CLINICAL AUDIT OF HEPARINS USE IN RIFT VALLEY GENERAL HOSPITAL, NAKURU COUNTY, KENYA

BY

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UNIVERSITY OF NAIROBI DECLARATION OF ORIGINALITY

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DEDICATION

This thesis is dedicated to my son Adrian who endured my absence from ten months of age when I left him to come back to school.
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My deepest gratitude to the Almighty God for His day to day guidance, control and protection.

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LIST OF ABBREVIATIONS

RVGH       Rift Valley General Hospital
ISMP       Institute of Safe Medication Practices
HITS       Heparin Induced Thrombocytopenia Syndrome
UFH        Unfractionated Heparin
LMWF       Low Molecular Weight Heparin
VTE        Venous Thromboembolism
DVT        Deep Venous Thrombosis
PE         Pulmonary Embolism
HCW        Health Care Worker
aPTT       Activated Partial Thromboplastin Time
CT         Computerised Tomography
MRI        Magnetic Resonance Imaging
KEML       Kenya Essential Medicines List
ECG        Electrocardiogram
GI         Gastro intestinal
ACCP       American College of Clinical Pharmacy
NICE       National Institute for Health and Care Excellence
FBC        Full Blood Count
INR        International Normalised Ratio
DEFINITION OF OPERATIONAL TERMS

Clinical Audit - The comparison of actual practice against agreed, documented, evidence based standards with the intention of improving patient care.

Standard - The percentage of events that should comply with the criterion. A standard is the desired and achievable level of performance against which performance can be measured.

Quality of Care - The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

Heparin-induced thrombocytopenia (HIT) - is a life-threatening complication mediated by auto antibodies against complexes of platelet factor 4 and heparin.

Unfractionated Heparin (UFH) - Is a heterogenous mixture of linear polysaccharide chains with variable molecular weight and biological activity, a well-defined pentasaccharide being its minimal active fragment.

Low Molecular Weight Heparin (LMWH) – These are heparin salts having an average molecular weight of less than 8,000 Daltons (Da). They are obtained by various methods of fractionation or depolymerisation of polymeric heparin.
ABSTRACT

Introduction:

Heparin remains the most widely used parenteral anti-thrombotic drug. It is a high risk medicine that may cause significant harm including death if not used properly. Heparin has low therapeutic index and is ranked among the top 5 “high alert” medications by the Institute of Safe Medication Practices. Heparin-related medication errors can occur at any stage from prescribing, dispensing, administration to monitoring of therapy. Its use should therefore be monitored to prevent possible errors and maximize benefits of use. There are no local studies assessing the heparin use process or highlighting the prevalence of outcomes related to heparin use. This is an important gap which this study seeks to address through the implementation of a clinical audit.

Aim:

To examine the processes and outcomes of heparin use in adult in-patients at the Rift Valley General Hospital, Nakuru through the conduct of a clinical audit.

Methodology:

An evidence-based, structured clinical audit tool was developed through a consolidation of information from various sources. The tool was then used to examine and audit the structures, processes and outcomes which characterize the current use of heparin. The structures supporting heparin use were examined by physically assessing availability of policies, guidelines or protocols for heparin use. Availability of antidote protamine and laboratory reagents for monitoring heparin use were also physically assessed in the pharmacy, wards and laboratory respectively. The processes and outcomes of heparin use were audited through the prospective observation of heparin administration and monitoring among eligible adult in-patients being managed with heparin regardless of diagnosis. Each patient was followed up for at least three days and data on the administration and monitoring of heparin use recorded. To supplement the clinical audit, a cross-sectional study of in-patient reports of patients managed with heparin was also carried out to establish the indications, laboratory monitoring, dose adjustment, and adverse effects that characterize in-patient heparin use. Descriptive statistics were then used to summarize and present this data.
Results:
The clinical audit revealed that there were no policies, protocols or guidelines to guide in the use of heparin at Rift Valley General Hospital. The reagents for tests used to monitor heparin use i.e. Full Blood Count, activated Partial Thromboplastin Time and International Normalised Ratio were available, though incidents of delayed or lack of heparin monitoring were observed. Heparin termination was done well by introduction of warfarin at least three days before stopping heparin in majority of the patients. Approximately half of patients and/or caregivers indicated that they were satisfied with the quality of care. The overall clinical audit score at Rift Valley General Hospital was 60.6% which showed minimal compliance to the performance threshold/standard of heparin use.

Analysis of the data from the records of 238 in-patients on heparin showed deep vein thrombosis as the most prevalent diagnosis at 74.8%; 18.9% had fractures while 6.3% had other diagnoses. A majority of the patients (57%) did not have any tests done to monitor heparin use. Information on any adverse drug reaction was poorly reported, with no such information in 236 (99.2%) of all the files.

Conclusions:
An evidence based tool was developed for the audit of heparin use and it was subsequently used to conduct a clinical audit for structures, processes and outcomes that characterize heparin use. This clinical audit for heparin use in Rift Valley General Hospital, concluded minimal compliance to the set standards. Heparin monitoring and reporting of adverse drug reactions is not adequate at Rift Valley General Hospital, though termination of heparin therapy was relatively well done. There is need to put strategies in place to ensure use of heparin is improved and maximum benefit is realized. A Quality Improvement Plan was developed for use by the Rift Valley General Hospital management for this purpose.
CHAPTER ONE: INTRODUCTION

Heparin is the most common parenteral anti-thrombotic drug (1). It is the most commonly used anticoagulant for the prevention and first treatment of venous thromboembolism, for cardiopulmonary bypass procedures, hemodialysis and, with aspirin, for the treatment of acute coronary syndromes. In venous thrombosis and coronary disease low molecular weight heparins (LMWHs) have been shown to be as safe and effective and unfractionated heparin (UFH) and the use of LMWH is increasing very fast (2).

Heparin is a high risk medicine that may cause significant harm including death to patients if not used properly. Heparin use is frequently associated with safety complications and the potential for medication errors which may have serious or significant consequences, including death. Heparin has a low therapeutic index, and has potential to cause bleeding or clotting. Its use should therefore be monitored to prevent possible errors and maximize benefits of use.

An Institute of Safe Medication Practices (ISMP) survey which was designed to identify medications frequently considered high-alert drugs identified heparin as one of the High-alert medicines (3). Its use therefore needs to be safeguarded to avoid undesirable consequences.

Heparin is on the World Health Organization's List of Essential Medicines, a list of the most crucial medications used in primary health care. Heparin is one of the drugs in the Kenya Essential Medicines List (KEML). Essential drugs are those that satisfy the needs of the majority of the population. This therefore confirms that heparin is an important medicine. As such, heparin should be available for use in patients from the National Referral Hospital right down to the Sub-District level of care. The drugs to be included in the KEML must have adequate data supporting their efficacy and safety.

While there are no documented reports of incidence and prevalence of heparin induced adverse outcomes in Kenya, a report approved by Quality and Patient Safety Committee on 19 February 2015 for the Royal Hospital for Women reported the incidence of heparin Induced Thrombocytopenia Syndrome (HITS) was 1-3% and 0-0.8% for Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) respectively (4). Heparin-induced thrombocytopenia (HIT) is a prothrombotic problem caused by auto antibodies against heparin-platelet complexes. It causes morbidity and it is deadly in 5%–10% of occurrences and causes
lifelong disability in another 10% of occurrences (5). Douglas et al. indicated that the prevalence of HIT is between 10% -30% of the patients receiving heparin in a clinical and economic review of HIT (5). HIT is caused by gathering of heparin on platelets directly (5).

Heparin-induced antibody formation and thrombocytopenia are well known and documented problems of heparin use and may be associated with thromboembolic incidents. According to an American Heart Association scientific statement on Guide to Anticoagulant Therapy by Jack Hirsh et.al, the occurrence of HIT differs in different clinical settings; the risk of venous thrombosis from HIT is higher in high-risk surgical patients than in medical patients. HIT occurs more often with UFH than with LMWH (6).

According to the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy, the chance of bleeding (Hemorrhagic Complication) related to UFH in patients with acute venous thromboembolism (VTE) is < 3% in recent experiments. The chance of bleeding increases with increasing heparin dosages and age (> 70 years). LMWH is related to less major bleeding compared with UFH (7).

Monitoring of the anticoagulant effect of heparins is usually recommended, especially in the management of acute Venous Thromboembolism (VTE), this allows for maximum antithrombotic effect with minimal risk of bleeding through over anticoagulation. However, accurate laboratory monitoring is often difficult for both UFH and LMWHs (7). The activated Partial Thromboplastin Time (aPTT) is used to track therapeutic doses of UFH in VTE. A target ratio versus mid-point of normal range of 1.5 to 2.5 is used to monitor the correct doses to use. This is based on evidence that delay in the achievement of sufficient anticoagulation is related to increased rate of thrombosis recurrence or progression (2).

Clinical audit is a quality improvement cycle that requires measurement of the effectiveness of healthcare against evidence-based standards and taking action to bridge the identified gaps in line with these standards so as to enhance the quality of care and health outcomes (8). It is important that heparin use is monitored closely to ensure that patients get maximum benefits and least harm. Finding out if guidelines and protocols on heparin use are being used by way of conducting a clinical audit is the only sure way to ensure that patients are protected from avoidable harm.
CHAPTER TWO: LITERATURE REVIEW

2.1 Overview of heparin use
Heparin was discovered 90 years ago, and it became very common within twenty years as an anticoagulant. The many advantages of heparin led to its widespread use, they include; immediate onset of action, relatively short half-life (60 minutes), low cost, simple laboratory monitoring (aPTT) and ability to counter its anticoagulant activity (using protamine). It took almost 4 decades to recognize that heparin can be intensely prothrombotic despite a long experience of using heparin (7). As mentioned above, heparin is used in management of several conditions with prevention and treatment of DVT being the most popular.

2.2 Heparin Pharmacology and Types
Heparin prevents reactions that make blood to clot both in vitro and in vivo. It acts at multiple sites in the natural coagulation cascade. Heparin in combination with antithrombin III (heparin cofactor) inhibits thrombosis by interrupting activated Factor X and preventing the conversion of prothrombin to thrombin. Larger amounts of heparin prevents further coagulation by interrupting thrombin and preventing the formation of fibrin from fibrinogen. Heparin inhibits formation of a stable fibrin clot by preventing activation of the fibrin stabilizing factor. Bleeding time is usually not affected by heparin. Clotting time is extended by adequate therapeutic doses of heparin; in many instances, it is not usually affected by low doses of heparin (10, 11).

Heparins commonly used are unfractionated heparin (UFH) and low molecular weight heparins (LMWHs). UFH has been used for a longer period than LMWH for the prevention and treatment of thrombosis. UFH has inconsistent anticoagulant and pharmacological properties and also limited bioavailability. LMWHs are derived from UFH by depolymerization. Each LMWH has a specific molecular weight that dictates its anticoagulant effects and duration of action. LMWHs have a predictable dose–response and have fewer non-hemorrhagic adverse effects. Therefore, LMWHs are gradually replacing UFH (11).

2.3 Patient Monitoring
Patients being managed with heparin require monitoring for ventricular tachycardia by use of an echocardiogram (ECG). They should also be examined for bleeding by checking any bruising, bleeding from the gums, epistaxis, gastrointestinal (GI) bleeding and hypotension. Patients receiving heparin infusions should be handled carefully to avoid bleeding. Heparin should be avoided in actively bleeding patients and also in patients with known or suspected intracranial
hemorrhage. Heparin used together with oral anticoagulants, thrombolytic and salicylates can increase the possibility of bleeding (12). As indicated in Appendices 2 and 3, in the guidelines and protocols of heparin use, close monitoring should be carried out to ensure safety during heparin use.

2.4 Heparin- a High Alert Medication

High risk medicines can cause major harm to the patient, even when used rationally. The Institute for Safe Medication Practices (ISMP) reports that, when there are cases the impact on the patient can be serious to cause even death. The ISMP uses the acronym APINCH to describe the list of high alert medications, as outlined in Table 2.1.

**Table 2.1: List of high alert medicines**

<table>
<thead>
<tr>
<th>A</th>
<th>Anti-infectives</th>
<th>Amphotericin- B, vancomycin, and aminoglycosides, but may also include others</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>Potassium and concentrated electrolytes</td>
<td>Injectable electrolyte preparations, for example potassium chloride and magnesium sulphate, but may also include other medicines</td>
</tr>
<tr>
<td>I</td>
<td>Insulin</td>
<td>All insulins</td>
</tr>
<tr>
<td>N</td>
<td>Narcotics and sedatives</td>
<td>All opioids, sedatives may include benzodiazepines and other sedating agents</td>
</tr>
<tr>
<td>C</td>
<td>Chemotherapy agents</td>
<td>Cytotoxic chemotherapy</td>
</tr>
<tr>
<td>H</td>
<td>Heparin and other anticoagulants</td>
<td>Heparins and all anticoagulants, including the New Oral Anticoagulants</td>
</tr>
</tbody>
</table>

High alert medicines are associated with various adverse reactions some of which are shown in Table 2.2 below.
Table 2.2: Examples of adverse events of some High Risk medicines

<table>
<thead>
<tr>
<th>Medicine Group</th>
<th>Risks to the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticoagulants (Warfarin and Heparin)</td>
<td>Narrow therapeutic index, potential for clot or bleed, heparin induced thrombocytopenia and hypersensitivity reactions, interactions with other medicines including herbal medication, over the counter products and food</td>
</tr>
<tr>
<td>Injectable sedatives (Midazolam, Lorazepam)</td>
<td>Over sedation, hypotension, delirium, lethargy</td>
</tr>
<tr>
<td>Opiates</td>
<td>Sedation, respiratory depression, confusion, lethargy, nausea, vomiting, constipation</td>
</tr>
<tr>
<td>Insulin</td>
<td>Loss of blood sugar control in post-operative patients; achieving blood sugar control without causing hypoglycemia</td>
</tr>
</tbody>
</table>

Heparin has a low therapeutic index, with potential for clotting or bleeding as well as drug-drug interactions with other therapeutic products and food (11). There are guidelines and policies in place to ensure safe practice when using heparin, however, there are many stages of care where errors may occur or where a safeguard needs to be in place. Harmful events with heparin have been associated with a lack of use of policies, guidelines and proper monitoring (13).

Studies have demonstrated that strategies that improve prescribing and monitoring of heparin have the potential to reduce major side effects such thromboembolic events (bleeding); standardizing steps to initiate and maintain heparin therapy is one of the plans of action that may be helpful (14). There are two types of low molecular weight heparins that are commonly used in hospitals. Dosage calculations are different depending on which heparin is being used the condition being treated. This can cause confusion and increase the chances of error (14, 15). Keeping minimal amounts of high dose forms of heparin in the wards is an effective strategy to reduce the risk of death or major injury associated with these heparin use (13). Performing a clinical audit of UFH and LMWHs in client service areas at least once every year can improve the safe use of heparin (14).
2.5 Hemorrhagic Complications of Anticoagulant Treatment

All patients receiving heparin, regardless of type or dose, are at risk of HIT, however, some do not develop the clinical syndrome. The incidence of HIT depends on patient characteristics, heparin type and source. LMWH has a much lower likelihood of causing HIT in comparison UFH. The risk of HIT is usually higher in those with prior heparin exposure (15). A meta-analysis of five studies demonstrated unfractionated bovine heparin is more likely to cause HIT than unfractionated porcine heparin (14).

It was concluded bleeding is the major complication of anticoagulant therapy by the seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy: (Evidence Based Guidelines), (10). The criteria for defining the severity of bleeding varies significantly between studies. The main determinants of oral vitamin K antagonist induced bleeding are the magnitude of the anticoagulant effect, the concomitant use of medications that interfere with hemostasis, patient characteristics and the duration of therapy. A history of bleeding is usually a risk factor for subsequent bleeding, although this observation has not been shown to be consistent (7). For vitamin K antagonist therapy, international normalized ratio (INR) of 2.5 (range, 2.0 to 3.0), is associated with a lower risk of bleeding (7).

UFH and LMWH are not shown to increase major bleeding in ischemic coronary syndromes, but are shown to increase major bleeding in ischemic stroke (7).

2.6 Development of Standards of Care

Standards are written documents that indicate the quality of services that health care workers (HCWs) should provide for all the patients. Ideally, HCWs should decide what these standards should be in collaboration with professional groups, management, government and clients/consumers of care (16).

Clinical audit is a self-improvement plan and is not supposed to be used for finding faults or who to blame. The aim is for hospitals managers to identify key problems in providing care. An action plan is then put into place to solve the identified problems. Follow up is then carried out to find out whether progress is being achieved. Re- audits are then carried out to find out if the solutions implemented were the correct ones. Hospitals should have a clinical audit team comprising 4 to 8 HCWs, led by a senior clinician and including nurses, administrator, laboratory personnel, and pharmacists. One or two people in that team should be chosen on a rotating basis to perform the clinical audit and report back to the clinical audit team (17).
The auditor is supposed to check the assessments, diagnoses, investigations, treatments and whether what was planned was done and recorded. He/she should also confirm if doses administered were correct and if clinical review and nursing procedures were timely and adequate. Findings should be summarized and the major factors that are common and need improving identified. Then the auditor should record the findings and areas that need action for reporting to the management (18).

The main aim of a clinical audit is to improve patient care. Clinical audit is about what is or ought to be the most important concern of any health professional to optimize clinical performance and provide the best possible health services to patients (17). A clinical audit cycle is presented in Figure 2.1 below.

Figure 2.1: A Clinical Audit Cycle (NICE 2002)

2.7 Conceptual Framework - Donabedian model
The Donabedian model is a conceptual model that gives a framework for evaluating health services and quality of health care. According to the model, information about quality of health care can be derived from three main categories: structures, processes, and outcomes. Structure is the
circumstance where health care is provided, including hospital buildings, staff, financing, and equipment. Process describes the interactions between patients and HCWs throughout the healthcare delivery. Outcomes are the effects of providing healthcare to individual patients and consequently the entire population. There are many quality of care frameworks, including the World Health Organization (WHO) -Recommended Quality of Care Framework and the Bamako Initiative but the Donabedian Model is the most authoritative model for assessing the quality of health care (19, 20). Figure 2.2 below present’s factors affecting safe use of heparin by use of the Donabedian Model.

![Donabedian Model Diagram]

**Figure 2.2: Factors affecting safe use of heparin**
2.8 Problem Statement
Heparin is the most widely used parenteral anti-thrombotic agent, and it is a lifesaving drug for the acute treatment of deep vein thrombosis (DVT) and/or pulmonary embolism (PE), prophylaxis in knee replacement and high-risk surgery, prophylaxis in hip replacement and hip fracture surgery and for the extended treatment of recurrent VTE. It is also used for the treatment and secondary prevention of VTE or PE for long period of up to 6 months in cancer patients. However, its use needs to be monitored because it has a low therapeutic index and may cause potentially fatal outcomes such as HITS, hemorrhage and hypersensitivity reactions including death.

To support the appropriate and safe use of heparin, standard guidelines and protocols are available locally and internationally. For example, Kenya’s Clinical Guidelines for Management and Referral of Common Conditions at levels 4-6: Hospitals outlines the use of heparin in several clinical circumstances. These guidelines and protocols are supposed to be used consistently during prescribing, preparation, administration and monitoring of heparin use. In order to realize their full benefits, these guidelines must be strictly followed.

The Clinical Audit is one of the most effective ways of evaluating if set standards of care and recommended procedures are adhered to. Coincidentally, clinical audit is not a routine practice in the Kenyan health sector. In the absence of local studies on heparin use, a clinical audit would therefore be important in evaluating the current characteristics of heparin use. The findings of such an audit would be useful in informing changes that would ensure safe, efficacious and cost effective care.

2.9 Justification of Study and Study Outputs
As mentioned previously, heparin is a widely used lifesaving drug, whose use needs to be monitored because of its low therapeutic index and potential for serious adverse outcomes. Adherence to guidelines and protocols, as well as careful monitoring of heparin use, is important in maximizing benefits of its use and minimizing on harm.

There are no local studies assessing the heparin use process or highlighting the prevalence of outcomes related to heparin use. This is an important gap which this study sought to address through the implementation of a clinical audit.
Clinical audits provide a systematic way of checking and monitoring the healthcare practice and making informed decisions for improvements. They may also inform the effectiveness of a service by highlighting gaps and suggesting ways to curb them. Overall, clinical audits are evidence-based methods of health care quality improvement strategies that identify and promote suitable practice that leads to improvements in patient care. Identifying gaps in standard management of heparin use would be important to ensure safe, efficacious and cost effective use of the drug, thereby improving quality of care and enhancing patient safety.

2.10 Research Questions
1. How do the structures, processes and outcomes that characterize the current use of Heparin compare with evidence-based clinical audit criteria?

2. What is the prevalence of heparin-induced thrombocytopenia, haemorrhage and hypersensitivity reactions among adult in-patients receiving heparin therapy at Rift Valley General Hospital (RVGH)?

2.11 Objectives of the Study
2.11.1 Main objective

To examine the processes and outcomes of heparin use in adult in-patients at the Rift Valley General Hospital, Nakuru through the conduct a clinical audit.

2.11.2 Specific objectives
1. To develop a Clinical Audit Tool for the evaluation of heparin use.

2. To examine and audit the structures, processes and outcomes which characterize the current in-patient use of heparin at RVGH.

3. To establish the indications, laboratory monitoring, dose adjustment, and adverse effects of in-patient heparin use at RVGH.
CHAPTER THREE: METHODOLOGY

This section describes in detail the study site, study design and methods of data collection, analysis and presentation that were used in this study, along with ethical considerations, expected study limitations and the dissemination plan.

3.1 Study Site
The study was carried out at RVGH, Nakuru, Kenya. Rift valley general hospital is the largest public teaching and referral hospital in Nakuru County. There are 622 beds and 68 Cots in RVGH. The services offered in RVGH include: Comprehensive care for HIV clients, out-patient and in-patient services, HIV counselling and testing, family planning and child welfare services including immunization. It is currently the fourth largest government referral hospital in Kenya serving most of the South and Central Rift Valley and neighboring districts. The hospital serves a population of about 3.6 million in south Rift valley plus patients coming from as far as western, Nyanza, North Rift valley and Central parts of Kenya. The bed occupancy at any given time is at an average of 120% i.e. 720. The hospital has 15 general wards and most of the facilities of a referral hospital; MRI and CT scan are also available. The hospital hosts both undergraduate and postgraduate training programs.

3.2 Study Design
This study had two components: a clinical audit of heparin use and a descriptive cross-sectional study of heparin use in adult in-patients.

3.2.1 Clinical Audit
3.2.1.1 Development of the Clinical Audit Tool
A clinical audit tool was developed to address the three aspects of heparin use, i.e. the structures, processes and outcomes which characterize the use of heparin. The optimum standards of heparin use, audit criteria and targets/ levels of performance were set \textit{a priori} and formed the basis of comparison with actual practice at RVGH. These were derived from Kenya’s Clinical Guidelines (20), and the Clinical Practice Guideline from the American College of Physicians and the American Academy of Family Physicians (21). These resources were supported by additional evidence that was obtained through the systematic identification and appraisal of clinical research studies on prevalence of adverse events following Heparin use, standards and protocols used in heparin administration and clinical audit of heparin use. These clinical research studies were
identified by the systematic searching of databases of biomedical journals like Medline through online tools such as PubMed and Google scholar.

The structure and format of the clinical audit tool was adapted from the Leicestershire partnership NHS Trust (www.leicspart.nhs.uk) and the clinical audit forms by Healthcare Quality Quest Limited in the UK (www.hqq.co.uk) which helps the management of health care institutions and HCWs to improve the quality of health care services and safety of patient care (22).

3.2.1.2 Implementation of the audit
The implementation of the audit was done with particular emphasis being put on the sources of information. This is in line with the expectation that the structure, process and outcome audit stages each had different sources of data as outlined below.

1. Structure audit.
The information on systems for example the management structure, staffing and training was sought from the hospital’s Health Management Information System (HMIS) department and the Human Resource Department. A physical check was also done for the laboratory reagents and pharmaceuticals like protamine sulphate at the hospital laboratory and the pharmacy department respectively.

2. Process audit.
The information on examination of the processes of heparin use (prescription, administration and monitoring) involved the observation of eligible patients from initial admission to discharge/termination of heparin use. Any patient above eighteen years, admitted to ward 9 (renal), wards 3&4 (Obstetrics and Gynecology), ward 7 (post-surgical), and wards 5, 11&12 (medical) during the period March and April 2016 (two months) and who was on heparin regardless of diagnosis was eligible for inclusion in the study. Informed consent was sought from both the HCWs and patients who were interviewed. The same Informed Consent form was used for this purpose (Appendix 1). A review of the medical files of included patients was also done to ensure comprehensiveness of process data collection. Patients who were on other anticoagulants were not included in the study. Following up of a minimum of 20 patients was considered adequate to inform success of the clinical audit of heparin use. This was in line with the conventionally
recommended and used sample sizes for clinical audits of between 20-50 subjects (24). It was also informed by the constraints in regard to time.

3. Outcome audit.
The information on examination of the outcome or results of the use of heparin was sought from two different sources depending on the outcome. Medical outcomes were sought from the patient’s medical records and patient satisfaction was from interrogating the patient and/or caregiver. Informed consent was sought to interrogate the patient for their views on the quality of care. The informed consent form was used for this purpose (Appendix 1). The patients who were interrogated to give information on patient satisfaction were the same patients who were followed up during heparin administration and monitoring. Each patient was interrogated at least once in the 2-3 day period during follow-up.

3.2.1.3 Analysis of audit data
Data analysis involved comparison of the clinical audit data that was retrieved with the pre-set audit criteria and targets/ levels of performance. It informed how use of heparin at the RVGH compared with the agreed standards, the areas of underperformance that required improvement as well as areas of adequate performance that needed to be maintained. The clinical audit data was collated on a Microsoft Excel (2010) spreadsheet. Simple descriptive statistics were the used to analyze clinical audit data i.e. averages and percentages. The various calculated descriptors were then compared to target performance thresholds set \textit{a priori} and which represent the minimum acceptable standards for each descriptor. The final findings of the clinical audit was summarized and presented in the form of an Audit Data Summary Form (Appendix 5).

3.2.2 Cross-Sectional Study of Heparin-Induced Adverse Outcomes
This component of the study was a hospital-based Cross-Sectional study of the in-patients who used Heparin at the Rift Valley General Hospital, Nakuru.

3.2.2.1 Study Population
The cross sectional part of the study targeted all adult in-patients above eighteen (18) years at the RVGH managed with heparin regardless of diagnosis admitted in the period July 2008 to June 2015.
3.2.2.2 Eligibility Criteria

a) Inclusion Criteria
Patient Records that were sampled for the cross sectional study were those of patients above eighteen (18) years admitted at RVGH and treated with heparin in the period July 2008 to June 2015.

b) Exclusion criteria

i. Patient records of patients who were managed using any other anticoagulants other than heparin.

ii. Patient records that indicate hemorrhage, hypersensitivity reactions or thrombocytopenia resulting from other causes other than heparin use.

3.2.2.3 Sample Size Determination
For the estimation of sample size for the cross-sectional part of the study, the Cochran 1997 formula was used as the primary objective was to estimate prevalence of heparin-related adverse outcomes.

\[ n = \frac{Z^2(p)(q)}{d^2} \]

Where:

\[ Z = \] \( z \) statistic for 95% level of confidence which conventionally is 1.96

\[ p = \] estimated prevalence or proportion in the population;

\[ q = 1 - p \]

\[ d = \] level of precision to be used in the study set at 5%

In a clinical and economic review on HIT by A. Douglas et al. the prevalence of HIT was found to be between 10% to 30% of patients receiving heparin (5). Using the average value of 20% therefore, the target sample size was;

\[ 1.96^2 \times 0.2 \times 0.8 = 250 \text{ patient records} \]

\[ 0.05^2 \]
To cater for insufficient or missing information the calculated sample size was inflated by 10%. So the estimated sample size for this arm of the study was 270 patient records.

**Finite population correction factor.**

Because the estimated sample represented a significant (e.g. over 5%) proportion of the population, a finite population correction factor was applied on the estimated target sample size. This reduced the sample size required.

In this study, it was estimated that the total number of files that would constitute the sampling frame would not exceed 2000. The target sample size was therefore expected to exceed 5% of this estimated population. For this reason, the finite population correction was applied. The formula for this correction is:

\[
na = \frac{n_r}{1 + (n_r - 1)/N}
\]

Where \(na\) = the adjusted sample size, \(n_r\) = the original required sample size and \(N\) = population size.

Assuming the maximum number of eligible files at RVGH for the study period was 2000, then the adjusted target sample size was 238 patient files.

**3.2.2.4 Sampling Method**

Systematic random sampling of patient records was done. The records were retrieved from hospital registry. Patients’ records were considered for all the wards that manage patients using heparin. All the files of patients managed with heparin within the period July 2008 to June 2015 were considered the sampling frame. An appropriate sampling interval was calculated that would yield the target sample size of 238. Every 3\textsuperscript{rd} file was then identified and, if the subject met the eligibility criteria, the relevant information was extracted. The relevant information was then recorded in the Data Collection Form (Appendix 4) from where the data was compiled for analysis. This process was continued until a satisfactory sample size of 238 patient files was attained.

**3.2.2.5 Data Collection**

Data that was used to determine the prevalence of adverse effects following use of heparin was obtained from patient records covering the study period and sampled as described above. The variables that were considered include; patient demographic information, whether the patient was
on UFH or LMWH, monitoring tests that were carried out and any adverse outcomes following heparin use.

A Data Collection Form was used for this purpose (Appendix 4).

### 3.2.2.6 Data Analysis

For the cross sectional part of the study, descriptive statistics were used to describe the data using percentages. Bivariate analysis was used to analyze the relationship between the diagnosis/ reason for heparin use and the laboratory monitoring of heparin use. The software used was IBM SPSS Statistics Version 22.

### 3.3 Data Management and Quality Assurance

The names of the patients who were interrogated were not used and instead special patient identifiers were used by the investigator. Hard as well as soft copies of data were stored safely under lock and key by the investigator. Back up files were stored in a flash disk and external hard disk. This was done regularly at least once every week to avoid loss or tampering.

### 3.4 Ethical Considerations

#### 3.4.1 Ethical Approval

The study used human participants and patient records hence ethical approval was sought and obtained from KNH/UON Ethics and Research Committee (Ref No. P644/10/2015, Appendix 6). Institutional approval was also sought and obtained from RVGH (Ref No. RII/VOL.I/08).

#### 3.4.2 Informed consent

Informed consent was sought for all the patients from whom descriptive information was required after adequate explanation of the study requirements (for the clinical audit section of the study). An informed consent form was used for this purpose. (Appendix 1)

#### 3.4.3 Withdrawal from the study

The participants were informed that they would be free to leave the study at any time without having to give any reasons (for the clinical audit section of the study).

#### 3.4.4 Compensation

There was no compensation in this study. Participants were informed that they would not benefit directly from this study but interventions that would improve care and treatment being offered at the facility was ascertained upon completion of the study. However, the findings would be
communicated to the healthcare workers and information would assist in establishment and development of routine clinical audit activities in the hospital which will go a long way in improving health outcomes.

3.4.5 Confidentiality
The names of the respondents were concealed and confidentiality of information upheld.

3.5 Dissemination Plan
Final copies of the finished dissertation book will be submitted to the medical library of the University of Nairobi and the Department of Pharmacology and Pharmacognosy for accessibility to other students and university staff. A copy will be given to the management of RVGH for implementation. A manuscript will be prepared and published in a peer reviewed, open access biomedical journal, ensuring that the study findings can be accessed worldwide through internet. The completed audit report will be shared with the RVGH management and a Continuous Medical Education (CME) will be conducted to the medical staff of RVGH. A copy of the developed audit tool will be left in the hospital with an aim of using it to complete the clinical audit cycle for the use of heparin.
CHAPTER FOUR: RESULTS

This chapter presents analysis of findings aimed at achieving the objectives of the study. Data has been summarised for both the clinical audit and the cross-sectional parts of the study. The data for the audit part of the study is summarised in the format described in the audit tool. The data for the cross-sectional part of the study was analysed using descriptive statistics and was then presented in form of frequency distribution tables, pie charts and graphs.

4.1 Clinical Audit

The main objective was to conduct a clinical audit of the use of Heparin in adult in-patients at the Rift Valley General Hospital (RVGH), Nakuru. To achieve this objective, an evidence-based Clinical Audit Tool for the evaluation of heparin use was developed. It was then used to examine and audit the structures, processes and outcomes which characterize the current use of heparin. The clinical audit tool is as shown in Appendix 5.

4.1.1 The Clinical Audit tool

4.1.1.1 Development of the Clinical Audit Tool

The clinical audit tool was put together through a consolidation of information from various sources including the Kenya’s Clinical Guidelines for Management and Referral of Common Conditions at levels 4-6: Hospitals (21), and the Management of Venous Thromboembolism: A Clinical Practice Guideline from the American College of Physicians and the American Academy of Family Physicians (22). Other evidence that was used to inform the tool was a clinical audit on Chronic Obstructive Pulmonary Disease (COPD) by Karen Moore, a Respiratory Specialist Nurse (24). The Clinical Guidelines from the National Institute for Health and Clinical Excellence (NHS), specifically the NICE Clinical Guideline 92, were also used to support evidence based practice (25). These NICE guidelines give a summary of the treatment and care of patients who have high chances of developing DVT while still admitted in hospital.

Other sources of information that guided the formulation of the format of the tool used were the Leicestershire partnership NHS Trust (www.leicspart.nhs.uk) and the clinical audit forms by Healthcare Quality Quest Limited in the UK (www.hqq.co.uk) (23).
4.1.1.2 Structure of the Clinical Audit Tool

The general structure of the audit tool consisted of six sections, each with a specific function (Appendix 5):

**Section 1:** this section was designed to collect information about the place/facility where the audit takes place, the audit period/date and the ward/unit involved. It also contains the patient/HCW number, to be filled when applicable. Information on who is carrying out the audit is also contained here. This section therefore informs where, when and by whom the clinical audit takes place. There is also a brief introduction and description of the tool.

**Section 2:** this section presents the optimum standards for heparin use in adult in-patients, against which the findings of the clinical audit are to be compared.

**Section 3:** this is the data collection section of the audit tool. The section consists of a series of targeted questions whose responses allow the scoring and audit of each of the four main criteria that were identified for this audit. The criteria are detailed in Section 4.1.1.3.

**Section 4:** this section presents instructions on how to score the criteria, and provides a table to guide in the calculation of the scores per each criteria. The overall clinical audit score can also be estimated from the summation of the actual score obtained divided by the total expected score expressed as a percentage.

**Section 5:** this section is an overall summary of the assessment of each criterion as per the relevant set standards of performance.

**Section 6:** this section presents a template for the Quality Improvement Action Plan. This informs the action points to improve the quality of delivery of services. It is meant for use by the Health Management Team. It also informs the basis for a re-audit for the purposes of the completion of the audit cycle.

4.1.1.3 Criteria for Audit

An audit criteria quantifies in a measurable way the practice addressed by the objective keeping in mind the optimal care that should be delivered. Audit criteria includes policies, procedures and requirements ([http://www.uhbristol.nhs.uk](http://www.uhbristol.nhs.uk)).
There are four main criteria that were identified for the audit of heparin use in adult in-patients. They were formulated from the sources of evidence mentioned in section 4.1.1 above. Each criteria had some main and specific issues to be evaluated as described in Section 3 of the clinical audit tool (Appendix 5).

**Criterion 1: Structural features**
This criterion was supposed to assess if there were adequate supporting structural features in the organization to enable safe use of heparin. These included the presence of protocols, policies and guidelines for heparin use in the institution, the availability of staff per cadre (which informs the adequacy of human capacity), the availability of laboratory reagents for use in heparin use monitoring as well as the antidote protamine sulphate. The sources of data to evaluate the structural features were the Health Management Information system (HMIS), The Human Resource department, Laboratory and Pharmacy.

The criterion was examined by exploring four specific questions as described in Section 3, Appendix 5.

**Criterion 2: Competent staff**
This criterion assessed if there were sufficient competent persons to provide appropriate heparin use service. Specifically it assessed the competence of HCW in terms of experience, training and awareness of availability of guidelines and protocols as well as ability to use these resources. It also assessed the knowledge on heparin monitoring.

The source of data for this criterion was interviewing the HCWs. This section consisted of nine specific questions as described in Section 3, Appendix 5.

**Criterion 3: Safe use of heparin**
This criterion assessed that proper precautions were taken to ensure that heparin was prescribed, administered and monitored appropriately. This criterion specifically assessed the type of heparin prescribed, and if the patient weight was taken and used as basis for dose calculation especially for the LMWH. The guidelines and protocol for the intravenous therapeutic maintenance heparin dose for adult was 20 units/kg/hour as indicated in Appendix 2.

The criterion also assessed if renal function was considered during prescribing process, if aPTT/INR were done 6 hours after initiation of treatment and if they were repeated in the course of treatment. These are the indicators that inform dose adjustments depending on individual patient’s requirements.
Also assessed was if FBC was checked at least once every week because this allows monitoring of platelets and enables early detection of HIT during heparin treatment.

The criterion also assessed how heparin use was terminated. Warfarin should be introduced at least three days before heparin is terminated. This is because the peak anticoagulant effect of warfarin may be delayed 72 to 96 hours. The source of data was process observation and patient records. A total of eight questions composed this section of the audit as shown in Section 3, Appendix 5.

**Criterion 4: Patient satisfaction on quality of care**

This criterion assessed patient-specific outcomes of heparin use, i.e. if patients were satisfied with the quality of care that they received in the institution as an outcome measure. It assessed if the HCW were friendly and if they answered to patient calls promptly and also the patient’s overall feel on the quality of care. There was also assessment of ADRs following heparin use as clinical outcome indicators.

The source of data for this criterion was interrogating the patients and the information on the patient files. There were five questions on this section (Section 3, Appendix 5).

**Scoring of Audit Criteria**

The scoring of an audit criteria gives the management and/or stakeholders the feel about the level of performance of their policies and procedures and allows for comparison with the set standards/performance thresholds. The scoring for the criteria was done by first reporting the number of activities/questions contained in the particular criteria. Then a score was assigned for every question answered yes or no. In this audit, a Yes was assigned a score of ten, a No was assigned a score of zero. If the question was not applicable, it was not considered for a score. For all the criteria the scoring was done the same way i.e.

Scores: Yes = 10, No = 0, N/A = doesn’t count in final score. The scoring is highlighted in Section 4, Appendix 5.

**4.1.1.4 Performance thresholds/Standards of Audit Criteria**

Performance threshold/standards are the minimum acceptable performance standards or the maximum allowable limits. The threshold values act as checkpoints and help in monitoring the performance of a particular criterion by providing a benchmark value. For example, assume we set a performance threshold value at 100% as the maximum, this indicates that absolute compliance is required, and criterion scores lesser than this indicate a problem. If we set a performance
threshold value of 80% and level as minimum, this indicates that deviations from complete compliance may be tolerated, but criterion scores lesser than 80% would indicate a problem.

Moore et al. (2013) recommended that all criteria for standards of care are set at 100%. However, in cases where deviations from complete compliance may be tolerated, standards for such criteria can be set at 80% (24). A similar principle was applied in the setting of the performance thresholds for the clinical audit of heparin, whereby the criteria on Structural Features, Safe use of Heparin and Staff Competence (all of which require complete compliance) were assigned a performance threshold/standard of 100% but the Patient Satisfaction on Quality of Care was assigned a performance threshold/standard of 80% (deviations from complete compliance may be tolerated).

A summary of the standard/ performance thresholds that were set for the clinical audit of heparin is shown below (Table 4.1). A similar table is included in the audit tool to guide in the evaluation of the clinical audit of heparin use (Section 2, Appendix 5).

**Table 4.1: Standards for Heparin Use in Adult In-Patients**

<table>
<thead>
<tr>
<th>Audit Criteria</th>
<th>Standard/Threshold</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Structural features</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are adequate supporting structural features in the organization to enable safe use of heparin.</td>
<td>100%</td>
<td>Structural features should be adequate to allow safe use of heparin</td>
</tr>
<tr>
<td><em>See section 3, Criterion 1</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Competent staff</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are sufficient competent persons to provide appropriate heparin use service.</td>
<td>100%</td>
<td>All staff handling heparin should be competent to avoid errors</td>
</tr>
<tr>
<td><em>See section 3, Criterion 2</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Safe use of heparin</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper precautions are taken to ensure that patients requiring heparin are prescribed, administered and monitored appropriately.</td>
<td>100%</td>
<td>No inefficiencies are allowed during prescribing, administration and monitoring of heparin</td>
</tr>
<tr>
<td><em>See section 3, Criterion 3</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient satisfaction on quality of care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients are happy with the care that they receive in the institution</td>
<td>80%</td>
<td>Some patients may not be able to respond and caregivers may not be present</td>
</tr>
<tr>
<td><em>See section 3, Criterion 4</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The key for interpretation of level of compliance from the scores and pre-set performance thresholds as per the NICE guidance audits is set as illustrated in Figure 4.1 below (25).

**Performance threshold/ Standard at 100%**

<table>
<thead>
<tr>
<th>Full compliance</th>
<th>Partial compliance</th>
<th>Minimal compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>90% x 100%</td>
<td>70% x&lt;89%</td>
<td>x&lt; 69%</td>
</tr>
</tbody>
</table>

**Performance threshold/ Standard at 80%**

<table>
<thead>
<tr>
<th>Full compliance</th>
<th>Partial compliance</th>
<th>Minimal compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>72% x 80%</td>
<td>56% x&lt;71%</td>
<td>x&lt; 55%</td>
</tr>
</tbody>
</table>

**Figure 4.1: Interpretation of the Level of Compliance with the set Performance Threshold**
Similar interpretations were used for the clinical audit of heparin use at the RVGH.

**4.1.2 Clinical Audit of Heparin Use at RVGH**

The clinical audit tool (Appendix 5) that was developed as described above was then used to conduct the audit of heparin use at the RVGH.

**4.1.2.1 Collection of audit data and Audit Results**
Using the audit tool as a key guide, data was collected for each criteria. Relevant data sources were used.

**Criterion 1**

The data sources for the structural features (Criterion 1) were the Health Management Information system (HMIS), The Human Resource Department (HRD), Laboratory and the Pharmacy. We enquired from the HCWs if there were any guidelines or protocols for heparin that are used. A member of staff from the HRD extracted the information on the availability of staff per cadre from the RVGH Human Resource Database. The presence of protamine was physically assessed in the Pharmacy. Similarly the presence of laboratory reagents for use in the monitoring of heparin use were physically assessed.

The clinical audit for criterion 1 showed that there are no policies, protocols or guidelines to guide in the use of heparin at RVGH. These documents were not available in any department including pharmacy, wards and even the laboratory. The reagents for tests used to monitor heparin use i.e. FBC, aPTT and INR were available. However, reagents for monitoring aPTT/ INR were available
as from March 2016. The two tests were previously being sourced privately outside the RVGH. Protamine was also not available in the facility during the period the Clinical audit was being carried out.

**Criterion 2**

The data for the criterion assessing for sufficient competent persons to provide appropriate heparin use service (criterion 2) was from interviewing ten HCWs. The HCWs were asked specific questions regarding their training in heparin use, knowledge on existence on protocols, guidelines or policies on heparin use. Other questions regarding the monitoring of heparin were also asked as outlined in Section 3, Appendix 5.

The audit results for the criterion indicated that none of the HCW (100%) had ever gone through heparin-specific post-qualification (in-service) training. The staff also don’t have any knowledge on the availability and use of protocols, standard guidelines or policies that guide heparin use.

**Criterion 3**

The data for the criterion that assessed the Safe use of heparin i.e. proper precautions are taken to ensure that heparin is prescribed, administered and monitored appropriately (criterion 3) was obtained from observation and patient records. Twenty eligible patients were followed up for at least three days during the course of treatment with heparin. Assessment of their weight being taken at the beginning of treatment especially for patients on LMWH was observed and recorded appropriately. The baseline assessment of Renal Function Tests, aPTT, INR and FBC were assessed and recorded appropriately. Follow up monitoring tests were assessed in the course of the three day follow up and recorded in the data collection tool for the audit of heparin use.

Introduction of warfarin before stopping heparin use was also assessed and recorded. Patient records were used to confirm relevant monitoring tests requested and if they were recorded after they were done.

For all patients who were put on UFH, baseline aPTT or FBC tests were not done within six hours of start of therapy. Four out of 20 (20%) patients did not even have these tests ordered by the prescriber. However out of 16 patients who had their tests ordered and not done within 6 hours, tests for 9 (56.3%) patients had been done within three days. Six out of 20 (30%) had their FBC checked at least once in a week. However heparin termination was done well by introduction of warfarin at least three days before stopping heparin in 17 out of the 20 (85%) of the patients.
**Criterion 4**

The data on the assessment of quality of care (criterion 4) was obtained from interrogating the patients. They were asked if the staff at RVGH is friendly according to them, if they answer to calls promptly and they were asked to give their own overall personal view on the quality of care. They were asked to indicate if they were satisfied with the care they received at the RVGH. This criterion also assessed the clinical outcomes of heparin especially the adverse drug reactions following heparin use.

The satisfaction on quality of care showed that 17 (85%) of patients and/or caregivers agreed that the staff at RVGH are friendly towards them. However only 11 (55%) indicated that the staff are prompt to answer calls by the patients. Overall, 11 (55%) of respondents indicated that they were happy with the care they received at RVGH, 5 (25%) said they were not happy with the care they received at RVGH and the rest 4 (20%) did not know if they were satisfied or not.

The Actual Criterion Score was obtained by adding up all the Yes answers multiplied by 10. This was guided by the scoring criteria as described in Section 4, Appendix 5.

The summary of the scores per criterion is shown in Table 4.2 below.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Actual Criterion Score (AC)</th>
<th>Maximum Criterion Score (MC)= Total Number of Questions x Maximum Score (10)</th>
<th>Criterion Score as a percentage= (AC/MC x 100/1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100</td>
<td>120</td>
<td>(100/120)*100 = 83.3%</td>
</tr>
<tr>
<td>2</td>
<td>50</td>
<td>90</td>
<td>(50/90)*100 = 55.5%</td>
</tr>
<tr>
<td>3</td>
<td>30</td>
<td>80</td>
<td>(30/80)*100 = 37.5%</td>
</tr>
<tr>
<td>4</td>
<td>20</td>
<td>40</td>
<td>(20/40)*100 = 50%</td>
</tr>
</tbody>
</table>

Overall audit = (Σ AC/ Σ MC)* 100   
(200/330) * 100 = 60.6%
4.1.2.2 Interpretation of Audit Results
The comparison of the audit findings with the pre-set performance targets is as shown in Table 4.3 below.

Table 4.3: Criterion Assessment per Set Standards

<table>
<thead>
<tr>
<th>CRITERION</th>
<th>PERFORMANCE THRESHOLD (%)</th>
<th>OBSERVED (%)</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural features</td>
<td>100</td>
<td>83.3</td>
<td>There was partial compliance to the performance threshold.</td>
</tr>
<tr>
<td>Competent staff</td>
<td>100</td>
<td>55.5</td>
<td>There was Minimal compliance to the performance threshold/standard.</td>
</tr>
<tr>
<td>Safe use of heparin</td>
<td>100</td>
<td>37.5</td>
<td>There was Minimal compliance to the performance threshold/standard.</td>
</tr>
<tr>
<td>Patient satisfaction on quality of care</td>
<td>80</td>
<td>50</td>
<td>There was Minimal compliance to the performance threshold/standard.</td>
</tr>
</tbody>
</table>

Using the NICE guidance for interpretation of the audit scores:
Criterion 1 (performance threshold/standard set at 100%) had an observed score of 83.3% which according to the NICE guidance for interpretation of audit showed partial compliance. Criterions 2 and 3 (performance thresholds/standards set at 100%) showed minimal compliance at 55.5% and 37.5% respectively.

Criterion 4 (performance threshold/standard set at 80%) had an observed score of 50% which means this criterion had minimal compliance to the performance threshold/standard. The overall clinical audit at RVGH was found to be 60.6% which showed minimal compliance to the performance threshold/standard of heparin use.

4.2 Cross Sectional Study
This section presents the results obtained from the cross-sectional part of the study that aimed to establish the characteristics of in-patient heparin use using data extracted from past patient files.

4.2.1 Demographic findings
The study embarked on collecting the patient records data and a total of 238 records were retrieved, thereby achieving the targeted sample size. The 238 patient files were retrieved and data was extracted and entered in the Data Extraction Form (Appendix 4). Out of the 238 records for patients, the largest proportion were aged between 25-34 years at 33.2% probably associated with contraceptive use. The majority of patients were women at 67.2%. This is presented in Table 4.4 below.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>F</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 - 24</td>
<td>36</td>
<td>15.1</td>
</tr>
<tr>
<td>25 - 34</td>
<td>79</td>
<td>33.2</td>
</tr>
<tr>
<td>35 - 49</td>
<td>70</td>
<td>29.4</td>
</tr>
<tr>
<td>50 and above</td>
<td>53</td>
<td>22.3</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>78</td>
<td>32.8</td>
</tr>
<tr>
<td>Female</td>
<td>160</td>
<td>67.2</td>
</tr>
</tbody>
</table>

4.2.2 Diagnosis/Reason for heparin use
According to the analysis of the data, deep vein thrombosis (DVT) was the most prevalent diagnosis at 74.8% of all the patients’ records. Further, 18.9% had fractures while 6.3% had other diagnoses, which included arterial fibrillations, bed-ridden patients, angina pectoris, myocardial infarction and pulmonary embolism.
The duration of complaints prior to hospital admission and subsequent heparin use recorded were mostly above 7 days with 62.2% recording this length. Figure 4.2 below presents a parallel depiction of these findings.

![Figure 4.2: Diagnosis of heparin use and duration of complaint prior to admission](image)

**Figure 4.2: Diagnosis of heparin use and duration of complaint prior to admission**

Assessment of age and reason (diagnosis) for heparin use found that a majority of patients diagnosed with DVT at 28.1% were in the age category 25-34 years while the least at 11.8% were aged between 18-24 years. The number of patients who were managed with heparin due to fracture increased with increasing age. However the number of patients managed with heparin for any other reason did not change across age groups. These results are indicated in Table 4.5 below.

**Table 4.5 Age vs. Diagnosis/Reason for heparin use**

<table>
<thead>
<tr>
<th>Age</th>
<th>Deep Vein Thrombosis (%)</th>
<th>Fracture (%)</th>
<th>Other (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 - 24</td>
<td>28 (11.8)</td>
<td>4 (1.7)</td>
<td>4 (1.7)</td>
<td>36 (15.1)</td>
</tr>
<tr>
<td>25 - 34</td>
<td>67 (28.1)</td>
<td>8 (3.4)</td>
<td>4 (1.7)</td>
<td>79 (33.2)</td>
</tr>
<tr>
<td>35 - 49</td>
<td>52 (21.8)</td>
<td>15 (6.3)</td>
<td>3 (1.3)</td>
<td>70 (29.4)</td>
</tr>
<tr>
<td>50 and above</td>
<td>31 (13.0)</td>
<td>18 (7.6)</td>
<td>4 (1.7)</td>
<td>53 (22.3)</td>
</tr>
<tr>
<td>Total</td>
<td>178 (74.8)</td>
<td>45 (18.9)</td>
<td>15 (6.3)</td>
<td>238 (100)</td>
</tr>
</tbody>
</table>
4.2.3 Other Medications and comorbidities
Varieties of other medications alongside heparin were prescribed to the patients as established from the records. The findings showed that most of the patients (36.1%) were given a combined prescription of analgesics and antibiotics followed by those who were given analgesics alone (23.1%). The most uncommon prescription was that of anti-retrovirals (ARV) with only 1 (0.4%). Importantly, 62.0% of the patients did not have any comorbidities i.e. apart from the admission diagnosis, they did not suffer from any other medical condition. A few of the patients had other comorbidities: 8.4% had hypertension and diabetes and 29.5% suffered other comorbidities like tuberculosis (TB), psychosis, pneumonia, abortion, colds and coughs in addition to admission diagnosis. Table 4.6 below presents the findings in detail.

Table 4.6: Other medications and comorbidities

<table>
<thead>
<tr>
<th>Medications</th>
<th>f</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesics and antibiotics</td>
<td>86</td>
<td>36.1</td>
</tr>
<tr>
<td>Analgesics</td>
<td>55</td>
<td>23.1</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>18</td>
<td>7.6</td>
</tr>
<tr>
<td>Antihypertensive and others</td>
<td>14</td>
<td>5.9</td>
</tr>
<tr>
<td>Antibiotics and other</td>
<td>10</td>
<td>4.2</td>
</tr>
<tr>
<td>Anti-hypertensive/anti-diabetics</td>
<td>7</td>
<td>2.9</td>
</tr>
<tr>
<td>Analgesics and others</td>
<td>6</td>
<td>2.5</td>
</tr>
<tr>
<td>ARVs and others</td>
<td>4</td>
<td>1.7</td>
</tr>
<tr>
<td>ARVs</td>
<td>1</td>
<td>.4</td>
</tr>
<tr>
<td>Others</td>
<td>9</td>
<td>3.8</td>
</tr>
<tr>
<td>None</td>
<td>28</td>
<td>11.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension and Diabetes</td>
<td>20</td>
</tr>
<tr>
<td>Other</td>
<td>70</td>
</tr>
<tr>
<td>None</td>
<td>147</td>
</tr>
</tbody>
</table>

4.2.4 Type of heparin used
An assessment was conducted from the retrieved data to ascertain the proportion of patients given (LMWH) and (UFH) types. It emerged that a majority were given unfractionated heparin (78%) while only a few (22%) were put on low molecular weight heparin. This is illustrated in
the Pie chart below (Figure 4.3).

![Pie chart showing heparin types](image)

**Figure 4.3: Types of heparin used in Rift Valley General Hospital**

### 4.2.5 Characteristics of heparin use

Heparin dosage changes depending on patient characteristics like weight and also depending on the outcome of a PTT test.

#### 4.2.5.1 Revision of heparin dosage

Heparin dosing is usually not standard to all the patient and is revised depending on individual patient characteristics especially the aPPT and FBC values as shown in Appendices 2 and 3. The initial aPPT should be done six hours after initiation of heparin use. Analysis on the revision of dosages was conducted to establish how many patients had their doses revised or even stopped altogether if the patient could not tolerate heparin. It emerged that 6 (2.52%) of patients had their heparin doses revised i.e. either increased or reduced. The therapeutic range of aPTT is 1.2 – 1.5 times the control as shown in Appendix 2. However, 2 (0.84%) of all the patient records examined indicated heparin was stopped. The reason for stopping heparin was indicated as pain but no further investigations were carried out/reported to ascertain the underlying problem and whether it was heparin-related.
4.2.5.2 Termination of heparin use
Correct termination of heparin should be done by introduction of warfarin at least three days prior to the cessation of heparin administration. This is to cater for the slow onset of action of warfarin. The termination of heparin use was correctly done in 69% of patients i.e. put on warfarin at least three days before stopping heparin, while the rest were not indicated if warfarin was given or not i.e. it was not reported that these patients received warfarin.

4.2.5.3 Laboratory monitoring and tests
Although laboratory monitoring was conducted, a majority of the patients (57%) did not have any tests done to monitor heparin use. Tests done included FBC (10.1%), aPTT (1.7%), INR (24.5%), a combination of FBC and INR (2.5%), aPPT and INR (3.8%), and FBC and aPPT and INR (0.4%). Table 4.7 below illustrates these findings in detail.

<table>
<thead>
<tr>
<th>Lab monitoring</th>
<th>f</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tests done</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International Normalized Ratio (INR)</td>
<td>58</td>
<td>24.5</td>
</tr>
<tr>
<td>Full blood count</td>
<td>24</td>
<td>10.1</td>
</tr>
<tr>
<td>aPPT + INR</td>
<td>9</td>
<td>3.8</td>
</tr>
<tr>
<td>FBC + INR</td>
<td>6</td>
<td>2.5</td>
</tr>
<tr>
<td>Activated Partial Prothrombin time</td>
<td>4</td>
<td>1.7</td>
</tr>
<tr>
<td>FBC + aPPT + INR</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Not Done</td>
<td>135</td>
<td>57.0</td>
</tr>
</tbody>
</table>

Analysis for an association between the diagnosis/reason for heparin use and the monitoring of heparin therapy in regard to the tests done revealed a majority of patients on heparin 135 (56.7%) did not have any laboratory tests done to monitor heparin use. Only 1 (0.4%) patient had all the relevant tests to monitor heparin use done.

A detailed breakdown of laboratory monitoring tests and diagnosis is presented in Table 4.8 below.
Table 4.8: Tests done to monitor heparin use vs. Diagnosis.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>DVT</th>
<th>Fracture</th>
<th>Other</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test done</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full blood count</td>
<td>12</td>
<td>8</td>
<td>4</td>
<td>24 (10.1)</td>
</tr>
<tr>
<td>Activated Partial Prothrombin time</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>4 (1.7)</td>
</tr>
<tr>
<td>International Normalized Ratio (INR)</td>
<td>56</td>
<td>1</td>
<td>1</td>
<td>58 (24.4)</td>
</tr>
<tr>
<td>FBC + aPTT + INR</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>FBC + INR</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>6 (2.5)</td>
</tr>
<tr>
<td>aPPT + INR</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>9 (3.8)</td>
</tr>
<tr>
<td>Not Done</td>
<td>92</td>
<td>36</td>
<td>8</td>
<td>135 (56.7)</td>
</tr>
<tr>
<td>Total</td>
<td>177 (74.4)</td>
<td>45 (18.9)</td>
<td>15 (6.3)</td>
<td>238 (100.0)</td>
</tr>
</tbody>
</table>

4.2.5.4 Adverse drug reactions (ADR)  
Information on any adverse drug reaction (ADR) was poorly reported in the files whose data was extracted. There was no information in 236 (99.2%) of all the files. The information in the other 2 (0.8%) patient files was very scanty indicating, pain as the observed complaint. No further investigations were done/reported to find out the underlying problem and whether it was heparin-related.

Predictors of heparin-induced adverse drug reactions at RVGH could not be explored due to absence of information on adverse drug reaction.
CHAPTER FIVE: DISCUSSION, CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

This Chapter describes the findings for both the audit and the descriptive cross-sectional parts of the study in line with the objectives of this study. Conclusion and the recommendations are also highlighted in this chapter.

5.1 Discussion
A tool for the conduct of regular clinical audits on heparin use was formulated and subsequently used to conduct the clinical audit of heparin use at RVGH. This was one of the expected outputs of this study.

Clinical audit of criterion 1 revealed that there were no standards or protocols of heparin use in the institution, and no protamine sulphate was available during the period of audit. It was found out during the clinical audit of heparin that the tests used for heparin use monitoring (aPTT, INR and FBC) are now all available in the RVGH starting March 2016. However, the uptake is low due to cost constraints. These findings may probably be contributed by some factors for example, lack of protamine may be due to previous expiries where it was procured but was not used leading to expiries. However, in case of any emergency such as hemorrhage, hypersensitivity reaction or HIT, the possibility of patient dying is high without protamine in the facility.

Criterion 2 revealed several gaps that may hinder appropriate heparin use. The audit established that none of the staff had ever been taken through post-qualification (in-service) training on appropriate heparin use. Also, inadequate monitoring of heparin use may be contributed by lack of guidelines, policies and protocols of heparin and the lack of training of the staff on heparin use. Inadequate staff training and the unavailability of guidelines could result in inappropriate use of heparin leading to harm or even death of patients. For improvement in the proper heparin use to be achieved, staff need to be orientated on guidelines, protocols and policies that guide heparin use. Similar findings were reported by Vikrant et al. This study was carried out in the community hospitals in the United States and it found that guidelines, protocols, or policies on use of anticoagulants are often lacking (28).
Criterion 3 revealed that some processes were closer to the required standard and need to be maintained, such as the introduction of warfarin at least three days before the cessation of heparin. However, the audit also revealed inadequate monitoring of heparin with overall criterion score of 60.6%, which may result in missing out on devastating outcomes like HIT which require close monitoring of platelet levels so as to be detected early in case it develops. The infrequent monitoring of heparin therapy has also been reported elsewhere by Baglin et al. (2006) and Quigley et al. (1988). These two are guidelines on the use and monitoring of heparin by the British Society for Haematology (British Committee for Standards in Haematology) and they acknowledge that monitoring of heparin treatment is not frequently practiced and it is often difficult to achieve (7, 26).

Criterion 4 revealed the patients are generally satisfied by the quality of care at the RVGH. The overall criterion score was 50%. This is probably because the staff is friendly, the hospital environment is generally clean and quiet. The implication of this finding may be that the patients are likely to recommend other patients to go to RVGH. Similar finding was found in Europe and the United States by Aiken et al. (2012) who established that patients were more likely to recommend other patients to a particular hospital with good hospital environment (29). However we feel that even though the staff is generally friendly, an improvement should be made on the responsiveness to patients’ calls.

A Quality Improvement plan after the audit was developed to address the gaps that were found after the audit. However, because it was not developed with consultation with the hospital management, it will be shared with the management during dissemination of the audit findings. This is important for ownership and implementation by the hospital management.

The cross-sectional part of the study revealed the majority of patients who were managed with heparin were suffering DVT or had fractures. This is in line with the indications of heparin use in the treatment and prophylaxis of DVT and PE which may result from the thrombi in circulation and subsequent death of a patient. There is adequate evidence from randomized clinical trials that indicate that prophylaxis is effective in preventing DVT and in reducing mortality from PE (27).

It was also noted that UFH is most commonly used at 78% with LMWH being utilized at 22% at RVGH. A similar finding was revealed by Makokha (2010) at Kenyatta National Hospital, Kenya.
He found that UFH was being used at 65.6% while LMWH was used at 18.3% (30). This shows that the uptake of LMWH is still low in Kenya. This might be attributed to its relatively high cost compared to UFH.

Another finding was that most patients were in addition to heparin being managed with antibiotics and analgesics. This is expected because most patients present with pain even before diagnosis is made. Antibiotics are given as a prophylaxis cover. Prophylactic administration of antibiotics inhibits growth of contaminating bacteria and thus reduce the risk of infection. Many patients were found to only have the diagnosis that led to heparin use. This is probably because, DVT (which is the major diagnosis leading to heparin use) can occur due to no apparent cause. However, more than 300 drugs are known to interact with heparin of which the interactions can either be major, moderate or minor (https://www.drugs.com/drugs-interactions/heparin.html).

According to the findings of this study, revision of heparin dose was only recorded in 2.5% of patients. This is probably because the tests that should guide dosing of heparin especially the aPTT and the FBC were rarely done at the RVGH. Heparin being a drug with a narrow therapeutic window, correct use is linked to the need for accurate laboratory control. Inadequate dosing may lead to risk of thrombo-embolic complications and higher dosing can lead to bleeding complications.

Termination of heparin use was one of the findings that was done relatively well with a relatively high percentage (69%) of patients reportedly being given warfarin at least three days before stopping heparin. This shows that the continuation of anticoagulant therapy after discharge from the hospital is relatively good although there is room for improvement. This practice should be maintained at the RVGH.

Laboratory monitoring of heparin use was found not to be optimal with a high percentage (57%) recording no laboratory results at all. This is probably because the tests were not available at the RVGH during the period of study, and sourcing privately is very expensive for most patients. This therefore meant that most patients were managed through trial and error because there were no test results that could even guide revision of heparin doses if required. Quigley et.al (26) found out that monitoring of heparin therapy is not frequently practiced. It is recommended that heparin use be monitored as shown in Appendices 2 and 3 considering that
heparin is a high risk medicine that can result even in death if not appropriately used. APTT should be performed six hours after initiation of therapy and continue being monitored at least every three days during the course of heparin therapy. Once warfarin is introduced to therapy with the intention of stopping heparin use, then INR should be conducted within six hours and then continue being monitored at least once every three days. Full blood count (FBC) should be monitored at least once every week to monitor any events that may lead to HIT.

The record of adverse drug reactions (ADR) was lacking in 99.2% of 238 files that were used for data extraction. The cross-sectional part of this study could therefore not establish the prevalence and possible determinants of heparin-induced thrombocytopenia, haemorrhage, and hypersensitivity reactions as outcome indicators of heparin use. This was because there were no records of any adverse drug reactions. However, Douglas et al. indicated that the prevalence of HIT is between 10% -30% of the patients receiving heparin in a clinical and economic review of HIT (5). This means that ADRs are likely to be occurring but going unreported at RVGH.

5.2 Conclusion
The main objective of this study which was to conduct a clinical audit at the RVGH, Nakuru was accomplished. This clinical audit for heparin use in RVGH, concluded minimal compliance to the set standards. This means that there is need to put some strategies in place to ensure use of heparin is improved and there is maximum benefit obtained. A Quality Improvement plan was developed for use by the RVGH management for this purpose. In-service training on appropriate heparin use needs to be done to HCWs in RVGH.

The cross-sectional study of heparin use revealed that heparin monitoring is not adequate at RVGH, though the process of termination of heparin therapy was relatively well done at 69%. The prevalence and possible determinants of heparin-induced thrombocytopenia, haemorrhage, and hypersensitivity reactions could not be established largely due to the absence of documented reports on adverse drug reactions following heparin use at the RVGH.

5.3 Study Limitations
Utmost effort was put to ensure the tool is comprehensive, however that there may be gaps and deficiencies in the extent and scope of questions included in this tool. This is only initial work for development of clinical audit tool for heparin. There being no other similar forms in Kenya, we hope the future versions will incorporate and build the existing initial version in scope and
questions, and incorporate both staff and management feedback and suggestions for improvement. Therefore, feedback on all aspects of the clinical audit tool for heparin will be essential in ensuring the tool ultimately meets the needs of Hospital and Health Services.

The information that was obtained by observation for the clinical audit may be biased owing to the HCW acting in a different way because of the knowledge that they are being observed. As it was expected that as data collection continued and the researcher became part of the team this limitation was be taken care of.

The data that was used for the cross-sectional part of the study was obtained from records. There was a possibility of finding incomplete data but the sample size had been adjusted upward by 10% to cater for this limitation. Some information may not be accurate which might compromise the integrity of the validity of results.

5.4 Recommendations
This section describes the recommendations for practice to improve the use of heparin so as to minimize on harm and maximize on the benefits of heparin at the RVGH. Also recommendations for future audits to ensure continuous quality improvement towards the achievement of the performance threshold/ standard targets of heparin use.

5.4.1 Recommendations for practice
It is recommended that all the staff at the institution who handle heparin at any stage of therapy should be trained on appropriate heparin use. The management should consider availing standard guidelines and protocols for heparin use and also procure the antidote protamine sulphate. All the staff especially the clinicians should be sensitized on how to identify any adverse drug reactions following heparin use and how to handle them and how to appropriately report them.

It is also recommended that the management of the RVGH will review and address any gaps that they may find in the Heparin audit tool depending on the institutional needs.

A summary of important gaps and accompanying recommendations are shown in the form of an abridged Quality Improvement Action plan (Table 5.1). It is also hoped that the management of the RVGH will go through the recommendations of the Quality Improvement Action plan and implement all the actions that will lead to heparin use quality improvement.
<table>
<thead>
<tr>
<th>Criterion</th>
<th>Area of Non Compliance</th>
<th>Corrective Action to be Taken</th>
<th>Responsible Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>There are no standard guidelines/protocols or policies on heparin use in place. Anti-dote Protamine sulphate is not available in RVGH</td>
<td>Standards/ protocols or policies to be put in place. Protamine sulphate to be procured in the hospital.</td>
<td>The hospital management</td>
</tr>
<tr>
<td>2.</td>
<td>No staff has been trained on heparin use, There are no standard guidelines/ protocols or policies on heparin use in place. Anti-dote Protamine sulphate is not available in RVGH</td>
<td>All staff involved in heparin use to be trained on its appropriate use. Standards/ protocols or policies to be put in place. Protamine sulphate to be availed in the hospital.</td>
<td>The hospital management</td>
</tr>
<tr>
<td>3.</td>
<td>LMWH- Patients weight not taken to determine doses, weight not repeated in course of treatment and renal function tests not considered. UFH- Baseline aPTT/INR not taken within 6hours of initiation of therapy, FBC not taken at least once every week</td>
<td>Take the patients weight, use it to determine the dose, repeat in the course of treatment. Consider RFTs - Baseline aPTT/INR should be taken within 6hours of initiation of therapy, FBC should be taken at least once every week</td>
<td>All prescribers, administrators and those who monitor heparin use</td>
</tr>
<tr>
<td>4.</td>
<td>HCWs do not satisfactorily respond promptly to patients calls.</td>
<td>HCWs to respond to patient call immediately</td>
<td>HCWs</td>
</tr>
</tbody>
</table>

It was noted that even with the introduction of the heparin monitoring tests at the RVGH in March 2016, it is still not accessible to many patients because of cost constraints. The management at the RVGH needs to address this gap if the heparin monitoring during therapy is expected to improve.

**5.4.2 Recommendations for Re-audit**

After the management of the RVGH implements the Quality Improvement Action plan as described above, it is recommended that a re-audit to be conducted at a period and time that will be agreed upon by the management of RVGH to complete the clinical audit cycle. A lot needs to be done to improve the quality of heparin use so as to maximize on its benefits and minimize harm.
5.4.3 Recommendations for other Health Institutions
Once the quality of heparin use is improved at the RVGH by way of clinical audit, it is recommended that other institutions will, by a way of benchmarking emulate the practice of conducting regular clinical audits.

It is also expected that clinical audit will be extended to other services offered at health institutions to ensure maximum benefits are derived from health care.

5.4.4 Recommendations for Further Studies
This study established majority of patients managed with heparin were young adults aged between 25-34 years. More studies should be conducted to establish possible causes for this finding.
REFERENCES:
22. Health Care Quality Quest Ltd. Clinical Audit Objectives, Quality. 2009; 1–7

APPENDICES

APPENDIX 1: INFORMED CONSENT PROCESS INFORMATION AND CONSENT FORM
Serial Number_____________ Version: 01 August 2015

Title of the study: Clinical audit of heparin use in Rift Valley General Hospital, Nakuru County, Kenya.

A. CONSENT EXPLANATION INFORMATION

Institution: Department of Pharmacology and Pharmacognosy, school of pharmacy, University of Nairobi, P.O BOX 30197-00400, Nairobi.

Investigator: Dr Alice NjeriGichobi P.O BOX 1214- 20100, Nakuru. Mobile 0725820525

Supervisors: Dr E. M Guantai, Dr K. A Sinei and Dr S. Ndwigah, School of Pharmacy, University of Nairobi

Ethical Approval
Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee, P.O Box 20723-00100, Nairobi. Tel 2726300/2716450 Ext 44102

Permission is sought from you to enroll in this clinical audit. You should understand the following general principals which apply to all participants in a medical research:

I. Your agreement to participate in this study is voluntary.

2. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.

3. After you have read the explanation please feel free to ask any questions that will enable you to understand clearly the nature of the study.

Introduction: In this Clinical audit, I wish to assess the extent of adherence to protocols, standards and guidelines in heparin use process.
**Purpose of the study:** To identify areas in heparin use process that may be contributing to heparin use medication errors and to identify strategies to mitigate them for maximal benefit in heparin use. The processes that are being carried out exceptionally well will also be identified and will be maintained.

**Procedure to be followed:** With your permission, I will administer a brief questionnaire seeking to find out your role in heparin use process and competency. All information will be handled with confidentiality.

**Risks:** There will be minimal risk involved in this study and there will be no physical or otherwise harm to you during the study. However, there may be some psychological and emotional risk associated with information disclosure by you. This will be minimized or completely eradicated by the investigator by upholding confidentiality strategies. Only the principal investigator will handle the primary data that may have some elements of your direct identifiers. However no information collected will bear your name in it. Any other research assistants involved in data entry and analysis will handle the secondary data that will be delinked from the primary data.

**Benefits:** There will be no direct benefits to you but the findings will be useful in improving the quality of care offered to the patients. This in turn will ensure maximum benefits will be obtained from heparin use ensuring minimal harm to the patients.

**Assurance of Confidentiality:** All information obtained from you will be kept in confidence. At no point will your name be used or mentioned during data handling or in any resulting publications. Serial numbers will be used instead of names.

**Contacts:** In case you need to contact me, my academic department or the Kenyatta National Hospital/University of Nairobi Ethics and Research committee concerning this study please feel free to use the contacts provided above.

I now request you to fill the attached consent form.

**B. PARTICIPANT CONSENT FORM**

I have understood the information on the consent form. I have had a chance of discussing the research study with the investigator and I have had my concerns addressed. The risks and benefits
have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I will receive a copy of this signed consent document to take away and keep.

Name and signature of study participant __________________ Date________________

INVESTIGATOR DECLARATION

I have explained the information in this document to this participant and encouraged him/her to ask questions which I will take time to answer. I am satisfied that the participant adequately understands all aspects of the research as discussed in the consent process information document above.

Name and Signature of investigator ____________________________ Date__________

Contacts:

Investigator: Dr. Alice Gichobi, P.O. Box1214-20100, Nakuru. Mobile +254 725820525.

ERC: Secretary, Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee, P.O. BOX 20723-00100, Nairobi. Tel 2726300 / 2716450 Ext 44102
FOMU YA KUIDHINISHA UTARATIBU WA KUKUSANYA UJUMBE NA MAAFIKIANO

Nambari ya usajili____________mtindo: 01 ___________ Agosti, 2015

Mada ya utafiti: Kudhibiti utumiaji wa dawa ya heparini kulingana na mikakati iliyowekewa katika hospitali ya rufaa ya kaunti ya Nakuru, Kenya.

A. Ujumbe wa kuidhinisha maelezo

Chuo: Idara ya famakolojia na famakognsia, chuo cha famasia behewa la Nairobi, SLP 30197-00400, Nairobi.


Tunakuomba ruhusa kwako ili ujisajili katika utafiti huu. Unafaa kuelewa mambo yafuatayo ya kimsingi yanayofaa kuzingatiwa na washiriki wote.

i. Mwitikio wako wa kushiriki katika utafiti hu ni wa hiari.

ii. Unaweza kujitokwa kutoka kwa utafiti huu wakati wowote pasipo kuhitajika kutoa sababu za kuchukua.

iii. Baada ya kufanya maelezo tafadhali, una uhuru wa kuuliza maswali yoyote yatakayokuwezesha kuelewa vizuri aina tofauti.

Utangulizi: Katika utafiti huu, natathmini kama dawa ya heparini inatumika kadiri ya mikakati iliyowekewa katika hospitali ya rufaa ya kaunti ya Nakuru.

Lengo la utafiti: Lengo la utafiti huu ni kujua ni katika daraja gani utumiaji wa dawa ya heparini haujaifiki kiwango kinachotajika ambacho husababisha matokeo mabaya. Mahala hii dawa hutumika vizuri pia patapelelezwa na umuhimu wake uhimizwe katika hospitali ya rufaa ya kaunti ya Nakuru.

Utaratibu: Kwa ruhusa yako, nitakuruhusu katika mjadala kuhusu maoni yako kuhusu jukumu lako katika utumiaji wa dawa ya heparini na vile umehitimu. Ujumbe wote utashughulikiwa kwa siri.

Umuhimu: Hakutakuwa pesa zozote zitakazotolewa ama faida ya moja kwa moja. Hata hivyo matokeo yatasaidia kuboresha utunzaji wa wagonjwa wanaohitaji kutumia dawa ya heparini.


Mawasiliano: Iwapo ungetaka kuwasiliana nami, ama hospitali kuu ya Kenyatta chuo kikuu cha Nairobi maadili na kamati ambayo imeniruhusu kufanya utafiti huu, kuwa huru na utumie nambari za mawasiliano zilizorodheshwa kwenye fomu hii.

B. FOMU YA IDHINI YA MSHIRIKI


Nitapokea nakala ya fomu hii iliyotiwa sahihi.

Jina na sahihi ya mshiriki wa utafiti _______________________________ tarehe ____________

MIADI YA MTAFITI

Nimeeleza ujumbe katika fomu hii kwa mshirika huyu na nimeemta moyo ili aulize maswali ambayo nitachukua wakati kuyajibu. Nimetosheleza kila mshirika kabisa na naelewa vipengee vyote vya utafiti kama ilivyoelezwa katika fomu ya kudhibitisha ruhusa hapo juu.

Jina na sahihi ya mtafiti _______________________________ Tarehe __________

MAWASILIANO

APPENDIX 2: INTRAVENOUS THERAPEUTIC DOSE HEPARIN GUIDELINES FOR ADULTS AND HEPARIN PROTOCOL

Therapeutic range for APTT is 30 to 40 seconds

Adult Loading Dose: 5000units Sodium Heparin by IV bolus (If for use in conjunction with tenecteplase and patient weighs less than 67kg, the bolus dose should be reduced to 4000units)

Maintenance Dose: Dosage is based on body weight at 20units/kg/hr

Always use Sodium Heparin at a concentration of 25,000units made up to 50ml with Sodium Chloride 0.9%

Suggested starting rates:

<table>
<thead>
<tr>
<th>Patient weight (Kg)</th>
<th>Heparin required (Units/ hr)</th>
<th>Flow rate (heparin sodium 25,000 units made to 50ml with sodium chloride 0.9%) (ml/ hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>800</td>
<td>1.6</td>
</tr>
<tr>
<td>50</td>
<td>1,000</td>
<td>2.0</td>
</tr>
<tr>
<td>60</td>
<td>1,200</td>
<td>2.4</td>
</tr>
<tr>
<td>70</td>
<td>1,400</td>
<td>2.8</td>
</tr>
<tr>
<td>80 or more</td>
<td>1,600</td>
<td>3.2</td>
</tr>
</tbody>
</table>

MONITOR

On initiation of infusion check aPTT ratio after 4 to 6 hours (during normal working hours only). Thereafter check aPTT ratio daily (to keep between 1.5 and 2.5) and adjust as shown in the table below according to aPTT ratio.
ADJUSTMENT OF I.V. HEPARIN DOSE

<table>
<thead>
<tr>
<th>aPTT Ratio</th>
<th>Infusion rate change</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;7.0</td>
<td>Stop for 30min – 1hr and reduce by 500 units/ hr (1ml/ hr)</td>
</tr>
<tr>
<td>5.1 -7.0</td>
<td>Reduce by 500 units/ hr (1ml/ hr)</td>
</tr>
<tr>
<td>4.1 -5.0</td>
<td>Reduce by 300 units/ hr (0.6ml/ hr)</td>
</tr>
<tr>
<td>3.1 -4.0</td>
<td>Reduce by 100 units/ hr (0.2ml/ hr)</td>
</tr>
<tr>
<td>2.6 -3.0</td>
<td>Reduce by 50 units/ hr (0.1ml/ hr)</td>
</tr>
<tr>
<td>1.5 -2.5</td>
<td>No change</td>
</tr>
<tr>
<td>1.2 -1.4</td>
<td>Increase by 200 units/ hr (0.4ml/ hr)</td>
</tr>
<tr>
<td>&lt;1.2</td>
<td>Increase by 400 units/ hr (0.8ml/ hr)</td>
</tr>
</tbody>
</table>

After each change wait about 10 hours before next aPTT unless ratio is greater than 5 when checks should be made every 4 hours.

The full blood count must be checked every week when a patient is on any kind of heparin therapy as there can be a rare but unpredictable development of heparin antibodies with life-threatening thrombocytopenia.

**Heparin protocol**

<table>
<thead>
<tr>
<th>Standard range PTT</th>
<th>Intervention</th>
<th>Cardiac range PTT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal ptt 57-84 (sec)</td>
<td>↑3 units/kg/h</td>
<td>goal ptt 57-70 (sec)</td>
</tr>
<tr>
<td>&lt;45</td>
<td>↑1 unit/kg/h</td>
<td>&lt;45</td>
</tr>
<tr>
<td>45-56</td>
<td>No change</td>
<td>45-56</td>
</tr>
<tr>
<td>57-84</td>
<td>↓1 unit/kg/h</td>
<td>57-70</td>
</tr>
<tr>
<td>85-100</td>
<td>Hold 30 min ↓2 units/kg/h</td>
<td>71-85</td>
</tr>
<tr>
<td>101-150</td>
<td>Hold 60 min ↓3 units/kg/h</td>
<td>86-135</td>
</tr>
<tr>
<td>&gt;150</td>
<td>Hold 30 min ↓3 units/kg/h</td>
<td>&gt;135</td>
</tr>
</tbody>
</table>

PTT: Partial thromboplastin times. Heparin infusion protocol, initial rate 16 units/kg/h, if obese or morbidly obese initial rate 12 units/kg/h.
**APPENDIX 3: HEPARIN INFUSION GUIDELINES**

UW Medicine Standard Protocols – Initiation Dosing

1. Order standard heparin infusion with starting rate defaulted based on indication

2. Order Loading Bolus, if warranted

3. Order Goal PTT (Regular intensity: 60-100 seconds; Low intensity: 60-80 seconds)

4. Order PRN rebolus for sub-therapeutic PTT, if warranted

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>LOADING BOLUS (maximum 10,000 units)</th>
<th>INITIAL INFUSION RATE</th>
<th>PRN RE-BOLUS FOR LOW PTT (maximum 5000 units)</th>
<th>FIRST PTT CHECK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Thrombosis Treatment (eg: DVT/PE)</td>
<td>80 units/kg</td>
<td>18 units/kg/hr</td>
<td>PTT 50-59: 25 units/kg</td>
<td>6 hours after starting infusion</td>
</tr>
<tr>
<td>Atrial Fibrillation, Valve Replacement, Peri-operative Bridging, Other</td>
<td>70 units/kg</td>
<td>15 units/kg/hr</td>
<td>PTT &lt; 50: 50 units/kg</td>
<td></td>
</tr>
<tr>
<td>Acute Coronary Syndrome</td>
<td>50 units/kg</td>
<td>12 units/kg/hr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Ischemic Stroke</td>
<td>none</td>
<td>12 units/kg/hr</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 4: DATA EXTRACTION FORM FROM PATIENT RECORDS FOR THE CROSS-SECTIONAL ARM OF THE STUDY.

STUDY TITLE: CLINICAL AUDIT OF HEPARIN USE IN RIFT VALLEY GENERAL HOSPITAL, NAKURU COUNTY, KENYA

Serial Number_________      Date of Data Collection_____________ Version: 01 AUGUST 2015

A. BIODATA

1. Patient code: ______________

2. Age: _________________

3. Gender: _____________________

B. PATIENT MEDICAL RECORD REVIEW

1. Admission Diagnosis ______________

2. Duration of complaint_______________

3. What type of heparin was prescribed? UFH [ ]          LMWH [ ]

4. Current Medication

<table>
<thead>
<tr>
<th>Date prescribed</th>
<th>Medication Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Include dose, frequency, route of administration and duration of treatment)</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>
5. Summary of Medical History

   a. Hypertension [ ] Other [ ] (state comorbidity)_________ None [ ]

   b. Has heparin dosing been revised? Yes [ ] No [ ]

   c. How was heparin termination done?

   __________________________________________

   d. Was protamine sulphate used on this patient? Yes [ ] No [ ]

   e. Did the patient experience any adverse reaction following use of heparin? Yes [ ] No [ ]

   f. If yes in (e above), what was the complication?

       HIT [ ] Hemorrhage [ ] Hypersensitivity reaction [ ]

       Other (explain):_____________________________________________

   g. Does the patient who experienced any adverse reaction have any history of bleeding? Yes [ ] No [ ]

6. Summary of Laboratory Data (Full blood count, aPTT or INR)

   a. What is the frequency of heparin use monitoring? __________________________

   b. What are the actual laboratory tests results recorded
APPENDIX 5: AUDIT TOOL FOR HEPARIN USE IN ADULT IN-PATIENTS

CLINICAL AUDIT TOOL FOR HEPARIN USE FOR ADULT IN-PATIENTS

Version 001 (July 2016)

SECTION 1: GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Ward /health services provided:</th>
<th>Facility name and code:</th>
<th>Date/ Audit Period:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department /Unit:</td>
<td>Patient No/ HCW No.:</td>
<td></td>
</tr>
<tr>
<td>Data Collector (Clinical Auditor):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**General Instruction:**

- Data will be collected prospectively or retrospectively from existing records as the case may be.
- Use one clinical audit tool per patient or Health care worker audited.
- Facilities should determine the audit questions that are relevant to their situation / health services for review.
- Some questions may not be applicable (e.g. at a ward/ dept. level) and can be adjusted accordingly to suit individual requirements.

*Scores: Yes = 10, No = 0, N/A = doesn’t count in final score.*

This clinical audit tool consists of six sections each with a specific function. All the sections should be filled in correctly and fully.

We recognize and appreciate that there may be gaps in the scope and questions included in this tool. However, as this is the first version of the tool, and future versions will build upon the existing scope and questions, and incorporate staff feedback and suggestions for improvement. Feedback on this audit tool and the measurement plans is therefore encouraged, to ensure the tool meets the needs of Hospital and Health Services. Feedback should be forwarded to the chairperson of the Institutional Research Committee.
SECTION 2: STANDARDS FOR HEPARIN USE IN ADULT IN-PATIENTS
Performance threshold/standards are the minimum acceptable performance standards or the maximum allowable limits. The threshold values act as checkpoints and help in monitoring the performance of a particular criterion by providing a benchmark value.

<table>
<thead>
<tr>
<th>Audit Criteria</th>
<th>Standard/Threshold</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Structural features</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are adequate supporting structural features in the organization to enable safe use of heparin. See section 3, Criterion 1</td>
<td>100%</td>
<td>Structural features should be adequate to allow safe use of heparin</td>
</tr>
<tr>
<td><strong>Competent staff</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are sufficient competent persons to provide appropriate heparin use service. See section 3, Criterion 2</td>
<td>100%</td>
<td>All staff handling heparin should be competent to avoid errors</td>
</tr>
<tr>
<td><strong>Safe use of heparin</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper precautions are taken to ensure that patients requiring heparin are prescribed, administered and monitored appropriately. See section 3, Criterion 3</td>
<td>100%</td>
<td>No inefficiencies are allowed during prescribing, administration and monitoring of heparin</td>
</tr>
<tr>
<td><strong>Patient satisfaction on quality of care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients are happy with the care that they receive in the institution See section 3, Criterion 4</td>
<td>80%</td>
<td>Some patients may not be able to respond and caregivers may not be present</td>
</tr>
</tbody>
</table>

SECTION 3: AUDIT DATA COLLECTION TOOL
This section contains the criteria used to perform the audit. There are four criteria each of which consists specific questions to assess heparin use in an institution.

**Instruction:**
- Use one clinical audit tool per patient or Health care worker audited.
- Facilities should determine the audit questions that are relevant to their situation / health services for review.
- Some questions may not be applicable (e.g. at a ward/ dept. level) and can be adjusted accordingly to suit individual requirements.

**CRITERION 1: Structural features**
This section examines the adequacy of supporting structural features in the organization to enable safe use of heparin.
Source of data and specific instruction: Data to be extracted from physical check in the pharmacy, laboratory, wards, Health Management information System (HMIS) and the human resource department (HRD). The auditor may seek the help of a staff in the relevant departments for guidance.

NOTE: Only one form to be used for this section.

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Are there protocols, policies and guidelines for heparin use?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>1.2 Are the following staff available in your facility per cadre?</td>
<td></td>
</tr>
<tr>
<td>i. Consultants</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>ii. Medical Officers</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>iii. Pharmacists</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>iv. Clinical Officers</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>v. Nursing Officers</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>vi. Pharmaceutical technologists</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>vii. Laboratory technologists</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>1.3 Are laboratory reagents available for performing relevant tests?</td>
<td></td>
</tr>
<tr>
<td>FBC</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>aPTT</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>INR</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>1.4 Is Protamine Sulphate available in the Pharmacy/service user areas?</td>
<td>Yes [ ] No [ ]</td>
</tr>
</tbody>
</table>

CRITERION 2: Competent staff
This section examines if there are sufficient competent persons to provide appropriate heparin use service.

Source of data and specific instruction: Data to be obtained from interviewing the Health care workers. The staff to be interviewed are those that handle heparin at any point during prescribing, dispensing, administration or monitoring.

NOTE: One form for each staff interviewed.
<table>
<thead>
<tr>
<th>QUESTION</th>
<th>RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 What is your cadre?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physician/ Consultant [ ]</td>
</tr>
<tr>
<td></td>
<td>Medical officer [ ]</td>
</tr>
<tr>
<td></td>
<td>Med. Officer intern [ ]</td>
</tr>
<tr>
<td></td>
<td>RCO [ ]</td>
</tr>
<tr>
<td></td>
<td>CO Intern [ ]</td>
</tr>
<tr>
<td></td>
<td>Nursing Officer [ ]</td>
</tr>
<tr>
<td></td>
<td>Pharmacist [ ]</td>
</tr>
<tr>
<td></td>
<td>Other [ ]</td>
</tr>
<tr>
<td>2.2 How many years have been in service?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5 Years [ ]</td>
</tr>
<tr>
<td></td>
<td>5-10 Years [ ]</td>
</tr>
<tr>
<td></td>
<td>&gt;10 Years [ ]</td>
</tr>
<tr>
<td>2.3 Have you ever been trained on heparin use?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td>2.4 If yes in Q 2.3, which specific area were you trained on?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prescribing [ ]</td>
</tr>
<tr>
<td></td>
<td>Dispensing [ ]</td>
</tr>
<tr>
<td></td>
<td>Administration [ ]</td>
</tr>
<tr>
<td></td>
<td>Monitoring [ ]</td>
</tr>
<tr>
<td>2.5 Do you have any protocols/ standards or guidelines in place for heparin use?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td>2.6 If yes in Q 2.5, which specific resources do you use?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1) _____________</td>
</tr>
<tr>
<td></td>
<td>2) _____________</td>
</tr>
<tr>
<td>2.7 Do you have antidote Protamine Sulphate available to you when using heparin?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td>2.8 How do you monitor heparin therapy? aPTT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td></td>
<td>INR [ ]</td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td></td>
<td>FBC [ ]</td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td>2.9 How often do you monitor FBC for HIT?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td></td>
<td>Weekly [ ]</td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td></td>
<td>After every two weeks [ ]</td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
<tr>
<td></td>
<td>Never [ ]</td>
</tr>
<tr>
<td></td>
<td>Yes [ ]</td>
</tr>
<tr>
<td></td>
<td>No [ ]</td>
</tr>
</tbody>
</table>

**CRITERION 3: Safe use of heparin**

Proper precautions are taken to ensure that patients requiring heparin are prescribed, administered and monitored appropriately.

*Source of data and specific instruction:* Data to be obtained from observation of processes during heparin use. Further information to be obtained from the patient files.
<table>
<thead>
<tr>
<th>QUESTION</th>
<th>RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 What type of heparin was prescribed?</td>
<td>[ ] UFH [ ] LMWH</td>
</tr>
<tr>
<td>3.2 For LMWH, was patient weight taken before start of therapy?</td>
<td>Yes [ ] No [ ] N/A [ ]</td>
</tr>
<tr>
<td>3.3 Was patient weight repeated in the course of treatment?</td>
<td>Yes [ ] No [ ] N/A [ ]</td>
</tr>
<tr>
<td>3.4 Was the patient’s weight used as the basis for calculating the treatment dose with LMWH?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>3.5 Was renal function considered during prescribing treatment dose with LMWH?</td>
<td>Yes [ ] No [ ] N/A [ ]</td>
</tr>
<tr>
<td>3.6 For UFH, were APTT/INR done 6hours after initiation of treatment?</td>
<td>Yes [ ] No [ ] N/A [ ]</td>
</tr>
<tr>
<td>2.7 Were APTT/INR repeated 3 days after initiation of therapy?</td>
<td>Yes [ ] No [ ] N/A [ ]</td>
</tr>
<tr>
<td>2.8 Was FBC checked at least once every week?</td>
<td>Yes [ ] No [ ] N/A [ ]</td>
</tr>
<tr>
<td>2.9 Was heparin use continued for at least 4 days after the initiation of warfarin?</td>
<td>Yes [ ] No [ ] N/A [ ]</td>
</tr>
</tbody>
</table>

**CRITERION 4: Patient satisfaction on quality of care**

Majority of patients are happy with the care that they receive in the institution.

*Source of data and specific instruction:* Data to be obtained from interviewing the patients (Q4.1 to Q4.3) and patient files (Q4.4 & Q4.5). Where the patient cannot be able to respond to questions and a caregiver is available then the question can be directed to the caregiver.

*NOTE:* One form to be used for one patient
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Are Health Care Workers (HCW) friendly to you?</td>
<td>Yes [ ] No [ ] Not sure[ ]</td>
</tr>
<tr>
<td>4.2</td>
<td>Do Health Care Workers (HCW) answer to your call promptly?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>4.3</td>
<td>What do you feel about the overall quality of care?</td>
<td>Satisfied [ ] Not satisfied [ ] Don’t know [ ]</td>
</tr>
<tr>
<td>4.4</td>
<td>Were there any adverse effects following heparin use that is recorded?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>4.5</td>
<td>If Yes in 4.3, were there investigations done to confirm if heparin was the cause?</td>
<td>Yes [ ] No [ ]</td>
</tr>
</tbody>
</table>

**SECTION 4: CRITERION SCORING SUMMARY SHEET**

**Scoring instructions:** Scores: Yes = 10, No = 0, N/A = doesn’t count in final score. A score of ten is assigned to every Yes answer and a score of zero to every No answer. In case the answer is not applicable, then there is no score assigned and that particular question will not apply when computing the final criterion score.

The Actual Criterion Score is obtained by adding up all the Yes answers multiplied by 10
<table>
<thead>
<tr>
<th>Criterion</th>
<th>Actual Criterion Score (AC)</th>
<th>Maximum Criterion Score (MC)= Total Number of Questions x Maximum Score (10)</th>
<th>Criterion Score as a percentage= (AC/MC x 100/1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall audit = (∑ AC/ ∑MC)* 100

Use the guide below to help in the interpretation of audit results as per NICE guidance.

**Performance threshold/ Standard at 100%**

- **Full compliance**: 90% x 100%
- **Partial compliance**: 70% x<89%
- **Minimal compliance**: x < 69%

**Performance threshold/ Standard at 80%**

- **Full compliance**: 72% x 80%
- **Partial compliance**: 56% x<71%
- **Minimal compliance**: x < 55%

**Interpretation of the Level of Compliance with the set Performance Threshold**
### SECTION 5: CRITERION ASSESSMENT PER SET STANDARDS

<table>
<thead>
<tr>
<th>CRITERION</th>
<th>PERFORMANCE THRESHOLD (%)</th>
<th>OBSERVED (%)</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  There are adequate supporting structural features in the organization to enable safe use of heparin.</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2  There are sufficient competent persons to provide appropriate heparin use service.</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3  Proper precautions are taken to ensure that patients requiring heparin are prescribed, administered and monitored appropriately.</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4  Patients are happy with the care that they receive in the institution</td>
<td>80%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### SECTION 6: QUALITY IMPROVEMENT ACTION PLAN

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Area of Non Compliance</th>
<th>Corrective Action to be Taken</th>
<th>Responsible Person</th>
<th>Timeframe</th>
<th>Review of Implementation of Action (Audit)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

We acknowledge the following sources of information in aid in the development of this clinical audit tool for heparin use.

APPENDIX 6: KNH-UON ERC APPROVAL LETTER

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P. O. BOX 19766 Code 0202
Tel./Fax: 272000 Ext 44355

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723 Code 00202
Tel: 726300-9
Fax: 726301
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/48

Alice Njeri Gichobi
Reg. No. U61/75080/2014
Dept. of Pharmacology and Pharmacognosy
School of Pharmacy
College of Health Sciences
University of Nairobi

4th February, 2016

Dear Alice,

Revised research proposal: Clinical Audit of Heparin Use in Rift Valley General Hospital, Nakuru County, Kenya (P644/10/2015)

This is to inform you that the KNH-UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above proposal. The approval period is from 4th February 2016 – 3rd February 2017.

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 24 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 24 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
Yours sincerely,

[Signature]

PROF. J. C. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
     The Deputy Director, CS, KNH
     The Chair, KNH-UoN ERC
     The Assistant Director, Health Information, KNH
     The Dean, School of Pharmacy, UoN
     The Chair, Dept of Pharmacology and Pharmacognosy, UoN
     Supervisors: Dr. Eric E. Guantai, Dr. K.A. Sinei, Dr. S. Ndiwigah