CURRENT PRACTICE OF VENOUS THROMBOEMBOLIC PROPHYLAXIS IN NEWLY ADMITTED MEDICAL PATIENTS AT KENYATTA NATIONAL HOSPITAL

BY;

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STUDENT'S DECLARATION

I declare that this dissertation titled **"Current Practice of Venous Thromboembolic prophylaxis in Newly Admitted Medical patients at Kenyatta National Hospital"** is the result of my original work and has not been submitted to any other University.

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DEDICATION

I dedicate this study to my loving husband Thanju and my dear daughters, Njeri and Wanjiru.

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My supervisors for invaluable guidance and wise counsel.

Professor Vardi Moshe for allowing me to use the study questionnaire..

My colleagues for their never-ending support in this journey we travel together.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

A/E	Accident and Emergency department
ACCP	American College of Chest Physicians
CT	Computed Topography
DVT	Deep Venous Thrombosis
ERC	Ethics and Research Committee
GCS	Graduated Compression Stockings
ICU	Intensive Care Unit
IPC	Intermittent Pneumatic Compression Devices
KAP	Knowledge Attitude and Practice
KNH	Kenyatta National Hospital
LDUH	Low Dose Unfractionated Heparin
LMWH	Low Molecular Weight Heparin
MOPC	Medical Outpatient Clinic
NYHA	New York Heart Association
PE	Pulmonary Embolism
PI	Principal Investigator
RAM	Risk Assessment Model
UFH	Unfractionated Heparin
UoN	University of Nairobi
VFP	Venous Foot Pumps
VTE	Venous thromboembolism

ABSTRACT

BACKGROUND

Venous thromboembolism (VTE) prophylaxis has been shown to be safe and effective. Underutilization of this intervention results in avoidable morbidity, readmissions, and mortality. The underutilization of VTE prophylaxis occurs despite there being evidence-based guidelines on VTE prophylaxis from various medical societies. Information on the prevalence of risk in the acute medical hospital care setting is scarce. The evaluation of VTE prophylaxis administration will aid in identifying possible gaps in administration of this life saving measure.

OBJECTIVE OF THE STUDY

The objective of this study was to determine the level of risk for VTE and prescription of thromboprophylaxis in medical in-patients and assess the knowledge and practice of senior house officers' (SHO) in the Department of Clinical Medicine and Therapeutics at Kenyatta National Hospital in regard to VTE prophylaxis.

STUDY DESIGN

Cross sectional descriptive study

PARTICIPANTS AND STUDY SITE

Eligible newly admitted medical in-patients on their third post admission day at Kenyatta National Hospital, a tertiary referral hospital, and SHOs in the Department of Clinical Medicine and Therapeutics in the University of Nairobi.

METHODS

Four hundred eligible study patients were selected using a random number generator. They were scored using the Padua Prediction Score and classified as low or high risk. Their medical files were reviewed for thromboprophylaxis prescription. Consenting senior house officers in the Department of Clinical Medicine and Therapeutics in the University of Nairobi training at the Kenyatta National Hospital were invited to fill a validated questionnaire on VTE prophylaxis.

DATA MANAGEMENT

The data was analyzed using SPSS version 21.0. Descriptive statistics were used to present the results.

RESULTS

Two hundred and sixty eight (67%) out of 400 were found to be in the high-risk category of VTE. Ninety-eight (36.6%) out of 268 had no prescription of VTE prophylaxis. Seventy-eight (19.5%) out of 400 had increased risk for bleeding. Most [164 (71.9%)] were offered unfractionated heparin while 64 (28.1%) were offered enoxaparin with correct prescription in 54 of those patients. Eleven (16.9%) of the residents were unaware of the ACCP 2012 guidelines for VTE prophylaxis. Sixty percent had either never had formal updates or had updates more than a year ago while eleven (16.9%) had not undertaken self-directed updates. In addition, while most (83.2%) felt that a patient who is entitled to VTE prophylaxis should receive it, 81.5%felt that VTE risk assessment was not incorporated into the work flow and 92.3% felt that they were left to make the decision on their own. The preferred agent for VTE prophylaxis was LMWH by 89.2%. This was however not observed in their prescriptions.

CONCLUSION

A majority of medical patients were at high risk for VTE with only slightly more than half receiving the appropriate action. The residents faced challenges in VTE prophylaxis prescription such as the lack of both VTE risk assessment models, guideline implementation into the workflow of patient care and updates on the existing international guidelines.

Key words: Venous thromboembolism, acutely ill medical patients, thromboprophylaxis

1.0 INTRODUCTION AND LITERATURE REVIEW

Venous thromboembolism (VTE) is a frequent complication in hospitalized patients and is a direct cause of potentially avoidable morbidity, mortality and high cost of medical care. Medical patients account for about 60% of hospital admissions worldwide and it is estimated that 50-70% of symptomatic thromboembolic events and 70% of fatal emboli occur in patients hospitalized for medical rather than surgical conditions [1-4]. Furthermore, recent hospitalization for medical illnesses accounts for almost one quarter of all VTE events diagnosed in the community [2].

The clinical and economic impact of thromboprophylaxis has also been established. In a retrospective study by Baser and colleagues [5] in which they assessed administrative claims in medical inpatients in regard to VTE prophylaxis. They found that there was significant reduction of the incidence of VTE in those receiving VTE prophylaxis compared with those not on VTE prophylaxis at 0.06% versus 3.44% respectively. VTE prophylaxis also significantly reduced the incidence of VTE in the 180 days post discharge. In the group not receiving thromboprophylaxis, there was increased hospital stay, readmission due to the development of VTE, and loss of man-hours, thereby, demonstrating the economic and clinical impact of not administering VTE prophylaxis to patients at high risk for VTE.

Whereas the risk factors for VTE have been long established and safe, efficacious, and cost effective interventions discovered, this life saving measure remains underutilized in medical patients [6,7]. There are guidelines that can be used by clinicians in the decision-making process as to which patients require VTE prophylaxis. The American College of Chest Physicians (ACCP) regularly publishes updated evidence-based guidelines on VTE prophylaxis. The ACCP recommendations are comparable to European guidelines [8, 9], and in addition offer guidance on a risk assessment model that would aid the clinicians on determining the level of risk for VTE in patients under their care. Despite the presence of these guidelines, various studies have shown that VTE prophylaxis remains underutilized in medical patients with acute medical illness [10].Researchers have used the ACCP guidelines to assess the practice on VTE prophylaxis around the globe and have demonstrated the underutilization of VTE prophylaxis. One such study is the Epidemiologic International Day for the Evaluation of Patients at Risk for VTE in the Acute Hospital Care Setting (ENDORSE) study [11]. The ENDORSE study is a cross-sectional survey that assessed the

adherence to the guidelines across 32 countries in 5 continents. The study showed considerable variation among countries in regard to adherence to 2004 American College of Chest Physicians (ACCP) guidelines on VTE prophylaxis. Appropriate VTE prophylaxis was offered at ranges of 3% to 70% in medical patients. In addition, Anderson and Spencer demonstrated that about half of the patients who presented to the outpatient departments and were diagnosed to have VTE had recently been admitted to hospital and had not been offered VTE prophylaxis[12]. Underutilization of VTE is further discussed below.

1.1 RISK FACTORS AND RISK ASSESSMENT MODELS

In 1884, Rudolph Virchow proposed that thrombosis was the result of at least 1 of 3 underlying etiological factors, which are vascular endothelial damage, stasis of blood, and hypercoagulable blood. The risk factors for VTE have been further explored in recent studies and have led to better understanding of them [13, 14]. In a patient with an acute medical condition, any of these may exist in solitude or in combination.

Risk factors for VTE in hospitalized medical patients are both intrinsic and extrinsic. Intrinsic factors include increasing age (especially more than70 years), previous VTE, known thrombophilia, and various comorbid illnesses, such as cancer, heart failure, or respiratory failure. Extrinsic factors include immobilization for three days or more and hormonal medications (Table 1) [2,15]. These risk factors often exist in various matrixes in medical inpatients, the combinations of which confer increased risk for VTE.

Determination of composite risk for VTE has been a significant challenge in adherence to thromboprophylaxis guidelines. Complex scoring systems have been criticized for discouraging the practitioner from applying them, more so, in a busy inpatient unit with a high number of patients. Only recently has there been a move to develop risk assessment methods (RAMs) that take into consideration medical patients thereby allowing for timely risk stratification and thromboprophylaxis. RAMs by Kucher [16] and Khorana [17] were found to be selective for patients who are receiving chemotherapy. To address the paucity of RAMs for general medical patients, Barbar [18](Table 1) modified the RAMs from Kucher and Syropoulos [19]. Barbar et al [18] incorporated heart and respiratory failure, acute myocardial infarction or ischemic stroke, and acute infections and rheumatologic conditions into the score each carrying a score of 1 to the Kucher RAM. This risk assessment model is now known as the Padua prediction score (Table 1). Patients who had a score of less than 4

had a 0.3% chance of developing VTE in 90 days while those with a score of 4 and more had an 11% risk of developing VTE in 90 days. The Padua prediction score is the recommended tool for determination of VTE risk in medical in patients in the ACCP 2012 guidelines [2].

Table 1. Padua Prediction score for the determination of risk for VTE in medical patients

Risk Factor	**Points**
Active cancer	3
Previous VTE (with the exclusion of superficial vein thrombosis)	3
Reduced mobility	3
Already known thrombophilia	3
Recent (≤1 month) trauma and /or surgery	2
Elderly age (equal to or more than 70 yrs.)	1
Heart and or respiratory failure	1
Acute myocardial infarction or ischemic Stroke	1
Acute infection and or rheumatologic disorder	1
Obesity (BMI≥30)	1
Ongoing hormonal treatment	1

The main limitation of the Padua prediction score is that it does not take into account the risk of bleeding prior to prescribing VTE prophylaxis. Bleeding risk is an important factor to consider when prescribing VTE prophylaxis as it allows for total evaluation of a patient who has presented with bleeding or has an inherent risk of bleeding. It would be detrimental to a patient's well-being if VTE prophylaxis is administered to such a patient despite them being categorized as high-risk for VTE on the Padua prediction score. In a large observational study conducted by Decousus et al., they were able to delineate the conditions that are considered as factors that would increase the risk of bleeding. The considered independent risk factors for bleeding were as shown in table 2. Indeed, in this study, these risk factors for bleeding and risk factors for VTE were considered in patient selection for VTE prophylaxis [19, 20]. The consideration of these risk factors protected the patients who were given VTE prophylaxis from major bleed. The tabulated risk factors for bleeding are among the factors that are recommended in the evaluation of patients for VTE prophylaxis in the ACCP 2012

guidelines on VTE prophylaxis. These risk factors for bleeding include an active gastroduodenal ulcer, bleeding in 3 months before admission, and platelet count less than 50 x 10^9/L all which have a significant odds ratio of 3 or more. Other risk factors for bleeding are as shown in Table 2 below [2].

Table 2. Independent Risk Factors for Bleeding in Hospitalized Medical Patients [2.18]

Risk Factor	**Total Patients No. (%) (N= 10,866)**	**OR (95% CI)**
Active gastroduodenal ulcer	236 (2.2)	4.15 (2.21-7.77)
Bleeding in 3 months before admission	231 (2.2)	3.64 (2.21-5.99)
Platelet count less than 50 x 10^9/L	179 (1.7)	3.37 (1.84-6.18)
Age equal to or more than 85 yrs. (versus less than 40 years)	1,178 (10.8)	2.96 (1.43-6.15)
Hepatic failure (INR more than 1.5)	219 (2.0)	2.18 (1.10-4.33)
Severe renal failure (GFR less than 30 mL/min/m^2)	1,084 (11.0)	2.14 (1.44-3.20)
ICU or CCU admission	923 (8.5)	2.10 (1.42-3.10)
Central Venous Catheter	820 (7.50)	1.85 (1.18-2.90)
Rheumatic disease	740 (6.8)	1.78 (1.09-289)
Current cancer	1,166 (10.7)	1.78 (1.20-2.63)
Male sex	5,367 (49.4)	1.48 (1.10-1.99)

1.2 METHODS OF THROMBOPROPHYLAXIS

Thromboprophylaxis is either pharmacologic or mechanical. The choice of the method used is dependent on patient characteristics in terms of risk for VTE and risk of bleeding.

1.2.1 PHARMACOLOGIC PROPHYLAXIS

The role of antithrombotic therapy in the prevention of VTE has been well established in admitted patients. The MEDENOX trial [21] assessed for the effective dose of LMWH in acutely ill medical inpatients. Recruited patients were offered placebo, enoxaparin at a dosage of 20 mg and 40 mg, all given once daily subcutaneously. They demonstrated that enoxaparin at 40mg was effective and is the correct dose in preventing VTE with no statistically significant increase in the risk of bleeding. Further, enoxaparin has been associated with fewer deaths, less bleeding and significantly fewer adverse events in comparison to unfractionated heparin [22, 23]. Researchers have also observed that low-molecular-weight heparin reduced rates of pulmonary embolism and symptomatic pulmonary embolism compared to unfractionated heparin[24-6]. Fondaparinux, a selective factor Xa inhibitors (pentasaccharides) and dalteparin have also been evaluated for their role in VTE prophylaxis. The ARTEMIS trial [25] which evaluated fondaparinux, and the PREVENT trial [26] which evaluated dalteparin found that they to conferred a significant reduction of VTE risk when compared to placebo. The ACCP 2012 guidelines have incorporated fondaparinux in the primary prevention of VTE. The choice of drug should be based on underlying medical conditions such as chronic kidney disease, patient preference, ease of administration and compliance (for example, daily versus twice daily versus thrice daily dosing), as well as on local factors affecting acquisition costs [2].

1.2.1.1 BLEEDING RISK IN VTE PROPHYALXIS

The risk of bleeding must be determined before offering VTE prophylaxis. Conditions that confer an increased risk of bleeding include congenital or acquired bleeding disorders, hemorrhagic strokes, thrombocytopenia (less than 50 x 10^9/L), bacterial endocarditis, active gastroduodenal ulcer or gastrointestinal bleed, or hepatic failure among others [20].

As there is no validated tool for the prediction of risk of bleeding, the ACCP 2012 panel considered patients to have an excessive risk of bleeding if they had multiple risk factors or had one of three risk factors with the strongest association with bleeding (OR.3.0): active gastroduodenal ulcer, bleeding in 3 months before admission, and platelet count less than 50 x 10^9/L [2, 20]. Patients at risk for VTE and have significant risk for major bleed should be offered mechanical prophylaxis.

1.2.2 MECHANICAL PROPHYLAXIS

Mechanical prophylaxis is done by the use of graduated compression stockings (GCS), intermittent pneumatic compression devices (IPCs), and venous foot pumps (VFPs) [27, 28]. However in a recent study, only IPCs were found to confer statistically significant mechanical VTE prophylaxis [29]. IPCs are therefore the recommended method for mechanical VTE prophylaxis.

1.3 GUIDELINES

Various medical societies have developed guidelines on VTE prophylaxis and encourage countries and institutions to develop their own guidelines on VTE prophylaxis in tandem with evidence provided by the research community [2,30]. The Ministries of Medical Services and Public Health and Sanitation of the Government of Kenya released a document entitled "Clinical Guidelines for Management and Referral of Common Conditions at Levels 4–6 Hospitals" [31]. This document gives dismal description of the possible risk factors associated with VTE. It does not address the risk of bleeding or define mechanical prophylaxis as a plausible method for preventing VTE.

1.4 PRACTICE OF VTE PROPHYLAXIS

Several studies have assessed the utilization of American College of Chest Physicians ACCP guidelines on VTE prophylaxis. In the DVT-Free registry 5451 patients with ultrasound-confirmed DVT, including 2892 women and 2559 men, from 183 United States (US) centers were enrolled in prospective registry. Of the 2726 patients who had DVT diagnosed while in the hospital, only 1147 (42%) had received VTE prophylaxis within 30 days before diagnosis [32].

The CURVE study conducted in Canada assessed VTE prophylaxis as per the recommendations of the sixth ACCP consensus guidelines for VTE prophylaxis. The CURVE study was a national multicenter [1] that assessed the medical records of patients in 20 teaching and 8 community hospitals. Of the 4124 medical admissions screened over the study period, 1894 patients (46%) were eligible for study inclusion. The median age of this cohort was 70 years. Forty-one percent of patients were bedridden for more than 24 hours and 31% had one or more identified risk factors for VTE. Overall, some form of thromboprophylaxis was administered only to 23% of all patients and to 37% of patients who were bedridden for more than 24 hours. However, appropriate prophylaxis was given to

only 16% of the patients. Similar findings were also reported in the IMPROVE study in which 15,156 high-risk medically ill patients with a median age of 71 years and a median length of hospital stay of 8 days were enrolled at 52 hospitals. In the IMPROVE study less than 60% of the patients received appropriate VTE prophylaxis [33].

The Assessment for VTE Management in Hospitals in the Middle East (AVAIL ME) study was the first comprehensive evaluation of VTE prophylaxis in the Middle East region. It was conducted to evaluate the status of anticoagulation practices in the Middle East and to serve as a source of baseline data for the region. The study included countries from the Middle East and Central Asia [34]. It showed consistently lower rates of adherence to the guidelines in the Middle East region compared to global figures, thereby confirming the findings of the ENDORSE study (Table 4). Moreover, the study clearly demonstrated the inappropriate utilization of VTE prophylaxis in the Middle East in patients with contraindications, further emphasizing the divergence from the guidelines. Of the 2,266 patients in the study, 82.9% were eligible for prophylaxis according to the guidelines. About 51.2% obtained some form of VTE prophylaxis, but only 37.8% according to the ACCP recommendations on VTE prophylaxis. Of the patients evaluated, 50.1% of eligible patients received drug prophylaxis (90.2% low molecular weight heparin, 10.7% unfractionated heparin, 1.5% vitamin K antagonists, and 0.1% fondaparinux. Mechanical prophylaxis was offered to 16.4% of the patients [34].

Many reasons have been cited to explain this consistent underutilization of VTE prophylaxis. Lack of physician awareness on published VTE prophylaxis guidelines and the underestimation of the risks in this group of patients continue to be important barriers. In addition, decisions on how and when to start VTE prophylaxis are easier to make in surgical patients and are often delayed or forgotten in the medical inpatients population as was reflected in the ENDORSE study (table 4)[7]. The previous lack of a validated VTE risk assessment model able to group medical patients into different risk categories was probably the most important barrier, one that has been addressed by the Padua prediction score.

Table 3. Summary of studies done to assess adherence to guidelines in medical and patients across regions

Study/yr.	Location	Study Design	N (n at risk of VTE)	% at risk	N(%) not on prophylaxis and were at risk
Goubran 2012 ENDORSE study	Egypt Arm	Cross Sectional Multicenter 11	530(168)	31	55(32.7)
Pinjala et al 2012 ENDORSE study	Indian arm	Cross sectional Multicenter 10	948(424)	44.7	99(23.3)
Sharif – Kashani 2012 MASIH Study	Iran	Cross sectional	481(221)	45.9	139(62.9)
Taher et al. 2011 AVAIL ME study	Middle East	Cross sectional	845(838)	99.1	401(47.8)
Languasco et al 2011 M	Argentina	Cross sectional	584 (310)	53	256(82.6)
Ge et al 2010 RAMP study	China	Multicenter Cross sectional Observational	1247(1232)	98.7	250(20)
Cohen et al 2008 ENDORSE study	Multinational 32 Americas, Asia, North Africa, Australia	Cross sectional	37,356 (7,844-26,522)	20 - 70	1,120 – 26,522 (3-71)
Khan et al. 2007 CURVE study M	Canada – 3 wks.	Cross sectional	1,894 (1,363)	71.9	329(24.2)

Table 4. Adherence to guidelines in medical and surgical patients across regions evaluated by the ENDORSE study.

Region	Medical	Surgical
America	49%	63%
Asia	12%	7%
Europe	41%	67%
Middle East	38%	39%
North Africa	28%	71%
Oceania	42%	72%

1.5 KNOWLEDGE AND ATTITUDE

Knowledge and attitude on VTE prophylaxis are important aspects in the evaluation and perception of VTE risk by the clinician. Two studies have been conducted to determine the knowledge, attitude, and practice (KAP) of VTE prophylaxis of internists both residents in-training and qualified. In a multinational survey of internists in Europe [35] the researchers used a validated questionnaire (Appendix E) and included 226 physicians from 30 countries. The researchers utilized clinical vignettes, awareness, adherence, practice, and belief to assess KAP of VTE prophylaxis. Seventy nine percent of the physicians were aware of international clinical guidelines to prevent VTE. Most considered their knowledge of the guidelines to be moderate. Many had not updated their knowledge recently. The magnitude of the clinical problem was over- and under- estimated by many (12.2% and 40.1%, respectively). Only 46.7% thought their patients were receiving appropriate VTE prophylaxis. Risk of bleeding, lack of awareness and lack of decision support systems were the three most common reasons for deferring treatment (88.6%, 32.3% and 27.9%, respectively). Most of the participants stated that they strongly believed in VTE prophylaxis as an intervention that prevents morbidity and mortality.

In a study conducted in the Philippines [36] that used the same validated questionnaire, Mendoza et al found that 58 respondents, 72% were aware of the clinical guidelines to prevent VTE. Most considered their knowledge of the guidelines as moderate. Majority (67%) believed that every patient should be entitled in a VTE prophylaxis regimen unless contraindications exist. However, 48 (83%) recognized that the institution had no formal VTE prophylaxis protocol. Risk of bleeding and cost of intervention were the most common cause of treatment deferral. Low molecular weight heparin was the most preferred drug

regimen. Physicians tended to overlook borderline cases with two or three risk factors.

These studies therefore indicate that while the physicians believe that VTE prophylaxis is an important preventive measure, there was a gap in knowledge and practice providing guidance on areas where interventions may be made.

2.0 STUDY JUSTIFICATION

Venous thromboembolism is a frequent and important cause of morbidity and mortality that has an economic impact on the health care system and patients. It is readily preventable and international evidence-based guidelines on VTE prophylaxis are available and accessible. It is important to know the level of VTE risk in medical in-patients and whether appropriate VTE prophylaxis is appropriately prescribed. The information derived from this study was aimed at providing important information on VTE prophylaxis in medical inpatients. The information derived from this study would be used to generate solutions to deficiencies found.

3.0 RESEARCH QUESTION

What is the current practice of VTE prophylaxis in recently admitted medical in-patients at Kenyatta National Hospital?

4.0 OBJECTIVES

4.1 BROAD OBJECTIVE

To document VTE risk and current practice of VTE prophylaxis in the medical wards at Kenyatta National Hospital.

4.2 SPECIFIC OBJECTIVES

1. To determine the VTE risk level in newly admitted medical patients using the Padua Prediction Score.
2. To determine the proportion of patients being offered VTE prophylaxis according to the ACCP 2012 guidelines on VTE prophylaxis.
3. To document the type and dosages of prophylaxis used.
4. To determine the knowledge, attitude and practice of senior house officers in the Department of Clinical Medicine and Therapeutics in regard to VTE prophylaxis.

5.0 METHODOLOGY

5.1 STUDY DESIGN AND SITE

This was a cross-sectional descriptive study in the medical wards at the Kenyatta National Hospital (a tertiary referral and teaching hospital). The Kenyatta National Hospital has a total bed capacity of 2,000 beds, of which 196 are in the 8 medical wards. The medical wards admit an average of 28 patients per day from the specialist clinics, medical outpatient clinics (MOPC) and Accident and Emergency (A/E) units.

5.2 CASE DEFINITIONS AND SELECTION CRITERIA

5.2.1 CASE DEFINITION

Patients considered for enrollment into the study were those on their third post admission day.

5.2.2 INCLUSION CRITERIA

Patients of 18 years or more who gave written and informed consent were included.

5.2.3 EXCLUSION CRITERIA

Patients who had a diagnosis requiring antithrombotic therapy were excluded.

5.2.4 CRITERIA APPLICABLE TO PHYSICIANS-IN-TRAINING

Senior house officers in the Department of Clinical Medicine and Therapeutics in the University of Nairobi, hereafter referred to as "the department", were included. SHOs were the prescribers of VTE prophylaxis in the study subjects.

5.3 SAMPLE SIZE CALCULATIONS AND SAMPLING PROCEDURES

The following were the determinants of sample size.

5.3.1 SAMPLE SIZE DETERMINATION OF THE PATIENTS

Adequacy of VTE prophylaxis has been estimated at **47.8%** as determined by Taher et al. Forty seven point eight percent was used to determine the sample size. The Daniel WW et al. formula was used and **383 participants** at a precision of 5% and a confidence interval of 95% were required to assess the level of VTE risk and practice of VTE prophylaxis.

$$n = \frac{Z^2\,PQ}{d^2}$$

$$\frac{1.96 \times 1.96 \times 0.478\,(1 - 0.478)}{0.05 \times 0.05} = \mathbf{383}$$

n – Sample size with infinite population correction

Z – Z statistic for a level of confidence of **95%**

P – expected population with adequate prophylaxis for VTE at **47.8%**

Q – 1-P

d – precision of **5%**

Patients were randomly selected using a random number generator.

5.3.2 SAMPLE SIZE DETERMINATION OF THE SENIOR HOUSE OFFICERS

There were, at the time of this study,**78** enrolled SHOs. Vardi and colleagues indicated that the respondents underestimated VTE as a clinical problem by **40.1%**.Using the Daniel WW et al formula and with a finite population of 78, at a precision of 7% and a confidence interval of 95%, **56** senior house officers were the minimum number required. Consecutive sampling was used.

$$n = \frac{Z^2\,PQ}{d^2}$$

$$\frac{1.96 \times 1.96 \times 0.401\,(1 - 0.401)}{0.07 \times 0.07} = \mathbf{56}$$

n – Sample size with finite population correction

Z – Z statistic for a level of confidence of **95%**

P – expected population with adequate prophylaxis for VTE at **40.1%**

Q – 1-P

d – precision of **7%**

5.4 CLINICAL METHODS

5.4.1.PATIENTS' VTE RISK AND PRESCRIPTION OF VTE PROPHYLAXIS

Eligible patients on the third post admission day were randomly selected using a random number generator until a daily target of 10 patients per day was achieved. Once the patients were identified, they were informed of the study purpose, harm and benefits, and consent was sought. Where the patient was incapacitated, consent was sought from the next of kin. These patients were then assessed for risk of VTE by use of the Padua Prediction Score and the risk of bleeding as specified in the ACCP 2012 guidelines. The following information was documented; prescription of VTE prophylaxis, the type and dose of drug used, and the contraindications to pharmacologic VTE prophylaxis.

Height and weight were determined using a standard platform scale. Correct weighing procedures such as the use of minimal clothing (hospital gown) and no shoes were adhered to. Height was reported in meters to one decimal points precision and weight was reported in kilograms to one decimal point precision. For those who had difficulty in standing, their heights were determined by use of a tape measure. Daily determination of accuracy of the weighing scale was done. Finally the BMI was determined using the standard formula of weight in kilograms divided by height in meters squared. BMI calculated was rounded off to one decimal place.

Determination of whether mechanical VTE prophylaxis was offered, as an alternative, was done by physical examination of the patients. Data derived from the evaluation of patients and their medical records was filled in a study proforma (Appendix C).

5.4.2 DETERMINATION OF KNOWLEDGE ATTITUDE AND PRACTICE OF VTE PROPHYLAXIS BY SENIOR HOUSE OFFICERS IN THE DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS-UON

Determination of knowledge, attitude, and practice of the senior house officer (SHOs)in regard to VTE was carried out after clinical data collection had been completed. SHOs in the department were invited to participate in the study. Residents were invited to fill the study questionnaire (Appendix E). There were five sections in the questionnaire, which were clinical vignettes, awareness, adherence, practice and belief. Clinical vignettes and the practice section were aimed at assessing if the SHOs could correctly identify the risk factors

for VTE. The awareness section of the questionnaire assessed the SHOs knowledge of the presence of guidelines, grading of knowledge, and how frequently they get updates on VTE. The adherence section was aimed at identifying barriers to guideline implementation by assessing the SHOs perception of the work environment. The last section on belief aimed at identifying the level of importance the SHOs place on VTE prophylaxis. Correct responses were determined by the information in the 2012 ACCP guidelines. Confidentiality was observed at all times.

6.0 STUDY DATA VARIABLES

Age was described using the appropriate measure of central tendency after evaluating the distribution in the two groups. Gender, level of risk and appropriateness of VTE prophylaxis prescription was described in terms of proportions. Duration of reduced mobility was in number of days and defined as being in bed for most of the day with limited movement allowing the performance of basic life functions such as going to the bathroom. Appropriate VTE prophylaxis in both risk categories refers to the correct application of VTE prophylaxis according to the ACCP 2012 guidelines. Knowledge, attitude, and practice questionnaire on VTE Prophylaxis was described in detail for each component of the questionnaire using proportions. These areas were clinical vignettes, awareness, adherence, practice, and belief.

7.0 DATA MANAGEMENT

7.1 DATA COLLECTION

The Principal investigator and two trained research assistants, who were clinical officers with experience in working in medical wards, collected the data. The principal investigator trained the research assistants over a three-day duration. They were trained on how to select eligible patients in the ward in reference to their day post admission, process of selection and sampling in reference to study exclusion criteria, study explanation and seeking of consent.

In addition, they were trained on how to take a history of relevant risk factors for VTE, examine the patients and determine the height, and weight. Further to that, they were trained on how to extract relevant data from the patients' records including platelet counts, prescription of VTE prophylaxis in the treatment sheets among other relevant data .The data

was stored in a secure location (offsite) and was only be accessible to the principal investigator.

7.2 DATA ANALYSIS

Data was collected and kept in a safe area by the PI. It was verified for completeness and fed into Excel 2010 database. It was analyzed using the Statistical Package for Social Sciences (SPSS) software version 21.0. Demographic and clinical characteristics of the study sample were summarized using means (standard deviations) or medians (inter-quartile range) for continuous variables and number (percent) for categorical variables. Padua prediction score was categorized into two dichotomous variables which are, less than 4 (low risk) and equal to or greater than 4 (high risk). Dosages of VTE prophylaxis were categorized into the appropriate and inappropriate doses as per the ACCP 2012 guidelines. Level-of-risk for VTE prophylaxis, type and dosages of VTE prophylaxis were presented as proportions with 95% confidence intervals. Types and dosages of VTE prophylaxis used were assessed in totality, regardless of appropriateness of action taken. Results were presented as numbers and percentages in tables and charts. In relation to the knowledge, attitude and practice (KAP) data, descriptive analysis was used to summarize the characteristics of SHOs. Age was reported in means. The data was analyzed using SPSS version 21 frequencies and proportions. Bar charts were used to display these data.

8.0 ETHICAL CONSIDERATIONS

Approval was sought from the department of clinical medicine and therapeutics in the University of Nairobi and the ethics and research committee (ERC) KNH/ UoN. The study was conducted within the stipulated period from the date of approval. Informed consent was sought from study participants. Personal unique study numbers were assigned and the information obtained was strict and confidential. Participants were allowed to opt-out from the study without prejudice. The SHOs were informed of the level-of-risk and the need to prescribe VTE prophylaxis where it had not been done.

The results of this study will be disseminated. Copies of this dissertation will be made available to the primary health care providers, the department, KNH research department and the ERC.

9.0 RESULTS

9.1 STUDY POPULATION

Patient's characteristics and reasons for hospitalization

Six hundred and twelve patients were admitted into the medical wards during the months of April to May 2014. Out of these, 400 were eligible and included (figure 1).

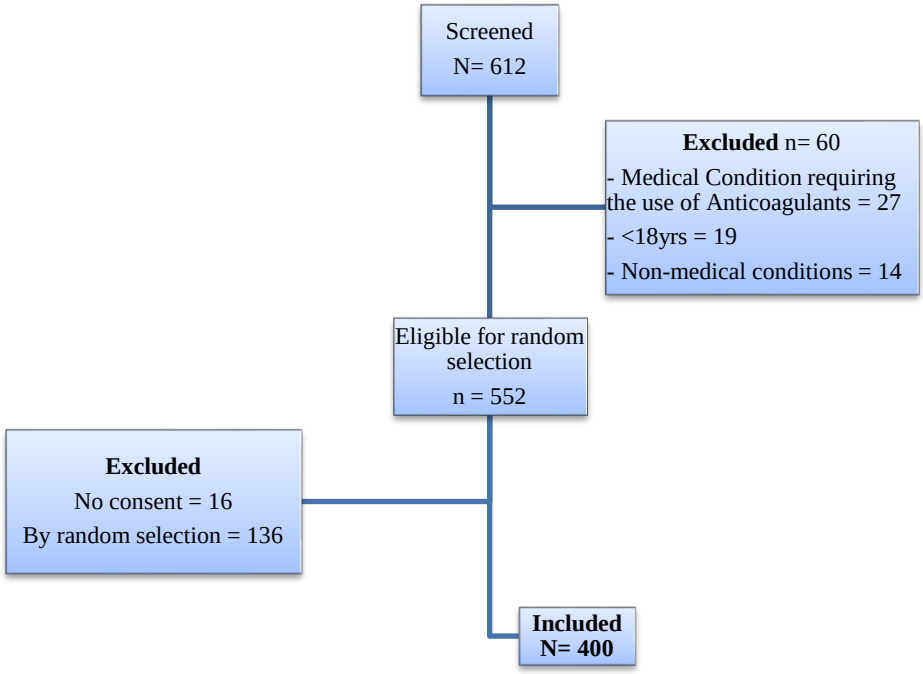

Figure 1: Patients' Recruitment Flow Chart

The mean age was 42 years (SD18), ranging from 18 - 89 years, with 50.5% aged between 30 and 49 years (figure 2). The mean BMI was 23.3 (SD 3.9) ranging from 11.9 to 34.0 with 22 (5.5%) having a BMI of more than 30.There were 202 (50.5%) females.

Fifty three (13.25%) patients were admitted with a diagnosis of congestive heart failure, followed by chronic kidney disease and tuberculosis at 9.5%, and infectious disease at 28.75 %. Other diagnoses are as shown in table 5. Comorbidities were human immunodeficiency viral infection at 22.25%, hypertension at 14.73% and diabetes mellitus at 11.75%. Other comorbidities are as shown in table 6. The patients' principal diagnosis was further sub classified as shown in table 7.

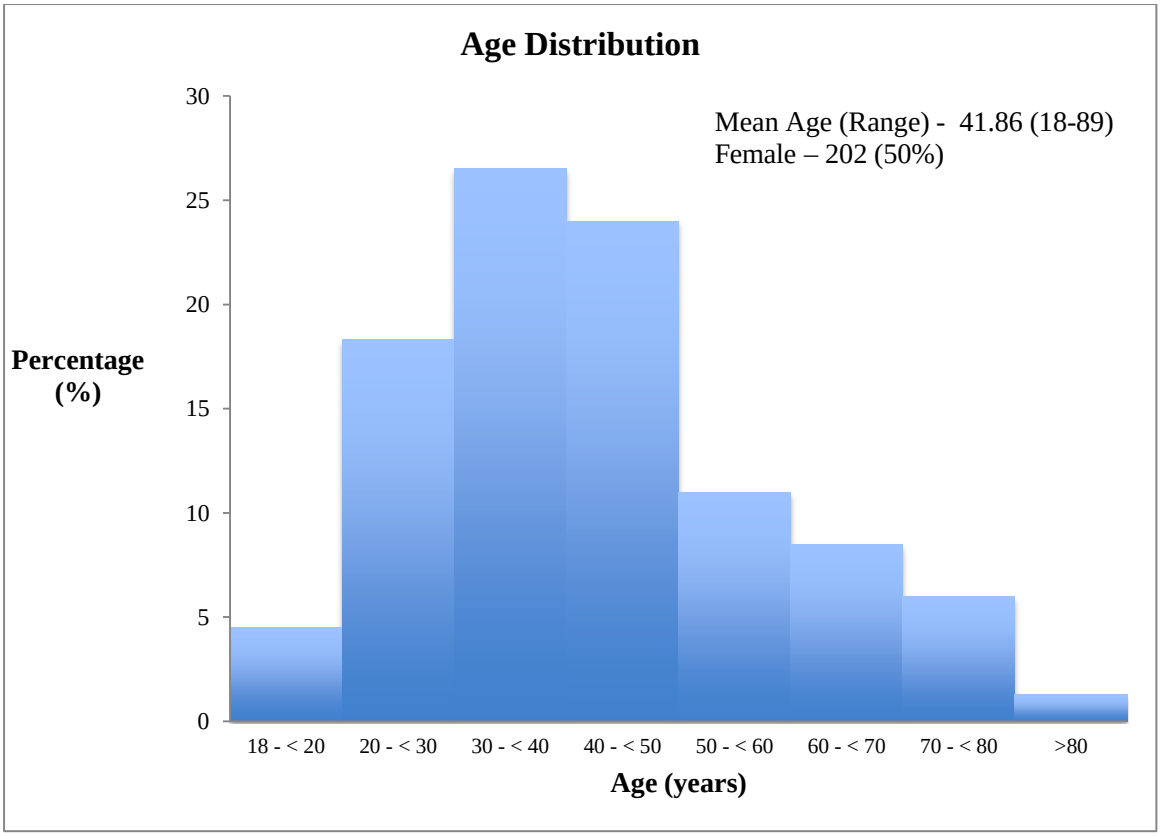

Figure 2: Age Distribution in the Study Sample

Table 5: Principal Diagnosis among Recruited Patients

Diagnosis N = 400	**n**	**%**
Congestive Heart Failure	53	13.25
Chronic Kidney Disease	38	9.5
Tuberculosis - Pulmonary	38	9.5
Stroke Ischemic	22	5.5
Meningitis	20	5
Meningoencephalitis	16	4
Upper Gastrointestinal Bleeding	15	3.75
Sepsis	12	3
Community Acquired Pneumonia	11	2.75
Hemorrhagic Stroke	9	1.75
Others	166	1.75

Table 6: Comorbidities among Recruited Patients

Comorbidities N = 235	**n**	**%**
Human Immunodeficiency Virus Infection	89	22.25
Hypertension	59	14.75
Diabetes Mellitus	47	11.75
Chronic Kidney Disease	11	2.75
Rheumatic Heart Disease	6	1.5
Chronic Liver Disease	5	1.25
Cancer of the Pancreas	3	0.75
Cancer of the Stomach	3	0.75
Liver Cirrhosis	2	0.5
Chronic Myeloid Leukemia	2	0.5
Gouty Arthritis	1	0.25
Alcohol Withdrawal	1	0.25
Multiple Myeloma	1	0.25
Gastrointestinal Stromal Tumor	1	0.25
Metastatic Cancer of Colon	1	0.25
Metastatic Cancer of the Lung	1	0.25
Metastatic Cancer of the Prostate	1	0.25
Metastatic Renal Cell Carcinoma	1	0.25

Table 7: Sub-classified Principal Diagnosis among Recruited Patients

Principal Diagnosis (N=400)	n	Percentage (%)
Infections		
Infections (Non-Respiratory)	66	16.5
Pulmonary Infections	49	12.25
Cardiovascular		
Acute Heart Failure	53	13.25
Other Cardiovascular Diseases	4	1
Neurologic		
Neurologic – (Non-Stroke, Non-Infectious)	31	7.75
Ischemic Stroke	22	5.5
Hemorrhagic Stroke	9	2.25
Renal (i.e. Acute Kidney Injury, End Stage Renal Disease)	52	13
Gastrointestinal/Hepatobiliary	42	10.5
Endocrine/Metabolic	11	2.75
Hemato-Oncologic		
Malignancy (Active)	33	8.25
Hematological	18	4.5
Other medical conditions		
Status Asthmaticus	1	0.25
Rheumatologic/ Inflammatory	4	1
Psychiatric (i.e. schizophrenia, suicide attempts)	5	1.25

9.2 THE LEVEL-OF-RISK FOR VTE IN NEWLY ADMITTED MEDICAL PATIENTS USING THE PADUA PREDICTION SCORE.

More than half of the patients 268 (67%) were at high risk for developing VTE. Figure 3 shows the distribution of total VTE risk score among study participants. Sixty seven percent had a score of 4 and above. The risk factor distribution within the various diagnoses is shown in table 8 below.

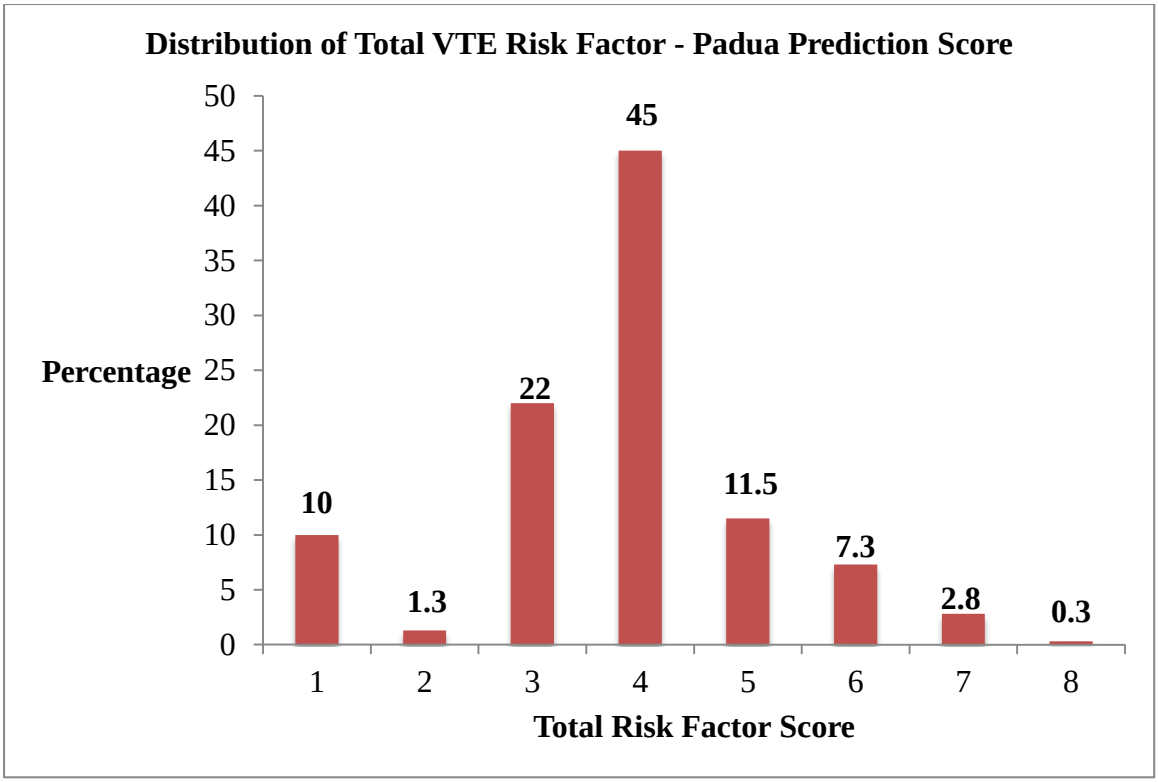

Figure 3: Distribution of Total VTE risk as determined using the Padua Prediction Score

Table 8: Distribution of VTE risk as determined using the Padua Prediction Score for VTE in the different Sub-classified Diagnosis

Principal Diagnosis	N=400	High Risk	Low Risk
		% (N = 268)	% (N = 132)
Infections (Non-Respiratory)	66	90.9	9.1
Acute Heart Failure	53	100	0
Renal	52	32.7	67.3
Pulmonary Infections	49	91.8	8.2
Gastrointestinal/Hepatobiliary	42	26.2	73.8
Malignancy (Active)	33	97	3
Neurological	31	35.5	64.5
Ischemic Stroke	22	100	0
Hematological	18	11.1	88.9
Endocrine/Metabolic	11	63.6	36.4

The most common risk factors for VTE as stratified in the Padua prediction score were reduced mobility observed in 361 (90.3%) of the patients and acute infection observed in 121 (32.8%) of the patients. Others are as shown in figure 4.

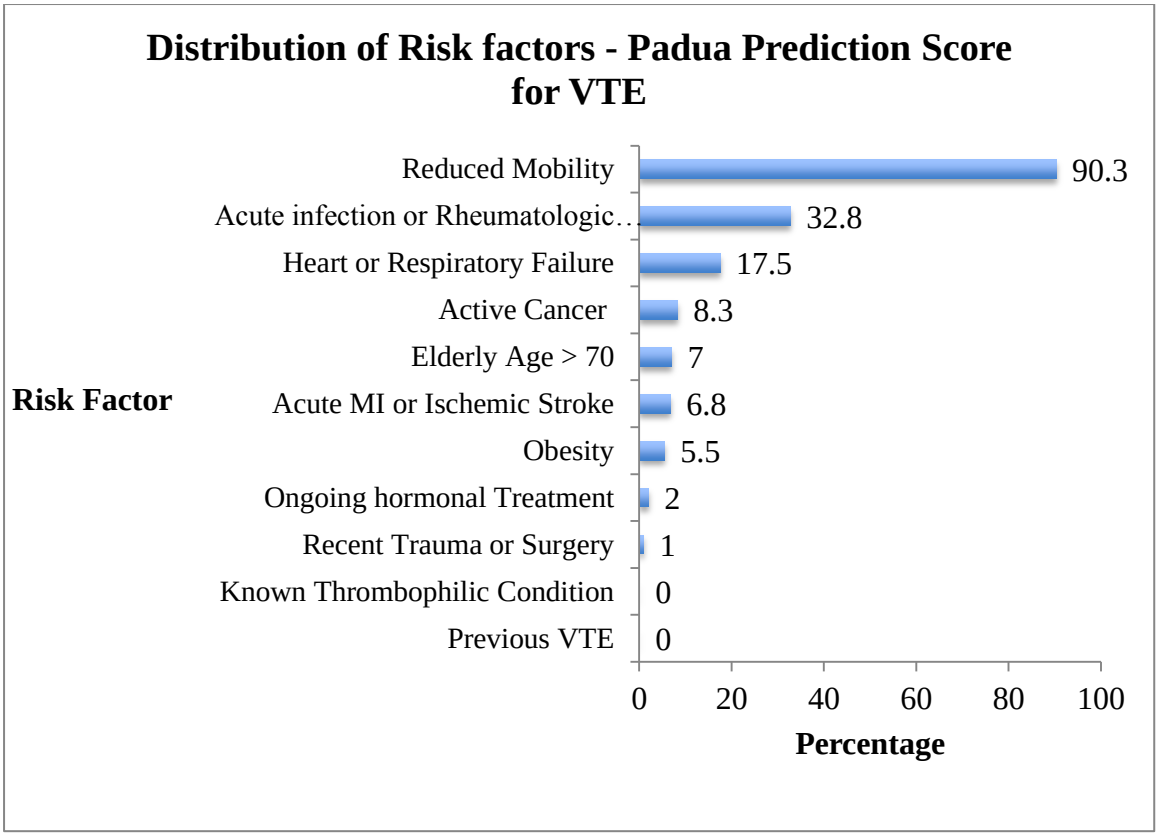

Figure 4: Distribution of Risk Factors for VTE – Padua Prediction Score

9.3BLEEDING RISK IN THE STUDY SAMPLE

Seventy-eight (19.5%) had contraindications to pharmacologic VTE prophylaxis. The most common contraindications to pharmacological prophylaxis were bleeding in the previous three months observed in 33 (8.3%) and thrombocytopenia observed in 22 (5.5%) of the study subjects (figure5). Twelve (4.5%) of those with high risk for VTE had contraindications to pharmacologic prophylaxis but were not offered mechanical prophylaxis. Thirty-eight (9.5%) had a GFR of less than 30 ml/min/1.73m^2. These are patients who have an increased risk of bleeding due to their medical condition as caused by bioaccumulation of the prophylactic VTE medication. In patients with a low estimated GFR, caution is needed in the choice of agent for VTE prophylaxis.

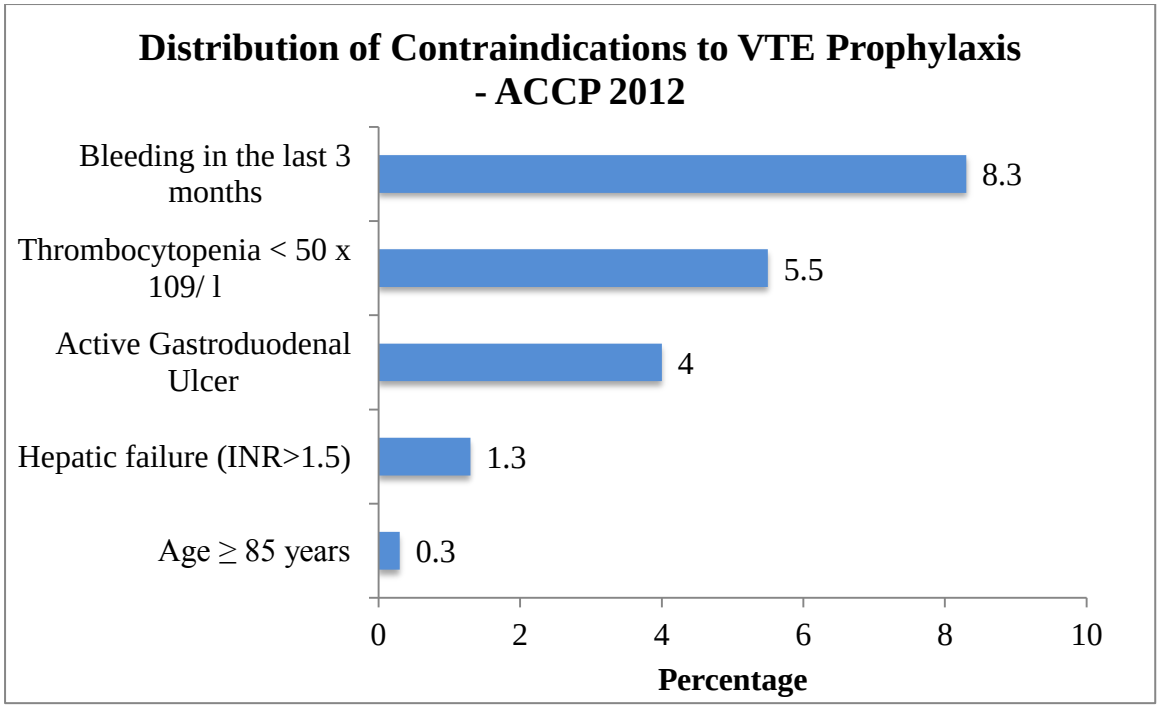

Figure 5: Distribution of Bleeding risk as Contraindications to VTE Prophylaxis – ACCP 2012

9.4 THE PROPORTION OF PATIENTS BEING OFFERED VTE PROPHYLAXIS ACCORDING TO THE ACCP 2012 GUIDELINES ON VTE PROPHYLAXIS.

VTE prophylaxis was appropriately prescribed or withheld in 244 (61%) out of 400 patients. VTE prophylaxis was wrongly offered to 58 (43.9%) out of 132 who were in the low risk category. There were 268 (67%) who were in the high-risk category. One hundred and seventy (63.4 %) out of 268 correctly received pharmacologic VTE prophylaxis, while 98 (36.6%) were not on any form of VTE prophylaxis (table 9).

Table 9: Level of Risk Versus Prescription of VTE Prophylaxis

VTE Prophylaxis	**High Risk** **n = 268**	**Low Risk** **n = 132**
Given	170 (63.4)	58 (43.9)
Not Given	98 (36.6)	74 (56.1)

The study revealed that the most appropriate action was predominantly taken on day zero with a peak at day 2. Appropriate prophylaxis was offered to 40% on day zero, 51.25% on day one, 58.5% on day two, and 60% on day three. While reasons for this escalation were not evaluated in this study, it may be that consultants or colleagues reminded the residents on the need for VTE prophylaxis in the post admission and major ward rounds.

Across the various principal diagnoses, the most appropriate action was taken in patients with acute heart failure at 79.2% and hemorrhagic cerebrovascular accidents at 77.8% (table 10).

Table 10: Appropriate Action in various diagnosis categories as Determined by ACCP 2012 Recommendations of the guidelines on VTE Prophylaxis

Principal Admission Diagnosis	**N=400**	**VTE Prophylaxis**	
		n (%)	
		Appropriate	**Inappropriate**
		n = 244 (61)	**n = 156 (39)**
Infections (Non-Respiratory)	66	62.1	37.9
Acute Heart Failure	53	79.2	20.8
Renal	52	36.5	63.5
Pulmonary Infections	49	61.2	38.8
Gastrointestinal/ Hepatobilliary	42	69	31
Malignancy (Active)	33	45.5	54.5
Neurologic	31	61.3	38.7
Ischemic Strokes	22	63.6	36.4
Hematologic	18	61.1	38.9
Endocrine/Metabolic	11	54.5	45.5
Hemorrhagic Stokes	9	77.8	22.2
Other Medical Conditions	5	40	60
Other Cardiovascular Diseases	4	50	50
Rheumatologic/Inflammatory	4	50	50
Acute Noninfectious Respiratory Diseases	1	100	0

9.5 THE TYPE AND DOSAGES OF VTE PROPHYLAXIS USED

Heparin, both unfractionated and low molecular, were the forms of prophylaxis used in 228 (57%) out of 400 patients, regardless of risk category (table 11). Unfractionated heparin was used in 164 (71.9%) out of 228 all at a dose of 5000IU given twice daily

subcutaneously. Enoxaparin was given to 64 (28.1%) out of 228 of those who were offered pharmacologic VTE prophylaxis. Thirty-eight of those with low GFR of less than 30 milliliters per minute per 1.73m^2, 3 (7.9%) were wrongly offered low molecular weight heparin while 35 (92.1%) were correctly offered unfractionated heparin. Mechanical prophylaxis was not used.

Table 11: Type and Dosage of VTE Prophylaxis used in Newly Admitted Medical Patients

TYPE OF PHARMACOLOGIC VTE PROPHYLAXIS	**NUMBER (%) N = 228 (57)**	**DOSAGE**	**NUMBER (%)**
Unfractionated Heparin (All given twice daily)	164 (71.9)	5000IU	164 (100)
Enoxaparin (All given once daily)	64 (28.1)	20mg	1 (1.6)
		40mg	54 (84.4)
		60mg	9 (14.1)

9. 6 THE KNOWLEDGE, ATTITUDE AND PRACTICE OF VTE PROPHYLAXIS OF SENIOR HOUSE OFFICERS IN THE DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS.

9.6.1 POPULATION DESCRIPTION

Data of KAP questionnaire from 65 (83.3%) out of 78 residents were analyzed (figure 6). The mean age was 31 years (SD 3; range 27 – 47). Twenty-eight (43.1%) were female. They were equally spread across the three categories of years of study; 21 (32.3%) in the first year; 20 (30.8%) in the second; and 24 (36.9%) in the third (table 12).

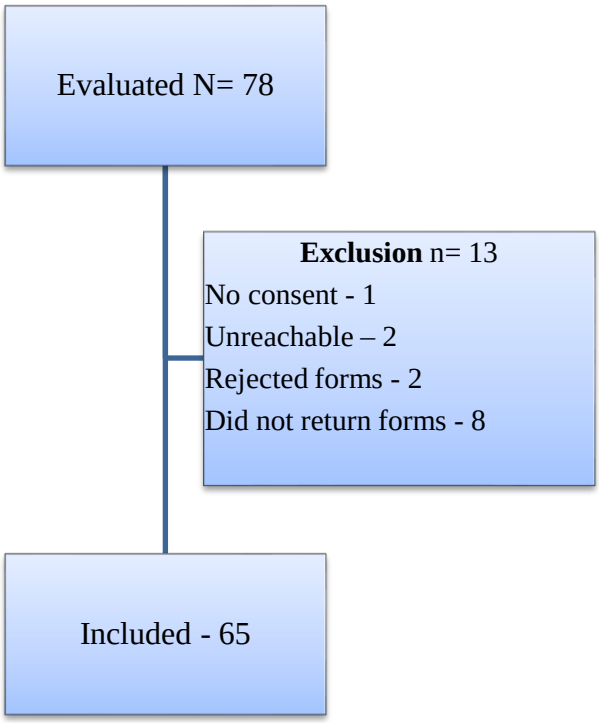

Figure 6: Residents' Recruitment Flow chart

Table 12: Recruited Residents' Characteristics

Residents (N=65)	**n (%)**
Female	28 (43.1)
Age (yrs.) – Mean (range)	31 (27-47)
Year of study	
First	21 (32.3)
Second	20 (30.8)
Third	24 (36.9)

9.6.2 AWARENESS OF GUIDELINES

Fifty-four (83.1%) out of 65 were aware that there were guidelines on VTE prophylaxis from various medical societies. Six felt that their knowledge on VTE prophylaxis was good, 43 (79.6%) rated their knowledge as moderate, while 5 felt that they had no knowledge in the subject matter. Two did not respond. Ten (15.4%) had updates on VTE prophylaxis less than 3 months prior, 16 (24.6%) had them between 3 and 12 months prior, and 16 (24.6%) had them over one-year ago. Majority, 23 (35.4%), had never had updates on the subject. Twenty one (32.3%) had self-directed updates on VTE prophylaxis

less than 3 months prior to the study, 22 (33.8%) between 3 and 12 months prior, and 10 (15.4%) over one-year prior. Eleven (16.9%) had never conducted self-directed updates (table 13). Only 17 (26.2%) correctly identified fever of unknown origin as the condition not included in the recommendations for VTE prophylaxis as referenced by the 2012 ACCP guidelines on VTE prophylaxis.

Table 13: Residents' Responses to Awareness of VTE Prophylaxis

AWARENESS OF VTE PROPHYLAXIS GUIDELINES AMONG RESIDENTS (N=65)	**N (%)**
Awareness of Formal Guidelines from Medical Societies on VTE Prophylaxis	
Yes	54 (83.1)
Self-Grading of Knowledge of these Guidelines on VTE Prophylaxis	
None	5 (7.7)
Moderate	52 (80)
Good	6 (9.2)
Formal Updates on these Guidelines	
Ever	42 (64.6)
Never	23 (35.4)
Self-directed Updates on VTE Prophylaxis Guidelines	
Ever	53 (81.5)
Never	12 (18.4)

9.6.3 ADHERENCE OF GUIDELINES

Fifty-four (83.3%) out of 65 felt that VTE prophylaxis was being prescribed to patients entitled to VTE thromboprophylaxis. However, 53 (81.5%) deemed that VTE was not incorporated into the workflow of patient care. Sixty 92.3% out of 65 felt that there lacked institutional guidance in decision making in regard to VTE prophylaxis. Sixty-two (95.4%) correctly noted the lack of departmental guidelines on VTE Prophylaxis in the hospital (table 14).

Table 14: Residents' Responses to Adherence to VTE Prophylaxis in the Medical Department

ADHERENCE TO VTE PROPHYLAXIS (N=65)	n (%)
Are there Departmental Guidelines on VTE Prophylaxis	
No	62 (95.4)
Patient entitlement to VTE prophylaxis where there are no contraindications	
Yes	54 (83.1)
No	10 (15.4)
VTE risk assessment incorporated into workflow	
No	53 (81.5)
Assessment, choice, and prescription: Residents' choice with no institutional guidance	
Yes	60 (92.3)

9.6.4 PRACTICE – TREATING, DEFERRING TREATMENT, AND TREATMENT PREFERENCES

Fifty-seven (87.6%) of the residents correctly selected to offer VTE prophylaxis where no contraindications existed. Majority, 58 (89.2%), preferred low molecular weight heparin as their choice of VTE prophylaxis agent, 3 (4.6%) preferred unfractionated heparin, and another 3 (4.6%) preferred fondaparinux. Reasons for deferment of treatment were risk of bleeding in 55 (84.6%), cost of intervention by 16 (24.6%), lack of proper awareness by 10 (15.4%), and lack of evidence based risk assessment tools by 21 (32.3%). Three (4.6%) thought that the guidelines on VTE prophylaxis were not fully evidence-based (figure 7).

Choices in regard to the agents that residents would have offered in a patient with a creatinine clearance of less than 30 milliliters per minute are as shown in table 15 below. The choice of agents for VTE prophylaxis in these patients is further discussed below. Five (7.7%) felt that a patient with a creatinine clearance of less than 30 milliliters per minute was a reason to defer treatment while 10 (15.4%) did not respond. In regard to patients with history of major bleed and had high risk of VTE, 49 (75.4%) out of 65 correctly preferred mechanical VTE prophylaxis. Other responses are as shown in table 15. In regard to patients with a history of minor bleed who were in high-risk category for VTE, 56 (86.2%) out of 65 would have correctly offered VTE prophylaxis. Eight (12.3%) would have wrongly deferred treatment.

Table 15: Residents' Responses to questions asked on the Practice of VTE Prophylaxis

PRACTICE OF VTE PROPHYLAXIS AMONG RESIDENTS N= 65	
Preferred treatment in patients with Creatinine Clearance of less than 30ml/min/1.73m^2	
LMWH	19 (29.2)
UFH	19 (29.2)
Fondaparinux	7 (10.8)
Preference in patients with history of major bleeding	
Defer Treatment	14 (21.5)
Fondaparinux	2 (3.1)
Mechanical Prophylaxis	49 (75.4)

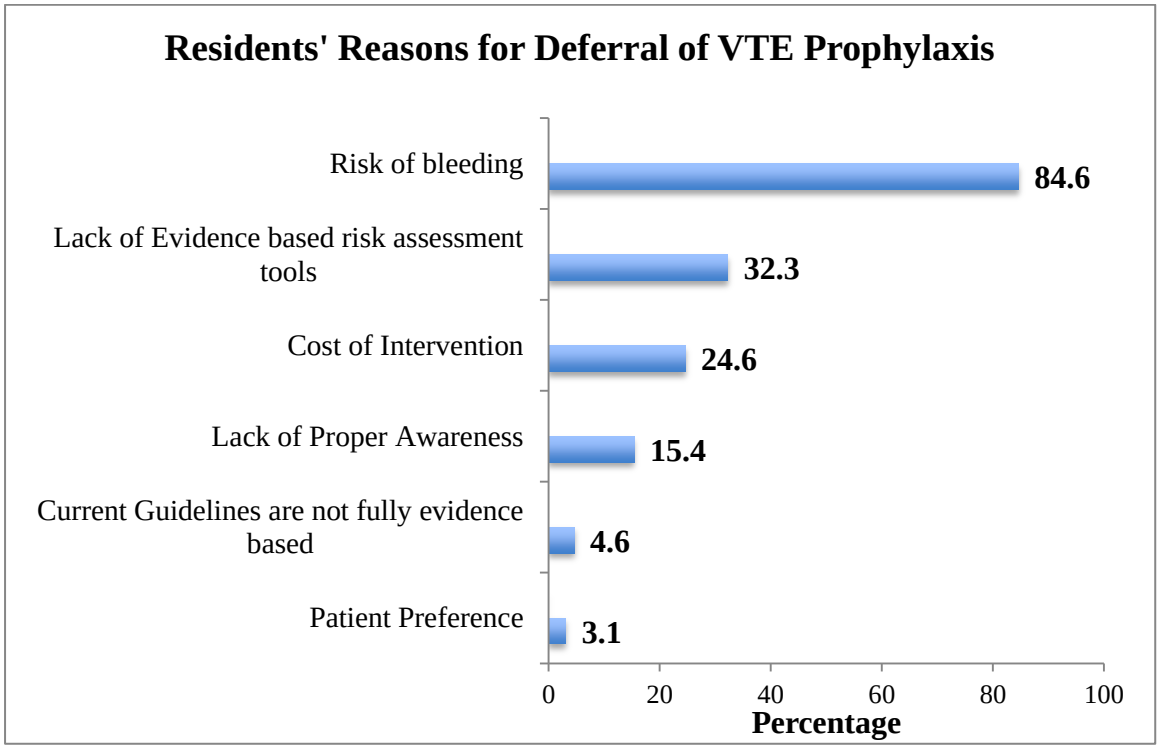

Figure 7: Residents' Reasons for Deferral of VTE Prophylaxis

9.6.5 CLINICAL VIGNETTES

In each vignette the residents were asked if the patient deserved VTE prophylaxis and what they preferred to offer. In the first clinical vignette, in which three major risk factors for VTE were described, one out of sixty-five wrongly thought that the patient did

not need VTE prophylaxis. Choices of prophylaxis agent in this scenario are as shown in table 16. In the second clinical vignette, 56 (86.2%) correctly recommended the need for VTE prophylaxis while 9 (13.8%) did not. LMWH was the preferred agent by 43 (76.7%) out of 56, 5 opted for fondaparinux, while 5 chose UFH. Three preferred mechanical prophylaxis that would have resulted in suboptimal VTE prophylaxis in this scenario. In the third clinical vignette, all 65 participants correctly recommended the need for chemoprophylaxis. Of these, 44 (67.7%) preferred LMWH, 17 (26.2%) preferred UFH while 4 (6.2%) opted for fondaparinux. In the fourth and final clinical vignette, 13 (20%) wrongly recommended VTE prophylaxis (table 16).

Table 16: Residents' Responses to Clinical Vignettes on VTE prophylaxis

CLINICAL VIGNETTES	**N=65 n (%)**
3 Risk Factors Creatinine Clearance of less than 30ml/min/1.73m^2	
LMWH	35 (53.8)
UFH	17 (26.2)
Fondaparinux	8 (12.3)
2 Risk Factors Normal Creatinine Clearance	
Not Prescribe VTE Prophylaxis	10 (15.4)
2 Risk Factors	
Not Prescribe VTE Prophylaxis	1 (1.5)
No risk Factors	
Give VTE Prophylaxis	13 (20)

9.6.6 BELIEF

Sixty-three (96.9%) strongly believed that VTE prophylaxis prevented morbidity and mortality, while only 2 (3.1 %) held moderate believes of the same. Forty-four (67.7%) strongly believed that there was adherence to quality care, in regard to VTE prophylaxis in the medical wards. Four (6.15%) did not hold this belief and 5 (7.7%) chose not to respond.

10.0 DISCUSSION

VTE remains one of the preventable causes of death among admitted medical patients. Prompt and appropriate antithrombotic prophylaxis is the mainstay of care. In this study the rate of prophylaxis was high and appropriate. Several of the issues noted were delays in decision-making and awareness of guidelines.

In our study the level of risk for VTE was high (67%) in comparison to studies around the world. In addition, we found the level of appropriate VTE prophylaxis to be high in comparison to studies around the world. There were gaps in knowledge of VTE prophylaxis and this influences care. Goubran et al of the ENDORSE study [37] assessed the level of risk for VTE in various hospitals in Egypt and found that 31% of their medical population were at high risk of developing VTE. They selected patients who were 40 years and above presenting with acute medical illness. The finding in the Egyptian arm of the ENDORSE study was comparable to that by Pinjala and colleagues in the Indian arm [38]. Pinjala et al found that 44.7% of the patients were at high risk for VTE. The reason for the differences in the studies may be found in the nature of the patients admitted in our national referral hospital. The hospitals selected in the ENDORSE studies included both peripheral and referral hospitals that had patients of varied degrees of illness. Majority of our patients are extremely ill and bed ridden, factors critical in determination of VTE risk. In another study conducted in the Middle East, 99.1% of those evaluated were at high risk for VTE [25]. Characteristics of the patient population in the MASIH study who had multiple and severe morbidities and may explain the high rate of VTE risk observed. This variation in level of risk highlights the importance of patient characteristics in the determination of VTE risk.

Appropriate VTE prophylaxis varies across the globe. In our study, 63.4% of our patients who were at high risk for VTE were offered some form of pharmacologic prophylaxis. This was comparable to the MASIH study where they found that 62.9% of the patients at high risk for VTE were offered prophylaxis [39]. These were among the highest rates of appropriate VTE prophylaxis prescription to study subjects at high risk of developing VTE. Lower rates were observed by Goubran et al (32.7%), Pinjala et al (23.3%) both of the ENDORSE Study and Taher et al of the AVAIL ME study (47.8%)[25, 37, 38]. While the reason for this variation was not explored in our study, factors including center practices, availability of drugs among others are important to consider. In our study, we found that

36.6% of patients with high risk for VTE and were not offered prophylaxis, which is a cause for concern. The most frequently occurring reason for not providing prophylaxis as assessed in the KAP was risk for bleeding at 84.6 %, which was comparable to that found by Vardi and Mendoza at 88.6% and 82.8% respectively. Further, we found that lack of evidence based risk assessment tools was the next most frequent reason for deferment of VTE prophylaxis at 32.3%. This was the highest in comparison to Vardi and Mendoza's findings. This suggests that if a validated risk assessment tool is provided then the compliance to VTE prophylaxis could be improved. For patients in low risk categories, inappropriate prescription of VTE prophylaxis was observed. Forty three point nine percent of those who were low risk were given some form of prophylaxis, thereby increasing the risk of bleeding in this subset of patients.

The most frequently offered prophylaxis was unfractionated heparin, yet the preferred choice of drug from the KAP was a low molecular weight heparin. Vardi et al., Mendoza et al., and Holler et al. studies found preference for enoxaparin at 95.6%, 83%,and 78.5% respectively[35, 36, 40]. The observed disparity in our study may be due to drug availability, an aspect that was not evaluated in this study. In patients with a GFR of less than 30 milliliters per minute per 1.73 meter squared caution in the prescription of VTE prophylaxis is required. Both fondaparinux and LMWH are unfavorable in this condition, as they would increase the risk of bleeding caused by bioaccumulation of these drugs. Our study revealed that up to half of the residents would have given LMWH to a patient with renal dysfunction. It is noted that 15.4% of our respondents did not respond to questions on VTE prophylaxis for patients in this category, indicating that they were unsure of what to do. In patients with GFR of less than 30 milliliters per minutes per 1.73 meters squared, unfractionated heparin is the recommended drug of choice for VTE prophylaxis.

Effective doses for VTE prophylaxis are 5000 IU of unfractionated heparin given twice or thrice daily and 40 milligrams of enoxaparin given once a day. These formed a majority of the prescriptions. However, in some instances, enoxaparin was given at 20 milligrams once a day (1.6%), which has been shown to be equal to placebo. Further, some prescriptions of enoxaparin were at 60 milligrams once a day (14.1%) that would confer increased risk of bleeding [39, 41]. Variations in enoxaparin dosages beyond the ACCP 2012 guidelines on VTE prophylaxis indicate a need for education on the right dosage of enoxaparin, and as explored above, its contraindications in VTE prophylaxis.

Evidence based guidelines are important in harmonization of clinical practice around the world. Knowledge of their existence and practice of them ensures quality care for patients. While only minority of the residents were not aware of formal international guidelines for VTE prophylaxis, lack of appropriate knowledge and application by those who are aware of them, allows for gaps in practice. Our study revealed that there were a higher percentage of residents with self-rated lack of knowledge of the ACCP 2012 guidelines on VTE prophylaxis at 9.3%,versus 2 (1.1%) and 2 (4.8%) seen in the Vardi and Mendoza studies respectively[35, 36]. The lack of updates on VTE prophylaxis guidelines may explain this difference.

Inclusion of VTE risk assessment in patient workflow sensitizes medical practitioners on VTE prophylaxis. A high percentage (81.5%) felt that VTE prophylaxis was not included into the workflow in comparison to Vardi et al (51.3 %) and Mendoza et al (65.5%). In addition, departmental guidelines in hospitals can aid in emphasizing the importance of VTE prophylaxis and offer guidance on the agent of choice in the local setting. Further, guidance in practice is critical in making the right choice of drug tailored to specific patient characteristics. Our study revealed that 95.4% felt that they were left to make the decision on their own. This was a high percentage when compared to findings by Vardi et al (64.6%) and Mendoza et al (82.7%)[35, 36]. There is, therefore, need for a stimulating environment urging for VTE prophylaxis. Methods that have been explored aimed at providing a stimulating environment are such as placement of risk evaluation forms in patients' charts with accompanying alert systems, and educational forums on VTE prophylaxis [42, 43]. Results suggest that combinations of these two methods are what are likely to cause a lasting improvement in prescription of VTE prophylaxis [40, 44].

Our residents strongly believed that VTE prophylaxis did prevent death for which they had the highest level of belief across the studies at 96.9%, versus 81% in the Vardi study, and 66% in the Mendoza study [35, 36]. This affirms the willingness to comply with VTE prophylaxis.

11.0 CONCLUSION

A substantial percentage of medical patients were at risk for VTE with only slightly more than half receiving the appropriate action. The prescribers did believe that VTE prophylaxis was a life saving measure but were handicapped by their level of knowledge of existing international guidelines and lack of incorporation of VTE risk assessment into the workflow of patient care.

12.0 RECOMMENDATIONS

To improve adherence to VTE prophylaxis guidelines, we make the following recommendations.

1. VTE risk assessment should be integrated into the workflow of patient management.
2. Enhance adherence to existing guidelines on VTE prophylaxis.
3. Formal regular updates on VTE prophylaxis need to be conducted to keep residents abreast on the subject. This will enhance risk assessment and appropriate prescription of VTE prophylaxis.
4. The medical fraternity should conduct studies that assess the impact of an introduced risk assessment model and educational updates on VTE prophylaxis on adherence to VTE prophylaxis prescription.

13.0 STUDY STRENGTHS

This is the first study in Kenya to determine level of risk for VTE, VTE prophylaxis and assess the knowledge, attitude and practice of SHOs in the department of medicine in the University of Nairobi.

14.0 STUDY LIMITATIONS

The protocol approval process included presentation of the protocol to the members of the department and this may have provided a platform to educate them on VTE prophylaxis. However, to mitigate the Hawthorne effect, the wards were not informed of the particular day that the study was conducted and ensured that the SHOs were maintaining their usual prescription patterns for VTE prophylaxis. In addition, the knowledge, attitude and practice questionnaire was distributed after clinical data had been obtained.

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APPENDIXES

APPENDIX A: STUDY EXPLANATION FORM

1. **Purpose of the study:**

   My names are Dr. Angela Wambui Nderi, a postgraduate student at the University of Nairobi. I am undertaking a study to determine the current use of venous thromboembolic prophylaxis in newly medical patients in KNH.

2. Procedures involved: Should you accept to join the study, you would be expected to:

i) Sign a consent form and participate in a survey that will take 10 to 15 minutes.

ii) Answer questions about your socio-demographic data, and estimation of your body mass index by taking your weight and height where feasible.

3. Your rights as a participant in this study:

i) Your participation in this research is voluntary.

ii) You will not be victimized if you refuse to participate in this study.

iii) If you choose to participate and not answer certain questions, you are free to do so.

iv) You are free to terminate the interview and withdraw from the study at any time.

v) You are free to ask questions before signing the consent form.

vi) All the results will remain confidential. Your individual responses will be stored in a locked place under my control and will only be seen by my statistician and me.

4. Risks to you as a participant in this study include:

- There are no risks that you will experience.

5. Benefits to you as a participant in this study include:

i) Your level of risk for VTE will be freely determined. Assessment of whether you are prophylaxis will be done. Exploration of any contraindications to pharmacological prophylaxis will be done. Appropriate prophylaxis will be recommended.

ii) The findings of this study will inform that medical community on our compliance to guidelines. Reinforcement of the following of guidelines will be achieved.

If you have any question during the course of the study, you may contact the following:

1. DR. ANGELA WAMBUI NDERI, UNIVERSITY OF NAIROBI, DEPARTMENT OF CLINICAL MEDICINE AND THERAPUTICS, Mobile: 0724-570292. ***OR***

2. CHAIRPERSON, KNH/UON ETHICAL REVIEW COMMITTEE, TEL: 020-2726300/0722829500/0733606400/EXT 44102. P.O. Box 20723, Nairobi.

If you agree to participate in the study, please sign the attached consent form. This consent form will not be linked to your answers.

APPENDIX B: CONSENT / ASSENT FORM

As regards the study entitled "**Current Practice of Venous Thromboembolic Prophylaxis in Newly Admitted Medical Patients in Kenyatta National Hospital**".

I confirm that I understand the purpose of this study.

☐ Yes No ☐

I confirm that a physical examination, my height and weight will be determined.

☐ Yes ☐ No

I understand that the researchers will use information about me (as explained to me) that is in my hospital records.

☐ Yes ☐ No

I confirm that I understand the participation in this study is voluntary.

☐ Yes ☐ No

I hereby give my written and informed consent to allow myself or my ……..…… to participate in the study.

☐ Yes ☐ No

NAME:……..… SIGNATURE:…….

DATE: _____

INVESTIGATOR'S STATEMENT:

I, the Principal Investigator, have fully informed the research participant on the purpose and implication of this study.

Signed: ..... Date: _____

APPENDIX C:STUDY PROFORMA

DATE		**STUDY NO.**	
DATE OF ADMISSION			
AGE	**GENDER**	**WT (kg)**	**HT (m)**
PRINCIPAL ADMISSION DIAGNOSIS			

Tick as appropriate and aggregate the score in the box given below.

Tick as appropriate	**Risk Factor for VTE**	**Points**
	Active cancer	3
	Previous VTE (with the exclusion of superficial vein thrombosis)	3
	Reduced Mobility	3
	Already known thrombophilic condition	3
	Recent (less than or equal to1 month) trauma and /or surgery	2
	Elderly age (more than or equal 70 yrs)	1
	Heart and or Respiratory Failure	1
	Acute Myocardial Infarction or Ischemic Stroke	1
	Acute infection and or rheumatologic disorder	1
	Obesity (BMI equal to or more than 30)	1
	Ongoing Hormonal treatment	1

Total VTE Risk Factor Score 

Score Interpretation

Total Factor Score	**Risk Level**
Less than 4	Low Risk
Equal to or more than 4	High Risk

Prophylaxis Safety Considerations: Indicate Y for yes, N for no and M for missing.

	Risk factor for bleeding
	Active gastro duodenal ulcer
	Bleeding in the last 3 months
	Thrombocytopenia of less than 50 x 10^9/L
	Age equal to or more than85
	Hepatic Failure (INR of more than1.5)
	GFR of less than 30 ml per minute per 1.73 meters square

Contraindications To Mechanical Prophylaxis
○ Severe Peripheral Artery disease
○ Congestive Heart Failure
○ Septic Phlebitis
○ Pre-existing gangrenous damage

Part B:Action in the ward

Tick as appropriate

Pharmacological anticoagulants		Yes	No
Date of commencement			
Drug	Dose	Frequency of Admin	Route
UFH			
LMWH			
Other (Specify)			

Mechanical prophylaxis		
Date of commencement		
Is the patient on mechanical Prophylaxis		
Intermittent pneumatic compression (IPC)		
Graduated compression stockings(GCS)		

Part C: IF PATIENT EXCLUDED

	EXCLUSION CASE
	No Consent
	Less than18 years
	Medical condition requiring the use of anticoagulants
	Patient with non-medical condition

Researchers Name: _____

APPENDIX D: QUESTIONNAIRE CONSENT FORM

Dear Doctor: I would like to ask your voluntary participation in this scientific study in the form of survey. A questionnaire is provided for you to answer as truthfully as possible.
TITLE OF THE STUDY: Current Practice of Venous Thromboembolic Prophylaxis in Newly Admitted Medical Patients in Kenyatta National Hospital.
PURPOSE OF THE STUDY: This study aims to assess the knowledge, attitude and practice of physicians on the prevention of venous thromboembolism (VTE) and to establish the current practice.
RISK OF THE STUDY: There is no risk in participating in the study.

POSSIBLE BENEFITS: By participating in the study, you will aid in generating an understanding of the current value placed on prevention of venous thromboembolism. This study will promote better practice on prevention of VTE, the most common preventable cause of in-patient mortality.

COMPENSATION: There will be no compensation given.

RIGHT TO WITHDRAW: Your participation in this study is completely voluntary. You are free to decline it. You have the right to change your mind anytime without giving explanations.

CONFIDENTIALITY: All answers obtained from you will be considered privileged information. These will be documented and analyzed anonymously. Only researchers have access to personal information, which only includes your age, gender, and year of study. Your identity will remain absolutely confidential. The researchers aim to publish this paper for pure academic and scientific purpose. You will be given a copy of consent form.

If you have any questions about your participation in the study, you should contact

ANGELA NDERI, MD Principal Investigator, Resident-in-training, University of Nairobi
Cellphone Number: 0724570292

CONSENT TO PARTICIPATE IN THE STUDY

I have read, or have had read to me, in language understandable to me, the above

information. The content and meaning of this information has been fully explained to me. I have had time and opportunity to ask any questions that I have about the study and this form, and all my questions have been answered. I voluntarily consent and offer to take part in this study. By signing this consent form, I certify that all information I have been given is true and correct to the best of my knowledge.

_____ Printed Name and Signature of Subject

_____ Printed Name and Signature of Investigator

APPENDIX E: KNOWLEDGE AND ATTITUDE QUESTIONNAIRE

KNOWLEDGE ATTITUDE AND PRACTICE OF VENOUS THROMBOEMBOLISM (VTE) PROPHYLAXIS IN ACUTELY ILL MEDICAL PATIENTS

You are being asked to voluntarily complete this questionnaire for a research project to establish your knowledge, attitude and practice of venous thromboembolism (VTE) prophylaxis in acutely ill medical patients. Before agreeing to take part in this research study, it is important that you read the consent information that describes it.

Please ask me for further clarification on **0724-570-292**.

Consent Information

1. VTE developing in the newly admitted patient and those who have recently been discharged has been found to be an avoidable cause of morbidity and mortality in medical patients. You have been selected to participate in this study, as you are an important decision-maker when it comes to timely VTE prophylaxis.
2. If you agree to complete this questionnaire, it should take you 2-10 minutes to fill.
3. It will enlighten you of any gaps in information that you may have not explored. Responses will be used to determine where gaps in information are and provide a way forward in designing a solution.
4. There are no known risks associated with completing this questionnaire.
5. This questionnaire is anonymous and confidential.
6. Proceeding with filling this form will be confirmation of consent.

Do you want to proceed to the questionnaire?

O Yes O No

GENERAL DATA

Age: ___ Gender: ___ Year of study: O 1 O 2 O ≥3

Instruction: **PLEASE CHECK (/) YOUR ANSWER**

CLINICAL VIGNETTES

CASE 1: A 78-year old male admitted to the medical wards with an acute exacerbation of congestive heart failure. He has a history of ischemic heart disease, recurrent urinary tract infections, obesity and tobacco use. His estimated creatinine clearance is 25. He also has history of DVT, but is not currently being treated.

a. According to your knowledge and practice, does this patient need VTE prophylaxis during his hospitalization?

O Yes

O No

b. What type of DVT prophylaxis would you recommend? (If your answer to previous question is yes)

O Low molecular weight heparin

O Unfractionated heparin

O High dose aspirin

O Fondaparinux

O Mechanical prophylaxis

CASE 2: A 55-year old female admitted in the cardiac intensive care unit wards for non-specific chest pain. She has diabetes mellitus and hypertension. She is treated with aspirin and confined to bed for cardiac monitoring for the first 48 hours. Her renal functions are within normal range.

a. According to your knowledge and practice, does this patient need VTE prophylaxis during his hospitalization?

O Yes

O No

b. What type of DVT prophylaxis would you recommend? (If your answer to previous question is yes)

O Low molecular weight heparin

O Unfractionated heparin

O High dose aspirin

O Fondaparinux

O Mechanical prophylaxis

CASE 3: A 65-year old male is admitted to the medical wards with sepsis secondary to cellulitis of the right leg. He has no significant past medical history. His estimated creatinine clearance is 45.

a. According to your knowledge and practice, does this patient need VTE prophylaxis during his hospitalization?

O Yes

O No

b. What type of DVT prophylaxis would you recommend? (If your answer to previous question is yes)

O Low molecular weight heparin

O Unfractionated heparin

O High dose aspirin

O Fondaparinux

O Mechanical prophylaxis

CASE 4: A 29-year old female admitted to the medical wards with fever and tachycardia and subsequently diagnosed with dengue fever.

She is sitting up in bed on the first day of her admission and on the second day she is able to walk to the bathroom.

a. According to your knowledge and practice, does this patient need VTE prophylaxis during her hospitalization?

O Yes

O No

b. What type of DVT prophylaxis would you recommend?

O Low molecular weight heparin

O Unfractionated heparin

O High dose aspirin

O Fondaparinux

O Mechanical prophylaxis

AWARENESS

1. Are you aware of formal guidelines from medical societies regarding VTE prophylaxis in medical patients?

O Yes

O No

2. How would you grade your knowledge of the clinical guidelines?

O None

O Moderate

O Good

3. When was the last time you were updated through formal teaching with these guidelines?

O less than 3 months

O 3-12 months

O over 12 months

O Never

4. When was the last time you were updated through self-directed learning with these guidelines?

O less than 3 months

O 3-12 months

O over 12 months

O Never

5. Which of the following medical conditions is NOT included in the recommendations for VTE prophylaxis from the American College of Chest Physicians?

O Congestive heart failure

O Severe respiratory distress

O Confined to bed

O Fever of unknown origin

O Has 1 or more additional VTE risk factors

ADHERENCE

1. Does your department have a formalized VTE prophylaxis protocol?

O Yes

O No

2. Do you believe every patient is entitled to VTE prophylaxis regimen unless contraindications exist?

O Yes

O No

3. Is a VTE risk assessment incorporated in the workflow in my environment and every patient is analyzed and followed by decision regarding intervention?

O Yes

O No

4. Is the choice of assessment and treatment of VTE prophylaxis left to the treating physician without institutional guidelines?

O Yes

O No

PRACTICE

1. My reasons for deferring treatment is/ are: (May choose more than one answer)

O Risk of bleeding

O Cost of intervention

O Lack of proper awareness

O Lack evidence based risk assessment tools

O Current guidelines are not fully evidence based

O Patient preference

2. I usually advise on treatment with: (For nos. 2-5, choose ONLY ONE ANSWER)

O Low molecular weight heparin

O Unfractionated heparin

O High dose aspirin

O Fondaparinux

O Mechanical prophylaxis

3. For patients with creatinine clearance less than 30, I usually advise on:

O Defer treatment

O Low molecular weight heparin

O Unfractionated heparin
O High dose aspirin
O Fondaparinux
O Mechanical prophylaxis

4. For patients with history of MAJOR bleeding (bleeding that causes hemodynamic instability or warranting blood transfusion), I usually advise on:
O Defer treatment
O Low molecular weight heparin
O Unfractionated heparin
O High dose aspirin
O Fondaparinux
O Mechanical prophylaxis

5. For patients with history of MINOR bleeding, I usually advise on:
O Defer treatment
O Low molecular weight heparin
O Unfractionated heparin
O High dose aspirin
O Fondaparinux
O Mechanical prophylaxis

BELIEF

1. Personal belief on VTE prevention
O I strongly believe in this intervention as preventive measure for morbidity and mortality
O I moderately believe in this intervention as preventive measure for morbidity and mortality
O I don't believe in this intervention as preventive measure for morbidity and mortality

2. Personal beliefs on quality measures in Internal Medicine
O I strongly believe in adherence to quality measures in IM wards
O I moderately believe in adherence to quality measures in IM wards
O I don't believe in adherence to quality measures in IM wards