BLOOD TRANSFUSION PRACTICES IN ORTHOPAEDIC TRAUMA UNITS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

BY

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DECLARATION

Declaration by candidate

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DEDICATION

This study is dedicated to the candidate's wife, Nelly and son, Ian for their endless support and patience in the academic career of Orthopaedic Surgery.

DISCLOSURE

The candidate did not receive any external funding or grants in support of this study. None of the members of the candidate's family received financial or other benefits in aid of this study.

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ABSTRACT

Background: Blood transfusion is required in the management of life threatening orthopaedic trauma hemorrhage. However, this practice is faced with erratic supply, increasing demand for safe blood and inappropriate transfusions which may expose patients to transfusion associated risks. Adherence to transfusion guidelines has been shown to ameliorate these challenges.

Objective: To describe socio-demographic and clinical characteristics and determine the level of adherence to blood transfusion guidelines and outcomes among transfused orthopaedic trauma patients at Moi Teaching and Referral Hospital in Eldoret, Kenya.

Methods: A hospital based descriptive cross-sectional study of 132 transfused orthopedic trauma patients was carried out between March 2019 and January 2020 at Moi Teaching and Referral Hospital. The patients were recruited by consecutive sampling method. Data was collected using interviewer administered structured questionnaire. Continuous data were summarized as median (inter-quartile range) and categorical data as frequency tables and proportions. Fisher's Exact Test was used to assess associations between categorical variables and non-parametric Kruskal-Wallis Test was used for continuous independent variables. A p value < 0.05 was considered statistically significant.

Results: Males were 101 (76.5%) and the median age was 36 (IQR 28, 47) years. Majority of the patients, 95 (72%) were referrals, 64 (48.5%) were unskilled workers and 64 (48.5%) had primary school level of education. Most of the patients, 105 (79.5%) were injured in road traffic accidents and those who sustained isolated femur fractures were 62 (47.0%). Of all patients, 61 (46.2%) underwent primary open reduction and internal fixation. Most patients, 105 (79.5%) and 115 (87.1%) had normal pulse rate and systolic blood pressure respectively while 77 (58.3%) had increased respiratory rate. The median pre-transfusion haemoglobin was 8.90 (IQR 7.98, 10.35) g/dl and the commonest blood group was O positive. Majority of the patients, 127 (96.2%) received packed red blood cells. The proportion adherent to transfusion guidelines was 16.7% [95% CI: (10.75, 24.14)]. The factors associated with adherence were pre-transfusion haemoglobin and haematocrit levels, Fisher's Exact and Kruskal-Wallis p value being < 0.001. Mild transfusion reactions were noted in 15 (11.4%) patients.

Conclusion: Most patients were males, transfused with packed red blood cells and majority of injuries sustained were due to road traffic accidents. The level of adherence to the institutional transfusion guidelines was low at 16.7%. Factors associated with transfusion guidelines adherence were pre-transfusion haemoglobin and haematocrit levels. Few and mild transfusion reactions were noted with no association with adherence to transfusion guidelines.

Recommendations: Moi Teaching and Referral Hospital Transfusion Committee to increase transfusion guidelines awareness among clinicians in orthopaedic trauma. High index of suspicion is necessary for diagnosis of transfusion reactions and cautions to eradicate these reactions be put in place.

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ABBREVIATIONS AND ACRONYMS

AIS	Abbreviated Injury Score
APTT	Activated Partial Thromboplastin Time
BTU	Blood Transfusion Unit
CRYO	Cryoprecipitate
FFP	Fresh Frozen Plasma
Hb	Haemoglobin
HCT	Haematocrit
INR	International Normalized Ratio
ISS	Injury Severity Score
KNBTS	Kenya National Blood Transfusion Service
KNH	Kenyatta National Hospital
MC	Motorcycle
MTRH	Moi Teaching and Referral Hospital
MV	Motor Vehicle
PCC	Prothrombin Complex Concentrates
PLT	Platelets
PRBCs	Packed Red Blood Cells
PT	Prothrombin Time
SPO2	Peripheral Oxygen Saturation
TURP	Trans-urethral Resection of Prostate
WB	Whole blood
WHO	World Health Organization

OPERATIONAL DEFINITIONS OF KEY TERMS

Adherence to guidelines: Compliance with MTRH blood transfusion guidelines criteria on haemoglobin or haematocrit threshold for acute blood loss or peri-operative transfusion in consideration of estimated or expected blood loss and/or patient's systolic blood pressure.

Blood Transfusion: A procedure in which blood is infused into one's circulation through a vein. The blood is donated by another person or taken from the patient and stored until needed.

Blood Transfusion Practice: Decision to request and administer blood or blood components as assessed by the clinicians in orthopaedic trauma units.

Mechanism of injury: The manner in which an injury occurred.

Non-adherence to guidelines: Non-compliance with the threshold for any indication of acute blood loss and peri-operative transfusion as per MTRH blood transfusion guidelines criteria.

Orthopaedic trauma: Injury that primarily affects bones, joints and associated tissues.

Proportion of adherence: Degree to which blood components are given correctly as per policy guidelines.

CHAPTER ONE:INTRODUCTION

1.0 Introduction to the chapter

This chapter covers the background to the study, the statement of the problem, justification, research questions and objectives of the study.

1.1 Background Information

Orthopaedic trauma is a major global health problem (Conway, Coughlin, Caldwell, & Shearer, 2017). In developed nations, most orthopaedic injuries are attributed to falls with a lower prevalence of road traffic injuries (Court-Brown, Biant, Bugler, & McQueen, 2014) in contrast with middle and low income countries where road traffic accident victims contribute a large proportion of trauma burden (Boughton, Jones, Lavy, & Grimes, 2015). At Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya, trauma is the leading cause of morbidity burden in orthopaedic surgery practice with most cases resulting from road traffic accidents (Ayumba, Lelei, Emarah, & Lagat, 2015).

Commonly, long bone and pelvis fractures are implicated in significant blood loss in orthopaedic trauma (Soviero et al., 2010). It has been documented that 40% of patients with an isolated long bone fracture present with about 30% of body blood volume loss (Gumm et al., 2018). Blood loss could even be more particularly in femur and pelvic bone fractures. These losses are compounded in multiple fractures and the presence of associated external and internal soft tissues lacerations or vascular injuries.

Pelvic arterial injuries account for 10 to 20% of bleeding in the pelvis and occurs in about half of unstable pelvic fractures with ligament disruption (Heetveld, 2007).Documented arterial pelvic bleeding points are ventrally the internal pudendal

(27%) and obturator (16%) arteries; dorsally the superior gluteal (25%) and the lateral sacral (23%) arteries (Heetveld, 2007). Additional bleeding sites include the iliolumbar and the inferior gluteal arteries (9%). Accordingly, 43% of pelvic arterial haemorrhage sources are anterior and 57% are posterior (Heetveld, 2007). Conversely, posterior thin walled pelvic venous plexus injuries account for approximately 80% of pelvic haemorrhage (Heetveld, 2007). Diverse magnitudes of cancellous bone retroperitoneal bleeding are also found in haemodynamically unstable pelvic fracture patients.

Empirically, a closed, unilateral femoral diaphyseal fracture can result in blood loss amounting to 1500 milliliters representing 30% of adult blood volume. For a closed, unilateral tibial diaphyseal fracture, blood loss could be as high as 1000 milliliters. Blood loss in open fractures of these long bones may even be double that of closed fractures (Lee & Porter, 2005).

Orthopaedic injuries especially high energy trauma (Soviero et al., 2010) cause a substantial amount of internal (invisible) and/or external (visible) blood loss. Surgery for orthopaedic trauma patients also leads to variable amounts of blood loss (Brunskill et al., 2015). This results in depletion of red blood cells leading to shock and / or anemia. Blood loss also leads to consumption or altered function of coagulation factors and platelets resulting in a vicious cycle of abnormal haemostasis.

Eventually, there is impaired oxygen delivery with ensuing hypoxia leading to tissue ischaemia and necrosis. Major bone injury patients may exhibit altered mental status (anxiety, confusion and lethargy), tachypnoea, tachycardia, hypotension, reduced pulse pressure and urine output (Ramenofsky & Bell, 2012).

Therefore, strategies to optimize tissue oxygenation are vital (Boutin et al., 2017). Blood transfusion, a practice routinely under appraisal and debate, is one such important strategy of optimizing oxygenation in orthopaedic trauma patients. It involves use of blood which is a specialized connective tissue with special properties composed of cells suspended in a protein-rich fluid matrix known as plasma (Mescher, 2013). Blood and blood components which comprise whole blood, packed red blood cells, platelets, fresh frozen plasma and cryoprecipitate play an essential role in orthopaedic trauma care (Basu & Kulkarni, 2014). Of these, the commonly used blood component is packed red blood cells and rarely whole blood (Salverda et al., 2017). They have been widely used and also overused since early 20thcentury (Yaddanapudi & Yaddanapudi, 2014) in treatment of anaemia and shock among orthopaedic trauma patients. Compared to alternative therapies, blood products are preferred by health care providers in acute situations. This is because they frequently and conveniently raise patient's haemoglobin levels quickly (Muñoz & Leal-Noval, 2013).

However, the presumed benefits of blood transfusion might be counterpoised by potential harms due to inflammatory, thrombotic and immunologic effects of transfusion (Boutin et al., 2017). Correct blood transfusion practices are lifesaving; while inappropriate practices endanger lives (Cherian, 2002). The hallmark of good blood transfusion practice is the prescription and administration of the right blood component to the right patient in correct dosage and at the right time (Kaur, Basu, Kaur, & Kaur, 2011). Immunologic considerations for transfusion require blood products such as leukocyte-reduced, CMV-negative and irradiated cellular blood components. Other blood products such as factors XIII, IX complex (prothrombin

complex), albumin, immune globulin, anti-thrombin and protein C concentrates are used for transfusion therapy in special conditions.

Considering all blunt trauma cases, orthopaedic trauma patients consume most of all blood components because of their frequent need for urgent surgical treatment (Dolenc, Morris, Como, Wagner, & Vallier, 2016). Pelvis, acetabulum (Dolenc et al., 2016) and femur fracture operations such as hip replacement consume substantial blood (Begic, Mujicic, Coric, Zec, & Zunic, 2016).

Diversity exists in blood transfusion practices as per geographical location (global, regional, and inter-centre), type of patient population and indications for blood and blood components use largely due to variations in transfusion thresholds (Salverda et al., 2017). Furthermore, this variation usually happens within institutions among various disciplines (Gatheru, Olang & Mwanda, 2012). Globally, a study done in trauma centers across United Kingdom revealed tremendous constraint in healthcare resources following trauma haemorrhage (Stanworth et al., 2016). In United States of America, a study showed that about 15 % of all packed red blood cells are used in treatment of injury patients (Como, Dutton, Scalea, Edelman, & Hess, 2004). Another study in Australia found that orthopaedic trauma patients consume majority of blood and blood components among trauma patients (Sisak, Manolis, Hardy, Enninghorst, & Balogh, 2013).

In Sub-Saharan Africa, there is paucity of published data on characteristics of blood transfusion recipients (Mafirakureva et al., 2015) and the demand for blood and blood components has gone up (Osaro & Charles, 2011). In another study, it was documented that about a fifth (19.3%) of admitted trauma cases needed blood transfusion (Saidi, 2016). However, there is paucity of published literature on

transfusion practices among orthopaedic trauma patients. Studies in Uganda and Tanzania were done on blood transfusion among thermal burns (Kilyewala, Alenyo, & Ssentongo, 2017) and trans-urethral resection of prostate (TURP) (Esan et al., 2012) patients respectively. The Ugandan study found that the prevalence of blood transfusion in thermal burns is higher (22.3%) compared to developed countries.

In Kenya, the majority of data regarding blood transfusion practices relates to elective orthopaedics (Muriithi, 2013) rather than orthopaedic trauma, elective surgery (Gatheru, Olang & Mwanda, 2012), paediatrics (Gitakah, 2006) and neonatology (Oeba, 2016). This clearly indicates minimal literature on utilization and effectiveness of blood transfusion practices among orthopaedic trauma patients in Kenya. Additionally, to presume that practices in various medical specialties and divisions are similar is inappropriate (Sisak et al., 2013).

There is need to conduct studies targeting blood transfusion practices in specific surgical disciplines such as orthopaedic surgery (Gatheru, Olang & Mwanda, 2012). As a follow up, it is therefore imperative to establish the blood transfusion practices among orthopaedic trauma patients at Moi Teaching and Referral Hospital (MTRH). Furthermore, there is need for adoption and implementation of WHO criteria for blood transfusion (Muriithi, 2013) plus judicious implementation of blood transfusion guidelines (Oeba, 2016).

At MTRH, blood and blood components need is on the rise (Rotich, 2017), partly due to increasing orthopaedic trauma cases from road traffic accidents such as motorcycle and motor vehicle crashes (Ayumba et al., 2015), falls and rarely violence. Secondly, the transfusion practice is still liberal, diverse and anecdotal. This has resulted in recurrent acute shortages. Cognizant of this, MTRH developed and promulgated

policy guidelines on safe and appropriate use of blood and blood components in 2016 to direct health care providers in rational usage (MTRH, 2016).

The guidelines were formulated by a committee of experts composed of pathologists, orthopaedic, paediatric and general surgeons; gynaecologist, physician, paediatricians, haematologists, anaesthetist and laboratory technologists among others in line with the Kenya National Blood Transfusion Service guidelines on the safe and rational use of blood and its components (Kenya National Blood Transfusion Service, 2009). KNBTS guidelines in turn were adapted from World Health Organization (World Health Organisation, 2002). The guidelines were reviewed by haematologists as transfusion medicine experts and MTRH Top Management before approval for use.

1.2 Problem Statement

At Moi Teaching and Referral Hospital, the practice of blood transfusion in orthopaedic trauma units is faced with a major problem of inappropriate blood transfusions. Additional problems include erratic supply of safe blood and its components attributed to decline in blood donors pool coupled with increasing demand of blood owing to upsurge in admissions of road traffic accident victims with musculoskeletal injuries.

According to the data extracted from MTRH blood transfusion registers for the year 2017, 260 patients in adult orthopaedic wards were transfused with blood and blood components. Among these patients, 211 (81%) sustained various forms of orthopaedic trauma. The trauma cases were largely due to ever increasing motor cycle and motor vehicle accidents. These patients eventually got transfused; mostly with more than one unit of blood components resulting in blood overuse. This suggests a lack of compliance with the existing evidence based blood transfusion guidelines. It has been

observed that clinicians tend to overshoot blood requests beyond the actual need resulting in blood wastage (Adegboye, 2018).

Unfortunately, there is a substantial and striking paucity of data on characteristics and outcomes among adult orthopaedic trauma patients transfused at MTRH. Very little data exist on optimal adherence to MTRH clinical practice guidelines on safe and appropriate use of blood and blood components among these patients. The scarcity of blood and its components is significantly prevalent. Unnecessary transfusions have led to the concomitant rise in costs of processing and administration of blood components with exposure of patients to allogeneic transfusion associated risks.

Besides, patients miss or wait several days longer for surgical operations because of anecdotal discretionary practices on transfusion thresholds. These challenges often compromise the quality of service delivery in the health care system. Judicious adherence to guidelines for safe and appropriate use of blood components has been shown to ameliorate these challenges by decreasing the inappropriate use and increasing availability of blood components.

1.3 Justification for this study

There is an urgent need for rationalized and appropriate usage of blood and blood components. This goes a long way as an invaluable measure to conserve these increasingly limited products.

Foremost, this study described the characteristics of orthopaedic trauma patients transfused at MTRH, Eldoret. The valuable information obtained will guide trauma care providers on early recognition of patients at greatest need for transfusion and the wider public on trauma prevention.

Secondly, carrying out this study helped in determining proportion of adherence to MTRH guidelines on safe and appropriate use of blood and blood components among orthopaedic trauma patients. The findings will assist the hospital transfusion committee to audit and review appropriateness and effectiveness of blood usage eventually enhancing availability of blood products. Streamlining transfusion practices improves accessibility of blood products. At the healthcare level, increased availability of blood products minimizes the length of hospital stay waiting for transfusion and the number of patients who miss surgery due to lack of blood.

Thirdly, this study delved into outcomes including acute blood transfusion reactions and mortality among transfused orthopaedic trauma patients at MTRH giving insight regarding blood safety.

Administration of blood products as per evidence based guidelines greatly reduces financial costs (Joy & Bennet, 2012), conserves limited blood supplies and ascertains patient safety. Optimization of blood transfusion practices in patients sustaining orthopaedic trauma is a major expectation by all stakeholders. It has been observed that by describing and mapping blood and blood component use patterns; important opportunities for improvement are generated (Stanworth et al., 2016).

Without a doubt, this is a timely study as failure to conduct it would have significant negative impacts on blood transfusion practices in orthopaedic trauma units at MTRH, Eldoret. The clinicians would miss knowledge on characteristics of transfused orthopaedic trauma patients and local blood safety profile which are essential for good transfusion practices. On the other hand, the hospital management and transfusion committee would lose out on baseline data for the appraisal of blood transfusion practices in orthopaedic trauma units.

1.4 Research question

How are the blood transfusion practices in orthopaedic trauma units at Moi Teaching and Referral Hospital, Eldoret?

1.5 Objectives

1.5.1 Broad objective

To determine blood transfusion practices in orthopaedic trauma units at Moi Teaching and Referral Hospital, Eldoret

1.5.2 Specific objectives

1. To describe socio-demographic and clinical characteristics of orthopaedic trauma patients transfused at Moi Teaching and Referral Hospital, Eldoret
2. To determine adherence to MTRH guidelines on safe and appropriate use of blood and blood components among orthopaedic trauma patients transfused at Moi Teaching and Referral Hospital, Eldoret
3. To establish the incidence of acute blood transfusion reactions and outcomes among orthopaedic trauma patients transfused at Moi Teaching and Referral Hospital, Eldoret

CHAPTER TWO:LITERATURE REVIEW

2.0 Introduction to Literature Review

This chapter gives an account on characteristics of transfused orthopaedic trauma patients. Additionally, it covers adherence to blood transfusion guidelines and outcomes of blood transfusion among orthopaedic trauma patients.

2.1 Socio-demographic and clinical characteristics of blood transfusion recipients

Blood transfusion practice in trauma should take into account individual patient characteristics (Kilyewala et al., 2017) such as vital signs, blood lost, circulating blood volume and end organ perfusion status. Activation for early transfusion is grounded on the patient's vital signs, expected major bleeding and injury patterns (Sisak et al., 2018). Sound clinical decisions to transfuse should consider multiple factors related to patient's clinical status, oxygen delivery (Wheeless, 2013) and all important physiological determinants that affect oxygenation (Sambandam, Batra, Gupta, & Agrawal, 2013) plus laboratory parameters (Kipkulei, Buziba, Mining, & Jepngetich, 2019). Transfusion should be based on concomitant consideration of hematologic and clinical characteristics of the patient (Oeba, 2016).

Young adults age bracket has been shown to be the median age for transfusion in trauma compared to the other age categories (Ilancheran et al., 2015; Sisak et al., 2018). However, it has been reported that the rate of transfusion is much the same for all age groups and highest among those with ISS >15 (Saidi, 2016). The proportion needing transfusion is higher among females (Saidi, 2016) and the likelihood of blood transfusion is higher among females compared to males (Verlicchi, Desalvo, Zanotti, Morotti, & Tomasini, 2011). Liberal transfusion strategies might result in better outcomes in older patients than restrictive strategies hence more demand for blood

(Simon, Craswell, Thom, & Fung, 2017). Blood transfusion among patients older than 65 years tend to be inappropriate (Shander et al., 2011).

Regarding the mode of injury, rate of transfusion is highest among gun-shot wound injuries (Saidi, 2016). Higher ISS was associated with an increased probability of blood product transfusion where every increase in ISS of 9 points results in a 2-fold increased risk of transfusion (Dolenc et al., 2016). The rate of transfusion is highest among those with ISS >15 (Saidi, 2016). Most transfusions are associated with interventions regarding the femur bone (Verlicchi et al., 2011).

Orthopaedic trauma may be associated with other injuries, risks and pre-existing conditions (Ayumba et al., 2015). For instance, ischaemic heart disease among patients is of utmost concern among anaesthetists (Young, Marsh, Akhavani, Walker, & Skinner, 2008). Peri-operative anaemia is associated with increased transfusion rates (Newman, Tran, McGregor, & Bramley, 2018). Therefore to minimize packed red cell transfusion, it is important to identify and correct pre-operative anaemia at least 4 weeks before surgery (Boralessa, Goldhill, Tucker, Mortimer, & Grant-Casey, 2009). Pre-injury haemoglobin level is a factor of consideration during transfusion in the first 2 days of admission (Wertheimer, Olaussen, Perera, Liew, & Mitra, 2018). Knowledge of local blood recipients profiles is useful in prediction of routine transfusion needs (Kipkulei et al., 2019).

2.2 Appropriate blood usage and adherence to transfusion guidelines

Blood transfusion practice is therapeutic in life and / or limb threatening orthopaedic trauma hemorrhage. However, not all patients will gain or have a boost on outcomes as a result of blood transfusion. Therefore this calls for its usage for the appropriate indications. Adherence to transfusion guidelines is helpful and must be tailored to individual circumstances.

2.2.1 Appropriate usage of blood and blood components

Packed red blood cells in general give circulatory (volume-related), rheological (viscosity-related) and oxygen transport benefits (Yaddanapudi & Yaddanapudi, 2014). Of these, the main function of red blood cells is transport of oxygen from lungs to various tissues. PRBCs are needed to restore oxygen carrying capacity of the circulating intravascular volume when 30-40% of blood volume has been lost (Gumm et al., 2018).

Primarily, it is not considered a volume expander. Hence early and empirical administration of crystalloids is recommended before transfusion of packed red blood cells in patients with class III or IV of haemorrhagic shock (Gumm et al., 2018). The recommended quantity of fluid is one to two liters of crystalloid solution (Ramenofsky & Bell, 2012). When cross matched packed red blood cells are unavailable, type O negative packed red blood cells are indicated for patients with exsanguinating bleeding (Ramenofsky & Bell, 2012). Rhesus negative packed red blood cells are preferred for females of childbearing age to prevent sensitisation and resultant complications.

Transfusion of packed red blood cells does not promptly improve oxygen delivery or uptake in tissues hence its use is limited in acute situations. Nonetheless, its administration is desired to improve viscosity in cases of severe haemodilution yet more viscosity may slow blood circulation to tissues (Yaddanapudi & Yaddanapudi, 2014).

The haemoglobin threshold at which transfusion is warranted is controversial (Carson et al., 2011). Conventionally, patients with haemoglobin below 10 g/dl are recommended for blood transfusion. Blood transfusion for a haemoglobin level >8g/dl in the absence of symptoms and signs of anaemia is not justified by current clinical

evidence (Ponnusamy, Kim, & Khanuja, 2014). Furthermore, restrictive packed red blood cells transfusion at haemoglobin of 8 g/dl to patients undergoing orthopaedic surgery is not associated with elevated rates of unfavourable clinical outcomes (Carson & Guyat, 2016). Exceptions to this recommendation include patients with acute coronary syndromes (Docherty et al., 2016), chronic transfusion-dependent anaemia and severe thrombocytopenia.

The trigger to give or hold back packed red blood cells in acute haemorrhage should not be based on packed cell volume (haematocrit) or haemoglobin as values do not fall for several hours (Gumm et al., 2018). It is not necessary to transfuse patients who are asymptomatic, not bleeding and have a haemoglobin level of greater than 8 g/dl (Boralessa et al., 2009). In the non-existence of active bleeding and other risk factors, the transfusion trigger for packed red blood cells in a stable patient should be haemoglobin level less than 7 g/dl (MTRH, 2016).

Avoiding aggressive fluid resuscitation in the bleeding patient until definitive control of haemorrhage may avert additional haemorrhage (Gumm et al., 2018). This is done by careful balanced resuscitation with regular re-evaluation (Ramenofsky & Bell, 2012). Aggressive fluid resuscitation leads to more bleeding by increasing blood pressure and dislodging early thrombus. It can also alter micro-vascular permeability by activation of cascade processes leading to abnormal inter-compartmental relocation of fluid, hydraulic acceleration of bleeding and dilution of clotting factors.

Whole blood has been used as a replacement of blood in acute blood loss with hypovolaemia (World Health Organisation, 2002) yet transfusion of fresher whole blood does not boost clinical outcomes (Carson & Guyat, 2016). Whole blood is progressively infrequently issued, hence its clinical indications are limited (Salverda et al., 2017). It is rarely used in current practice in developed countries although in

many resource poor countries, it accounts for most transfusions. At MTRH, its use has been declining (Rotich, 2017).

Haemorrhage from trauma may result in increased consumption of platelets. Also, transfusion of packed red blood cells leads to thrombocytopenia from haemodilution. Some platelets are dysfunctional. Therefore, platelet concentrates which are prepared from whole blood or collected by platelet-pheresis are indicated in these situations (World Health Organisation, 2002). Platelet transfusion should be based on both clinical criteria and laboratory values. Platelet levels should be maintained at $\geq 50 \times 10^9$/L for patients with ongoing bleeding; $\geq 100 \times 10^9$/L and $\geq 150 \times 10^9$/L among those due for minor and major surgery respectively (MTRH, 2016).

Fresh frozen plasma is made by separating plasma from whole blood within 6 hours of collection and rapidly freezing to negative twenty five degrees Celsius or colder (World Health Organisation, 2002). It contains stable clotting factors that are useful during excessive micro-vascular bleeding, coagulation factor deficiency and urgent reversal of warfarin therapy when prothrombin complex concentrates are not available. It is also used in massively transfused patients with significant coagulation abnormalities. Fresh frozen plasma is used in the presence of an international normalized ratio greater than 2.0 in the absence of heparin and activated partial thromboplastin time one and half times mean normal value. The dosage is 10-15 ml/kg body weight (KNBTS, 2009). It is not indicated if prothrombin test or international normalized ratio and activated partial thromboplastin time are normal. Fresh frozen plasma is not used as a volume expander. A study among neonates in Eldoret, Kenya found that no coagulation tests were done before administration of FFP for the neonates who were given this component (Oeba, 2016).

Cryoprecipitate is a blood product prepared from FFP containing factor VIII and fibrinogen (World Health Organisation, 2002). It is indicated in patients with fibrinogen deficiency in the presence of excessive bleeding (hypofibrinogenemia). It can also be utilised as a supplement in massively transfused patients when fibrinogen levels cannot be measured in a timely fashion. Cryoprecipitate may be handy in situations of fibrinogenolysis, persistent hypofibrinogenemia refractory to FFP and dilutional hypofibrinogenemia. Additionally, it plays a role in the treatment of bleeding trauma patients with Haemophilia A (factor VIII deficiency), von Willebrand's disease and factor XIII deficiency. Cryoprecipitate is indicated when fibrinogen concentration is less than 100 mg/dl. The dosage is usually 2 ml/kg body weight.

New evidence places greater emphasis on the preoperative assessment of the patient and the use of adjunct therapies to prevent and /or treat bleeding. This includes more use of pharmacologic therapies to minimise blood transfusions, such as erythropoietin for anaemic cases, prothrombin complex concentrates for urgent reversal of warfarin and intraoperative antifibrinolytic administration for procedures having a high risk of bleeding (The American Society of Anesthesiologist, 2015). The use of platelets, cryoprecipitate, and fresh-frozen plasma among injured patients who do not need massive transfusion should be informed by coagulation studies, along with fibrinogen levels and balanced resuscitation principles (Ramenofsky & Bell, 2012). Need for assessment of coagulation tests (PT, INR, aPTT) and fibrinogen levels in patients with excessive bleeding before administration of fresh frozen plasma and cryoprecipitate respectively.

2.2.2 Adherence to blood transfusion guidelines

Several blood transfusion guidelines are in existence but awareness and adherence to these guidelines in aiding appropriate indications of blood components appear to be inadequate (Yudelowitz, Scribante, Perrie, & Oosthuizen, 2016). In the United Kingdom, it was shown that there is an extensive inconsistency in attitudes and practices towards orthopaedic blood transfusion practice (Young et al., 2008). A study at Aga Khan University Hospital, Karachi, Pakistan revealed that the proportion of inappropriate transfusion in orthopaedic surgery was rather high at 65% (Abbas et al., 2014). Adherence to patient blood management guidelines significantly reduces transfusion rates (Kopanidis et al., 2016; Newman et al., 2018). Pre-transfusion haemoglobin level is the most significant factor associated with adherence to transfusion guidelines and clinicians tend to use it as the sole deciding factor in initiating blood transfusion (Shander et al., 2011).

A study carried out at KNH on blood requests, cross-match and transfusion practices for elective multidisciplinary surgery recommended that clinicians standardize blood transfusion practice through adherence to guidelines on appropriate use of blood products and need for studies targeting specific disciplines such as orthopaedic surgery (Gatheru, Olang & Mwanda, 2012). It is worth noting that this study was done more than half a decade ago yet blood transfusion practices evolve yearly due to advent of technology plus knowledge and skill updates from newly generated scientific evidence. Therefore, it is important to continually appraise existing practice and guidelines. A study done at MTRH on blood transfusion practices among neonates whose clinical conditions were largely non-trauma reported that adherence to transfusion guidelines is generally less than optimal (Oeba, 2016). Perhaps these

guidelines (Kenya National Blood Transfusion Service, 2009) underestimate patient transfusion requirements.

In an endeavor to streamline blood transfusion service; MTRH in the year 2016 formulated, approved and issued policy guidelines on safe and appropriate use of blood and blood components. The guidelines are in line with Kenya National Blood Transfusion Service guidelines (Kenya National Blood Transfusion Service, 2009) which were largely adapted from World Health Organization (World Health Organisation, 2002). This guideline is the one that is widely circulated and in use at MTRH to promote good practices in transfusion medicine by minimizing variations in blood use.

It recommends restrictive (conservative) use of transfusion requiring a reduction in the use of blood and blood components and that transfusion should only be used when it is absolutely necessary after comprehensive consideration of the patient's clinical condition. The transfusion threshold should be primarily led by a criteria consisting of blood pressure level, estimated or expected blood loss and haemoglobin or haematocrit levels (MTRH, 2016). Acute blood loss or peri-operative transfusion is indicated when at least one criteria of the intended component is met (MTRH, 2016).

Blood transfusion is considered adherent to MTRH guidelines (MTRH, 2016) if any of the following thresholds is observed.

2.2.3 Whole blood transfusion thresholds

Whole blood is indicated for:

- Blood loss $\geq$ 40% of the total body blood volume
- Hypotension unresponsive to appropriate and adequate intravenous fluids
- Packed cell volume $<$ 15%

2.2.4 Packed red blood cells transfusion thresholds

Packed red blood cells are indicated for:

i. Emergency cases with:

- Haemoglobin level <7g/dl with minimal blood loss
- Haemoglobin level <9g/dl and expected blood loss is >500mls
- Haemoglobin <10g/dl with significant co-morbidities such as cardiovascular, respiratory and hepato-renal disorders

ii. Elective cases with haemoglobin < 10g/dl and blood loss > 30% of the patient's total blood volume

2.2.5 Platelets

Platelets are indicated for:

- Minor surgery with platelet count $< 100 \times 10^9/L$
- Major surgery with platelet count $< 150 \times 10^9/L$

2.3 Blood transfusion complications and outcomes

2.3. 1 Complications associated with blood transfusion

The complications of interest in this study were acute blood transfusion reactions which usually occur during, or within, 24 hours of cessation of transfusion (Murphy, Roberts & Yazer, 2017). World Health Organisation (WHO) strongly advocates for safe and effective blood since needless transfusions, precarious transfusion practices expose patients to the risk of serious adverse transfusion reactions and transfusion-transmissible infections (WHO, 2002). These incidents can have dangerous effects on patients and therefore evidence based transfusion is strongly advocated (Brunskill et al., 2015). Debate exists over the relation of blood transfusion with complications (Dolenc et al., 2016). A study done in Indianapolis, United States of America found that there is significant risk of postoperative complications such as ischemic events,

infections and immunity alterations among transfused orthopaedic surgery cases (Mullis et al., 2015). Issues such as immune reactions and infections are considerably worrisome (Sambandam et al., 2013). Most blood transfusion reactions are mild involving urticaria and moderate pyrexia. Acute, severe reactions may occur in 1-2% of transfused patients (Cherian, 2002). Immunologic complications include acute and chronic haemolysis, febrile and allergic reactions, transfusion associated graft-versus-host disease and transfusion related acute lung injury (Hoffman, Benz, Silberstein, Heslop, Weitz, Anastasi, Salama, & Abutalib, 2018). Non-immunologic complications comprise hypothermia, physical or chemical haemolysis, citrate toxicity, transfusion associated circulatory overload, transfusion induced haemosiderosis (Friedman, Javidroozi, Lobel, & Shander, 2017) and infections. Transfusion of blood and blood components has been documented to be linked to thromboembolism and infections (Ristagno et al., 2018). In Nigeria, it was noted that complications and risks of blood transfusion notwithstanding, there are orthopaedic trauma patients who require blood and blood products (Agaja, 2009).When blood and blood components are given without appropriate indication, the patient seldom benefits and is subjected to iatrogenic risks (Muriithi, 2013). Transfusion-related adverse events are rather common and transfusion may affect infection risk by altering immune function; therefore decreasing blood transfusion may be beneficial for patients in some cases (Teng et al., 2015).

2.3.2 Outcomes of blood transfusion

Blood transfusion is a compelling independent predictor of mortality in trauma (Malone et al., 2003). However, in the United Kingdom, a study among operated hip fracture patients suggested that transfusion is not associated with a change in mortality or infection rates (Johnston et al., 2006). Further, no differences in

mortality have been shown between liberal and restrictive transfusion strategies (Parker, 2013). Need for more blood transfusion is among the most important determinants of outcome in traumatic pelvic fracture patients (Paydar, Chaabi, Akhavan, Ghahramani, & Dehghankhalili, 2017). Transfusion is significantly associated with mortality in patients who receive blood during total knee arthroplasty (Hart et al., 2014; Newman et al., 2018). Studies have demonstrated no advantage in patient functional status with higher transfusion thresholds (Young et al., 2008).

CHAPTER THREE:METHODOLOGY

3.0 Introduction to methodology

This chapter describes the methodology of the study.

3.1 Study Site

The study was conducted in orthopaedic wards at Moi Teaching and Referral Hospital (MTRH); an ISO 9001:2015 certified hospital which is located along Nandi Road in Eldoret Town, Uasin-Gishu County (310 kilometers North West of Nairobi). Eldoret is the headquarters of Uasin-Gishu County in the North Rift region of Western Kenya.

Currently, MTRH is the second largest national teaching and referral hospital (level 6 public hospital) in the country with a bed capacity of 991 patients. The hospital serves residents of Western Kenya region (representing at least 22 counties), parts of Eastern Uganda and Southern Sudan catchment areas with a population of about 24 million people.

The hospital is a major trauma centre in the region being the highest referral center, its location along a major highway and having a wide catchment area. It has male, female and paediatric orthopaedic wards with a total bed capacity of 56 patients. Most patients admitted to these wards have conditions that are trauma related.

Majority of the patients are self-referrals who arrive in an unpredictable manner using a variety of means including public and private transport. Others are referred or transferred from peripheral health facilities.

MTRH has a Blood Transfusion Unit (BTU) that issues packed red blood cells, platelets, fresh frozen plasma and cryoprecipitate. The hospital has a transfusion committee and haemovigilance officer to promote safe and appropriate blood transfusion practice.

3.2 Study Design

This was a hospital based descriptive cross-sectional study.

3.3 Study Population

The study population consisted of adult patients admitted into MTRH orthopaedic wards after sustaining trauma and being transfused with blood or blood components between March 2019 and January 2020.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

- Adult orthopaedic trauma patients aged 18 years and above who were transfused with blood or blood components in MTRH and gave consent to participate in the study.

3.4.2 Exclusion Criteria

- An orthopaedic trauma patient who had concomitant brain injury since lower threshold for transfusion is advised in head injury (Salverda et al., 2017). Brain injury was diagnosed by using a standard set of signs and symptoms and head computerized tomography scan images.

3.5 Sample Size

The Cochran formula for calculating a sample size for proportions (Cochran & Wiley, 1977) was used to calculate the sample size as follows:

$n_0 = Z^2pq/e^2$

Where;

n_0 = desired sample size

Z = the standard normal deviation at desired confidence level (1.96 for 95% confidence level)

p = 35% i.e. the proportion of orthopaedic surgery patients who received blood transfusion as per guidelines in a previous study conducted at Aga Khan University Hospital, Karachi, Pakistan (Abbas et al., 2014).

q = 1 – p

= 1 - 0.35 = 0.65

e = 5% i.e. the desired level of precision

Substituted as:

$$n = \frac{1.96^2 \times 0.35 \times 0.65}{(0.05)^2}$$

= 349.6, rounded off to 350 patients.

MTRH Blood Transfusion Unit records for the year 2017 were checked and it was found that 211 patients with orthopaedic trauma were transfused. Therefore, the study population was anticipated to be smaller compared to the one in Abbas et al., 2014 study.

As a result, the sample size obtained from Cochran formula above was adjusted using the following equation for finite population correction for proportions:

$n = n_0 / (1 + ((n_0 - 1) / N))$

Where:

- n_0 is Cochran's sample size recommendation
- N is the population size
- n is the new, adjusted sample size

The population size N was taken as 211, which is the number of orthopaedic trauma patients transfused with blood and blood components at MTRH in the year 2017 as per records at the Blood Transfusion Unit.

These values were then substituted into the formula as follows:

$n = 350 / (1 + (349/211)) = 132$.

3.6 Sampling Method

Patients who met the inclusion criteria were enrolled consecutively upon admission until the desired sample size was reached.

3.7 Study Variables

3.7.1 Independent Variables

Socio-demographic data were age, sex, education level, occupation, and referral status. Clinical characteristics included injury mechanism and type, Injury Severity Score (ISS), heart rate, respiratory rate, systolic blood pressure and expected or estimated blood loss. Pre transfusion laboratory characteristics encompassed haemoglobin, haematocrit, platelets and patient blood group.

Injury Severity Score (ISS) is an anatomic scoring system with a range of 0 to 75. It is determined by identifying the three most injured body regions, then determining the severity of each as defined by the Abbreviated Injury Scale (AIS) designated as A, B, and C. The ISS = $A^2 + B^2 + C^2$.

3.7.2 Dependent Variables

The dependent variables in this study were adherence to blood transfusion guidelines and blood transfusion reactions.

3.8 Data Collection Tool

Data was collected from patients or next of kin who gave consent using a structured questionnaire consisting of two sections. The first section was interviewer administered whereby patient or next of kin responses on socio-demographic and part of trauma data were obtained and filled in the questionnaire. In the second section, clinical and laboratory data was extracted from the medical charts. Questionnaire content was adopted from KNH Trauma Registry and MTRH Transfusion Guidelines then modified as per study objectives.

3.9 Study Execution

Data was collected from March 2019 to January 2020 by the Principal Investigator and three research assistants under the supervision of the supervisors. The research assistants included one clinical officer intern and two nursing officers. They were selected on the basis of availability and being conversant with our orthopaedic trauma care units. The Principal Investigator trained the research assistants on patient enrolment, ethics and data collection.

The Principal Investigator and research assistants then identified orthopaedic trauma patients undergoing blood transfusion and checked for eligibility criteria. Patient's index transfusion episode was evaluated in this study. The decision to transfuse a patient was made by clinicians of various cadres including consultants, residents, medical and clinical officers. Estimated blood loss was done and documented by the primary clinicians in the patient medical records. Subsequently, those eligible and gave consent were enrolled into the study.

The first objective was addressed by describing socio-demographic and clinical characteristics of transfused patients. The second objective was addressed by evaluating clinical, laboratory and transfusion data against adherence to MTRH transfusion guidelines. The third objective was addressed by monitoring the patient for any blood transfusion reactions within a twenty four hour period post transfusion onset.

3.10 Study Procedure Schema

A schema on the study procedure for each patient is as follows:

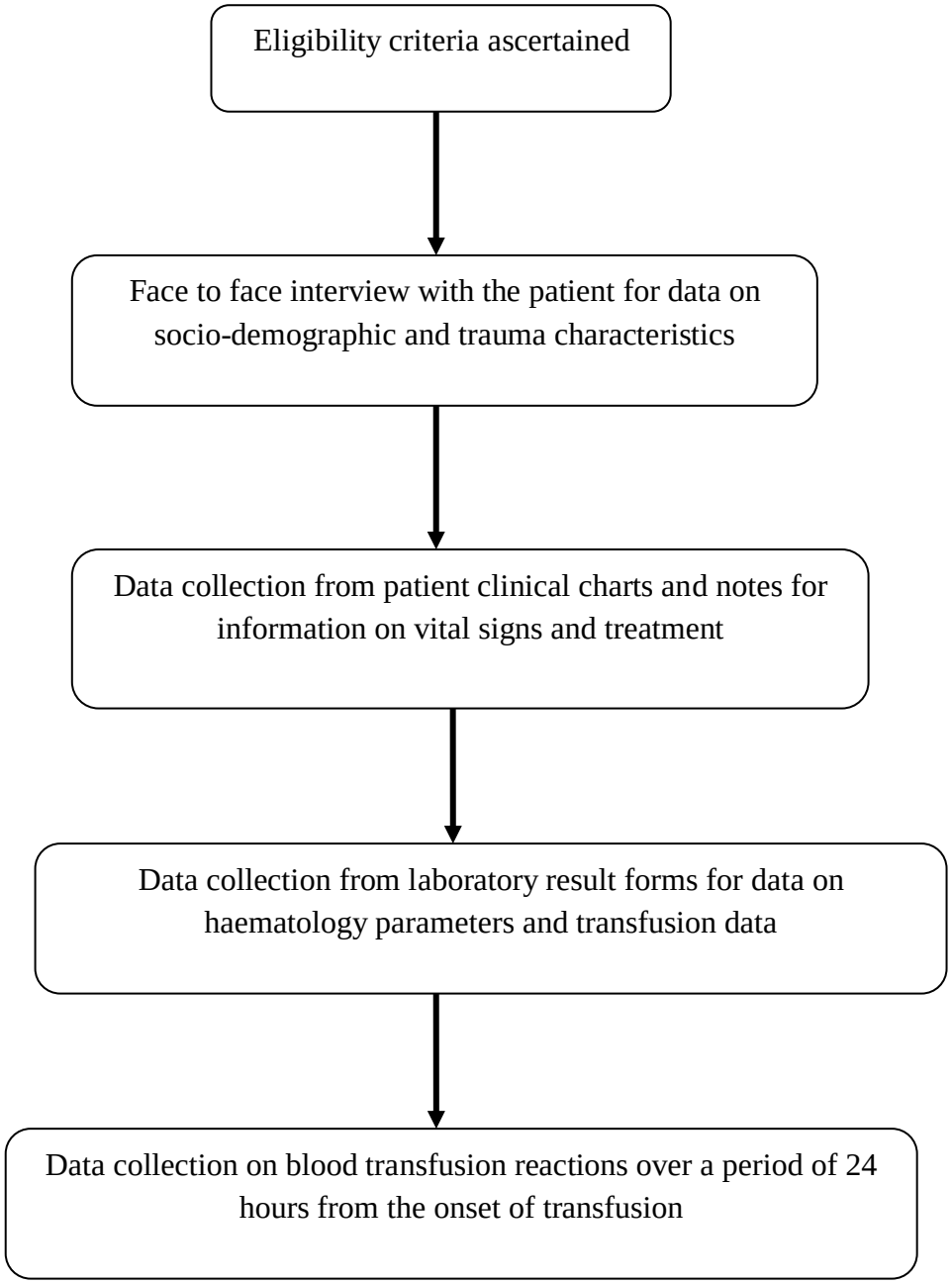

Figure 1: Study Procedure Schema

3.11 Data Management, Analysis and Presentation

3.11.1 Data Management

Filled questionnaires were checked for errors and corrected. They were also checked for completeness and coded accordingly. Data was entered in Microsoft® Access® 2019 version 16.0 software package for storage and back up. Then, data was exported to R version 3.6.0 (R Core Team, 2019) statistical software for analysis. Strict patient confidentiality was maintained at all times with no use of identifiers on the questionnaires. Hard copies of the questionnaires were securely kept under lock and key while soft copy data was password protected.

3.11.2 Data Analysis

3.11.2.1 Descriptive Statistics

Descriptive analyses were done for socio-demographic characteristics of the population. Continuous data were summarized as mean with standard deviation and median with inter-quartile range while categorical data were summarized as frequency tables and proportion.

3.11.2.2 Inferential Statistics

Fisher's Exact Test was used to assess associations between categorical variables and Kruskal-Wallis Test was used for continuous independent variables. A p value of less than 0.05 was considered statistically significant.

3.11.3 Data Presentation

Results were presented in prose, tables and figures.

3.12 Ethical Considerations

The study was done after approval from Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC) was sought. Permission to carry out the study was also obtained from Moi Teaching and Referral Hospital Chief Executive Officer. Only patients who had given voluntary informed written consent participated in the study. A third party (adult relative/guardian) consented on behalf of critically ill patients who were unable to give informed consent on their own.

All patients received routine care with no direct financial benefit. Additional costs on medical care were not meted on the patients for the purpose of this study. No coercion or payment was done to influence patients join the study.

There were no risks associated with the study. Neither incentives nor inducements were used to coerce patients into the study. The patients were free to withdraw from the study at any point in time with no consequences.

3.13 Dissemination of findings

The research findings from this study will be disseminated through relevant institution channels, thesis defense presentation, scientific conferences and publication journals. Bound copies of thesis will be submitted to supervisors and Moi University library.

3.14 Study Limitation

A few patients had charts whose transfusion data entry was incomplete or unavailable. This was mitigated by verifying against the patients' files.

CHAPTER FOUR:RESULTS

4.0 Introduction to the chapter

This chapter consists of results presented in prose, tables and figures according to the study objectives.

4.1 Socio-demographic and clinical characteristics

This section encompasses socio-demographic, trauma, vital signs and laboratory characteristics.

4.1.1 Socio-demographic characteristics

A total of 132 patients participated in this study. Males comprised 101 (76.5%) and females were 31 (23.5%) giving a male to female ratio of 3.3:1. The mean and median ages were 40.35 (SD17.90) and 36 (IQR 28, 47) years respectively. The age range of the patients was 18 to 90 years. Most patients, 95 (72.0%) were referrals, 64 (48.5%) were unskilled workers, 64 (48.5%) had primary school level of education and 42 (31.8%) were aged 21 to 30 years. The socio-demographic characteristics are shown in Table 1.

Table1: Socio-demographic characteristics

Characteristics	Overall n=132
Sex	
Female	31 (23.5%)
Male	101 (76.5%)
Age Group	
< 20 years	7 (5.3%)
21 to 30 years	42 (31.8%)
31 to 40 years	34 (25.8%)
41 to 50 years	20 (15.2%)
51 to 60 years	8 (6.1%)
61 to70 years	9 (6.8%)
>70 years	12 (9.1%)
Education Level	
College/University	8 (6.1%)
High School	48 (36.4%)
No Formal Education	12 (9.1%)
Primary School	64 (48.5%)
Occupation	
Semi-skilled worker	53 (40.2%)
Skilled worker	10 (7.6%)
Student	5 (3.8%)
Unskilled worker	64 (48.5%)
Referral Status	
Non-Referral	37 (28.0%)
Referral	95 (72.0%)

4.1.2 Trauma characteristics

Most of the patients, 105 (79.5%) had injuries due to road traffic accidents. Gunshot and assault injuries were uncommon. The overall mean and median injury severity score were 12.05 (SD 6.21) and 10 (IQR 9, 13) respectively. Majority of the patients, 62 (47.0%) had isolated femur fractures while 30 (22.7%) had multiple trauma. About half of the patients, 61 (46.2%) underwent open reduction and internal fixation (ORIF) while 58 (43.9%) had debridement primarily. Table 2 describes the trauma characteristics.

Table 2: Trauma characteristics

Characteristics	Overall n=132
Mechanism of injury	
Assault	5 (3.8%)
Falls	19 (14.4%)
Gunshot	3 (2.3%)
Road Traffic Accidents	105 (79.5%)
Injury Severity Score	
Mean (SD)	12.05 (6.21)
Median (Q1,Q3)	10 (9,13)
Type of injury	
Femur fractures	62 (47.0%)
Fibula fracture	1 (0.8%)
Humerus fracture	1 (0.8%)
Multiple trauma	30 (22.7%)
Pelvis fractures	3 (2.3%)
Spine fracture	1 (0.8%)
Tibia fractures	34 (25.8%)
Surgery	
Amputation	6 (4.5%)
Debridement	58 (43.9%)
External fixation	6 (4.5%)
Grafting	1 (0.8%)
ORIF	61 (46.2%)

Motorcycle passengers and riders were almost equal in number with a ratio of 1.06:1 and comprised majority of injured road accidents victims. Notably, motorcycle riders were the youngest [mean age of 30.0 (SD 7.4) years], mostly males (97.1%) and had a lower mean injury severity score [11.8 (SD 6.9)] compared to motorcycle passengers as shown in Table 3.

Pedestrians involved in motorcycle accidents were older at a mean age of 46.3 (SD 14.5) years and were mostly males (60.0%). Motor vehicle passengers had the highest mean injury severity score of 15.1 (SD 10.9). Overall, 80 of 105 (76.2%) patients

were afflicted by injuries from motorcycle associated road traffic accidents predominating 25 of 105 (23.8%) patients who sustained trauma from motor vehicle road traffic accidents.

Table 3: Road traffic accidents

Mechanism of injury	n = 105	Mean age	Sex		Mean ISS
			Male	Female	
MC Passenger	36	37.3 (17.1)	21 (58.3%)	15 (41.7%)	12.6 (6.3)
MC Pedestrian	10	46.3 (14.5)	6 (60.0%)	4 (40.0%)	12.6 (5.8)
MC Rider	34	30.0 (7.4)	33 (97.1%)	1 (2.9%)	11.8 (6.9)
MV Driver	4	41.0 (12.9)	4 (100.0%)	0 (0.0%)	13.0 (3.8)
MV Passenger	8	37.9 (18.8)	8 (100.0%)	0 (0.0%)	15.1 (10.9)
MV Pedestrian	13	40.6 (13.8)	11 (84.6%)	2 (15.4%)	13.5 (6.7)

On average, those who fell from a standing height were older [73.1 (SD 15.4) years] compared to those who fell from a significant height [44.8 (SD 21.3) years]. However, their mean injury severity score was similar as shown in Table 4. Most patients who fell from a significant height, 6 of 8 (75.0%) were males.

Table 4: Falls

Mechanism of injury	n = 19	Mean age	Sex		Mean ISS
			Male	Female	
Fall (height)	8	44.8 (21.3)	6 (75.0)	2 (25.0)	9
Fall (standing)	11	73.1 (15.4)	6 (54.5)	5 (45.5)	9

4.1.3 Vital signs

Pre-transfusion vital signs just before transfusion commencement were recorded. Majority of the patients, 105 of 132 (79.5%) had normal pre-transfusion pulse rate and 115 of 132 (87.1%) had normal systolic blood pressure as shown in Table 5. However, more than half of them, 77 of 132 (58.3%) were found to have increased respiratory rate.

Table 5: Vital Signs

Characteristics	Overall n=132
Pulse Rate	
Bradycardia	1 (0.8%)
Normal	105 (79.5%)
Tachycardia	26 (19.7%)
Respiratory Rate	
Normal	55 (41.7%)
Tachypnoea	77 (58.3%)
Systolic Blood Pressure	
Hypertension	9 (6.8%)
Hypotension	8 (6.1%)
Normal	115 (87.1%)

4.1.4 Laboratory characteristics

The median (IQR) pre-transfusion haemoglobin (g/dl), haematocrit (%), platelets (10^9/L) were 8.90 (7.98, 10.35), 26.10 (23.15, 30.48) and 330.0 (218.5, 578.0) respectively. Majority of the patients, 78 of 132 (59.1%) had pre-transfusion haemoglobin level in the category of 7 to 10 g/dl. Only 16 of 132 (12.1%) patients had hemoglobin less than 7 g/dl while 38 of 132 (28.8%) had hemoglobin more than 10 g/dl. The commonest blood group among the transfusion recipients was O positive followed by A positive and B positive as shown in Table 6.

Table 6: Laboratory characteristics

Characteristics	Overall n=132
Haemoglobin (g/dl)	
Median (IQR)	8.90 (7.98, 10.35)
Haematocrit (%)	
Median (IQR)	26.10 (23.15, 30.48)
Platelets (10^9/L)	
Median (IQR)	330.0 (218.5, 578.0)
Haemoglobin Category (g/dl)	
<7	16 (12.1%)
7 – 10	78 (59.1%)
>10	38 (28.8%)
Patient Blood Group	
A-	1 (0.8%)
A+	44 (33.3%)
AB-	1 (0.8%)
AB+	2 (1.5%)
B-	2 (1.5%)
B+	20 (15.2%)
O-	2 (1.5%)
O+	60 (45.5%)

4.2 Adherence to guidelines on safe and appropriate use of blood components

4.2.1 Proportion of adherence to guidelines

The proportion adherent to blood transfusion guidelines criteria was 16.7% [95% CI: (10.75, 24.14)]. Majority of the patients, 127 of 132 (96.2%) received packed red blood cells followed by 5 of 132 (3.8%) patients who received whole blood. Only two patients received platelets in addition to packed red blood cells transfusion.

Out of the whole blood transfusions, the proportion adherent to guidelines was 20% attributed to compliance with pre-transfusion systolic blood pressure threshold while non-adherence to guidelines was 80 % due to non-compliance with any of the whole blood transfusion guidelines criteria.

Of packed red blood cells transfusions, the proportion adherent to guidelines was 16.5%. Of these, 81% were due to compliance to pre-transfusion haemoglobin / haematocrit thresholds, 9.5 % to estimated / expected blood loss threshold and another 9.5% due to both. Conversely, the proportion non-adherent to guidelines was 83.5%. Among packed red blood cells transfusions non-adherent to guidelines, 0.9% were due to non-compliance to haemoglobin / haematocrit thresholds, 70% to estimated / expected blood loss threshold and 29.1% due to non-compliance with both as shown in Figure 2.

According to the blood transfusion requests, the transfusion prescribers were residents at 55%, medical officers at 25% and clinical officers at 20%.

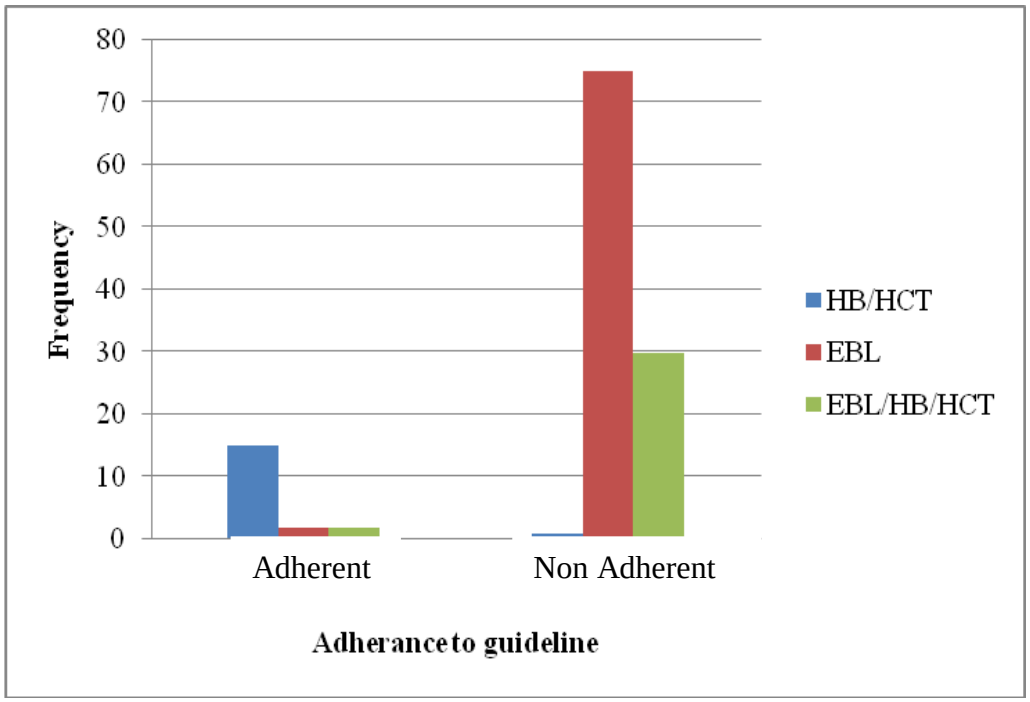

Figure 2: Comparison of reasons for adherence / non adherence to guidelines

4.2.2 Factors associated with adherence to blood transfusion guidelines

There was no statistically significant association between socio-demographic characteristics and adherence to blood transfusion guidelines at bivariate analysis as shown in Table 7.

Table 7: Bivariate analysis of association between socio-demographic characteristics and adherence to blood transfusion guidelines

	Adherence to blood transfusion guidelines			
Characteristics	**Yes n = 22**	**No n = 110**	**Total n=132**	***p* value**
Age Group				0.54[1]
< 20 years	1 (14.3%)	6 (85.7%)	7 (100%)	
21 to 30 years	6 (14.3%)	36 (85.7%)	42 (100%)	
31 to 40 years	9 (26.5%)	25 (73.5%)	34 (100%)	
41 to 50 years	1 (5.0%)	19 (95.0%)	20 (100%)	
51 to 60 years	1 (12.5%)	7 (87.5%)	8 (100%)	
61 to 70 years	2 (22.2%)	7 (77.8%)	9 (100%)	
> 70 years	2 (16.7%)	10 (83.3%)	12 (100%)	
Sex				1.00[1]
Female	5 (16.1%)	26 (83.9%)	31 (100%)	
Male	17 (16.8%)	84 (83.2%)	101(100%)	
Education Level				0.77[1]
College/University	2 (25.0%)	6 (75.0%)	8 (100%)	
High School	9 (18.8%)	39 (81.2%)	48 (100%)	
Primary School	10 (15.6%)	54 (84.4%)	64 (100%)	
No Formal Education	1 (8.3%)	11 (91.7%)	12 (100%)	
Occupation				0.63[1]
Semi-skilled worker	9 (17.0%)	44 (83.0%)	53 (100%)	
Skilled worker	3 (30.0%)	7 (70.0%)	10 (100%)	
Student	0 (0.0%)	5 (100.0%)	5 (100%)	
Unskilled worker	10 (15.6%)	54 (84.4%)	64 (100%)	
Referral Status				1.00[1]
Non-Referral	6 (16.2%)	31 (83.8%)	37 (100%)	
Referral	16 (16.8%)	79 (83.2%)	95 100%)	

[1]Fisher's Exact Test

There was no statistically significant association between trauma characteristics and adherence to blood transfusion guidelines at bivariate analysis as shown in Table 8.

Table 8: Bivariate analysis of association between trauma characteristics and adherence to blood transfusion guidelines

	Adherence to blood transfusion guidelines			
Characteristics	**Yes n = 22**	**No n = 110**	**Total n=132**	***p* value**
Mechanism of injury				0.83[1]
Assault	1 (20.0%)	4 (80.0%)	5 (100%)	
Falls	2 (10.5%)	17 (89.5%)	19 (100%)	
Gunshot	0 (0.0%)	3 (100.0%)	3 (100%)	
Road Traffic Accidents	19 (18.1%)	86 (81.9%)	105(100%)	
Injury Severity Score				0.26[2]
Count	22	110	132	
Median (IQR)	10 (9, 14)	10 (9, 13)	10 (9, 13)	
Site of injury				0.48[1]
Isolated long bone	15 (15.3%)	83 (84.7%)	98 (100%)	
Multiple trauma	6 (20.0%)	24 (80.0%)	30 (100%)	
Pelvis	1 (33.3%)	2 (66.7%)	3 (100%)	
Spine	0 (0.0%)	1 (100.0%)	1 (100%)	
Surgery				0.40[1]
Amputation	0 (0.0%)	6 (100.0%)	6 (100%)	
Debridement	12 (20.7%)	46 (79.3%)	58 (100%)	
External fixation	2 (33.3%)	4 (66.7%)	6 (100%)	
Grafting	0 (0.0%)	1 (100.0%)	1 (100%)	
ORIF	8 (13.1%)	53 (86.9%)	61 100%)	

[1]Fisher's Exact Test

[2]Kruskal-Wallis rank sum test

There was a statistically significant association between adherence to blood transfusion guidelines and pre-transfusion haemoglobin and haematocrit levels at bivariate analysis (p <0.001) as shown in Table 9.

Table 9: Bivariate analysis of association between laboratory characteristics and adherence to blood transfusion guidelines

	Adherence to blood transfusion guidelines			
Characteristics	**Yes n = 22**	**No n = 110**	**Total n=132**	***p* value**
Haemoglobin(g/dl)				**<0.001[1]**
Count	22	110	132	
Median (IQR)	6.90 (6.38, 7.53)	9.00 (8.50, 10.80)	8.90 (7.98, 10.35)	
Haemoglobin Category				**<0.001[2]**
<7	15 (93.8%)	1 (6.2%)	16 (100%)	
7 – 10	3 (3.8%)	75 (96.2%)	78 (100%)	
>10	4 (10.5%)	34 (89.5%)	38 (100%)	
Haematocrit (%)				**<0.001[1]**
Count	22	110	132	
Median (IQR)	19.15 (17.80, 22.65)	26.85 (24.23, 31.88)	26.10 (23.15, 30.48)	
Platelets (10^9/L)				0.838[1]
Count	22	110	132	
Median (IQR)	437.00 (196.50, 589.25)	325.00 (223.00, 548.25)	330.00 (218.5, 578.00)	
Blood component				1.000[2]
PRBC	21 (16.5%)	106 (83.5%)	127 (100%)	
Whole blood	1 (20.0%)	4 (80.0%)	5 (100%)	

[1]Kruskal-Wallis rank sum test

[2]Fisher's Exact Test

There was no statistically significant association between blood transfusion reactions and adherence to blood transfusion guidelines at bivariate analysis as shown in Table 10.

Table 10: Association between blood transfusion reactions and adherence to blood transfusion guidelines

	Adherence to blood transfusion guidelines			
	Yes n = 22	**No n = 110**	**Total (n=132)**	***p* value**
Blood Transfusion reaction				0.464[1]
None	21 (17.9%)	96 (82.1%)	117 (100.0%)	
Present	1 (6.7%)	14 (93.3%)	15 (100.0%)	

[1]Fisher's Exact Test for Count Data

There was no statistically significant association between the prescribing clinician cadre and adherence to blood transfusion guidelines at bivariate analysis as shown in Table 11.

Table 11: Association between prescribing clinician cadre and adherence to blood transfusion guidelines

	Adherence to blood transfusion guidelines		
Cadre	**Yes n = 22**	**No n = 110**	***p*-value**
Resident	13 (17.8)	60 (82.2)	0.815[1]
Medical officer	6 (18.2)	27 (81.8)	
Clinical officer	3 (11.5)	23 (88.5)	

[1]Fisher's Exact Test for Count Data

4.3 Blood transfusion outcomes

In this study, few patients 15 (11.4%) had acute blood transfusion reactions. These reactions were however mild in severity. Among the 15 patients who experienced the reactions, 11 (73.3%) had fever, 3 (20.0%) had chills/rigors and 1 (6.7%) had multiple symptoms consisting of rigors, urticaria and generalized body swelling.

During the study period, there was no mortality documented in the follow up period of 24 hours after onset of transfusion.

Table 12: Blood transfusion complications and outcomes

Characteristics	Overall n=132
Blood transfusion reaction	
None	117 (88.6%)
Present	15 (11.4%)
Mortality	
Alive	132 (100.0%)

4.4 Factors associated with blood transfusion reactions

There was no statistically significant association between socio-demographic characteristics and blood transfusion reactions at bivariate analysis as shown in Table 13.

Table 13: Association between socio demographic characteristics and blood transfusion reactions

	Blood transfusion reactions		
Variable	**None n = 117**	**Present n = 15**	**p value**
Age in categories			0.349[1]
<20	7 (100.0%)	0 (0.0%)	
21 to 30	36 (85.7%)	6 (14.3%)	
31 to 40	31 (91.2%)	3 (8.8%)	
41 to 50	15 (75.0%)	5 (25.0%)	
51 to 60	7 (87.5%)	1 (12.5%)	
61-70	9 (100.0%)	0 (0.0%)	
>70	12 (100.0%)	0 (0.0%)	
Sex			0.343[1]
Female	26 (83.9%)	5 (16.1%)	
Male	91 (90.1%)	10 (9.9%)	
Referral			0.761[1]
Non-Referral	32 (86.5%)	5 (13.5%)	
Referral	85 (89.5%)	10 (10.5%)	

There was no statistically significant association between trauma characteristics and blood transfusion reactions at bivariate analysis as shown in Table 14.

Table 14: Association between trauma characteristics and blood transfusion reactions

	Blood transfusion reactions		
	None	Present	
Variable	**n = 117**	**n = 15**	**p value**
Mechanism of Injury			0.082[1]
Assault	3 (60.0%)	2 (40.0%)	
Falls	19 (100.0%)	0 (0.0%)	
Gunshot	3 (100.0%)	0 (0.0%)	
RTA	92 (87.6%)	13 (12.4%)	
Type of Injury			0.596[1]
Long bones	88 (89.8%)	10 (10.2%)	
Multiple bones	25 (83.3%)	5 (16.7%)	
Pelvis	3 (100.0%)	0 (0.0%)	
Spine	1 (100.0%)	0 (0.0%)	
Type of Surgery			0.959[1]
Amputation	6 (100.0%)	0 (0.0%)	
Debridement	50 (86.2%)	8 (13.8%)	
External fixation	6 (100.0%)	0 (0.0%)	
Grafting	1 (100.0%)	0 (0.0%)	
ORIF	54 (88.5%)	7 (11.5%)	

There was no statistically significant association between laboratory haematologic characteristics and blood transfusion reactions at bivariate analysis as shown in Table 15.

Table 15: Association between laboratory characteristics and blood transfusion reactions

	Blood transfusion reactions		
Variable	**None n =117**	**Present n = 15**	**p value**
Haemoglobin			0.249[1]
<7	15 (93.8%)	1 (6.2%)	
>10	36 (94.7%)	2 (5.3%)	
7.1 to 10	66 (84.6%)	12 (15.4%)	
Blood group			0.179[1]
A-	1 (100.0%)	0 (0.0%)	
A+	39 (88.6%)	5 (11.4%)	
AB-	0 (0.0%)	1 (100.0%)	
AB+	2 (100.0%)	0 (0.0%)	
B-	2 (100.0%)	0 (0.0%)	
B+	17 (85.0%)	3 (15.0%)	
O-	1 (50.0%)	1 (50.0%)	
O+	55 (91.7%)	5 (8.3%)	

CHAPTER FIVE:DISCUSSION

5.0 Introduction to the chapter

This chapter covers the discussion of the study results as per the objectives.

5.1 Socio-demographic and clinical characteristics

5.1.1 Socio-demographic characteristics

A male predominance was observed with males being about three and half times the females. This concurs with findings by Ayumba et al., (2015) in their study among patients with post-traumatic exposed bones where they found that majority of patients were males. Ostensibly, males are more exposed and vulnerable to musculoskeletal trauma owing to their propensity for outdoor bread winning and social activities. The mean and median ages were 40.35 (SD 17.90) and 36 (IQR 28, 47) years respectively with majority in their third and fourth decades of life. This concurs with findings by Ayumba et al., 2015; Dolenc et al., 2016 and Sisak et al., 2013. This is the age at which most people are socio-economically active. Injury prevention initiatives should place more focus and effort on this age group.

Most patients were referrals and had primary school level of education in concurrence with findings by Ayumba et al., 2015. Further, majority of the patients were found to be unskilled (no formal job training).The high rate of referrals concurs with MTRH status as the apex of the healthcare delivery system in Western Kenya region, parts of Eastern Uganda and Southern Sudan catchment areas whose population is about 24 million people . No formal job training drives people to informal occupations for income generation.

The relatively lower rate of literacy (48.5% primary school level graduates) and salaried employment could explain exposure to more injury prone occupations and

activities. In this study, socio-demographic characteristics did not have significant association with appropriate blood transfusion. This concurs with other studies where basic demographics such as age (Saidi, 2016; Sisak et al., 2013) and gender (Abbas et al., 2014) were shown not to influence transfusion.

5.1.2 Trauma characteristics

Most patients were injured due to road traffic accidents with mean and median injury severity scores of 12.05 (SD 6.21) and 10 (IQR 9, 13) respectively. In low and middle income countries , road traffic victims represent a large proportion of trauma burden (Boughton et al., 2015).This is in contrast with findings documented by Court-Brown et al., (2014) from a study in Royal Infirmary of Edinburgh, Scotland where road traffic accidents accounted for 4.7% of injuries. The lower prevalence of road traffic accidents in developed nations (Court-Brown et al., 2014) is probably attributable to better infrastructure, adherence and enforcement of traffic laws.

Almost half of the patients had isolated femur fractures and one quarter presented with tibia fractures only while a fifth sustained multiple injuries. This shows a higher proportion of lower limb compared to upper limb injury admissions. Seemingly, lower limb injuries render victims immobile hence need for direct admissions unlike those with upper limb injuries who are mostly booked into orthopaedic outpatient clinics. Patients with femur, tibia, acetabular, unstable pelvic among other lower limb fractures are usually admitted for operative treatment at the earliest opportunity to enable early mobilization and restoration of pre-injury limb functions.

About half of the patients (46.2%) underwent open reduction and internal fixation (ORIF) while 43.9% had debridement primarily. However, in the study as with other trauma characteristics, type of surgical intervention was not significantly associated with appropriate blood transfusion in concurrence with Saidi, 2016.

Overall, motorcycle associated injuries (76.2%) comprised majority of road traffic accidents. This contrasts findings in Ayumba et al., (2015) and Saidi, (2016) studies where motorcycle related accidents had a contribution of 16.5% and 22.6% respectively. The predominance of motorcycle associated injuries in this study could be attributed to upsurge of motorcycle usage due to need for convenient mobility in widespread parts of Kenya. Perhaps there is need for a tailored regulation of the rapidly expanding motorcycle sector.

Falls (14.4%) were the second leading cause of injuries in this study. This concurs with findings from Ayumba et al., (2015) and Boughton et al., (2015) studies. However, it contrasts findings by Court-Brown et al., (2014) where falls from standing height were the commonest cause of injury accounting for 62.5% of all fractures in their study at Royal Infirmary of Edinburgh, Scotland. Falls from a standing height tend to be more prevalent among older people and are the most frequent cause of fragility fractures owing to age and gender related endocrine, musculoskeletal and neurologic changes. Also, these people are more exposed to environmental and medical risk factors.

5.1.3 Vital signs

Majority of the patients had normal pre-transfusion pulse and systolic blood pressure. This concurs well with the findings by Abbas et al., (2014) in a study carried out among transfused orthopaedic trauma patients at Aga Khan University Hospital, Karachi, Pakistan.

The proportion of patients (58.3%) with increased respiratory rate contrast the 1.6% in Abbas et al., 2014 study. Raised respiratory rate in trauma is often related to pain, anxiety or airway and / or ventilatory compromise (Ramenofsky & Bell, 2012). Acute

blood loss initially leads to tachycardia then hypotension later on as more blood (31 to 40% of total body blood volume) is lost (Ramenofsky & Bell, 2012).

5.1.4 Laboratory Characteristics

In this study, the proportion of patients with pre-transfusion hemoglobin less than 7 g/dl concurred with the findings in Abbas et al., (2014) study at 12.1% compared to 14.3%. However, in the categories of 7 to 10 g/dl and more than 10 g/dl, this study findings contrast those of Abbas et al., (2014) study at 59.1% versus 79.4% and 28.8% versus 6.3% respectively. The discordant results are likely explained by the heterogeneity of the populations studied.

The commonest blood group was O positive (45.5%) followed by A positive (33.3%) and B positive (15.2%). This concurs with findings by Kipkulei et al., (2019) in their study on demographic and clinical profiles of blood transfusion recipients at a teaching and referral hospital in Kenya where the commonest blood groups were O positive (49.5%) followed by A positive (28.9%) then B positive at (13.3%). Information about local patient blood groups helps in predicting routine transfusion needs.

5.2 Adherence to guidelines on safe and appropriate use of blood components

Although numerous blood products are now in existence, this study in concurrence with Rotich (2017) found that packed red blood cells was the most transfused blood component followed by whole blood and platelets being the least. Perhaps the health workers are now more knowledgeable about available blood products plus their uses and are utilising the transfusion guidelines in their prescription. Whole blood is also increasingly being separated into various blood components at the local regional blood bank. Additionally, packed red blood cells are the appropriate blood products for correction of anaemia.

The proportion adherent to blood transfusion guidelines in this study was low at 16.7 % in contrast with findings by Abbas et al., (2014) where 35% of transfusions were adherent to guidelines criteria. This difference could be attributed to variance in specific transfusion criteria thresholds applied in evaluation of adherence to transfusion guidelines. In literature, the proportion of appropriate transfusions ranges from 3% to 42.3% (Abbas et al., 2014) and 4% to 66% (Kipkulei et al., 2019). Thus, it is evident that large proportions of transfusions do not adhere to guidelines criteria and result in unnecessary blood transfusions. The low proportion of adherence in this study could also suggest inadequate awareness of institutional transfusion guidelines.

Generally, transfusion practices vary enormously because of variability in guidelines criteria, study population characteristics, institutional processes and practices. In this study, the reasons for non-adherence to the blood transfusion guidelines were non-compliance with patient's clinical status findings threshold at 70 %, haemoglobin threshold at 0.9 % and both at 29. 1%.

In this study, only 5.3% of patients had documentation for estimated blood loss in contrast with findings by Abbas et al., (2014) in a study among transfused orthopaedic trauma patients at Aga Khan University Hospital, Karachi, Pakistan where estimated blood loss was documented for all patients. Estimated and / or expected blood loss forms an essential part of decision making in blood transfusion (Abbas et al., 2014). Blood requests in which clinical findings including blood loss are documented have a reduced risk of inappropriate transfusions. If clinical findings are well documented and given a proper consideration as per blood transfusion guidelines, inappropriate transfusions are eventually reduced resulting in blood conservation. Hospital blood transfusion units might be of help in issuing blood only for properly documented requests that meet transfusion thresholds.

Most of the prescriptions were done by the residents with the least by clinical officers. The variation in the prescription pattern among these cadres could be attributed to level of knowledge hierarchy and responsibility in decision making. These cadres may not be the actual decision makers since clinical decisions in patient care are usually made by the senior most health care team member, usually a consultant.

This study found that the factors significantly associated with adherence to transfusion guidelines were hemoglobin and haematocrit levels ($p < 0.001$) in agreement with Shander et al., (2011) where pre-transfusion haemoglobin was noted to be associated with appropriateness of transfusion. This finding also concurs with the observation made by Verlicchi et al., (2011) where clinicians waited for lower haemoglobin values for blood transfusion to be triggered. Factors not significantly associated with adherence to transfusion guidelines included socio-demographic and trauma characteristics plus blood transfusion reactions.

5.3 Outcomes

The results of this study revealed that 11.4% of patients had mild acute blood transfusion reactions in contrast to 3.2% in the study by Abbas et al., 2014. In this study, the findings were allergic and febrile nonhaemolytic transfusion reactions. Generally, allergic transfusion reactions occur in 1 to 3% of all transfusions (Hoffman et al., 2018) and 0.04 to 0.44% for febrile nonhaemolytic reactions (Murphy, M., Roberts, D., & Yazer, 2017). It is noteworthy to recognise that many of these blood transfusion reactions can mimic sequelae of comorbidities such as infections and are not necessarily related to transfusion of blood products (Murphy, M., Roberts, D., & Yazer, 2017).

By and large, allergic blood transfusion reactions are Type I IgE antibodies mediated hypersensitivity response. These antibodies bind to foreign plasma proteins ,

substances in the donor blood product that either is lacking or has a distinctly different allelic expression in the recipient (IgA, haptoglobin, C4) and to extraneous substances in the donor blood component (Murphy, M., Roberts, D., & Yazer, 2017) leading to activation of mast cells. Some of the extraneous substances include IgE antibodies, drugs and other allergens.

Febrile nonhaemolytic blood transfusion reactions are due to patients' antibodies reacting with leucocytes in donor blood leading to pyrogens (cytokines) release which act on the hypothalamus to cause fever (Murphy, M., Roberts, D., & Yazer, 2017). Also, during storage of donor blood, cytokines are gradually released into the blood. When this blood is infused, the preexisting cytokines cause fever.

In this study, no particular patient characteristic was found to be associated with blood transfusion reactions. Furthermore, there was no statistically significant association between blood transfusion reactions and appropriate blood transfusion ($p = 0.464$). There was no mortality documented during the follow up period of 24 hours post transfusion.

CHAPTER SIX:CONCLUSION AND RECOMMENDATIONS

6.0 Introduction to the chapter

The chapter covers the conclusions emanating from the results and discussion followed by recommendations.

6.1 Conclusions

1. Most patients were males, transfused with packed red blood cells and majority of injuries sustained were due to road traffic accidents.
2. The proportion adherent to the institutional transfusion guidelines was low at 16.7%. Pre-transfusion haemoglobin and haematocrit levels were the factors associated with adherence to guidelines.
3. Few and mild blood transfusion reactions were noted in 11.4% of patients. There was no association between transfusion reactions and adherence to guidelines.

6.2 Recommendations

Based on results and the stated objectives, the following recommendations are proposed:

1. Moi Teaching and Referral Hospital Transfusion Committee to sensitize and encourage adherence to blood transfusion guidelines among clinicians in orthopaedic trauma units by increasing awareness.

2. Need for a high index of suspicion among clinicians and nurses for the diagnosis of blood transfusion reactions and cautions to minimize these reactions be put in place.

3. A study among clinicians to assess their knowledge about blood transfusion and their experiences on transfusion practices in orthopaedic trauma units at MTRH.

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APPENDICES

APPENDIX 1: IREC APPROVAL

MU/MTRH-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
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MOI UNIVERSITY
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Reference: IREC/2018/302
Approval Number: 0003213

31st January, 2019

Dr. Ngetich Geoffrey Kibiwott,
Moi University,
School of Medicine
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Ngetich,

RE: FORMAL APPROVAL

The MU/MTRH- Institutional Research and Ethics Committee has reviewed your research proposal titled: -

Blood Transfusion Practices in Orthopaedic Trauma Units at Moi Teaching and Referral Hospital, Eldoret, Kenya".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 3213*** on 31st January, 2019. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; hence will expire on 30th January, 2020. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date. You will be required to submit progress report(s) on application for continuation, at the end of the study and any other times as may be recommended by the Committee.

Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. You will also be required to seek further clearance from any other regulatory body/authority that may be appropriate and applicable to the conduct of this study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

APPENDIX 2: HOSPITAL APPROVAL (MTRH)

An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone :(+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

25th March, 2019

Dr. Ngetich Geoffrey Kibiwott,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Blood Transfusion Practices in Orthopaedic Trauma Units at Moi Teaching and Referral Hospital, Eldoret, Kenya".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

MOI TEACHING AND REFERRAL HOSPITAL
C.E.O
25 MAR 2019
SIGN.....
P. O. Box 3 - 30100, ELDORET

DR. WILSON K. ARUASA, *MBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

cc - Senior Director, (CS)
- Director of Nursing Services (DNS)
- HOD, HRISM

APPENDIX 3: STRUCTURED DATA COLLECTION FORM

(*Adapted from MTRH Transfusion Guidelines and KNH Trauma Registry)*

Serial No.....

Date of admission...../...../…….....

A. Demographic data:

1. Age.....
2. Sex: Male □ Female□
3. Referral □ Non-Referral □
4. *Level of Education:*

- No Formal Education□ Primary School □ High School □College/University□

5. *Occupation*

- Student □Unskilled worker□ Semi-skilled worker □Skilled worker □

B. Trauma characteristics:

6. *Injury mechanism*

- MV Pedestrian□ MV Passenger□ MV Driver□ MC Pedestrian□ MC Rider□ MC Passenger□ Blunt Assault□ Penetrating Assault□ Gunshot□ Fall from a standing height□ Fall from a significant height□ Sports□

7. *Injury severity score:*

Region	Injury description	AIS	Square of the top three
Head and Neck			
Face			
Chest			
Abdomen			
Extremity			
External/skin			

8. Anatomic body site injured…….....
9. **Pre-transfusion clinical characteristics:**
10. *Vital signs*

- Heart Rate.....beats per minute; Respiratory Rate.....breaths per minute; Systolic Blood Pressure.....mmHg; Diastolic Blood Pressure.....mmHg

11. Threshold for anticipated or estimated blood loss met: Yes□ No□

12. Pre-existing co-morbidity…….....

C. Pre-transfusion care:

13. Was intravenous crystalloid fluids given: Yes□ No□

D. Pre-transfusion laboratory parameters:

- Haemoglobin.....g/dl Haematocrit.....% Platelets..... 10^9/L

E. Transfusion data:

Date	Type of blood component	Patient blood group	Transfusion reaction

F. Guidelines adherence

- Was MTRH transfusion guidelines observed appropriately? Yes□ No□
- Prescriber's cadre…….

G. Treatment

- Surgery performed…….....

H. Other outcome measures

- Mortality during transfusion period: Alive□ Died□

APPENDIX 4: INDICATIONS FOR BLOOD TRANSFUSION IN ORTHOPAEDIC TRAUMA

Adapted from MTRH Transfusion Guidelines (MTRH, 2016).

Whole blood

- Acute blood loss more than 40% and 25% of total blood volume in adults and children respectively
- Acute blood loss with hypotension refractory to intravenous fluids
- Haematocrit below 15% in acute blood loss

Packed red blood cells

- Haemoglobin level <7g/dl with minimal blood loss
- Haemoglobin level <9g/dl and expected blood loss is >500mls
- Haemoglobin <10g/dl with significant co-morbidities such as cardiovascular and respiratory disorders, uraemia and jaundice
- Anticipated blood volume loss >30% during surgery

Fresh frozen plasma

- Patients on warfarin who are bleeding or need to undergo surgery
- Massively transfused patients with clinically significant coagulation abnormalities

Cryoprecipitate

- Hypofibrinogenemia
- Trauma with haemophilia A, von Willebrand's disease and factor XIII deficiency

Platelets

- In minor surgery, the platelet count should be at least 100
- In major surgery, the platelet count should be at least 150

Massive transfusion

- For every six (6) units of blood given, give fresh frozen plasma and platelet concentrate

APPENDIX 5: INJURY SEVERITY SCORE (ISS)

Adapted from major injury cases in Nairobi: characterization of contexts, outcomes and injury documentation (Saidi, 2016).

The Injury Severity Score is an anatomic injury scoring system introduced in 1974 as a method to classify the extent of injury in poly-trauma based on the Abbreviated Injury Scale (AIS) scores for each of the following nine body regions

1. Head and neck
2. Face
3. Neck
4. Thorax
5. Abdomen and pelvis
6. Spine
7. Upper extremity
8. Lower extremity
9. Integument

Factoring the relative injury severity of each region based on the following six point AIS ordinal scale

1 = Minor

2 = Moderate

3 = Serious (non-life threatening)

4 = Severe (life threatening / survival probable)

5 = Critical (survival uncertain)

6 = Untreatable (fatal)

To calculate ISS:

- Each injured body region is assigned a score according to AIS scale
- Each assigned score is then squared
- The squares of the highest AIS severity in each of the three most injured ISS body regions are summed up:

  $ISS = A^2 + B^2 + C^2$
- A, B, C are AIS scores of the three most injured ISS body regions
- When AIS scores are identical in a multiply injured patient, the maximum AIS body score is classified according to risk of death: head and neck > thorax > abdomen > extremities

It is used to correlate injury with morbidity and mortality

APPENDIX 6: CONSENT FORM

Consent

English version

Hello. My name is Dr. Ngetich Geofrey Kibiwot, an orthopaedic surgery resident at Moi Teaching and Referral Hospital with keen interest in orthopaedic trauma. I am conducting a study on the effectiveness of blood transfusion among orthopaedic trauma patients at Moi Teaching and Referral Hospital. The study aims to describe socio-demographic and clinical characteristics of blood recipients; appropriateness and adverse events of blood transfusion. The results will help all relevant stakeholders in early recognition of patients at greatest need of blood and more appropriate blood products utilization. Data generated will also be useful in policy reviews, future research and overall contribution to the body of knowledge.

The study involves interview of orthopaedic trauma patients who are transfused together with getting information relevant to transfusion which are recorded in the patient's file and blood transfusion register. Information shall be kept strictly confidential and the identity of the patient will not be disclosed.

Your participation is entirely voluntary. This study will not add any extra cost on your treatment. There is no direct benefit for participating in this study. You are at liberty to ask any questions regarding this study and to terminate your participation without any consequences.

I therefore request your permission to participate in this study.

Consent:

I, the undersigned, having understood the explanation given to me about this study hereby willfully give consent for participation in the study.

....

Patient/Next of Kin signature/thumb print Date

....

Investigator/Informant Date

Kiswahili version

Maelezo ya kibali

Jambo. Jina langu ni Ngetich Kibiwot Geofrey, daktari anayesomea utabibu wa magonjwa ya mfupa katika hospitali ya rufaa ya Moi, Eldoret. Ninafanya utafiti ya kuchunguza matumizi ya damu kwenye matibabu ya shida za mifupa yanayotokana na majeraha na ajali mbalimbali. Ninauendeleza utafiti huu kuyachunguza kwa uwazi zaidi majeraha yanayosababishwa na ajali. Utafiti huu utazipa umuhimu sababu tofauti zinazohusiana na matumizi ya damu pamoja na matokeo. Utafiti huu utawezesha wagonjwa kupata damu kwa uadilifu na utasaidia vyuo vikuu, hospitali na wizara ya afya kubuni mbinu za matumizi bora ya damu.

Ili kupata maelezo kamilifu, nitakuuliza maswali na pia kunakili mambo mengine yatakayohusika na matibabu kamili ya majeraha yako kutoka kwenye rekodi za hospitali. Sitawalipa wanaokubali kushiriki katika utafiti huu na hakutatokea madhara yoyote kwa washirika. Maelezo yako yatakuwa ni siri kati yako nasi na matokeo ya utafiti yataelezwa kwa ujumla.

Kujiunga kwako kwenye utafiti ni kwa hiari. Una uhuru wa kukataa ama kuuliza maswali wakati wowote. Kukataa kwako hakutatumiwa kukunyima tiba.

Kibali

Mimi,……,nimeeleze wa kwa uwazi lengo la uchunguzi huu, nikasoma na kuelewa maelezo, nikapewa muda wa kuuliza maswali juu ya yale yaliyotatanisha na nikapata majibu mwafaka. Kwa hiari yangu mwenyewe, nakubali kushiriki katika utafiti huu.

…… ……

Mgonjwa/jamii ya mgonjwa Tarehe

…….. …….

Daktari Tarehe

APPENDIX 7: WORK PLAN

Activity	Duration	Person responsible	Location of activity
Proposal Concept Development	October to December 2017	Principal researcher	School of Medicine, Moi University
Research proposal writing	January to September 2018	Principal researcher	School of Medicine, Moi University
Review by supervisors and corrections by the candidate	October2018	Principal researcher and Supervisors	School of Medicine, Moi University
Submission to IREC	November 2018	Principal researcher	School of Medicine, Moi University
Patient recruitment and data collection	March 2019 to January 2020	Principal researcher and research assistants	MTRH Orthopaedic Wards
Data analysis and interpretation	February to June 2020	Principal researcher and biostatistician	School of Medicine, Moi University
Thesis writing	September 2020	Principal researcher and Supervisors	School of Medicine, Moi University
Thesis defense	March 2021	Principal researcher and Supervisors	School of Medicine, Moi University
Submission of corrected thesis copies	April 2021	Principal researcher and Supervisors	School of Medicine, Moi University

APPENDIX 8: BUDGET

ITEM	**QUANTITY**	**UNIT COST(Kshs)**	**TOTAL COST(Kshs)**
Printing research proposals	8	300	2400
Printing questionnaires	200	10	2000
Printing thesis	6	500	3000
Binding thesis	6	100	600
Biostatistician	1	25000	40000
Research assistants	2	15000	30000
IREC fee			2000
Note books	4	100	400
Pens	20	15	300
Internet data	1 GB per month for 36 months	500 per GB	18000
Miscellaneous	10% of total budget		9870
TOTAL			108,570