BLOOD TRANSFUSION IN ELECTIVE ORTHOPAEDIC SURGERIES AT THE KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF MEDICINE DEGREE IN ORTHOPAEDIC SURGERY,

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DECLARATION

I declare that this dissertation is my original work and that it has not been submitted for a degree award in any university.

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DEDICATION

To my parents Mr Bernard kirii and Mrs Regina Kirii for raising me with devotion and affection

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LIST OF ABBREVIATION

ABO-blood group systems
C-reactive protein
Estimated Blood Loss
Enzyme linked immunosorbent assay
Hepatitis B virus
Hemoglobin
Hematocrit
Human immunodeficiency virus
Hemolytic transfusion reaction
Intensive care unit
Interleukin 1
Interleukin 6
Interleukin 8
Kenyatta National Hospital
National Aids & STI control programme
Open Reduction and Internal Fixation
Polymerase chain reaction
Packed cell volume
Systematic inflammatory response syndrome
Statistical Package for the Social Services
Transfusion associated sepsis
Tumor necrosis factor

- TRALI Transfusion Related Acute Lung Injury.
- TRICC Transfusion requirement in critical care
- UON University of Nairobi
- WHO World health organization

ABSTRACT

Introduction

Blood transfusion can be a life saving intervention. However if given when it is not necessary, the patient receives no benefit and is exposed to unnecessary risk. Many of the patients undergoing major elective orthopaedic surgeries are cross matched and transfused despite having an adequate pre-operative hemoglobin level. Some degree of blood loss can be incurred provided the loss is replaced with intravenous fluid to maintain normovolemia before blood transfusion becomes necessary. The patient hemoglobin though important should not be the sole deciding factor of initiating transfusion. This study is to assess the number of patients that get transfused during elective orthopaedic surgeries, and if the transfusions are rational and not just based on clinical acumen.

Objective: To evaluate the rationale for blood transfusion in patients undergoing elective orthopaedic surgeries at the Kenyatta National Hospital

Design: cross sectional descriptive study

Study setting: The orthopaedic wards, orthopaedic theatres and the blood transfusion unit at the KNH.

Study population: All patients over the age of 12 years undergoing elective orthopaedic surgery at the KNH

Methodology: The patients' demographic data, medical history and physical examination findings was recorded in a patient proforma. Total blood loss of patients undergoing various orthopaedic surgeries was assessed and calculated by measuring the blood soaked swabs, measuring the weight of blood in the suction bottle and estimating the amount of blood that had spilt on the floor. The allowable blood loss was also assessed, this will be compared to the amount of intravenous fluid the patient has received. A pre transfusion hematocrit was done and the amount of blood that was transfused was noted. Patients that were transfused were assessed to determine if the transfusions were rational or irrational.

Data collection: The allowable blood loss was calculated using the hemodilution method (Appendix I). Blood loss was calculated by weighing blood soaked gauze swabs

measuring the weight of blood in the suction bottle and estimating the amount of blood on the floor. The amount of intravenous fluid was recorded and monitoring of the patients pulse rate, blood pressure and urine output was done

Results: A total number of 80 patients were assessed. Male comprised a higher percentage (66.3%) compared to females 33.7%. patients that were transfused were put in four categories including trauma, spine arthoplasty and tumors. Patients that had comminuted fractures were associated with more blood loss with a mean of 1325.55ml compared to patients who had simple fractures (570.27ml). Patients operated after six weeks also lost more blood (1148ml) compared to patients operated earlier. Patients who were operated using general anesthesia lost more blood (1248 ml) compared to those that received spinal anesthesia. This is probably attributable to the hypotensive effect spinal anesthesia has. Surgeries that diathermy was used lost less blood (1071ml) compared to no diathermy (1818ml). Most of the patients that were transfused only received one pint of blood. This contributed about 76 % of the patients in the study. Of those transfused 35% were irrationally transfused according to the WHO criteria.

Conclusion and Recommendation;

Of all the patients who received blood transfusion during the study period only 65 % required blood by the WHO criteria. 35% were transfused irrationally. The risk of disease transmission especially during the window period is quite high and transfusion should be avoided unless necessary. The cost also of preparing a pint of blood is quite high and also technically demanding. Thus blood that is available should be used only when absolutely necessary.

The WHO criteria for blood transfusion during surgery should be adapted and implemented for patients undergoing elective orthopaedic surgeries at Kenyatta National Hospital

INTRODUCTION

Allogenic blood transfusion refers to the use of another individual's blood to meet the need of a patient. There are procedures for donor selection and screening which minimize the chances of patients with contaminated blood. All blood should be screened for HIV 1 and 2, Hepatitis B and treponema pallidum¹.

Transfusion has been in clinical use for over fifty years and has become an indispensable part of modern medical practice especially to allow ever increasing aggressive therapy in older, sicker and debilitated patients².

Approximately fourteen million units of whole blood is collected and transfused each year predominantly red cell units seen mostly in the west while whole blood is what is used mostly in Africa and developing countries^{3,4}.

With the emerging risks associated with transfusion, economic consequences and few proved benefits, new and gathering evidence is beginning to be created to answer controversial questions about transfusion. Yet in spite of long standing and well entrenched beliefs on the benefits of blood transfusion very few well conducted studies are available to support existing clinical practice guidelines^{1,4,5}.

However, despite advances to ensure that blood is safe, it is never completely without risk ⁷. The probability of window period infection is very high in endemic area .The window period for ELIZA is six weeks; for western blot three to four weeks and for PCR is two to three weeks⁸. ELIZA and western blot still remain the preferred method of screening in the developing countries. In addition, blood is associated with incompatibility reactions, other infections such as malaria, coagulopathies and hypothermia during transfusion.

In Canada, the total number of people infected with HIV in the year 2002 was 56000. The total new cases in the same year were 5200. The population of Canada in that year was 32,805,041 people. The residual risk for HIV in blood donors was found to be 0.38%. Screening was by PCR method. In most of the developing countries screening is done by the ELIZA method, which has a longer window period, one can draw a conclusion that residual risk for HIV in blood donors is much higher⁹.

In most orthopaedic surgeries, blood loss is characterized by slow continuous hemorrhage characteristic of muscle stripping, subperiosteal dissection and osteotomy¹⁰. Blood loss is however minimized by meticulous surgical technique which is perfected by training and experience, positioning the patient to encourage free venous return at the operation site and use of diathermy. Good anesthetic technique reduces episodes of hypertension and tachycardia due to sympathetic over activity by ensuring adequate analgesia and anesthesia. Regional and spinal anesthesia is associated with less blood loss¹⁰.

The patients hemoglobin, although important should not be the sole deciding factor in starting transfusion. Some degree of blood loss can be incurred before blood transfusion becomes necessary, provided that the loss is replaced with intravenous fluid to maintain normovolemia. The decision should be supported by the need to relieve symptoms and prevent morbidity and mortality¹.

Over-ordering of blood for elective surgeries is a common practice. This can be decreased by changing the blood cross-matching and ordering schedule. The ready availability of blood and blood components has resulted in liberal use of blood transfusions. The increasing demand for blood and blood products together with rising costs and transfusion associated morbidity led to a number of studies in the late 1970s reviewing blood ordering and transfusion practices. These studies showed gross over- ordering of blood much in excess of actual or anticipated needs. Many units of blood routinely ordered by surgeons and anesthetists are not utilized but are held in reserve and thus are unavailable for other needy patients. This can impose inventory problems for blood bank, loss of shelf life and wastage of blood. Recently there has been a growing demand for blood and blood products. This demand has often exceeded the resources of the local blood bank and thereby disrupting both the planning and nature of surgical lists¹¹.

Elective surgery commits valuable supplies and resources both in technician time and reagents by demanding large quantities of blood each day. The criteria for ordering blood are often vague and established policies, where they exist, may be outdated since the amount transfused for a given procedure has fallen over the years as surgical and anesthetic techniques evolve. There also exists considerable variability in perioperative transfusion practices. The decision to transfuse should be determined by concerns for tissue oxygenation. Other factors such as to accelerate wound healing and to promote graft uptake are often quoted without a sound scientific basis. Rarely, if ever, is a pre-transfusion haematocrit test performed to aid in the decision to transfuse and rarely is there a post- transfusion haematocrit. Single unit transfusions are still quite common despite evidence that they are seldom necessary¹².

PATHOPYSIOLOGY

Under normal circumstances, the oxygen delivery to the tissues is 1000ml per minute and the oxygen consumption is 200ml per minute, hence the ratio of oxygen delivery to oxygen consumption is 5:1 and only 20% of the delivered oxygen is extracted leaving behind a mixed venous oxygen saturation of $80\%^{13}$.

In patients with anemia, hypoxia or myocardial infarction in whom the oxygen cannot be increased and in whom the consumption is increased, this 5:1 ratio will fall with the patient using up the inherent oxygen reserves. This scenario persists until the ratio falls to 2:1 up to which level the patient still remains stable.

The transfusion is only required when oxygen consumption is supply dependant and with aggressive hemodynamic and ventilator management only few patients will reach this critical threshold¹³.

Thus, the recommendation to transfuse a patient must focus on the compensatory ability of the patient and the physiologic parameters and not on the pack cell volume (PCV) as is the general case. Transfusion therefore is only necessary when patients cannot compensate for their anemia.

When the compensatory mechanisms are normal with adequate oxygen delivery it may not be necessary to transfuse patients until their PCV drops below 16 % (Hb 5.3) and in patients with poor compensatory mechanism transfusion is only advised when the PCV drops below 25% (Hb 8.3)^{13,14}.

Thus, physiologically, transfusion indicator specific to procedures/surgical specialties' does not make much sense and patients must only be transfused when absolutely necessary¹⁴.

IMPACT OF THE STUDY IN AFRICA AND KENYA

HIV/AIDS in Kenya is an epidemic with an estimate of 1.5 million people living with HIV and around 1.2 million children having been orphaned by AIDS as per 2009 NASCOP survey¹⁵.

Current prevalence of HIV is recorded to be on the decrease at approximately 7% of the Kenyan population with most transmissions still being through sexual intercourse and incidences of blood transfusion transmissions still being noted. Thus preventing unnecessary transfusions should still be advocated for. There is an estimated 250,000 new infections per year as a result of reuse of needles and syringes and approximately 200-500 people are newly infected with HIV as a result of unsafe blood transfusions.

Testing/screening of blood is essential but remains absent in many low and middle income countries.

The majority of new HIV infections in Kenya occur among young people especially young women between the ages of 15 and 24 years and young men under the age of 30 years with the first sexual contact averaging 15 years in women and 18 years in men. This is still the same age group that contributes to major blood donors especially in schools¹⁵.

Jayaraman et al published the results of a mathematical model predicting viral transmission by blood transfusion in Africa. They modelled 45 sub Saharan countries and estimated the prevalence of disease, the extent of testing, the accuracy of testing, and the susceptibility of recipients. They reported that "The median overall risks of becoming Infected with HIV, HBV, and HCV from a blood transfusion in sub-Saharan Africa were 1, 4.3 and 2.5 infections per 1000 units, respectively. If annual transfusion requirements projected by the WHO were met, transfusions alone would be responsible for 28,595 HBV

infections, 16,625 HCV infections, and 6650 HIV infections every year¹⁶.

Blood is an expensive and scarce commodity, it costs approximately 30 to 40 dollars to prepare one unit and there are few willing donors. Some of the blood collected incurs disposal costs if found to be unsuitable for transfusion. This calls for judicious use of blood.

LITERATURE REVIEW

According to Mann and Russell in Bailey and Love's 'A Short Practice of Surgery', indications for transfusion of blood and blood products include to improve oxygen delivery to the tissues and to replace coagulation factors as in some bleeding disorders.¹⁶ Although blood transfusion today is relatively safe, there remain some hazards associated with storage of blood and its transfusion. Machin et al reported the leading causes of transfusion related mortality, in the order of reported number of deaths, as, transfusion-related acute lung injury (TRALI), ABO and non-ABO hemolytic transfusion reactions (HTRs), and transfusion-associated sepsis (TAS). Other than transfusion associated sepsis, the infectious causes of death have been declining as a proportion of all deaths caused by allogeneic blood transfusions over the past three decades¹⁷.

The first documented report of blood transfusion was in 1492 in Rome where Pope Innocent V111 had an apoplectic stroke and went into coma and his physician advised blood transfusion as treatment. However the pope died shortly after. In 1818 James Blundel a British obstetrician performed the first successful transfusion for post partum hemorrhage where the donor was the husband, using a syringe from the arm. In 1901, Karl Landsteiner discovered blood groups which led to an increase in the use of allogenic blood transfusion. The use of intravenous fluid dates back to 1873 where US doctor's transfused milk from cows and goats to humans but this was associated with frequent serious reactions. The use of normal saline started in 1884¹⁸.

The supply of oxygen in a resting healthy adult with normal hemoglobin is three times greater than required by tissues for metabolism. With significant blood loss, compensatory mechanisms help to maintain the supply of oxygen to tissues. These compensatory mechanisms are facilitated if the normal blood volume is maintained with intravenous fluids by increased cardiac output. Use of crystalloids reduces viscosity of blood which improves capillary blood flow¹.

The effects of acute blood loss include; reduced oxygen delivery to the periphery, reduced oxygen storage by hemoglobin and reduced transfer of oxygen from the lungs to the blood¹.

Compensatory mechanisms include, influx of fluid from extracellular compartments to the vascular compartments, baroreceptors activate sympathetic which increase the heart rate force of contraction and peripheral vasoconstrictions to preserve flow to vital organs. Metabolic acidosis causes an increase in depth and rate of ventilation, oxygen dissociation curve shifts to the right to release oxygen in the periphery, release if vasopressin and aldosterone to retain water, mobilization of preformed albumin and circulation within six to twelve hours¹.

Up to 20% of allogenic blood transfusions have been reported to have some adverse effects. Human error during labeling continues to cause fatal hemolytic reactions even in developed countries¹⁹. Immune reactions occur even with sophisticated cross-matching techniques²⁰. Febrile reaction occurs in 1 to 3 % of patients due to antibody reactions to white blood cells in the blood. Mortality is approximately 1 in 100,000 transfusions¹. There is rarely justification for the use of pre operative blood transfusions to facilitate elective surgery¹. Without ongoing blood loss, oral iron supplementation is sufficient for endogenous erythropoietin mediated red blood cell expansion. However, for two weeks after surgery, increase in IL-6 and CRP by surgery induced inflammation inhibits erythropoietin response to iron²⁰.

Allogenic blood transfusion is associated with detrimental immunomodulation, increase in TNFalpha, IL-1, IL-6 and IL-8 enhances an acute inflammatory reactions²¹.

In trauma patients blood transfusion has been shown to be an independent risk factor for death, perioperative infections, post injury multiple organ failure and SIRS and admission to intensive care unit. In a retrospective cohort study of 9598 consecutive hip patients who underwent repair, blood transfusion was associated with 1.35 fold increased risk of bacterial infections²².

During acute normovolemic anemia, patients without cardio vascular disease endured low hemoglobin values and even lower hemoglobin values when anaesthetized without deleterious effects. Blood loss may however be minimized by meticulous surgical techniques which is perfected by training and experience, use of diathermy and positioning of the patient to encourage free venous drainage at the operative site¹⁰. The operative site should be little above the level of the heart¹⁰. Good anesthetic technique reduces episodes of hypertension and tachycardia due to sympathetic of activity by ensuring good anesthesia and analgesia¹⁰. Regional anesthesia is associated with less blood loss. Hemodilution has been shown to be a cost effective way of decreasing blood loss. Other methods of reducing blood loss include; use of collagen pads, thrombin powders and fibrin glue²².

In critically ill patients some fall in hematocrit may be beneficial as decrease in viscosity may increase oxygen availability to cells by improving the micro circulation. Mortality rates have been increased in patients who have been transfused²³.

About five decades ago, it was commonly taught and practiced that a patient needed a transfusion if the hemoglobin was below 10gm/dl. This was discredited by the Canadian led TRICC(transfusion requirement in critical care) trial which showed a restrictive transfusion trigger of 7g/dl resulted in equally good outcomes as a liberal transfusion trigger of 10g/dl²⁴.

A review of 10 randomized controlled trials of transfusion triggers showed that a restrictive approach to transfusion resulted in 42% fewer patients receiving transfusion, and no increase in mortality, morbidity, or length of stay in hospital²⁵.

Cell salvage techniques have been found to decrease the volume of required allogenic blood in orthopedic surgery by 75 %. Rates of transfusion are also reduced by 80%. However, the side effects include hemolysis and haemoglobinuria, air embolism, sepsis, dissemination of malignant cells, aspiration of products added to the surgical fields and DIC²⁶.

The use of autologous blood in surgery also decreases the use of allogenic blood. Some of the disadvantages are; half of the blood collected is discarded because the amount drawn needs to exceed the median routinely needed to avoid allogenic transfusion, left over blood is rarely used because it may not meet the health requirements, it thus incurs a higher cost because of wastage. Volume overload may occur if the patient is transfused when he doesn't need to. Bacterial contamination may occur during storage. Auto transfusion is only suitable for elective surgery. For the donors travelling to and fro hospital is expensive and usually decreases the productivity at work. The use of allogenic blood transfusion therefore continues to dominate²⁷.

Postoperative anemia results in fatigue, diminished physical performance and weakness. No difference was found in physical performance in patients with hemoglobin of 9g/dl without transfusion and those with hemoglobin of 14g/dl after transfusion²⁸. The minimum hemoglobin level of optimum recovery is still unknown^{29,30,31}.

The indications for transfusion involve multiple factors. According to the traditional ten/thirty rule, transfusion is recommended when the level of hemoglobin is less than ten grams per deciliter or the hematocrit is less than 30 per cent. This rule was questioned at the National Institutes of Health Consensus Development Conference in 1988. The recommendation at the Conference was for a lower level of hemoglobin as the indication for transfusion, and it was suggested that decisions regarding transfusion should include an assessment of clinical needs and symptoms rather than be based on laboratory values alone³².

In a review of intraoperative assessment of blood transfusions during elective surgery done by G.Niraj in a tertiary hospital in India 40.7 % were appropriate transfusion and 19.2% were inappropriate. The criteria used to evaluate the rate of appropriate transfusion were hemoglobin less than 8g/dl and less than 10g/dl in patients with cardiac cormobidities. The primary trigger for transfusion was low hemoglobin (measured intraoperatively or derived from blood loss). Patient whom had hemoglobin done intraoperatively had a significantly higher appropriate use of blood. They recommended intraoperative hemoglobin estimation to be an effective & simple measure to improve appropriate use of blood ³³.

In a different study done to review intraoperative blood transfusion practice in a tertiary hospital in Nigeria in a setting where patients were thought to be transfused based on the anesthetist clinical acumen, hemoglobin as measured prior to transfusion and 24 hours postoperatively. The mean pretransfusion hemoglobin was 8.06 ± 2.45 g/dl. Thirty four patients were studied, twenty one patients (61.4 %) had appropriate transfusion while 34% were inappropriate. The commonest transfusion trigger was clinical palour, excess blood loss, delayed capillary refill and severe hypotension. They concluded that the use of physiologic parameters and monitoring devices would improve on the blood transfusion pracises³⁴.

Kinyanjui in 2005 reviewed the intraoperative blood transfusion practices in Mulago Hospital, forty patients were studied and only 55% of the patients required blood intraoperatively. Thirty

five percent had irrational blood transfusions. They assessed appropriate transfusion based on physiologic monitoring ³⁵.

In a retrospective study of 53 patients with isolated fractures of the femur, 21 patients required transfusion. Important variables determining transfusion were the admission hematocrit, preoperative estimated blood loss and total estimated blood loss after surgery. Fracture patterns classified as high or low energy were not found to correlate with pre or intraoperative blood loss or incidence of transfusion³⁶.

There are no available local studies that have reviewed if there are irrational transfusions at the Kenyatta National Hospital.

RESEARCH PROBLEM

There are quite a number of patients scheduled for elective orthopedic surgeries that miss surgery due to lack of blood every week. Of those who are transfused this no clear documentation of the reason for transfusion and if transfusion was warranted or not.

Research Question:

What is the rationale for blood transfusion of patients undergoing orthopedic operations at the Kenyatta National Hospital?

Objectives:

General objectives

• To evaluate the rationale for blood transfusion in patients undergoing elective orthopaedic surgeries during the study period in KNH.

Specific objectives

• To assess the amount of blood lost during the various orthopaedic operations.

- To determine the percentage of patients undergoing an elective orthopedic operation requiring blood transfusion.
- To assess intravenous fluid replacement regimen before transfusion is commenced during an orthopedic operation.
- To determine if physiologic monitoring is an effective way of determining the need for blood transfusion in patients undergoing elective orthopaedic operation.
- To determine if monitoring of PCV/HCT before on set of blood transfusion is an effective measure before commencement of transfusion.
- To determine if use of diathermy reduces the amount of blood lost in different elective orthopedic surgeries.

JUSTIFICATION OF THE STUDY

Rational use of blood will ensure that blood is available for those in need. Most of the patients undergoing elective orthopedic operations have a good hemoglobin level of above 10g/dl and may have allowable blood loss. There is no need of exposing them to unnecessary risk associated with blood transfusion if they do not need it. Those not requiring blood will avoid being exposed to the window period residual risk of allogenic blood. The increased risk of postoperative infection associated with blood transfusion after surgery will also be avoided

By answering the research question, it will help to develop a protocol and guidelines for transfusing patients. Those not requiring blood will avoid being exposed to residual risk of allogenic blood transfusion. Proper documentation of reasons for transfusion in patients' records will help in future should medical-legal questions arise.

Using less blood also means cutting cost for the blood bank and laboratory reagents. Knowing estimates of blood loss during surgery will help both the surgeon and the anesthetists in planning

for the elective cases and advice patients who refuse blood transfusions for religious or other personal reasons

METHODOLOGY

Study setting

This study was carried out at Kenyatta National Hospital (KNH) at the orthopaedic wards level 6, orthopaedic theatre and blood transfusion unit.

Design

• Cross sectional descriptive study

Study Population

• Patient scheduled for open reduction internal fixation who are 12years and above of age.

Inclusion criteria

All the patients of 12 years and above undergoing elective orthopaedic surgeries

Exclusion criteria

Patients with a known bleeding disorder/ cardiovascular cormobidities

Patients with a pathological fracture

Patients who do not consent

Patients undergoing closed nailing of the long bones

Patients less than 12 years of age.

Study Duration

This study was carried out for duration of 14 weeks, from February to May, 2013 after approval by the KNH/UON Ethics and Research Committee.

SAMPLE SIZE

Sample size calculation for proportions (Woolson, 1987)

$$n = \frac{\frac{Z^2 \underline{\alpha} \left(P(1-P) \right)}{2}}{d^2}$$

Where

 $Z_{\frac{\alpha}{2}}$ is critical value for 95% confidence interval = 1.96

P is the estimated proportion of patients getting blood transfusion

in patients undergoing orthopaedic operations = 60%

d is the level of precision = 5%

n is the number of patients required

$$n = \frac{1.96^2 \ (0.6(1 - 0.6))}{0.05^2}$$

n = 362 patients

The final sample size will be calculated by Applying Finite Population Correction (FPC) to N=103Estimated number of Patients undergoing surgery within the proposed study period.

$$n' = \frac{n}{1 + \frac{n}{N}} = \frac{362}{1 + \frac{362}{103}} = 80Patients$$

MATERIAL AND EQUIPMENT

Procedure of data collection

All patients undergoing elective orthopaedic surgeries who were twelve years and above and who had consented or whose guardian had consented for the study were thoroughly assessed to rule out any cardio respiratory or any other illness. Patient preoperative renal function test were done to ensure adequate monitoring of the input and output.

Patient's baseline weight, blood pressure, and pulse rate were taken on the morning of the operation. Allowable blood loss was be calculated using the following formula

1. Allowable blood loss calculated

Allowable blood loss (mls) = Blood Volume \times (Pre-op Hb(ml) – Lowest acceptable Hb(mls))

Average of Pre-op and lowest acceptable Hb(mls)

Total blood volume will be calculated using 70ml/kg

Variables

Dependant (outcome) variables

- Blood loss –both the allowable blood loss and the total blood loss that will have occurred
- Physiologic monitoring parameters-blood pressure, pulse rate, respiratory rate.
- Fluid regimen that is administered/fluid replacement.
- Type of anesthesia used-spinal/ general anesthesia.
- Use of diathermy or not-will alter the amount of blood loss incurred

Independent variables

- Demographic variables- age , gender, weight
- Clinical variables- preoperative hemoglobin / packed cell volume, timing of injury, fracture pattern, configuration of the fracture

During the operation

During the operation, gauze swabs were weighed in their dry state while in their sterile packs (the weight of the sterile pack was noted and subtracted to quantify the actual weight of the dry swabs). Blood soaked swabs were also be collected and weighed as soon as they are discarded.

The suction bottle was weighed before and after use. This is because the calibration on the suction bottle is widely spaced and hence difficultly to quantify small differences in blood loss by visual observation. Any gauze swab not used was subtracted from the initial dry swab. It has been shown that 1ml of blood approximately weighs 1gm. This was the difference between dry and wet swabs. Volume of irrigation was noted and subtracted from the measured blood loss. Sixty ml of syringes was used to account for the volume of irrigation fluid used. Blood loss on to the floor was estimated and added to the wet swabs and the suction bottle to get the total blood loss. Blood on the floor was estimated at the ratio one litre of blood spreads over an area of one square meter. Gauze mops spread around the surgical drapes to absorb any blood spillage were also measured.

The total volume of crystalloid solution such as normal saline given by the anesthetists was charted. Quarter hourly pulse rate, blood pressure were charted and urine output was noted. Post operative haematocrit was done on day one and day three. Haematocrit is a sensitive measure of acute blood loss. Hemoglobin will be reflected only after the compensatory mechanisms have taken place on approximately day three. The use of diathermy was also noted and its influences the amount of blood lost.

Instruments

- Weighing machine or weighing scale. (Patients weight was measured using electronic platform weighing scale (seca). patients who could not stand were sat on a platform and weighed.
- Blood pressure machine
- Sterile swabs(swabs were weighed using the CS-20KS water resistant electronic weighing scale)

- Stethoscope
- Urine catheters
- Urine bags
- Hemoglobin and haematocrit levels done by the laboratory technicians
- Ruler(measure type ruler)
- Calibrated jar(100ml calibrated measuring cylinder)
- Sixty millitre syringes

Data record keeping

All the clinical and laboratory data were collected by use of precoded evaluation form.

Two laboratory technicians were recruited to assist in laboratory investigations. Four ward nurses and four research assistants were also recruited for monitoring and charting of the vital signs of the patient post operative. Two theatre nurses were also recruited to assist in weighing of the gauze swabs

Data Analysis

All data was checked for completeness, consistency and accuracy. All identifiers including names were deleted before the start of data analysis. The questionnaire is pre coded; the coded answers from the questionnaire were entered onto Statistical Package for Social Sciences v.17 (SPSS) data sheet which was used for data capture. Stata v.12 (Stata Corp, College Station Texas) was used for the descriptive and bivariate statistical analysis.

Descriptive analysis began with summaries of continuous variables from the questionnaire and will be presented descriptively in form of means (standard deviations [SD]) or median (interquartile range [IQR]) as appropriate for the continuous variables. Tables of frequencies (percentages) were created for the categorical variables and some pictorial presentation using bar graphs ,box plots and pie charts as appropriate.

Bivariate analysis was done using students t-tests/rank-sum or chi- square/fishers test for continuous and categorical data as appropriate and p values reported. Bivariate analysis was conducted to determine presence of statistically significant association between explanatory variables and the outcome variable. Tables were used to display results.

Quality Control

- The evaluation forms were pre tested before data collection.
- The patients' history and physical examination was conducted by the principle investigator.

- All laboratory investigations were conducted at the UON/KNH lab facilities.
- Two laboratory technicians who carried out the study were blinded to avoid bias

Ethical Considerations

- Study was done after approval by KNH ethical and research committee & department of Orthopaedic surgery
- Participation in the study was voluntary, by consent of the patient or guardian (parent) and failure to give consent did not invite penalties.
- Information contained was kept confidential.
- The blood samples and material used collected were discarded safely in an incinerator on conclusion of the study
- Results of the study will be published and is to be made available to the members of the medical fraternity and patients where relevant.

RESULTS

Categories of Surgeries

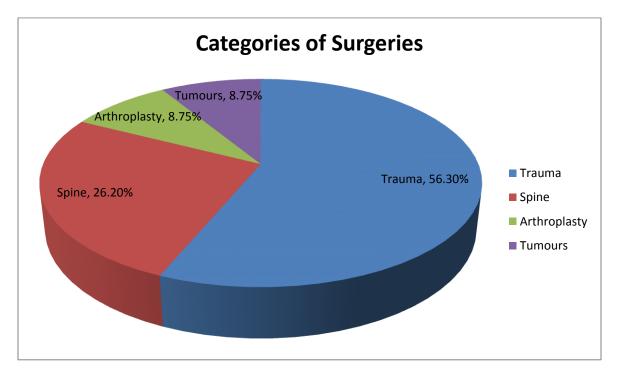


Figure 1

The study was divided into four main catergories that depicted the different surgeries that the patients underwent as shown above in figure 1.

Age Categories

The mean age of the participants was 35.39 years (SD = 14.59). Majority of the participants, 31 (38.8%), were aged between 26 to 30 years. They mainly consisted of males 53(66.3%).

PATIENT CHARACTERISTICS	Statistics
Age Mean Years (SD)	35.39 (14.59)
AGE CATEGORIES n(%)	
< 26 YEARS	14 (17.5)
26-35 YEARS	31 (38.8)
36-45 YEARS	18 (22.5)
>45 YEARS	17 (21.3)

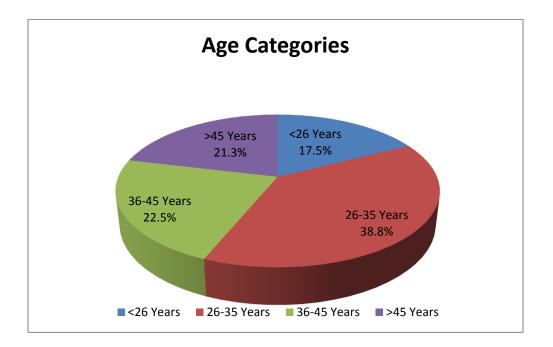


Figure 2

Gender

F-27 (33.75) M-53 (66.25)

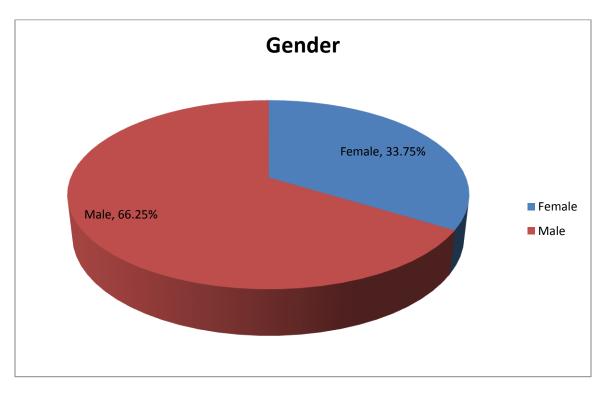


Figure 3

The male gender contributed to the biggest sample of patients (66.25%) as shown above.

Correlation of gender of patients to trauma

Majority of the sample under the trauma category were males as compared to females however without statistical significance, 33(63.3%) vs. 12(44.4%), p= 0.129.

Gender n(%)			
Trauma	F	М	p value
No	15 (55.6)	20 (37.7)	0.129
Yes	12 (44.4)	33 (62.3)	

Table 1

Patients under the trauma categories consisted mostly of men probably as they were involved in high energy activities and more prone to injuries. This was however not statistically significant.

Correlation of delay of surgery in weeks and blood loss

The blood lost intra-operative (ml) increased significantly with the weeks delay in the surgery timing, F(2,42) = 4.54, p= 0.017.

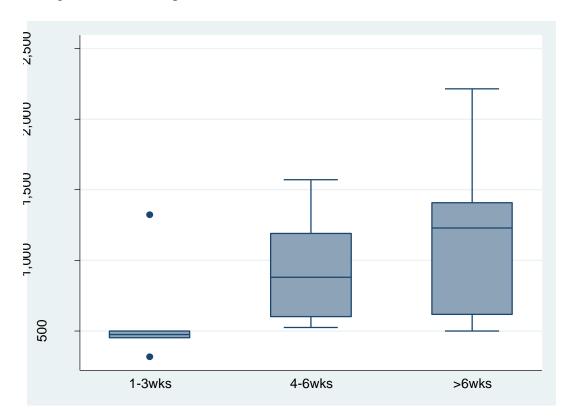


Figure 4

Correlation of duration of surgery in hours and blood loss

There was a high positive and significant linear correlation ,r=0.7739, between the duration of opertaion hours and the blood lost ,p <0.001

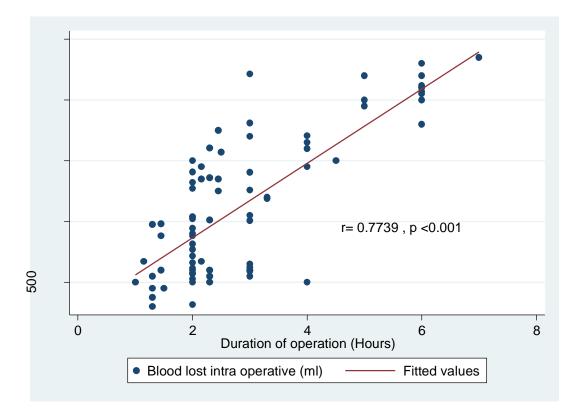


Figure 5

Blood loss Intraoperative (ml)					
Timing of Surgery	Mean (SD)	Median (IQR)	ANOVA F value	p value	
1-3wks	589.5(365.2)	475 (450 - 500)	F(2,42) = 4.54	0.017*	

4-6wks >6wks	918.92(366.23) 1148.89(467.1)	880 (600 - 1190) 1228.5 (615 - 1408)	
Total	1007.87(462.23)	1007 (600 - 1351)	
* Statistically significant			
Table 2			

Fractures that took longer to be operated resulted to more bleeding as shown in the above table 2.

Correlation of fracture communition versus Blood loss

There was significant difference in the blood lost intra-operative with respect to the configuration of the fracture, F(2, 41) = 20.4, p < 0.001.

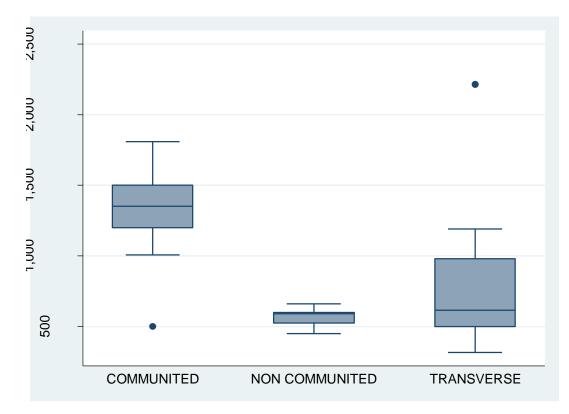


Figure 6

Blood loss Intraoperative (ml)							
Configuration	Mean (SD)	Median (IQR)	ANOVA F value	p value			
TYPE A/SIMPLE	570.27(59.8)	590 (525 - 600)	F(2,41) = 20.4	<0.001*			
TYPE B/WEDGE	842.64(527.77)	615 (500 - 980)					
COMMUNITED	1325.55(294.77)	1350.5 (1200 -1500)					
Total	1016(464.3)	1015 (595 - 1355.5)					
* Statistically significant							
Table 3							

Types of Anesthesia

General Anaesthesia-72.5%

Spinal Anaesthesia-27.5%

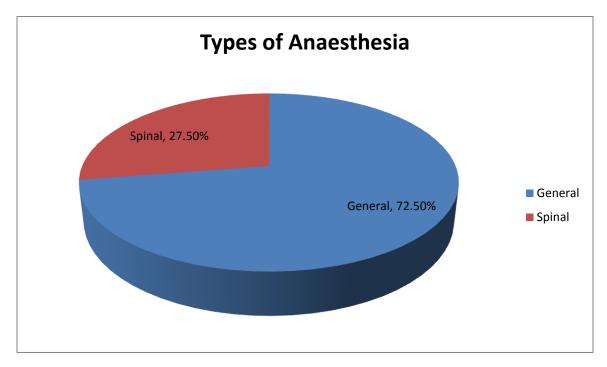
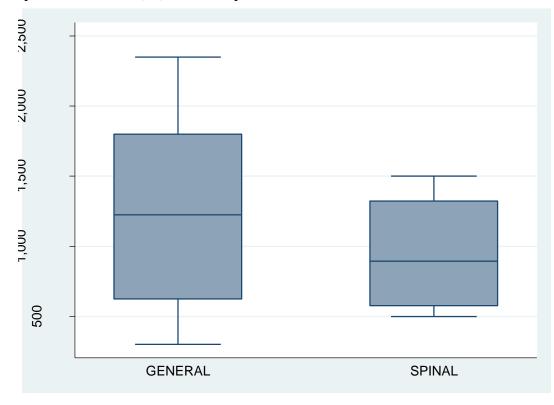


Figure 7

There were more patients operated under general anesthesia than compared spinal anesthesia. This is demonstrated in figure 7 above.

Correlation between type of anesthesia and blood loss



Those who received general anesthesia lost significantly more blood intra-operative compared to spinal anesthesia, t(78) = 2.3673, p=0.020 as shown below.

Figure 8

Blood loss Intraoperative (ml)						
Type of anaesthesia	Mean (SD)	Median (IQR)	T-test value	p value		
GENERAL	1248.47(632.6)	1225 (623 - 1800)	t(78) = 2.3673	0.020*		
SPINAL	909.64(356.95)	895 (575 - 1322)				
Total	1155.29(588.04)	1029.5 (600 - 1602.5)				
* Statistically significant						
Table 4						

DIATHERMY USE

NO -9

YES -71

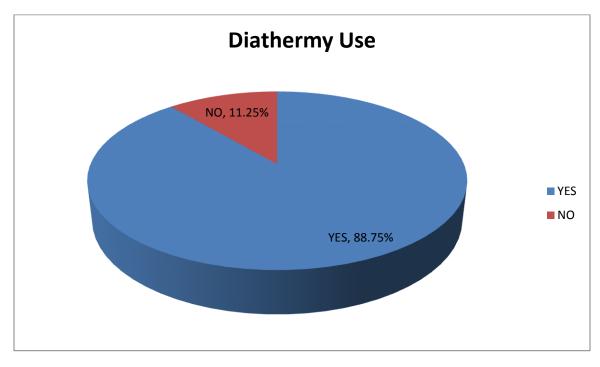


Figure 9

The mean blood lost intra-operative among those who used diathermy was slightly lower than those who did not , this was statistical significant ,t(78) = 3.901 ,p = 0.0002.

Blood loss Intraoperative (ml)					
Use of Diathermy	Mean (SD)	Median (IQR)	T test value	p value	
NO	1818.44(313.71)	312 (104 - 1578)	t(78) = 3.901	0.0002	
YES	1071.22(561.56)	938 (561 - 1210)			
Total	1155.29(588.04)	1024.4 (588 - 1286.1)			
Table 5					

Blood and Fluid Summary

The mean blood lost was 1155.29 ml (SD= 588.04). The minimum amount of blood lost intraoperatively was 315ml while the maximum amount lost was 2350 ml. The mean expected fluid was 1637.50 ml (SD= 405.46), with mean fluid replaced 1406.44(SD = 545).

Blood and Fluid Summary	Statistic
	1155.29
BLOOD LOST INTEROPERATIVE (ml) Mean (SD)	(588.04)
	1406.44
FLUID REPLACEMENT (ml) Mean (SD)	(545.64)
	1637.50
EXPECTED FLUID (ml) Mean (SD)	(405.46)
Table 6	

Fluid Replaced verses Expected fluid replaced

There was also a high positive and significant linear correlation r= 0.817, between the expected fluid and the fluid replaced p < 0.001.

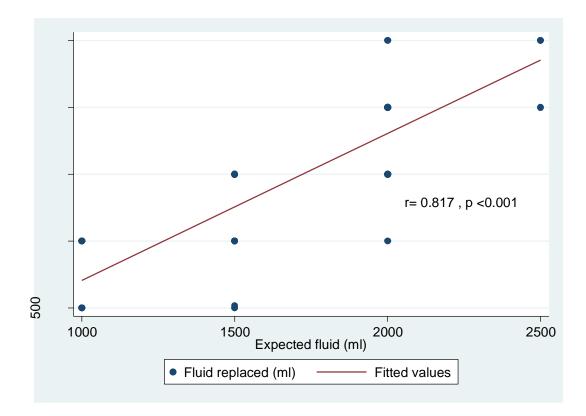


Figure 10

RATIONAL VERSUS IRRATIONAL TRANSFUSION AS PER THE WHO CRITERIA

Rational-65%

Irrational-35%

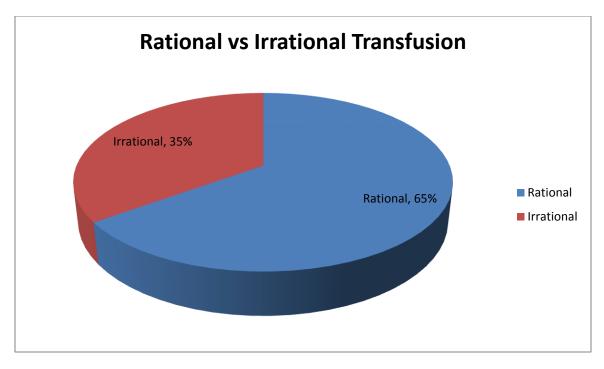


Figure 11

There were 35 % of patients in the study who were irrationally transfused as per the WHO criteria. This is shown in the figure above (figure 11).

UNITS OF BLOOD USED

1 Pint-76.25%

More than 1 pint-23.75%

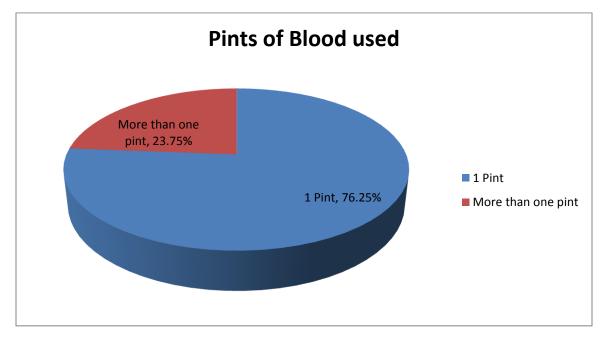


Figure 12

Most of the patients in the study were only transfused one pint of blood as compared to patients who were transfused two or more pints of blood as demonstrated above in figure 12.

DISCUSSION

Many changes have occurred in transfusion practices in Africa and in Western countries over the years. Blood transfusion remains a key component in the resuscitation of surgical patients suffering from operative losses and trauma causes³⁷. Nothing has replaced the life saving potential of appropriate transfusion. Increased clinical evidence surrounding appropriateness of transfusion, increased understanding of the risks of transfusion, and better ways of managing these risks have been active topics of discussion in the literature³⁷

Kenyatta National Hospital is a 2500 bed capacity national referral and teaching hospital. Whole blood is routinely transfused during and after most elective surgical procedures and especially patients undergoing orthopaedic surgeries.

DEMOGRAPHICS

The total number of patients in the study was eighty. Data was collected over a period of four months. The average number of patients that underwent elective orthopaedic operations were approximately six hundred and night five patients over the same period. Approximately eleven point four percent (11.4 %) of total number of patients that underwent elective orthopaedic operations was transfused.

Patients who were transfused were put in to four main categories including trauma, spine, arthroplasty and tumours. The biggest fraction of patients was in the trauma category, this contributed 56.3 % of the total number of patients followed by spine surgeries which were 26.2% and 8.75% for both arthroplasty and tumours which is shown in figure 1.

The biggest fraction of patients in the study fell in the age bracket of 26- 35 years (38.8 %), (shown in figure 2) this comprises people in early adult hood who are active and involved in various high risk activities such as motor cycling, sports, and construction works which predisposes them to a high incidence of injuries. The same group also formed a bigger percentage because patients who sustained trauma formed a bigger study population.

Men comprised of 66.3 % of the patients population in this study while the female comprised of 33.8 % (shown in figure 3). This may be explained by the fact that more men are engaged in the

high risk activities which predispose them to high energy trauma; this however was not statistically significant as is shown in table 1.

Patients undergoing spine surgery majority contributed approximately 26.2 % of the total study. Majority of the patients were due to deformities such as scoliosis followed by degenerative diseases. This may be attributed due to the fact that during the study period there was a spine project and many of the patients recruited during the project had spine deformities.

Patients who underwent transfusion secondary to arthroplasty (either total hip arthroplasty or total knee arthoplasty) and transfusion secondary to tumours either biopsy or debulking formed equal percentage 8.75% as shown in figure 2.

Approximately 57.8% of patients under the trauma category were operated after 6-9 weeks from the day of injury which is statistically significant as shown in table 2/figure 4 and 5, this was attributed to the late presentation to hospital either from referrals from other hospitals or were offered an option of ORIF after skeletal traction had failed to achieve healing. Delayed surgeries led to increased blood loss as compared to similar fractures that had been operated much earlier.

For the patients under trauma category majority of the femoral fractures occurred in the mid third region followed by the upper third region, which normally require high energy trauma to occur. The most common procedure was k-nailing which contributed about 22.5%, followed by interlocking nail 15.2%.

Fracture communition was classified into type A (simple), type B (wedge), type C (communited). Fractures that fell in type C were associated with more blood loss compared to fractures that were simple and this was statistically significant as is shown in table 3/figure 6. This may be attributed to the fact that complex fractures were associated with more soft tissue stripping to achieve adequate reduction.

Seventy two point five percent (72.5 %) of patients were operated under general anesthesia while 27.5% were operated under spinal anesthesia as shown in figure 7/8. Epidural and spinal anesthesia for various types of surgery offer advantage over general anesthesia by decreasing blood loss and transfusion requirements. Hemodynamic differences with lower arterial blood pressure, lower central venous blood pressure and lower peripheral venous blood pressure in the

surgical wound seem to explain the lower blood loss intra- operatively and post-operatively in patients given regional anesthesia³⁸. The differences in hemodynamic give rise to less arterial and notably less venous oozing of blood from the surgical area. The latter observation is strengthened by the significant correlation between the intra-operative peripheral venous blood pressure and the intra-operative blood loss³⁸. In this study the mean blood loss with spinal anesthesia was 909ml which is statistically significant as shown in table 4. This is in tandem with what has been found by other studies and is attributable to the regional hypotensive effect of spinal anesthesia caused by sympathetic nerve blockage hence less oozing at the operation site. Hypotensive anesthesia has been found to decrease blood loss by up to forty percent (40 %) ³⁸.

Use of diathermy is a common method of reducing intra-operative blood loss. Sheen-chen et al 1993 demonstrated the effectiveness of diathermy in reducing intra-operative blood losses³⁹.

Eighty eight point eight percent (88.8 %) of patients were operated using diathermy while 11.3 % were operated using the traditional surgical dissection and standard surgical knotting of bleeding vessels as shown in figure 8. Diathermy has been associated with less blood loss in this study. The mean blood loss with use of diathermy was 1071 ml while without it was 1818ml this was statistically significant as shown in table 5. This is comparable to a different study in which electrocautery decreases the incision time , blood loss post operative pain and analgesic requirement⁴⁰. Other strategies that could have been employed intra-operatively to reduce need for transfusion include use of adrenaline gauzes , surgical, plasma gel or fibrin sealants.

The intra-operative management of fluid therapy has great potential of influencing intraoperative and post operative morbidity and mortality⁴¹. Awareness of pre- operative hemodynamic status, particularly as it influences the ventricular output is critical in avoiding serious cardiovascular complications. Limited scientific evidence on optimal intra-operative fluid management has resulted in large variation in administering fluid regimes in daily practice. Currently there is a tendency towards liberal peri-operative fluid administration⁴¹. The stress response to surgery profoundly alters fluid homeostasis leading to fluid conservation ⁴¹. The primary mediators are aldosterone , anti-diuretic hormone and rennin angiotensin system. However the effect of different fluid regimens on these hormones and response to surgery is largely unknown⁴¹. Although peri-operative administration of high volumes may be deleterious in correction with major surgical procedures studies in minor surgery suggest that fluid substitution aiming to correct preoperative dehydration may improve some parameters of recovery such as drowsiness and dizziness⁴²⁻⁴³.

Most patients routinely received 1000- 1500ml of crystalloid fluids prior to transfusion despite having different rehydration needs. The rehydration need per patient also differed significantly as per the WHO rehydration criteria. The mean fluid administered in the study was 1406ml that differed with the expected as per the WHO criteria of 1637ml. This is depicted in figure 11 and table 6.

BLOOD LOSS

The mean intra-operative blood loss was 1155ml, with a minimum of 315ml and a maximum of 2350ml. Surgeries that required took longer hours bled more and thus required transfusion.

The mean allowable blood loss for patients who underwent k- nailing was 926ml, suggesting that most patients were capable of undergoing k-nailing without requiring transfusion if they had adequate preoperative hemoglobin. Blood loss increased gradually from the time of injury due to longer operating time in such fractures which sometimes have partially malunited and contain a lot of fibrous tissue. The new bone in form of callus at the fracture site is also more vascular that contribute to more bleeding.

In patients undergoing spine surgery the mean blood loss was 1752ml. This is comparable to a study which averages a blood loss was 1157+/- 998ml. The amount of blood lost was determined by the number of laminectomies done, experience of the surgeon and distension of epidural veins. Spine surgeries that took longer were associated with more blood loss⁴⁴.

In patients undergoing total joint replacement surgeries the mean blood loss was 760ml. This is comparable to a study where patients undergoing primary hip replacement surgery blood loss were 1500ml- 2000ml, while in patients undergoing total knee replacement blood loss was 500-1000ml. Revision surgeries bleed more and required more transfusion⁴⁵.

Patients who underwent oncological surgeries bleed more due to increased risk of bleeding secondary to the effects of chemotherapy, the administration of anti coagulant drugs, tumour related fibrinolysis, tumour location, tumour vascularity and the extent of the disease. Several

surgical and anesthesia intervention including preoperative tumour embolization, major vessel occlusion, hemodynamic manipulation and preoperative antifibrinolytic therapy have been used to prevent or control blood loss with varying success⁴⁶. In our study the mean blood loss for oncological surgeries was 598 ml that was not massive comparable to other studies. This may be partly attributed to the fact that most of the patients were either undergoing amputation or were having a biopsy done to confirm the diagnosis of the tumour. Most of them were index admissions and had not received any form of chemotherapy that would also predispose them to increased risk of bleeding.

BLOOD TRANSFUSION

Using the WHO criteria for blood transfusion 65 % of patients were transfused rationally, 35% were irrationally transfused as shown in figure 11. Many of the patients were transfused based on the clinical acumen of the anesthetist.

Among the patients requiring blood transfusion diastolic blood pressure was found to be a more reliable indicator of transfusion needs than the pulse rate. Pulse rate may change depending on the depth of anesthesia or analgesia¹. The major trigger for transfusion was a drop in diastolic blood pressure by 20% of the pre-operative level and an increase heart rate by 20% beyond the pre- operative level after adequate fluid replacement had been done. However this was not consistent as different patients received different form of anesthesia.

Pre transfusion hematocrit also was a good indicator of the patients who required to be transfused. Twelve out of the twenty eight patients that were irrationally transfused were confirmed to have been irrationally transfused buy using their pre transfusion hematocrit this contributed to approximately 15 % of the total study. Hematocrit though an indicator of the concentration of the red blood cell in the blood, it does not reveal the RBC volume , plasma volume, or total blood volume nor does it give an indication of whether the patient is hypovolumeic normovoluemic , or hypervolumeic. The hematocrit values in hypovolumic anaemic patients are elevated because the plasma volume does not increase to achieve the normovolumic anaemic state⁴⁷.

Single unit transfusion is common during elective surgeries in Kenyatta National Hospital, although effective transfusion requires a minimum of two units of blood for an adult. According

to the national guidelines for the appropriate use of blood and blood products, transfusion of one unit or less in adults often suggests that the transfusion was not necessary⁴⁸. Approximately 76.3% of patient of those who were transfused only received one unit of blood while 23.8 % received more than one unit as shown in figure 12.

CONCLUSION

- Of all the patients who received blood transfusion during the study period only 65 % required blood by the WHO criteria. 35% were transfused irrationally.
- Patients who sustained communited fractures and stayed for longer without definitive management were associated with more bleeding.
- Spinal anaesthesia and use of diathermy was associated with less blood loss and should be adapted where useful.
- Fluid replacement in a patient undergoing surgery should put in account both the ongoing losses and the maintenance fluid deficit.
- Physiological monitoring of the patients as per the WHO criteria is an effective way of determining which patients requires transfusion and should be adapted.

RECOMMENDATION

- The WHO criteria for blood transfusion during surgery should be adapted and implemented for patients undergoing elective orthopaedic surgeries at Kenyatta National Hospital.
- Patients should receive blood transfusion if they bleed beyond the allowable blood loss or if their diastolic blood pressure and pulse rate drops beyond 20% of their preoperative value after adequate fluid replacement.
- Diathermy should be used in all cases as it significantly reduces the intraoperative blood loss.
- Patients should be operated early as it reduces their blood loss.
- Patients waiting for a long time in the wards for open reduction internal fixation should be started on haematinics to boost their haemoglobin level preoperatively.

LIMITATIONS

• Blood spilt the floor on the surgeons gowns, gloves and drapes might decrease the accuracy of the measurement of blood loss

• Lack of ECG CVP and blood gas monitors may interfere with monitoring of patients with cardioresipratory cormorbidities

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APPENDIX I: HAEMODILUTION METHOD

Patient Clinical	Healthy Adult	Average Clinical	Poor Clinical
Condition		Condition	Condition
Lowest Acceptable			
Packed cell volume	27 %	30 %	33%

Lowest acceptable Hb prior to surgery as per WHO recommendation

Haemodilution method for calculating allowable blood loss

Allowable blood loss=Blood volume (mls) × (preoperative Hb (mls) Lowest acceptable Hb)

Average of preoperative and lowest

acceptable Hb (mls)

APPENDIX 1I: QUESTIONNAIRE

Serial number	
Patients Particulars,	Initials,Age
	GenderWeight (if known)
Pre op Hb,	g/dl or PCV,%
Pre op diagnosis	
Timing from date of	injurydays

Configuration of the fracture.....

Location of the fracture.....

Allowable blood loss.....mls

Estimated blood loss.....mls

Bp.....b/min PR.....b/min

Intra operatve indices

Procedure

Type of anesthesia given......spinal() General() Other specify.....

Use of Diathermy......Yes/No

Duration of surgery.....hrs

Pre-transfusion HCT.....g/dl

Hb/HCT 24hrs post operative.....g/dl

			TIME IN N	AINUTES			
	0-15MIN	15-	30-	45-	60-	75-	90-
		30Mins	45mins	60mins	75mins	90mins	105mins
BP							
PR							
URINE							
OUTPUT							

REMARK				

Blood loss

- 1. Total weight of dry swabs(g) unused dry swabs (g) = Weight of used dry swabs (g)
 - -_____ = _____
- 2. Total weight of wet swabs used dry swabs = mls of blood lost

3. Amount in suction bottle _____mls

- 4. Estimated amount on the floor _____mls
- 5. Total blood loss = (mls in swabs + mls in bottle) Irrigation fluids

6. Replacement fluids

Туре		Quantity (mls)
1.Normal saline		
2.5% Dextrose		
	Total	

- _____ = _____

7. Units of blood given (intraoperative) _____ mls

Post operative indices

- Fluid given postoperatively_____ mls
- Units of blood given postoperatively _____mls
- HCT on day 1 post operatively_____%

APPENDIX III: WHO recommended replacement of fluids and blood as follows

- 1. Replace blood loss up to the allowable blood loss with crystalloid saline three times the volume of blood loss.
- 2. Maintenance fluid requirement of normal physiological losses at 1.5ml/kg/hr

- 3. Blood loss in excess of allowable blood loss is replaced with blood transfusion.
- 4. A decrease in diastolic blood pressure of 20% of pre-operative level with an increase in heart rate of 20% beyond pre-operative level after adequate fluid replacement are indications for blood transfusion. Blood loss beyond the allowable blood loss is replaced with blood. These guidelines may be abandoned and patient transfused at an earlier stage if the situation warrants it.

APPENDIX IV: CONSENT EXPLANATION TO THE PATIENT

My name is Dr.Paul Miano, MBchB (UON) Nairobi. Kenya. Tel.0722-912596

I am currently pursuing a Postgraduate degree in orthopedic surgery.

The Study

The purpose of this study is to obtain information regarding the clinical indicators and rational of blood transfusion. Reduction in blood transfusion rates will benefit the patients to avoid risks associated with transfusion. I am doing a study whose purpose I would like to explain to you.

The purpose of my study is to determine the transfusion practices among our surgical medical staff and see how we compare to International guidelines. To achieve this, data on your age, weight, gender, hemoglobin level and disease condition will be recorded without revealing your identity. We shall also record how much blood loss you experience, how much fluids are administered and how much blood if any is transfused to you.

The results of this study will help us to improve on our transfusion practice during surgery. The results of this study will be made available to you on request.

Participation in the study

Your participation in this study will be voluntary and you may decide to withdraw from it at any stage without any penalty. The study is purely observational, non-invasive and will not attract any additional cost to your treatment. Your participation will not interfere with the regular management of your condition before, during or after surgery. There will be no monetary benefit to you for participating in the study.

Study Approval

This study is being conducted with the approval of The Kenyatta National Hospital /University of Nairobi's Ethical and Research Committee at 2726300 for the next four months.

Confidentiality

Your identity will be protected with utmost confidentiality during the study and only your initials and inpatient number will be recorded for purposes of follow up.

Potential benefit to me

There will be no cost payment to (me/ my child) for the study

Risk to me

I understand that there is no risk directly related to the study to (me/my child). I also understand that blood for transfusion will be ready in theatre and postoperatively should (I/my child) require it.

Fate of the data

The blood samples and raw material will be safely discarded in an incinerator at the conclusion of the study

This information will help us understand the blood transfusion practices at the Kenyatta National Hospital. Like any other scientific information, we will seek to share our findings with other doctors in Kenya and the rest of the world.

APPENDIX V: CONSENT FORM FOR THE PATIENT

I..... (Initials only) have understood the explanation of this study,

BLOOD TRANSFUSION IN PATIENTS UNDERGOING ORIF AT THE KENYATTA NATIONAL HOSPITAL.

It has been explained to me by Dr. Paul Miano, MBchB (U.O.N) Tel.0722-912596 the Principal investigator.

I have freely chosen to participate in this study and understand that whether or not I participate, the care I receive will not be compromised in any way whatsoever.

I also understand that I may choose to withdraw from the study at any stage without any penalty.

Signed	(Patient)
Signed	(Guardian/parent/next of kin)
Signed	(The Principal Investigator)