EFFECT OF A DESIGNED WARFARIN BASED EDUCATION PROGRAM ON PATIENTS' KNOWLEDGE AND ANTICOAGULATION CONTROL AMONG ADULT OUTPATIENTS ATTENDING CLINICS AT KENYATTA NATIONAL HOSPITAL.

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Dissertation-Effect Of A Designed Warfarin Based Education Program On Patients' Knowledge And Anticoagulation Control Among Adult Outpatients Attending Clinics At Kenyatta National Hospital.

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DEDICATION

I dedicate this dissertation to my dad Iqbal Mamdani and my husband Said Abdullatif for all the love, support and prayers throughout my studies.

ACKNOWLEDGEMENT

I am grateful to God without whom I would not have made it this far. Thank you for strength, wisdom and understanding throughout my studies.

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My special thanks to the study participants and their families who agreed to particicpate in this study.

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

ADRs-	Adverse Drug Reactions
BMI-	Body Mass Index
CI-	Confidence interval
ERC-	Ethics and Research Committee
ESRD-	End stage renal disease
GCP-	Good Clinical Practices
ICH-	International Conference on Harmonization
INR-	International Normalized Ratio
IN-RANGE-	International Normalized Ratio Adherence and Genetics study
ISI-	International Sensitivity Index
KNH-	Kenyatta National Hospital
OAK-	Oral Anticoagulation Knowledge
OAT-	Oral Anticoagulation therapy
OTC-	Over the Counter
INR-	International Normalized Ratio
SPSS-	Statistical package for the Social Science
TTR-	Time in Therapeutic Range
UoN-	University of Nairobi
VKAs-	Vitamin K Antagonists
VTE-	Venous thromboembolism

LIST OF TABLES

LIST OF FIGURES

DEFINITION OF TERMS

Adherence: The extent to which a patient continues an agreed-upon mode of treatment without close supervision.

Anticoagulation: This refers to prevention of clot formation.

INR: This is the blood test that checks how long it takes for blood to clot. The higher the INR, the longer it will take blood to clot (and the higher the risk of bleeding.

Knowledge: The scope of one's awareness or extent of one's understanding of a particular subject matter.

Thrombosis: This refers to clotting within a blood vessel which may cause infarction of tissues supplied by the vessel.

ABSTRACT

Background: Warfarin is a widely used oral anticoagulant drug for the prevention of thrombosis associated with atrial fibrillation, deep vein thrombosis and pulmonary embolism. The drug has a narrow therapeutic index thereby necessitating frequent patients' assessment. Patients' knowledge on warfarin use promotes optimal anticoagulation, including adherence and control

Study Objective: The main objective of this study was to evaluate the effect of a warfarin based patient education program on oral anticoagulation knowledge, adherence and control among adult outpatients attending anticoagulation clinics at Kenyatta National Hospital.

Study Design and Participants: This was a pre-test/post-test single group quasi experimental study. A total of 45 patients aged ≥18 years and taking warfarin, were recruited by convenience sampling as they came for clinic appointments. They had to be attending the cardiothoracic, cardiac, deep vein thrombosis and hemato-oncology clinics at Kenyatta National Hospital.

Methods: A pre-designed structured questionnaire was administered to the patients to obtain information about their knowledge and adherence to anticoagulation therapy. The patients' most recent International Normalized Ratio tests were also recorded for assessment of the level of anticoagulation control. Warfarin education program detailing the indications, precautions, side-effects and monitoring of the drug was then provided to the patient on a one to one basis. The patients were also given a warfarin education booklet for reference. Evaluation of the knowledge, adherence and level of anticoagulation control was done 30 days after providing the education intervention. The raw data was entered into Microsoft Access version 2010, cleaned and exported to IBM Statistical package for social sciences version 21.0 for analysis. Student t-test was used to compare the knowledge, adherence level and anticoagulation control pre and post intervention at 95% confidence level. P-value of ≤ 0.05 was considered significant.

Results: Study participants had a mean age of 42.89±13.67 years with majority of them being female (86.7%) and married (66.7%). Only 26.7% of the participants had good knowledge (≥70%) before the intervention while 84.4% of them scored ≥70% at post-test. Middle aged participants had better anticoagulation knowledge before the intervention (p=0.04). However, none of the patient socio-demographic factors was statistically significantly associated with

knowledge scores after the intervention. There was an improvement between the pre-test and post-test knowledge mean scores ($p \leq 0.001$).

Adherence to anticoagulation therapy increased from a third to two-thirds after the intervention and this was statistically significantly associated with patients' occupation. There was a statistically significant difference in the mean adherence scores before and after the intervention (mean=6.29±1.590) and (mean= 7.38±1.029), $t(45) = -3.811$, respectively ($p \leq 0.001$).Additionally, therapeutic anticoagulation control was maintained by 30% and 50% of the patients at pre and post-tests, respectively. Therapeutic anticoagulation control was maintained by a third and 50% of the patients at pre and post-tests, respectively.

Conclusion: Provision of a warfarin based education program may help in improving patient knowledge and adherence in anticoagulation therapy

Recommendation: A designed warfarin education program, consisting of one to one patient counseling and a warfarin education booklet should be provided to patients to boost their knowledge and adherence to anticoagulation.

CHAPTER 1: INTRODUCTION

1.1 Background

Warfarin has been the oral anticoagulant of choice for many years (1). However, it requires more monitoring then other drugs due to its narrow therapeutic index (2). It is known to be one of the top three drugs that increase patient morbidity and mortality (3). Due to the many disadvantages of this drug including variability in patient doses, multiple drug – drug and drug – food Interactions, hemorrhagic complications and thrombotic recurrence, it requires frequent laboratory and clinical monitoring in order to attain optimal anticoagulation control (4).

Patient education increases compliance and decreases warfarin toxicity (5–8), and is important for a successful warfarin therapy. The education should touch on aspects regarding signs and symptoms of bleeding, impact of diet, drug-drug interactions, missed dose, target INR (9).

Even though patient education is an important component of warfarin therapy, published reports on warfarin anticoagulation vary greatly with strategy and content. Due to the time required in providing an effective patient education, most patients tend to neglect this important aspect of warfarin therapy (8).

A study done in KNH found out that 80% of the patients on warfarin had inadequate knowledge on anticoagulation. Knowledge was found to be least in aspects of INR interpretation, food and drug interactions with warfarin, signs and symptoms of under dosing and over dosing and what to do in the event of missing a warfarin dose (10).

Various studies have found that there is a positive relationship between knowledge and optimal anticoagulation control (11–14). Furthermore one study found that patient knowledge level increased by 50% after an individualized knowledge intervention in patients who had just started oral anticoagulants (15). Another study concluded that one of the effective risk reduction strategies that will help in promoting patient safety and improving the quality of life for patients is provision of an education program on warfarin therapy (12).

However, not all studies show a positive association between patient knowledge and anticoagulation control (16,17). This study aims at evaluating the effect of a designed

warfarin based education program on patients' knowledge, level of adherence and anticoagulation control.

1.2 Problem statement

Two thirds of the time patients on warfarin may not be in the therapeutic range (1). Insufficient education is related to poorly controlled anticoagulation (18). Regular monitoring using the INR test and patient education on various aspects of warfarin therapy is necessary to achieve stable anticoagulation (9).

Previous studies have documented that anticoagulation control for patients on anticoagulants is poor in Kenyatta National Hospital (10,19,20) and inadequate patient knowledge is presumed to be a contributing factor (21–23). A recent study found that patients were least knowledgeable on aspects of drug and food interactions; effect of missing a dose; interpretation of INR values and recognition of symptoms of over or under anticoagulation (10).

This study aimed to include the above aspects to help improve anticoagulation control

1.3 Study Justification

Literature provides a general consensus that improved patient knowledge about warfarin therapy improves therapeutic outcomes and reduces the incidence of side effects (6,7,9,23,26). A study done in Mexico found out that face to face knowledge intervention improved knowledge by up to 50% (15).

There was a marked decrease in warfarin related readmissions from 7.2% to 1.4% after initiation of warfarin team that focused on International Normalized ratio (INR) testing, warfarin dosing and patient education (27). Several studies have also shown that pharmacist managed anticoagulation therapy has been more successful with some demonstrating better INR control than conventional management (28–30). Another study concluded that insufficient knowledge on oral anticoagulation therapy was the major factor that predicted bleeding (6)

This study aims at evaluating effectiveness of a designed warfarin program on patients' knowledge, anticoagulation control. There is no published data to show how face to face educational intervention would affect oral anticoagulation management at KNH. The information obtained will help in the formulation of an educational program for patients on

warfarin therapy that will best help them in anticoagulation control thereby leading to provision of quality healthcare

1.4 Study Objectives

1.4.1 Broad Objective

The main objective of this study was to evaluate the effect of a designed warfarin based patient education program on oral anticoagulation control among adult patients attending anticoagulation clinics at Kenyatta National Hospital.

1.4.2 Specific Objectives

1. To find out the effect of the designed warfarin based education program on the level of knowledge on anticoagulation among adult patients attending anticoagulation clinics at KNH.

2. To find out the effect of a designed warfarin based education program on the level of adherence to oral anticoagulants among adult patients attending anticoagulation clinics at KNH.

3. To find out the effect of a designed warfarin based education program on anticoagulation control among adult patients attending anticoagulation clinics at KNH.

1.5 Hypothesis

- $H_{1:}$ patients who receive warfarin based education program have higher knowledge scores related to warfarin therapy than those who do not.

- $H_{2:}$ Patients who receive warfarin based education program have a higher level of adherence to warfarin therapy than those who do not.

- H_3: Patients who receive warfarin based education program have better controlled INR levels than those who do not.

1.6 Conceptual Framework

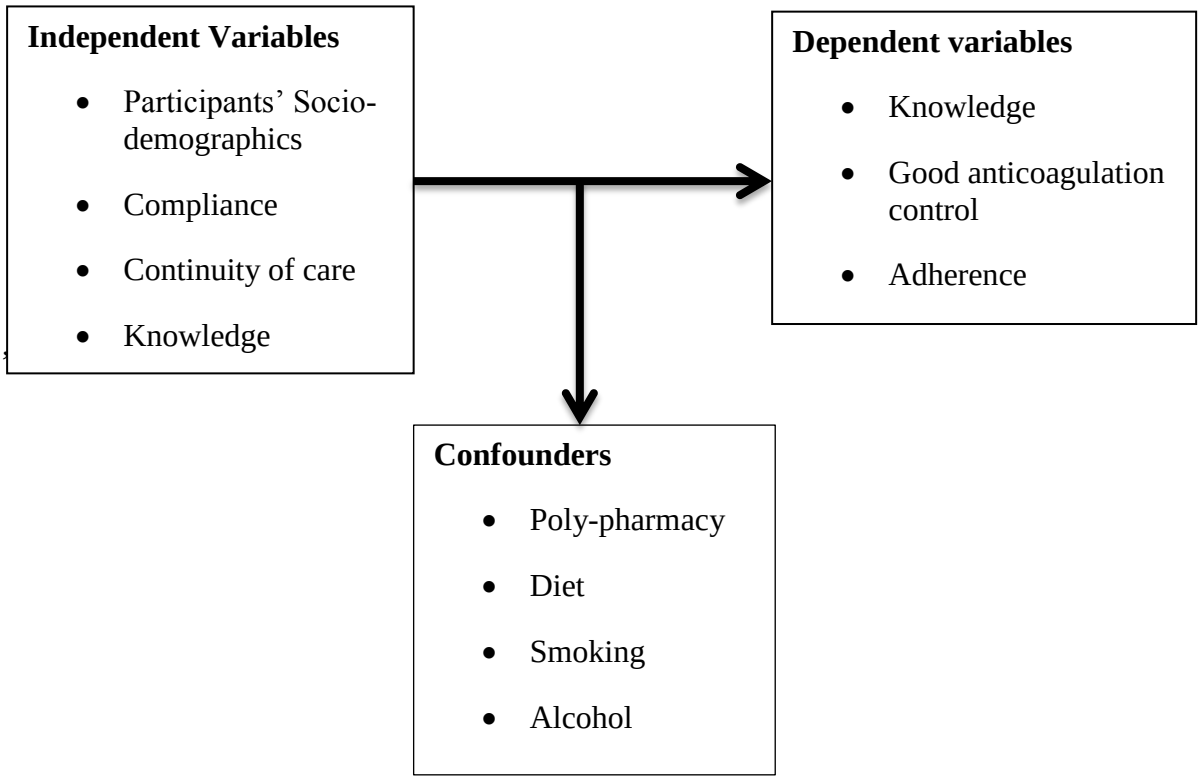

Figure 1: Conceptual Framework

Socio-demographics, continuity of care, compliance and effective patient prescriber relationship are the independent variables. Patient knowledge was the dependent variable. Knowledge also affects patient adherence and good anticoagulation control. The confounders were found to be interacting medication, diet, smoking and alcohol. This study sought to identify how an education intervention can effect on the knowledge of anticoagulation of patients, adherence and good anticoagulation control

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CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

The chapter summarizes by examining the various gaps in literature which would be required to be filled by conducting the present study.

2.2 Adverse effects of warfarin

Warfarin is a vitamin K antagonist whose main use is to prevent formation of blood clots. It is used in the management of stroke, deep vein thrombosis, pulmonary embolism an atrial fibrillation(31).

Warfarin is considered as a drug with a narrow therapeutic index (32). Bleeding is the most common side effect of warfarin therapy. It can manifest as bleeding of the gums after brushing the teeth, easy nose bleeds, bruising of skin and heavy menstrual bleeding in females(33)

Maintaining the balance between bleeding and clotting is vital in warfarin therapy management (34). Bleeding is prevented by closely monitoring of INR (35) as measure of how long it takes the blood to clot. An INR between 2.0 and 3.0 is considered ideal (36). It has been found out that the rate of hospitalization is directly proportional to an uncontrolled INR (37,38). In a national survey carried out in the United States of America, warfarin was found to be one of the three top most medications responsible for emergency department visits. Of the cases attributed to warfarin,73.0% involved clinical evident bleeding and 44.2% required hospitalization (39). In another study, readmission rates due to bleeding attributed to warfarin therapy was 8.4% (3). In contrast, a study by Gallager *et al* found that the readmission rate due to warfarin was 3.8 incidences of all bleeding per 100 patient years (40).

2.3 Factors that contribute to adverse effects of warfarin

2.3.1 Poly-pharmacy

Several studies have shown the effect of poly-pharmacy and interactions of warfarin with other drugs. A study done in Scotland in 2008, found out that 68% of patients on warfarin were concomitantly prescribed other drugs. Of these 12.3% was antibiotics, 5.3% non-selective NSAIDS and 1.4%fibrinolytics thereby increasing their risk of bleeding (41). Such studies have also demonstrated increased risk of either over anticoagulation or under anticoagulation if there was concurrent use of warfarin and other medications (42).

A study done in Ethiopia found that bleeding events for patients on warfarin were to be blamed on drug-drug interactions (35), while another done in Seoul found out that there was an increase in INR by 39.8% after an NSAID was added to warfarin therapy. This later study found out that a dose of more than 40mg/week of warfarin and co-administration of meloxicam were responsible for an increase in INR (3)

A systemic review and meta-analysis of RCTs comparing combination use of aspirin and warfarin versus warfarin therapy alone noted that combination therapy was only beneficial to patients with a mechanical heart valve though with an increased risk of bleeding. For patients suffering from thromboembolism there was no added advantage of combination therapy even though the chances of bleeding increased (43)

Another study found that taking an average of 2 grams of acetaminophen per day increased the INR thereby increasing the risk of bleeding (44). Smoking increases warfarin clearance thereby decreasing the INR and leading to a higher risk of clotting (45).

A study done in Melbourne claimed that 37 out of 40 patients did not know that warfarin could interact with other medications (46)

2.3.2 Continuity of Care

A systematic review validated the belief that continuity of care is associated with optimum clinical outcomes and patient satisfaction (47). Additionally, an intervention study that provided continuity of care across settings resulted in lower hospitalization rates for patients who received the intervention n rates at 30 days (8.3% vs. 11.9%, P=.048) and at 90 days (16.7% vs. 22.5%, P=.04) than control subjects. Intervention patients had lower readmission rates for the same condition that precipitated the index hospitalization at 90 days (5.3 vs. 9.8, P=.04) and at 180 days (8.6 vs. 13.9, P=.046) than controls (48).

An intervention study in India, where the intervention group was given anticoagulation counseling by a clinical pharmacist noted that 44 adverse effects related to anticoagulation therapy were found in the intervention group compared to 56 in the control group(49). Furthermore, a study by Dager *et al* noted that pharmacist managed anticoagulation clinics enhanced continuity of care in patients (50).

2.3.3 Patient Prescriber Communication

Besides specialized skills, a doctor needs to have effective communication skills. A successful doctor is one who communicates with his patients on three levels; emotionally, culturally and intellectually (51).

A survey found out that in most cases the prescriber dominates the discussion not taking into account the patient's point of view (52). In elderly patients, this relationship is very important since most of them have comorbidities and are on more than one drug leading to an increased risk of adverse drug reactions (53).

A study assessing similarity between doctors' records and patients' demographic, clinical, cognitive and psychosocial characteristics noted that there was disharmony between the doctors' records and the researcher's assessment of patients. Of the 36 doctors' interviewed, 12 were unaware of their patients' cognitive imbalance. Additionally, the medication history that 25 of the doctors' had was conflicting with the patients history of medication use (46).

2.3.4 Poor Medication Compliance

Patients' treatment satisfaction, accessibility and affordability of healthcare are important aspects of medication compliance. Long queues and long waiting time led to patients being non-compliant thereby increasing chances of an adverse drug reaction. Another aspect that affects compliance is the type of illness. With chronic diseases having a higher frequency of non-compliance as compared to acute diseases (54).

2.4 Knowledge on anticoagulation

Various studies have shown that there is a positive relationship between patient knowledge of warfarin and good anticoagulation control (7,12,21,55). Unfortunately there is no set strategy, rules or regulations regarding dissemination of warfarin education. Standardization of the education programs coupled with dissemination of knowledge in a clear and understandable manner is necessary to improve quality of education (26,56). An educated patient is the best defense against bleeding complications in warfarin therapy (57)

A study looking into the responsibility and perception of doctors' in warfarin management reported that only 14 out of 36 doctors' admitted to conducting patient education at initiation of warfarin therapy. The rest deferred responsibility to the initiating specialist, pathology service or dispensing pharmacist. This study also noted that there was a huge gap in the

transfer of patient information from the prescribing specialist to the general practitioner and the pharmacist. This gap can lead to huge errors in the movement of warfarin therapy especially in high risk patients (46).

In 2008, a study done by Baughman *et al*, noted that one of the main problems leading to inadequate patient education could be the hospital medication distribution system. Once a patient was prescribed warfarin, it was ordered from the pharmacy and distributed to the patient by the nursing staff. This bypassed the interaction between the pharmacist and the patient which is pertinent to provide patient warfarin education. The author reported that lack of teaching materials such as warfarin education booklets and posters in both the wards and the pharmacy could have contributed to the problem(5).

Studies have revealed that patients have very little knowledge on their anticoagulation therapy. One such study, done in New York City found out that only 37% of the patients had good knowledge on anticoagulation. (16). A study done in Malaysia, using a Malaysian version of the OAK tool also concluded that knowledge was not up to par in patients taking warfarin with a mean score of only 48% among 382 patients (21). Additionally, another study done in Malaysia found that only 44.2% off the patients knew about their medication even though 98% of the patients admitted to having being given verbal education by nursing officers (58).

In a cross sectional study done in India, half of the patients were found to have poor knowledge scores with regard to drug-drug interactions, drug-food interactions, and INR monitoring adverse effects. This study found out that 62.9% of patients were found to be oblivious about their target INR values (59).

Locally, a study done at Kenyatta National Hospital Nairobi in 2015 found out that >75% of the study participants had poor knowledge on OAT (10). Conversely, a study done by Khudair *et al* noted that more than 50% of patients had good knowledge scores > 75% (14).

Several factors have been cited to effect on patient's knowledge on anticoagulation. In some studies age was found to be indirectly proportional to anticoagulation knowledge (18,60) with elderly patients having a higher chance of not understanding OAT due to decreased cognitive functions (61,62). It has also been noted that the knowledge that is provided to elderly patients is in most counts at a higher educational level thus making it hard for them to understand (63). Furthermore, a study involving 1500 geriatric patients found that there was a

higher risk of bleeding in patients who had been insufficiently educated. This study also noted that 61% of the patients who reported not having been educated spent only 20% of their time in therapeutic range (6). Moreover, education in elderly patients has been found to be suboptimal (64), and can lead to higher chances of hospitalization and adverse effects (65).

In other studies, participants' formal education level has been shown to effect on anticoagulation knowledge. For instance patients who have had of up to 8^{th} grade or more have more awareness of their OAT than the lower grades (13,66)

The practice of anticoagulation has also effected on patients' knowledge on warfarin. Studies have revealed that pharmacist managed anticoagulation clinics are beneficial to the patients by not only improving their knowledge of OAT but also improving their anticoagulation control (30,67). Clinical pharmacists' have been shown to achieve therapeutic goals in OAT by bringing their expertise in clinical pharmacy, knowledge of pathophysiology of blood clotting and clotting disorders and the vital knowledge of drug interactions to the field of anticoagulation management (68).

A study done in the United States of America by Bond *et al* evaluating the relationship between pharmacist provided anticoagulation management and major health outcomes such as length of hospital stay, death rate and bleeding complications found out that in hospitals' without pharmacist provided warfarin management length of hospital stay was 5.86% higher, bleeding complications were 8.09% higher and death rate was 6.2% higher. Also these hospitals had 316,589 more patient days, 429 more bleeding complications and 2786 more deaths (69).

A cohort study done by Elewa *et al* in Qatar compared the anticoagulation control of pharmacist based warfarin clinics and usual doctor based clinics found out that those who attended pharmacist based clinics had a superior TTR at 81.8% compared to those who attended the doctors clinics at 69.8% (70).

A study done by Mazor *et al* in 2007, examined if there was an increase in knowledge score in patients who received oral anticoagulant education as compared to those who did not. The authors' reported that patients who watched the video had higher knowledge scores ($p<0.001$),better understanding of laboratory testing ($p=0.010$) and understood importance of taking the oral anticoagulant therapy ($p=0.012$) (71).

In a randomized controlled trial carried out in Kerala, India, patients in the intervention group received knowledge pertaining to various aspects of OAT by a clinical pharmacist. In addition to that they also received patient information booklets on anticoagulation therapy. Knowledge scores in the intervention group increased from an average 5.6±3.2 to 13.8±0.94 while in the control group there was no significant increase from 8.0±1.59 to 8.3±2.6 (p=0.218) (49).

Another study examining the benefit of pharmacist provided patient education at home noted that there was significant difference between intervention patients base line knowledge at 64.5% (95% C.I 61.0-68.5%) and 8 day mean warfarin knowledge at 78.0% (95% C.I 74.5-81.5%) (72).

A study done in Indiana reported significant improvement in mean post test scores after a knowledge intervention was given to the patients on OAT (73). The revelation was almost similar to a study that used theory driven interventions using patient interviews and focus group which reported improvement in knowledge scores over time (63).

A study done in Cairo, Egypt also found that the mean pre-test scores (8.896) significantly increased after provision of an intervention to mean scores of 115.869 (12). Yet another study reported that knowledge improved by 50% in patients who were given a face to face education on OAT (15).

A study that was assessing the reduction in readmission rates 90 days after hospitalization reported that there was a decrease by 5.8% in the readmission rates of the total patient groups after a one on one education session on warfarin therapy by a registered nurse (27)

In conclusion, even though anticoagulation control and patients' knowledge improved with education, the level of improvement varied across settings perhaps due to lack of designed structured education programs. Studies have shown that structured education programs in OAT need to be designed to fill these gaps (66,74).

2.5 Anticoagulation Control

Anticoagulation control is defined as time spent in therapeutic range. Studies on the relationship between the level of patient's knowledge and anticoagulation control have conflicting findings.

A systemic review study done by Clarkesmith *et al* tested the effect of a theory driven educational intervention found out that atrial fibrillation patients who received the intervention had significantly higher TTR for 6 months after receiving the intervention (76.2% vs. 71.3%; p=0.035). After 12 months there was no significant change in TTR. The authors of this study concluded that for effective anticoagulation control education is very important at the start of therapy but is of no consequence in long term therapy (63).

In an intervention study where the intervention group were counseled about anticoagulation therapy by a clinical pharmacist and also provided with patient education booklets over a period of 6 months, 73.45% of INR were within the therapeutic range, 8.45% were supra-therapeutic and 18.5 were sub-therapeutic whereas in the control group the results were 53.2%, 18.4% and 28.4% respectively (49).

This was in contrast to a study done by Baker *et al* who noted that there was no significant relationship between patients' knowledge on warfarin and INR values (75). This study, done in Saudi Arabia which showed that 75.2% of the patients had good knowledge on anticoagulation, but only 33.3% had good anticoagulation control leading to the author's conclusion that there was no significant relationship between knowledge and anticoagulation control (75).

An evidence based practice project done in an Illinois medical center, examined the effect of an educational intervention on patients knowledge of warfarin and INR values. A single group pre-test post-test design was used on a sample of 38 patients. The intervention included booklet, video and food models. Patient INR values were tracked every two weeks for a period of 12 weeks. No significant difference was found between the pre-test and the post-test INR ($t(26)=-2.002$, $p>0.056$), but could have been attributed to the fact that only 26 patients had their INR measured instead of the entire sample size of 38 (73).

Locally, a study done in KNH in 1999, concluded that only 6.9% of the patients were able to maintain adequate anticoagulation control for 50% or more of their follow up time (20) Additionally another study done in the same setting noted that 855 of the study participants had low TTRs of less than 60%. When INR was used to determine anticoagulation control, 69% of the study population had INRs that were outside the therapeutic range (19). Locally, a study found that adherence to warfarin and anticoagulation control were 52.2% and 43.5% respectively (10).

2.6 Patient Adherence

The safety and efficacy of any drug depends on the degree to which a patient takes the medication as prescribed (76). In a systematic review that included 76 studies, mean compliance was 71% ±17. This decreased significantly as number of doses per day increased ($p<0.001$) (77).Warfarin is a highly efficacious drug. And for it to show optimum clinical results patient adherence is paramount (78) as has been reviewed in a number of studies in a number of studies conducted using Morisky questionnaires to assess patient adherence of OAT (24,79). Studies have revealed that the risk factors for non-adherence included education beyond high school, employment, impaired cognition, and disability (80). Another study noted that patients who exhibited non adherence to warfarin therapy included younger age, non-ischemic etiology, smoking and those with improved left ventricular ejection fraction (81). On the contrary, another study carried out in patients with mechanical valve replacement found out that elderly patients were more compliant. Marital and employment status were insignificantly associated with adherence (82).However, interventions like monthly medical organizers, financial incentives for adherence, and home visits to patients taking warfarin could improve adherence (83).

Adherence level can effect on anticoagulation management. In a study that examined the relationship between warfarin non-adherence and control of INR, majority of the INRs that were out of range were due to warfarin or dietary non-adherence (84).

The IN-RANGE study that was determining the influence of patient adherence on anticoagulation control used the Medication Events Monitoring System (MEMS) medication bottle caps to study the adherence of patients. The MEMS caps were fitted on patients' medication bottles of warfarin. They recorded the exact time and date of pill bottle opening every time a patient opened or closed them to take their dose of warfarin. Results of this study exhibited a significant association between sub optimal anticoagulation and decreased adherence. In this study, a 10% increase in missed bottle openings led to a 14% odd of clotting. The study also established that a 10% increase in bottle opening led to a 1.73% odd of bleeding (85).

An interventional study that used a 28 day medication organizer showed an improvement in adherence in patients who had a history of non-compliance from a pre enrollment mean of 55±25% to a post enrollment mean of 67±21%. It also noted a significant decline in

proportion of INR values and a significant increase in time spent in therapeutic INR range (86). Another study found that adherence to warfarin was at 43.5% among patients (10).

In contrast to the above studies, one study noted that 73% of patients who had adequate adherence showed poor anticoagulation control. They also concluded that poor knowledge on OAT did not necessarily affect adherence (16). However, another study did not find any relationship between knowledge, anticoagulation control and adherence (87).

Studies done locally have revealed poor adherence at 39% (19) and 43.5% (10). Though both these studies found no significant relationship between adherence and anticoagulation control

2.7 Gaps in literature

Published research on patient education differs in design and content. Giving the educational domain importance, making the content standardized, effectively and efficiently delivering the content is important in improving anticoagulation control with warfarin. Patient education is an important aspect of warfarin anticoagulation management. Since it is time consuming and there is shortage of staff, patient education is not given the importance it deserves (26)

Most of these studies have been done in developed countries. A study that was done in Egypt (12), evaluated the effect of a warfarin education program on patients and the incidence of side effects found a statistically significant difference between the pre and the post knowledge scores and also a decline in the incidence of side effects after the education program.

The studies done at Kenyatta National Hospital Marita *et al*, Kibiru *et al* and Ogendo *et al* respectively (10,19,20), show that there is poor adherence and anticoagulation control. There has been no study that measures the effect of an education intervention on anticoagulation control

CHAPTER 3: RESEARCH METHODOLOGY

3.1Research Design

This was a pre-test/post-test single group quasi experimental design. This design is mainly used when the researcher is introducing and evaluating an intervention as was in the present study. Randomization was not done. This type of design is ideal to measure the effect of an intervention (88).

3.2 Study Area and Site Description

The study was conducted at the various outpatient anti-coagulation clinics based at Kenyatta National Hospital (KNH), a teaching and referral hospital in Nairobi, Kenya with a bed capacity of approximately 2000 beds.

The clinics were: the cardiothoracic, cardiac, deep vein thrombosis (DVT) and hemato-oncology clinics. The cardio-thoracic clinic attends to valve replacement patients who are on prophylactic anticoagulant therapy; the cardiac clinic attends to patients with disorders such as atrial fibrillation or any other cardiac problem and who are on prophylactic anticoagulation therapy; the DVT clinic attends to patients who are on warfarin while the hemato-oncology clinic attends to patients with a high risk of thrombosis and undergoing cancer chemotherapy. An average of 20 patients on anticoagulation therapy is seen on each clinic day.

3.3 Target Population

The study targeted all adult out patients taking warfarin who attended the cardiothoracic, cardiac, DVT and hemato-oncology clinics for various indications.

3.3.1 Inclusion Criteria

- Outpatients on Oral Anticoagulation Therapy.
- Patients with age of 18 years and above.
- Patients who sign the informed consent.
- Female patients who are not pregnant.
- Next regular appointment should not exceed 4 weeks to allow time for evaluating the intervention.

3.3.2 Exclusion Criteria

1. Patients below age of 18 years.
2. Patients with cognitive impairment.
3. Pregnant women.

4. Treatment naïve patients. This is because they could have received education on warfarin medication.
5. Patients who are not willing to participate in the study.

3.4 Sample Size Determination

The formula that was used in determining the sample size is as shown below. It is used when there is an expected difference in mean scores between the pre-test and post- test, as stipulated in our study hypothesis (89)

$$n = \frac{\sigma^2\left(Z_{1-\beta} + Z_{1-\propto/2}\right)^2}{(\mu_d)^2}$$

n = required minimum sample.

$Z_1-_{\propto/2}$ = Standard normal deviate at 95% confidence level =1.96.

$Z_1 -_{\beta}$ = power of the study=84% (This is recommended in most interventional studies as it gives reasonable inference s).

μ_d= Differenence in mean between the pre test and post test=7 as cited by El Naby et al (12).

The values used in sample calculation were from two studies. A study that was done by El Naby *et al* in Cairo Egypt (12) that found a difference in mean between the pre-test and post-test as seven (7) and a study by Kizito *et al* (10) who found out that the standard deviation of knowledge on anticoagulation at Kenyatta National Hospital was sixteen (16).

Therefore substituting the values for the above equation gives:

$$n = \frac{16^2(0.84 + 1.96)^2}{(7)^2}$$

n=40.96

The calculated minimum sample size was therefore 41. However due to anticipated attrition and loss to follow up, the sample size was adjusted by 10% to give the final sample size of 45 participants.

3.5 Ethical Consideration

Ethical approval and authorization to carry out the study in KNH will be obtained from KNH/UON Ethics and Research Committee and Kenyatta National Hospital authority. Before recruitment each participant was explained clearly the purpose, nature, risks and benefits of the study in a simple, clear and easy to understand language. Emphasis was placed on the fact that the study is voluntary and the study participant can withdraw at any time and point in the study without fear of consequences. The participants were further assured that confidentiality will be strictly maintained by coding all the data and storing it in a safe and secure place. This was done by storing the data under lock and key or password protecting it. Only the principal researcher and the supervisors will be able to access it at any point of time to ensure confidentiality. Before enrolment in the study a written consent form was obtained from each participant (Appendix 3).

The general finding of the study and recommendations will be disseminated to the clinicians to better equip them in the management of oral anticoagulation inpatients. The findings will also be sent for publication to a peer-reviewed journal. Kenyatta National Hospital administration will receive a copy and the University of Nairobi library will also receive a copy for information dissemination to the students.

3.6 Sampling, Screening and Recruitment

Convenience sampling was used to achieve the sample size. On the clinic days, patient files were perused and patients on warfarin were identified by two research assistants. Screening was done using the screening and eligibility forms (Appendix 2).The inclusion and exclusion criteria was used to screen the patients and determine eligibility for the study. All eligible patients were undertaken through the consent explanation and asked to sign the consent form (Appendix 1). After recruitment, they were asked to fill a pre-test questionnaire (Appendix 2).

3.7 Materials and Methods

Questionnaires were used as a tool for the study to carry out the pre-test and the post-test. This questionnaire was divided into 3 parts. Part one included personal demographic data and clinical characteristics of the patient, part two included questions pertaining to the Oral Anticoagulation Knowledge test (OAK) which is a validated tool to test patient knowledge on warfarin (12), while part three was the 8 point Morisky adherence scale (90) for testing the rate of adherence. The most current patient INR was also recorded.

Once the patient was explained about the study, screened, recruited and his/her consent obtained in writing, he/she was asked to do a pre-test. The researcher introduced an education intervention and the patient was given a booklet to take home for revision purposes. Date of the next clinic appointment was noted. This was regarded as the first session.

During the patient's next clinic visit, the patient was asked to do the post-test. After the patient had completed the post-test, INR results for that day were noted down and any further questions or queries the patient were answered.

3.8 Intervention

The intervention was delivered soon after the pre-test. It included information about drug interactions with warfarin, foods to avoid when taking warfarin, adverse drug reactions to look out for when taking warfarin, what to do when an adverse drug reaction is noted, how often to measure INRs, standard INR range and what to expect if INR is too low or too high. A booklet with information on an overview of warfarin was given to the patient. It included information on dose regimen of warfarin, why warfarin dose can be changed abruptly, the importance of blood tests and information about the INR, such as normal values, ideal range of expected INR values for the patient and factors that increase or decrease INR. The aspect of side effects and what to do when one notices a side effect was also included in the booklet. Foods and drugs that are susceptible to interactions with warfarin were also mentioned in the booklet and what to do in case of persistent bleeding.

3.9 Research Instruments

The screening and eligibility form contained the inclusion and exclusion criteria which were used to check eligibility of the patient. The informed consent information and the consent form (Appendix 2) contained the title of the study, name of the principal investigator, purpose and procedure of the study, risks and benefits of the study, voluntary consent, and confidentiality, withdrawal from study, study subjects' consent and contact details. This form was both in English and Kiswahili.

Data was collected using a semi structured, pre constructed questionnaire. Same questionnaires were used both for the pre-test and the post-test.

3.9.1 Questionnaire

The questionnaire had three main parts. The first part included patient demographics and clinical characteristics. Patient demographics included age, gender, marital status, education level and occupation. The last attended clinic visit and most recent INR.

The second part of the questionnaire was adapted from the Oral anticoagulation Knowledge Test. This is a validated tool for testing the knowledge of Warfarin by Zoella *et al* (24). It consisted of seventeen multiple choice questions. Each correct answer was scored as one and an incorrect answer as zero. The questions were checking patient knowledge on warfarin such as food-drug interactions, drug-drug interactions, INR monitoring and its importance, which side effects to expect and when to seek emergency medical attention.

The third part had questions on the 8-point Morisky adherence scale. This is a validated tool to check for adherence for medications. It contains 8 yes/no questions that assess intentional and non-intentional non- adherence and also various factors that affect non adherence. A score of 8 will indicate high adherence, 6-8 indicates moderate adherence and less than 6 indicated low adherence (90). The questionnaire was in both English and Kiswahili. The same questionnaire was used for both the pre-test and post-test.

3.10 Pilot Study

After ethical approval from the KNH/UoN ethics and research committee, a pilot study of the questionnaire was carried out on 5 patients (10% of the sample size). The pilot study was carried out at the hemato-oncology clinic which is held every Friday between 8 a.m. and 1 p.m. The reason for choosing the hemato-oncology clinic was because it is one of busiest clinics. The 5 patients representing 10% of the sample size were randomly selected and asked to fill the questionnaire. This helped in ensuring the adequacy, clarity and feasibility of the questionnaire. No modifications were deemed necessary before commencing the actual study.

3.11 Data Collection

Two research assistants (nurses by profession) were trained to assist in data collection. The training included recruitment of patients, how to use the data collection tools and how to maintain confidentiality of the collected data.

3.12 Study Variables

Dependent variables: Oral anticoagulation therapy knowledge, adherence to warfarin and INR levels.

Independent variables: Patients' socio-demographics, compliance, education, clinical characteristics of patient and effective patient follow up.

3.13 Validity

Validity refers to how well a study measures what its purporting to measure. In this study internal validity was ensured by piloting for pre testing the data collection tools and the external validity was maintained by choosing representative samples of the target population.

3.14 Reliability

Reliability is the extent to which a study can provide consistent results. In this study reliability was maintained by giving clear and concise explanations on the study methodology and data collection techniques to enable reproducibility.

3.15 Informed Consent

Voluntary consent was obtained from the patient in writing after a detailed consent explanation pertaining to the study. The patient was assured that he/she is at liberty to withdraw from the study without any penalties or consequences. Furthermore, the risks, benefits, confidentiality issue and any other issues that the patient raises were addressed before consent to participate in the study is sought.

3.16 Confidentiality

All the data collected was coded to ensure confidentiality and anonymity of the participants. All data collected was both stored under lock or key or was password protected. It was only accessible to the principal researcher and the supervisors.

3.17 Risks to the Patients

This was a minimal risk study as it involved face to face interview. Although, INR determination was done at some point, this is a usual check for evaluating the effectiveness of warfarin. It was done by the usual staff so as to avoid risks to the patient. The hematology laboratory where the INR was done is WHO accredited.

3.18 Data Management and Quality Assurance

Data was collected using a validated questionnaire. The same questionnaire was used for both, the pre-test and the post-test. The intervention given to the patients was standardized and it followed the same course. A standard booklet was given to the study participants to help in the better understanding of the one on one session. The standard GCP guidelines were followed for INR measurement. INR measurement was done at one of the University of Nairobi hematology laboratory which meets the required standards for WHO.

3.19 Data Analysis

Raw data from the questionnaires was entered into Microsoft Excel 2010, organized and cleaned. Cleaning of the data was done by comparing data entered in the electronic system to the questionnaires. Once all the data entry had been done, a logic check was performed. This was done through a careful review of all the electronically entered data to ensure that data entry has been done correctly. All this was done before the commencement of any data analysis.

Data was analyzed using IBM SPSS software Version 21.0. Descriptive statistics such as percentages, frequencies were used to analyze the demographic characteristics of the patient. Continuous variables for example age were analyzed using mean and standard deviation.

A paired samples t-test was used to compare the mean OAK pre-test scores and the mean OAK post test scores. The same test was also used to compare the mean pre-test INR of the mean post-test INR and mean pre-test adherence to the post-test adherence. P value of less than 0.05 was considered significant.

Bivariate analysis was carried out to correlate the independent variables to knowledge, INR values and adherence. Logistic regression analysis was also done to determine independent variables associated with the intervention. This helped adjust for confounders. Odds ratio was calculated and 95% confidence interval and p values less than 0.05 were considered significant.

CHAPTER 4: RESULTS

4.1: Introduction

This chapter gives the results based on the objectives.

4.2: Socio-demographics of the study participants

The participants were aged between 19 and 78 years and had a mean age of 42.8 ±13.67 years. The majority of the participants were female 39 (86.7%) and married 30 (66.7%) with at least secondary level of education 27 (60%). Additionally, most participants were unemployed 17(37.8%) while 10 (22.2%) were on casual jobs, 12 (26.7%) on formal employment and 6 (13.3%) retired. Almost half of our participants had visited the clinic in the past one month prior to the study (Table 1).

Table 1: Social demographic characteristics of the study participants (N=45)

Variable	N	Percent (%)
Age		
19-37	17	37.8
38-57	22	**48.9**
≥58	6	13.3
Gender		
Male	6	13.3
Female	39	**86.7**
Marital status		
Single	11	24.4
Married	30	**66.7**
Widowed	4	8.9
Education level		
Informal	4	8.9
Primary	9	20.0
Secondary	27	**60.0**
Tertiary	5	11.1
Occupation		
Unemployed	17	**37.8**
Casual jobs	10	22.2
Formal jobs	12	26.7
Retired	6	13.3
Last anticoagulation clinic visit		
In the last 1 month	18	**40.0**
Between 1 and 2 months ago	10	22.2
> 2 months ago	17	37.8

4.3 Knowledge on warfarin anticoagulation

Knowledge was determined by scoring the seventeen questions, adapted from the Oral Anticoagulation Knowledge test. It tested knowledge on warfarin indications, dietary restrictions, side effects and drug interactions. Each question was rated (1) if correct and (0) if incorrect. The highest score was seventeen (17) and lowest zero (0). Scores above 12 were considered satisfactory while those between 9 and 12 were considered fair and below 9 were considered below average.

Figure 2 below shows the comparison of knowledge pre and post warfarin based education on coagulation. The best answered questions on pre warfarin education (over 90% correct scores) were questions on use of warfarin (question 1), use of INR test (question 2), effect of alcohol intake on warfarin (question 6), what to do when a dose is missed (question 15) and foods high in Vitamin K (question 17). Deficiency was noted in questions concerning pain killers and interacting medication (questions 8 and11), a question pertaining to diet (question 10), and symptoms that required seeking medical attention (question 16).

The best answered questions during the post warfarin education (100% scores) were questions on ideal INR range (question 5), effect of alcohol intake on warfarin (question 6) and foods rich in Vitamin K (question 17). The rest of the questions were scored correctly by more than 70 % of the participants. The question that had the least score (73%) was based on interacting medication (question 11). Figure 2 below shows the comparison of responses in the pre and post-test.

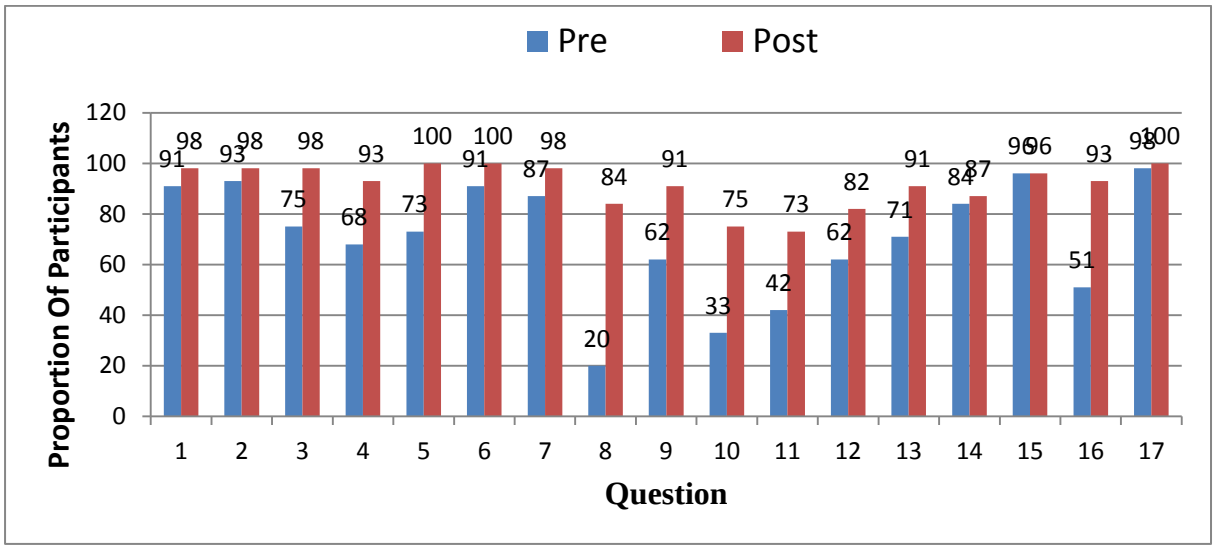

Figure 2: Comparison of responses in the assessment of knowledge pre ad post warfarin based education program

Knowledge levels were compared pre and post the study and the findings are shown in table 3 below. Only 1 participant had below average scores on knowledge on both pre and post education. On the other hand 32 (7.1%) and 6 (13.3%) had fair knowledge pre and post education respectively, while 12 (26.7%) and 38 (84.4%) had good knowledge pre and post education respectively (Table 2).

Table 2: Comparison of knowledge scores pre and post education of warfarin anticoagulation

Knowledge score category	n	Pre(%)	n	Post(%)
Below average	1	(2.2%)	1	(2.2%)
Fair	32	(7.1%)	6	(13.3%)
Good	12	(26.7%)	38	(84.4%)
Total	45	(100%)	45	(100%)

4.3.1 Factors associated with knowledge on anticoagulation

Bivariate analysis was done using the Chi square test to determine the association between the socio-demographic characteristics of participants and the knowledge scores prior to the intervention. Age was the only socio-demographic factor that was found to be statistically significantly associated with knowledge in the pre-test whereby 66.6% of patients between the age of 38-57 scored well in the pre-test (table 3).

Table 3: Association between participants' socio-demographic characeteristics and the knowledge scores prior to the intervention

	Knowledge score			
Variable	≤ 50% (%)	51-70% (%)	≥70% (%)	P value
Age group (years)				
19-37	0 (0%)	15 (46.9%)	2 (16.7%)	
38-57	0 (0%)	14 (43.8%)	**8 (66.7%)**	**0.040**
≥58	1 (100%)	3 (9.4%)	2 (16.7%)	
Gender				
Male	0 (0%)	2 (6.3%)	4 (33.3%)	0.058
Female	1 (100%)	30 (93.8%)	8 (66.7%)	
Marital status				
Single	1 (100%)	8 (25%)	2 (16.7%)	0.473
Married	0 (0%)	21 (65.6%)	9 (75%)	
Widowed	0 (0%)	3 (9.4%)	1 (8.3%)	
Education				
Informal	0 (0%)	2 (6.3%)	2 (16.7%)	
Primary	1 (100%)	6 18.8%)	2 (16.7%)	0.429
Secondary	0 (0%)	21 (65.6%)	6 (50%)	
Tertiary	0 (0%)	3 (9.4%)	2 (16.7%)	
Occupation				
Unemployed	0 (0%)	14 (43.8%)	3 (25%)	
Casual jobs	0 (0%)	7 (21.9%)	3 (25%)	0.180
Formal job	0 (0%)	7 (21.9%)	5 (41.7%)	
Retired	1 (100%)	4 (12.5%)	1 (8.3%)	
Last visit to the clinic				
In the last one month	0 (0%)	12 (37.5%)	6 (50%)	
Between 1 and 2 months ago	1 (00%)	8 (25%)	1 (8.3%)	0.282
> 2 months ago	0 (0%)	12 (37.5%)	5 (41.7%)	

Significant bivariate association between any of the participants' socio-demographic characteristics and knowledge scores was not observed on performing the chi-square test (table 4)

Table 4: Association between participants' socio-demograpphic characteristics and knowledge scores after the intervention

	Knowledge score			
Variable	<50 (%)	50-70 (%)	>70 (%)	P value
Age group (years)				
19-37	1 (100%)	1 (16.7%)	15 (39.5%)	
38-57	0 (0%)	4 (66.7%)	18 (47.4%)	0.585
≥58	0 (0%)	1 (16.7%)	5 (13.2%)	
Gender				
Male	0 (0%)	1 (16.7%)	5 (13.2%)	
Female	1 (100%)	5 (83.3%)	33 (86.8%)	0.899
Marital status				
Single	0 (0%)	1 (16.7%)	10 (26.3%)	
Married	1 (100%)	5 (83.3%)	24 (63.2%)	0.796
Widowed	0 (0%)	0 (0%)	4 (10.5)	
Education				
Informal	0 (0%)	0 (0%)	4 (10.5%)	
Primary	0 (0%)	1 (16.7%)	8 (21.1%)	0.951
Secondary	1 (100%)	4 (66.7%)	22 (57.9%)	
Tertiary	0 (0%)	1 (16.7%)	4 (10.5)	
Occupation				
Unemployed	0 (0%)	14 (43.8%)	3 (25.0%)	
Casual jobs	0 (0%)	7 (21.9%)	3 (25.0%)	0.180
Formal job	0 (0%)	7 (21.9%)	5 (41.7%)	
Retired	1 (100%)	4 (12.5%)	1 (8.3%)	
Last visit to the clinic				
In the last one month	0 (0%)	3 (50%)	15 (39.5%)	0.274
Between 1 and 2 months ago	1 (100%)	2 (33.3%)	7 (18.4%)	
> 2 months ago	0 (0%)	1 (16.7%)	16 (42.1%)	

4.3.2 Hypothesis testing

A paired sample t test was used to compare the knowledge scores of patients before and after the education intervention. It is clear from table 6 that there was a statistically significant difference in the pre-test scores (M=11.9333, S.D 2.01585) and post-test scores (M=15.5778, S.D 2.18974), $t(45) = -8.615$, $p \leq 0.001$ (table 5).

Table 5: Comparison of mean knowledge scores

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Total knowledge score (PRE)	11.9333	45	2.01585	.30050
	Total knowledge score (POST)	15.5778	45	2.18974	.32643

Paired Samples Test

		Paired Differences							
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	T	df	Sig. (2-tailed)
Pair 1	Total Pretest – Total Posttest	-3.64444E0	2.83770	.42302	-4.49698	-2.79191	-8.615	44	0.000

4.4 Adherence to warfarin therapy

Adherence of patients to warfarin was determined by the 8 point Morisky tool. None adherence was noted in 71.1% of the patients with a score of < 6 while 28.9% of patients had adherence with a score of 8 during the pre-test. During the post-test after the intervention, 33.3% had none adherence while 66.7 % had adherence (figure 3).

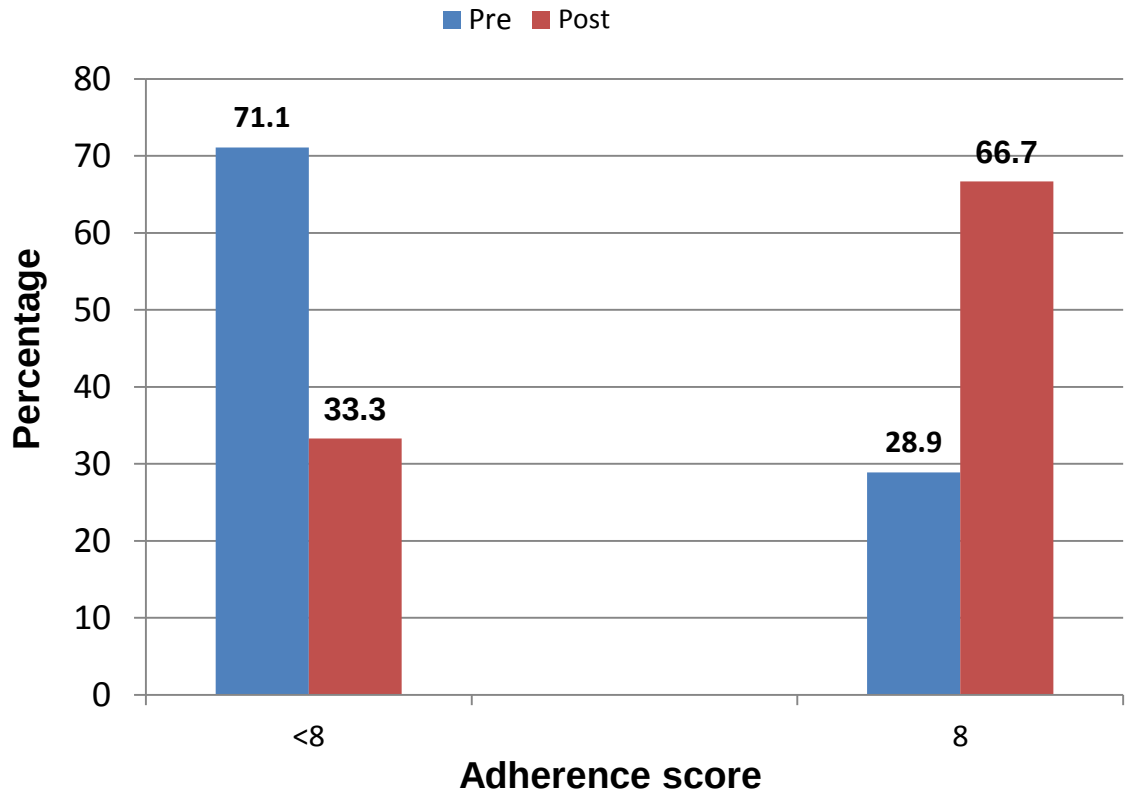

Figure 3: Adherence score at pre and post education on warfarin coagulation.

4.4.1 Factors associated with adherence to Anticoagulation

After bivariate analysis, using the chi square test, it was noted that occupation was the only socio-demographic factor that was statistically significantly associated with adherence prior to the education intervention with a p value of <0.05. Most of the patients above the age of 58 were adherent, while most patients between the ages of 19 and 37 had none adherence. Female participants were noted to be more adherent as compared to their male counterparts while most retired participant had high adherence. (Table 6)

Table 6: Association between participants' socio-demographic characteristics and adherence before the intervention

Variable	None adherence	Adherence	P value
Age			
19-37	14 (43.8%)	3 (23.1%)	0.073
38-57	16 (50.0%)	6 (46.2%)	
≥58	2 (6.3%)	4 (30.8%)	
Gender			
Male	4 (12.5%)	2 (15.4%)	1.000
Female	28 (87.5%)	**11 (84.6%)**	
Marital status			
Single	7 (21.9%)	4 (30.8%)	
Married	23 (71.9%)	7 (53.8%)	0.445
Widowed	2 (6.3%)	2 (15.4%)	
Education level			
Informal	1 (3.1%)	3 (23.1%)	
Primary	6 (18.8%)	3 (23.1%)	0.958
Secondary	20 (62.5%)	7 (53.8%)	
Tertiary	5 (15.67%)	0 (0%)	
Occupation			
Unemployed	15 (46.9%)	2 (15.4%)	
Casual jobs	7 (21.9%)	3 (23.1%)	
Formal jobs	9 (28.1%)	3 (23.1%)	**0.011**
Retired	1 (3.1%)	**5 (38.5%)**	
Last anticoagulation clinic visit			
In the last 1 month	13 (40.6%)	5 (38.5%)	
Between 1 and 2 months ago	7 (21.9%)	3 (23.1%)	0.991
> 2 months ago	12 (37.5%)	5 (38.5%)	

Adherence score at pre education by occupation

A significant number of unemployed participants had a none adherence score 15 (46.9%), while a high number of participants who had an adherence score were retired 5 (38.5%) (Table 7)

Table 7: Adherence score at pre education by occupation

	Total adherence score		
Occupation	None adherence	Adherence	Total
Unemployed	15 (46.9%)	2 (15.4%)	17 (37.8%)
Casual jobs	7 (21.9%)	3 (23.1%)	10 (22.2%)
Formal job	9 (28.1%)	3 (23.1%)	12 (26.7%)
Retired	1 (3.1%)	5 (38.5%)	6 (13.3%)
Total	32 (100%)	13 (100%)	45 (100%)

Bivariate analysis to determine the association between the participants' socio-demographic factors and adherence after the intervention found no statistically significant association between any of the socio-demographic factors and adherence after the education intervention (table 8).

Table 8: Association between participants' socio-demographic characteristics and adherence after the intervention

Variable	None adherence	Adherence	P value
Age			
19-37	5 (33.3%)	12 (40.0%)	0.641
38-57	7 (46.7%)	15 (50.0%)	
≥58	3 (20.0%)	3 (10.0%)	
Gender			
Male	1 (6.7%)	5 (16.7%)	0.647
Female	14 (93.3%)	25 (83.3%)	
Marital status			
Single	4 (26.7%)	7 (23.3%)	
Married	9 (60.0%)	21 (70.0%)	0.706
Widowed	2 (13.3%)	2 (6.7%)	
Education level			
Informal	2 (13.3%)	2 (6.7%)	
Primary	4 (26.7%)	5 (16.7%)	0.251
Secondary	6 (40.0%)	21 (70.0%)	
Tertiary	3 (20.0%)	2 (6.7%)	
Occupation			
Unemployed	7 (46.7%)	10 (33.3%)	
Casual jobs	2 (13.3%)	8 (26.7%)	
Formal jobs	3 (20.0%)	9 (30.0%)	0.494
Retired	3 (20.0%)	3 (10.0%)	
Last anticoagulation clinic visit			
In the last 1 month	5 (33.3%)	13 (43.3%)	
Between 1 and 2 months ago	3 (20.0%)	7 (23.3%)	0.680
> 2 months ago	7 (46.7%)	10 (33.3%)	

Multivariate analysis was done using binary logistic regression. The enter method was used, meaning that all socio demographic variables were considered simultaneously, there was no patient socio-demographic characteristics that was significantly associated with adherence before the intervention (table 9)

Table 9: Independent predictors of adherence score at pre-education

							95% C.I.for EXP(B)	
	B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Age	20.408	27731.434	.000	1	.999	7.292E8	.000	.
Gender(	.296	1.402	.045	1	.833	1.344	.086	20.972
Marital Status	1.158	1.899	.372	1	.542	3.183	.077	131.718
Education Level(	20.250	17274.429	.000	1	.999	6.228E8	.000	.
Occupation	-22.182	27731.434	.000	1	.999	.000	.000	.
Last visit to the anticoagulation ıic	-2.487	1.814	1.881	1	.170	.083	.002	2.907
Constant	-19.977	17274.429	.000	1	.999	.000		

OR: Odds ratio; C.I: Confidence Interval; S.E: Standard Error

Multivariate analysis was done using binary logistic regression. The enter method was used, meaning that all socio demographic variables were considered simultaneously, there was no patient socio-demographic characteristics was that significantly associated with adherence before the intervention (table 10).

Table 10: Independent predictors of adherence score at post education

							95% C.I. for EXP(B)	
	B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Age	0.048	1.685	0.001	1	0.977	1.049	0.039	28.511
Gender	1.403	1.409	0.992	1	0.319	4.067	0.257	64.322
Marital Status	0.961	1.332	0.521	1	0.471	2.615	0.192	35.59
Education Level	1.43	1.125	1.614	1	0.204	4.178	0.46	37.924
Occupation	0.048	1.685	0.001	1	0.977	1.049	0.039	28.511
Last visit to the anticoagulation clinic(2)	0.529	1.077	0.242	1	0.623	1.698	0.206	14.012

OR: Odds ratio; C.I: Confidence Interval; S.E: Standard Error

4.4.2 Hypothesis testing

A paired sample t test was used to compare the adherence scores before and after the education intervention. There was a statistically significant difference in the scores before the intervention (M=6.29, S.D=1.590) and after the intervention (M= 7.38, S.D=1.029), t (45) = -3.811, $p \leq 0.001$ (table 11)

Table 11: Comparison of mean adherence scores

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Total adherence score (PRE)	6.29	45	1.590	.237
	Total adherence score (POST)	7.38	45	1.029	.153

Paired Samples Test

		Paired Differences					T	Df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Total adherence score (PRE) - Total adherence score (POST)	-1.089	1.917	.286	-1.665	-.513	-3.811	44	.000

4.5 Anticoagulation control with warfarin therapy

Each participants INR was performed before and after the education intervention. Only 15 participants had normal range of INR before the intervention, contrary to 23 participants who had normal INR after the intervention (table 12).

Table 12: Comparison of INR levels during pre and post test

INR level	Pre-intervention		Post intervention	
	n	%	n	%
Normal (2-3)	15	33.3	23	51.1
Out of range (<2 or >3)	30	66.7	22	48.9
Total	45	100	45	100

4.5.1 Factors associated with INR Control

Significant bivariate association between any of the participants' socio-demographics and INR levels was not observed before the education intervention (Table 13)

Table 13: Association between participants' socio-demographic characteristics and INR levels prior to the intervention

	INR levels		P value
Variable	Within range	Out of range	
Age group (years)			
19-37	5(33.3%)	12(40.0%)	
38-57	8(53.3%)	14(46.7%)	0.901
>=58	2(13.3%)	4(13.3%)	
Gender			
Male	3(20.0%)	3(10.0%)	0.311
Female	12(80.0%)	27(90.0%)	
Marital status			
Single	2(13.3%)	9(30.0%)	0.409
Married	11(73.3%)	19(63.3%)	
Widowed	2(13.3%)	2(6.7%)	
Education			
Informal	0(0.0%)	4(13.3%)	
Primary	3(20.0%)	6(20.0%)	
Secondary	11(73.3%)	16(53.3%)	0.381
Tertiary	1(6.7%)	4(13.3%)	
Occupation			
Unemployed	5(33.3%)	12(40.0%)	
Casual jobs	2(13.3%)	8(26.7%)	0.564
Formal job	5(33.3%)	7(23.3%)	
Retired	3(20.0%)	3(10.0%)	
Last visit to the clinic			
In the last one month	4(26.7%)	14(46.7%)	
Between 1 and 2 months ago	5(33.3%)	5(16.7%)	0.320
> 2 months ago	6(40.0%)	11(36.7%)	

Significant bivariate association between any of the participants' socio-demographics and

INR levels were not observed after the education intervention. However, there was an improvement in the INR control of patients aged between 19 and 57. The number of females and unmarried participants with normal INR also increased after the intervention. Moreover the unemployed participants showed an improvement in INR levels too (Table 14).

Table 14: Association between the participants' socio-demographic characteristics and INR levels after the intervention

Variable	INR levels		P value
	Normal	Abnormal	
Age group (years)			
19-37	10(43.5%)	7(31.8%)	
38-57	11(47.8%)	11(50.0%)	0.556
≥58	2(8.7%)	4(18.2%)	
Gender			
Male	3(13.0%)	3(13.6%)	
Female	20(87.0%)	19(86.4%)	0.646
Marital status			
Single	6(26.1%)	5(22.7%)	
Married	16(69.6%)	14(63.6%)	0.548
Widowed	1(4.3%)	3(13.6%)	
Education			
Informal	1(4.3%)	3(13.6%)	
Primary	5(21.7%)	4(18.2%)	0.403
Secondary	13(56.5%)	14(63.6%)	
Tertiary	4(17.4%)	1(4.5%)	
Occupation			
Unemployed	11(47.8%)	6(27.3%)	
Casual jobs	3(13.0%)	7(31.8%)	0.384
Formal job	6(26.1%)	6(27.3%)	
Retired	3(13.0%)	3(13.6%)	
Last visit to the clinic			
In the last one month	7(30.4%)	11(50.0%)	
Between 1 and 2 months ago	5(21.7%)	5(22.7%)	0.311
> 2 months ago	11(47.8%	6(27.3%)	

4.5.2 Independent predictors of poor anticoagulation control

Multivariate analysis was done using binary logistic regression. The enter method was used, meaning that all socio demographic variables were considered simultaneously, there was no patient socio-demographic characteristics was significantly associated with INR control before the intervention (table 15).

Table 15: Predictors of poor anticoagulation control before the intervention

					95% C.I. for EXP(B)	
	Coefficient	S.E of coefficient	P value.	OR	Lower	Upper
Age	20.568	28179.16	0.999	8.56E+08	0	.
Gender	1.245	1.243	0.316	3.473	0.304	39.677
Marital Status	-1.327	1.855	0.475	0.265	0.007	10.07
Education Level	0.557	1.42	0.695	1.745	0.108	28.199
Occupation	-21.878	28179.16	0.999	0	0	.
last visit to the anticoagulation clinic	-1.022	1.005	0.309	0.36	0.05	2.579

OR: Odds ratio; C.I: Confidence Interval; S.E: Standard Error

Multivariate analysis was done and none of the patient socio-demographic characteristics was significantly associated with INR control after the intervention (table 16).

Table 16: Predictors of poor anticoagulation control after the intervention

					95% C.I.for EXP(B)	
	Coefficient	S.E.of Coefficient	P Value	OR	Lower	Upper
Age			.999		.000	
Gender	-1.156E+00	1.152	.316	.315	.033	3.010
Marital Status	1.113	1.671	.505	3.044	.115	80.537
Education Level	-8.097E-01	1.286	.529	.445	.036	5.531
Occupation	-2.142E+01	25990.955	.999	4.991E-10	.000	.
last visit to the anticoagulation clinic	-8.492E-01	1.049	.418	.428	.055	3.343

OR: Odds ratio; C.I: Confidence Interval; S.E: Standard Error

4.5.3 Hypothesis testing

A paired sample t test was used to compare the INR results before and after the education intervention. There was no statistically significant difference in the mean scores before the intervention (M=2.375, S.D=1.009) and after the intervention (M= 2.39, S.D=1.015), t (44) = -0.73, p≥0.005 (table 17)

Table 17: Comparison of mean INR levels

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	INR _PRE	2.375	45	1.1009	.1641
	postINR	2.39	45	1.015	.151

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
		Mean	Std .Deviation	Std. Error Mean	Lower	Upper			
Pair 1	INR _PRE post INR	-.0131	1.2014	.1791	-.3740	.3478	-.073	44	.942

4.6 Summary of results

Study participants had a mean age of 42.89±13.67 with majority of them being female (86.7%) and married (66.7%). Only 26.7% of the participants had good knowledge (≥70%) before the intervention while 84.4% of them scored ≥70% at post-test. Advancing participants' age was statistically significantly associated with better anticoagulation knowledge before the intervention (p=0.04). None of the patient socio-demographic factors was statistically significantly associated with knowledge scores after the intervention. There was a statistically significant difference in the pre-test and post-test knowledge mean scores (M=11.993, S.D=2.01585) and (M=15.5778, S.D=2.1874), t (45) =-8.615, respectively (p≤0.001).

Adherence was noted in a third of the patients before the intervention and this increased to two thirds after the intervention. Patients' occupation was the only socio-demographic factor that was statistically significantly associated with adherence before the intervention unlike at

post intervention when none of the socio-demographic factors was associated with adherence. There was a statistically significant difference in the mean adherence scores before and after the intervention (M=6.29, S.D=1.590) and (M= 7.38, S.D=1.029), t (45) = -3.811, respectively ($p \leq 0.001$).

Therapeutic anticoagulation control was maintained by a third and 50% of the patients at pre and post-tests, respectively.

CHAPTER 5 DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses the finding of the study, recommendations to further improve patient knowledge on anticoagulation control.

5.2 Discussion

Our study revealed female predominance which tallies with results from other studies (10,16,17,19) . The mean age was 42.8 (±13.67) years with the participants' age ranging between 19 and 78 years. Majority of our study participants were married. This finding is comparable with other studies (12,21).

Studies done to evaluate levels of patient knowledge on anticoagulation have revealed that most patients have very little knowledge on anticoagulation (16,21,58). Literature generally notes the fact that patient knowledge and anticoagulation control go hand in hand (7,59). Providing patient education helps improve anticoagulation control (12,16,27). A study done locally by Kizito *et al* (10), showed that only 10.1% of patients had adequate knowledge which is in contrast to our study which revealed 26.7%. This difference could be attributed to the fact that in Kizito's study the pass mark was 75% while in our study, a cut-off of 12 (70%) was used to define adequate knowledge. We decided to use 70% since this was an average mark of a similar studies done in Egypt, Cairo whereby 60% was used as thee pass mark (12) and one done in Illinois, U.S.A whereby 78% was used (73). Our findings however, are close to the study done in Cairo whereby 23.9% of patients had satisfactory knowledge scores (12).

Nasser *et al,* (64) noted that provision of education improved knowledge whereby more than 90% of participants passed the post test. These findings are comparable to what we found in our study whereby 84.4% managed to pass the post test.

Our findings revealed that age was the only socio-demographic factor that was statistically significantly associated with knowledge in the pre-test unlike in the post-test. Participant's age has been found to impact on anticoagulation knowledge with ages between 38 and 57 having better knowledge. The plausible reasons cited include poor cognitive functions with a rising age (71) and use of complex words which leads to poor understanding among the elderly. It is possible that this age group was better experienced in anticoagulation management compared to the young

Marital status was not found to have any statistically significant association with knowledge, These findings mirror the study done by Deck *et al* (73) which found no significant association between marital status and patient knowledge on warfarin. In contrast a study done locally found out that patients who had been previously married had more knowledge than those who were married or those who were single.(10) This difference could be due to the fact that there is increased oral anticoagulation awareness and patients are becoming more conscious of their health.

During the pre-OAK test, most participants exhibited knowledge in matters of use of warfarin, INR test, alcohol consumption but there was lack of knowledge in aspects concerning diet and interacting medication. This finding mirrors other similar studies which showed that most patients did not have enough knowledge on interacting medication and diet (10,14,58). On the other hand, during the post test, all questions had a score of more than 75 %. This revelation suggests that these aspects of warfarin knowledge require more education intervention with experts in medication therapy for patient understanding.

Furthermore, a vast improvement was noted between the pre and the post test scores, whereby before the intervention only 12 patients (26.7%) had good knowledge as compared to 38 (84.45%) after the intervention. . This can be attributed to the handbook that was provided for the patients and counseling by the pharmacist. Furthermore, the findings can be supported by previous literature that confirms increase in patient knowledge after counseling by pharmacist (12,15,68,73).

Patients' mean scores showed a statistical significant difference ($t = -3.64$, $p < 0.001$) between the pre and the post test scores on knowledge. These results mirrored a similar study that was carried out by El-Naby *et al* (12), in Cairo Egypt, which evidenced a significant increase in the patient mean scores ($F=114.303$, $P \leq 0.001$). A similar study carried out in Illinois (73), demonstrated a statistically significant difference that existed between the pre-test and post test scores ($t(37)=-4.61$, $p<0.001$). Additionally, another study, carried out in Sudan, found a sixty five percentage improvement in the knowledge scores after a clinical pharmacist education intervention (68). A prospective RCT carried out in India, with 40 participants in the control group an 40 in the intervention group found out that there was a significant increase in the patients' knowledge scores 5.6 ± 3.2 to 13.8 ± 0.94 ($P \leq 0.001$) after counseling by a clinical pharmacist as compared to the control group which had no statistical significant difference in the knowledge scores (8.0 ± 1.59 vs. 8.3 ± 2.6) ($P=0.218$) (49).

Approximately 25% of our patients were adherent to anticoagulation therapy before the intervention while 66.7% were adherent after the intervention. This is comparable with another study where 69.75 of patients were adherent after the intervention (68). In contrast, a study done locally reported adequate adherence in 50% of the patients (10).. This difference could be attributed to the high rate of patient prescriber discordance that occurred during the study period whereby it was observed that doctors were mostly unavailable for clinic sessions.

In our study, there was a statistically significant association between patients' occupation and adherence whereby the employed or high income participants showed better adherence than their counterparts. These findings are consistent with another study that found higher income as a factor associated with adherence (16). Similarly a study done at KNH reported general treatment cost influenced adherence whereby patients who were financially comfortable had higher adherence (10).

There was a statistically significant difference in mean adherence score in the pre and post warfarin based education program (M=6.29, S.D=1.590) (M= 7.38, S.D=1.029), t (45) = -3.811, respectively ($p \leq 0.001$). These findings are consistent with another study that tried to find out the effect of a clinical pharmacist's education intervention on patient adherence with their results showing that a significant increase in adherence after the intervention ($p < 0.001$) (68).

Various studies have found different factors impacting on adherence, such as socio-economic status, age, income, marital status (81–83). However, there is conflicting evidence on which particular socio-demographic factor impacts most on adherence. This could be because each patient is different with a different condition, a different warfarin dosage and a different lifestyle. A one on one education intervention and the booklet gives the patient enough time to understand importance of adherence and why it is important in effective anticoagulation management.

Our study also wanted to find out if an education intervention had any effect on INR stability. Approximately a quarter of our study participants had INR within range before the intervention, in comparison to half after the intervention. There was no statistical significant difference in the mean INR levels at pre and post education program on warfarin coagulation ($p=0.942$). These finding are similar to a study that was done in Saudi Arabia whereby no relationship was found between patients knowledge of warfarin and anticoagulant control (75). Another study that used a similar study design to ours also found no significant

relationship between knowledge and INR control which they attributed to the fact that the whole study population did not get INR done (73). On the other hand, a study done in Egypt found out that incidence of bleeding greatly reduced after an education intervention (12). Another study concluded that patient education was effective in INR control during the start of the therapy but had no role for long term therapy(63). These variations in conclusions could be due to the different study populations and the difference in frequency of measuring INR among the study participants.

Our study found a positive correlation between an education intervention and patient knowledge and adherence. Conversely, the study did not find any significant relationship between education intervention and INR control. The improvement in knowledge scores and adherence could be due to the personalized counseling that each patient received and the patient education handbook that was given to all study participants.

Other studies that used a similar study design also found a relationship between an education intervention and improvement in knowledge and adherence (12,68,73) but did not find any significant relationship between an education intervention and INR control (73).

5.3 Study Limitations

Elderly patients especially those above the age of 70 years might have had difficulty in answering the pre/post questionnaires' and understanding the education intervention. This could have led to misinterpretation of information.

We did not take into account some of the other variables such as prescribers' change in dosage that could affect INR and anticoagulation control.

5.4 Conclusion

Patients' knowledge on anticoagulation, adherence and INR control are poor in KNH. Patients are least knowledgeable on aspects of drug-drug and drug-food interactions. Patients' age is associated with anticoagulation knowledge with the elderly being less knowledgeable about anticoagulation therapy.

There is significant improvement in patients' level of knowledge and adherence after the education intervention. This suggests that provision of a designed, well organized warfarin education program can improve patient knowledge and also their degree of adherence.

5.5 Recommendations

5.5.1 Policies and Procedures

Based on our study findings, warfarin education sessions should be made frequently available to all patients on warfarin therapy. A standard warfarin education booklet that has simple easy to understand language should be made available to all patients on warfarin therapy

5.5.2 Recommendations for research

Replication of this study with a larger study sample and different methods of education intervention, for example; focus groups, videos should be done in KNH.

Research on other independent factors that are associated with poor anticoagulation should be done. Furthermore, research should be conducted on the inter-individual variability in the dose anticoagulation effect of warfarin.

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APPENDICES

Appendix 1: WRITTEN INFORMED CONSENT

TITLE OF PROJECT: EFFECT OF A DESIGNED WARFARIN BASED EDUCATION PROGRAM ON ORAL ANTICOAGULATION CONTROL AMONG ADULT OUTPATIENTS ATTENDING CLINICS AT KENYATTA NATIONAL HOSPITAL.

Principal Investigator: Dr. Sakina Iqbal Mamdani. P.O. BOX 11014 (00400)

Supervisors: Dr. D. G. Nyamu: Department of Pharmaceutics and Pharmacy practice, University of Nairobi. P.O. Box 19676-00202, Nairobi.

Dr. T. B. Menge: Chief Pharmacist, Kenya

Ethical Approval: Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee, P.O. Box 20723-00202, Nairobi. Tel 2726300/2716450 Ext 44102

Introduction: My name is Dr. Sakina Iqbal Mamdani. I am a postgraduate student in the Department of Pharmaceutics and Pharmacy practice, University of Nairobi. I am pursuing a degree of Master of Pharmacy in Clinical Pharmacy. I am conducting a study on **'effect of a designed warfarin based education program on oral anticoagulation control among adult patients attending anticoagulation clinics at Kenyatta National Hospital.'**

I would like to seek your permission to participate in the study. Kindly read the consent form below.

Purpose of the Study: The purpose of this study is to determine if knowledge and adherence are increased after an education intervention. This will be determined using the pre-test/post-test Oral Anticoagulation Knowledge Test tool, a 17 multiple choice questions tool and an 8 question adherence questionnaire

Procedures to be followed include: Should you agree to participate in the study, you will be required to answer a questionnaire that will take approximately 15 minutes. Thereafter you will have a one on one session with the principal investigator who will provide you with knowledge about warfarin, after which you will be provided with a booklet. During your next visit, you will be asked to complete the same questionnaire. This exercise will help the researcher find out if there was an improvement in your test results after the intervention. During this same visit you will also do your routine INR test. The results of this test will be used by the researcher in the study.

Reason to Participate/Benefits: The benefits you may receive by participating in the study include gaining knowledge about important aspects of warfarin treatment such as side effects to expect, drugs to avoid when using warfarin and INR control. Any queries regarding warfarin will also be answered.

Risks: This is a minimal risk study as it involves face to face interview. Although, INR determination will be done at some point, this will be a usual check for evaluating the effectiveness of warfarin. It will be done by the usual staff so as to avoid risks to you.

Confidentiality: All of your records will be in a password-protected electronic medical record and be kept confidential. Signed copies of your consents authorizations will be kept in a locked office file cabinet. No one other than the principal investigator and her supervisor will be allowed to see the information, subject to legally prescribed exceptions. You will not be identified in any reports on this study.

C**ompensation**: You will not get paid for taking part in the study

Participation is voluntary: Choosing to be a participant becoming a subject in this study is entirely voluntary.. You may also drop out of this study by your own free will, after having agreed to participate. You may refuse to enroll in this study or drop out of the study at any time without any problem. By doing so, you will not lose any benefits that you may be entitled.

Contacts: You are free to contact the Principal investigator before, during and after the study for any queries you might have regarding the study. Please feel free to use the contacts below.

Dr. Sakina Iqbal Mamdani. P.O. Box 11014-00400, Nairobi. Telephone Number – 0720519398.

Email: sakinamamdani@gmail.com

Supervisors:

Dr. D. G. Nyamu: Department of Pharmaceutics and Pharmacy practice, University of Nairobi. P.O. Box 19676-00202, Nairobi. Tel: +254 2726771, +254771946687

Dr. T. B. Menge: Chief Pharmacist, Kenyatta National Hospital.

This proposal has been reviewed and appoved by Kenyatta National Hospital/University of Nairobi Ethic Review Committee, which is a committee whose task is to make sure that research participants are protected from harm. Hence, further information regarding your rights as a study participant can be obtained from the Secretary KNH/UON ethics and research committee at uonknh_erc@uonbi.ac.ke, P.O Box 20723-00202 Nairobi, Tel. 2726300 Ext. 44102.

Please feel free to ask any questions.

I now request you to sign the consent form attached

CONSENT DECLARATION

I …… being 18 years and more have been informed about the study, hereby do consent to voluntarily participate in this study.The nature of the study has been explained to me by the principal investigator and I have been given opportunity to ask questions concerning the study which have been answered to my satisfaction. The benefits and risks of this study have been clearly explained to me and I am aware that I am free to withdraw from this study at any point and this will not jeopardize the care I receive at the hospital.

I therefore give consent to be interviewed and that information from my file can also be used having understood the purpose of the study.

Signature: …… Date: …….....

Witness Name and sign……..Date:…….....

Researcher's statement:

I …… confirm that I have explained to the patient the purpose and nature of the study.

Signature: …… Date: ……..…...

KISWAHILI VERSION OF THE CONSENT FORM

Jina langu ni Dkt. Sakina Iqbal Mamdani. Mimi ni mwanafunzi wa shahada ya uzamifu katika kitengo cha 'clinical pharmacy, katika chuo kikuu cha Nairobi. Ninaendeleza utafiti wa kuchunguza athari za maarifa juu ya udhibiti wa kuzuia mgando katika wagonjwa wanaohudhuria kliniki ya tatizo la damu.

Ningependa kuomba ruhusa yako ili katika utafiti wangu. Tafadhali soma fomu ya ridaa iliyo hapo chini.

Je, utafiti huu una lengo lipi?

Lengo la somo hili ni kuamua kama mgonjwa atapata maarifa baada ya kupata elimu. Hii itaamuliwa kwa kutumia mitihani kabla na baada ya kupata elimu.

Taratibu ya kufuatwa Katia tafiti huu?

Ukikubali kushiriki katika utafiti huu utaulizwa maswali kadaa ambayo yatachukua kama dakika kumi na tano. Baada ya hayo utaongea na mpelelezi mkuu ambaye atakupatia elimu kuhusu warfarin. Ukija kliniki wakati wako wa pile utaulizwa maswali yale yale uliyoulizwa wakati wa kwanza. Kila kikao itachukua Takriban dakika 30

Sababu ya kushiriki/faida

Faida unaweza kupokea kwa kushiriki katika utafiti huu ni kupata elimu juu ya dawa ya warfarin. Elimu huu itakusaidia kwa usimamizi wa tiba. Maswali yeyote ambayo unayo zitajibiwa na mpelelezi mkuu

Je, kuna hatari inayohusika katika utafiti huu?

Utafiti huu haina hatari yoyote.

Je,nitaruhusiwa kutoka katika utafiti huu?

Una uhuru wa kutoka kwenye utafiti huu na hakutaathiri kwa njia yeyote huduma unayopata kila siku. Asante kwa ushirikiano wako.

Kwa maelezo zaidi unaweza kuwasiliana na mmoja wa wanaofuata;

1. Dkt. Sakina Iqbal Mamdani, Kitengo cha Pharmaceutics na Pharmacy Practice, University of

Nairobi. P.O Box 11014 – 00400. Anwani ya barua pepe: sakinamamdani@gmail.com. Nambari ya simu: 0720519398

2. Dkt. D.G. Nyamu, Kitengo cha Pharmaceutics na Pharmacy Practice, University of Nairobi. Tel: +254 2726771, +254771946687

3. Dkt. T. B. Menge: Pharmacist Mkuu, Kenyatta National Hospital.

4. Sekretary KNH/UON ethics and research committee P.O. Box

20723-00202, Nairobi. Tel 2726300/2716450 Ext 44102. Anwani ya barua pepe uonknh_erc@uon.ac.ke

Tafadhali ukiwa na maswali yoyote unaweza uliza

Nigeomba ufanye sahihi katika fomu ya ridha. Asante

Fomu ya Ridhaa

Mimi, niliyetia kidole change hapa chini, nakubali kushiriki katika utafiti wa kuchunguza athari za maarifa juu ya udhibiti wa kuzuia mgando katika wagonjwa wanaohudhuria kliniki ya tatizo la damu katika hospitali kuu ya Kenyatta'.

Nakubali kushiriki nikifahamu malengo na taratibu za utafiti huu ikiwemo kujibu maswali. Nimeelezwa lengo la utafiti huu na hautanidhuru.

Taarifa itakayotolewa itakuwa siri. Ninafahamu ya kwamba naweza kujiondoa kutoka

utility huu wakati wowote bila kuathiri huduma ninazopata. Baada ya kuelezwa haya

yote, ninakubali kwa hiari yangu kushiriki Katia huu utility.

Sahihi: …… Tarehe: …….....

Jinan a sahihi ya shahidi……Tarehe…….

Taharifa ya mtafiti:

Mimi ……. Nathibitisha kuwa nimeeleza kwa kina aina

na madhumuni ya utility huu.

Sahihi: …… Tarehe: ……..…...

Appendix 2: DATA COLLECTION TOOL
SCREENING AND ELIGIBILITY FORM

Screening No..... Date of screening.....

Section A: Inclusion criteria; Items 1-4 need to be answered yes for the participant

to be eligible. For female participants item 5 needs to be answered no for eligibility

1. Is the patient on Oral Anticoagulation Therapy? Yes/No
2. Is the patient of 18 years of age or above? Yes/No
3. Has the patient given informed consent? Yes/No
4. Is the next regular appointment within a period of 4 weeks? Yes/No

Answer the next question only if the patient is female

5. Is the patient preganant? Yes/No

Section B: Exclusion criteria; Item 6 needs to be answered NO for the participant to

be eligible.

6. Is the patient mentally incapacitated? Yes/No
7. Based on the criteria above is the participant eligible? Yes No
8. If not eligible what is/are reason(s) for exclusion.....

.....

Comments (enrolled/not enrolled).....

QUESTIONNAIRE

PART 1: PATIENT DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

Patient Code Number..... INR_____

A) Demographics

1. Age (years).....

2. Gender: □ Male □ Female

3. Marital status: □Single □Married □Separated □Divorced □ Widowed

4. Education level: □ Informal □ Primary □ Secondary □ Tertiary

5. Occupation: □ Unemployed □ Casual jobs □Formal job □ Retired

6. When was your last visit to the anticoagulation clinic

□ In the last 1 month □ Between 1 and 2 months ago □ > 2 months

ago

PART 2: THE ORAL ANTICOAGULATION KNOWLEDGE (OAK) TEST

For each, tick the answer you think is correct or best completes the sentence correctly.

1. Warfarin may be used to:

a) Treat people that are likely to a clot

b) Treat people that have high blood sugar levels

c) Treat people with high blood pressure

d) Treat people that have severe wounds

2. The INR test is a blood test that:

a) Is used to monitor your warfarin therapy

b) Is rarely done while on warfarin

c) Checks the amount of vitamin K in your diet

d) Determines if you need to be on warfarin

3. A patient with a INR value below their ‘goal range’:

a) Is at an increased risk of bleeding

b) Is at an increased risk of developing a clot

c) Is more likely to have a skin rash from the warfarin

d) Is more likely to experience side effects from warfarin

4. Once you have been stabilized on the correct dose of warfarin, how many times should your INR be checked?

a) Once a week

b) Once a month

c) Once every 2 months

d) Once every 3 months

5. An ideal INR should be

a) Less than 1

b) Between 2 and 3

c) More than 3

d) I don’t know

6. Drinking alcohol while taking warfarin

a) Is safe as long as you separate your dose of warfarin and the alcohol8consumption

b) May affect you INR

c) Does not affect your INR

d) Is safe as long as you are on a low dose of warfarin

7. Which of the following vitamins interacts with warfarin?

a) Vitamin B12 b) Vitamin A c) Vitamin B6 d) Vitamin K

8. Taking a medication containing aspirin or other pain killers such as brufen while on warfarin will:

a) Reduce the effectiveness of warfarin

b) Increase your risk of bleeding from the warfarin

c) Cause a blood clot to form

d) Require you to increase your dose of warfarin

9. Occasionally eating a large amount of leafy green vegetables eg, sukuma wiki while taking Warfarin can:

a) Increase your risk of bleeding from the warfarin

b) Reduce the effectiveness of warfarin

c) Cause stomach upset and vomiting

d) Reduce your risk of having a blood clot

10. When it comes to diet, people taking warfarin should:

a) Never eat foods containing large amounts of vitamin K

b) Keep a diary of all the foods they eat

c) Be consistent and eat a diet that includes all types of food

d) Increase the amount of vegetables they eat

11. When is it safe to take medication that interacts with warfarin?

a) If you take warfarin in the morning and the interacting medication at night

b) If your healthcare provider is aware of the interaction and checks your INR regularly

c) If you take warfarin once every two days

d) It is never safe to take a medication that interacts with warfarin

12. A patient with a INR value above their ‘goal range’

a) Is at an increased risk of developing a clot

b) Is more likely to have drowsiness and fatigue from the warfarin

c) Is at an increased risk of bleeding

d) Is less likely to experience side effects from warfarin

13. It is important for a patient on warfarin to monitor for signs of bleeding:

a) Only when their INR is above the range

b) At all times

c) Only when their INR is below the range

d) Only when you miss a dose

14. Missing one dose of warfarin:

a) Has no effect

b) Can alter the drug’s effectiveness

c) Is permissible as long as you take a double dose the next time

d) Is permissible as long as you watch which foods you eat

15. The best thing to do if you miss a dose of warfarin is to:

a) Double up the next day

b) Take the next scheduled dose and inform your healthcare provider

c) Call your healthcare provider immediately

d) Discontinue warfarin altogether

16. A person on warfarin should seek medical attention if they:

a) Skip more than two doses of warfarin

b) Notice blood in their stool

c) Experience a minor nose bleed

d) Develop bruises on their arms or legs

17. Tick all the foods high in Vitamin K

a) Green leafy vegetables like sukuma wiki and kale

b) Onions

c) Sweet potatoes

d) Tomatoes

PART 3: 8 POINT MORISKY ADHERENCE SCALE (Yes=1, No=0)

(Adapted from Morisky et al (90)

1. Do you ever forget to take your anticoagulation medicine? □ Yes □ No

2. In the last 2 weeks, is there any day you did not take your medicine? □Yes □No

3. Sometimes if you feel worse when you take anticoagulation medicine, do you stop taking it without telling your doctor? □ Yes □ No

4. When you travel, do you sometimes forget to carry your medicine? □Yes □No

5. Did you take your medicine yesterday? □ Yes □ No

6. Sometimes when you feel better, do you stop taking medicine? □Yes □No

7. Do you ever feel inconvenienced about sticking to your treatment plan?□Yes □No

8. How often do you have difficulty remembering to take warfarin?

[a=0, b) to e) = 1]

a) Never/rarely b) Once in a while c) Sometimes d) Usually e) All the time

Score ---/8 Adherent……..Non-Adherent----------

KISWAHILI VERSION OF QUESTIONNAIRE

SEHEMU YA KWANZA: MAELEZO KUHUSU MSHIRIKI

Numbari ya utility ya mshiriki..... INR_____

A) Maelezo kwa jumla

1. Uko na miaka mingapi?.....

2. Jinsia: □ Mme □ Mke

3. Ndoa: □Sijaoa □Nimeowa □Tuliwachana □ Tulitalakiana □ Mjane

4. Ulisoma shule hadi: □ Sikusoma □ Shule ya msingi □ Shule ya upili

5. Kazi: □Sina kazi □Kazi za mkono □Kazi ya kudumu □Nimestaafu

6. Ni lini mwisho ulienda kwenye cliniki ya kushughulikia shida yak ya damu

kuganda kwa urahisi

□ Siku thelathini hazijaisha □ Mwezi 1 au miwili iliyopita □ > miezi miwili

Iliyopita

SEHEMU YA PILI: UFAHAMU KUHUSU DAMU KUGANDA KWA URAHISI

NA MATIBABU YAKE

Maelezo: Katika kila swali, chagua jibu moja lililosahihi au linalotamatisha sentensi kikamilifu.

1. Warfarin inatumika kutibu:

a) Watu ambao wana damu imeshikana

b) Watu ambao wana ugonjwa wa kisukari

c) Watu ambao wana pressure ya juu

d) Watu ambao wana vidonda vikubwa

2. Test ya INR ni test ya damu ambayo:

a) Inatumika kuchunguza kiwango cha matibabu unapotumia warfarin

b) Mara nyingi huwa haifanywi

c) Inapima kiwango cha vitamin K kwenye lishe

d) Inaonyesha kama unahitaji warfarin

3. Mtu akiwa na INR chini ya anayostahili kuwa nayo:

a) Anaweza kutokwa na damu kwa urahisi

b) Damu yake yaweza kuganda kwa urahisi

c) Uwezekano wa ngozi yake kuharibika unaongezeka

d) Uwezekano wa warfarin kumdhuru unaongezeka

4. Unafaa kupimwa INR mara ngapi wakati kiwango cha warfarin kinachokufaa kimejulikana?

a) Mara moja kwa wiki

b) Mara moja kwa mwezi

c) Mara moja kila miezi miwili

d) Mara moja kila miezi mitatu

5. INR bora ni

a) chini ya 1

b) katikati ya mbili na taut

c)zaidi ya taut

d) mimi sijui

6. Kutumia pombe ukiwa Katia matibabu na warfarin:

a) Ni salama bora tu masaa ya kunywa pombe na kumeza warfarin yawe tofauti

b) Yaweza kuhitilafiiana na matokeo ya INR

c) Haiwezi kuhitilafiiana na matokeo ya INR

d) Ni salama bora tu uwe unatumia kiwango cha chini cha warfarin

7. Ni vitamin ipi iliyo na uhusiana na warfarin?

a) Vitamin B12 b) Vitamin A c) Vitamin B6 d) Vitamin K

8. Kutumia madawa yaliyo na aspirin au mengine ya maumivu kama Brufen kwa wakati mmoja na warfarin kunaweza:

a) Kupunguza nguvu za warfarin

b) Kuongenza uwezekano wa wewe kutokwa na damu

c) Kufanya damu ishikane

d) Kufanya uhitaji kiwango kikubwa cha warfarin

9. Wakati mwingine, kukula mboga nyingi za kijani kibichi wakati ukiwa Katia matibabu na warfarin waweza:

a) Kuongenza uwezekano wa wewe kutokwa na damu

b) Kupunguza nguvu za warfarin

c) Kufanya ukaumwa na tumbo na kutapika

d) Kupungunza uwezekano wa damu yak kushikana

10. Chakula wanaotumia warfarin wanafaa:

a) Kutokula chakula kilicho na kiwango kikubwa cha vitamin K

b) Kuandika chini lishe yao ya kila mara

c) Kula kiwango sawa cha vyakula aina yote kila mara wanapokula

d) Kuongeza kiwango cha mbogo ya kijani kibichi wanachokila

11. Ni wakati upi mzuri wa kutumia dawa inayo hitilafiana na warfarin?

a) Kumeza warfarin asubuhi na hiyo dawa nyingine jioni

b) Wakati daktari wako anaifahamu hiyo dawa nyingine na hupima INR yak mara kwa mara

c) Ikiwa unameza warfarin kila baada ya siku mbili

d) Si salama kutumia madawa yanayo hitilafiana na warfarin

12. Mtu akiwa na INR iliyo juu kuliko anayostahili kuwa nayo:

a) Damu yake yaweza kuganda kwa urahisi

b) Uwezekano wa kukosa nguvu unaongezeka

c) Anaweza kutokwa na damu kwa urahisi

d) Uwezekano wa warfarin kumdhuru unapungua

13. Ni muhimu kwa mtu anayetumia warfarin kuwa makini na kutambua dalili za kutokwa damu:

a) Wakati INR iko zaidi ya kipimo kinachofaa peke yake

b) Wakati wote

c) Wakati INR iko chini ya kipimo kinachofaa peke yake

d) Unapokosa kumeza warfarin peke yake

14. Kukosa kumeza tembe moja ya warfarin:

a) Hakuna madhara yoyote

b) Hakuwezi badilisha utendakazi wa warfarin

c) Kunakubalika bora umeze kiwango mara mbili zaidi utakapokumbuka

d) Kunakubalika bora utilie maanani vyakula unavyokula

15. Kitu kizuri cha kufanya iwapo umekosa kumeza tembe moja ya warfarin ni:

a) Kumeza tembe mbili siku itakayofuata

b) Meza tembe inayofuata vile ilivyo ratibiwa na umjulishe daktari wako

c) Wasiliana na daktari wako wakati huo huo

d) Uwache kutumia warfarin kabisa

16. Mtu anayetumia warfarin anapaswa kumwona daktari ikiwa:

a) Amekosa kumeza warfarin mara mbili mfululizo

b) Ameona dalili za damu kwenye kinyezi chake

c) Anatokwa na damu kwenye mapua

d) Anapata majeraha ya kutoa damu kwenye ngozi kwa urahisi

17) Chagua vyakula vyote ambavyo viko na kiwango cha juu ya Vitamini K

a) Sukuma wiki

b) Kitunguu

c) Viazi tamu

d) Nyanya

Appendix 3: WARFARIN BOOKLET

Introduction

This booklet has been given to you because you are on Warfarin. It is also known as an oral anticoagulant. The researcher will go through this book with you, contents and answer any questions you may have.

Oral anticoagulants

Warfarin prevents harmful blood clots from forming in your blood vessels by making your blood thin.

Dose

Always take your warfarin pills EXACTLY as directed. The daily dose you are told to take can change often. You might have to take a different dose on different days of the week. Take Warfarin at the SAME TIME EVERY DAY, you can take it in the morning or in the evening. If you forget to take a dose, take it as soon as you remember,

Monitoring you while you are taking an anticoagulant

You must have a regular blood test called an INR test. INR stands for International Normalized Ratio. This is a standard test that measures how long your blood takes to clot. Normally, blood for patients who are not taking warfarin has an INR of approximately 1.0. Patients who are taking warfarin are supposed to have an INR of between 2 and 3. The dose of warfarin that you need to take will depend on your INR test result. If your result is out of the INR level for your condition, your dose of anticoagulant will be increased or decreased accordingly. The warfarin dose required to achieve the target INR varies for each person. A low INR can increase the chances of a blood clot while a high INR can increase the chances of bleeding. Some food and medicine can affect your INR. You should always inform your doctor or pharmacist before taking any medicine even if it is over the counter. Abrupt changes in diet should also be informed to your doctor or pharmacist who can advise you.

Alcohol

If you don't take alcohol while on the drug is good for you because it can react with warfarin. However, if you do take it is recommended that you do not exceed three units a day for men, and two units a day for women. One unit is 10 ml of pure alcohol

Diet

It is important to eat a well-balanced diet. Consult your nutritionist or practice nurse if you need the diet to lose weight. Any major changes in your diet may affect how your body responds to your anticoagulant medication. Foods rich in vitamin K may affect your INR result. Such foods include green leafy vegetables like 'sukuma wiki', chick peas, liver, egg yolks, cereals containing wheat bran and oats, mature cheese, blue cheese, avocado and olive oil. These foods are important in your diet but eating them in large amounts may lower your INR result. Try to take the same amount of these foods on a regular basis. It is the change in the vitamin K intake that affects your INR result. Drinking grapefruit juice can also affect your INR and so should be avoided altogether if possible. If your diet changes greatly over a seven-day period, you should have an INR test.

Other medicines

Many medicines can interact with warfarin. If during your course of warfarin you are also starting or stopping another medication, the pharmacist or doctor may advise that you should have a blood test within five to seven days of starting the new medication. This is to make sure that your INR remains within the desired range. If you are planning to buy over-the-counter medicines, including alternative remedies, tell the pharmacist that you are taking warfarin. The Pharmacist will advise you on medicines that are safe for you to take. You should not take aspirin unless it has specifically been prescribed by a qualified medical practitioner. This is because aspirin together with warfarin can highly increase your chances of bleeding. It is also advisable to avoid other pain killers like diclofenac (diclomol), indomethacin (Indocid), Aspirin containing drugs (Mara moja, APC, Action) or ibuprofen (Brufen). This is because a combination of either of these with warfarin can also increase the chances of bleeding. Paracetamol and codeine-based painkillers are acceptable, although be aware that some paracetamol 'plus' products contain aspirin like APC.

Serious side effects

The most serious side effect of warfarin is bleeding. If you experience any of the following please, seek medical attention and have an urgent INR test: prolonged nosebleeds (more than 10 minutes), blood in vomit, blood in sputum, passing blood in your urine or feces, passing black faeces, severe or spontaneous bruising, unusual headaches, heavy or increased bleeding during your menstrual period or any other vaginal bleeding(for women). If you accidentally cut yourself, apply firm pressure to the site for at least five minutes using a clean, dry dressing so as to stop the bleeding.

KISWAHILI VERSION OF BOOKLET

Umekipewa kitabu hiki kwa sababu unameza dawa inaloitwa warfarin.Mtafiti mkuu atapitia maelezo yaliyomo ndani ya kitabu hiki na wewe. Atajibu maswali yoyote unayo kuhusu hiki kitabu.

Warfarin

Dawa inaloitwa warfarin hufanya damu nyembamba. Hili dawa linazuia damu kuganda kwa mshipa wa damu.

Dozi

Unafaa kumeza dawa la warfarin HASA vile ulivyoambiwa.Dozi yako ya kawaida inaweza badilishwa mara kwa mara.Unaweza ambiwa umeze dozi tofouti masiku tofouti ya wiki. Unafaa kumeza dawa ya warfarin wakati huo huo kila siku.Unaweza kumeza dawa asubuhi ama jioni.Ukisahau kumeza dawa lako, limeze unapokumbuka.

Kipimo Cha Damu

Unafaa ufanyiwe uchunguzi wa damu unayoitwa INR. Huu ni uchunguzi kawaida wa damu wa watu ambao wanameza dawa la warfarin. INR ya mtu ambaye hamezi warfarin ni 1.Kipimo cha INR cha mtu anayemeza dawa la warfarin inafaa kuwa kati kati ya 2 na 3 Dozi lako la dawa la warfarin inategemea matokeo yako ya kipimo cha INR. Dozi ya warfarin ya kila mtu ni tofauti. Kipimo cha INR kikiwa chini sana kinaweza fanya damu ya mgonjwa igande. Naaye, kipimo cha INR kikiwa juu sana kinaweza fanya mtu atoke damu.

Madawa na vyakula kadha yanaweza athiri kipimo chako cha INR. Kabla umeze dawa lolote umwulize daktari ama mfamasia wako.

Ukiwa na mabadiliko yoyote katika mlo wako, unafaa kumjulisha daktari wako au mfamsia wako.

Pombe

Ni vizuri usikunywe pombe ukiwa ukimeza dawa ya warfarin. Lakini kama unataka kukunywa pombe sharti ni, usizidi kipindi kitatu ukiwa mwanamume na usizidi kipindi kiwili ukiwa mwanamke. Kipindi kimoja kinakuwa na mililita 10.

Chakula

Ni muhimu ule utaratibu bora ya mlo. Unaweza kumwuliza lishe wako ama muuguzi wako ukitaka utaratibu sahihi ya kupungua kilo. Ubadilishi kuu katika mlo wako unaweza athiri vile mwili yakoinaitikia dawa la warfarin.

Vyakula ambavyo viko na vitamini ya K kwa nyingi yanaweza athiri kipimo chako cha INR. Vyakula kama haya ni, sukuma wiki, kunde, maini,avocado na kadhalika. Unaweza kula vyakula hivi kwa kiasi. Lakini ukizidi ya kawaida, kipimo chako cha INR kinaweza enda chini.

Ukibadilisha mlo wako kwa ghafla lazima ufanye kipimo cha INR kwa muda wa siku saba.

Madawa mengine

Madawa mengi yanaweza kuathiri dawa ya warfarin**.** Ukiwa ukimeza dawa la warfarin na unafaa kuanza ama kumaliza dawa lolote linguine, unafaa kufanya kipimo cha INR kwa muda wa wiki moja. Hii ni kuhakikisha kipimo chako cha INR kitabaki katikaa kiwango sahihi.

Ukienda kununua dawa lolote katika duka la dawa,lazima umwambie mfamasia kwamba unakuwa ukimeza dawa la warfarin. Mfamasia atakushaurimadawa yale unaweza meza.

Haufai kumeza dawa ya aspirin isipokuwa umeamuriwa na daktari wako. Hii ni kwa sababu, dawa ya aspirin na dawa ya warfarin pamoja yanaweza ongeza nafasi ya mwili kutoka damu.

Ni vizuri usipomeza madawa ya kuzuia maumivu kama dilofenac (diclomol®), indomethacin (indocid®), madawa ambayo yako na aspirin kama Mara Moja ®, APC®, Action® ama ibuprofen (Brufen®). Hii ni kwa sababu madawa haya yakimezwa pamoja na dawa la warfarinyanaweza ongeza nafasi ya mwili kutoka damu.

Dawa ya paracetamol na madawa mengine ya maumivu ambayo yako na codeine yanaweza tumika ilhali unafaa kuwa na fahamu kwamba madawa mengine ya paracetamol yanakuwanga na aspirin

Appendix 4: ETHICS APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
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KNH-UON ERC
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Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 05 MAY 2017 KNH/UoN-ERC P.O. Box 20723-00202 NAIROBI

Ref: KNH-ERC/A/151

5th May 2017

Sakina Iqbal Mamdani
Reg. No.U56/81109/2015
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Sakina

REVISED RESEARCH PROPOSAL – EFFECT OF A DESIGNED WARFARIN BASED EDUCATION PROGRAM ON ORAL ANTICOAGULATION CONTROL AMONG ADULT OUTPATIENTS AT KENYATTA NATIONAL HOSPITAL (P50/01/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 5th May 2017 – 4th May 2018.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely,

PROF M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH-UoN ERC
The Dean,School of Pharmacy UoN
The Chair, Dept. of Pharmaceutics and Pharmacy Practice, UoN
Supervisors: Dr. David G. Nyamu, Dr.Tom B. Menge

Appendix 5: APPROVAL FROM FACILITY

KENYATTA NATIONAL HOSPITAL
P. O. Box 20723, 00202 Nairobi

Tel: 2726300/2726450/2726550
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Ref: KNH/AD-MED/42B/VOL.I/

Date: 11th May 2017

Sakina Iqbal Mamdani
School of Pharmacy
College of Health Sciences
University of Nairobi

RE:APPROVAL TO CONDUCT A STUDY IN MEDICINE DEPARTMENT

Following approval of your study by the KNH/UoN ERC and completion of the KNH study registration form, permission is hereby granted for you to collect data from the Department of Medicine to enable you complete your study on *"Effect of a designed warfarin based education program on oral anticoagulation control among adult outpatients at* Kenyatta *National Hospital, Nairobi County, Kenya.*

Kindly liaise with the Senior Nursing Officer Incharge Medicine for facilitation. By a copy of this letter, the Senior Nursing Officer Incharge Medicine is informed and requested to facilitate.

12/05/2017

DR. M. MURAGE
AG. HOD - MEDICINE

Copy to: Senior Nursing Officer Incharge - Medicine

Vision: A world class patient-centered specialized care hospital

ISO 9001: 2008 CERTIFIED