**EVALUATION OF THE CLINICAL BLOOD TRANSFUSION PRACTICE AT MOI TEACHING AND REFERRAL HOSPITAL**

**ELDORET, KENYA**

**BY**

**JAPHETH C. KIPKULEI**

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**SCHOOL OF PUBLIC HEALTH**

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**OCTOBER 2018**

# DECLARATION.

I declare that this is my original work and has not been submitted in any university for examination.

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**JAPHETH C. KIPKULEI** DATE

Reg. No. SPH/PGH/04/12

# 

SUPERVISORS

# This thesis has been submitted with our approval as the University supervisors.

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**PROF SIMEON K. MINING** DATE

PROFESSOR OF IMMUNOLOGY,

DEPARTMENT OF IMMUNOLOGY,

MOI UNIVERSITY.

------------------------------ -----------------------

**DR NATHAN BUZIBA** DATE

SENIOR LECTURER,

DEPARTMENT OF HAEMATOLOGY AND BLOOD TRANSFUSION,

MOI UNIVERSITY.

# **DEDICATION**.

I dedicate this work to all blood donors who donate blood purely out of altruistic reasons

# ACKNOWLEDGEMENTS

I would like to acknowledge the following who in one way or another contributed to the successful completion of this work

The Almighty God for the gift of life and grace which has been sufficient.

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**ABSTRACT**

**Background**: Blood transfusion is an essential component of modern health care. It can restore normal life expectancy and improve quality of life when used appropriately. Blood is scarce, costly and its use could be associated with complications. Adequate blood supply and good clinical practice, which includes appropriate blood use and proper documentation, ensures safe and effective transfusion practice. One of the ways of achieving appropriate blood transfusion is use of blood transfusion guidelines.

**Objective**: To determine the appropriateness of the clinical indication of blood transfusion at Moi Teaching and Referral Hospital.

**Methodology**: A hospital based medical chart review of 384 patients who were transfused from June 2013 to November 2013 was carried out. Systematic random sampling method was used and a data collection form was used to collect data. Data analysis was done using SPSS software version 20. Descriptive statistics, ANOVA, Pearson Chi-square and logistic regression were used to analyze the data. A p-value of <0.05 was deemed statistically significant. Data is presented in form of prose, tables, graphs and charts. Approval from Institutional Research and Ethical Committee of Moi University was obtained and the patient’s medical records were de-identified

**Results**: The median age of the recipients was 31.5 years (IQR 13,45.8) and the range was 1 day to 89 years. Females comprised 55.2% of the patients. The majority of the patients were from surgical (30.7%) and medical (29.2%) wards. The main indication of the transfusion was anaemia with the mean pretransfusion Hb being 7.8g/dl (SD 2.9) and most of the transfused patients (6 .8%) were being treated for neoplastic, pregnancy related, injuries and infectious & parasitic conditions. The proportion of inappropriate transfusion was 49% and the associated factors were pre-transfusion haemoglobin (p < 0.001), clinical department (p=0.043 presenting condition (p= 0.01) and the cadre of the prescribing clinician (p=0.008). Whole blood was transfused to 60.2% of the recipients and most of the transfusions (71.6%) were prescribed by registrars and medical interns. The consent, blood and blood product unit number, start times, duration of transfusion and observations of vital signs were documented in the charts of 0.7%, 73.4%, 43%, 47.1% and 27.6% of all the recipients respectively.

**Conclusion**: The proportion of patients who had inappropriate blood transfusion was 49% and the associated factors were pre-transfusion haemoglobin, clinical department, presenting condition and the cadre of clinician. The documentation of the transfusion process was inadequate. Majority of the patients, who required transfusion were young, had anaemia as the main indication and presented with neoplasms, infectious and pregnancy related conditions.

# Recommendations: The strategies of clinical audit and continuing medical education of health workers ought to be applied in order to improve the clinical practice of blood transfusion. In addition, studies to establish the reasons for inadequate documentation of the transfusion process and unsatisfactory compliance to the national guidelines on blood transfusion should be carried out. Finally, a separate consent form dedicated to blood transfusion need to be introduced

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# List of abbreviations

AABB American Association of Blood Banks

AIDS Acquired Immunodeficiency Syndrome

APH Ante partum haemorrhage

ANOVA Analysis of variance

BCSH British Committee for Standards in Haematology

BTU Blood Transfusion Unit

COC Clinical Officers Council

DH Department of Health

EC European Commission

ERBTC Eldoret Regional Blood Transfusion Centre

GOK Government of Kenya

Hb- Haemoglobin

HBV- Hepatitis B virus

HCV- Hepatitis C virus

HCT- Haematocrit

HIV- Human Immunodeficiency Virus

HTC- Hospital Transfusion Committee

ICU- Intensive Care Unit

IQR- Interquartile range

IREC- Institutional Research and Ethics Committee

KNBTS Kenya National Blood Transfusion Service

KNH Kenyatta National Hospital

KMPDB Kenya Medical Practitioners and Dentists Board

MO Medical officer

MTRH Moi Teaching and Referral Hospital

NHMRC National Health and Medical Research Council

NICU Neonatal Intensive Care unit

PPH Post-partum haemorrhage

PRBCs Packed Red BLOOD Cells

SPSS Statistical Package for Social Scientists

TTI Transfusion Transmitted Infections

WHA World Health Association

WHO World Health Organization

OPERATIONAL DEFINITIONS

**Appropriateness of a transfusion episode**- A transfusion episode was considered inappropriate violated the criteria of an appropriate clinical indication as per the Kenya National Guidelines for the appropriate use of blood and blood products (Annex I). A transfusion episode was also considered inappropriate when the reason for the transfusion was not clear or not documented.

**Blood transfusion episode**- All blood that was transfused within 24-hour period was considered to be the result of a single blood transfusion episode. This was based on the assumption that, in general all blood transfused during a 24-hour period would be for the same indication. Only one transfusion episode was counted for any particular patient event if multiple transfusions occurred within the study period.

**Blood product**- Any therapeutic substance prepared from human blood (World Health Organization, 2002). For purposes of this study this was confined to whole blood and PRBC

Clinical officer- Is a licensed practitioner of medicine who is trained (with a diploma in medicine and surgery or higher diploma in a specialized field) to perform general or specialized medical duties such as administration of anaesthesia and are registered by Clinical Officers council (COC) for independent practice (Clinical Officers Council, 2009).

**Clinician**- For the purposes of this research, consultant, registrar, medical officer, medical officer intern and clinical officer were referred to as clinicians

Consultant- Is a medical doctor who has a specialist qualification in a particular field of medicine endorsed by the Kenya Medical Practitioners and Dentists Board (KMPDB)

**Haemorrhage**- Is a loss of a large amount of blood in a short period, either externally or internally (Mosby, 2009). For the purposes of this study this was grouped into medical, surgical and obstetric/gynaecologic haemorrhage, where:

* **Medical haemorrhage** was confined to bleeding due to coagulopathy, thrombocytopenia and peptic ulcer disease
* **Surgical haemorrhage**-was confined to bleeding due to trauma and intra-operative blood loss
* **Obstetric/gynaecologic haemorrhage** was confined to bleeding due to abortion/miscarriage, APH, PPH, intra-operative blood loss, gynaecologic neoplasms and abnormal uterine bleeding.

**Medical intern**-A medical doctor who has graduated from university and is completing further supervised training for a period of one year as recognised by the KMPDB

**Medical officer**- A doctor employed by the national government or the county government in a designated medical officer post. These doctors may have no formal postgraduate training in the discipline in which they may work and they are registered by the KMPDB for independent practice

**Medical specialties**- Are the specialties in which the major diagnosis and treatment is achieved through non-surgical means. For the purposes of this research these disciplines include adult medicine/’medical’ and child health

Packed red blood cells (PRBC)-Red cells obtained from a unit of whole blood that have the plasma and buffy coat removed (McClelland, 2007)

**Registrar**- A medical doctor who is in the process of training to acquire a specialist qualification endorsed by the KMPDB

**Surgical specialties**- Are the specialties in which an important part of diagnosis and treatment is achieved through major surgical techniques. For the purposes of this research these include the disciplines of surgery and reproductive health

**Whole blood**- Unseparated blood collected into an approved container containing an anticoagulant-preservative solution (World Health Organization, 2002).

# 

**CHAPTER 1: INTRODUCTION**

**1.1 Background**

Blood transfusion is an essential component of modern health care. It can restore normal life expectancy and improve quality of life when used appropriately. According to (World Health Organization [WHO], 2008), someone in the world needs blood every second.

The demand of safe blood in many countries has continued to outstrip the supply and therefore many patients do not have access to blood when they need it. The high demand of blood is due to advancement in health systems with improved diagnosis and sophisticated surgical and medical procedures. This great demand is also aggravated by population growth and changing demographic dynamics (WHO, 2008).

In Africa, the demand for blood is compounded by high burden of conditions requiring blood transfusion, including pregnancy related hemorrhage, anemia due to malaria, sickle cell anemia, malnutrition, trauma and high prevalence of transfusions transmitted infections (TTIs). The region is also often plagued by manmade and natural disasters which require blood transfusion. In addition, wastage of blood aggravates the problem of blood shortage in sub-Saharan Africa and this has been attributed to inappropriate use, use of whole blood instead of components, the high prevalence of TTIs (WHO, 2009). The increasing need for blood is faced with the challenge of scarcity of blood, especially in developing countries (WHO, 2009)

Kenya, just like any other Sub-Saharan African country, is faced by the challenge of increasing demand compounded by acute and chronic shortages (Merab, E; & Mosota, M., 2015; Angote, 2014). The country collected 169369 units in the year 2013 (Chevalier, 2016) against the WHO recommendation that an equivalent of 1 % of the population should donate blood annually to meet a country’s needs (WHO, 2008) which implies that the country needed 418000 units per year with a shortage of 248631 units. The shortages are also aggravated by increasing demand due to road traffic accidents, terrorist attacks and over dependence on donations from students (Kenya National Blood Transfusion Services, 2012).

Blood transfusion practice is a costly affair. According to Koistinen, (1996), blood transfusion costs are incurred during collection, component production, laboratory testing, storage, handling and administration of the blood. It is estimated that a unit of safe blood in Africa costs between US$26 to US$52 (Oduor, 2009). The costs are also incurred when treating transfusion complications resulting from unsafe practices or mistakes. According to Dzik (2007), the estimated cost of treating healthcare errors or mistakes in the USA is about $3 billion of which a third is avoidable cost.

Though blood transfusion is lifesaving, its use is not without risks. The risks associated with blood transfusion can be infectious (TTIs) and or noninfectious. These risks arise due to errors during the process of blood transfusion and transfusion of unsafe blood of which in developing countries is mainly due to collection from unsafe donors, irregular or inadequate supplies of testing kits, poor laboratory testing procedures, inadequately trained staff, absence of quality systems and unnecessary transfusions (WHO, 2006)

The clinical practice of blood transfusion is a multistep process and it entails appropriate use of blood, proper bedside procedures, monitoring of patients during transfusion for adverse events and documentation of the process.

The two main elements for safe and effective transfusion are a sufficient supply of safe blood and good clinical practice. Good clinical practice contributes to safe and effective transfusion by ensuring that the right blood and blood product is given to the right patient at the right time, appropriate decision-making about the appropriate use of blood based on assessment of clinical findings and laboratory parameters, and the monitoring of patients for adverse effects of transfusion and their management if they occur and documentation of the process (Murphy, Stanworth, & Yazer, 2011).

One of the ways for achieving appropriate blood transfusion practice is use of blood transfusion guidelines (WHO, 2006). According to the WHO, (2002), one of the principles of clinical transfusion practice is that prescription of blood should be based on national guidelines on clinical use of blood. In fact, blood transfusion practice is defined by (Gray et al., 2007) as ‘the process of administering blood and blood products to the patient, relative to the current requirements of national guidelines and laws.

Clinical practice guidelines defined as ‘systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances’ (Institute of Medicine (US) Committee on Clinical Practice Guidelines, 1992) have been shown to have the potential for making a positive contribution to health care rationing through the better direction of resources and by limiting inappropriate variation in clinical practice. Furthermore, clinical practice guidelines offer an opportunity for introducing evidence-based health care into local practice and for influencing the commissioning of effective health care (Rowan & Carter, 2000)

The guidelines are not absolute rules but a guide to clinicians on the most appropriate use of blood. The final decision to transfuse blood is dependent on the clinician’s assessment of the patient’s clinical condition and appropriate laboratory parameters. However, the justification of the decision to transfuse blood or blood products has to be clearly documented (Nel, 2008).

In Kenya, the blood transfusion guidelines were developed in the year 2001 by the Kenya National Blood Transfusion Service (KNBTS) *(Guidelines for the appropriate use of blood and blood products)* and were compiled after consultations with haematologists, transfusion medicine experts, prescribers of blood within Kenya, and review of guidelines found in the published literature. The guidelines in its third edition, covers appropriate use of red cells, platelets and fresh frozen plasma in medicine, surgery, obstetrics and pediatrics (Kenya National Blood Transfusion Services [KNBTS], 2009). (Appendix1I). In this study, the appropriate use(indication) of red cells (packed red cells and whole blood) was assessed.

The entire process of clinical blood transfusion has to be well documented. Good record keeping is an essential component in the provision of safe and effective health care (Nursing and Midwifery Council, 2016). In addition, proper documentation can also prevent future costs resulting from malpractice claim as cases of malpractice are frequently decided based on the documentation that occurred (Frank-Stromborg, Christensen, & Do, 2001).

**1.2 Problem statement**

One of the challenges facing blood transfusion practice is inappropriate blood use (WHO, 2009). This has been attributed, among other reasons, to failure by clinicians to align practice with the recommended guidelines (Friedman, 2011). Studies have demonstrated inappropriate level of blood use ranging from 4-66% (Hubert et al.,1997). At Kenya National Hospital (KNH), the level of inappropriate clinical indication of blood transfusion was found to be 27.8% (Gitakah et al., 2006). Inappropriate transfusion exposes patients to unnecessary risks, leads to blood wastage and costly health care (WHO, 2009)

Furthermore, the quality of blood transfusion documentation has been shown to be poor and this has major safety and legal implications (Grewal, Neffendorf, & Williams, (2012).

**1.3 Justification**

Monitoring of blood transfusion practice ensures appropriate blood use and improved access of blood (WHO, 2016). Use of transfusion guidelines as one of the ways of achieving appropriate blood transfusion, has been shown to decrease blood use and complications. A study by Politsmakher et al., (2013), showed a decrease in red cell use by 30.1% and 37.1% during year 1 and 2 respectively of monitoring after introduction of guidelines. This decrease in product use was also accompanied by 28.1% reduction in complications.

In addition, accurate record keeping is a crucial component of good medical practice and blood transfusion documentation is essential for patient safety. Thus, the first step in improving the quality of health care is to investigate the current practices of clinical blood transfusion.

The findings of this study would be used to plan and implement policies, guidelines and policies geared towards improving the safety and efficiency of the blood transfusion practices.

**1.4** **Research questions**

1. To what extend do clinicians adhere to the guidelines on the appropriate clinical indication blood and blood products as per the KNBTS guidelines?
2. What is the documentation practice of the clinical blood transfusion at MTRH?

**1.5 Objectives**

**1.5.1 Broad objective**

To determine the appropriateness of clinical blood transfusion practice in accordance with KNBTS guidelines at MTRH.

**1.5.2 Specific objectives**

1. To determine the proportion of inappropriate clinical indication of blood transfusion at MTRH.
2. To establish the factors associated with inappropriate clinical indication of blood transfusion at MRTH
   * 1. **Secondary objectives**
3. To determine the documentation practice of clinical blood transfusion at MTRH
4. To describe the pattern of blood and blood product use according to the demographic and clinical profiles of the transfusion recipients at MTRH

**CHAPTER 2: LITERATURE REVIEW**

**2.1 Overview of the history of the practice of blood transfusion**

The practice of blood transfusion can be traced back to 17th Century after the discovery of circulatory system by William Harvey and the work of Christopher Wren and Robert Boyle in 1663 on the infusion of different materials into dogs. Later animal to human transfusion by Lower and Jean-Baptiste Denis and human to human transfusion by James Blundell were performed. These transfusions were met with challenges of clotting of blood and deaths due to adverse reactions (Learoyd, 2012).

A great milestone towards safer transfusion was realized after the discovery of ABO blood group system by Karl Landsteiner in 1901and Rhesus group in 1940. The discovery of the anticoagulant, sodium citrate by Adolph Hustinin 1914 (American Red Cross, 2013)) further improved the practice of transfusion

The practice of blood transfusion advanced during and after the world wars. This period saw the adoption of indirect transfusion practices, better definition of blood groups, blood screening and testing, establishment of blood banks, and discovery of polythene as blood bags and separation of blood into various components (American Red Cross, 2017).

In Kenya, blood transfusion just like in many African countries started with the coming of colonialists. The transfusion was organized along surgical practice. After independence, the Government of Kenya (GOK) with the assistance of Kenya Red Cross took over the service. From late 60s to early 2000, blood transfusion service was run as part of hospital laboratory service with each hospital sourcing for their own blood. The early 80s saw the advent of HIV/AIDS, reduced blood collections and increased cost of blood and this necessitated a more critical emphasis on blood safety (KNBTS, 2012).

In order to deal with the above challenges of blood transfusion, the GOK developed national blood policy and guidelines in the year 1994 and later established a national blood transfusion service (NBTS) in 2001 in accordance with the WHO/WHA recommendations of 1975.

**2.2 Blood and blood products: Indications and guidelines**

Blood is composed of cells and plasma. The blood cells are red, white and platelets. Blood can be transfused as whole blood or individual blood products. The blood products which are commonly used include packed red blood cells (PRBC), platelet concentrate, fresh frozen plasma and cryoprecipitate. This study focused on the use of whole blood and PRBC.

**2.2.1 Indications and guidelines for whole blood**

In developed countries, whole blood is rarely indicated except in autologous transfusion (Council, 2011) and severe haemorrage (Repine, Perkins, Kauvar, & Blackborne, 2006; Spinella, 2008). However, whole blood is still used widely in resource poor countries where preparation of the blood products is costly (WHO, 2002). It is always advisable that a diuretic is administered when using whole blood in patients with severe chronic anemia to reduce the risk of transfusion related circulatory overload.

**2.2.2 Indications and guidelines for packed red blood cells (PRBC)**

Packed red blood cells are indicated in symptomatic reduced oxygen-carrying capacity of the blood or tissue hypoxia due to severe anemia and severe blood loss (Miller et al., 2007; Council, 2011). As it is difficult to directly measure intracellular oxygenation in the clinical setting, surrogate markers such as haemoglobin (Hb) level are used, together with a patient’s signs and symptoms in relation to blood loss, volume depletion or anemia, and consideration of other co-morbidities (Council, 2011).

Packed red blood cells are transfused depending on patient’s clinical condition, ability to tolerate anemia and bleeding status. In the past the rule of 10/30 has been used as a transfusion trigger to keep patient’s Hb above 10g/dl and HCT above 30%. However, in the1990s up to now with advances in research and clinical evidence, it is acknowledged that the decision to transfuse should not be based on a single automatic trigger but on both clinical assessment and laboratory testing (KNBT, 2009; Council, 2011; Szczepiorkowski & Dunbar, 2013) as this has been shown to reduce inappropriate transfusions and hence avoid unnecessary exposure to risks and reduces wastage (Ts & Das, 2012).

Current guidelines recommend restrictive thresholds for red cell transfusions based on clinical experience, professional consensus and evidence of clinical outcomes of controlled trials of restrictive versus liberal thresholds.

A Cochrane meta-analysis by Carson, Carless, & Hebert, (2012), of 19 randomized controlled studies comparing clinical outcomes in patients randomized to restrictive or liberal transfusion thresholds found no effect of conservative triggers on mortality, rates of cardiac events, morbidity or length hospital stay. Other randomized controlled trials in children have also reported no difference in outcome between restrictive and liberal groups (Nopoulos et al., 2011; Whyte & Kirpalani, 2011; Chen et al., 2009)

**2.3 The process of clinical practice blood transfusion**

The clinical practice of blood transfusion is a complex multi-step process involving professionals of different background, including clinicians and nurses. The key steps include the decision to transfuse, obtaining an informed consent, taking and labeling of blood samples, collecting of blood from the laboratory, administration, monitoring and documentation.

**2.3.1 Decision to transfuse**

The decision to transfuse has to be rational and should be based on clinical assessment of the patient and appropriate laboratory parameters (Nel, 2008). This is aimed at reducing inappropriate transfusions and hence avoiding unnecessary exposure to risks and reduces wastage (Ts & Das, 2012). The rationale for the decision to transfuse and the specific components to be transfused should be documented in the patients’ clinical records (British Committed for Standards in Haematology[BCSH], 2009); WHO, 2002)

**2.3.2 Obtaining an informed consent**

Informed consent must be obtained from the recipient of blood transfusion before commencing the procedure. Consent is important in transfusion medicine because practice carries a certain risk to the patient and as such it is imperative that the patient should be informed of the benefits, risks and the alternatives of the therapy (American Association of Blood Banks, 2014; Friedman et al., 2012; Miller et al., 2007)

According to the United Kingdom Department of Health, (2009)), it is legal and ethical principle that consent must be obtained before starting treatment. Sufficient verbal or written informed consent should be obtained and documented in the patient’s medical records (American Association of Blood Banks [AABB], 2014); Gray & Mitchers, 2008). Competent patients have the right to decline the transfusion while incapacitated and unconscious patients may be transfused in emergency situations (Gray A & Mitchers, 2008). Special care should be given to patients who decline transfusion on religious grounds like Jehovah’s Witnesses.

**2.3.3 Bedside administration**

The administration of blood and blood products must be carried out by a trained, competent and registered health professional and the transfusion of blood and blood products should begin as soon as possible after the blood has arrived in the clinical area (British Committee for Standards in Haematology, 2009) to avoid the risk of bacterial proliferation (McClelland, 2007). It is recommended that transfusion of whole blood or packed cells should be started within 30 minutes of removal from the refrigerator (KNBTS, 2009; WHO, 2017)

Blood products should be transfused within the recommended durations. Whole blood and Red blood cells should be transfused within 4 hours (McClelland, 2007). The recommended transfusion rates for whole blood and PRBC are 3-5ml/kg/hr depending on clinical circumstances. (WHO, 2017; Hijji, Parahoo, Hussein & Barr, 2013).

**2.3.4 Patient monitoring**

Close monitoring of patient being transfused has to be carried out in order to detect any early adverse reactions. According to the KNBTS, (2009), patient’s appearance and vital signs (pulse, temperature, blood pressure, respiratory rate and fluid input and output) should be monitored before starting the transfusion, as soon as the transfusion is started, 15 minutes after onset of transfusion, at least every 30 minutes during transfusion, on completion of transfusion and four hours after completing the transfusion.

The observations must be recorded in patient’s transfusion chart or patient’s notes record (BCSH, 2009; KNBTS, 2009). The following must also be recorded on the transfusion chart: date of transfusion, time transfusion started and finished, type and volume of blood or products given, blood unit numbers and any adverse effects (KNBTS, (2009).

**2.3.5 Documentation of the transfusion process**

The entire process of clinical blood transfusion practice has to be well documented. The indication or the reason for the transfusion, informed consent, blood and blood product unit number, start times, duration of the transfusion and the vital signs of the recipient before, during and after the transfusion have to properly recorded in the patient’s chart.

Studies have shown that the quality of the documentation of blood transfusion is poor. A study by Grewal, Neffendorf, & Williams, (2012) found that consent was documented in only 1.85% (2/108) of the cases. A similar finding was also noted in a study by Audet, Goodnough, & Parvin, (1996) where evidence of patient consent was documented in only two 1% (2/155) of transfusion events

de Graaf, Kajja, Bimenya, Postma, & Sibinga, (2009) in their study found that documentation of the transfusion process was carried in around 50% of the patients but only briefly and inaccurately. In the same study, blood product number, the starting times and duration of the procedure were documented occasionally, but not consistently while the pre and post transfusion vital signs were not recorded at all. Another study by Natukunda et al., (2010) found that there were no records for pre-transfusion hemoglobin, transfusion start-times and vital signs in 30.2%, 21.5% and 97.6% of all recipients respectively.

**2.4 Appropriateness of use of blood and associated factors**

Different studies have reported varying levels of inappropriate use of blood and blood products. In a review of the literature, Hebert et al., (1997) established that the levels of unnecessary transfusions of allogenic red blood cell ranged from 4% to 66%.

Barr et al., (2011) in their study titled ‘appropriateness of red blood cell use and the extent of over transfusion: Right decision? Right amount?’ found that the level of inappropriate use of red blood cells was 23%. The same study established that age, pre-transfusion Hb, burden of disease (co-morbidities), bleeding, preexisting condition (diagnosis), cancer related hospital admission, clinical department and the grade (cadre) of prescribing clinician were associated with inappropriate transfusion.

Another study in Venezuela which audited the appropriate use of blood products using preset criteria (guidelines), (Martí-Carvajal, Muñoz-Navarro, Peña-Marti, & Comunian, 1999) found the level of inappropriate use of packed red cells to be 48.7%. The study did not find any association between inappropriate blood use and either age or sex.

Mozes et al., (1989) in their study evaluating the appropriateness of blood and blood product transfusion using preset criteria found that 42.3% of the transfusions were inappropriate. Whole blood was found to be used more appropriately than those of red cells. The study also showed that blood transfusions were used more appropriately in the management of acute bleeding or anemia associated with cardiovascular problems. Furthermore, patients with end-stage renal disease or terminal cancer and cancer patients on chemotherapy were more prone to inappropriate transfusions. In this study age, sex, and specific hospital wards were not associated with inappropriate use.

The overall prevalence of inappropriate use of blood and blood products according to a study done in India was 10% and the prevalence for whole blood and packed red cells was 9% and 8% respectively (Gomathi & Varghese, 2012).

In Kenya, studies on appropriateness of blood use have looked mainly only on paediatric patients (Nabwera et al., 2016; Oeba, 2015; Gitakah, 2006; Lackritz et al., 1993). The study done by Oeba, (2015) on blood transfusion practices at the newborn unit of MTRH found that the level of inappropriate clinical indication of PRBC and whole blood was 53.3% and 71.4% respectively. In her prospective study on blood transfusion practices among children at KNH, Gitakah, (2006) showed that 27.8% of the transfusions were inappropriate based on the criteria of appropriate clinical indication. Lackritz et al., (1993) in their study established that 47% of pediatric transfusions were inappropriate in which 23% did not meet the criteria of having hemoglobin < 5.0 g/dl and clinical evidence of respiratory distress, and 27% were transfused 2 or more days after requested. The same study showed that 90% of adult transfusions were inappropriate of which 68% of them received one unit of blood or less and the rest were transfused 2 or more days after the day of request

**2.5 The pattern of blood and blood product use in relation demographic and clinical profiles of the recipients**

Blood is required universally to manage various medical, surgical and obstetric conditions. However, the demographic and clinical profiles of the recipients of blood and blood products differs between developed and developing countries. According to WHO, (2008), blood transfusion in developed countries is commonly used to support advanced medical and surgical procedures, including trauma, cardiovascular surgery, neurosurgery, transplantation etc.; while in developing countries, a much greater proportion of blood is used to treat women with obstetric emergencies and children suffering from severe anemia, often resulting from malaria and malnutrition

Various studies on blood use have demonstrated different profiles in terms of demographics, diagnoses and clinical indications. These differences might be due to varying geographical location and methodological heterogeinity of these studies (Biggin, Warner, Prescott, & McClelland, 2010).

In a study done to assess the demographics of blood use in the USA, England, Australia and Denmark (Cobain, Vamvakas, Wells, & Titlestad, 2007) it was found that red blood cells were used mainly for the elderly (> 65 years) and the main indications were cardiovascular surgery, trauma and neoplasms. The use between males and females was approximately equal

Bosch et al., (2011) in their study done in Spain showed that 50% of the red cells units were used by patients > 70 years with males compromising 52%. The main indications were gastrointestinal hemorrhage and lower limb orthopedic surgery. In another study done in Germany on blood use in children and adolescence, it was found that blood components were used during correction of congenital defects, mainly cardiac, in neoplastic diseases and in nonmalignant disorders of blood and blood forming organs (Zimmermann et al., 1998).

A study of blood usage by diagnoses in a Korean university hospital showed that blood and blood products were used mainly for neoplastic disorders (Acute myeloid leukaemia, liver cell carcinoma, advanced gastric cancer) and liver cirrhosis (Lim, Lee, Cho, Hyun, & Sc, 2004).

Gaur et al., (2009) in their study carried out in an Indian tertiary hospital found that the range of the patients transfused was 3 months to 92 years with those from 20-60 years received 74% (318/428); the male: female ratio was 1:1.6. Trauma (20.6%), malignancy (17.3%) and elective surgery (14.7%) were the top three diagnoses of the recipients. The main indications for blood transfusion were anaemia (41.1%), elective surgery (28.7%) and haemorrhage (11.9%). Whole blood was indicated mainly in surgical procedures (posttraumatic and elective (113/211) followed by anaemia (82/211) whereas PRBC was used for anaemia (94/104) and surgery (10/104).

In Africa, studies on pattern of blood use are scarce. In a study carried out in a regional referral hospital in Uganda, the median age of the recipients was 19 years (range, 1 day to 88 years); female to male ratio 1:1.4 and the main indications for transfusion were malaria (38.8%), bleeding (27.1%) and other infections (16.1%) (Natukunda, Schonewille, & Smit Sibinga, 2010). Mafirakuvera et al., (2015), in their study ‘Profiles of blood and blood component transfusion recipients in Zimbabwe’, found that most of the transfusion recipients were females ((63.2%, 1133/1793) and in the reproductive age group 15-49 years (63.2%). In the same study, the median age of the recipients was 33 years with the range of 0-93 years and the majority of the patients were diagnosed with conditions related to pregnancy and childbirth (22.3%), and diseases of blood and blood-forming organs (17.7%).

A study in Namibia by Pitman et al., (2015) found that the median age of transfused patients was 45 years with patients in the 25-39 years age range consuming the highest number of blood units (34.8%). The major diagnoses of the recipients were diseases of blood and blood forming organs (38.9%), infectious disease (14.8%) and pregnancy related (11.1%). Kuliya-Gwarzo, (2007) in his study in a Nigerian hospital found that anemia (49.1%), surgery (23.9%) and hemorrhage (21.1%) were the main indications for blood transfusion.

**CHAPTER 3: METHODOLOGY**

**3.1 Study site**

The study was carried out at MTRH which is a 900-bed capacity hospital located in Eldoret town, western Kenya. The hospital is an ISO 9001: 2008 certified institution and serves western Kenya which has a population of about 15 million, parts of Southern Uganda and South Sudan.

The hospital carries out blood transfusion service which is supported by Eldoret Regional Blood Transfusion Center (ERBTC). It has a blood transfusion unit (BTU) whose work is to receive blood transfusion requests and specimens from various wards and units and carry out compatibility tests and dispatch blood and blood products to the wards. The hospital also has a hospital transfusion committee (HTC) whose roles includes developing systems for the implementation of the national guideline within the hospital, formulation and review of policies, procedures and ensure compliance of the same; enhance timely administration (time of request, time of start and completion of transfusion) among other roles.

In the year 2012, the hospital had a total of 36,925 admissions and 11300 of these required blood transfusions. This shows that blood is one of the main treatment modalities in the hospital.

**3.2 Study design**

The study design was a retrospective hospital-based chart review.

**3.3 Target and study population**

The target population was all patients admitted to the hospital and the study population was patients who required a blood transfusion as part of their treatment

**3.4 Eligibility criteria**

In-patients admitted into the general wards and were transfused whole blood or PRBC were included in the study.

Patients who were transfused platelet concentrate or fresh frozen plasma and were admitted in private wings of the hospital were excluded.

**3.5 Sample size**

A sample of 384 patient medical charts were studied and this was calculated using the Cochran’s formula (Cochran, 1977).

n = z2pq

d2

Where:

* n - Minimum sample size.
* z - Standard normal deviation at desired confidence interval i.e. 1.96 for the 95% confidence interval.
* p- Expected level of prevalence of appropriate use which was taken to be 50% because there is no local data on the prevalence of appropriate blood use among both adult and paediatric patients based on the national transfusion guidelines
* q- Expected level of inappropriate use (1-p).
* d- Accepted error =0.05

**3.6 Sampling procedure**

Systematic sampling method was used to sample the study subjects. There were 9198 patients who were transfused whole blood and PRBC in the general wards of the hospital in the year 2012 and this translated to 4599 recipients in six months and hence our sampling frame. The kth interval was 12 (4599/384). Those who were studied were determined by first obtaining from the BTU records the hospital numbers of all the patients who met the inclusion criteria and had their blood units cross matched and issued for use. The hospital numbers of these patients were used to retrieve their charts from the medical records department. The first patient chart to be reviewed was chosen randomly among the first twelve patients transfused in the month of June of 2013. To do this, the hospital numbers of these patients gotten from the BTU were written on pieces of papers of equal size. The papers were then folded and placed in a bowl and shuffled. One piece of the folded paper was taken out randomly and that was taken as the first patient chart to be studied. The subsequent 12th patient chart was chosen till the desired sample size was reached. A transfusion episode was ascertained by ensuring that the actual transfusion was documented in the clinician’s and or the nursing notes. Only the first transfusion episode identiﬁed for any patient was included in the study; thus, any patient appeared only once in the study population and only one transfusion event was studied.

**3.7 Data collection**

A data collection form was used to collect data from the medical records of those patients who were transfused during the study period. Information was extracted from the clinical notes, laboratory request forms, blood transfusion chart and the nursing notes. The information collected included data on age, gender, presenting condition, pre-transfusion Hb, blood and blood product transfused, cadre of clinician who ordered the blood transfusion and documentation of the transfusion process (indication, consent, time taken from ordering of blood to arrival in the ward, time taken from arrival of the unit to initiation, start times and observations of vital signs).

The International Classification of Diseases (ICD-10) version was used for classification of the presenting conditions requiring transfusion of blood and blood products. The primary and the secondary ICD-10 codes were matched with the clinical details and diagnosis obtained from the patient clinical notes and request forms to select the most appropriate condition requiring transfusion. The diagnoses were then grouped into broad categories according to the 21 (I-XXI) chapters of ICD-10**.**

**3.8 Validity**

The data collection tool/form was drawn up based on the review of the literature (Barr et al., 2011; Martí-Carvajal, Muñoz-Navarro, Martí-Peña, Matheus-Fernández, & Medina-Laurentín, 2005; Martí-Carvajal, Muñoz-Navarro, Peña-Martí, et al., 1999; Mozes et al., 1989; de Graaf, Kajja, Bimenya, Postma, & Sibinga, 2009) and the KNBTS guidelines on the appropriate use of blood and blood products (KNBTS, 2009). This ensured content validity. In order to ensure face validity, two haematologists reviewed the. Minor changes were made based on the recommendations given.

**3.9 Study variables**

The dependent variable was the inappropriate clinical indication of the blood transfusion (whether inappropriate or appropriate as per the KNBTS guidelines) and the independent variables were age, sex, presenting condition (diagnosis), pre-transfusion haemoglobin (Hb), the cadre of clinician (prescriber) and the clinical department (table 3.1)

Table 3.1 Study variables

|  |  |
| --- | --- |
| **Variable** | **Variable definition/unit of measurement** |
| Inappropriate clinical indication of blood transfusion | Inappropriate or appropriate clinical indication as per the criteria set out in the Kenya National Guidelines on appropriate use of blood and blood products |
| Sex/gender | The gender of the recipient (Male or female) |
| Age | The age of the recipient at the time of transfusion |
| Clinical Department/ward | The clinical unit in which the patient was admitted to during the transfusion. For this study, this was confined to medical, child health, surgical and reproductive health. |
| Presenting condition | The primary condition being treated at the time of transfusion. The conditions were classified broadly according to the International Classification of Disease (ICD)-10 as infectious and parasitic(A00-B99), neoplasms(C00-048), diseases of blood and blood forming organs(D50-D89), diseases of the digestive system(K00-K93), genitourinary diseases(N00-N99), pregnancy, childbirth and puerperium related(O00-O99), conditions in the perinatal period(P00-P99), injuries(S00-T98) and other chapters. |

Table 3.1 Study variables (cont.)

|  |  |
| --- | --- |
| **Variable** | **Variable definition/unit of measurement** |
| Cadre of clinician | The cadre of the clinician prescribing the blood transfusion. This was categorized into consultant/specialist; registrar/resident; medical officer; medical intern; clinical officer |
| Pre-transfusion Hb | The last recorded result of the Hb just before transfusion |

**3.10 Data analysis and presentation**

The data obtained was analyzed using SPSS software version 20. Data was summarized using frequency tables, median (IQR) and range. Data was summarized into frequency, median (IQR) percentages, mean and standard deviation. ANOVA was used to compare the mean pre-transfusion Hb between groups. Bivariate analysis was done for testing association between main outcome: inappropriate clinical indication of the transfusion (inappropriate/appropriate) and patient demographic and clinical variables. Chi-square test of independence was used. Univariate logistic regression analysis was then carried out on all variables associated with inappropriate blood use (0 = no; 1 = yes) in the bivariate analysis (p<0.05). Finally, a multivariate logistic regression analysis was carried out on all the variables with p value <0.05 in univariate analysis.

**3.11 Ethical considerations.**

An approval was sought and obtained from Institutional Research and Ethical Committee (IREC) of Moi University and Moi Teaching and Referral Hospital. Permission to carry out the study was also obtained from the hospital administration of MTRH. The patients’ medical records were de-identified.

**CHAPTER 4: RESULTS**

**4.1 Demographic data of the transfusion recipients**

A total of 384 patient medical records were reviewed. The median age of the patients (IQR) was 31.5(13, 45.8) and the range was 1 day to 89 years. About 8.9% of the recipients were at least 65 years and 27.6% were below 15 years of age. Males comprised 172 (44.8%) and females were 212(55.2%) giving a male: female ratio of 1:1.2. The age and gender of the transfusion recipients is as shown in table 4.1

Table 4.1 Age and gender of the recipients

|  |  |  |
| --- | --- | --- |
|  | **Frequency (n)** | **Percent (%)** |
| **Age groups (years)**  0-4  5-14  15-24  25-34  35-44  45-54  55-64  65+ | 54  52  31  78  71  41  23  34 | 14.0  13.5  8.0  20.2  18.4  10.6  6.0  8.8 |
| **Sex**  Male  Female | 172  212 | 44.8  55.2 |

**4.2 Clinical data of the transfusion recipients**

**4.2.1 Clinical department**

Of all the transfused patients, 59.9% (230) were admitted to the medical and surgical wards. The distribution of the recipients among the various clinical departments is as shown in fig. 4.1

Figure 4.1 The clinical departments of the recipients

**4.2.2 Presenting condition**

Neoplasms accounted for the majority of the presenting conditions for the recipients, 23.2% (89/384), of which 73/89(82%) were malignant. This was followed by pregnancy and childbirth related cases (12.5%), injuries (11.5%) and infectious & parasitic conditions (11.2%) as shown in table 4.2.

Table 4.2 Presenting conditions of the recipients

|  |  |  |
| --- | --- | --- |
| **Presenting conditions** | **Frequency (n)** | **Percent (%)** |
| Infectious and parasitic diseases (A00-B99)  Neoplasms (C00-O48)  Diseases of blood & blood forming organs (D00-D89)  Endocrine, nutritional and metabolic disease (E00-E90)  Diseases of the digestive system(K00-K93)  Diseases of the genitourinary system(N00-N99)  Pregnancy, childbirth &Puerperium(O00-O99)  Conditions in the perinatal period(P00-P99)  Injuries (S00-T98)  Other Chapters  Total | 43  89  31  13  28  35  46  27  44  27  384 | 11.2  23.2  8.1  3.4  7.8  9.1  12.0  7.0  11.5  7.0  100 |

**4.2.3 Cadre of clinician who prescribed the blood transfusion**

One hundred and fifty (39.1%) of the clinicians who ordered transfusion were registrars and 125(32.6%) were medical officer interns (Fig. 4.2)

Figure 4.2 Cadre of clinician who prescribed transfusion

**4.2.4 Clinical indications for blood transfusion**

Majority of the patients 240(62.5%) had anaemia as the indication for blood transfusion, 55(14.3%) were transfused in preparation for elective surgery and 55(14.3%) for haemorrhage. Thirty-four (8.8%%) of the patients did not have any documented reasons for being transfused (Fig. 4.3)

Figure 4.3 Indications for blood transfusion

Among the patients who were transfused because of hemorrhage, 61.8% (34/55) had obstetric/gynaecologic bleeding, 21.8% (12/55) had medical hemorrhage and 16.4% (9/55) had surgical hemorrhage.

**4.2.5 Pre-transfusion Hb**

The mean pre-transfusion Hb for all the recipients was 7.8 (SD 2.9). The mean pre-transfusion Hb according to the age, gender, clinical department and presenting condition of the recipients is as shown in table 4.3. There was a statistically significant difference of the mean pre-transfusion Hb between those who had appropriate transfusion and those who had inappropriate transfusion (p<0.001).

Table 4.3 The mean pre-transfusion Hb according to the age, gender, clinical department and presenting condition of the recipients

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | N | Mean pre-transfusion Hb±SD | F | P value |
| **Age groups (years)**  0-4yrs  5-14yrs  15-24yrs  25-34yrs  35-44yrs  45-54yrs  55-64yrs  65+  Total | 54  52  31  78  71  41  22  34 | 10.2±2.9  7.9±3.3  7.3±2.7  7.6±2.5  7.1±2.8  7.0±2.6  8.4±2.4  7.4±2.6  7.8±2.9 | 7.396 | **<0.0001** |
| **Gender**  Male  Female  Total | 169  211  380 | 7.18±  7.56±  7.8±2.9 | 4.297 | **0.039** |
| **Clinical department**  Medical  Surgical  Reproductive health  Child health  Total | 109  117  75  79  380 | 6.3±2.1  8.7±2.7  7.3±2.6  9.1±3.4  7.8±2.9 | 23.054 | **< 0.0001** |
| **Presenting condition**  Infectious and parasitic  Neoplasms  Diseases of blood  Endocrine, nutritional and metabolic disorders  Digestive system diseases  Genitourinary disorders  Pregnancy related  Perinatal conditions  Injuries  Others  Total | 43  88  31  12  28  36  45  27  43  27  380 | 6.1±1.9  8.1±2.8  6.3±2.4  6.6±1.9  7.9±3.2  6.1±2.1  7.4±2.6  12.0±2.1  9.0±2.5  8.9±2.4  7.8±2.9 | 18.609 | **<0.0001** |
| **Appropriateness of transfusion**  Appropriate  Inappropriate  Total | 196  184  380 | 6.2±2.2  9.6±2.4  7.8±2.9 | 216.871 | **<0.0001** |

**4.2.6 Blood and blood product used**

Whole blood was transfused to 231(60.2%) of the recipients while PRBC was used by 153(39.8%) patients.

**4. 3 Appropriateness of blood transfusion**

The overall proportion of inappropriate blood use was 49% for all the departments. The inappropriate transfusion was 40% (45/112), 58% (48/117), 43% (32/75) and 54% (43/80) in the medical, surgical, reproductive health and child health departments, respectively (Table 4.4)

**4.3.1 Factors associated with inappropriate blood transfusion**

The factors found to be significantly associated with inappropriate blood transfusion were the pre-transfusion Hb (p< 0.001), clinical department (p=0.043), presenting condition (p=0.01) and the cadre of prescriber of the transfusion (p = 0.008) (Table 4.4).

Table 4.4 Chi square test of association between inappropriate blood transfusion and patient demographic and clinical variables.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Inappropriate transfusion | | Statistic | *p* value |
| Yes, n(%) | No, n(%) |
| **Age(years)**  0-4yrs  5-14yrs  15-24yrs  25-34yrs  35-44yrs  45-54yrs  55-64yrs  65+ | 32(59)  24(46)  16(52)  35(45)  32(45)  19(46)  13(57)  17(50) | 22(41)  28(54)  15(48)  43(55)  39(55)  22(54)  10(43)  17(50) | χ2= 4.148 | 0.763 |
| **Sex**  Male  Female | 92(53)  96(45) | 80(47)  116(55) | χ2= 2.558 | 0.110 |
| **Clinical department**  Medical  Surgical  Reproductive health  Child health | 45(40)  68(58)  32(43)  43(54) | 67(60)  50(42)  43(57)  37(46) | χ2=8.706 | **0.043** |

Table 4.4 (cont.) Chi square test of association between inappropriate blood transfusion and patient demographic and clinical variables

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Inappropriate transfusion | | Statistic | P value |
| Yes n(%) | No n(%) |
| **Presenting condition**  Infectious and parasitic(A00-B99)  Neoplasms (C00-D49)  Diseases of blood (D50-D89)  Diseases of digestive system (K00-K93)  Endocrine, nutritional & metabolic  Genitourinary diseases (N00-N99)  Pregnancy related conditions (O00-099)  Conditions of perinatal period (P00-P99**)**  Injuries (S00-T98)  Other chapters | 22(50)  50(56)  12(39)  15(54)  7(54)  7(20)  18(39)  15(56)  23(52)  19(70) | 22(50)  39(44)  19(61)  13(46)  6(46)  28(80)  28(61)  12(44)  21(48)  8(30) | χ2= 22.683 | **0.01** |
| **Cadre of clinician**  Consultant  Registrar  Medical officer  Medical intern  Clinical officer | 15(32)  66(44)  15(47)  71(57)  21(68) | 31(68)  84(56)  17(53)  54(43)  10(32) | χ2=13.905 | **0.008** |

In an unadjusted logistic regression analysis, patients admitted to the surgical ward were more likely to have an inappropriate transfusion (reference category = medical ward) (OR 2.025; 95%CI, 1.197-3.424) (p= 0.01). Though this association became statistically insignificant after adjusted logistic regression, patients admitted to the surgical ward were 1.5 times more likely to have an inappropriate transfusion compared to those admitted to the medical ward (table 4.5).

The level of inappropriate blood use varied with the presenting conditions of the patients. Using infectious and parasitic conditions as the reference category, patients with genitourinary disorders were least likely to have inappropriate transfusion (OR, 0.233; 95%CI, 0.80-0.677) (Table 4.5).

The proportion of inappropriate blood transfusion was found to be higher among patients in whom the transfusion was prescribed by a clinical officer (OR 5.513; 96%CI, 1.953-15.563) followed by medical intern (OR, 2.761; 95%CI, 1.304-5.842). (Ref category= medical officer) (Table 4.5).

Table 4.5 Logistic regression analysis of the factors associated with inappropriate blood transfusion: (inappropriate: no=0, yes=1)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Variable | Inappropriate blood use | | uOR(95%CI) | p value | aOR(95%CI) | p value |
| Yes, n (%) | No, n (%) |
| **Clinical Department,**  Medical  Surgical  Reproductive  Child health  **Presenting condition**  Infectious  Neoplasms  Disorders of blood  Digestive disorders  Metabolic& nutritional diseases  Genitourinary diseases  Pregnancy related  Perinatal conditions  Injuries  Others  **Cadre of clinician**  Consultant  Registrar  Medical officer  Medical intern  Clinical officer | 46(40)  68(58)  32(43)  43(54)  22(50)  50(56)  12(39)  15(54)  7(54)  7(20)  18(39)  15(56)  23(52)  19(70)  15(32)  66(44)  15(47)  71(57)  21(68) | 67(60)  50(42)  43(57)  37(46)  22(50)  39(44)  19(61)  13(46)  6(46)  28(80)  28(61)  12(44)  21(48)  8(30)  31(68)  84(56)  17(53)  54(43)  10(32) | Reference category  1.995(1.179-3.377)  1.170(0.647-2.115)  1.730(0.969-3.089  Reference category  1.282(0.621-2.645)  0.632(0.248-1.606)  1.167(0.338-4.033)    1.154(0.447-2.981)  0.286(0.107-0.764)  0.607(0.261-1.412)  1.250(0.478-3.271)  1.095(0.474-2.527)  2.375(0.860-6.558)  1.624(0.810-3.256)  1.824(0.721-4.615)  Reference category  2.717(1.335-5.531)  4.340(1.640-11.485) | **0.010**  0.604  0.064  0.501  0.335  0.808  0.768  **0.013**  0.247  0.649  0.831  0.095  0.172  0.205  **0.006**  **0.003** | Reference category  1.521(0.761-3.040)  1.426(0.588-3.456)  1.590(0.768-3.294)  Reference category  1.255(0.565-2.787)  0.683(0.257-1.819)  1.217(0.337-4.388)  1.038(0.378-2.848)  0.259(0.091-0.734)  0.485(0.149-1.585)  1.194(0.396-3.601)  0.725(0.254-2.068)  2.103(0.698-6.338)  1.547(0.740-3.236)  2.575(0.943-7.029)  2.621(1.246-5.511)  5.375(1.916-15.098) | 0.236  0.432  0.212  0.577  0.446  0.764  0.943  **0.011**  0.132  0.753  0.548  0.187  0.247  0.065  **0.011**  **0.001** |

uOR- Unadjusted Odds RatioaOR- Adjusted Odds Ratio

**4.4 Documentation practice of the clinical blood transfusion**

Only 0.7% (3/384) of patients had documented evidence of informed consent in their medical records. The duration of completion of the transfusion was documented in 47.1% (181/384) and it was within 4hrs for 33.9% (130/384) of the patients. Documentation of transfusion start times was carried out in 57% (219/384) of the transfusion recipients. The number of recipients who had blood product unit number and vital signs documented were 73.4 % (282/384) and 27.9 (107/384) respectively. The recording of vital signs before, during and after transfusion is as shown in figure 4.4. The Frequency and percentages of the documentation of transfusion procedures according to the clinical department are shown in table 4.6.

Table 4.6 Frequency and percentages of the documentation of transfusion procedures according to the clinical department.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Transfusion procedures** | **Clinical department** | | | |
| Medical (n=112) | Surgical (n=117) | Reproductive health (n=75) | Child health (n=80) |
| Consent | 0(0%) | 0(0%) | 3(4%) | 0(0%) |
| Blood unit number | 83(74.1%) | 93(79.5%) | 54(72%) | 52(65.5%) |
| Start times | 44(39.3%) | 46(39.3%) | 22(29.3%) | 53(66.3%) |
| Duration of transfusion | 49(43.8%) | 55(47%) | 23(30.7%) | 54(67.5%) |
| Observation of Vital signs | 29(25.9%) | 35(30%) | 11(14.7%) | 31(38.9%) |

Figure 4.4 Observations of the vital signs before, during and after transfusion

The duration form ordering of blood to arrival in the ward was within 24 hours for most of the patients 344(89.6%). The reasons for the delay for those whose blood took more than 24 hours to arrive in the ward were documented for only 40% (16/40) of the recipients. The reason given for the delay in all the documented cases was lack of blood in the blood bank.

**4.5 The pattern of blood and blood product use according to the demographic and clinical profiles of the recipients**

**4.5.1 Distribution of blood and blood product use according to age and gender**

Patients in the 20- 49 years age range utilized 48.4% (186/384) of all the blood and blood products, out of which 69.9% (130/186) was whole blood. Majority of the transfused patients were women (55.2%), with recipients in the reproductive age group (15-49 years) accounting for the majority, 55.7% (118/212). Whole blood was mostly transfused to women (126/212, 59.4%) and paediatric patients below the age of 9 years received 13.2% (28/212) of whole blood and 36.6% (56/153) of PRBC. The distribution of blood and blood product use by age and gender is as shown in figures 4.5 and 4.6.

Figure 4.5 The distribution of recipients according to age and gender

Figure 4.6 The distribution of blood and blood product use according to age

**4.5.2 Distribution of blood and blood product use according to the clinical department**

In terms of blood and blood product transfused per department, whole blood accounted for 74.7% (62/116) and 75.7% (56/74) in the surgical and reproductive health departments respectively. Packed red blood cells was transfused to 70% (56/80) of patients admitted to child health department (Fig. 4.7).

Figure 4.7 The distribution of blood and blood product use according to the clinical department

**4.5.3 Distribution of blood and blood product use according to the presenting condition**

Recipients who had pregnancy and child birth related conditions whole blood accounted for 82% (37/45) of all the blood of the blood and blood products transfused, followed by those with digestive system disorders 75% (21/28). Of all the blood and blood products transfused to patients who had conditions in the perinatal period, packed red blood cells accounted for 88.9% (24/27) (Fig.4.8)

Figure 4.8 The distribution of blood and blood product use according to the presenting condition

**4.5.4 Distribution of blood and blood product use based on the indication**

Of all the whole blood transfused, 134(58%) was used in patients who had anaemia, while 39(16.9%) was transfused by those with haemorrhage (Fig. 4.9)

Figure 4.9 The distribution of blood and blood product use based on the indication

CHAPTER 5: DISCUSSION

**5.1 Appropriateness blood and blood product use and associated factors**

The proportion of inappropriate blood use in our study was 48.4% and it falls within the range of results reported in other studies of 4% to 66% (Hebert, Schweitzer, Calder, Blajchman, & Giulivi, 1997). The variation in results reported from different studies could be due to different study time periods, study designs, study population, practice guidelines and the specific appropriateness criteria applied (Hebert, Schweitzer, Calder, Blajchman, & Giulivi, 1997).

The factors associated with inappropriate transfusion in our study were the pre-transfusion Hb (p< 0.001), clinical department (p< 0.033), presenting condition (p<0.01) the cadre of the prescribing clinician (p=0.008). Other studies have had mixed findings (Barr et al., 2011; A. J. Martí-Carvajal, Muñoz-Navarro, Peña-Martí, et al., 1999; Mozes et al, 1989) and this could be because of the differences in study setting, study design and the criteria used to evaluate the appropriateness of blood use. In the study by Barr et al., 2011, age, pre-transfusion Hb, comorbidity and presenting condition were found to be associated with inappropriate blood transfusion.

Patients admitted to surgical ward were more likely to have an inappropriate transfusion (reference category = medical ward) (OR, 2.025; 95%CI, 1.197-3.424). This finding compares to those from studies by Barr et al., (2011) and Martí-Carvajal, Muñoz-Navarro, Peña-Marti, & Comunian, (1999).

The transfusion recipients with genitourinary disorders were less likely to have inappropriate transfusion (OR, 0.233; 95%CI, 0.80-0.677). This finding differs from that by Barr et al., (2011) where patients with urologic and gynaecologic conditions were found to have high level of inappropriate transfusion with OR,1.51;95%CI,1.04-2.20 and OR,1.50; 95%CI,1.17-1.93 respectively. The patients in the Barr et al study tended to have high mean pretransfusion Hb levels (8.1 and 8.2 g/dL (p < 0.001), whereas, the ones in our study tended to have lower mean pretransfusion Hb levels, 5.9g/dL (p<0.001).

There appeared to be a higher level of inappropriate transfusions among the patients in whom transfusion was prescribed by clinical officers (68%; OR 4.340, 95%CI, 1.640-11.487) and medical interns (57%, 2.717, 95%CI, 1.335-5.531) compared to other cadres of clinicians; consultant (32%), registrar (44%) and medical officer (47%). This finding differs from the study by Barr et al., 2011) where higher proportion (31%) of the inappropriate transfusion was by a consultant compared to other grades even though firm conclusions on the actual level of inappropriate prescribing by clinician grade could not be drawn because of missing data on information regarding prescriber grade in 13% (197/1474) of cases.

The different levels of appropriate use of blood among the various cadres of clinicians might be attributed to varying level of knowledge about appropriate use of blood among clinicians (Friedman, 2011). In the study by Yudelowitz et al., (2016), it was established that the clinician rank means for correctly answered questions on knowledge of appropriate blood product use from 32 questions were 14.82 (4.49), 15.65 (4.03), 17.0 (4.34) and 20.09 (3.67) for interns, medical officers, registrars and consultants respectively.

The high proportion of transfusions prescribed by registrars and medical interns might be explained by the fact that these clinicians, in most cases, make the first contact with patients in the wards and hence make the first decision concerning the need for blood transfusion.

**5.2 Documentation practices of the clinical blood transfusion**

There were inadequacies regarding documentation of the transfusion process. There were no records for informed consent, transfusion start times, duration of completion of the transfusion, blood and blood product unit number in and vital signs in 99.7%, 57%, 52.9%%, 26.6% and 27.9% of all recipients, respectively. There were also no records for vital signs before, during and after transfusion in 69.9%%, 48.2% and 98.4% of patients respectively. Our findings compare with those of other studies (Reis et al., 2016; de Graaf, Kajja, Bimenya, Postma, & Sibinga, 2009; Natukunda et al., 2010; Grewal, Neffendorf, & Williams, 2012 and Audet, Goodnough, & Parvin, 1996). Proper and diligent monitoring of the patients receiving a blood transfusion for adverse signs or symptoms, can help prevent or manage a potentially fatal reaction such as haemolytic reaction caused by an earlier process error or an unavoidable physiologic condition (Fastman & Kaplan, 2011).

As our study was a retrospective medical chart review and hence it cannot be ascertained whether the consent was not documented or it was not obtained at all from the patients in the first place. It is also of importance to note that there was no specific consent form for blood transfusion in our hospital.

Forty patients (10.4%) had to wait for blood for more than 24 hours after being ordered before getting the transfusion. The main reason for the delay was lack of blood in the blood bank. In their study, Mosha et al., (2009) found that 8% of patients had to wait more than 6 hours from the doctor’s decision for a blood transfusion to the actual initiation of it due to lack of blood. The limited availability of blood has been reported by the (World Health Organization, 2016) and the Kenya National Blood transfusion Service (Merab, E; & Mosota, M., 2015; VOA news, 2010). The delay in initiating blood transfusion might increase mortality due severe anaemia (Thomas et al., 2016; Lackritz et al., 1992; Lackritz et al., 1993). Thomas et al., (2016), in a model adjusting for such features of severe illness, showed that children who had a transfusion ordered and given on the same day compared with those with a delay in receiving blood (≥1 day after prescription) had lower mortality (OR = 0.58, 95% CI = 0.38–0.87), whereas those not transfused had higher mortality (OR = 1. 8, 95% CI = 1.3–2.49).

The duration of the blood transfusion completions was more than 4 hours in 13.0% of the patients and this finding differ from that of a study by Reis et al., (2016) where the duration of the transfusion was more than the recommended time in 8% of the patients and another one by Mosha et al., (2009) where 40% of the transfusions exceeded the recommended 4 hours. However, in our study, 57 % of the recipients did not have any documentation of the start times of the transfusion. Long transfusion time increases risk of bacterial growth (McClelland, (2007) and of haemolysis (Johnson, Langeberg, Taye-Makuria, & Sandler, 2006) of the blood. It may also delay the time before a viable Hb level is restored.

**5.3 The pattern of blood and blood product use according to the demographic profiles of the recipients**

The profile of demographic and clinical features of blood recipients is significant in that it would help in predicting the long term needs of blood transfusion as changing patterns of populations, diseases and health care will result in changing demands for blood and blood products.

**5.3.1 The pattern of blood use according to demographic profiles of the recipients**

In our study, blood was used mainly by relatively young population of which the median age for the recipients was 31.5 years with patients in the 20-49 years age range using the highest proportion of the transfused units. This finding concurs with those of other studies from developing countries (Mafirakuvera et al., 2015; Pitman et al., 2015; Gaur et al., 2009; Natukunda et al., 2010; Kuliya-Gwarzo, 2007). However, it varies from studies from developed countries (Cobain, Vamvakas, Wells, & Titlestad, 2007; Barr et al., 2011; Bosch et al., 2011). This could be attributed to differences in age distribution of transfused patients in these countries, whereby in developing countries, most transfusions are utilized by younger patients while in the developed countries the elderly (65 years and above) patients are ones mostly transfused (WHO, 2016).

The recipients below 9 years of age utilized more packed red cells as compared to whole blood. This finding is similar to that of a study by (Ambroise, Ravichandran, Ramdas, & Sekhar, 2015)

In terms of gender, females (55.2%) utilized more blood transfusions than males, with those in the reproductive age group (15-49 years) accounting for the majority (118/212, 55.7%). This observation is consistent with findings in other countries in sub-Saharan Africa where women receive more blood for pregnancy-related complications resulting from intra-partum and post-partum hemorrhage (Okoroiwu & Okafor, 2018; Mafirakureva et al., 201) and Natukunda et al., 2010). In our study, of all the patients admitted to the reproductive health department, 45.3% (34/75) were transfused due to obstetric/gynaecologic haemorrhage, out of which 61.8% (21/34) resulted from abortions, ante-partum and post-partum haemorrhage.

**5.3.2 The pattern of blood and blood product use according to the clinical profiles of the recipients.**

The number of units of blood and blood products used was slightly higher in the surgical disciplines (51%) than in medical disciplines (49%). This finding is similar to those of studies by Gaur et al., (2009); Geißler et al., (2012) and Zimmermann et al., (1997).

Whole blood accounted for a higher proportion of the total blood and blood products transfused in the surgical 61.6% (69/112) and in the reproductive health 75.7% (57/75) departments and this is similar to the study by Gaur et al., (2009). This finding could be due to the fact that one of the few indications of whole blood is severe haemorrhage (Repine et al., 2006; Spinella, 2008) which can result from traumatic injuries seen in surgical practice and from obstetric and gynecologic complications. In our study haemorrhage accounted for 14.3% (55/384) of all the indications of transfusion, of which surgical and obstetric/gynaecologic haemorrhage comprised 78.1% (43/55) of the cases.

The top five common presenting condition of patients requiring blood transfusion in our study neoplasms (23.2%), pregnancy related (12.0%), injuries (11.5%), infections (11.2%) and genitourinary (9.2%). Our findings are relatively similar to those reported in Zimbabwe (Mafirarkuvera et al., 2015) and Nigeria (Okoroiwu & Okafor, 2018). The Zimbabwe study found that the top five common diagnoses were pregnancy related (22.4%), disorders of blood and blood forming organs (17.5%), neoplasms (10.1%), infectious (9.0%) and digestive diseases (8.2%). The study by Okoroiwu & Okafor, (2018) reported diagnoses in the pregnancy & childbirth, perinatal, genitourinary, blood and blood forming, neoplasms and injury categories as accounting form 38.9%, 14.4%, 7.9%, 7.8%, 6.7% and 4.4% of the blood and blood products issued, respectively. Studies from non-African countries reported neoplasms, injury and poison, digestive system diseases and circulatory system diseases as the main diagnosis associated with transfusion (Cobain, Vamvakas, Wells, & Titlestad, 2007; Mathoulin‐Pélissier, Salmi, Verret, & Demoures, 2000). This strongly demonstrates that blood utilization pattern vary significantly within regions and this difference could be attributed to the variation in the clinical practices, diseases burden, level of organization and advancement of healthcare in the different settings (WHO, 2008).

The finding in our study that neoplasm was the commonest presenting condition among transfused patients could be attributed to the large number of patients with neoplasms coming to MTRH, as it is the only referral health facility serving Western Kenya, Eastern Uganda and South Sudan (Armitage, 2013).

Red blood cells increase the oxygen carrying capacity of the blood among other beneficial effects (Aryeh Shander, Gross, Hill, Javidroozi, & Sledge, 2013). Therefore, transfusion of whole blood and PRBC is indicated when the oxygen carrying capacity is impaired in cases of haemorrhage or anaemia arising from chronic disease, chronic blood loss etc. (Schots & Steenssens, 1994; Yaddanapudi & Yaddanapudi, 2014).

Our study found that anaemia was the most common indication of blood transfusion and this finding is similar to that by Gaur et al., (2009), Mathew et al., (2014) and Kuliya-Gwarzo, (2007). Majority of the patients who were transfused because of anaemia could have had anaemia of chronic disease as 66.4% (160/241) of them had neoplasms, infectious and chronic renal disease which are associated with anaemia of chronic disease (Cullis, 2011). Anaemia of chronic disease is also the most common type of anaemia among hospitalized patients (Mitlyng, Singh, Furne, Ruddy, & Levitt, 2006).

In terms of the specific blood product used, whole blood was mainly used in patients with anaemia (62.5%). This compares with finding by Okoroiwu & Okafor, (2018), where 71.57 % of the transfusion recipients received whole blood. This reflects common practice of requesting for whole blood in resource limited settings owing to non-availability of facilities to prepare blood products. In standard practice, whole blood is only issued for transfusion following cases of massive hemorrhages and exchange transfusion. Anaemia is associated with impaired cardiac function (Mozos, 2015) and giving these patients whole blood may cause cardiac failure due to fluid overload (A. Shander, Javidroozi, Ozawa, & Hare, 2011). The recommended blood product for transfusing patients with severe anaemia is PRBC (Lawler, Bradbury, Fonda, Gaziano, & Gagnon, 2010; Alexandrakis & Tsirakis, 2012) as it contains minimal amounts of plasma.

**5.4 Study limitations**

One of the main finding of our study is inadequate documentation of the events of transfusion. Because of this, important factors pertinent to the transfusion decision, such as the actual decision maker, the ability to tolerate anaemia, the clinician’s education experience and personality, etc. could not be readily captured. Such missing information may have contributed to the variance of some findings between our study and other studies.

Another limitation is that, since our study was carried out in the year 2013, some of our findings and conclusion may still not be valid, considering the dynamic nature of medical practice.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The proportion of inappropriate blood transfusion was 49%, indicating that the adherence of the transfusion guidelines was unsatisfactory. The factors associated with inappropriate blood transfusion were pre-transfusion haemoglobin, the clinical department, the presenting condition and the cadre of the prescribing clinician. The documentation of the blood transfusion process was inadequate. Most of the transfused patients were young, had anemia as the main indication of the transfusion and majority presented with neoplasms, pregnancy and childbirth related conditions, infections and injuries.

6.2 Recommendations

1. The clinicians and nursing staff involved in blood transfusion need be to be trained on the importance of appropriate clinical use of blood, adherence of guidelines, informed consent and documentation of the transfusion process.
2. The hospital needs to adopt the strategies of clinical audit to monitor the usage of blood and adherence to the national guidelines.
3. A consent form dedicated solely for the blood transfusion service should be designed and utilized.
4. As for further research:

* There is a need to establish the reasons for the poor documentation of the transfusion process and non- adherence to the national guidelines, hence unsatisfactory level of appropriate blood use
* The knowledge of clinicians and nurses at MTRH on various aspects of blood transfusion e.g., informed consent, bed side procedures, documentation and appropriate use of blood need to be assessed.

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**APPENDICES**

**APPENDIX I**

**CASE REPORT FORM**

**1.** Age in days, months or years ----------------------------------

2. Sex:

1. Male
2. Female

3. Clinical department

1. Medical:
2. Surgical
3. Reproductive
4. Child Health

4. Presenting condition-------------------------------------------------------------------------

5. The ICD-10 diagnostic category of the presenting condition------------------------------

6. Recorded pre-transfusion Hb recorded

1. Present
2. Absent

7. The value of the recorded pre-transfusion Hb --------------------------------------

8. Documentation of the reasons/indication for the transfusion

1. Documented/reasons clear
2. Not documented/reasons not clear

9. The documented reasons/indication of the transfusion

1. Anaemia
2. Elective surgery
3. Haemorrhage

10. The nature of the haemorrhage

1. Medical
2. Surgical
3. Obstetric/gynecologic

11. The indication for the transfusion in accordance with the recommended guidelines

1. In accordance
2. Not in accordance

12. The cadre of clinician who ordered the transfusion

1. Consultant/specialist
2. Registrar/Resident
3. Medical officer
4. Medical officer intern
5. Clinical officer

13. The blood and blood product transfused/used?

1. Whole blood
2. Packed red blood cells

14. Documented evidence of informed consent

1. Documented
2. Undocumented

15. Blood transfusion chart in the patient’s file

1. Present
2. Absent

16. Documented blood and blood product unit number

1. Documented
2. Undocumented

17. Documented observations before transfusion

1. Documented
2. Undocumented

18. Documented observations during transfusion

1. Documented
2. Undocumented

19. Documented observations after transfusion

1. Documented
2. Undocumented

20. Duration from ordering the blood till the arrival in the ward

1. Within 24 hours
2. More than 24 hours

21. The documented reasons for the delay in arrival of ordered blood

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22. Documented transfusion start and completion time

1. Documented
2. Undocumented

23 Duration of completion of the transfusion

1. <4 hours
2. >4 hours

**APPENDIX II**

**SUMMARY OF THE KENYA NATIONAL GUIDELINES FOR THE APPROPRIATE USE OF BLOOD AND BLOOD PRODUCTS**

**GUIDELINES FOR RED BLOOD CELL TRANSFUSION**

ADULTS

1. Acute and perioperatove blood loss

* Transfuse if blood loss is > 30-40% of rapid blood loss
* Transfuse if tachycardia and hypotension are not corrected with volume expanders
* Hb of < 5 g/dl : transfuse red cells
* Hb of 5-10 g/dl: red blood cells may be needed, determined by additional clinical conditions
* Hb of > 10: red cells rarely needed

1. Preoprerative transfusions

* Patients with a Hb level of less than 5g/dl may need transfusion prior to surgery anaemia cannot be corrected by other means
* Blood should be crossmatched and made available for immediate use during surgery for patients with a high likelihood of needing a transfusion. Transfusion may be necessary during surgery for patients with a Hb level less than 8g/dl who lose more than one litre of blood during surgery

1. Chronic anaemia

* Hb of < 5g/dl: transfuse red cells
* Hb of > 5 g/dl: do not transfuse unless patient is symptomatic

1. Chronic anemia in pregnancy

* Pregnancy < 36 weeks
  + Hb < 5 g/dl: transfuse even without clinical signs of cardiac failure
  + Hb 5-7 g/dl: transfuse with clinical signs of cardiac failure and/or infection
* Pregnancy > 36 weeks gestation
  + Hb < 6 g/dl: transfuse even without clinical signs of cardiac failure
  + Hb 6-8 g/dl: transfuse with clinical signs of cardiac failure and/or infection
* Elective caeserian section
  + Hb 8-10g/dl: establish/confirm mother’s blood group and confirm availability of blood in the laboratory
  + Hb < 8 g/dl: cross match and reserve 2 units of blood

PAEDIATRIC

1. Acute blood loss

* Blood is given in cases of continued shock or bleeding

1. Non- hemolytic chronic anemia

* Blood is not generally recommended when the Hb between 4 and 5 gm/dl and the child is clinically stable
* Blood is recommended when the Hb is less than 5g/dl with signs of cardiac failure or respiratory distress

1. Severe anemia in a severely malnourished child

* Blood transfusion is required if the Hb is less than 4g/dl or if there is respiratory distress and Hb is between 4 and 5g/d

1. Sickle cell disease

* Blood transfusion is indicated in the following situations
  + Aplastic anemia with Hb < 4g/dl
  + Hyperhemolytic anemia with Hb < 4g/dl
  + Pre-surgery to raise Hb > 10g/dl
  + Splenic sequestration

NEONATES

* Indications for PRBC transfusion are
  + Hb > 13 g/dl and the baby is < 24 hours or baby needs NICU/ventilation with high O2 needs
  + Hb < 11g/dl and chronic O2 dependence; Signs of anemia: unexplained apnea, tachycardia (rate > 160/min for > 48 hours), poor weight gain (< 10/kg/day) with adequate fluid intake and environmental temperature and signs of CCF
  + Anemia of prematurity with Hb > 8 g/dl with baby requiring O2 or < 7g/dl with baby in room air

**CLINICAL PRACTICE GUIDELINES**

1. Assess the patient’s need for blood transfusion.

2. Record the indications for transfusion in the patient’s notes.

3. Complete a request form accurately and legibly. Include:

- Patient identification

- Reason for transfusion

- Component and amount required

- Date required; urgency

4. Collect and correctly label blood samples (5 cc in a plain tube) for grouping and compatibility testing.

5. Send blood request form and sample to the laboratory.

6. Collect or receive blood or blood products from the laboratory.

7. Check the identity of patient and blood product by checking:

- Patient’s name (from patient records and ask the patient)

- Hospital number

- Ward

8. Confirm blood or plasma is compatible by checking the blood group on:

- Patients notes

- Label on blood bag

9. Check expiry date of blood or plasma

10. Check blood for:

- Clots

- Haemolysis (is the plasma pink?)

- Appearance of red cells (are they purple or black?)

11. Check for leakage of blood bag

12. Start transfusion of whole blood and red cells within 30 minutes of removalfrom refrigerator

13. Return unused blood or blood products to the laboratory within 30 minutes of removal from the refrigerator

14. Complete infusion of whole blood and red cells within 4 hours, and plateletsand plasma within 30 minutes

15. Monitor patient before, during and after transfusion of blood product:

- Before starting the transfusion

- As soon as the transfusion is started

- 15 minutes after starting the transfusion

- At least every half-hour during transfusion

- On completion of transfusion

- 4 hours after completing transfusion

16. Record the following:

- Patient’s appearance

- Pulse

- Temperature

- Blood pressure

- Respiratory rate

- Fluid balance: input and output

17. In the patient’s notes record:

- Date of transfusion

- Time transfusion started and finished

- Volume and type of blood or products given

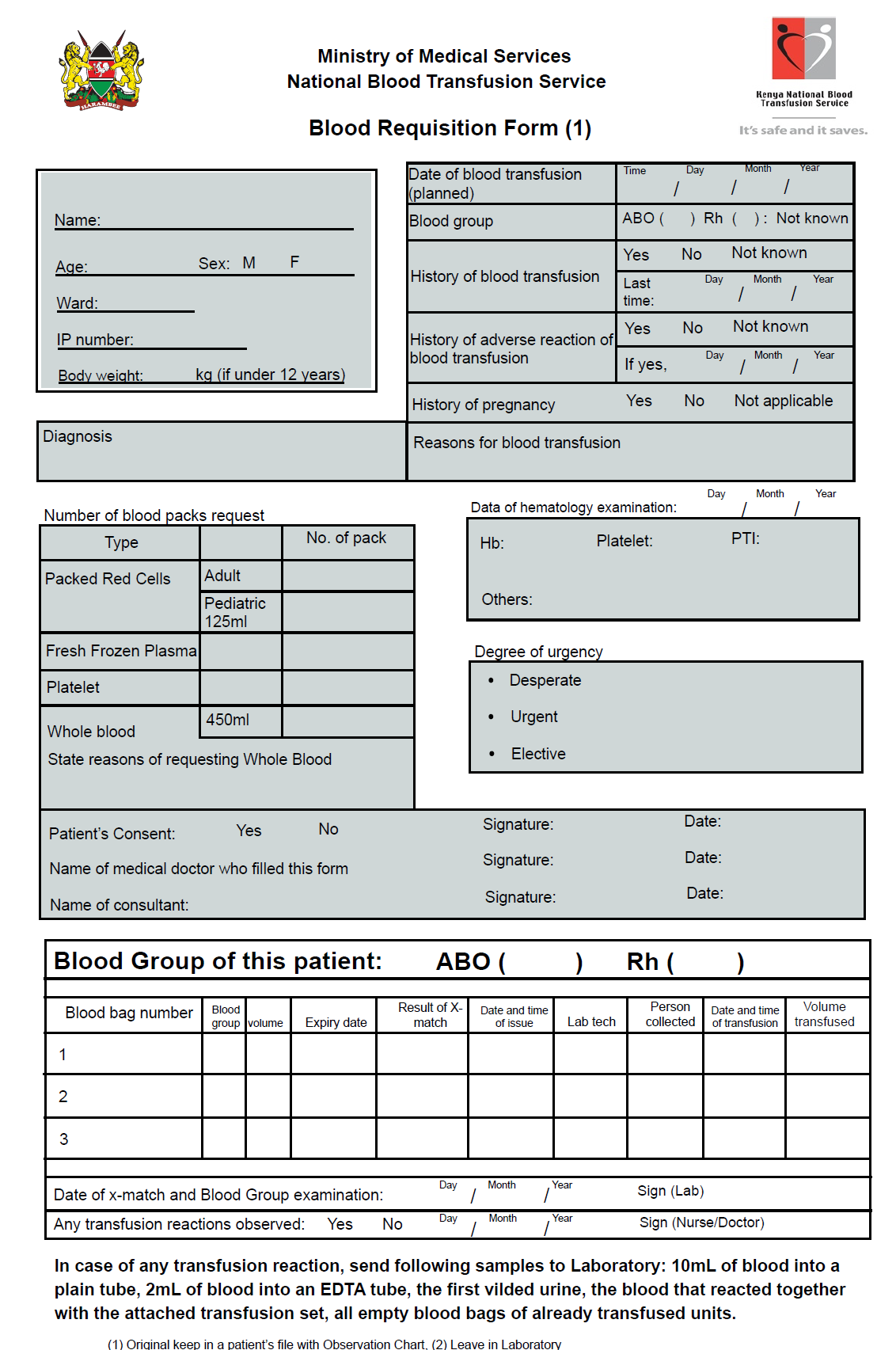
- Blood or plasma unit numbers

- Any adverse effects

18. Sign the patient’s notes

19. Report any adverse reactions immediately to the laboratory

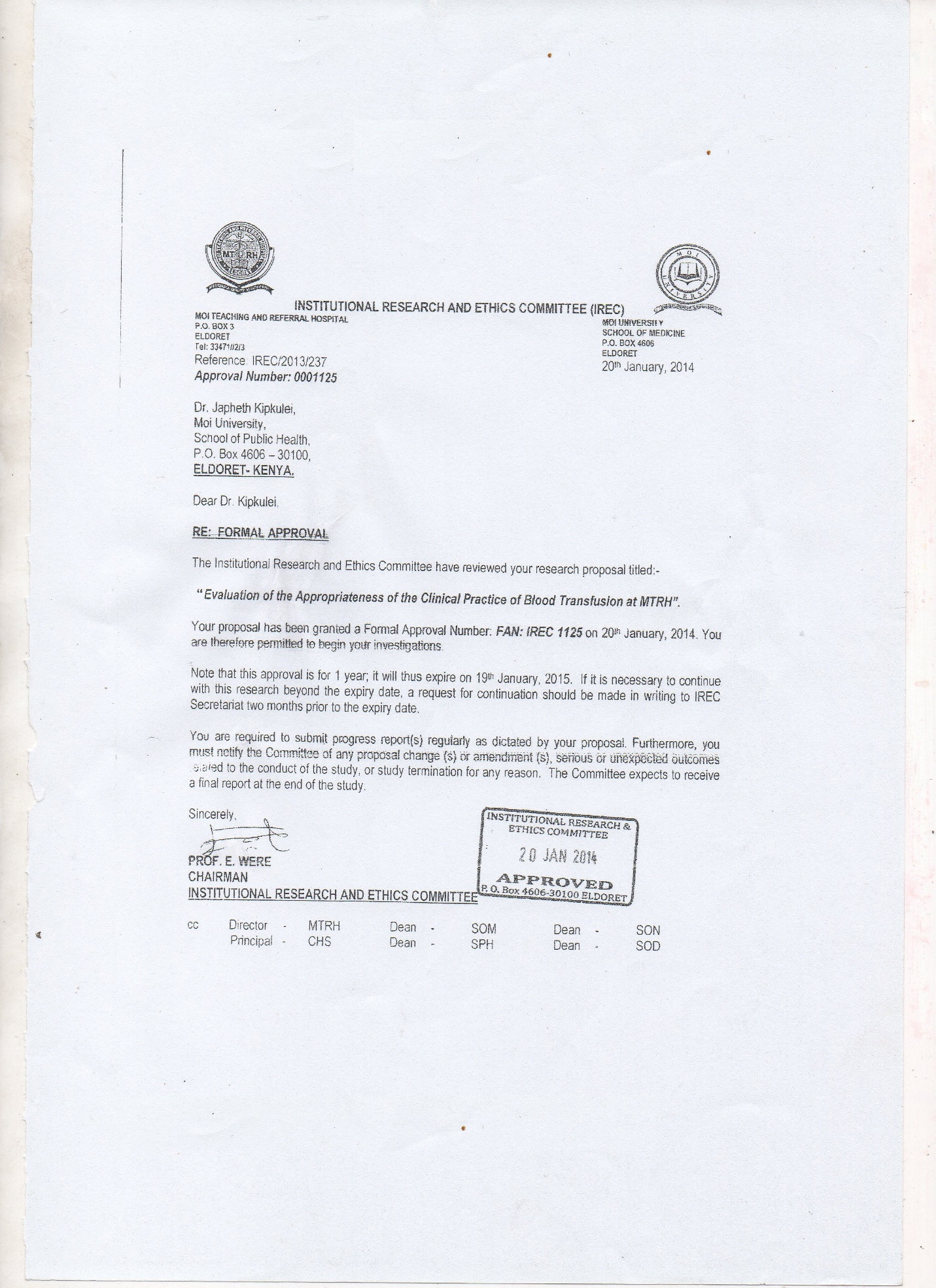
20. Return used/partially used blood bags to the laboratory

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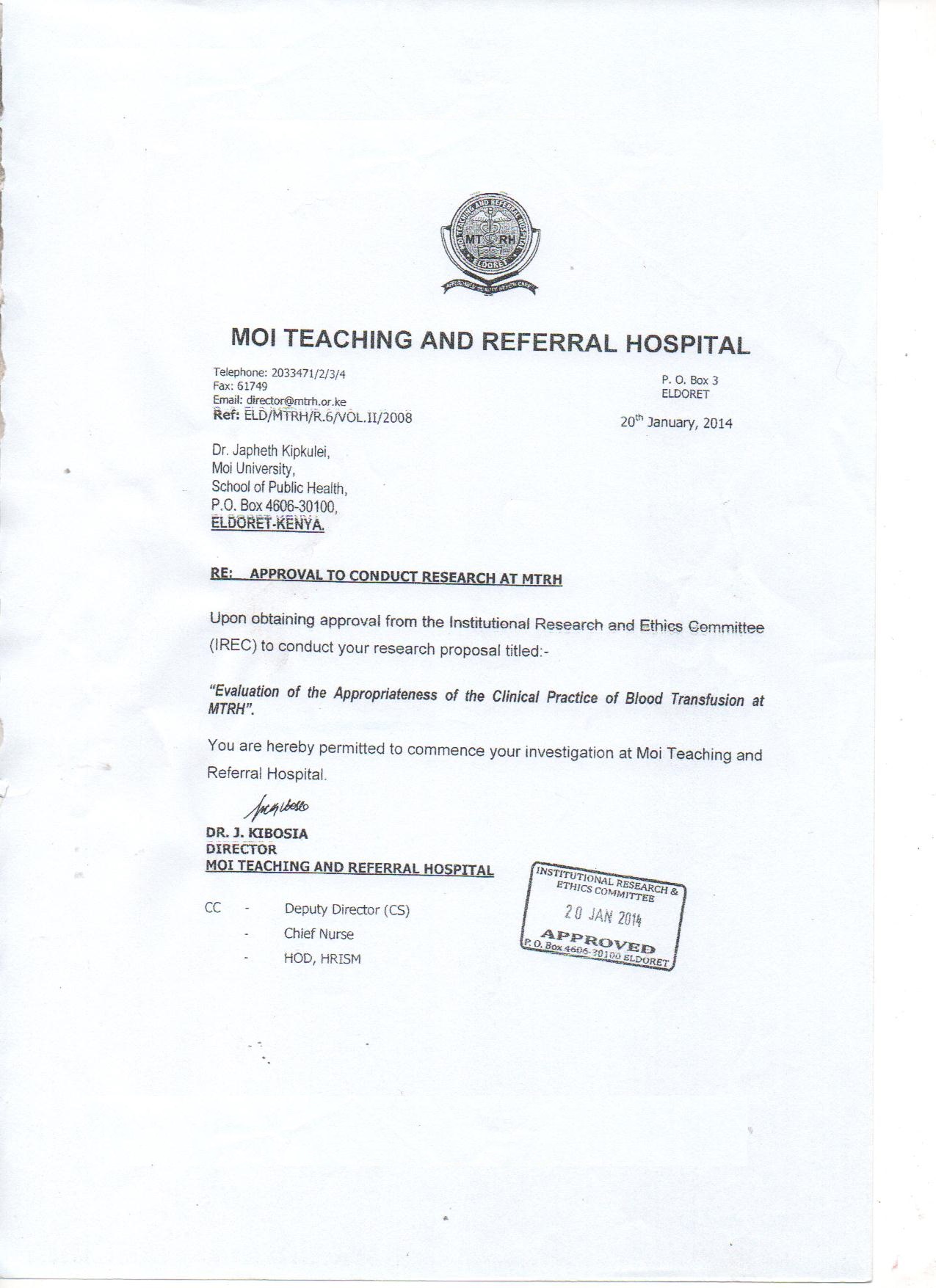
**APPENDIX III**

**APPENDIX IV**



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APPENDIX V: IREC APPROVAL LETTER



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APPENDIX VI: APPROVAL LETTER FROM MTRH