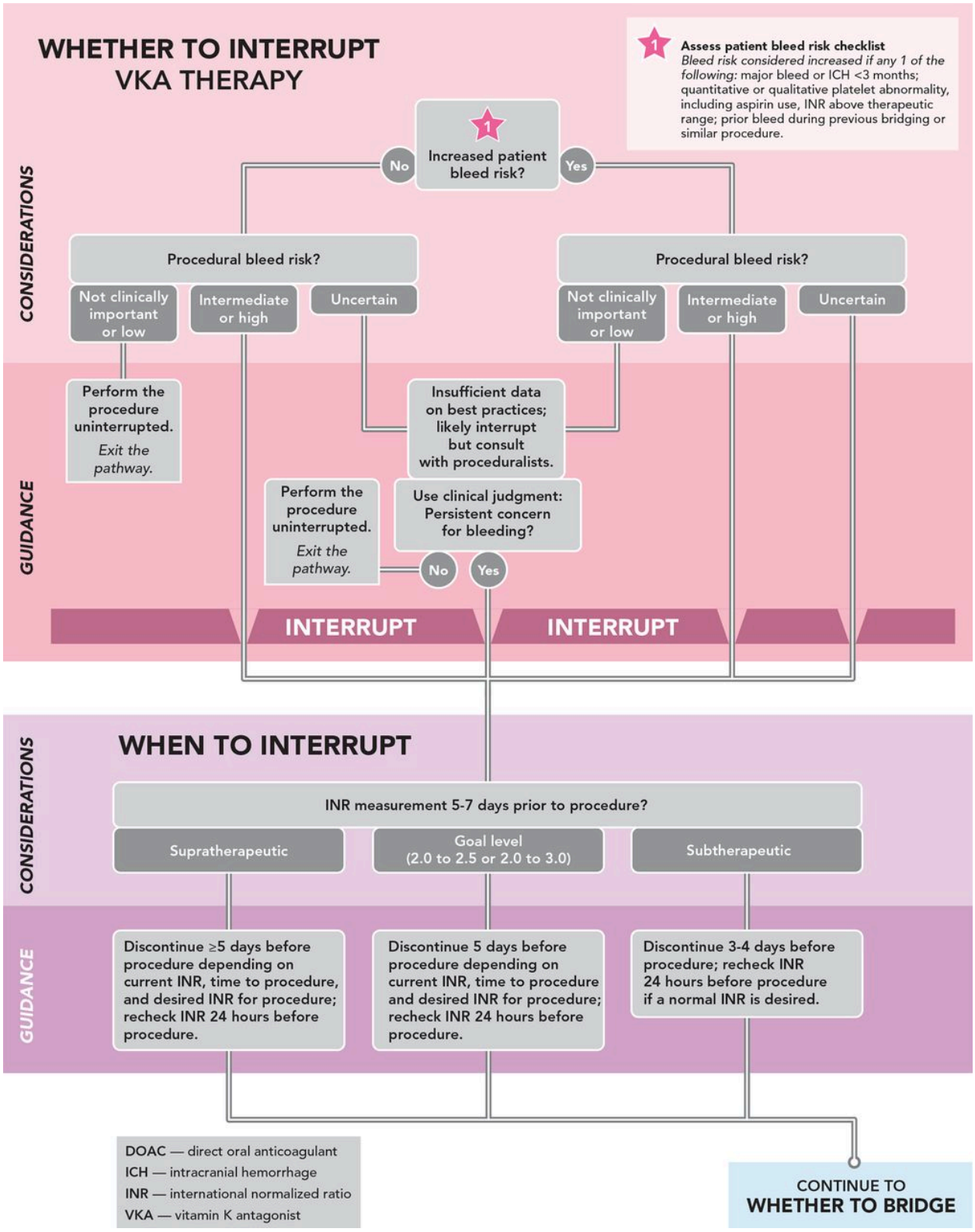
10. Which of the following factors may increase thrombotic risk for a patient?
a) Diabetes Mellitus
b) Vascular Disease
c) Female
d) All of the above
Answer: **D**

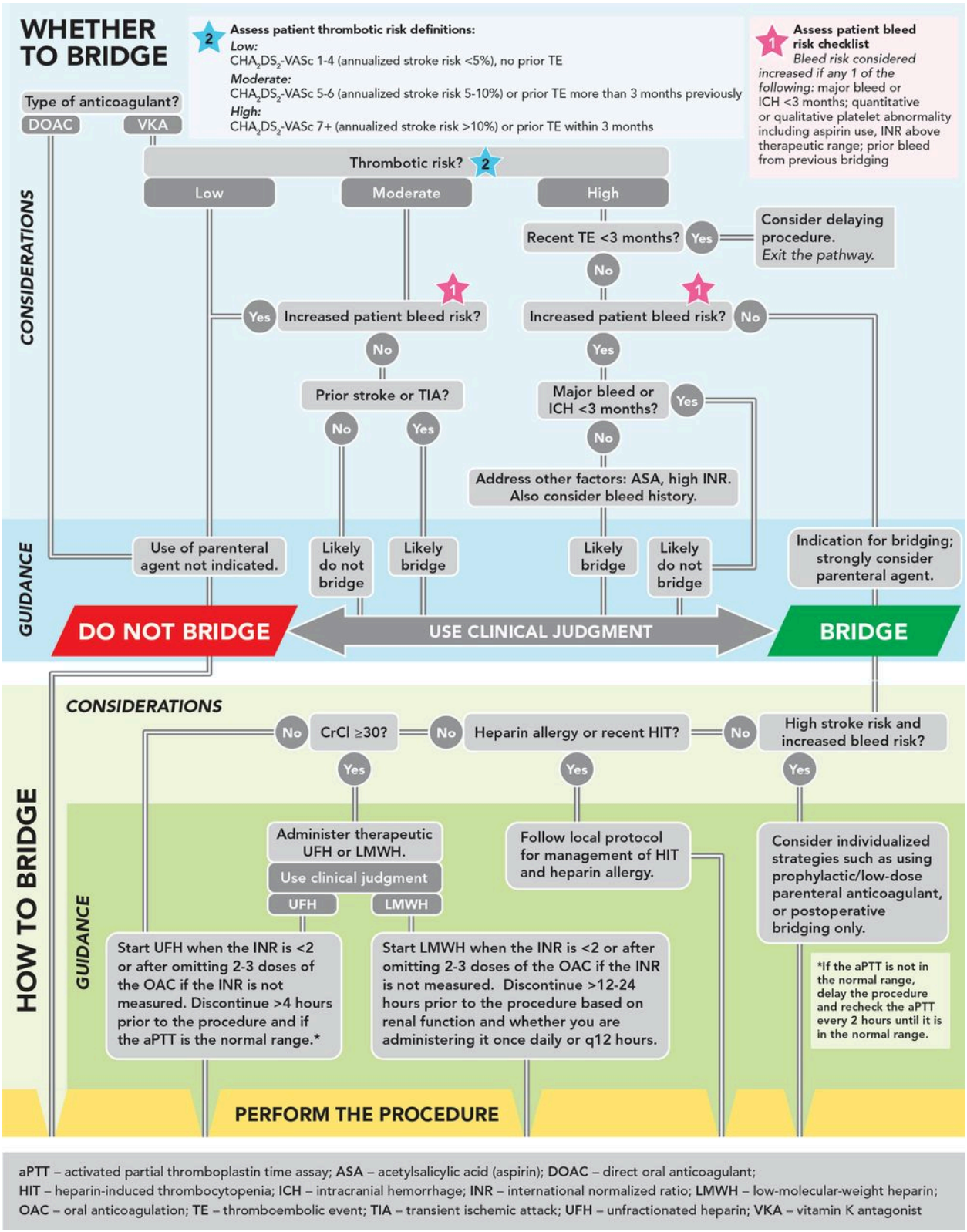
Appendix C

2017 Periprocedural Management of Anticoagulation Pathway (PMAC) Decision Algorithm

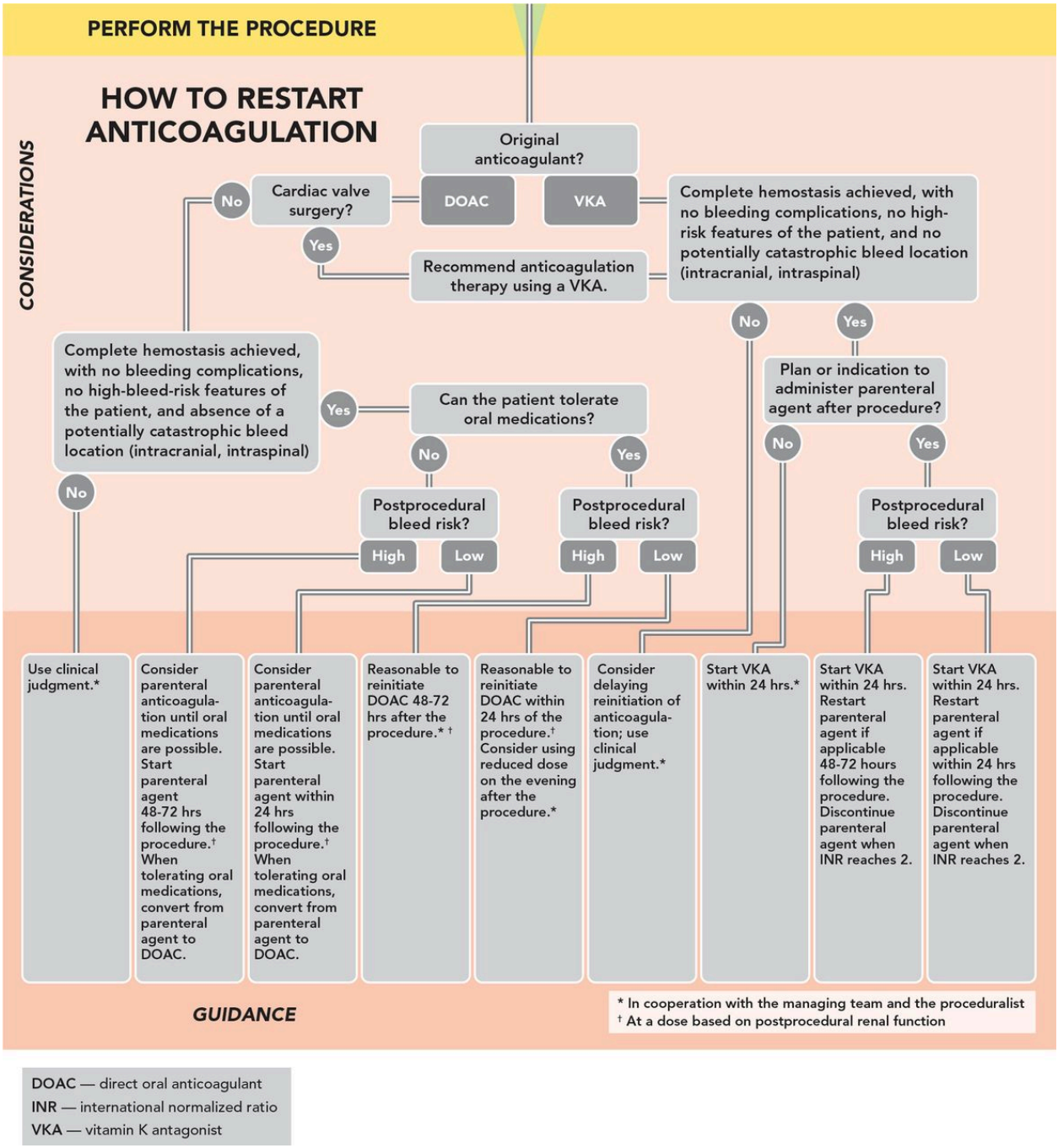


CrCl = creatinine clearance; DOAC = direct oral anticoagulent; DTI = direct thrombin inhibitor
FXa = factor Xa; INR = international normalized ratio; VKA = vitamin K antagonist


WHETHER TO INTERRUPT VKA THERAPY
1 Assess patient bleed risk checklist
Bleed risk considered increased if any 1 of the following: major bleed or ICH <3 months; quantitative or qualitative platelet abnormality, including aspirin use, INR above therapeutic range; prior bleed during previous bridging or similar procedure.
CONSIDERATIONS
1 Increased patient bleed risk?
No
Yes
Procedural bleed risk?
Not clinically important or low
Intermediate or high
Uncertain
Procedural bleed risk?
Not clinically important or low
Intermediate or high
Uncertain
GUIDANCE
Perform the procedure uninterrupted. Exit the pathway.
Insufficient data on best practices; likely interrupt but consult with proceduralists.
Perform the procedure uninterrupted. Exit the pathway.
Use clinical judgment: Persistent concern for bleeding?
No
Yes
INTERRUPT
INTERRUPT
WHEN TO INTERRUPT
CONSIDERATIONS
INR measurement 5-7 days prior to procedure?
Supratherapeutic
Goal level (2.0 to 2.5 or 2.0 to 3.0)
Subtherapeutic
GUIDANCE
Discontinue ≥5 days before procedure depending on current INR, time to procedure, and desired INR for procedure; recheck INR 24 hours before procedure.
Discontinue 5 days before procedure depending on current INR, time to procedure and desired INR for procedure; recheck INR 24 hours before procedure.
Discontinue 3-4 days before procedure; recheck INR 24 hours before procedure if a normal INR is desired.
DOAC — direct oral anticoagulant
ICH — intracranial hemorrhage
INR — international normalized ratio
VKA — vitamin K antagonist
CONTINUE TO WHETHER TO BRIDGE



aPTT – activated partial thromboplastin time assay; ASA – acetylsalicylic acid (aspirin); DOAC – direct oral anticoagulant; HIT – heparin-induced thrombocytopenia; ICH – intracranial hemorrhage; INR – international normalized ratio; LMWH – low-molecular-weight heparin; OAC – oral anticoagulation; TE – thromboembolic event; TIA – transient ischemic attack; UFH – unfractionated heparin; VKA – vitamin K antagonist



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Appendix D
CHA2DS2-VASc
Scoring System

Abbreviation	Risk Factor	Points
C	Congestive Heart Failure (LVEF<40%)	1
H	Hypertension	1
A	Age≥75 years	2
D	Diabetes Mellitus	1
S	Stroke/TIA or systemic embolism	2
V	Vascular Disease	1
A	Age 65-74 years	1
Sc	Sex category (female)	1

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Appendix E
HAS-BLED
Scoring System

HAS-BLED

Letter	Clinical Characteristic	Points
H	Hypertension	1
A	Abnormal Liver or Renal Function	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INR	1
E	Elderly (age > 65)	1
D	Drugs or Alcohol	1 or 2
Maximum Score		9

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Appendix F

Patient Anticoagulant Management (PAM) Protocol Compliance Checklist

Was the PAM protocol utilized during surgical clearance visit?

- ☐ Yes
- ☐ No

Signature: _____ Title: _____

Date: _____