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Self-Learning, DVD-Based Education Versus Traditional Education Approaches to Improve the Safety of Warfarin Use Among Patients with Atrial Fibrillation

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SELF-LEARNING, DVD-BASED EDUCATION VERSUS TRADITIONAL EDUCATION APPROACHES TO IMPROVE THE SAFETY OF WARFARIN USE AMONG PATIENTS WITH ATRIAL FIBRILLATION

by

Jessica Oliver Hatch

A thesis submitted in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

in

Nutrition and Food Sciences

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UTAH STATE UNIVERSITY
Logan, Utah

2015
ABSTRACT

Self-Learning, DVD-Based Education Versus Traditional Education Approaches to Improve the Safety of Warfarin Use among Patients with Atrial Fibrillation

by

Jessica Oliver Hatch, Master of Science

Utah State University, 2015

Major Professor: Dr. Heidi Wengreen
Department: Nutrition, Dietetics, and Food Sciences

Warfarin anticoagulation therapy is an essential component of atrial fibrillation (AF) management. There is a growing need to examine alternative education strategies to increase patient knowledge of warfarin independent of clinician time as there is limited time to instruct patients in most outpatient settings.

A randomized education trial was conducted to determine if self-learning, DVD-based education could increase patient knowledge regarding basic warfarin management and its interaction with herbal and dietary supplements (HDS).

Study participants (n=120) with known AF on warfarin were randomized into 2 groups: one-on-one education (n=60), and self-learning, DVD-based education (n=60). Participants completed a multiple-choice test 3 times over the course of the study to quantify knowledge increase and retention as a result of the intervention.

Paired t-tests were used to show participants increased their knowledge from pre-test to post-test (p=<0.001). Scores remained higher at the 3-month follow-up assessment
compared to the pre-test assessment, indicating that participants retained information gained during the intervention (p=<0.001). ANOVA tests were used to examine differences in knowledge gained between education groups. The one-on-one education group scored higher on the post-test than did the DVD-based education group (p=0.026); however, there was no difference in scores by group at the pre-test or 3-month follow-up assessment (p=0.122, 0.187).

The self-learning, DVD-based education increased patient knowledge of warfarin-HDS interactions; the degree of retention of this information 3 months after the education was delivered was not different than that observed for those receiving the one-on-one education. This research provides evidence that self-learning, DVD-based education may be an effective way to educate AF patients regarding HDS management at a lower cost than one-on-one education delivered in a clinic or other healthcare settings.

(122 pages)
PUBLIC ABSTRACT

Self-Learning, DVD-Based Education Versus Traditional Education Approaches to Improve the Safety of Warfarin Use among Patients with Atrial Fibrillation

Jessica Oliver Hatch

Atrial fibrillation (AF) is a common cardiac arrhythmia that requires extensive medical and pharmaceutical management. The coagulation antagonist warfarin is commonly prescribed to reduce AF-associated stroke. Although warfarin effectively mediates thromboembolic risk, its management is complex as many factors influence its therapeutic range including: genetics, diet, medication, and herbal and dietary supplement (HDS) interactions. Lack of patient knowledge regarding these factors contributes to poor patient outcomes. With the emerging epidemic of AF, readily available educational tools are necessary to improve patient outcomes while reducing clinician burden.

The purpose of this study was to develop both a self-learning, DVD-based and one-on-one education program to educate patients with atrial fibrillation about the risks of HDS-warfarin interactions and to compare education method efficacy in AF disease management. This study found patients lack knowledge regarding HDS-warfarin management, and both DVD-based and one-on-one education models could increase patient knowledge regarding HDS-warfarin factors. It is hypothesized this education method may be employed to further educate chronic disease populations about essential disease-associated factors to improve outcomes while reducing clinical burdens.
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I offer very special thanks to my major professor, Dr. Heidi Wengreen. As a latecomer to this project, I appreciate the long hours she spent getting to know the project’s objectives and plowing through the statistical analyses with me. I could not have done this thesis without the ample time she spent patiently addressing my many questions and concerns. She has a gift for inspiring curiosity and excellence in the students she interacts with. Her insights into my experiences as a graduate student at USU helped me remember why I wanted to get a master’s degree and truly revitalized my excitement for collegiate learning.

I offer gratitude to the memory of Nedra Christensen. I am pleased to know the completion of this project successfully finishes one of her final endeavors with Utah State. Her life was spent in dedication to the dietetic students of this university, and I am proud to know this thesis can be an endnote to her legacy with USU.

Finally, I am eternally grateful for my loving husband, family, and friends for their continued support, encouragement, and many hours of editing help. I couldn’t ask for a better group of cheerleaders. I could not have done it without them!

Jessica Oliver Hatch
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CHAPTER 1
INTRODUCTION AND BACKGROUND

Abstract

Atrial fibrillation (AF) is a common arrhythmia in clinical practice. Warfarin anticoagulation therapy is an essential component of AF management as it reduces stroke risk. However, warfarin has a narrow therapeutic index and, if uncontrolled, will pose significant risk of bleeding. Confounding factors must be identified to reduce stroke and bleeding risk. This document will explain the implications of an increasing AF population and the factors that influence warfarin management. Warfarin carries a risk of bleeding or thromboembolism but may be taken safely if influencing factors are accounted for.

Introduction

Atrial fibrillation (AF) is the most common arrhythmia in clinical practice. In patients with AF, thromboembolism is of concern as it can lead to stroke with significant morbidity and mortality. Warfarin anticoagulation has been shown to reduce stroke risk, particularly in patients with other factors that increase stroke prevalence, such as hypertension, diabetes, prior stroke, or heart failure. Therefore, good anticoagulation control becomes essential in patients with AF.

This document seeks to further define the AF diagnosis, to highlight the need for anticoagulant interventions to mediate AF-induced stroke risk, and to address the known interactions between warfarin and diet or other factors. It also seeks to explain the implications of an increasing AF population and the importance of self-learning and/or group education to mediate warfarin-induced adverse events while reducing clinician
burden. This paper identifies three key aims which, when completed, will help define the efficacy of alternative education modalities in elderly populations with AF. If effective, this research will move to improve potential patient care in a disease, which has a high prevalence in the US population.

Background

DEFINITION OF ATRIAL FIBRILLATION

Atrial fibrillation (AF) is cardiac arrhythmia caused by irregular electrical activity in the upper chambers of the heart. Abnormal electrical impulses interrupt atrial and ventricle systole which reduces the efficiency of heart contraction and diminishes overall cardiac output. Although AF is often asymptomatic, the decrease in systemic blood flow causes blood stasis, particularly in lower cardiac chambers and appendages. As plasma pools in these areas, platelet aggregation risk is significantly increased. Blood cell aggregates, or thrombi, can travel through the circulatory system and become wedged in capillary structures in other organs, including the brain and lungs. Stroke or pulmonary embolism (PE) may result from these insults. Even a minor cardiac output reduction due to AF, as little as 10%, can place an individual at an increased risk for mortality because of altered coagulation patterns and subsequent predisposition for thrombus formation. Seven percent of individuals with AF will experience thromboembolic events, which is a five-fold increase in stroke incidence when compared to the general US population.

Strokes resulting from AF are usually severe and are associated with a high rate of systemic organ damage and long-term disability when compared to strokes from alternate thromboembolic origins. As stroke and PE are associated with significant injuries and
mortalities, thromboembolism risk must be mediated to decrease AF comorbidities and their subsequent complications.\textsuperscript{7}

**INCIDENCE, PREVALENCE, AND RISK FACTORS OF ATRIAL FIBRILLATION**

AF is the most common arrhythmia in clinical practice, and its incidence has increased in recent years.\textsuperscript{8} In 2010, the Center for Disease Control reported 1.2 million new AF diagnoses each year from 2000-2010.\textsuperscript{12} They further projected AF disease onset would double from 1.2 million cases annually to 2.66 million by 2030.\textsuperscript{12-13} To date, the incidence of this disease increases by as many as 2.3 million individuals every year, which far exceeds the previous disease predictions made by the CDC in 2010.\textsuperscript{10-11,14}

AF disease prevalence has also grown in past decades. In 2006, Heeringa et al reported one percent of the total US population had AF.\textsuperscript{15} In 2012, Colilla et al reported 5.2 million, or 1.6% prevalence.\textsuperscript{13,16} This trend is expected to continue. Projections show possible prevalence to increase to 12.1 million cases in 2030, a 7.6 fold increase from current population occurrence.\textsuperscript{13} Atrial fibrillation’s escalating diagnosis has been attributed to multiple factors including: coexisting cardiovascular diseases, rising obesity prevalence, improving healthcare, and increasing population age.\textsuperscript{8}

Although AF can be present without any underlying structural heart disease, most patients experience AF as a result of concurrent cardiac conditions and metabolic disorders including: hypertension, coronary artery disease, myocardial infarction, cardiomyopathy, and diabetes.\textsuperscript{9,17} These conditions influence the normal systole of the cardiac chambers; therefore, AF is a common co-morbidity as these diseases progress. For example, hypertensive heart disease can increase AF disease development risk by 1.5 fold.\textsuperscript{18} Although this is a relatively small increase in risk, hypertensive diseases occur
with great frequency in the general population; in 2011, the CDC reported 32.5 percent of U.S. adults had hypertension. As a result, 40-80% of AF cases are attributed to hypertension.

In addition, obesity is associated with an increase in AF prevalence. Obesity increases one’s risk for concurrent health problems that can lead to AF, including cardiovascular diseases, elevated blood pressure, and diabetes. Therefore, AF incidence is expected to rise with the concurrent increase in obesity.

Age is an independent risk factor of AF. Presently, 1 in 4 adults are at risk of acquiring AF as they age. AF prevalence is rare before the age of 50, but almost 10% of people greater than 80 years old are affected. Medical advancements and current population demographics, including the large baby boomer population, are expected to dramatically increase the size of the elderly population in the United States.

**TREATMENT OF ATRIAL FIBRILLATION**

AF is not an inherently malignant arrhythmia, but it can heighten concurrent cardiac conditions that result in stroke or PE, angina, vascular syndromes, and coronary artery disease. Standard medical therapies such as electrical conduction or ablation procedures may correct or reduce atrial arrhythmia and establish appropriate cardiac patterns. These are effective treatment options, but they do not always completely alleviate atrial imbalance. Many patients are not able to receive these interventions due to other medical or physical limitations. Comprehensive medical care of AF must therefore include clinical interventions that address the arrhythmia while providing pharmacological anticoagulation therapies to reduce thromboembolic stroke risk.
The coagulation antagonist warfarin is commonly prescribed as a prophylaxis or treatment for thromboembolic complications associated with AF.\textsuperscript{23} This medication has been shown to reduce stroke by 75\% when compared baseline populations without pharmacological interventions.\textsuperscript{8} The US Food and Drug Administration (FDA) estimate two million patients are placed on this anticoagulation therapy each year.\textsuperscript{24} Warfarin efficacy is particularly apparent in patients who have other conditions that may increase stroke risk such as hypertension, diabetes, prior stroke, or heart failure.\textsuperscript{2,4,25-26}

**WARFARIN MECHANISMS**

Warfarin reduces thrombus-related morbidity by interfering with vitamin K-dependent coagulation pathways and subsequently diminishing platelet aggregation. Reduced vitamin K, or hydroquinone, activates many clotting factors in both the intrinsic and extrinsic coagulation pathways that allow proper thrombus formation. Hydroquinone plays an essential role by post-translationally carboxylating glutamic acid residues on multiple clotting factor peptides. Blood coagulation could not take effect without vitamin K.\textsuperscript{27}

As vitamin K exerts its effect on the clotting cycles, hydroquinone becomes oxidized. Also, uncoupled oxygen in plasma can oxidize vitamin K. As a result of these two actions, vitamin K must be re-reduced to function. Quinone reductase and epoxide reductase enzymes can reduce oxidized vitamin K and re-establish hydroquinone functionality. These enzymatic processes significantly contribute to the body’s ability to maintain a constant supply of active vitamin K. Warfarin antagonizes the vitamin K reduction cycle by interfering with the quinone reductase and epoxide reductase enzymes,
thereby diminishing active clotting factors and significantly reducing the efficiency of the coagulation pathways.27

Although the body heavily relies on the reduction of oxidized vitamin K to maintain an adequate supply of active vitamin K for coagulation, hydroquinone is also introduced into the body system from exogenous sources through the diet in green leafy vegetables and some legumes. Endogenous vitamin K is synthesized by anaerobic flora found in the gastrointestinal tract. These sources of hydroquinone contribute to systemic vitamin K levels. Therefore, warfarin dosing must account for both the metabolism of vitamin K in the body and dietary intake to ensure coagulation is kept within a safe range.27

WARFARIN MONITORING

Warfarin therapies reduce stroke risk by as much as 64% through altered coagulopathy, but excessive therapy can increase bleeding risk, particularly in elderly populations.28-29 As a result, warfarin may remain significantly under-prescribed due to the possible risk of over-medicating that can cause hemorrhagic events.17

Warfarin should be dosed to ensure appropriate coagulation without increasing hemorrhagic risk. However, maintenance doses of warfarin fluctuate significantly, ranging from less than two milligrams per day to more than ten milligrams per day. Medication variability stems from many factors including: nutritional status, availability of both dietary and endogenous sources of vitamin K, genetic polymorphisms, hepatic function, medication clearance, intestinal absorption, schedule compliance, drug interactions, and herbal and dietary supplement intake.8,30-32 Consistent blood coagulation monitoring is essential to account for these diverse sources of warfarin variability and to
prevent stroke or bleeding risk. Monitoring is especially important when one is initially placed on warfarin, as the previously mentioned patient-related factors are difficult to both identify and to determine their influence of warfarin dosing.

Coagulation adequacy is determined by assessing the International Normalized Ratio (INR). This test evaluates blood to determine how long it takes plasma to clot after a tissue factor is added. The INR evaluates the proportion of active and inactive vitamin K dependent factors in both the intrinsic and extrinsic clotting pathways. Normal INR ratios range from 0.8-1.2. For most patients with AF, optimal INR ranges between 2-3. This value reflects a delayed blood clotting time to reduce stroke risk without increasing risk of hemorrhagic events. INR levels below two indicate uninhibited blood clot formation, which increases one’s risk for thrombus formation if the individual has poor blood circulation, as is the case with AF. An INR greater than three shows severe delay in clot creation and increased bleeding risk.

The frequency one’s INR is in the therapeutic range (between 2-3) has been inversely correlated with major blood loss, thrombosis, and mortality. Many studies show that suboptimal anticoagulation control is commonplace; a meta-analysis of 67 studies involving more than 50,000 patients on warfarin discovered that the INR was in the therapeutic range only 64% of the time. This research suggests there is an urgent need to improve oral anticoagulation care for most patients.

WARFARIN AND HERBAL AND DIETARY SUPPLEMENTS

Many herbal and dietary supplements (HDS) interact with warfarin. HDS therapies can augment warfarin through alterations in hepatic drug metabolism, competitive digestive and metabolic inhibition, warfarin displacement from albumin, and
direct gastrointestinal injury. HDS therapies can also influence the synthesis and
degradation of clotting factors, thrombocytes, and the overall symbiotic relationship
between the clotting cascades and warfarin functionality. Many natural and herbal
medications inhibit cytochrome p-450, which may escalate the warfarin response, thereby
elevating the INR and significantly increasing hemorrhagic risk. Other products may
decrease warfarin’s effectiveness by altering its metabolism or by influencing vitamin K
synthesis or functionality, which can increase stroke risk.

Although HDS-warfarin interactions have been reviewed, it is difficult to identify
interactions between herbal remedies and warfarin because HDS therapies have limited
regulatory oversight and are known to have dramatic inconsistencies in HDS supplement
content. As such, the absence of evidence regarding interactions does not negate
potential HDS-induced warfarin alterations. Also, there are limited clinical trials to test
interactions and direct literature is not extensive, making definitive recommendations
difficult.

There is a substantial individual dose-response relationship, making it difficult to
give recommendations of HDS to individuals in a known safe range. It is hard to isolate
specific HDS products and their interactions with warfarin in individuals who require
multiple medications. Therefore, the implications of HDS therapies on long-term
coagulation control remain unclear.

HDS-induced warfarin alterations are a widespread problem in clinical practice
due to their extensive utilization by the US population. HDS consumption in the
US increased by 380% from 1990-1997 and this trend is increasing. Potential interactions
increase almost daily as new supplements enter the market. Many individuals who
consume HDS therapies are unaware of their potential interactions with warfarin. They believe these products are safe because they are natural. This belief exponentially increases potential risk as individuals do not always disclose their HDS use to healthcare professionals.\textsuperscript{38,40}  

Due to the high risk of interactions, HDS therapies may be used only with caution and under the direction of a healthcare professional.\textsuperscript{1} Patients may be able to take some HDS therapies with critical medical management. INR monitoring remains the best protection against major harm due to polypharmacy, and this value can be used to determine an individual’s response to HDS products.\textsuperscript{39}  

Prior to initiating HDS therapies, patients must first consult with a health care professional. Medical teams must understand which HDS therapies are known to interact and what HDS products should be avoided while on warfarin (Table 1-1).

| Table 1-1. HDS Therapies Known to Interact with Warfarin |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Alfalfa         | Anise           | Arnica          | Bilberry        | Bladderwrack    |
| Bromelain       | Butchers Broom  | Cat’s Claw      | Celery          | Chamomile       |
| Choleys         | Coenzyme Q10    | Cordyceps       | Cranberry       | Dong quai       |
| Feverfew        | Fenugreek       | Fish oil        | Forskolin       | Garlic          |
| Ginger          | Gingko Balboa   | Ginseng         | Glucosamine     | Grape seed      |
| Green Tea       | Guggul          | Horse Chestnut  | Horseradish     | Inositol        |
| Licorice        | Multivitamins   | Omega-3 acids   | Pau d’arco      | Hexaphosphate   |
| Primrose Oil    | Red Clover      | Reishi          | SAMe            | Prickly Ash     |
| Sweet Clover    | Sweet Woodruff  | Turmeric        | Vitamin E       | St John’s wort  |
| White Willow    | Willow bark     | Wheat Grass     | Vitamin K       |                 |

Bold Font shows products that should be avoided while on warfarin. Normal font shows products that can be taken with warfarin but must be used with caution.
If a product is approved, patients must take HDS products consistently to maintain appropriate INR values. When interactions between HDS therapies and warfarin are suspected, INR monitoring should be increased. Patients must be instructed not to take any new medications, including herbal products, supplements, or over-the-counter medications without the approval of their attending physicians. Dose responses must be closely monitored to reduce over or under-coagulation.

Conclusions

Although warfarin effectively reduces thromboembolic risk, its management is complex due to many influencing factors including: genetics, diet, medication, and HDS interactions. Effective warfarin management relies on both attentive medical care teams and pro-active patients that understand key factors in anticoagulation. With the emerging epidemic of AF in an aging population, readily available and easy to use educational tools are necessary to improve patient outcomes by increasing patient knowledge and improving behavior while reducing clinician education burden.

Proposed Project Aims

1. Develop a patient education program in DVD format that will increase patient knowledge concerning supplement drug interactions. The education will address:
   a. Why compliance to warfarin medication is critical
   b. The risks associated with supplement and herbal product use
   c. Commonly used supplements and herbal products that interact with warfarin
   d. How to read a supplement facts label
   e. Need to consult with a health care provider prior to:
1. Continuing any HDS therapy

2. Beginning any new HDS therapy

3. Making any changes to current HDS regimen

2. Develop an equivalent education program for one-on-one format that include all components addressed in objective one act as a control group to assess the effectiveness of DVD-based education and its implications in reducing physician time required to educate patients when compared to one-on-one education.

References


CHAPTER 2

ALTERNATIVE EDUCATION STRATEGIES IN AN AGING POPULATION

Abstract

Chronic disease prevalence is rising in an aging population. Common diseases, such as atrial fibrillation (AF), place clinical and economic burdens on healthcare systems due to increased medical management needs. Education deficits regarding subsequent medical therapies, such as warfarin, place patients at increased risk for adverse events. There is a growing need for alternative education strategies to increase patient knowledge and to minimize clinician burden. This document will evaluate the effectiveness of alternative education modalities to instruct a growing AF population. Self-learning education tools can be an effective instrument to educate patients and about long-term disease management.

Introduction

Chronic disease prevalence is rising in the aging US population. Common diseases such as atrial fibrillation (AF) require extensive medical management to optimize patient outcomes. The subsequent need for physician oversight and increased patient engagement places clinical and economic burdens on the already taxed healthcare system. For example, warfarin anticoagulation therapies are an essential component to reduce stroke risk in patients with AF. Although effective, warfarin requires close follow-up and monitoring because suboptimal medication control increases the probability of adverse hemorrhagic or thromboembolic events.

In conjunction with medical supervision, adequate education regarding global warfarin management is essential to patient participation, safety, and symptom control.
Appropriate patient knowledge is associated with improved patient outcomes.\textsuperscript{6,7} Unfortunately, patients often exhibit limited knowledge of their anticoagulation therapy and its cofactors, including herbal and dietary supplement (HDS) intake.\textsuperscript{8-10} Physician, pharmacist, and/or nurse led teaching in clinic and inpatient settings is predominantly underutilized because there is limited time to instruct patients about all essential warfarin-related factors. These education constraints are expected to increase in proportion to the growing elderly population and chronic disease prevalence.\textsuperscript{2,8,11-13} Therefore, alternative education strategies must be considered to increase patient understanding and warfarin regimen compliance independent of the one-on-one teaching models commonly used in clinical settings.

This document will explore the implications of an aging population, patient knowledge deficits regarding warfarin management, the shortcomings of limited one-on-one patient teaching opportunities, and how these factors relate to long-term regimen compliance and safety. It will also pose to examine appropriate education structuring for elderly adults with high chronic disease incidence. Finally, this text will consider alternative education strategies, including self-learning and group education teaching, to determine if these modalities can increase patient knowledge concerning basic warfarin therapies and HDS management while minimizing clinical burden.

**Background**

**HEALTHCARE IMPLICATIONS OF A GROWING ELDERLY POPULATION**

US populations are living longer, healthier lives.\textsuperscript{14} In 1965, the average life expectancy was 70.2 years, and it will likely to advance to 80 years by 2020.\textsuperscript{15} Similarly,
the number of people over the age of 65 is growing rapidly due to the large baby boomer population. One of every 5 people will be over 65 by 2030.\textsuperscript{16}

Overall, elderly people are the largest consumers of American healthcare. A major goal of the healthcare system therefore must maintain health and prevent and/or delay chronic diseases in the US population.\textsuperscript{14,17} Consequently, there is a great need to develop methods to reduce healthcare costs and increase quality of care for the elderly.\textsuperscript{17}

High prevalence diseases, such as AF, are expected to increase with the rising age of the overall population.\textsuperscript{1} As AF incidence increases, it poses a significant economic burden on the healthcare system. The medical burden associated with AF increased by 18.8\% from 1990 to 2010, and this trend is expected to continue.\textsuperscript{11} Also, warfarin anticoagulation-related episodes place significant clinician burden worldwide independent of AF medical management. The prevalence of warfarin use is expected to increase in proportion with advancing population age.\textsuperscript{4,8}

These factors will increase the need for inpatient and outpatient medical treatments and therapies, pharmacological interventions, disease and medication monitoring to improve patient outcomes.\textsuperscript{4,8} However, treatments must also be cost-effective to minimize the consequent healthcare and economic burdens presented by the large chronic disease population, as is the case with AF and warfarin therapies.

\textbf{ANTICOAGULATION CONTROL}

Warfarin continues to be a successful component of coagulation control despite bleeding risks due to its high efficacy in stroke prevention and clot degradation.\textsuperscript{18} Although alternative anticoagulation therapies have been implemented in AF management, limited head-to-head trial comparisons have been completed to determine if
new medications are superior warfarin therapies.\textsuperscript{1} There are situations in which warfarin may continue to be an appropriate anticoagulant choice including: patients who are already comfortable with INR management, are not likely to comply with increased dosing requirements, are unable to take the new medications due to contraindications such as severe kidney disease or increase in pharmaceutical cost.\textsuperscript{1}

Even with alternative anticoagulation therapies, seven percent of elderly adults in the United States take warfarin.\textsuperscript{19} However, warfarin is frequently associated with adverse drug events.\textsuperscript{20} Its use requires routine international normalized ratio (INR) monitoring to maintain a tight therapeutic index. Inconsistent INR values place patients at increased risk of over- or under-coagulation that can lead to stroke, bleeding, and/or cardiomyopathy.\textsuperscript{2,21}

Keeping the INR within prophylactic range is complex as many factors contribute to warfarin regulation. These factors include: genetic, hepatic, and digestive variation, vitamin K intake, and medication and/or HDS interactions.\textsuperscript{1} Warfarin control has improved over the past decades due to clinical trials and specialized anticoagulation clinics where close attention has been given to INR levels and its confounding factors.\textsuperscript{22} However, poor warfarin related outcomes still occur. A patient’s INR may be out of range as much as 64\% of the time an individual is on warfarin, and 93\% of warfarin users may experience adverse events.\textsuperscript{23-24} Overall, there are as many as 4-7 serious bleeding events per 100 patient years of warfarin exposure, many of which cause morbidity and mortality.\textsuperscript{25}

Many elements complicate the clinical outcomes of warfarin therapy. Poor INR control and coagulation outcomes are most commonly associated with limited medical
oversight and inadequate patient understanding of warfarin and its influencing factors. Many sources suggest INR values are more often within the therapeutic range when patients have a greater knowledge of warfarin therapy, and poor patient knowledge was associated with worse coagulation control. For example, Kagansky et al. showed that patient INR values were more frequently within therapeutic range when patients received adequate education (45.1%) compared to those who were not adequately educated (34.9%). Also, insufficient education was associated with more bleeding events (5.2 events per 1000 patient months) when compared to an appropriately educated population (0.5 per 1000 patient months (p=<0.001)).

Patient warfarin literacy is a predictor of medication adherence. Davis et al. reported patients do not follow medication-related recommendations as much as 50% of the time, and these participants could only state understanding of 37% of warfarin management components. In another study, Parker et al. reported that 21% of patients were non-adherent to warfarin recommendations; these patients more often missed pills rather than took too many. In both studies, patients often perceived they were more adherent to medical advice than they actually were. These research findings highlight the large gaps between clinical awareness of patient knowledge and their actual warfarin management comprehension and behaviors. The inability to follow appropriate regimens due to misunderstanding leads to acute exacerbations of chronic complications and reduces patient safety and outcomes. Conversely, participants who have good information and understanding of medication guidelines are more likely to act as proactive participants in their healthcare decisions and will adhere to overall medical advice.
Although some studies have not shown a significant association with adherence and good anticoagulation knowledge, other factors including vitamin K intake, medications, and genetics also influence coagulation levels. These components may confound study results. Many factors contribute to warfarin efficacy and safety, and patient education should not be discounted, as patient understanding may be the most robust way to impact modifiable variability in INR management and improve coagulation control.\(^9, 28, 36-37\)

**WARFARIN ANTICOAGULATION KNOWLEDGE DEFICITS**

Evaluation of patient knowledge is the first step to improve quality of anticoagulation therapy education and patient care.\(^{38}\) Poor patient understanding may be easier to influence than medication metabolism, but knowledge deficits can be difficult to identify and correct.\(^{28}\) Overall, many patients have very low knowledge of AF symptoms, limited health literacy regarding warfarin medications, and are unable to identify signs of a thromboembolism. They also do not always comprehend the need for routine INR monitoring, consistent vitamin K dietary intake, caution with HDS therapies and drug-drug interactions, and the need to disclose medication-related factors to health care professionals.\(^1, 6, 8-9, 34\)

Successful anticoagulation treatments are dependent on patient warfarin knowledge. Hu et al. found 61% of their study population had insufficient warfarin understanding.\(^{39}\) Makaryus et al. discovered that less than 50% of individuals were able to list their diagnoses and outline the purpose of the medications they consumed.\(^{33}\) Similarly, another study found that while 75% of patients could state that factors like vitamin K
were significant to warfarin therapies, only 20% of individuals recognized there was a
dose-dependent relationship between vitamin K and warfarin.6

Overarching medical organizations have also recognized these knowledge deficits
and the severe risks associated with poor warfarin comprehension. The Warfarin National
Patient Safety Goal (NPSG) guidelines created by the Joint Commission identify key
education factors that are essential to improve INR values and to reduce inadvertent
complications from anticoagulant interventions. These guidelines state education
strategies should address the importance of medication monitoring, regimen compliance,
and basic cautions regarding drug-food and drug-drug interactions (including HDS
therapies).40-41

Numerous studies have attempted to show patient education can increase INR
control and improve patient safety, but study testing tools and questions have been
inconsistent, making it difficult to corroborate findings across studies.42 Zeolla et al.
examined previous studies’ methodologies and questions to create a validated self-
administered instrument to assess warfarin therapy comprehension.52 Their validated tool
showed INR variability decreased if patients could state understanding of five education
and testing domains including: basic drug information (such as dosing), adverse reactions
associated with poor patient compliance, drug-drug and dietary interactions, and the need
for long-term monitoring.42

Other researchers have supported the guidelines outlined by the Warfarin NPSG
and Zeolla et al.6,23,29-30 Therefore, future study designs regarding warfarin education
efficacy in long-term disease populations should address these key deficits.6,32,40-42
HERBAL AND DIETARY SUPPLEMENT KNOWLEDGE DEFICITS

According to the 2007 National Health Interview Survey, 39% of US adults take multivitamin and mineral supplements, and 17.7% of individuals consume herbal products or remedies. Many of these products can increase patient risk of under- or over-coagulation through altered warfarin metabolism or interfere with the coagulation pathway. Increased HDS use is associated with reduced INR control, which can intensify one’s risk for stroke or hemorrhage. Chan et al. discovered 50% of their study population took more than one HDS therapy known to interact with warfarin. Additionally, individuals who took less than one HDS therapy fewer than four times per week were more likely to have an INR in range when compared to frequent users who took more than one HDS therapy more than four times per week (p=0.068).

Patients may still consume some HDS products while taking warfarin, but healthcare professionals must be aware of patient use to account for potential interactions. Patients must be transparent in supplement intake as simple changes HDS therapies can cause life-threatening complications.

Patients on anticoagulation therapy with warfarin should be educated about and monitored for possible drug-herb interactions. Research regarding patient HDS knowledge and warfarin are limited, but those select studies show patient awareness to warfarin and HDS interactions is poor. Over 50% of HDS users do not disclose their supplement intake to medical professionals. Individuals often do not know it is important to discuss their HDS use with care providers. The vast majority of patients cannot identify products that potentially interact with warfarin. Further research would be helpful in identifying knowledge deficits and educating elderly patients regarding HDS-warfarin management.
EDUCATING AN ELDERLY POPULATION

Although the need for chronic disease education is well established, the best teaching strategy for elderly patients with AF on warfarin has yet to be determined.\textsuperscript{33,52} Disease and medication information can only increase patient knowledge and compliance if the education content and techniques are appropriate for the target population.\textsuperscript{1,22,53} Therefore, educators must critically analyze patient demographics, education levels, and lack of previous knowledge to ensure education modalities are appropriate to effectively relay essential information to individuals for disease management.\textsuperscript{53-54}

Education programs for the elderly must be tailored to the functional and psychosocial conditions of the participants.\textsuperscript{37,55} Historically, education programs structured on extensive quantitative data are difficult to understand. Even highly educated patients struggle with numerical data and its extrapolation to determine risk. Lengthily data and/or high amounts of medical jargon appear to have limited impact on patient knowledge retention and adherence. Education complexity minimizes the applicable components of education.\textsuperscript{53,55}

Education for the elderly appears to be most effective when messages are provided as observational learning and/or health narrative techniques.\textsuperscript{37} Information should be presented in a conversational format, and should also provide concrete messages that easily allow individuals to follow instructions.\textsuperscript{37,53,55} Written material should not exceed a seventh-grade reading level.\textsuperscript{42} These observational learning education principles have been proven essential in multiple disease formats, including AF and warfarin education for elderly populations.\textsuperscript{1,55} Warfarin education materials are most effective when messages focus on essential patient safety topics rather than quantitative data regarding coagulation.\textsuperscript{56} Participants educated using these techniques are more likely
to recall essential factors that are important for appropriate coagulation control. See Table 2-1 for examples.

Table 2-1. Examples of Inappropriate and Appropriate Education Techniques

<table>
<thead>
<tr>
<th>Inappropriate education technique</th>
<th>Fish oil supplements are contraindicated in patients taking warfarin as these products decrease clotting factor VII levels and interfere with platelet aggregation (Buckley).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate education technique</td>
<td>You should not take fish oil supplements while you are on warfarin. This product can raise your bleeding risk.</td>
</tr>
</tbody>
</table>

**CHALLENGES TO ONE-ON-ONE TEACHING**

In addition to appropriate content, education methods must be suitable for the expected practice setting. Major strides have been made to identify medical-related knowledge deficits in elderly populations, but effective education programs and policies have yet to be routinely implemented in many medical care areas. Education is time consuming for clinicians, and patients are often overwhelmed by new diagnoses. Therefore, initial education usually addresses only critical elements of medication and disease management to prevent mortality.

Even patients who receive formal education at the time of diagnosis do not always recall essential disease management factors. Patients who are new to warfarin therapies are at particular risk for poor knowledge retention. Winans et al. discovered patients educated by nursing staff on medical and surgical floors during admission for initial disease onset failed to gain sufficient knowledge to pass a follow-up warfarin therapy exam; their mean post-test score was only 55%. Metlay et al. showed patients who reported receiving initial warfarin education had lower hospitalization admissions due to inaccurate medication management over two years (p=<0.001). However, researchers
discovered only 55% of participants reported they received medication instructions during admission. Those who reported lack of education had similar hospital admission risk as the general AF population.\cite{23} If patients do not recall receiving information about their medication, they are at an increased risk for adverse warfarin related events.\cite{26,33,38}

The high variability in patient recall regarding initial warfarin teaching may be explained by the high nursing-to-patient ratio when compared to one-on-one education in an outpatient clinic setting. There is also a large variability in education content and nursing explanations within a single medical facility.\cite{26} In general, hospital education by nurses can provide basic knowledge of warfarin management, but in-depth understanding of all essential education components is not found.\cite{39}

Knowledge retention from inpatient settings appears to be poor when compared to in-depth intervention group educations in coagulation clinics; however, universal changes to office scheduling patterns reduce time available in outpatient settings for education. Education tasks assigned to the general physician are growing.\cite{26,57} Many individuals on warfarin have INR follow-up in pharmacy-run clinics, but these health care professionals also face severe time constraints. Practitioners are not always able to provide extensive education, and patients followed in these settings still show limited knowledge retention regarding global warfarin management.\cite{33} Baker et al. showed patients who received education about warfarin-food interactions in INR clinic settings frequently missed questions on follow-up exams.\cite{38}

In the current era of both physician and nursing shortages, continued one-on-one education and follow up is likely unfeasible for diseases that are highly prevalent in the community, such as AF.\cite{33} If patients do not receive follow-up education, knowledge
deficits will likely continue and can increase adverse event risk. As a result, more complex elements of warfarin control, like HDS therapy management, are often neglected. Much research highlights the need for continued education and long-term follow-up to ensure patients retain needed knowledge regarding therapies and are appropriately implementing medical recommendations.

**SELF-LEARNING EDUCATION PROGRAMS**

Patient-driven and self-learning education programs may reduce clinic burden in a time of shrinking financial and human resources. Videotape instruction has long been recognized as an effective education tool in the healthcare industry. If appropriately developed and implemented, these tools can provide similar education when compared to one-on-one teaching strategies. Audiovisual presentations have been shown to be effective in chronic disease management if the presentations deliver essential education components and the audience-appropriate content is presented in a brief and focused manner.

Self-learning strategies can standardize materials presented, which may reduce education content bias in populations. Theoretically, consistent education content can decrease modifiable INR variability in warfarin management.

Wofford et al. reviewed many warfarin-related education studies using diverse teaching strategies such as one-on-one nurse or physician education and videotape sessions. Their meta-analysis found high variability in education content. However, when factors for content were accounted for, there was no difference shown in education gained across study groups. Ford et al also compared knowledge retention by comparing one-on-one education models to self-learning DVD education. These researchers
discovered patient post-test scores for the DVD group were unexpectedly higher, which may be attributed to increased patient engagement.  

Self-learning education strategies are generally well received by patients. Programs that educate patients on appropriate self-management are linked to positive health-related outcomes including decreased complications and increased reported quality of life. Self-learning programs appear to increase patient-driven care and individual accountability for long-term disease management.

Follow-up education and content reiteration are important factors of long-term knowledge retention. Many studies have shown patients lack knowledge regarding appropriate warfarin monitoring even if initial education was provided. Video recordings may increase knowledge retention over time as participants may view these materials frequently.

In conjunction with improved patient knowledge, self-learning programs can maximize office efficiency by delegating education to independent learning areas, like an office computer or DVD education in waiting rooms and homes. If correctly made, these materials can provide low-cost, patient-centered education with minimal office operational impact.

Although effective, self-learning education has limitations. Primarily, patient-driven learning limits patient-physician interaction. This reduces available patient time to ask follow-up questions regarding education implementation. Also, DVD-based programs require high patient engagement. Individuals must view required content to obtain any education benefits. Many recent technologies, such as computers, tablets, and DVDs, are foreign to elderly populations. These individuals will likely continue to require in-
person question time and to both navigate education materials and to clarify disease management needs. Practitioners must be aware of these potential confounding factors when using these education strategies.\textsuperscript{6,54}

**Conclusions**

One-on-one education is difficult for high prevalence diseases, such as AF. As the elderly US population expands, clinicians will have less time to educate patients and patient knowledge may be compromised.\textsuperscript{53} Identifying knowledge deficits and improving patient understanding of warfarin use is critical to improve patient outcomes. When anticoagulation therapies are effectively monitored for accuracy and are accompanied by appropriate education, the majority of individuals can safely take warfarin.\textsuperscript{1,59} Adherence requires commitment from both health care providers and patients to make sure the INR is in range and medication is taken in time.\textsuperscript{10,36,54}

Current research shows interactive, self-learning audiovisual tools, such as DVD-based strategies, can educate patients about elements of chronic disease management while decreasing practitioner strains.\textsuperscript{53-54} Although standard and alternative teaching strategies have proven effective in educating and patients with AF regarding general warfarin management, little research has been done to address HDS knowledge deficits.\textsuperscript{36} Further research is warranted to determine if these self-learning strategies can also be effective in educating an elderly AF population about HDS products.

**References**


CHAPTER 3

SELF-LEARNING, DVD-BASED EDUCATION VERSUS TRADITIONAL EDUCATION APPROACHES TO IMPROVE THE SAFETY OF WARFARIN USE AMONG PATIENTS WITH ATRIAL FIBRILLATION

Abstract

BACKGROUND: Warfarin anticoagulation therapy is an essential component of atrial fibrillation management. There is a growing need to examine alternative education strategies to increase patient knowledge of warfarin independent of clinician time, as there is limited time to instruct patients in most outpatient settings.

OBJECTIVE: A randomized education trial was conducted to determine if self-learning, DVD-based education could increase patient knowledge regarding basic warfarin management and its interaction with herbal and dietary supplements (HDS).

METHODS: Study participants (n=120) with known AF on warfarin were randomized into 2 groups: one-on-one education (n=60), and self-learning, DVD-based education (n=60). Participants completed a multiple-choice test three times over the course of the study to quantify knowledge increase and retention as a result of the intervention.

RESULTS: Paired t-tests were used to show participants increased their knowledge from pre-test to post-test (p=<0.001). Scores remained higher at the three-month follow-up assessment compared to the pre-test assessment, indicating that participants retained information gained during the intervention (p=<0.001). ANOVA tests were used to examine differences in knowledge gained between education groups. The one-on-one

1Jessica Hatch, Heidi Wengreen, Barbara Fiechtl
education group scored higher on the post-test than did the DVD-based education group (p=0.026); however, there was no difference in scores by group at the pre-test or 3-month follow-up assessment (p=0.122, 0.187).

CONCLUSIONS: The self-learning, DVD-based education increased patient knowledge of warfarin-HDS interactions; the degree of retention of this information three months after the education was delivered was not different than that observed for those receiving the one-on-one education. This research provides evidence that self-learning, DVD-based education may be an effective way to educate AF patients regarding HDS management at a lower cost than one-on-one education delivered in a clinic or other healthcare settings.

Introduction

ATRIAL FIBRILLATION AND WARFARIN MANAGEMENT

Chronic disease prevalence is rising in the aging US population.\(^1\)\(^-\)\(^2\) Atrial fibrillation (AF), a common chronic disease, requires extensive medical management to optimize patient outcomes.\(^3\)\(^-\)\(^6\) The subsequent need for medical interventions, physician monitoring, and increased patient engagement places clinical and economic burdens on the already taxed healthcare system.\(^7\)\(^-\)\(^9\)

In patients with AF, thromboembolism is of concern as it can lead to stroke with significant morbidity and mortality.\(^1\)\(^-\)\(^5\) Warfarin anticoagulation has been shown to reduce stroke risk, particularly in patients with other factors that increase stroke prevalence, such as hypertension, diabetes, prior stroke, or heart failure; therefore, good anticoagulation control becomes essential in patients with AF.\(^7\)\(^-\)\(^13\) Warfarin, though effective, requires
close follow-up and monitoring as suboptimal medication control increases the probability of adverse hemorrhagic or thromboembolic events.\textsuperscript{6-9, 14}

**EDUCATION NEEDS IN THE AF POPULATION**

In conjunction with medical supervision, adequate education regarding comprehensive warfarin management is essential to patient participation, safety, and symptom control. Appropriate patient knowledge is associated with improved outcomes; unfortunately, patients often exhibit limited knowledge of their anticoagulation therapy and its cofactors, including herbal and dietary supplement (HDS) intake.\textsuperscript{4, 15-18} It is imperative that teaching regarding HDS management be included with standard warfarin education to avoid potentially lethal interactions and high variability within standardized International Normalized Ratio (INR) values.\textsuperscript{4}

Research regarding patient HDS knowledge and warfarin are limited, but select studies show patients’ awareness of interactions between warfarin and HDS therapies is poor.\textsuperscript{4, 18-19} Over 50\% of HDS users do not disclose their supplement intake to medical professionals.\textsuperscript{4, 18-19} The vast majority of patients cannot identify products that potentially interact with warfarin.\textsuperscript{18-20}

**EDUCATION CONSTRAINTS IN CLINICAL SETTINGS**

Although education is essential for patient safety, there is limited time to instruct patients about all warfarin-related factors in clinical or inpatient settings. General clinic flow does not allow for comprehensive education due to time constraints. Healthcare professionals must address multiple disease and medication factors during a typical outpatient appointment. As a result, there is limited time to both identify and to correct patient knowledge deficits in clinical settings. During a typical visit to a healthcare
professional, a patient will only receive short (three to five-minute) education at the end of an appointment and may therefore only receive fragmented education over many outpatient visits.\textsuperscript{4-5, 9, 19-20}

The limited time for patient education coupled with poor patient retention will increase in proportion to the growing elderly population and chronic disease prevalence; therefore, alternative education strategies must be considered to increase patient understanding and warfarin regimen compliance independent of standard teaching models commonly used in clinical settings.\textsuperscript{4-5, 9, 19-20}

**ALTERNATIVE EDUCATION STRATEGIES**

Patient-driven and self-learning education programs may reduce clinical burden in a time of shrinking financial and human resources.\textsuperscript{21} Video instruction has long been recognized as an effective education tool in the health care industry.\textsuperscript{22} If appropriately developed and implemented, DVD-based teaching methods may provide similar educational efficacy when compared to one-on-one teaching strategies, and these approaches are associated with better patient retention.\textsuperscript{23-25} Concise and focused presentations can effectively educate populations about chronic disease management if they outline essential educational components.\textsuperscript{17, 26-27}

DVD-based educational tools are most efficacious in elderly populations if messages are presented in a conversational format and provide instructions that are easy to follow.\textsuperscript{2, 8-29} Patient instruction should give definitive recommendations while providing minimal quantitative or numerical data. Written materials and testing tools should not exceed a seventh-grade reading level.\textsuperscript{28} Participants educated using these
techniques are more likely to recall essential factors that are important for appropriate coagulation control.\textsuperscript{2, 28-29}

Education content must address comprehensive disease management to improve patient outcomes.\textsuperscript{30} Many studies have attempted to address the gap between warfarin education and patient behaviors, but inconsistent teaching and evaluation methods make it difficult to corroborate findings across studies.\textsuperscript{30} Zeolla et al. reviewed previous studies’ methodologies and developed examination questions to create a validated testing measure to determine what patients needed to know to have minimal INR variability.\textsuperscript{30} This validated tool calls for five education and testing domains including: 1) basic drug information and medication management, 2) adverse reactions associated with poor patient compliance, 3) drug-drug interactions, 4) dietary interactions, and 5) the need for long-term medication monitoring.\textsuperscript{30}

Similarly, the Warfarin National Patient Safety Goal (NPSG) Guidelines created by the Joint Commission identified key education factors that are essential to improve INR values and to reduce inadvertent complications from anticoagulant interventions. These guidelines address the importance of medication monitoring and regimen compliance as well as basic cautions regarding drug-food and drug-drug interactions (including HDS therapies).\textsuperscript{31-32} Future study designs regarding warfarin education in long-term disease populations should address the education domains addressed by Zeolla et al. and the NSPG guidelines.\textsuperscript{21, 30-33}

The study described here is a prospective, randomized education trial designed to compare the efficacy of self-learning, DVD-based education strategies to one-on-one
teaching methods to increase patient knowledge concerning basic warfarin therapies and HDS management.

Methods

SUBJECT RECRUITMENT AND RANDOMIZATION

A randomized education trial was developed in cooperation with Utah State University, Logan, Utah, and Intermountain Healthcare, Salt Lake City, Utah. Institutional Review Board (IRB) approval was obtained through both collaborators’ organizations prior to beginning participant enrollment. Study participants were recruited from the Intermountain Rhythm Specialist Clinic at Intermountain Medical Center, Murray Utah, from October 8, 2010 to February 9, 2011. Individuals with known AF who were receiving warfarin anticoagulation treatment (excluding those who had their INR time based upon genotyping for variance in vitamin K metabolism) were invited to participate. Individuals provided signed informed consent prior to participating in the study interventions.

Subjects (n=120) were randomized into two education groups: one-on-one (n=60), and self-learning, DVD-based education (n=60). Group randomization was created using an Excel software-generated randomization chart to determine which individuals were placed in each group. All patient recruitment, education, and follow-up practices were performed in compliance with IRB guidelines.

INSTRUMENT DEVELOPMENT

The education programs were made to assist and to supplement education provided in a typical outpatient appointment. The educations taught HDS-warfarin
management skills in one sitting, rather than the fragmented education that may or may not be provided over many medical visits.

Both education programs addressed basic warfarin management principles as outlined by Zeolla et al. and NSPG guidelines including: regimen compliance and adverse reactions associated with poor control. The education was also designed to increase patient awareness of HDS-warfarin interactions. Design structure, reading level, and content reflected previous study designs that showed statistically significant reduction in warfarin INR variability after education was completed.\textsuperscript{21,30-36} The education domains included: why compliance to warfarin medication is critical, the risks associated with supplement and herbal product use, commonly used HDS products that interact with warfarin, and how to read a supplement facts label. Education reiterated the need to consult with a healthcare provider prior to beginning any new HDS therapy or making changes to a current HDS regimen.

The one-on-one education was created as a structured curriculum that outlined specific education objectives, required discussion points, and suggested phrasing to reduce education variability. Participants in the one-on-one education group also received handouts outlining education objectives to view at home. All one-on-one teaching was completed by three trained and CITI certified instructors. The DVD-based education addressed identical objectives as outlined in the one-on-one education. Both the education programs took twenty minutes to complete.

The pre-test, post-test, and three-month follow-up tests included the same nine, multiple-choice questions which were based on the Zeolla et al and NSPG guidelines (Appendix A). The exams intended to assess participant knowledge of the education
domains and objectives addressed in education both groups. A panel of education and anticoagulation specialists who had patient care experience with warfarin management verified education content and face validity. Content reviewers included two pharmacists, three registered dietitians, and a cardiologist.

DESIGN IMPLEMENTATION

The pre-test was given before either education intervention was administered to assess patient’s existing knowledge of basic warfarin safety and HDS-warfarin interactions (one-on-one n=60, DVD n=60). Group one received the one-on-one education with an in-person instructor directly following the pre-test administration. Group two received the self-learning, DVD-based education to watch in their own home. Due to technology and space constraints in the clinic, participants did not view the DVDs at the clinic.

Participants from both groups completed an initial post-test after education was received. Group one completed the post-test directly after the education. Participants who received the DVD-based education were contacted via telephone one week after they received the DVD, and this group was called five times over seven days after the initial phone call was made to attempt post-test completion. Participants who did not complete the post-test after these calls were made were considered dropouts and were not contacted for further information. Twenty-one percent of all study participants completed the pre-test but did not complete the post-test (one-on-one n=60, DVD n=35). In addition to the questions asked at the pre-test, all participants who completed the initial post-test were asked to identify if they would make any changes as a result of the education.
The 3-month follow-up exam was administered to both groups via telephone three months after the post-test was completed to quantify knowledge retention of HDS-warfarin interactions over time (one-on-one n=39, DVD n=21). All participants were contacted five times over seven days if the follow-up test was not completed on a previous telephone call. Fifty percent of participants did not complete the 3-month follow-up assessments. Participants who finished the 3-month post-test also completed a satisfaction questionnaire to assess patient-perceived efficacy of the provided education. No adverse events or unintended effects were identified over the course of the study.

STATISTICAL ANALYSIS

Analyses were completed using SPSS statistical software. Criteria for statistical significance included a 95% confidence interval, and the p-value of the two-tailed significance was set at <0.05.

Chi-square analysis was used to determine if there were any differences in demographic variables including age and gender by group assignment. Fisher’s exact analysis was used if the data comparison frequency was less than five (i.e. gender and HDS intake). Two-tailed, paired t-tests were used to examine differences in pre-test (range 0-8), post-test (range 3-9), and three-month follow-up exam scores (range 3-9) and the self-reported number of behaviors the participant intended to change for the overall population and each study group, independent of the other group. A repeated measures analysis of variance (ANOVA) was used to examine whether change in mean scores differed by group over time. In these analyses, the knowledge scores were coded as a three level factor (pre-test, post-test, and 3-month follow-up), and results were used to examine the effect of group on knowledge scores over the three assessment periods. An
interaction term for the three level factor and group was noted as significant (p=<0.001).
Multivariable ANOVA tests included gender and age as covariates.

As this study experienced a high level of dropout, demographic and mean post-test scores of the dropout population were compared to those who completed the 3-month follow-up test via an ANOVA and chi-squared analyses.

**PRIMARY AND SECONDARY OUTCOME MEASURES**

Primary research outcomes aimed to determine if education would improve patient knowledge regarding HDS-warfarin management. Secondary research outcomes posed to determine if there was a difference in knowledge gained between education methods in clinical settings.

**Results**

**DEMOGRAPHIC ANALYSIS**

Analysis of demographic data revealed study groups were not significantly different in terms of age, education, or HDS intake (p=0.96, 0.85, 0.69 respectively; Table 1). Of note, there were more males in the DVD-based group when compared to the one-on-one group, and this difference reached statistical significance (p= 0.03; Table 3-1).

Seventy-two percent of the study population consumed vitamin or mineral supplements, and 45% of individuals consumed herbal products. Of those individuals who reported HDS use, 85% reported routine HDS intake (once daily). Individuals frequently reported they used products that are known to interact with warfarin. Of concern, 54% of study participants reported they did not talk to medical professionals
Regarding their HDS intake, and 46% of these individuals did not feel there was a need to address HDS intake with their healthcare provider. These results reflect previous studies’ findings that HDS product use is widespread in populations with AF, and consumers have limited understanding their implications in warfarin management.\textsuperscript{4,18-19}

<table>
<thead>
<tr>
<th>Table 3-1. Participant Characteristics by Education Group (n=120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
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<tr>
<td>-------------</td>
</tr>
<tr>
<td>41 (70)</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
</tr>
<tr>
<td>Education Level, n (%)</td>
</tr>
<tr>
<td>Some High School, n (%)</td>
</tr>
<tr>
<td>High School Graduate, n (%)</td>
</tr>
<tr>
<td>College Graduate, n (%)</td>
</tr>
<tr>
<td>Take Supplements\textsuperscript{4}, n (%)</td>
</tr>
<tr>
<td>Take Herbal Products\textsuperscript{5}, n (%)</td>
</tr>
<tr>
<td>Pre-test Mean Score, mean (SD)</td>
</tr>
</tbody>
</table>

\textsuperscript{1} Fisher’s Exact Test, \textsuperscript{2} Chi-Square Analysis, \textsuperscript{3} ANOVA Analysis
\textsuperscript{4} Supplement use is defined as ingestion of a pill, capsule, tablet, or liquid containing a vitamin or mineral that is intended as a supplement to the normal diet.
\textsuperscript{5} Herbal product use was defined as intake of a pill, capsule, tablet, or liquid containing an herb or other plant product that is intended to supplement the normal diet.
\textsuperscript{6} n=59, \textsuperscript{7} n=60
\textsuperscript{*} p-value for significance = < 0.05
Paired sample t-tests were used to examine differences in scores from the pre-test to post-test, post-test to 3-month follow-up, and pre-test to 3-month follow-up.

Participants increased knowledge from pre-test to post-test (p= <0.001; Table 3-2).

Researchers observed no statistically significant difference at the 3-month follow-up assessment compared to the post-test (p=0.051; Table 3-2), indicating no difference in mean scores between groups. Scores remained higher at the three-month follow-up assessment compared to the pre-test assessment, indicating that participants retained information gained during the intervention (p= <0.001; Table 3-2).

Both groups showed statistically significant improvement in knowledge from pre-test to post-test, indicating both groups gained knowledge from the education (p= <0.001 for both groups; Table 3-2). The one-on-one group had statistically significant higher scores at the post-test when compared to the DVD-based group (p=0.03), but the variance in

<table>
<thead>
<tr>
<th>Table 3-2. Mean scores from pre-test to post-test; post-test to 3-month follow-up test; pre-test to 3-month follow-up test; test an assessment of knowledge for overall education population and within groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-test Score, mean (SD)</td>
</tr>
<tr>
<td>All, n=97</td>
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<tr>
<td>DVD, n=37</td>
</tr>
<tr>
<td>One-on-one, n=60</td>
</tr>
<tr>
<td>Post-test Score, mean (SD)</td>
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<tr>
<td>All, n=60</td>
</tr>
<tr>
<td>DVD, n=21</td>
</tr>
<tr>
<td>One-on-one, n=39</td>
</tr>
<tr>
<td>Pre-test Score, mean (SD)</td>
</tr>
<tr>
<td>All, n=60</td>
</tr>
<tr>
<td>DVD, n=21</td>
</tr>
<tr>
<td>One-on-one, n=39</td>
</tr>
</tbody>
</table>

* p-value for significance = < 0.05; paired t-tests
mean scores between groups was only 0.3 points, which has little clinical relevance to differences in knowledge gained. Also, the one-on-one group completed the post-test directly following the education. The DVD-based group was contacted at least one week after receiving the DVD to complete the post-test; therefore, time could be a factor in difference regarding post-test scores.

The DVD-based group had higher mean scores from the post-test to 3-month follow-up within the group, but the difference between groups was not statistically significant (p=0.20; Table 3-2), indicating no significant change in knowledge retention from the post-test to the 3-month follow-up test. Interestingly, the one-on-one group showed a statistically significant reduction in knowledge retained from post-test to 3-month follow-up (p=0.005; Table 3-2). A reduction in knowledge retained from post-test to 3-month follow-up test was not observed for the DVD-based education group (p=0.20; Table 3-2).

Overall, both the DVD-based and one-on-one groups had a statistically significant increase in knowledge from pre-test to 3-month follow-up scores (p=<0.001; Table 3-2). There is no statically significant difference in 3-month follow-up scores between groups (p=0.187).

A repeated measures analysis of variance (ANOVA) was used to examine whether the change in scores was different by group over time. The interaction term of group over time was included in the model and found to be significant (p=<0.049). This indicated there was a differential effect of change in knowledge scores over time by group.

Participants in the DVD-based group had higher scores at the 3-month follow-up than they did at the post-test, whereas participants in the one-on-one group had lower scores at the 3-month follow-up than they did at the post test. This finding suggests that the DVD-
based group may have retained and internalized information to a greater degree than those in the one-on-one group. This interaction is visually displayed in Figure 3-1.

Figure 3-1. ANOVA line graph analysis by group over time

However, gender was associated with both group assignment and knowledge score at the 3-month follow-up exam (p=0.025). A repeated measures ANOVA was conducted while controlling for gender, age, and education level to determine if the variability in these factors would account for differences in scores between groups.

After controlling for gender, age, and education in the multivariate repeated measures ANOVA, the interaction term representing the differential effect of group on scores over time (group*time) was attenuated and was no longer significant (p=0.07). This finding suggests that the differences in knowledge retention over time are associated with these factors, and the differences across groups may account for the statistically significant difference between groups.
Even when accounting for covariates that may influence group scores over time, overall findings suggest both education modalities increase patient knowledge regarding HDS-warfarin management, and both are associated with good retention over time.

**PATIENT-STATE** **D** **D** **C** **HAG** **N** **E** **N** **AND** **S** **ATISFA** **C** **T** **N** **A** **N** **O** **N**

Patients were asked to identify changes they would make as a result of the education at the time of the post-test. Overall, the participants reported they would make an average of 2.59 out of 6 possible changes as a result of the education, and there was no significant difference in number of possible changes between education groups (p=0.48; Table 3-3). Possible changes are listed in Table 3-4.

Of the reported behavior changes, 63% of participants stated they would consult with a medical professional regarding their current HDS intake, and 67.5% stated they would talk to their medical team regarding prospective use. Sixty-nine percent of participants also stated they would read a supplement facts label on current or prospective products to verify content. There were no differences in reported behavior change components between groups (Table 3-4).

These stated behavior changes are encouraging as patients are not likely to recall all products that interact with warfarin, but transparency of intake to their healthcare provider will likely allow better management, INR control, and patient safety on warfarin.

<table>
<thead>
<tr>
<th>Table 3-3. Mean Behavior Changes Across Groups, n=97, Range 0-6</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVD, n=37</td>
</tr>
<tr>
<td>Overall reported change, Mean (SD)</td>
</tr>
</tbody>
</table>

*Significance = <0.05, ANOVA Analysis*
Participants completed a satisfaction questionnaire upon finishing the 3-month follow-up exam to inspect patient-perceived efficacy of the education. Both groups reported the frequency they viewed the education materials about two times after completing the post-test, and this was not statistically significant between groups ($p=0.8$; Table 3-5).

Participants were asked to rank their satisfaction for the overall education. Components of satisfaction included the usefulness of content and provided materials and if the participant felt more comfortable with both warfarin and HDS intake as a result of the education. Satisfaction rating was ranked from zero to four; zero being not satisfied, and four being completely satisfied. Participants reported average satisfaction of 3.5 out of 4, indicating participants were highly satisfied with education provided, and there was no statistical difference found regarding any satisfaction rating component between groups ($p=0.4$; Table 3-5).

<table>
<thead>
<tr>
<th>Table 3-4. Reported Behavior Changes, n= 97</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported Behavior Change Component</td>
</tr>
<tr>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Continue current HDS regimen, n (%)</td>
</tr>
<tr>
<td>Stop consuming HDS products, n (%)</td>
</tr>
<tr>
<td>Talk to medical professional regarding current HDS use, n (%)</td>
</tr>
<tr>
<td>Talk to medical professional regarding prospective HDS use, n (%)</td>
</tr>
<tr>
<td>Continue to refrain from consuming HDS products, n (%)</td>
</tr>
<tr>
<td>Read label on HDS products one may or is currently taking, n (%)</td>
</tr>
</tbody>
</table>

* p-value for significance = $< 0.05$; Chi-Square Analysis
Table 3-5. Mean Patient Reported Satisfaction Across Groups, n=60, Range 0-4

<table>
<thead>
<tr>
<th>Reported Satisfaction Component</th>
<th>DVD, n=21</th>
<th>One-on-one, n=39</th>
<th>p-value (2-tailed)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency viewed provided materials, mean (SD)</td>
<td>1.9 (0.7)</td>
<td>2 (0.76)</td>
<td>0.8</td>
</tr>
<tr>
<td>Overall satisfaction rating, mean (SD)</td>
<td>3.5 (0.5)</td>
<td>3.4 (0.5)</td>
<td>0.4</td>
</tr>
<tr>
<td>Useful content, mean (SD)</td>
<td>3.5 (0.5)</td>
<td>3.4 (0.5)</td>
<td>0.5</td>
</tr>
<tr>
<td>More comfortable with warfarin prescription, mean (SD)</td>
<td>3.2 (0.7)</td>
<td>3.2 (0.6)</td>
<td>0.98</td>
</tr>
<tr>
<td>More comfortable with HDS management, mean (SD)</td>
<td>3.3 (0.6)</td>
<td>3.3 (0.5)</td>
<td>0.98</td>
</tr>
</tbody>
</table>

*Significance = <0.05, ANOVA Analysis

ANALYSIS OF PARTICIPANTS WHO DROPPED OUT OF THE EDUCATION

A significant study limitation included high rates of dropout. Of the 120 initial participants, only 50% of participants completed the final 3-month follow-up exam. This was possibly due to high patient-engagement required to complete all follow-up examinations, or technology knowledge limitations in an elderly population. ANOVA was used to examine differences between post-test data of individuals who dropped out of the education and those who completed the 3-month follow-up exam.

There were no differences in post-test score age or education level between study dropouts and those that completed the education (p=0.07, 0.958, 0.3; Table 3-6). Of note, there is a gender effect here as well; more males dropped out of the education than those that completed the education (p=0.007; Table 3-6).
Table 3-6. Participant characteristics by individuals who dropped-out versus those who completed the follow-up examinations (n=116)

<table>
<thead>
<tr>
<th></th>
<th>Dropped Out After the Post-Test</th>
<th>Completed 3-month follow-up exam</th>
<th>p-value (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>40 (60.6)</td>
<td>26 (30.4)</td>
<td>0.007&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Age, n (SD)</td>
<td>71.2 (10.4)</td>
<td>71.3 (12.1)</td>
<td>0.958&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td>0.312&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Some High School, n (%)</td>
<td>3 (5.2)</td>
<td>2 (3.4)</td>
<td></td>
</tr>
<tr>
<td>High School Graduate, n (%)</td>
<td>27 (47)</td>
<td>31(53)</td>
<td></td>
</tr>
<tr>
<td>College Degree, n (%)</td>
<td>28 (47.8)</td>
<td>25 (45.6)</td>
<td></td>
</tr>
<tr>
<td>Take Supplements, n (%)</td>
<td>34 (41)</td>
<td>49 (59)</td>
<td>0.004&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Take Herbal Products, n (%)</td>
<td>25 (47)</td>
<td>28 (53)</td>
<td>0.711&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Pre-test Score, mean (SD)</td>
<td>4.1 (1.8)</td>
<td>4.1 (1.6)</td>
<td>0.876&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>Post-test Score, mean (SD)</td>
<td>6.3 (1.9)</td>
<td>6.0 (1.2)</td>
<td>0.072&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>1</sup> Fisher’s Exact Test, <sup>2</sup> Chi Squared, <sup>3</sup> ANOVA Analyses

STUDY FINDINGS

This study showed patients had a lack of knowledge regarding HDS therapies and warfarin management. Our research findings mirror previous studies’ results in regards to patient knowledge of HDS therapies. Poor patient understanding of HDS-warfarin management places patients at increased risk for adverse reactions. Analysis revealed there is a gender difference that may have influenced study results; it appears that men gained more knowledge over time when compared to females, but males more frequently dropped out of the education.

Overall, when gender differences were accounted for, results of the study suggest that both self-learning, DVD-based education and one-on-one teaching strategies can successfully increase AF patient knowledge regarding HDS-warfarin management. This
study shows both education programs can effectively increase patient knowledge, and education modalities are also well received by participants, which increases their viability in high patient load areas.

These findings indicate alternative education strategies may be employed in high-prevalence populations to increase patient knowledge while minimizing clinical and physician burden. Although one-on-one education programs are considered an education gold standard, this method may not be effectively implemented in clinical settings, as it requires additional patient and clinician time; well-educated staff must be available to provide the education. As a result, self-learning, DVD-based education methods may educate patients about more intensive components of warfarin management, such as HDS therapies, without adding significant clinician training or time.

Limitations

In a time of joint-accountability in healthcare, high patient engagement is required to ensure patient safety and appropriate medical management. High patient engagement is associated with increased education levels, and participant knowledge. Unfortunately, it was difficult to obtain follow-up data for much of our study population. This is concerning as participants who did not follow-up may not receive benefits of the education. Results of statistical analysis did not reveal any large differences across groups save for gender, yielding little explanation as to the factors that contribute to high patient dropout.

Also, self-learning, DVD-based educations provide limited time to ask follow-up questions. If DVD education strategies are to be effective, patients must know to follow-up with healthcare providers to ensure clarifications.
Conclusions

Future study design and implementation should identify key factors to facilitate further patient participation or accountability for education. This could include employing technology-facilitated education in the patient waiting room in the form of a video for participants to view, or implementing a web-based technology.

Here we assessed observed gains in knowledge over baseline at both the post-test and 3-month follow-up period for both groups. However, this study did not examine actual warfarin variability in the form of INR testing. Many research studies have shown adequate education about warfarin management can reduce patient INR variability.29-36 As such, further research is warranted to examine if DVD-based education regarding HDS management yielded actual changes in patient behavior and improved INR values.

While further testing is needed to discover methods of education implementation in clinical settings, this pilot study showed self-learning, DVD-based education can increase patient knowledge regarding HDS-warfarin management, and is associated with patient reported behavior changes. These education methods may be further examined to increase patient knowledge regarding essential disease-related components in clinical settings.

References


CHAPTER 4
SUMMARY AND CONCLUSIONS

Abstract

Warfarin anticoagulation therapies continue to be a key treatment component for many individuals with atrial fibrillation (AF). Despite its high efficacy, warfarin use requires extensive patient knowledge about many factors that may interact with warfarin, such as herbal and dietary supplements (HDS), to minimize adverse reactions. Education can be difficult in many clinical settings due to time and personnel constraints. This document will review the feasibility of alternative education strategies in clinical settings to improve patient knowledge independent of extensive clinician management. Self-learning, DVD-based education strategies may effectively increase patient knowledge regarding HDS intake, and further research is warranted to examine its routine use in clinical settings.

Summary

Atrial fibrillation (AF) is a common cardiac arrhythmia that significantly impacts the health of many aging adults. Pharmaceutical therapies, such as warfarin, are essential for effective disease management, but these drugs are frequently sited as a major factor for morbidity due to their narrow therapeutic index and the significant adverse effects that may occur when anticoagulation therapies are out of range. Patients must understand the many factors that influence International Normalized Ratio (INR) values to decrease medication variability and to improve patient outcomes. Similarly, an effective education tool must be implemented to increase patient knowledge regarding
environmental factors that can contribute to poor warfarin control while minimizing clinical healthcare burdens in a time of shrinking financial and human resources. Of these influencing factors, herbal and dietary supplement (HDS) intake is associated with suboptimal coagulation control. Though knowledge regarding HDS management is essential to minimize unintended INR variability, there is limited research regarding patient understanding of HDS-warfarin interactions. The select studies that have explored HDS-warfarin management show patients have poor understanding of these factors and their influence on warfarin control. Also, alternative education strategies have not been explored to routinely to educate AF patients regarding specific disease and medication management.

STUDY OBJECTIVES AND FINDINGS

This study aimed to develop an education tool that could increase patient knowledge of HDS-warfarin control independent of extensive clinician time. A self-learning, DVD-based format was chosen for its validated effectiveness in chronic disease education, the minimal cost to developers and care providers, and the reduced time required by clinicians to educate patients. An equivalent one-on-one education program was created to serve as a control for the alternative education outcomes (please see appendices A-H for education materials and testing data). Researchers also hoped to obtain INR values of study participants to determine if this education could improve warfarin control.

A 120-participant pilot study was conducted in collaboration with the Intermountain Rhythm Specialty Clinic in Murray, Utah. This population was chosen as patients on warfarin routinely receive education in similar outpatient venues where INR
values are being monitored. Researchers felt if the proposed alternative education modalities could effectively increase patient knowledge regarding HDS-intake strategies while reducing needed clinician time for one-on-one education, these tools could be more extensively researched and implemented in clinics to improve warfarin-associated outcomes.

The findings from this research study are consistent with the current literature and provides additional evidence that patients routinely consume HDS products, but have limited knowledge regarding HDS-warfarin interactions and management.\textsuperscript{5-11} Although our study did not show patients could routinely recall all products that interact with warfarin, patients did state increased understanding that these products do interact with coagulation therapies, and the majority understood their healthcare provider must be aware of HDS intake to minimize unintended INR variability.

This study found education provided in a self-learning, DVD-based format had similar efficacy when compared to one-on-one teaching methods. These findings add to current literature regarding warfarin and chronic disease management because alternative education stratagems have not been statistically validated to increase patient knowledge regarding warfarin interactions.

**STUDY LIMITATIONS**

A large limitation of the DVD-based education was there was limited space in the clinic to allow participants to view the DVD; therefore, participants were asked to view the DVD in their home, and researchers followed up via telephone. Continued participation engagement was difficult, and follow-up to receive only 35% DVD-based participant completion took extensive time. This education modality can only be effective
if patients view the DVD, and in-home viewing requires high patient engagement and motivation. Therefore, this education format may be more successful if the education was provided to a captive audience, for example, in office waiting rooms or while patients are waiting for the clinician.

Researchers did obtain INR statistics for study participants (Table 4-1) during the course of the study, but field experts including the collaborating physician and lead pharmacist felt the research model did not account for other factors that could influence INR variability. These factors could include: nutritional status, availability of both dietary and endogenous sources of vitamin K, genetic polymorphisms, hepatic function, medication clearance, intestinal absorption, schedule compliance, drug interactions, and herbal and dietary supplement intake; therefore, this measure was not used as an indication of efficacy of the education models tested. 7,2-16

Further research should be done to determine if DVD-based education could increase patient knowledge regarding medication-associated factors and show-validated improvement in medication safety (i.e. INR data). Future study methods must account for other influencing factors to provide statistical power to this measure.

<table>
<thead>
<tr>
<th>Table 4-1. Participant INR Values During Education Intervention, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total INR Values Collected</strong></td>
</tr>
<tr>
<td><strong>Below Therapeutic range</strong></td>
</tr>
<tr>
<td><strong>In Therapeutic Range</strong></td>
</tr>
<tr>
<td><strong>Above Therapeutic Range</strong></td>
</tr>
</tbody>
</table>

**Conclusions**

Patients must know how to account for influencing medical factors for disease and medication safety, and healthcare providers must have effective education tools to
address these knowledge deficits.\textsuperscript{17-20} This study showed self-learning, DVD-based strategies can address patient knowledge and provide an acceptable education method for clinical settings. Although further research is needed to determine the most effective way to implement these tools in clinical settings, these research findings show DVD-based education strategies are an effective tool for the elderly chronic disease population. These findings may be useful even as new mediations and disease management approaches enter the healthcare industry as chronic disease prevalence is rising in an aging US population.\textsuperscript{21} Teaching strategies must be robust and effective to address knowledge deficits in these populations.\textsuperscript{17-20}

**References**


APPENDICES
Identification Number: ______________

1. Why is it important to take your warfarin every day?
   a. To prevent a heart attack
   b. To prevent blood clots
   c. To control blood pressure

2. What should you do if you forget to take your warfarin?
   a. Take your dose as soon as you remember
   b. Double up on your warfarin
   c. If it has been less than 12 hours, take your warfarin dose

3. What is a supplement?
   a. A vitamin or mineral
   b. A product that can be used instead of eating foods
   c. All of the above

4. What is an herbal product?
   a. A product that is made from a natural source to provide functional support
   b. A product that can be used instead of eating foods
   c. A product that is only made in tablet form

5. What can happen if you use herbal or dietary supplements while you are taking warfarin?
   a. Stroke or bleeding
   b. A heart attack
   c. Change in heart rhythm

6. Which of the following should not be used while taking warfarin without first discussing this with your health care provider? (Please circle all that apply.)
   a. Fish oil
   b. Glucosamine
   c. Coenzyme Q 10
   d. Green tea
   e. Any product containing vitamin K
   f. Ginger
   g. Spices used in cooking
   h. Iron
Supplement Facts
Serving Size 1 tablet
Suggested Use: Adults, take one tablet per day with meal

<table>
<thead>
<tr>
<th>Amount per serving</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Folic Acid 600 mcg</td>
<td>100</td>
</tr>
<tr>
<td>Vitamin K 160 mcg</td>
<td>200</td>
</tr>
<tr>
<td>Vitamin A 500 I.U.</td>
<td>100</td>
</tr>
<tr>
<td>Vitamin D 400 I.U.</td>
<td>100</td>
</tr>
<tr>
<td>Vitamin B12 4 mcg</td>
<td>66</td>
</tr>
<tr>
<td>Iron 18 mg</td>
<td>100</td>
</tr>
<tr>
<td>Copper 1 mg</td>
<td>50</td>
</tr>
</tbody>
</table>

Ingredients: Vitamin A acetate, folic acid, menoquinone, vitamin D, vitamin B12, ferrous iron, copper sulfate

Please use the label below to answer questions 7-8.

7. Which of the following nutrients listed in the label may interact with warfarin?
   a. Copper
   b. Iron
   c. Folic Acid
   d. Vitamin A

8. Taking this supplement while using warfarin could:
   a. Increase your risk of bleeding or having a stroke
   b. Increase your risk of a heart attack
   c. Have no effect on your warfarin medication

9. You should speak to your doctor:
   a. Before taking any new supplement or herbal product
   b. If you make any changes to what supplement or herbal product(s) you are already taking
   c. If you stop taking a supplement or herbal product
   d. A and B
   e. All of the above
Post-test only question:

10. Because of this education, I will (please circle all that apply):
   a. Stop taking any supplements or herbal products
   b. Read a supplement facts label before taking supplements or herbal products
   c. Talk to my doctor or pharmacist about the supplements I am currently taking
   d. Talk to my doctor or pharmacist before taking any new supplement or herbal product
   e. Continue not to take any supplements or herbal products
   f. Continue to take the supplements and herbal products I was taking before the education
APPENDIX B. INFORMED CONSENT

Patient authorization and consent to participate in a research study

DVD (Self Learning) Versus Traditional Education Approaches to Improve The Safety Of Warfarin Anticoagulation Therapy In Patients With Atrial Fibrillation

<table>
<thead>
<tr>
<th>Principal investigator:</th>
<th>Thomas Jared Bunch MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub-investigators:</td>
<td>Jessica Oliver RD</td>
</tr>
<tr>
<td>Sponsor and Location:</td>
<td>Intermountain Healthcare</td>
</tr>
</tbody>
</table>

Dr. Jared Bunch, MD, in collaboration with Utah State University, is conducting a research study to find out more about supplement use in patients with atrial fibrillation who are on warfarin. You have been asked to take part in this study because you have atrial fibrillation and are currently taking warfarin. The purpose of this consent form is to provide you with information you and your family need to make an informed decision whether to take part in this study.

Why is this study being done?

The purpose of this research study is to educate patients about some of the risks of using supplements while they are on warfarin. By informing patients about how to appropriately consume supplements, patient safety will likely be increased.

How many people will take part in this study?

150 patients will be enrolled in this study through the Coumadin Clinic at Intermountain Medical Center in Murray, Utah.

What is involved in this study?

Study Procedures
If you agree to participate in this study, you consent to:

1. Complete an initial demographic questionnaire and pre-test to assess your current knowledge concerning warfarin and supplements and herbal products.
2. Participate in a one-on-one education, a group class, or view an educational DVD concerning supplement use and warfarin.
3. Complete a post-test immediately following the education.
4. Three months following the education, you will be contacted via telephone to re-administer the post-test. This will help researchers see how much information taught was helpful and remembered.
5. Grant researchers permission to look at your past medical records to record your INR levels for three months before and after you participate in the study.
What are the risks of this study?

Participating on this study may involve some added risks or discomforts. These include: loss of personal time from completing the education and telephone calls, an inadvertent disclosure of personal information. These risks will be minimized by following confidentiality protocols as listed below, and ensuring the education and telephone calls will be conducted by competent, capable instructors to minimize time required by you as the participant.

How long will I be in the study?

You will participate in this study for three months. The investigator may decide to take you off the study at any time if he/she feels your continued participation would in any way impair your health.

What are the benefits to taking part in the study?

Possible benefit to you
There may be a direct benefit to you from participating in this study by increasing your knowledge about supplements, herbal products, and warfarin.

Potential benefit to others
Your participation in the education may help future patients who are placed on warfarin by providing investigators more information about the type of education patients need about warfarin and supplements. This information will allow investigators to provide an educational tool to other patients with atrial fibrillation to help these individuals safely consume supplements and warfarin.

What other options do I have?

Instead of being in this study, you have the option to not enroll in this study.

What are the costs?

- You will not be charged to enroll in this study.
- You or your insurance carrier will be billed in the usual manner for the normal standard of care patients with your condition(s) would receive if hospitalized for medical conditions not directly related to participation in this registry. This includes your hospital room charges, routine tests and procedures, medications, and any follow up visits you may need after you are discharged from the hospital. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including but not limited to: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures.
- You will not be paid for participating in this study.
What if I get hurt or ill from my participation?

As a research subject, you may be harmed as a result of your participation. It is the nature of medical research that all adverse events are not preventable or foreseeable. In the event you sustain injury resulting from your participation in the research project, Intermountain Healthcare can provide to you, emergency and temporary medical treatment and will bill your insurance company. Since this is a research study, payment for any injury resulting from your participation in this research study may not be covered by some health insurance plans.

If you believe that you have sustained an injury as a result of your participation in this clinical investigation, we ask that you contact the investigator as soon as possible. You may also contact the Office of Research at (1-800) 321-2107.

What about confidentiality?

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Intermountain Healthcare has a commitment to protect your confidentiality. Federal regulations require that you understand how your protected health information (PHI) is used for this study.

This is the information we will use:

- Your initials may be attached to a study identification code (for example ABC-123).
- Your name, initials, date of birth, address and telephone number(s) will be placed into a study document entitled “confidential enrollment log”. This log is not available to anyone except Intermountain Healthcare staff members who are conducting this clinical trial at Intermountain Medical Center. There are several reasons investigators keep the confidential enrollment log:
  - We may need to contact you with information regarding the trial or results of the trial after your participation has ended and/or regulatory agencies may request to examine all records generated during a clinical trial.
- Your family medical history may be reviewed to assess risk factors that may affect your eligibility to participate in this trial.
- Your previous medical history may be reviewed to determine your eligibility to participate in this trial. Hospital admission and discharge summaries placed in your hospital chart(s) give us the most reliable information.
- Your most current medical history or information specific to the condition for atrial fibrillation may be reviewed to determine your eligibility to participate in this trial. Hospital admission and discharge summaries placed in your hospital chart(s)
give us the most reliable information.

- Current and past medications or therapies/results which may affect your eligibility for this trial or your safety while participating in it may be reviewed to determine your eligibility to participate in this trial.

- Information (results) from tests, procedures and physical examinations, such as blood pressure readings, heart rate, breathing rate, and temperature at specified times, may be reviewed for the purpose of establishing your baseline condition and to continue monitoring your progress and/or safety while participating in this trial.

- We may need to review your prior medical history (PMI)/medical records kept by other physicians you may see for your medical conditions(s) to establish eligibility, to document any adverse events/side effects you may have during the trial and to assure that you can safely participate in this trial. If this information is needed we will ask you to give us permission to ask your doctor for it by signing a medical release of information form.

- Dates of surgeries, device implants, or procedures related to this clinical trial.

- The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

Others who will have access to your identifiable PHI for this research project include: (Intermountain Healthcare) Intermountain Medical Center’s Institutional Review Board (the committee that oversees research studying people) and authorized members of Intermountain Healthcare’s workforce who need the information to perform their duties (for example: provide treatment, to ensure integrity of the research, and for accounting or billing matters), the Food and Drug Administration (FDA), and others as required by law.

Except as addressed in this authorization form, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Intermountain Healthcare. Information received during the study will not be placed on any mailing lists or sold to anyone for marketing purposes. For records disclosed outside of Intermountain Healthcare, your information will be assigned a unique code number (for example 123-ABC). The key to the code will be kept in a password protected file stored in the Intermountain Healthcare computer network.

Signing this document means you allow us, the researchers in this study, and others working with us to use PHI about your health for this research study. You can choose whether or not you will participate in this research study; however, in order to participate you have to sign this consent form.
You may change your mind later, and ask us to stop using or disclosing your PHI. You must either give this notice, called a revocation, in writing to the principal investigator, Thomas Jared Bunch MD, the principal investigator’s staff, or mail it to Thomas Jared Bunch MD c/o Cardiology Department, Intermountain Medical Center, 5121 South Cottonwood Street, Murray, UT 84157-7000. If you revoke this authorization, we will not be able to collect new information about you, and you will not be able to participate in the study; however, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

If we send PHI about you outside Intermountain Healthcare, based on this or any other authorization you sign, we cannot guarantee that the recipient will not redisclose your PHI to a third party. The recipient of the information may not be required to abide by this authorization or applicable federal and state law governing the use and disclosure of your PHI.

You have a right to information used to make decisions about your health care; however, your information from this study will not be available to you during the study. It will be available after the study is finished and the results are made available. This authorization does not have an expiration date.

If I agree to participate what are my responsibilities?

We would expect that you, as a patient at Intermountain Medical Center and as a study participant in the trial, would have the following responsibilities:

- You will keep your scheduled clinic visits with your doctors.
- It is very important you discuss taking over-the-counter medications with your study doctor. This includes common over-the-counter medications you may not think important to mention to your physician such as headache or cold remedies.
- You will also be asked to review any other medications you may have taken since your last visit.
- If you decide you no longer wish to participate in this study, you will notify your doctor or coordinators immediately so that we can adjust your care appropriately.

What are my rights as a participant? Where can I get more information?

A copy of this form will be given to you as a participant in this study if you agree to enter the study.

Taking part in this study is your choice and your participation is voluntary. If you agree to take part and then decide against it, you can withdraw for any reason. If you decide to stop taking part in the study, you should talk to the researcher so it can be done safely. Leaving the study will not result in any penalty or lost benefits to which you are otherwise entitled and the medical care you receive will not be affected in any way.
If you have any questions now or at any point during the study concerning the research or related matters, or, if you think you have had study related injury, you should call the principal investigator, Thomas Jared Bunch MD at (801) 507-4701 (24 hour voicemail).

If you would like to speak to someone not associated with the study about your rights as a participant, or any other matter related to clinical research conducted at Intermountain Healthcare facilities, contact the Intermountain Healthcare Office of Research at (1-800) 321-2107.

Sometimes during the course of a research project, new information becomes available about the treatment/drug/procedure/data that is being studied or there is a change in the trial protocol (directions on how to conduct the trial). If this happens, your research doctor will tell you about how it will affect your participation in the trial and discuss with you whether you want to continue in the study. If you decide to withdraw from study treatment, the investigator will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form, which will contain the new information. (You may sign more than one consent document throughout the duration of the trial.) Also, upon receiving new information the investigator might consider it to be in your best interest to withdraw you from participation in the study. He/she will explain the reasons and arrange for your care to continue.

For more information about my rights to my PHI, how to revoke this authorization, and how (Intermountain Healthcare) Intermountain Medical Center uses my health information, I may ask to see or obtain a copy of the Intermountain Healthcare Notice of Privacy Practices. I hereby acknowledge that I have received or been offered a copy of Intermountain Healthcare’s Notice of Privacy Practices.
Signatures

My signature below indicates that I have read or had read to me and understand all of the information given to me in this document. The information in this document has been explained to me and I have had the opportunity to ask questions. My signature below indicates that I voluntarily agree to participate in the study described in this document and I have received a copy of my signed/dated consent.

_________________________  ______________________  ______
patient’s printed name      patient’s signature     date

If the patient is unable to give consent and authorization, consent and authorization is given by the following authorized personal representative of the individual:

_________________________
Name of authorized personal representative

_________________________
Signature of authorized personal representative  date

If the participant is unable to give authorization and consent, describe the legal representative’s authority to act for the individual. __________________________

I, the undersigned, certify that I have fully explained this clinical investigation to the patient (and to the patient’s legal/personal representative(s), if the patient wishes) signing this consent form and the patient/representative (if applicable) has been given the opportunity to ask questions regarding the contents of this consent form and the expectations associated with his/her participation in this research study.

_________________________
Signature of person obtaining consent  date
APPENDIX C. ONE-ON-ONE AND GROUP HDS-WARFARIN CURRICULUM

Objectives:
1. Participant will provide one reason why compliance with warfarin therapy is critical.
2. Participant will verbalize what to do if a warfarin dose is missed.
3. Participant will define HDS.
4. Participant will identify three risks associated with HDS use while on warfarin therapy.
5. Participant will identify three commonly used HDS that interact with warfarin.
6. Participant will identify and interpret three components of a supplement label.
7. Participant will verbalize the importance of consulting with a health care provider prior to:
   a. Continuing use of any HDS while on warfarin.
   b. Beginning any new HDS therapy.
   c. Making any changes to current HDS regimen.

Total Time: 20-25 minutes

Materials needed:
- Attached handout entitled “Commonly Used Supplements and Herbal Products that May Interact with Warfarin”.
- Attached handout detailing how to interpret a supplement label. Additionally, you may show the participant an actual supplement containing vitamin K to discuss during objective six.
- The pre- and post-test to administer to the participant.

Introduction and Pre-test

Time: 2 minutes

Thank the participant for volunteering to participate in this education.

Explain to the participant:
- The purpose of this education is for you to learn more about warfarin and the risks associated with using HDS products while on warfarin.
- Although all supplements and herbal products are not dangerous, many interact with warfarin and should be avoided and/or used with caution.
- The purpose of the pre-and post-test is to determine if my instruction is effective.

Verbally administer the pre-test to the participant. You may clarify questions but you may not provide answers to the participant.
Invite the participant to ask any questions about supplements and warfarin during the course of the education.

**Objective 1:** Participant will be able to state why compliance to warfarin is critical.

Time: 2 minutes

Ask the participant: Why is it important to always take warfarin as prescribed by your doctor?

Explain to participant:
- Warfarin helps prevent blood clots. Common types of blood clots include deep venous thrombosis clots in your leg or a pulmonary embolism (a clot in your lungs). Blood clots can cause a stroke. If you at risk for a stroke, your doctor might prescribe you warfarin. Warfarin does not prevent heart attacks or affect your heart rhythm or blood pressure.
- If you miss a dose, or do not take warfarin as directed, your risk for stroke increases. If you double your dose, your risk for bleeding increases.
- Your doctor can monitor if warfarin is working correctly by testing your International Normalized Ratio (INR), which is also known as your blood warfarin level.

**Objective 2:** Participant will verbalize what he/she should do if a warfarin dose is missed.

Time: 2 minutes

Ask the participant: What should you do if you miss a warfarin dose?

Explain to the participant:
- Warfarin is only taken once a day. If you forget to take your dose, but remember within 12 hours of when you were supposed to take your warfarin, take your dose at that time. Take your next dose of warfarin (the following day) as you normally would.
- If it has been more than 12 hours since you were supposed to take your warfarin, skip that daily dose and take your warfarin the next day as you normally would.
- For example: if you are supposed to take your dose at 9:00 am and you remember at 1:00 pm (4 hours later), it is okay to take your warfarin at 1:00 pm and then take your next dose of warfarin the next day as you normally would. However, if you remember at 10:00 pm (13 hours later) do not take your warfarin at 10:00 pm, but take it the next day as you normally would.
- DO NOT double up on your warfarin dose even if you have skipped a dose. This may lead to bruising, bleeding, or even death.
• If you notice any signs of increased bruising or bleeding, contact your medical professional immediately.
• If you miss more than one dose, contact your health care provider.

Objective 3: Participant will define what an HDS product is.

Time: 2 minutes

Ask the participant: What is the difference between a supplement and an herbal product? Explain to the participant:
• A supplement can be a vitamin, mineral or a combination of these. Supplements should not replace food.
• Examples of supplements include:
  o A multivitamin
  o Any individual vitamin or mineral (vitamins A,C, and K, magnesium, etc.)

• An herbal product is a product made from a natural source that may contain vitamins, minerals, and other products including fish oils, botanicals or other naturally occurring compounds. Herbal products can be in capsule, teas, drinks, or powder form. Herbal products are often used to provide functional support.
• Examples of herbal products include:
  o Green tea
  o Evening Primrose Oil
  o Ginger tablets
  o Garlic pills
    ▪ Ginger and garlic are safe to use as spices in cooking.

Objective 4: Participant will identify three risks associated with HDS product use while taking warfarin.

Time: 3 minutes

Ask the participant: What are the risks of using supplements or herbal products when taking warfarin?

Explain to the participant:
• Although patients commonly use HDS products, many interact with warfarin. This may lead to:
  o Bruising or bleeding
  o Stroke or clots, such as:
- Deep vein thrombosis (DVT), which is a clot usually found in the leg
- Pulmonary Embolism (PE), which is a clot usually found in the lungs

- It is important to know that your INR level will not always tell you if the HDS product you are taking has affected how well warfarin is working in your body. Before taking any HDS product, please ask your doctor or pharmacist if the product is safe to use while taking warfarin.

**Objective 5:** Participant will identify three commonly used supplements and/or herbal products that interact with warfarin.

Time: 5 minutes

Explain to participant:
- We don’t know a lot yet about which supplements and herbal products are safe to use when taking warfarin.
- We will now talk about a few of the most popular supplements and herbal products on the market today and whether or not they interact with warfarin.

Give participant the supplement handout entitled “Commonly Used Supplements and Herbal Products that May Interact with Warfarin” and discuss this handout with the participant.

These supplements and herbal products have been broken down into 3 categories:
1. HDS products that interfere with warfarin.
2. HDS products that interact with warfarin.
3. HDS products that we are unsure of their interaction or may have a small interaction with warfarin.

No matter what, if you are taking an HDS product or are thinking about it, you need to contact your health care professional before beginning or stopping use of any HDS product.
1. Supplements and herbal products that interfere with warfarin.
   - Baldo
   - Garlic
   - Ginseng
   - St. John’s Wort
   - Wintergreen
   - Gingko
   - Green tea
   - Vitamin K

2. Supplements and herbal products interact with warfarin.
   - Vitamin A
   - Vitamin D
   - Vitamin E
   - Coenzyme Q10
   - Glucosamine
   - Carnitine
   - Melatonin
   - Chondroitin
   - Cranberry

3. Supplements and herbal products that may have a minor interaction with warfarin and should be used with caution and only with the approval of a health care professional.
   - Soy
   - Chelation therapy
   - Ginger
   - Grapefruit
   - Cod liver oil

Explain to the participant:
- There are many HDS products that are not listed in this handout. However, that does not mean that they are safe to take while taking warfarin. Contact your doctor or pharmacist before beginning ANY supplement or herbal product.

**Objective 6:** Participant will be able to identify and interpret three components of a supplement label.
Time: 5 minutes

Show participant the supplement label handout while discussing the components of a supplement label.

Points to discuss:

- **Amount per serving:** This column lists all nutrients in the product and the quantity of each nutrient.
- **Ingredients:** All nutrients and all other ingredients contained in the product can be found in the ingredient list and in the amount per serving column.
- **You should look at both the amount per serving and the Ingredients column to see if the HDs product contains anything that could interact with warfarin.**
  - For example: If Baldo, Vitamin K, green tea, and glucosamine were listed in either location, you should not take that supplement until you talk to your doctor or pharmacist to make sure it is okay to use, and, if so, how to take it safely.
- **Serving Size:** This is the manufacturer’s recommended serving.
- **Percent Daily Value:** This number is the percentage of the recommended amount of each nutrient in the supplement. If an asterisk (*) is present, a recommended amount has not been set for that specific nutrient.

Ask the participant:

- Now that you are familiar with a supplement facts label, let’s look at the label and determine whether this supplement contains ingredients that may interact with warfarin.
Explain to the participant: This supplement contains vitamins K, A, and D. All of these vitamins can interact with warfarin, and should be used with caution, but vitamin K is of special concern. Vitamin K helps blood clot in the body. It is important to know that just because you are taking warfarin, it does not mean you don’t need vitamin K. However, taking too much vitamin K, especially from supplements, may increase your chance of a stroke. Please talk to your doctor or pharmacist before taking vitamin K or any supplement containing vitamin K. It is important to note that it may be possible to take these supplements ONLY if you take them consistently and you have discussed them with your health care professional.

**Objective 7:** Participant will verbalize understanding of the need to consult with his/her health care provider before:

a. Continuing use of any HDS product while on warfarin.
b. Before taking any new HDS product.
c. Making any changes to your current HDS product regimen.

Time: 2 minutes

Explain to the participant:
• Because HDS products may cause warfarin to not work properly, you should talk to your health care provider before:
  o Continuing use of any HDS product.
  o Before taking any new HDS product.
  o Making any changes to your current HDS product regimen.

**Closing and Post-test**

Time: 5 minutes

Reinforce with participant:
• Talk to your health care provider about any HDS products that you are currently taking or that you may wish to take.
• It is possible to take HDS products safely if you:
  o Take them consistently
  o Take the same brand/manufacturer
  o Tell your healthcare professional if you start or stop using HDS products.
• It may be a good idea to bring any HDS product you are taking with you to your next doctor visit so he/she can help you decide if it is okay to take while using warfarin.

Administer the post-test. You may verbally give the test or allow the participant to complete it independently. You may clarify questions but you may not provide answers to the participant. Thank the participant for participating in this education. Collect the pre- and post-test and place in provided folder to return to research team.
APPENDIX D. ONE-ON-ONE EDUCATION HANDOUTS
How to Read a Supplement Facts or Herbal Product Label

**Serving Size** is the manufacturer’s recommended serving.

**Percent Daily Value** (DV) is the percentage of the recommended amount of each nutrient in the supplement. If an * asterisk is present in this column, it means that a recommended daily allowance has not been made yet for that nutrient.

**Supplement Facts**
Serving Size 1 tablet
Suggested Use: Adults, take one tablet per day with meal.

<table>
<thead>
<tr>
<th>Amount per serving</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Folic Acid 600 mcg</td>
<td>100</td>
</tr>
<tr>
<td>Vitamin K 160 mcg</td>
<td>200</td>
</tr>
<tr>
<td>Vitamin A 500 I.U.</td>
<td>100</td>
</tr>
<tr>
<td>Vitamin D 400 I.U.</td>
<td>100</td>
</tr>
<tr>
<td>Vitamin B 12 4 mcg</td>
<td>66</td>
</tr>
<tr>
<td>Iron 18 mg</td>
<td>100</td>
</tr>
<tr>
<td>Copper 1 mg</td>
<td>50</td>
</tr>
</tbody>
</table>

Ingredients: Vitamin A acetate, folic acid, menoquinone, vitamin D, vitamin B12, ferrous iron, copper sulfate

The **Ingredients** lists everything contained in the supplement.

To find out if a supplement or herbal product is safe to use while you are taking warfarin, you need to look at both the **amount per serving** column and the **ingredient list**. Then, look at the handout given to see if the supplement or herbal product is safe to use while taking warfarin.
Commonly Used Supplements and Herbal Products that Can Interact with Warfarin

**Stop**: These products interfere with warfarin. Talk to your health care professional before taking any of these products.

- Baldo
- Dansen
- Dong
- Quai
- Garlic
- Gingko
- Ginseng
- Green tea
- St. John’s Wort
- Wintergreen

**Caution**: These interact with warfarin. It is important to talk to your health care professional before taking any of these products.

- Vitamin A
- Vitamin D
- Vitamin K
- Vitamin E
- Carnitine
- Chondroitin
- Coenzyme Q10
- Evening Primrose Oil
- Glucosamine
- Melatonin

**Yield**: These products have an unknown interaction with warfarin. It is important to talk to your health care professional before taking any of these products.

- Chelation therapy
- Cod liver oil
- Ginger
- Grapefruit
- Fish oil
- Soy

Note: Many supplements and herbal products are not listed on this handout. However, that does NOT mean that they are safe to use while taking warfarin. Talk to your health care professional before using ANY new supplement or herbal product.
What does warfarin do?

• Warfarin helps prevent blood clots. Blood clots can lead to stroke or heart attack.
• In order for warfarin to help prevent blood clots, you must take it as prescribed by your doctor.
• Your doctor can check how well your warfarin is working by looking at your International Normalized Ratio (INR).
• Warfarin is working best when your INR is between 2 and 3.

Why must I take warfarin every day?

• If you miss a dose, or do not take warfarin as recommended, your chance for stroke or heart attack is higher.
• If you double up on a dose, your chance of bleeding is higher.
What do I do if I miss a warfarin dose?

- Warfarin is usually taken once a day.
- If you forget to take your dose, but remember within 12 hours of when you were supposed to take your warfarin, take your dose at that time.
- If it has been more than 12 hours since you were supposed to take your warfarin, do not take that dose.
- Resume taking your warfarin medication at the normal time the next day.
- DO NOT double up on your warfarin dose.
- If you miss more than one dose, contact your health care provider.

When should I talk to my health care provider about supplements and herbal products?

- Because supplement and herbal products can interact with warfarin, you should talk to your health care provider before:
  - Continuing to use any supplement or herbal product
  - Before taking any new supplement or herbal product
  - Making any changes to your current supplement or herbal product regimen
Slide 1 Script: Hello. You are watching this video because you take the medicine, warfarin. Warfarin, also known as coumadin, is a life-saving medication. However, taking it is not without risks. In the next few minutes, we will review some of the most important things you need to remember while taking warfarin. Then, we will discuss some basics about supplements and herbal products so you can take them safely while you are on this medication.
Slide 2 Script: Warfarin helps prevent blood clots. Blood clots can occur in your legs, lungs, and arteries. These blockages can cause a stroke, heart attack, or tissue death. If you are at risk for a stroke, your doctor may prescribe warfarin. Warfarin does not prevent heart attacks, affect your heart rhythm, or increase your blood pressure.

Slide 3 Script: If you miss your dose of warfarin, or do not take warfarin as directed, your risk for stroke increases. If you double your dose of warfarin, your risk for bruising or bleeding increases. This is why it is important to always take warfarin as prescribed by your health care professional.
Slide 4 Script: Your doctor can check to see if warfarin is working correctly by testing your International Normalized Ratio, or INR, which is also known as your blood warfarin level.

Slide 5 Script: Your INR level can be influenced by many factors including:

- Compliance to your warfarin prescription
- Food
- Medications
- Alcohol
- Herbal and dietary supplements

Your compliance to your warfarin prescription, the foods you eat, the medications you take, the alcohol you may consume, and the herbal and dietary supplements you use.

Making any major lifestyle changes as outlined in this list could increase your clot or stroke risk.
An increase in your INR leads to delayed blood clotting.

Signs that your INR may be too high include:

- Abnormal bruising
- Abnormal bleeding

Slide 6 Script: An increase in your INR leads to delayed blood clotting. If your INR is too high, you may experience abnormal bruising and bleeding. A slight increase in bruising can occur while you are on this medication. However, excessive bruising is problematic and should be addressed by your health care professional.

You will also need to monitor for any signs of excessive bleeding. For example, if you receive what seems to be a minor injury that does not stop bleeding, your INR may be too high. Furthermore, be particularly cautious to avoid falls that may lead to more serious injuries, including internal bleeding.

The major sign of internal bleeding is blood in your stool. Although you may not notice this sign after a fall, bleeding may still have occurred. Either way, be sure contact your health care professional immediately.
A decrease in your INR may result in a blood clot which usually originates in your leg or another large vein or artery. Clots are very dangerous because they can move to your lungs or brain and cause a stroke.

Signs of clot formation include: an abnormally swollen, warm, flushed, or discolored area of skin. This usually happens very quickly and is most commonly found in the leg or pelvis. If you ever notice these dangerous symptoms, please contact your doctor immediately.

Your healthcare team is constantly watching for signs that you are at an excessive stroke risk.
Slide 9 Script: Your health care team is constantly watching for signs that you are at an excessive stroke risk. Unfortunately, it is not always possible to prevent all strokes. Therefore, you need to know the symptoms of a stroke.

Signs that you may have experienced a stroke include:
  • Sudden numbness or weakness, particularly on one side of your body,
  • confusion or trouble speaking,
  • troubles with balance, walking, or dizziness, or a sudden, severe headache without an apparent cause.

If you notice any of these symptoms, seek medical attention immediately.
Slide 10 Script: Warfarin should be taken once a day unless your doctor tells you otherwise. However, it is important for you to know what to do if you accidentally miss a dose.

If you forget to take your warfarin, you need to consider how long it has been since you were supposed to take that day’s dose. If you remember within 12 hours of when you were supposed to take your warfarin, take your warfarin at that time.

If it has been more than 12 hours since you were supposed to take your warfarin, skip that dose. In either scenario, take your warfarin the next day as you normally would.

Slide 11 Script: As an example, Walter usually takes his warfarin at 9:00 am but one morning, he forgets.
Slide 12 Script: At 1:00 pm, Walter realizes he did not take his warfarin that morning. It is safe for him to take his dose at 1:00 pm because it is only 4 hours later than his normally scheduled time.

Slide 13 Script: However, if Walter had remembered at 10:00 pm, it would not be safe for him to take his warfarin that day. It has been too long, 13 hours, since that day’s dose was scheduled.

He should take his 9:00 am dose the following day as scheduled by his health care professional.
Slide 14 Script: Following Walter’s example and the other simple guidelines as outlined in this DVD, will help to ensure that you are safe while taking warfarin.

It is important to remember:
{Click 1} Not to double up on your warfarin dose, even if you have skipped a dose. This may lead to bruising, bleeding, or even death.

{Click 2} If you miss more than one warfarin dose, contact your health care provider.

Slide 15 Script: As mentioned earlier, herbal products and dietary supplements may affect how warfarin works in your body. Therefore, these products should be used with caution and only under the direction of your health care professional when used in combination with warfarin.
Slide 16 Script: Many herbal products and dietary supplements interact with warfarin. These interactions can increase your risk for: bruising, bleeding, blood clots, stroke, and possibly death.

Your INR level will not always tell you if the herbal product or dietary supplement you are taking is interacting with your warfarin medication. Therefore, ask your doctor or pharmacist if the product or products you wish to take are safe to use while you are on warfarin.

Let’s further discuss some of the important things you need to know about dietary products and herbal supplements.
Ask your doctor or pharmacist if the product you wish to take is safe to use while you are on warfarin.

Dietary Supplements

Products that contain vitamins and minerals and are used to complement the diet.

- Individual vitamin or mineral
  - Calcium, Magnesium, Zinc, Vitamins A, C, or K

- A multivitamin
  - Vitamin D and Calcium
  - Folic Acid, Vitamin B, and Zinc

Slide 17 Script: Ask your doctor or pharmacist if the product you wish to take is safe to use while you are on warfarin.

Slide 18 Script: Dietary supplements are products that contain vitamins, minerals or a combination of these. Supplements should not replace food but are used to complement the diet.

For example, a dietary supplement can contain any individual vitamin or mineral including calcium, magnesium, zinc, vitamins A, C or K.
An herbal product is made from a natural source and it may contain vitamins, minerals, and other products including fish oils, botanicals or other naturally occurring compounds.

Herbal products can be in capsule, liquid, or powder form. These products, such as green teas, ginger tablets, and garlic pills, are often used for functional support.

It is important to note that garlic and ginger spices are safe to use in cooking, but do not confuse spices with supplements in capsule form.
Slide 20 Script: Intermountain Health Care doctors and pharmacists have spent a lot of time researching how supplements and herbal products interact with warfarin.

We will now discuss some of their findings about a few of the most popular supplements and herbal products on the market today.

These products have been broken down into 3 categories [next slide]

Slide 21 Script: {Read three categories}
Slide 22 Script: {Read list} all interfere with your warfarin.

Talk to your doctor if you are currently taking, or are interested in taking these vitamins, minerals, or herbal products because they can increase your risk for bruising or stroke. If you still wish to take these products, your doctor or pharmacist can adjust your warfarin dose to account for their use, and he or she will monitor your INR more closely to make sure that they do not increase your bleeding or stroke risk.

If you are taking any of these products, do not stop taking them until you talk to your health care professional as doing so will also alter your warfarin.
Slide 23 Script: Vitamins A, D, K, E… {Read the rest of this list} are some supplements and herbal products that interact with warfarin. It is important to talk to your health care professional before starting, stopping, or continuing the use of any of these products.

Slide 24 Script: {Read list} may interact with warfarin. Just because we may not know if these supplements or herbal products interact with warfarin, it does not mean that you can take these without first discussing these therapies with your doctor or pharmacist.
Slide 25 Script: Although we have discussed some of the most commonly used herbal products and dietary supplements, there are many other products that interact with warfarin. If a product is not on this list, that does not mean that it is safe to take. Contact your health care professional before using any supplement or herbal product.

Slide 26 Script: Now that you know a little about which supplements and herbal products interact with warfarin, you need to know how to identify these products.

{make supplement label pop out}: By looking at the supplement label on the back of the product, you can find out which vitamins, minerals, and herbal compounds are in the supplement.
Slide 27 Script: Look at this supplement facts label. There are 4 components to this label that you need to understand.

Slide 28 Script: First, look at the top section of the supplement facts label. This section shows the both the serving size and the manufacturer’s suggested use.
Slide 29 Script: Next, the amount per serving column, found on the left side of the label, lists all nutrients in the product and the quantity of each nutrient. For example, this supplement contains folic acid, vitamin K, vitamin A, vitamin D, Vitamin B, iron, and copper.

Slide 30 Script: In a smaller font at the bottom of the supplement label, all nutrients and other components in the product are listed. This is known as the ingredient list.
Slide 31 Script: Finally, the right side of the label contains the percent daily value column. Here you find the recommended daily value for each nutrient contained in this supplement, listed as a percentage. If an asterisk (*) is present in this column, a recommended amount for that nutrient has not been determined.

As a general rule, we recommend you find supplements which contain about 100% or less of the daily value for each nutrient. Exceeding the recommended amount does not necessarily provide more health benefits, and it may actually be harmful. Note, this particular supplement contains 200% of the daily value for vitamin K. This is another example of why it is important to pay attention to supplement labels, and why consulting with your health care professional is crucial.
Slide 32 Script: Now that we have examined this supplement label, let’s put it to use.

Look at both the amount per serving column and the ingredient list to see if there is anything in the product that could interact with warfarin.

Slide 33 Script: This particular supplement contains vitamins K, A, and D. All of these vitamins interact with warfarin, and should be used with caution. Do not take this supplement until you talk to your doctor or pharmacist.

This label is just one example of the type of ingredients you may find in a supplement. Many ingredients in supplements and herbal products interfere, interact, or may interact with warfarin.
It may be possible to take supplements and herbal products ONLY if you:

- Take your herbal product or dietary supplement consistently
- Discuss them with your healthcare professional

Please remember to talk to your health care professional if you wish to START or STOP any herbal or supplement therapy.
Thank you for taking the time to view this DVD. We hope that it provided you with some new information that will help you better manage your warfarin therapy.

If you have any other questions about this DVD or your supplement or herbal product regimen, please discuss these concerns with your health care professional.
APPENDIX F. ONE-ON-ONE WARFARIN AND SUPPLEMENT EDUCATION CURRICULUM INSTRUCTION AND EVALUATION FORM

This curriculum is intended to educate patients who have atrial fibrillation about the risks associated with supplement and herbal product use while they are on warfarin anticoagulation therapy. For the purpose of this research project, a Utah State graduate student or undergraduate dietetics students will teach the learning module. However, this is also intended to be a standalone curriculum that could be taught by nurses or other health care professionals.

Included for your review are:
• The educational curriculum
• The pre-test and post-test
• Handouts for participants

Please feel free to make any suggestions you may have on these components directly on the attached documents. After reading through the curriculum, please indicate your agreement with the following statements:

4=Strongly Agree  3=Agree  2=Disagree  1=Strongly Disagree

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The curriculum is easy to follow.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>The education appropriately teaches all outlined objectives.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>The curriculum provides all the necessary components to effectively teach the information.</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Its content is accurate.</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>The curriculum appropriately answers all pre-post-test questions.</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>The handouts are well organized and helpful.</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Please provide any additional comments you may have in the space below.
Identification Number_______
Age _____
Please circle:

<table>
<thead>
<tr>
<th>Gender</th>
<th>Education Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>Less than the 8th Grade</td>
</tr>
<tr>
<td></td>
<td>8-12th Grade</td>
</tr>
<tr>
<td></td>
<td>High School Graduate</td>
</tr>
<tr>
<td>Female</td>
<td>College Graduate</td>
</tr>
<tr>
<td></td>
<td>Advanced Degree</td>
</tr>
</tbody>
</table>

**Vitamin and Mineral Supplements**
1. Do you take vitamin supplements? Yes/No

2. If yes, which ones (Circle all that apply)

<table>
<thead>
<tr>
<th>Vitamin A</th>
<th>Vitamin E</th>
<th>Vitamin D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin C</td>
<td>Vitamin K</td>
<td>Vitamin B</td>
</tr>
<tr>
<td>Calcium</td>
<td>Magnesium</td>
<td>Zinc</td>
</tr>
<tr>
<td>Folate</td>
<td>Multivitamin</td>
<td>Iron</td>
</tr>
<tr>
<td>Potassium</td>
<td>Selenium</td>
<td>Beta Carotene</td>
</tr>
</tbody>
</table>

Other (please specify): ______________________________________

**Herbal and Natural Medications**
1. Do you take any herbal or natural products? Yes/No

2. If yes, which ones? (Circle all that apply)

<table>
<thead>
<tr>
<th>Garlic</th>
<th>Ginger</th>
<th>Glucosamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ginko</td>
<td>Biloba</td>
<td>CoEnzyme Q10</td>
</tr>
<tr>
<td>St. John’s Wort</td>
<td>Flaxseed</td>
<td>Melatonin</td>
</tr>
<tr>
<td>Papaya Extract</td>
<td>Ginseng</td>
<td>Soy Protein Products</td>
</tr>
<tr>
<td>Green Tea</td>
<td>Chondrotin</td>
<td>Cranberry</td>
</tr>
<tr>
<td>Saw Palmetto</td>
<td>Soy</td>
<td>Primrose</td>
</tr>
<tr>
<td>Red Clover</td>
<td>Black Cohosh</td>
<td>Fish oil supplements</td>
</tr>
</tbody>
</table>

Other (please specify): ______________________________________
If you take supplements or herbal products, please answer the following questions:

1. Why do you take supplements or herbal products? Circle all that apply.
   a. They are good for me
   b. Recommended by family
   c. Recommended by my doctor
   d. To supplement poor eating habits
   e. Other (please specify): __________________________

2. How often do you take supplements or herbal products?
   a. Once a day
   b. Two to three times a week
   c. Once a week
   d. Every other week
   e. Once a month
   f. Other (please specify): __________________________

3. Do you ask your doctor before using a natural supplement or herbal product if it interacts with Warfarin? Yes/No

4. If not, why?
   a. Didn’t think there was a need
   b. Forgot to mention it
   c. Other (please specify): __________________________

Warfarin Intake

1. Have you missed a warfarin dose in the past:
   a. Day
   b. 3-5 days
   c. Week
   d. Month
   e. 6 months
   f. I never miss a warfarin dose
   g. Other (please specify): __________________________

2. If you answered that you have missed a warfarin dose in the past year, how often does this occur?
   a. Once a week
   b. Twice a week
   c. Once a month
APPENDIX H. SATISFACTION QUESTIONNAIRE

Identification Number: _________________________

1. Which education format were you asked to complete?
   a. Take-home DVD education
   b. One-on-one education

2. How often have you looked at the educational materials since you completed the initial education?
   a. Never
   b. Once
   c. Twice
   d. Other (Please specify): ________________________________

Indicate your agreement with the following statements:
4= Strongly Agree  3= Agree  2= Disagree  1= Strongly Disagree

3. The education’s content was useful.
   4 3 2 1

4. The instructional method was effective.
   4 3 2 1

5. The handouts enhanced my learning
   4 3 2 1

6. As a result of this education, I feel more comfortable with my warfarin prescription.
   4 3 2 1

7. As a result of this education, I feel more comfortable managing my supplement and herbal product intake.
   4 3 2 1

Additional Comments?