WARFARIN USE AMONG PATIENTS OVER THE AGE OF 65 TO TREAT ATRIAL FIBRILLATION: IS FALL RISK A FACTOR IN THE DECISION-MAKING PROCESS?

A Systematic Review

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Trisha Meyers

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Committee Chair

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ABSTRACT
OF
WARFARIN USE AMONG PATIENTS OVER THE AGE OF 65 TO TREAT ATRIAL
FIBRILLATION: IS FALL RISK A FACTOR IN THE DECISION-MAKING PROCESS?

A SYSTEMATIC REVIEW

By

Trisha Meyers

Statement of Problem
The percentage of people over the age of sixty-five diagnosed with the cardiac condition Atrial Fibrillation (AF) is rising, consequently increasing the risk of cerebral vascular accidents. The current recommendation for treatment of AF is warfarin, a vitamin K antagonist or anticoagulant. As age increases, the risk of falls increase among those over the age of 65, and warfarin use increases the risk of morbidity and mortality. What is the current standard of practice in the decision-making process regarding prescribing warfarin in patients over the age of 65 with AF and at risk for falls?
Sources of Data
Four electronic databases were searched including EBSCO Host, CINAHL, PubMed and Google Scholar for peer-reviewed research articles between the years 2006 and 2012. Key concept terms entered into the database included MeSH terms “atrial fibrillation,” “anticoagulant,” “warfarin,” “decision-making,” “aged,” “aged over 65,” “falls,” and “accidental falls.”
Conclusions Reached
This systematic review was inconclusive. The sample of research was heterogeneous and lacked transparency among the studies. This systematic review identifies areas in need of further research regarding decision-making for treatment with warfarin for Atrial Fibrillation among people over the age of 65, who are at risk for falls. Clearly, additional research must be conducted and educational tools developed prior to establishing an evidenced-based guidelines or recommendations. Health literacy, a Healthy People 2020 goal, should be the foundation in assessing and collaborating care to maintain the four pillars of the Hippocratic Oath in medicine.

Dr. Karen McGurk
Committee Chair

Date 7/31/13
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INTRODUCTION

The definition of “a good life,” remains a timeless question. Is “a good life” defined by the number of days lived or the quality of those lived days? This philosophical question challenges multiple disciplines on many different levels and clearly, there is no one right answer. As science and medicine continue to develop resources making it possible to keep people alive for a larger quantity of days, it is imperative that the healthcare community remain mindful of integrity and steadfast in the effort to ensure the quality of one’s increased number of days is held in equal regard.

The date of January 1, 2011 was significant in America as it marked the day that the baby boomer generation first began to turn sixty-five years of age. The baby boomer generation accounts for an estimated 78 million people, and throughout their history, they have had a significant influence on society. As baby boomers continue to move into retirement, their greatest impact in the areas of healthcare and healthcare costs has yet to be seen. According to the Department of Health and Human Services Administration on Aging (AOA), in the year 2000, the population of people over the age of sixty-five was 35 million, and the projected number for the year 2030 is expected to be greater than double that number—an estimated 72 million people ("Profile on aging," 2011).

As the number of older persons is expected to rise, so are the number of injuries due to accidental falls. It is estimated that every year, one in three people over the age of 65 will fall. In addition to the pain and suffering experienced after a fall, the Centers for Disease Control (CDC) reports that the medical costs directly incurred from falls was 30 billion dollars in the
Many of the factors that increase the risk of falling coincide with the normal aging process. Robnett (2010) identified multiple age-related risk factors including sensory changes, visual changes, auditory changes and changes in perception, as well as physical changes such as decreased range of motion and muscle strength and a decrease in endurance and reaction time. The highest percentage of fatal outcomes following an accidental fall includes traumatic brain injuries (TBI) and injuries affecting the lower extremities, particularly among those persons taking anticoagulants. These injuries cause the greatest mortality and incur the highest costs (Stevens, 2006).

The most commonly sustained cardiac arrhythmia-affecting people over 65 is atrial fibrillation (AF) (Abel Latif, Peng, & Messinger-Rapport, 2005). Atrial fibrillation is described as an irregularly irregular rhythm caused by chaotic electrical activity in the atrium of the heart, resulting in a heart rate of up to 600 beats per minute, and is an independent risk factor for stroke (Berry & Padgett, 2012). Currently, it is estimated that AF affects approximately 2.5 million people in the United States and it is predicted that by the year 2050, AF will affect as many as 16 million people (Friedman & Holmes, 2011). When the diagnosis of AF is made, a patient must understand complex pathophysiology and electrophysiology in order to understand the risks and benefits of treatments available.

As pharmaceutical and technological advances in medicine allow people to live a greater number of days or even years, the question of “a good life” is more relevant than ever before. In addition to familiarity with new medical treatments and anticoagulation medications available to
treat AF, particularly warfarin, it is essential that healthcare professionals assess patients’ understanding of treatments and provide comprehensive education prior to decision-making regarding a plan of care. This is particularly true for vulnerable populations including the elderly. Standard procedures in medicine and in treatments offered today require all persons to have informed consent, which includes the potential negative effects that treatments may have on quality of life. Healthcare providers must be equally skilled in the art of communication as they are in the art of medicine. A strong patient-practitioner relationship requires direct and honest communication with patients as well as a sense of honor for personal values in the decision-making process. It is not uncommon in science for the pendulum to swing in opposite directions before coming to a comfortable stop. In the case of warfarin, at first scientists believed it was too dangerous for human consumption, and now warfarin is commonly prescribed for people well into their nineties. The net benefits must exceed the risks of using warfarin in people over the age of 65 prior to prescribing it.

Currently, there are no evidence-based practices in place to assess the level of understanding or lack thereof among patients diagnosed with AF, in regards to treatment options and the net risks versus benefits. This systematic review aims to examine current literature and to evaluate standards of practice among healthcare practitioners in regards to decision-making concerning warfarin use in the treatment of AF for people over the age of 65 who are at an increased risk of falls.
THE PROBLEM

Background

The science of medicine is based on the four pillars of the Hippocratic Oath, which include beneficence, nonmaleficience, justice, and respect for autonomy. Physicians in the United States of America continue to take a pledge to honor these principles prior to entering into the practice of medicine. The effort to incorporate these principles remains vital in the treatment of patients seeking medical care. However, upholding these principles often presents a challenge to healthcare providers. It seems an inverse relationship now exists in medicine: as the complexity of medical treatments and medications available to treat disease goes up, the understanding of the net risks and benefits goes down. Along with this inversion, the capacity for the patient to make an informed decision becomes more complicated.

One common condition that healthcare providers frequently encounter is atrial fibrillation (AF). It is the most common cardiac arrhythmia affecting the elderly population. When the heart is in the abnormal rhythm of AF, a person has 6 times the risk of having a stroke than a person in a normal sinus rhythm (Keller, Sabatino, Winland-Brown, & Porter, 2011). Currently, the prevalence of AF is estimated to affect approximately 2.5 million people in the United States with costs estimated at $8 billion dollars annually (Amin, 2012). Sellers (2011) reports that as age increases, the risk of AF also increases with 5% of diagnoses occurring in people under the age of 65 to an estimated 23.5% in people in the 80-90 age range. The incidence of AF is
approximately 1.5 greater for men than for women and the onset typically occurs at a later age in women (Bajpai, 2007).

Although much of the etiology is still unknown for AF, Keller (2011) reports underlying heart disease including cardiomyopathy, valvular heart disease, atrial septal defects, heart failure and hypertension are some of the primary causes of AF. In addition to the cardiac risk factors, other non-cardiac risk factors that can precipitate AF include diabetes, electrolyte depletion, smoking, use of drugs and alcohol, obstructive sleep apnea and thyroid dysfunction (Berry & Padgett, 2012). Bajpai (2007) reports the instances of AF without any known risk factors accounts for approximately 12-30% of AF patients.

The pathophysiology of AF is due to abnormal conduction of electricity in the atrium of the heart. This abnormal heart rhythm or arrhythmia is caused by the pacemaker cells of the atrium firing up to 600 beats per minute (Berry & Padgett, 2012). It is the role of the atrio-ventricular (AV) node to block the majority of these impulses from reaching the ventricles thereby, protecting the ventricles. However, as many as 200 beats may pass down into the ventricles compared to a normal rate of 60-70 beats (Cottrell, 2011). This irregular ventricular rhythm will result in an irregular pulse rate and an irregular ventricular rate on an electrocardiogram (EKG) (Berry & Padgett, 2012).

The fibrillating upper atria of the heart cause a decreased cardiac output, which may result in the symptoms that the patient may complain about with AF (Keller et al., 2011). Some of the common symptoms that patients experience that cause them to seek medical care include
palpitations, dizziness, and shortness of breath. All of these symptoms may precede or cause a person to have a syncopal episode (Keller et al., 2011). Often people have no symptoms of AF. It is not until they have a cerebral vascular accident (CVA) or stroke that the diagnosis of AF is made.

Some differential diagnoses that may be discovered during the work-up for these symptoms include dysrhythmia, anxiety, panic attacks, valvular disorders, as well as neurologic causes of syncope (Keller et al., 2011). Some of the general recommendations from a cardiology standpoint for the work-up of AF include an electrocardiogram (EKG), a thorough physical examination, laboratory studies, chest x-ray, and in the event of syncope, a tilt-table test may be performed.

People diagnosed with AF are further differentiated into three classifications that include paroxysmal atrial fibrillation, persistent atrial fibrillation, and permanent atrial fibrillation (Cottrell, 2011). Paroxysmal atrial fibrillation is short in duration (less than 7 days) and is self-terminating. Persistent atrial fibrillation lasts greater than 7 days and either self-terminates or is medically or electrically cardioverted. The third classification is permanent atrial fibrillation, which is based on failure to convert to normal sinus rhythm and lasts for greater than one year (Cottrell, 2011).

The risk of AF becoming more frequent and lasting for longer periods of time is caused by changes that the heart makes through remodeling, making it more difficult for the heart to return to a normal sinus rhythm. The turbulent blood flow in the heart places a person at great
risk for developing an embolus that can travel to the brain and cause a stroke. The Seventh American College of Chest Physicians (ACCP), the American College of Cardiology/American Heart Association/European Society of Cardiology (ACC/AHA/ESC) and the American Geriatric Society all have guidelines recommending the use of warfarin or aspirin to prevent stroke in patients with atrial fibrillation (Garwood & Corbett, 2008).

The three primary goals of treating AF include preventing a thromboembolic event, controlling the ventricular rate, and controlling the rhythm (Kalus, 2010). In an effort to identify the risk of a thromboembolic event, use of the acronym CHA$_2$DS$_2$-VAS$_c$ is recommended by the American College of Chest Physicians. Point values are assigned to each letter in the acronym, which adds to a value and determines low, moderate and high stroke risk and correlates to a medication recommendation. Using the CHA$_2$DS$_2$-VAS$_c$ scoring system, the pharmacological recommendations are as follows: patients with a score of zero are considered a low stroke risk with the recommendation to take an aspirin 75 mg to 325 mg; patients with a score of 1 are recommended to take either aspirin or warfarin, also referred to as a vitamin K antagonist (VKA); treatment with warfarin or a VKA is the recommendation for any patients with a score of 2 or greater (Guyatt, Akl, Crowther, Gutterman, & Schuunemann, 2012).

The acronym and point value of the CHA$_2$DS$_2$-VAS$_c$ score is as follows: 1 point is earned for congestive heart failure (C), 1 point for hypertension (H), 2 points for age greater than 75 years of age (A), 1 point for diabetes mellitus (D), 2 points for having had a prior stroke (S) or transient ischemic attack, 1 point for history of vascular disease (V), 1 point for age (A) 65-74
and finally, 1 point for being female (S). This risk stratification system recommends warfarin use with a score of 2 points. For example, a patient without serious medical comorbidities, using this risk stratification system would earn 1 point for being a woman and 2 points for being 75 years of age, totaling 3 points. This score would place the individual at moderate-high risk for having a stroke and the recommendation would be warfarin use.

Secondary studies of the original cohort of Boston University’s Framingham Heart Study report a five-year stroke risk after a diagnosis of atrial fibrillation of 5% to 78% depending on associated risk factors (Kannel & Benjamin, 2008). Researchers agree that outcome measures vary among studies; however, one review of current literature estimates quality-adjusted life expectancy based on different treatments. The study reported treatment with warfarin would add 12.9 years, aspirin therapy would add 11.17 years and taking no medication at all would add 10.15 (Man-Son-Hing, Nichol, & Lau, 1999). This result is a net gain of 2.75 years versus 1.02 in treating with warfarin versus aspirin respectively. Notably, a New York state study, which included 49,464 people treated for a fall, revealed that participants on long-term anticoagulant therapy had a 50% increase in intracranial hemorrhage and a 57% increase in death (Pieracci, Eachempati, Shou, Hydo, & Barie, 2007). It is essential that these statistics be considered and evaluated with patients prior to the decision-making process of prescribing warfarin in people over the age of 65.

A wide range of chronic health problems exist among people in the over 65-age category as does the literature pertaining to this topic. A literature review, performed by Man-So-Hing in
1999, reported that a person would have to fall greater than 300 times for warfarin not to be an effective treatment for stroke prevention. This statistic is cited in the literature approximately 159 times even though the article clearly states that there were significant weaknesses presented in the reviewed studies (Man-So-Hing, 1999).

Every day emergency departments treat patients as a direct result of having an accidental fall. Elderly people are more prone to falls. Estimates report that one in every three persons 65 and older will fall every year (AOA, 2011). As warfarin use increases in the United States, emergency rooms are treating more patients with more severe injuries including intracranial bleeding secondary to falls. According to researchers, the number of deaths caused by falls among the elderly doubled between the years 2000 and 2010 (Chisholm & Harruff, 2010). The study reported that incidence of death directly caused by a head injury was four times greater in the anticoagulated group of elderly fall victims than was observed in those that were not treated with anticoagulants (Chisholm & Harruff, 2010).

Garwood (2008) reports many of the current medical management guidelines for the treatment of patients over the age of 65 with AF are based on expert consensus, and are not supported by clinical research. Fall risk is not recognized as a factor. However, Dharmaragan (2006) presented a standardized case scenario to 107 physicians measuring prescribing practices. The physicians in the study overwhelmingly agreed not to prescribe long-term anticoagulation therapy naming fall risk as the primary reason.
In addition to the decision to use warfarin, the risks and benefits of warfarin use must be discussed openly and honestly with patients. A baseline measurement tool should be used to assess understanding. Standardized educational programs and tools appropriate for people over the age of 65 as well as for family members and caregivers are essential to a successful therapeutic regimen with warfarin. Clearly, there is a gap in the research pertaining to warfarin use in those over 65 years of age, and further evaluation of the literature is essential prior to the development of standardized treatment protocols.

**Concepts, variables, phenomena**

Warfarin was discovered in the 1930s by a group of agricultural scientists searching for a cause of death among herds of cattle in Canada. The scientists Karl Paul Link and Harold Campell of the University of Wisconsin identified a substance named dicoumarol produced by a mold growing on sweet clover feed as the cause of death among the cattle. Scientists broke dicoumarol down further into warfarin and named it using the initials of the scientists’ funding agency, Wisconsin Alumni Research Fund (McAlister, 2006). Initially, the anticoagulant was determined to be too dangerous for human consumption and the only use was as a pesticide to eliminate rodents. Interestingly, this belief changed in 1955 when one of the first heart attack patients treated with warfarin was President Dwight Eisenhower (McAlister, 2006).

Even though doctors have used warfarin for over fifty years, it continues to have a black box warning and is listed in the top ten drugs with adverse reactions (Gulseth, Grice, & Dager, 2009). One of the difficulties working with the drug is its very narrow therapeutic window.
Established in the late 1990s, a universal measurement called the International Normalized Ratio (INR) attempted to help prescribers gain tighter control on use of the drug in an attempt to eliminate major unexpected bleeding events. Additionally, the Human Genome Project helped to identify specific genetic markers that cause an increase in sensitivity to warfarin as well as to identify differences within different ethnic groups that often require lower dosing of the drug (Gulseth et al., 2009).

With advancing age comes the breakdown of a body’s normal physiology and defense mechanisms and can result in disease. As the scientific community better understands the process of disease, new medications are developed to assist people to live longer lives. This often requires the use of multiple medications (polypharmacy) that may require careful monitoring. A common problem with taking multiple medications is the multiple drug-drug and adverse reactions that can occur. Many drugs interfere with warfarin making it difficult to establish a therapeutic INR, which increases the risk of bleeding. Some of the difficulties in managing stable INR’s within the recommended range of 2.0 – 3.0 are the many food and drug interactions that can alter the effectiveness of the anticoagulation properties making the drug less effective for stroke prevention or more likely to cause bleeding and death. Often people over the age of 65 are on a fixed income and have limited means for obtaining food. The use of warfarin requires a steady state intake of vitamin K to maintain a therapeutic warfarin level. If people have limited control of the meals they eat, it may make their medication regimen difficult to manage. In addition, the amount of alcohol a person drinks is an important factor in prescribing
and managing warfarin both because of the way the drug is metabolized in the liver as well as alcohol’s effects on the lining of the gastrointestinal tract increasing the risk for bleeding.

In addition to the difficulties managing a therapeutic INR, lack of patient education is cited numerous times in the literature as a significant risk factor potentially increasing complications and difficulties in managing bleeding risk among older patients (Pautas, Gouin-Thibault, Debray, Gaussem, & Siguret, 2006). However, several models have been developed to help in assessing the bleeding risk including HAS-BLED, Outpatient Bleeding Risk Index, HEMORR2HAGES and the ATRIA risk score. The five variables included in all the models are age greater than 75, prior bleeding, hypertension, anemia, and renal disease (Fang et al., 2011). Other variables that are important but not necessarily included in scoring are alcohol intake, prior malignancy, polypharmacy, and low platelet count or function (Lip, Frison, Halperin, & Lane, 2011). Studies have also found that the risk of bleeding increases over the course of the drug use, with an estimated risk of 2-3% at one month’s time and 12-22% at two years’ time (Gulseth et al., 2009).

The increased risk of falls secondary to polypharmacy among the aged is of great concern. Studies have shown that the risk for falling increases in proportion to the number of medications taken. The side effects of many medications include dizziness, sedation, hypoglycemia and orthostatic hypotension, which increase the risks of falls. Medications that pose a significant risk include laxatives, diuretics, benzodiazepine derivatives and anticholinergic medications (Sergi, De Rui, Sarti, & Manzato, 2011).
In addition to polypharmacy, environmental factors increase the risk of falling. With the addition of visual and hearing deficits affecting the elderly, this risk is increased. Intrinsic factors are other factors that may cause someone to fall. Some intrinsic factors include chronic medical conditions, general weakness, poor balance, and dementia.

Problem Statement and Research Question

The purpose of this systematic review is to examine multiple sources of quantitative and qualitative literature to assess current practices in healthcare as it relates to the decision-making process of prescribing long-term anticoagulation therapy in people greater than 65 years of age, who are diagnosed with atrial fibrillation and are at risk for falls. A systematic review was chosen in an effort to evaluate current literature and to identify current treatment practices in regards to warfarin. With the evidence ascertained from this systematic review, recommendations will be suggested, protocols developed, and recommendations for future research.

Significance to Nursing

Successful treatment of AF in the over 65 years of age population presents many challenges and nurses stand on the frontlines protecting this vulnerable population. Nurses act in a variety of ways both in front of and behind the scenes in orchestrating successful warfarin use among patients. This includes the area of education, laboratory monitoring, and medication management. Nurses also facilitate caring for patients and their families after a catastrophic event secondary to warfarin use, including gastrointestinal bleeding or bleeding in the brain. As
Advanced Practice Nurses (APN’s) take a more active role in caring for the growing elderly population, it is essential that the best possible care be provided and appropriate decisions made.

As technological advancements and complex procedures are continuously developed in medicine, it is vital that healthcare providers uphold the principles of the Hippocratic Oath. Excellent communication skills are necessary to achieve this goal. The profession of nursing often acts as the go-between, between the doctor and the patient, deciphering information and interpreting complicated medical jargon. It is essential that doctors and APNs have a strong foundation in the art of communication to provide information and education to patients on the risks, benefits, and inconveniences of the available treatment options keeping in mind the importance of quality of life. Estimates predict that warfarin use increases the quality adjusted life years by 23% in persons 65 years-old in atrial fibrillation but only increases the quality adjusted life years by 4% in a 100-year-old (Dharmarajan, Varma, Akkaladevi, Lebelt, & Norkus, 2006). It is equally important to assess a person’s baseline quality of life prior to the use of warfarin and additionally, weigh the risks and benefits of therapy. The goal of safety continues to be significant in nursing today in the care of all people, but particularly the elderly. Promoting proper education and taking the time to identify goals and create individualized patient care plans helps create a sense of empowerment among the elderly.

Fraenkel (2011), in a study on AF decision-making process, reported that many patients had difficulty understanding how something that was wrong with their heart could potentially cause a problem with their brain. According to the United States Department of Education’s
2003 survey, “Adults aged 65 and older had the lowest average prose, document, and quantitative literacy” (Stableforth, 2010, p. 375). It is the responsibility of healthcare providers to be knowledgeable about health literacy and have resources to meet the needs of adults aged 65 and older as education is essential both for the basic understanding of the diagnosis as well as for treatment compliance. Health literacy must be addressed prior to decisions being made. Healthcare providers must receive standardized training in communication skills and must be direct, honest and facilitate decision-making that incorporates a patient’s values into the process to ensure the best quality of life for the patient. This is an important aspect in the development of a strong patient-practitioner relationship. This can be done by first discussing the risks versus the benefits of treatments and medication use and second, in respecting the patient’s choice.
SEARCH STRATEGY

The conceptual framework for this systematic review is in accordance with the recommendations of the Cochran Collaboration. Formerly known as Quality of Reporting of Meta-analyses (QUOREM), The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) is one of the many guidelines listed in the Cochrane Library’s Methodology Register (Liberati et al, 2009). PRISMA is useful when conducting a systematic review, particularly when reviewing non-randomized studies as it helps maintain transparency of the review (Glaros, 2003). It is the guideline chosen for this systematic review.

Following this formula, the evidence obtained from a literature search of the following electronic databases: EBSCO Host, CINAHL (cumulative index to nursing and allied health literature), PubMed and Google Scholar. The concept terms entered into the database included MeSH terms “atrial fibrillation,” “anticoagulant,” “warfarin,” “decision-making,” “aged,” “aged over 65,” “falls,” and “accidental falls.”

The search of the databases and reference lists identified 12,789 articles published between the years 2006 to 2012 using concept terms. Limiting the search using the five key concept terms of “atrial fibrillation,” “warfarin,” “aged,” “falls,” and “decision-making” into the search database resulted in only one article written in 2006 by Dharmarajan. Articles were removed if they were duplicate articles, non-research articles, or published in other countries. Twenty-four articles remained and reviewed for content. Several articles were excluded based on content, as many articles were not research, but rather summaries of other studies offering
recommendations for clinical protocol and management guidelines. Two articles were excluded because they were not peer-reviewed. The total studies that qualified for this systematic review includes three qualitative research study and three quantitative studies. These articles best incorporated the key concepts related to people over the age of 65 at risk of falls, being treated with warfarin for atrial fibrillation and identified the concept of decision-making, either on the behalf of the physician or the patient, as a relevant factor.
# of records identified through databases: EBSCO Host, CINAHL, PubMed and Google Scholar

- "atrial fibrillation" - 8,814
- "AF" + "warfarin" - 972
- "AF" + "warfarin" + "aged" - 416
- "AF" + "warfarin" + "aged" + "falls" - 11
- "AF" + "warfarin" + "aged" + "falls" + "decision-making" - 1

# of additional records identified through other sources: 13

# of records excluded: 40

Articles excluded include those that are not scientific research, did not meet inclusion criteria, not peer-reviewed, editorials, and clinical protocols

# of records screened: 64

# of full text articles assessed for eligibility: 24

# of studies included in qualitative synthesis: 3

# of studies included in quantitative synthesis (meta-analysis): 3
THE SAMPLE

Selection Criteria

i. Inclusion

The EPICOT system was used for presenting the inclusion criteria as part of the structure in the systematic review. This acronym is broken down into the following sections: evidence, population, intervention, comparison, outcomes, and time stamp. The evidence derived from the databases EBSCO Host, CINAHL, PubMed and Google Scholar and included the “snowball technique” of reviewing the reference lists of articles for completeness. Studies were eligible if they were written in the English language. Additional inclusion criteria required the studies be either qualitative or quantitative and required that they be reproducible. The population criteria include males and females of any ethnicity over the age of 65. Other inclusion criteria included a diagnosis of atrial fibrillation, recommended treatment with warfarin and discussion of the decision-making concerning the risk of falls. Any clinical setting was included in this review.

The intervention in these research studies is warfarin use as treatment for AF. No placebos were used in the studies. Comparisons vary among the research studies and included identifying significant events that occurred during the treatment period, prescribing recommendations among physicians on case presentations and patient’s opinions on the development of a tool for decision-making. The outcomes included no change of treatment, significant patient events and withholding warfarin use. The time stamp will be research articles published from 2006 through 2012.
i. **Exclusion**

For this systematic review, studies were excluded if they were unpublished or if they were informally published referred to as grey literature. Research that was not written in the English language was also excluded. In addition, all articles published prior to the year 2006 were excluded.

**Strengths and Limitations of the Sample**

The most significant strength of the sample research articles is that they bring to light the significance of decision-making and the need for further research and tools. The primary goal of systematic reviews are to gather evidence to formulate guidelines and recommendations that practitioners can take back to their patients to provide the highest level of care. Identifying areas in need of research and development is the foundation to improving healthcare and providing quality care. An additional strength of the sample was the inclusion of patients in the oldest-old category, who typically do not qualify for clinical research studies.

The limitations of the sample in this systematic review are many. A commonly cited and critical limitation of the sample in this systematic review was the lack of transparency among the research studies. Another limitation of the sample is its heterogeneity or rather the variation among the studies selected. Bartolucci (2010) recommends attempting to identify the differences and measuring the heterogeneity of a sample prior to doing a meta-analysis to ensure transparency. Additionally, two of the six studies selected in this proposal were retrospective cohort studies. This type of study extracts information from data already collected and then
researchers choose what they wish to include as well as what they wish to exclude. A negative aspect of this process is that it can exclude some valuable data that may change the results of the study or make the evidence less meaningful (Man-Son-Hing, Nichol, & Lau, 1999). Multiple confounding variables such as blood pressure measurements, polypharmacy with over the counter medications such as aspirin or non-steroidal anti-inflammatory medications, and history of alcoholism were not reported in the research studies and can greatly skew results. Other confounding variables excluded from the majority of the research was the stability of the INR level, length of time in AF as well as the level of health literacy of the patient regarding warfarin use. Studies show that the highest level of adverse effects, and unexpected bleeding events occur within the initial phase of warfarin use and these studies were conducted primarily on patients who have been managed on warfarin within the two to three year window and have close INR monitoring that is maintained within the tight therapeutic range of 2-3 (Jacobs, 2008). These factors are critical to maintain transparency of the research studies and may negatively affect the reported results.

The exclusion criteria in this systematic review created limitations. Of the six research studies presented, only one was done outside of the United States. Expanding the number of databases to include more European research studies may have been of value. Publication bias was also a limitation in this study. A false sense of security may exist when grey literature is excluded. This false sense is the belief that because a research study made it to publication it equals quality evidence. Research studies with negative results or inconclusive results often don’t make it to publication, and unfortunately, these studies could provide valuable evidence.
and prove statistically significant when combined with other research using a disciplined approach such as a systematic review (Bartolucci, 2010).
QUALITY APPRAISAL

Systematic reviews are unique as they can be reproduced and verified through the specific methodical approach defined by the author (Polit & Tatano Beck, 2012). They are of great benefit to the healthcare community as a way to compare and evaluate large amounts of data and attempt to make sense out of it and siphon off the best evidence (Glaros, 2003). In an effort to develop evidenced-based practice (EBP), it is essential for healthcare to have a grading scale to evaluate research and identify bias and poor study design. David Sackett, MD, a strong advocate of developing evidenced-based practice, developed a level-of-evidence model as a grading system to evaluate the strength of research (Glaros, 2003). Sackett’s Level of Evidence Table was used to grade the evidence for this review.

Figure 2: Sackett’s Levels of Evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Systematic Review of Randomized Controlled Trials (RCTs)</td>
</tr>
<tr>
<td>1B</td>
<td>RCTs with Narrow Confidence Interval</td>
</tr>
<tr>
<td>1C</td>
<td>All or None Case Series</td>
</tr>
<tr>
<td>2A</td>
<td>Systematic Review Cohort Studies</td>
</tr>
<tr>
<td>2B</td>
<td>Cohort Study/Low Quality RCT</td>
</tr>
<tr>
<td>2C</td>
<td>Outcomes Research</td>
</tr>
<tr>
<td>3A</td>
<td>Systematic Review of Case-Controlled Studies</td>
</tr>
<tr>
<td>3B</td>
<td>Case-controlled study</td>
</tr>
<tr>
<td>4</td>
<td>Case Series, Poor Cohort Case Controlled</td>
</tr>
<tr>
<td>5</td>
<td>Expert Opinion</td>
</tr>
</tbody>
</table>
Based on Sackett’s Level of Evidence Table, the studies for this systematic review were primarily retrospective cohort studies meeting the criteria for 3B, four and/or five grade evidence. Retrospective cohort studies and observational studies attempt to extract existing data and attempt to evaluate it. The nature of doing research on human subjects, particularly those over the age of 65, make it difficult to do randomized controlled trials or prospective studies particularly due to the ethical considerations.
CONCLUSION

Evidence Related to Research Question

The results of this systematic review are inconclusive in deciphering a clear-cut answer to the question of whether or not to prescribe warfarin to patients at risk for falls. However, this systematic review does highlight critical areas in need of further research. Several barriers were identified in regards to optimal warfarin use among elderly patients including barriers with patient, the physician and the healthcare system. The studies chosen in this systematic review also stressed the need for improvement and the significance of this growing problem.

Using the PICO (population, intervention, comparison, outcomes) formula, the six studies chosen for this review shed light to areas in clinical practice that may not be in accordance with current recommendations. Jacobs (2009) reports that under-prescribing of warfarin is a significant problem. Her research reports estimates of warfarin use may be as low as 41% in the elderly population who may benefit from the drug (Jacobs, Billett, Freeman, Dinglas, & Jumaquio, 2009). However, the research done by Hylek (2007) identifies the difficulties in managing warfarin therapy during the first year of use. This research study reported 81% of patients over the age of 80 had to be taken off the drug, compared to only 37% of patients younger than 80 years old (Hylek, Evans-Molina, Shea, Henault, & Regan, 2007). The study done by DeBreuker (2010) attempted to decipher the specific characteristics among geriatric patients responsible for the under-prescribing of warfarin use among older patients with AF. The results of this study were inconclusive. No statistical significance was found among the variables used in the study (DeBreuker, Herzog, & Pepersack, 2010).
Two of the studies in this systematic review looked specifically at decision-making tools both to educate patients on AF as well as to improve communication between the patient and the practitioner. Fraenkel (2012) identifies the variability of health literacy among the elderly population as a barrier in the development of a standardized tool. Her research also identified a common barrier among patients specifically, when a patient’s preference is not to be involved in the decision-making process for their medical care (Fraenkel, Street, & Fried, 2011).

The management of warfarin therapy in elderly patients comes with a variety of challenges. There is not a one-size-fits-all answer in deciding whether to use warfarin for people over the age of sixty-five, who are at risk for falls. This systematic review clearly identifies the heterogeneous nature of current research surrounding warfarin use to treat AF. Undoubtedly, the gaps in the literature regarding the decision-making process pertaining to warfarin use and the risk of falls among those over age 65 in need of future research.
Implications for Clinical Nursing Practice, Policy, Education, and Research

Systematic reviews are essential for the betterment of healthcare. Quality reviews take large quantities of research, interpret the data, and provide evidence for the development of guidelines and recommendations. Several of the studies reviewed report recommendations based on expert opinion. It is imperative that healthcare professionals do not interpret this as evidence. Expert opinion does not equal evidence. Healthcare practitioners must be able to navigate their way through the literature in order to decipher quality research based on evidence versus one man’s opinion.

Each decade the United States sets goals for Americans under the Healthy People initiative to establish healthy goals and track progress of the health across America. One of the Healthy People 2020 goals is to improve health literacy disparities among people and therefore, to improve equality and quality of accessing necessary medical care among Americans. Healthy People 2020 defines health literacy as "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" (HealthyPeople.gov, n.d.). According to the American Medical Association (AMA), poor health literacy is “a stronger predictor of a person’s health than age, income, employment status, education level, and race” (National Network of Libraries of Medicine, 2012, para. 1).

Warfarin use requires some level of understanding on the part of the patient in order for warfarin to be an effective treatment for AF. This may include having literary skills such as
reading, writing, speaking and computing in a health context. Some of the challenges seniors may face include understanding complex medical vocabulary, understanding laboratory monitoring, being able to read and understand the labels on medications and food labels at the supermarket to comply with dietary restrictions required to maintain a therapeutic level of warfarin. Garwood (2008) reports 21.3% of patients 80 years and older were satisfied with the education they received on their anticoagulation medication regimen. Providing education and assessing health literacy should be at the core of patient-centered care in clinical practice. One of the benefits of education is that it can empower patients to feel more in control of their life as well as more in control of their chronic medical condition.

Healthcare professionals should be well versed in successful aging to facilitate those greater than 65 years of age in reaching their developmental milestones. According to Erikson’s Developmental Theory’s final stage, ‘Ego Integrity Versus Despair,’ the goal of this stage is a greater sense of a fulfillment rather than feelings of despair. Receiving a diagnosis of AF can be frightening to a person and negatively affect their quality of life. Many of the problems that elderly people face can create a domino effect on other areas of their lives. With appropriate education, early recognition and proper intervention the goal would be that some of these negative effects of warfarin use may be avoided. For example, in an effort to assess fall risk, a healthcare practitioner might order a home safety evaluation or physical therapy evaluation prior to prescribing warfarin. This clinical judgment may prove beneficial, but the evidence is not yet there to support a recommendation.
A deficit exists in knowledge and research of people over the age of sixty-five. First, in regards to the pharmacodynamics and pharmacokinetics of warfarin among the elderly and secondly, in regards to educational programs and decision-making tools as it relates to co-directing their medical care alongside their provider. As people are living longer, new questions regarding the risks versus benefits of treatment options and quality of life issues among the elderly population have surfaced. The goal among healthcare professionals and policy-makers must be to enforce recommendations that enhance the safety and well-being of our seniors as well as ensure these policies are in alignment with the four pillars of the Hippocratic Oath.
Does fall risk come into the decision-making process when deciding to use warfarin in the aged (age ≥ 65) patient with atrial fibrillation?

Type of research design
Sample size (actual sample size/Power (1-B = N or value or appears adequate (AA)/Sampling (Probability = P, Nonprobability =NP)

Population characteristics: Confirms representativeness (Yes/No)

Measurement: Questionnaire (Q), Physiologic (P=INR), Semi-structured Interviews (SI), Data Collection Tool (DCT), Other

Replicability of study

Variables: Age, Fall-risk score(FRS), Fall risk other (FRO), decision-making tool (DMT), decision-making process =0 drug (ND), ASA, Warfarin (W), Atrial Fibrillation (AF), Other (O)
### Figure 1: Evidence Table

<table>
<thead>
<tr>
<th>Study #</th>
<th>Research study</th>
<th>Type of Design</th>
<th>Sample Size/Power/Sampling</th>
<th>Confirms Representativeness</th>
<th>Measurement</th>
<th>Replicability</th>
<th>Age</th>
<th>FRS</th>
<th>FRO</th>
<th>DMT</th>
<th>ND</th>
<th>ASA</th>
<th>W</th>
<th>AF</th>
<th>O</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Hylek, et al (2007)</td>
<td>Inception cohort study</td>
<td>N=472/P&lt;0.05</td>
<td>Yes</td>
<td>DCT</td>
<td>Yes</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>4</td>
<td>DeBreuker, et al (2010)</td>
<td>Retrospective observational study</td>
<td>N=768/P&lt;0.05</td>
<td>Yes</td>
<td>DCT</td>
<td>Yes</td>
<td>X</td>
<td>X</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Research study</td>
<td>Type of Design</td>
<td>Statistical analysis</td>
<td>Sacketts' Level of Evidence</td>
<td>Main Aim/Research Question</td>
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<tr>
<td>Dharmarajan, et al (2006)</td>
<td>Case study questionnaire</td>
<td>Student t tests Chi-squared analyses</td>
<td>4/5</td>
<td>A survey questionnaire was distributed to physicians to solicit opinions on the decision to anticoagulate based on an actual case for a LTCF and the results were analyzed.</td>
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<tr>
<td>Hylek, et al (2007)</td>
<td>Inception cohort study</td>
<td>Poisson regression models</td>
<td>4</td>
<td>Aim of study to define tolerability and determine risks of bleeding with warfarin use among an elderly inception cohort with atrial fibrillation</td>
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<tr>
<td>Jacobs, et al (2009)</td>
<td>Retrospective Observational Study</td>
<td>Did not elaborate. All analyses were conducted using SAS version 9.1.</td>
<td>3B</td>
<td>Aim of study was to determine the prescribing patterns, risks, and benefits of anticoagulation with warfarin or acetylsalicylic acid (ASA) in elderly patients with AF at risk for stroke and hemorrhage, including those with falls and/or dementia.</td>
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<tr>
<td>Fraenkel, et al (2011)</td>
<td>Pilot study</td>
<td>Sample size too small for statistical significance</td>
<td>4</td>
<td>Pilot study to introduce a decision-making tool developed for patients to facilitate communication between patient and provider when prescribing warfarin to treat atrial fibrillation.</td>
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<td>Fraenkel, et al (2012)</td>
<td>Clustered randomized controlled trial</td>
<td>Statistical analysis SAS software with statistical significance set at P&lt;0.05</td>
<td>2B</td>
<td>Pilot study to evaluate effectiveness of decision-making tool as well as to inform patients who are treated with warfarin for atrial fibrillation.</td>
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