BLOOD ORDERING AND UTILISATION PRACTICES FOR ELECTIVE THORACIC AND CARDIOVASCULAR SURGERY AT KENYATTA NATIONAL HOSPITAL: A STEP TOWARDS ESTABLISHING A MAXIMUM SURGICAL BLOOD ORDERING SCHEDULE.

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Dissertation submitted in part fulfilment of the requirement for the Award of Master of Medicine in General Surgery degree of the University of Nairobi

2018
DECLARATION

I declare that this dissertation is my own original work and to the best of my knowledge has not been presented anywhere else for consideration for publication or for the award of another degree.

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DEDICATION:

To my wife Elizabeth, my friend, my critic, my number one supporter. And to my daughter Elise for the inspiration.
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LIST OF ABBREVIATIONS


BTU: Blood Transfusion Unit.

CABG: Coronary Artery Bypass Graft

C/T RATIO: Crossmatch: Transfusion Ratio

CPB: Cardio-Pulmonary Bypass.

Hb: Haemoglobin

HCT: Haematocrit

HIV: Human Immunodeficiency Virus

KNH: Kenyatta National Hospital


MSBOS: Maximum Surgical Blood Ordering Schedule

PDA: Patent Ductus Arteriosus

PRBC: Packed Red Blood Cells

TI: Transfusion Index

T%: Transfusion Probability
ABSTRACT:

Introduction:

Blood is a valuable resource and is vital in the safety of major operations. Its use for such surgeries should be guided by evidence-based protocols and guidelines. This is however not the case at the Kenyatta National Hospital where blood ordering for peri-operative use, like in many other institutions in Kenya and in Africa, has been based on habit, past experiences, and on the subjective anticipation of blood loss. This highlights the need for development of such protocols, an example of which is the Maximum Surgical Blood Ordering Schedule (MSBOS). This schedule, if developed for thoracic, cardiac and vascular surgeries, which are the largest consumers of blood, would minimise blood wastage, costs of its production and lead to a reduction in theatre cancellation rates for these procedures.

Objectives:

This study was carried out to determine the blood ordering and utilisation practices for elective thoracic and cardiovascular surgery at the Kenyatta National Hospital. Factors influencing these practices were also determined. Development of a Maximum Blood Ordering Schedule (MSBOS) was a secondary objective.

Methods:

This was a cross-sectional descriptive study carried out on patients undergoing thoracic, cardiac, and vascular surgery at the Kenyatta National Hospital from June to November 2017. Pre and intra-operative data was recorded from consecutively recruited participants who gave an informed consent and a questionnaire was filled. Amount of blood requested and transfused was recorded and the Cross-match to Transfusion ratio, Transfusion Probability and the Transfusion Index calculated. This aided in the tabulation of an MSBOS. A t-test was used to compare the means and multiple regression analysis done to predict blood utilisation from the clinical variables. A significance level of 0.05 was set.

Results:

A total of 52 study participants were recruited into the study with a mean (SD) age of 42.60 (15.66). 7 procedures were recorded; 3 thoracic, 3 vascular and 1 cardiac. Females had more pints cross-matched (p=0.016) and underwent longer procedures (p=0.005) than males. They
also had more pints transfused (p=0.016), which was however not statistically significant after multivariate regression analysis (p=0.148). Length of procedure significantly predicted blood loss (p <0.005) and ultimately pints of blood transfused (p <0.005). The overall C/T ratio was 2.1:1 with thoracic procedures having the highest C/T ratios. The transfusion probability and transfusion index were 59% and 1.3 respectively.

**Conclusion:**

This study shows that there was appropriate blood utilisation for cardiac, vascular and thoracic surgery at the Kenyatta National Hospital though this differed for individual procedures. Age, gender, weight and preoperative haemoglobin didn’t affect blood utilisation practices while longer procedures led to more blood loss and more transfusions. Finally, we can conclude that at the Kenyatta National Hospital, 5 units of blood are needed for single cardiac valve replacement, 3 units for AAA repair, 2 units for pneumonectomy, and 1 pint each for oesophagectomy and decortication. Only a G & S would be needed for AV Fistula and venous stripping. This would ensure appropriate blood use.
INTRODUCTION

Blood is a valuable resource and has been shown to have a limited shelf life (1). Blood transfusion is an essential component of quality medical care and it is vital in the development of modern surgery and in the safety of major operations (2). Globally, transfusion of donor (allogeneic) blood is the mainstay of management of a patient at risk, or one who has had a major surgical bleed (2). Each hospital should have a performance monitoring and quality management programme that addresses the use of blood and blood components (3). This is especially because blood transfusion is a form of therapy that involves some risk to the patient.

At the Kenyatta National Hospital, and for many other health institutions, it is the surgeons, in consultation with anaesthesiologists who decide on the blood requests for pre-and peri-operative use. This however has often been based on routine, habit, past experiences and on the subjective anticipation of blood loss (4–6). Requests for large amounts of blood have also been seen to arise from the fear of not having enough during the surgery itself (4). As a result, a lot of blood wastage has been witnessed (1,7,8). In many blood transfusion units, a lot of blood is still being cross matched unnecessarily for operations that don’t require blood.

Worldwide, and especially in advanced centres, the introduction of evidence-based transfusion guidelines and strategies for improving blood utilisation have been shown to be cost-effective and safe (6). An example of such a guideline is the Maximum Surgical Blood Ordering Schedule (MSBOS), which is a list of recommended pre-operative blood orders for various types of elective surgical procedures (9,10). The aim of such a schedule is to determine whether to obtain a Group and Screen (G/S) or a Group and Crossmatch (GXM) in anticipation of transfusion for such procedures (10). The MSBOS should be developed and implemented in each hospital by analysing hospital data either retrospectively or prospectively, sampling a sufficient number of each procedure for a meaningful assessment (8).

Such evidence-based protocols for the transfusion of blood and blood products are lacking in Kenya and in Africa as a whole. This is due mainly to the paucity of studies and clinical trials in an attempt to develop them. Similarly, Protocols for thoracic, cardiac and vascular elective surgery are lacking worldwide. This is despite the fact that these procedures have been shown to be the biggest consumers of blood and blood products due to their high blood requirements (1,11). This study aimed to investigate the blood ordering and utilisation practices for elective thoracic, cardiac and vascular surgery at the Kenyatta National Hospital with an ultimate goal
of the development of a blood ordering schedule from the evidence collected and analysed. The MSBOS thus developed, if adopted by the Kenyatta National Hospital will guide appropriate application and use of blood and blood products, a reduction in the cost of production and storage of these products, and a reduction in the cancellation rates for these procedures.
LITERATURE REVIEW:

Kenyan guidelines on the peri-operative use of blood and blood products:

The Kenya National Blood Transfusion Services (KNBTS) has general guidelines on the appropriate use of blood and blood products in Kenya. As per these guidelines, blood should be transfused to save life, especially by ensuring adequate tissue – oxygen delivery. Transfusion is also best given immediately at the time it is requested, rather than delayed and the guidelines also note that transfusion is rarely required for patients with a haemoglobin of more than 10g/ dl. A greater indication is noted for those patients with a value of less than 5g/dl, though this is subject to clinical correlation.

The indications for blood transfusion in Kenya are mostly urgent conditions. Supportive therapies in such emergent situations should however be considered immediately and before blood is made available, which could take time. If a patient is noted to stabilise after such supportive measures, then a transfusion may no longer be necessary. A post-transfusion assessment of the Hb should be done to assess the efficacy of transfusion. The guidelines also note that transfusion should not be assumed to be a cure for anaemia, rather, the underlying cause of the anaemia should be investigated and treated.

Red blood cells are essential in a blood transfusion as they increase the delivery of oxygen to the tissues. These cells can either be transfused in whole blood or as concentrates known as Packed Red Blood Cells (PRBCs). A unit of whole blood contains approximately 400-500 ml and has a HCT of 45-55%, whereas a unit of PRBCs contains all the red blood cells concentrated from a unit of whole blood. Each unit of PRBCs contains approximately 180-200 ml of RBCs, 50-70 ml of plasma and has a HCT of 60-70%. In addition, each unit of blood contains about 60g of Hb and 250 mg of iron predominantly in the form of haemoglobin. An anticoagulant, citrate, and additional preservative solutions are also contained making it possible to store blood for up to 35 days.

Red blood cells must be compatible with the ABO antibodies in the recipient’s serum and must be cross-matched prior to transfusion in order to confirm compatibility. One unit of blood raises the patient’s haemoglobin by approximately 1g/dl. Transfusion of blood and its products has been known to save lives , but it hasn’t been without risks and costs (3). Some of the known common adverse effects of blood transfusion include haemolytic and non-haemolytic reactions, immunosuppression and alloimmunisation. Transfusion of certain infectious
Blood is a valuable resource and must be kept safe from these diseases and reactions which makes the process of blood collection, processing and administration expensive. Blood transfusion should thus be limited to clear indications to reduce unnecessary exposure of patients to the risks of transfusion.

Blood for peri-operative use is in two groups; a blood grouping & red cell antibody screening (G & S), or a blood grouping and a cross match (GXM) (12). In the first group, the laboratory determines the blood group, performs ABO and Rhesus typing and screens for atypical red blood cell antibodies of the patient’s blood and serum. In the second group, a cross match and blood reservation is done unlike for the first group. A negative antibody screen signifies that the patient does not demonstrate any clinically significant antibodies, and therefore, only an immediate spin cross match is required (13). An immediate spin cross match has been described as an easy and simple test to carry out, taking only 10 minutes. And so, if an un-anticipated need would arise intra-operatively, blood would be made available, and fast. So, in performing a type and screen, no blood is being unnecessarily cross-matched and reserved, making it a cost-effective and safe strategy.

**The maximum surgical blood ordering schedule (MSBOS):**

The MSBOS is a method of inventory control created to assist in reducing excessive blood requests and use pre-operatively for patients due for elective surgery. It is in the form of a table that lists the number of units of blood routinely requested and cross matched for a number of specific elective surgical procedures based on a retrospective analysis of actual blood usage (8,13,14). In surgical procedures where blood will rarely be used peri-operatively, no red cell issue is required but a valid group and save serum request must be processed by the blood transfusion unit in the case of unforeseen bleeding.

The MSBOS was first proposed by Friedman et al in 1973 in a 1,000-bed hospital at the University of Michigan. It had an aim to minimise blood wastage from that cross-matched for elective surgical procedures (1). The MSBOS, once established in a hospital by a team of operating surgeons, anaesthesiologists and haematologists can ensure appropriate pre-operative ordering of blood (8). Since then, similar studies have been done all with an aim to optimise blood use peri-operatively. Lack of specific guidelines for blood requests have led to excess requests for blood and blood products preoperatively from fear of not having sufficient
blood peri-operatively (4). The more the blood remains in a cross-matched state, the more it is unavailable for other patients and the higher the chance of it getting outdated. An effort should thus be made to reduce the amount of time that blood remains in this reserved state (1,15).

The MSBOS is a simple predictor of the number of units of blood cross-matched versus the actual units used for these procedures and patients. However, it was created to apply for elective procedures and no similar schedule is available for emergency procedures. In addition, the schedule should be interpreted in accordance with the clinical condition of the patient and other prevailing circumstances (8). A well-designed schedule should provide flexibility to the user as its ultimate goal is to raise efficiency without compromising patient safety. The ideal MSBOS should be institution-specific, procedure-specific and it should be based on objective data on blood use (12).

An MSBOS is best calculated retrospectively by analysing the hospital blood usage data for a six-month period for all elective surgical cross-match requests. The use of computer technology has been proposed to greatly facilitate this process in health care facilities that are technologically equipped. It has also been proposed that a significant number of each surgical procedure be collected to give a meaningful assessment and to eliminate bias. The Ontario Regional Blood Coordinating Network’s (ORBCON) development tool for MSBOS, data collection for its development may either be defined over a specific timeframe, or for a predetermined number of procedures performed. ORBCON suggests that data can either be retrospectively collected over a 1-2-year period where a review of historical data is done, or prospectively on a ‘real-time’ basis. A third category is the benchmarking category, where data from another facility performing similar procedures can be used.

In the creation of a MSBOS, consideration of certain local factors should be made. These include but are not limited to; the speed at which compatible blood would be made available for a patient intra-operatively in the case in which only a group and save had been done. Another important factor is the distance from the blood transfusion unit to the operating rooms which would affect blood transport in the case of an urgent requirement.

Surgeons and clinicians in the health institutions in which an MSBOS is to be established should be involved in its development. All other personnel in the operating rooms and in the blood transfusion units should equally be educated on this algorithm (16). Failure to involve them would lead to its failure (1). An important role for the surgeon is that they may override the MSBOS. This is especially for selected cases in which certain patients have certain unique
problems medically. This role of the surgeon for such cases is also vital to the success of this tool. A collaboration with the haematologists and blood transfusion specialists should also be considered in this discussion. The accepted schedule should be distributed to the staff, and preferably in a pocket-sized format. Junior medical staff should be inducted on its use to promote success. Education is advised for staff found to disregard the schedule.

Certain advantages accrue from the establishment of an MSBOS. Such include a reduction in the workload of the blood transfusion unit or laboratories. Reductions of up to 25% have been reported in the past (14). The same study reports a reduction in the levels of stress in these units, and in a more efficient use of blood.

As per the British Committee for Standards in Haematology (BCSH) blood transfusion task force, certain prerequisites are vital for the success of a MSBOS.

1. That pre-operative blood should be graded in two categories for elective surgical procedures; a group and save category and a group and cross-match category.
2. A sample saved for cross-matching should be readily accessible and accurately labelled in the case that blood is required.
3. Procedures should be defined clearly to enable staff in the blood transfusion unit to provide blood should an emergent indication rise during a group and save operation.
4. There must be clear and well-defined communication between the operating theatres and the blood transfusion unit. The anaesthetist or the deputy should communicate an urgent need for blood to the laboratory. The communication, once received by a laboratory technologist should be acted upon immediately.
5. There must be an established priority for blood transport between the laboratory and the operating room.

It is suggested that even after an algorithm has been developed in an institution, follow up studies are advised to evaluate the success of the MSBOS and calculate financial savings made (11). In addition, regular reviews and adjustments should be made to the protocol as is deemed necessary.
The Cross-Match-to-Transfusion (C/T) ratio, Transfusion Probability (T%), Transfusion Index (TI) and MSBOS calculation.

The Cross-match to Transfusion ratio has been calculated as the number of Packed Red Blood Cells (PRBCs) cross-matched for the procedure divided by the actual number of units transfused. The ideal value for the C/T ratio would be 1:1, meaning that for every unit of blood cross-matched, a unit is transfused. This is however less practical. It is universally accepted therefore that a ratio above 2.0, which means that less than 50% of all of the cross-matched units of blood are transfused, is indicative of excessive cross-matching. The Transfusion Probability is calculated as the number of patients transfused, divided by the number of patients having that particular procedure that had a cross match and then multiplied by 100 to make a percentage. The T% is a marker of blood wastage.

The transfusion Index is calculated by dividing the number of units of blood transfused, by the number of patients having the procedure that have had a crossmatch. An index of less than 0.3 indicates that there is no need for a crossmatch for that particular procedure (16), though some literature quote a value of 0.5 (12). The patient would then only require an ABO grouping and an antibody screen and in the case that blood would be required on the particular theatre day, a rapid spin crossmatch would suffice if the antibodies tested are negative (17). A TI of >0.3 on the other hand indicates that a crossmatch is necessary.

These ratios and indices have been shown to be easy to calculate and determine. They have been shown to be helpful in the development of a proper MSBOS which in turn has been shown to guide in the appropriate use blood and its products. This way, blood wastage can be avoided for elective cases.

The final step in the creation of a blood ordering schedule is made possible after these calculations have been done. Institutions have used different ways to arrive at algorithms best suited for them. One such example is at the John Hopkins hospital, in which the transfusion index, the estimated blood loss and a new entity, the risk of major bleeding was introduced to the algorithm. The C/T ratio was not used. In this study, no type and screen was done if the estimated blood loss was less than 50 ml, the TI was less than 0.3 and if there was no major risk of bleeding. A group and cross-match was done if the estimated blood loss was more than 50 ml and a TI of >0.3 or if there was a risk of major bleeding (12).
The Mead’s criterion is used for estimating the number of pints of blood needed to be cross-
matched pre-operatively when the transfusion index is above 0.3 (17–20) or 0.5 in some studies
(18,20). Mead et al in a 1980 study described guidelines to aid in this estimation. Those with a
TI of >0.3 should have a group and cross-match, but this should not exceed 1.5 times the
transfusion index as shown below (21).

Mead’s criterion when the TI is >0.3:

$$MSBOS = Transfusion \ Index \times 1.5$$

Where the Transfusion index is described as the number of units transfused divided by the
number of units of patients cross-matched.

**MSBOS at KNH:**

The Kenya National Blood Transfusion Services (KNBTS) doesn’t outline or highlight a
formal or specific MSBOS schedule for elective procedures carried out in the country. It only
gives a guideline on general use of blood and blood products in the peri-operative period. No
formal MSBOS exists at the Kenyatta National Hospital either. There are a few studies done at
the institution with an aim to ascertain the blood ordering and transfusion practices for surgical
procedures done but only one with an aim to establish an MSBOS. In other hospitals in Kenya,
no published data was found and only few studies done in Africa to date.

Only one study has been done at the KNH with an aim at establishing an MSBOS. This was a
cross- sectional descriptive study with data collected prospectively over a 6 month period in
1993 as part of a thesis (22). All elective surgical procedures were included in the study, with
a sample size of 442 operations. The overall C/T ratio was 2:1. This study led to a proposed
schedule for all procedures. An example of cases done by the cardiothoracic department is
shown in the table below.
Table 1: An excerpt from the proposed MSBOS by Mugenya in 1995 showing only the schedule for thoracic, vascular and cardiac cases.

<table>
<thead>
<tr>
<th>Type of operation</th>
<th>Number of cases</th>
<th>Units of blood cross-matched (C): Total and Average</th>
<th>Units of blood transfused (T): Total and Average/ TI</th>
<th>C/T ratio</th>
<th>Proposed MSBOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracotomy (exploratory)</td>
<td>26</td>
<td>44</td>
<td>1.7(1-3)</td>
<td>9</td>
<td>0.3(0-2)</td>
</tr>
<tr>
<td>Thoracotomy + decortication</td>
<td>4</td>
<td>10</td>
<td>2.5(2-3)</td>
<td>7</td>
<td>1.8(1-2)</td>
</tr>
<tr>
<td>Sternotomy + thymectomy</td>
<td>4</td>
<td>4</td>
<td>1(1)</td>
<td>3</td>
<td>0.8(0-1)</td>
</tr>
<tr>
<td>Oesophagectomy</td>
<td>6</td>
<td>13</td>
<td>2.2(1-4)</td>
<td>10</td>
<td>1.7(0-3)</td>
</tr>
<tr>
<td>Aortic aneurysm repair</td>
<td>5</td>
<td>15</td>
<td>3(2-4)</td>
<td>9</td>
<td>1.8(0-4)</td>
</tr>
<tr>
<td>Closed valvotomy</td>
<td>8</td>
<td>12</td>
<td>1.5(1-2)</td>
<td>2</td>
<td>0.3(0-1)</td>
</tr>
<tr>
<td>Varicose vein stripping</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

From this study, it is noted that there was relatively a small range and variety of cases done in the cardiothoracic unit, as compared to the other departments. This is likely because data was collected in 24 years ago, in 1993 when the arts of surgery and anaesthesia were not as advanced as they are today. The only cardiac procedure documented in his study was a closed valvotomy. Closed mitral valvotomy (CMV), was first performed by Henry Sunltar in 1925 before the advent of the CPB (Cardio-Pulmonary Bypass) which enables open mitral valve replacement surgery (23). This procedure has been largely abandoned in KNH, after the adoption of open mitral valve replacement in the advent of the CBP, though the procedure remains to be simple and cost efficient (24).

It is also not clear as to how the MSBOS was calculated and proposed for the procedures listed. It is clear that a Group and save was proposed for TI of less than 0.3 which is recommended, but for those above 0.3, the calculation used is not apparent. It seems as if a rounding off was done. The mead’s criterion was not used as is recommended. Studies have also recommended that C/T ratios should only be calculated for procedures carried out more than five times in the six month period the study is carried out (6).

8,500 elective surgeries are carried out per year at the KNH (25). In a study by Gatheru et al, carried out over a 10- week period in 2011 with a sample size of 365, the mean preoperative haemoglobin was found to be 11.2g/dl. A haemoglobin level of 10g/ dl was deemed as the lower cut-off for patients scheduled for elective surgery. A quarter of all cross matched blood
for elective surgery ended up not being transfused to the patients, highlighting a significant wastage of blood and a need for a strict MSBOS in KNH.

The overall C/T ratio was 1.42 in this study, which differed widely from another study done in the same institution in 2006 with an aim to estimate blood loss during elective surgery (26). Values for individual operations were however not determined, as is recommended (1). This C/T ratio seems low, even for studies done in centres where an MSBOS has already been established. The aim of this study was not to establish an MSBOS, but rather to highlight the blood requests, crossmatch and transfusion practices for elective surgeries at KNH. Thus, a transfusion index and the transfusion probability were not calculated for this study. As a result, blood wastage and the need for a preoperative crossmatch or group and save for various procedures cannot be statistically concluded from its findings.

Data from this study was collected in theatre and not preoperatively. Important recommendations are made however; That the hospital’s transfusion committee should come up with a MSBOS and that further studies be done on the same in various disciplines.

**MSBOS for cardiac and vascular surgery.**

According to the American society of thoracic surgeons and the society of anaesthesiologists clinical practice guidelines, six important variables are noted as being associated with an increased risk of peri-operative bleeding after cardiac surgery (27). These include, an advanced age, a small body size, a pre-operative anaemia, a patient on anticoagulants pre-operatively, complex procedures and reoperations, emergency operations and patient comorbidities that are non-cardiac in nature. Emergent operations and reoperations all lead to an increase in the Cardio-Pulmonary Bypass (CPB) time. It would therefore be important to limit anticoagulants pre-operatively and identify patients at a higher risk of bleeding before surgery.

With this realisation of the huge risk cardiac patients pose for bleeding, clinicians and cardiac anaesthesiologists tend to order for more pints of blood pre-operatively than would usually be necessary. This practice puts a huge burden in terms of work force and resources on blood banks and blood transfusion units (13).
Very few studies have been done towards the establishment of an MSBOS for cardiac and vascular surgery, unlike is the case for the other surgical specialties. The first MSBOS established by Friedman et al omitted cardiac cases citing a diversity of procedures in this specialty and unusually high amounts of blood required for them (1,16). Other studies recommend that all patients undergoing cardiac operations be cross-matched irrespective of procedure (28).

Emerging studies on the peri-operative blood requirements for cardiac surgery are reporting that up to 50% of patients don’t actually receive transfusions intra-operatively (16). However, some of these low transfusion rates have been reported in centres where there is use of cell salvage, retrograde autologous priming and ultrafiltration.

Table 2: Indications of blood transfusion for patients undergoing cardiac operations as guided by the pre-operative haemoglobin levels, age and blood loss (Adopted from the American Society of Anaesthesiology Guidelines for transfusion of packed red cells in adults (29).

<table>
<thead>
<tr>
<th>American Society of Anaesthesiology Guidelines for transfusion of packed red cells in adults.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Transfusion for patients on CPB with Hb &gt; 6.0g/ dl is indicated.</td>
</tr>
<tr>
<td>• Hb level &lt;7g/ dl in patients older than 65 years and patients with chronic cardiovascular or respiratory justifies transfusion.</td>
</tr>
<tr>
<td>• For stable patients with haemoglobin level between 7 and 10 g/dl, the benefit of transfusion is unclear.</td>
</tr>
<tr>
<td>• Transfusion is recommended for patients with acute blood loss more than 1,500 ml or &gt;30% of blood volume.</td>
</tr>
<tr>
<td>• Evidence of rapid blood loss without immediate control warrants blood transfusion.</td>
</tr>
</tbody>
</table>

11
The MSBOS adopted by the National Health Services (NHS) in the United Kingdom was as per the guidelines by the British Committee for Standards in Haematology and blood transfusion (BCSH) task force of 1990 (14). A 2012 update has since been published (27). Shown here below is an example from the updated version.

Table 3: An excerpt from an MSBOS (Adopted from the National Health Services (NHS) as per the BCSH guidelines)

<table>
<thead>
<tr>
<th>No G &amp; S required</th>
<th>G &amp; S only</th>
<th>GXM, number of pints required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest drain</td>
<td>Aortic balloon dilatation</td>
<td>Cardiac non-bypass, 1 unit</td>
</tr>
<tr>
<td>Cardiac catheterisation</td>
<td>Interventional catheterisation</td>
<td>Cardiac bypass, 2 units</td>
</tr>
<tr>
<td>with no intervention.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuss bar removal</td>
<td>PDA ligation</td>
<td>All re-do operations, 2 units</td>
</tr>
<tr>
<td></td>
<td>Pulmonary valve balloon dilatation</td>
<td>All re-do sternotomies, 2 units</td>
</tr>
<tr>
<td></td>
<td>Pulmonary valve implants</td>
<td>Open thoracotomy, 1 unit</td>
</tr>
<tr>
<td></td>
<td>Stenting</td>
<td>Thoracic tumour resection, 3 units</td>
</tr>
<tr>
<td></td>
<td>VSD repair</td>
<td>Tracheal procedures, 3 units</td>
</tr>
<tr>
<td></td>
<td>Thoracoscopy</td>
<td></td>
</tr>
</tbody>
</table>

Of the few studies done with the aim of establishing proper pre-operative blood use for elective procedures in cardiac, vascular and thoracic surgery, one such study was published in 2016 with an aim to tailor blood ordering processes for cardiac surgeries. Two hundred and sixty-four patients were analysed. All of these patients had a cross-match done and of these, only 98 patients were actually transfused. The transfusion probability was 37.12%. A total of 1,175 units of blood were cross-matched but only 370 units were transfused, giving a C/T ratio of 3.17, which shows excessive and unnecessary transfusion. Very high C/T ratios were noted for CABG and for single valve replacement and reduction of this wastage could lead to cost savings (16).

From the findings of this study, the concerned institution created an MSBOS for two cardiac procedures, CABG and single valve repair or replacement. This is because these two
procedures were found to have CPB times of less than 180 minutes, high C/T ratios and lowest T%. Patients thus due for these two procedures in this institution and having a pre-operative Hb of more than 10g/ dl, a negative antibody screen and if not, a redo procedure have only a type and screen done. No cross-match is done for these patients. It is however noted in this paper that in the case that blood is required for these cases, an immediate spin cross-match should be performed in 10 minutes. Type O blood should also be immediately released in the case of an emergent need peri-operatively.

In a similar study, the most common thoracic and cardio-vascular procedure was a Patent Ductus Arteriosus (PDA) ligation. Followed by decortication for empyema. The C/T ratio for PDA ligation was 7 and 4 for sternotomy, which is quite high above the recommended value. However, for most other cardiovascular procedures, the C/T ratio is reported to be less than 2, which is within the MSBOS criteria (8).

In another study done for cardiac surgery cases in a hospital in Florida, a type and screen only was recommended in surgical procedures that met the following criteria (13).

1. For elective isolated valve replacements.
2. For minimally invasive procedures.
3. If no antibodies were identified during the screening process.
4. If the haematocrit is >30% or the Hb > 10g/ dl.
5. If the surgical procedure is not a re-do.
6. If the aspartate aminotransferase is <50 U/ l.
7. If the creatinine is <1.5 mg/ dl.

From this study, there was a C/T ratio of 2.36 and savings of up to $ 12, 244.00 over a period of four months an MSBOS was established for the cardiac surgery department.

MSBOS studies have been done for other surgeries as well. An example is a study done by Hossein et al in Iran to determine blood ordering and utilisation patterns in elective urological surgery, 435 patients were analysed over a period of 6 months. The mean number of units of blood requested for each operation was 2.8±1.12, while the man number of units transfused was 0.59±0.24. Only 8.5% of patients in this study required blood transfusion intra-operatively and 10.8% post-operatively. The C/T ratio was higher than the recommended 2.0 for all types of operations in this study. The overall C/T ratio was quite high at 14.16, the TI was 0.11 and the T % was 8.85%. this shows that for urological surgeries in this institution, there was
significant blood wastage and that most of the operations did not require a pre-operative cross-match.

Most MSBOS recommend a group and save for thyroidectomy. In a recent study done in India with an aim to establish a MSBOS for a newly set-up tertiary care hospital, twelve cases of thyroidectomy were studied amongst other common surgical procedures. The C/T ratio for these was 2.33, a transfusion probability of 54.5% and a transfusion index of 0.5, suggesting that a cross match may not be necessary for thyroidectomy.

**Factors affecting the blood ordering and utilisation practices:**

Several factors have been found to affect the cross match to transfusion (C/T) ratios of various surgical procedures. These factors, have as a result been shown to influence the blood ordering practices for these procedures. The distance to the blood transfusion unit and the efficiency of the unit in its ability to provide blood in emergency situations are examples (30). Hence, for procedures that don’t require a group and cross match, one may end up being done in fear of unavailability of blood in case of an urgent need (8). Confidence of surgeons and anaesthesiologists has been affected by inefficient laboratories. In hospitals where the blood transfusion laboratory is at a great distance from the operating rooms, or where the transport system of the blood is a challenge, a group and save protocol may not suffice. Some hospitals have had to rely on bigger sister hospitals or even on neighbouring hospitals to supply them with blood peri-operatively, and this would affect the blood ordering practice for such procedures.

The pre-operative condition of the patient has also been shown to affect the C/T ratio (4,7). In one study, anaemic patients ended up having an over-order of blood pre-operatively (8). At the KNH, a preoperative Hb of 10g/dl is deemed as the lower cut-off for patients scheduled for elective surgery (25). It is widely accepted that a patient should have a haematocrit of above 30 before elective surgery and that if the patient has a level lower than this, then a cross-match has to be done as the patient will most likely require a transfusion (3,16,31). However, as per the KNBTS guidelines in the perioperative patient, transfusion decisions should not be based on a single Hb measurement. A clinical correlation is advised (3).

Thirdly, in certain procedures as for cancer surgery, blood may be wasted if the operation is done but a decision is made intra-operatively not to resect the tumour in which case the blood will not be utilised. In such cases, blood is best released only after the surgeon has decided to
proceed further and an exploratory laparotomy in the case of an abdominal tumour for example (32). Other factors noted to affect the decision to transfuse peri-operatively include age, atherosclerotic heart disease, the patient’s cardiopulmonary reserve and the amount of anticipated blood loss (31). It is also important to make an effort to correct anaemia identified pre-operatively in an attempt to avert a transfusion on the table. Blood should be cross-matched and availed immediately during surgery for patients with a high likelihood of transfusion especially for those patients with a Hb of <8 g/dl who lose >1 L of blood intra-operatively.

JUSTIFICATION:

Blood and its products are a limited resource (33). An association has been found between ordering of excessive blood for elective surgery, its wastage and shortage (34). Thoracic, cardiac and vascular surgeries are the largest consumers of blood in a hospital (35). Good blood management is an important determinant of outcome in these operations (36). A quarter of all blood cross matched for elective surgery at the Kenyatta National Hospital ends up not being transfused, highlighting a need for a strict MSBOS at the institution (25). Yet none exists and none was adopted after the only one study done at the KNH with an aim to establish a protocol for blood ordering. This study was done 23 years ago, when the arts of surgery and anaesthesia at the cardiothoracic unit of the hospital were still poorly developed and when cardiopulmonary bypass surgery was not well developed. Thus only 7 procedures were documented in that study, with only one cardiac procedure. Of further concern from that study is that the MSBOS calculation was not clearly indicated.

Our study will aim to establish the blood ordering and utilisation practices for these procedures and it will provide a basis and act as a guide in the establishment of a MSBOS at the Kenyatta National Hospital for thoracic and cardiovascular surgery. With the advances in cardiac and vascular surgery at the KNH over recent years, we hope to document more cases and provide stronger evidence to enable the hospital to adapt the proposed MSBOS from our findings.

In an unpublished survey done for the first three quarters of 2015/16 in an attempt to establish cancellation rates for elective cases at the Kenyatta National Hospital, the general cancellation rate for elective procedures was 23.75%. 18.75% of the surgeries were cancelled due to lack of blood for the operation. The cancellation rate for general and urological surgeries was 18%, while that for cardiothoracic procedures was the highest at 33%. The rate of cancellation of operations on elective theatre lists secondary to lack of blood ordered for pre-operatively was
18.1% in a similar study done in Kuala Lumpur (37). Our study will aid in reducing theatre cancellation rates for these procedures.

Technician time has been shown to reduce significantly by the use of recommendations from MSBOS implementation (8, 14). Our study, by optimising blood ordering and utilisation, will assist in this reduction. Laboratory technicians in the blood transfusion unit can then spend their time and resources handling more urgent blood requests.
Pre-operative Hb >10g/dl or HCT >30%

Were PRBCs Cross-matched pre-operatively for the particular procedure?

Calculation of C/T ratio, T% and Transfusion Index.

Meads criterion to guide MSBOS development.

Tabulate results. Develop an algorithm/schedule to determine the appropriate blood order for each procedure category.

Pre-operative Hb <10g/dl or HCT <30%

Consult with the clinician and anaesthesiologist on way forward in view of the Hb/HCT level.

Was blood transfused intra-operatively?
If Yes, how many pints per patient?

Conceptual Framework
Patient admitted for a thoracic, cardiac or vascular elective surgical procedure at KNH
RESEARCH QUESTION:

What are the blood ordering and utilisation practices for elective thoracic and cardiovascular surgery at the Kenyatta National Hospital?

OBJECTIVES:

GENERAL OBJECTIVE:
To determine the blood ordering and utilisation practices for elective thoracic and cardiovascular surgery at the Kenyatta National Hospital.

SPECIFIC OBJECTIVES:

1. To determine the factors that influence blood ordering and utilisation practices for thoracic and cardiovascular elective surgery at Kenyatta National Hospital.
2. To determine the amount of blood cross matched and transfused for each thoracic and cardiovascular elective surgical procedure at Kenyatta National Hospital.
3. To calculate the cross match to transfusion ratio, transfusion probability and transfusion index.

SECONDARY OBJECTIVE:

1. To calculate and tabulate the Maximum Surgical Blood Ordering Schedule for thoracic and cardiovascular elective surgery at Kenyatta National Hospital.

METHODOLOGY:

STUDY SETTING:

This study was undertaken at the Kenyatta National Hospital. The Kenyatta National Hospital is a tertiary teaching and referral hospital in Kenya. It is one of the largest hospitals in East and Central Africa and is located in the Upper Hill area of Nairobi located next to the University of Nairobi’s school of medicine. Because of this, it forms the convergence point of patients in the public health care system in Kenya, by virtue of which it would be appropriate for the purpose of fulfilling the sample size requirements for this study. KNH is at the apex of the public health system, thus the results of this study would have external validity to the majority of the Kenyan population, who receive medical attention in the public health system.
STUDY DESIGN:
This was a Cross-sectional descriptive study involving patients admitted for elective thoracic and cardiovascular surgery from June to November 2017.

STUDY POPULATION:
The study population included all patients above 13 years of age undergoing elective thoracic and cardiovascular surgery at the KNH from June to November 2017.

ELIGIBILITY CRITERIA:

INCLUSION CRITERIA:
1. All patients, 13 years and above, who underwent elective thoracic, cardiac and vascular surgery who gave consent for inclusion to the study.

EXCLUSION CRITERIA:
1. Any adult patient who did not consent to the study and any patient below 18 years of age whose parent/guardian declined to give consent.
2. ASA grade 3 and 4
3. Patients who had a suspected or confirmed coagulation disorder.
4. Patients who were on anticoagulants.
5. Emergency surgery.
6. Patients requiring massive blood transfusion intra-operatively, described as >10 units of PRBCs or transfusion of >50% blood volume within 3 hours.

SAMPLING:

SAMPLE SIZE CALCULATION:
This was a cross-sectional study design and the sample size was calculated for estimation of proportions. Thoracic, cardiac and vascular surgeries are carried out on an estimated number of 120 patients in the cardio-thoracic unit at the Kenyatta National annually (38). This study was done in 6 months and hence 60 patients was accessible for recruitment. Since this was a finite population, the sample size was estimated using the formula with finite population correction as follows (39):
\[ n' = \frac{NZ^2P(1 - P)}{d^2(N - 1) + Z^2P(1 - P)} \]

Where

- \( n' \) = sample size with finite population correction,
- \( N \) = size of the target population = 60
- \( Z \) = Z statistic for 95% level of confidence = 1.96
- \( P \) = Estimated proportion of patients who were transfused out of the number of patients who were cross-matched = 61\% (Transfusion probability in previous study) – Mugenya et al, 1995 (22).
- \( d \) = margin of error = 5\%

\[
\begin{align*}
60 \times 1.96^2 \times 0.61 \times 0.39 &= 0.05^2 (60-1) + 1.96^2 \times 0.61 \times 0.39 \\
n &= 52
\end{align*}
\]

A minimum of 52 patients who underwent thoracic, cardiac and vascular surgery were sampled to estimate proportion of blood usage within 5\% level of precision.

**SAMPLING TECHNIQUE:**
Selection of patients was done by convenient sampling of all eligible patients until the desired sample size was achieved. An explanation of the purpose of the study was given verbally and an information sheet was also used (Appendix I). The patients were then invited to participate in the study.

**DATA MANAGEMENT:**

**DATA COLLECTION:**
After consenting to participate in the study by filling an informed consent form (Appendix I), a questionnaire (Appendix III) was administered to all eligible patients admitted to the cardio-thoracic ward 4B at KNH and scheduled for elective thoracic, cardiac or vascular surgery. The patient’s age, gender, weight, pre-operative haemoglobin and haematocrit levels were recorded. The number of pints of blood ordered for by the clinician and the amount cross matched were determined from the theatre lists made and from the BTU record book.
respectively. This is the blood transfusion unit on the ground floor of the hospital, which is where all blood for peri-operative use was cross-matched from.

The intra-operative details of the procedure were recorded from the patient’s operation notes as documented by the surgeon and by the anaesthetist. Estimated and calculated blood loss were recorded as well as the type and length of procedure and amount of blood transfused intra-operatively.

DATA ANALYSIS:

Data was entered and managed in Microsoft Excel 2013 spreadsheet. Data analysis was done in SPSS version 21.0. Shapiro wilk’s test was used to check for normality. The study population was described by summarizing categorical and continuous variables. Continuous variables were presented in form of means, standard deviations, medians and inter-quartile ranges. An independent-samples t-test was done to compare the means. Multiple regression analysis was done to predict amount of blood ordered and that transfused from the various clinical variables. All statistical tests were performed at 5% level of significance.

The C/T ratio, Transfusion Probability and Transfusion Index were calculated for each of the elective procedures as shown below, and the parameters analysed against selected independent variables;

The formulae used for the different parameters were as follows:

- **Cross-Match to Transfusion Ratio:**

  \[
  C/T \text{ Ratio} = \frac{\text{Number of Units Cross matched}}{\text{Number of Units Transfused}}
  \]

  A ratio of >2 was considered to be indicative of significant blood wastage (8,16).

- **Transfusion Probability:**

  \[
  \text{Transfusion Probability } \% = \frac{\text{Number of Patients Transfused}}{\text{Number of Patients cross matched}} \times 100
  \]
A value of <30% was considered to be indicative of blood wastage. (8,16).

- **Transfusion Index:**

\[
\text{Transfusion Index} = \frac{\text{Number of Units Transfused}}{\text{Number of patients cross matched}}
\]

A value of <0.3 signified no need for a cross match (1,8,17).

**Table 4: Data entry tool for tabulation of the transfusion indices**

<table>
<thead>
<tr>
<th>Surgical procedure</th>
<th>Units cross-matched</th>
<th>Units transfused</th>
<th>Patients cross-matched</th>
<th>Patients transfused</th>
<th>C/T Ratio: No. of units X-matched/Units Transfused</th>
<th>Transfusion Probability: No ofPts transfused/No of pts X-matched (%)</th>
<th>Transfusion Index: No of units transfused/No of patients X-matched</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoracic Procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4 above was used as a data entry tool for all the procedures analysed. The first column represents a sample of cases expected as an example i.e. vascular, cardiac and thoracic. Units of blood and patients cross-matched and transfused were entered. Data obtained was used to calculate the ratios as shown. Any procedure with less than 5 cases recorded was disregarded in the calculation of the Maximum Surgical Blood Ordering Schedule for a meaningful assessment (8).

The mead’s criterion was used to calculate the MSBOS for each procedure and the information obtained used to develop an algorithm to guide the pre-operative ordering of blood for thoracic, cardiac and vascular surgeries at the KNH.
DATA DISSEMINATION:

The information thus obtained will be used to develop an algorithm to guide the pre-operative ordering of blood for thoracic, cardiac and vascular surgeries at the Kenyatta National Hospital. The results of this study will be presented to the department of Surgery and to the staff of the cardio-thoracic unit at the KNH. The same will be shared with cardiac anaesthetists, perfusionists and with all other staff working in the cardiothoracic theatre. Copies will also be availed to the UoN department of Surgery and the College of Health Sciences library. A manuscript will also be submitted to a peer-reviewed journal for publication.

QUALITY ASSURANCE:

All aspects of this study were subjected to strict quality control. The study instrument was pre-tested to ensure clarity of the questions. There was strict adherence to the inclusion criteria which avoided collecting irrelevant data. Regular meetings were scheduled and held to review any emerging issues that were relevant to quality control among the principal investigator and the research assistant. Stringent training of the research assistant was undertaken, including the observation of the ethical considerations while handling the study participants. There was strict surveillance of the data collection and entry procedures that ensured that the risk of omission-generated biases and transcriptional errors were minimized. The primary investigator verified each questionnaire to confirm that responses were filled correctly, with no skipped questions.

ETHICAL CONSIDERATION:

This proposal was subjected to review by the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee (KNH/UON ERC). The data collected from this study was used to provide information geared towards development of a Maximum Surgical Blood Ordering Schedule for elective thoracic, cardiac and vascular surgery at the Kenyatta National Hospital. Consent was sought from the respondents before the administration of the questionnaire. Participation was voluntary and any participant that free to withdraw from the study at any time without giving any reason; and that this did not affect the quality of care that they received.
The findings of the study were treated with utmost confidentiality and for the purposes of this research only. The objectives of the study were explained to the subjects. The entire interview was done in private, and the identities of the study participants and their personal particulars were kept strictly confidential. Identity codes were used for the questionnaires in order to keep the data anonymous.

**LIMITATIONS OF THE STUDY:**

Intra-operative blood loss calculation may have differed from clinician to clinician.

There were incomplete records for estimated blood loss and risk of major bleeding pre-operatively and hence these were not analyzed. Re-operations, which have been shown to require more blood transfusions, were not compared against primary operations as they were only two, and hence too few for a reasonable comparison.

While records show that more open-heart surgeries are done at the Kenyatta National Hospital, there was a break-down of the heart-lung machine at the institution during the study period, which meant that single valve replacement was the only cardiac procedure that fit the criteria for analysis.

One limitation of a prospective MSBOS study is the Hawthorne effect (40) which means that the clinicians may alter their blood-ordering behaviour if they know that they are under observation (8). For example, they may have ordered for less blood.

**RESULTS:**

A total of 52 study participants were recruited into the study.
Demographic Profile:

The mean (SD) age of the study population was 42.60 (15.66) years. The ratio of male to female was 1.3:1. Table 5 below shows the baseline demographic variables of the study participants.

Table 5: Baseline Demographic Variables of the study Participants

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (SD)</strong></td>
<td>42.60 (15.66)</td>
</tr>
<tr>
<td><strong>Min-Max</strong></td>
<td>15-76 years</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td>29(55.8%)</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>23(44.2%)</td>
</tr>
</tbody>
</table>

The figure below shows the age distribution of the population as per the various clusters. Majority of the study participants were in the 31-40-year age group.

Figure 2: Age distribution of the study population

Procedure Distribution of the study population

The study participants underwent 7 different procedures: 3 thoracic, one cardiac and 3 vascular as documented in the table 6 below. The thoracic procedures included oesophagectomy for cancer of the oesophagus, decortication and pneumonectomy. While all decortication procedures were for empyema thoracis and were unilateral, 5 of the patients had a pneumonectomy for aspergilloma with 1 patient each with a lung abscess and empyema. Single
cardiac valve replacement was the only cardiac procedure included in the study, 3 being aortic and 3 mitral. The vascular procedures were graft repair for abdominal aortic aneurysm, arteriovenous fistula fashioning for chronic renal failure and venous stripping for varicose veins. All abdominal aortic aneurysms were infrarenal.

![Procedure Distribution](image)

**Figure 3: Procedure distribution**

**Clinical variables:**
The mean (SD) weight of the population was 60.66 (11.49) kg, while the mean Hb was 13.57 (SD ±2.25) g/dl. While blood requested was between 0-6, the maximum number of pints transfused was 4. The table below shows these clinical variables and their means.

**Table 7: Clinical Variables**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>60.66(11.49)</td>
<td>33</td>
<td>87</td>
</tr>
<tr>
<td>Pre-op Hb (g/dl)</td>
<td>13.57(2.25)</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td>Pints requested</td>
<td>2.54(1.55)</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Pints cross-matched</td>
<td>2.31(1.4)</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Pints transfused</td>
<td>1.1(1.3)</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Blood Loss (ml)</td>
<td>916(1097)</td>
<td>50</td>
<td>4450</td>
</tr>
<tr>
<td>Length of procedure (minutes)</td>
<td>223(87)</td>
<td>60</td>
<td>420</td>
</tr>
</tbody>
</table>
The clinical variables were then run to determine for differences between gender. There were no statistical differences of the age, weight or preoperative Hb between the gender as shown in the table below. Females, however, had more pints cross matched ($p = .016$), more pints transfused ($p = .005$) and underwent longer procedures ($p = .005$) than males.

### Table 8: Clinical Variable between gender

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
<th>Male vs female p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (yrs.)</strong></td>
<td>Median (IQR)</td>
<td>Min-Max</td>
<td>Median (IQR)</td>
<td>Min-Max</td>
</tr>
<tr>
<td></td>
<td>39 (26)</td>
<td>16-76</td>
<td>41 (24)</td>
<td>15-66</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>61 (13)</td>
<td>40-82</td>
<td>60 (21)</td>
<td>33-87</td>
</tr>
<tr>
<td><strong>Preoperative HB</strong></td>
<td>13.8 (4.65)</td>
<td>8.6-17.4</td>
<td>13.3 (3.1)</td>
<td>9.3-16.2</td>
</tr>
<tr>
<td><strong>Pints cross-matched</strong></td>
<td>2 (2)</td>
<td>0-3</td>
<td>3 (2)</td>
<td>0-6</td>
</tr>
<tr>
<td><strong>Pints transfused</strong></td>
<td>0 (1.5)</td>
<td>0-2</td>
<td>2(3)</td>
<td>0-4</td>
</tr>
<tr>
<td><strong>Length of procedure</strong></td>
<td>190 (120)</td>
<td>60-360</td>
<td>270 (165)</td>
<td>120-420</td>
</tr>
</tbody>
</table>

### Factors influencing Blood Ordering:
While age of the participants and the pre-operative haemoglobin did not influence how blood was ordered, gender was found to be statistically significant, ($p = .016$). This meant that males had $1(1.069)$ lesser pints requested for than females as shown in the table below.

### Table 9: Predictors of Blood Requests

<table>
<thead>
<tr>
<th></th>
<th>Unstandardized Coefficient B (95% CI)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative Hb</td>
<td>0.003 (-0.188 – 0.193)</td>
<td>0.979</td>
</tr>
<tr>
<td>Age</td>
<td>0.005 (-0.022 – 0.032)</td>
<td>0.710</td>
</tr>
<tr>
<td>Gender</td>
<td>-1.069 (-1.927 – (-0.211)</td>
<td>0.016</td>
</tr>
</tbody>
</table>

Dependent variable: Pints requested

### Factors influencing Blood Utilisation:

The length of procedure significantly affected the pints of blood transfused intra-operatively ($p < .005$). This was a non-linear relationship. Age, gender, weight and pre-operative haemoglobin however, did not. The table below shows these variables, and how they affected blood utilisation for the various procedures.
Table 10: Predictors of Blood Utilisation

<table>
<thead>
<tr>
<th></th>
<th>Unstandardized Coefficient B (95% CI)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.005 (-0.011 – 0.021)</td>
<td>0.545</td>
</tr>
<tr>
<td>Gender</td>
<td>-0.408 (-0.967 - 0.150)</td>
<td>0.148</td>
</tr>
<tr>
<td>Weight</td>
<td>0.016 (-0.007 – 0.039)</td>
<td>0.179</td>
</tr>
<tr>
<td>Length of procedure</td>
<td>0.010 (0.007 – 0.013)</td>
<td>0.000</td>
</tr>
<tr>
<td>Preoperative Hb</td>
<td>-0.080 (-0.197 - 0.003)</td>
<td>0.179</td>
</tr>
</tbody>
</table>

Dependent variable: Pints transfused

Factors affecting blood loss: Length of Procedure

The length of a procedure significantly predicted the amount of blood loss calculated, $F (1, 50) = 66.040$, $p < .0005$, $R^2 = .569$. This meant that there was a loss of 9.409 ml of blood for every extra one minute of time spent on procedure.

Table 11: Length of Procedure as a predictor of blood loss

<table>
<thead>
<tr>
<th></th>
<th>Unstandardized Coefficient B (95% CI)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of Procedure</td>
<td>9.409 (7.1 – 11.7)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Dependent variable: Calculated blood loss
Crossmatch and Transfusion data by Length of Procedure.

All patients were grouped based on the length of the procedure and calculated the clustered transfusion indices and the cross-match to transfusion ratios. This was done for surgeries which took less than 180 minutes and those which took more. From the results below, the length of procedure affected the transfusion indices. The C/T ratio for procedures that took less than 180 minutes was significantly high at 4.6, which reduced to 1.87 for those above 180 minutes. The transfusion probability for the former cluster was 27% and increased to 66.7% for the latter.
Table 12: Crossmatch and Transfusion data by Length of procedure

<table>
<thead>
<tr>
<th>Length of procedure</th>
<th>Units cross-matched</th>
<th>Units transfused</th>
<th>Patients cross-matched</th>
<th>Patients transfused</th>
<th>C/T ratio</th>
<th>Transfusion probability</th>
<th>Transfusion index</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;180 minutes (n=19)</td>
<td>23</td>
<td>5</td>
<td>11</td>
<td>3</td>
<td>4.6</td>
<td>27%</td>
<td>0.45</td>
</tr>
<tr>
<td>&gt;180 minutes (n=33)</td>
<td>97</td>
<td>52</td>
<td>33</td>
<td>22</td>
<td>1.87</td>
<td>66.7%</td>
<td>1.58</td>
</tr>
</tbody>
</table>

Cross-match and Transfusion Indices of the various procedures:

44 (85%) of the total of 52 patients had a blood request. Of these, only 26 (50%) patients received a blood transfusion. A total of 132 pints of blood were requested, However, 120 (91%) pints were actually cross-matched in the blood transfusion unit (BTU), and only 57 units were transfused intra-operatively. The resultant overall C/T ratio for all the cardiac, thoracic and vascular elective surgeries in the study was 2.1:1. The Transfusion probability and Transfusion Index for the study was 59% and 1.3 respectively with the values for the individual procedures varying widely.
**Figure 5**: Units cross-matched vs those transfused for the various procedures *

**Table 13**: Crossmatch and transfusion data by procedure

<table>
<thead>
<tr>
<th>Surgical procedure</th>
<th>Units cross-matched</th>
<th>Units transfused</th>
<th>Patients cross-matched</th>
<th>Patients transfused</th>
<th>C/T Ratio: No. of units X-matched/Units Transfused</th>
<th>Transfusion Probability: No of Pts transfused/No of pts X-matched (%)</th>
<th>Transfusion Index: No of units transfused/No of patients X-matched</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single cardiac valve replacement (n=6)</td>
<td>31</td>
<td>21</td>
<td>6</td>
<td>6</td>
<td>1.48</td>
<td>100</td>
<td>3.5</td>
</tr>
<tr>
<td>AAA repair (n=7)</td>
<td>22</td>
<td>14</td>
<td>7</td>
<td>6</td>
<td>1.57</td>
<td>85.7</td>
<td>2</td>
</tr>
<tr>
<td>AVF fashioning (n=6)</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Venous stripping (5)</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Oesophagectomy (n=12)</td>
<td>27</td>
<td>7</td>
<td>12</td>
<td>4</td>
<td>3.86</td>
<td>33</td>
<td>0.58</td>
</tr>
<tr>
<td>Decortication (n=8)</td>
<td>19</td>
<td>7</td>
<td>8</td>
<td>5</td>
<td>2.7</td>
<td>62.5</td>
<td>0.88</td>
</tr>
<tr>
<td>Pneumonectomy (n=8)</td>
<td>20</td>
<td>8</td>
<td>8</td>
<td>5</td>
<td>2.5</td>
<td>62.5</td>
<td>1</td>
</tr>
</tbody>
</table>
Calculation and tabulation of a Maximum Surgical Blood Ordering Schedule (MSBOS):
The Mead’s criterion was used to calculate the Maximum Surgical Blood Ordering Schedule (MSBOS). This was based on the transfusion index for the individual procedures. For any value less than 0.3, only a Group and Save was recommended and for transfusion indices above 0.3, a multiplication factor of 1.5 was used to predict the units of blood required for each procedure. This gave an MSBOS of 5 units for a single valve replacement, 3 units for repair of an abdominal aortic aneurysm, 2 for pneumonectomy and 1 unit each for oesophagectomy and decortication.

Table 14: Calculation of the Maximum Surgical Blood Ordering Schedule (MSBOS)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Transfusion Index</th>
<th>MSBOS (TI x 1.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single cardiac valve</td>
<td>3.5</td>
<td>5 units</td>
</tr>
<tr>
<td>replacement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAA repair</td>
<td>2</td>
<td>3 units</td>
</tr>
<tr>
<td>AVF fashioning</td>
<td>0</td>
<td>G &amp; S</td>
</tr>
<tr>
<td>Venous stripping</td>
<td>0</td>
<td>G &amp; S</td>
</tr>
<tr>
<td>Oesophagectomy</td>
<td>0.58</td>
<td>1 unit</td>
</tr>
<tr>
<td>Decortication</td>
<td>0.88</td>
<td>1 unit</td>
</tr>
<tr>
<td>Pneumonectomy</td>
<td>1</td>
<td>2 units</td>
</tr>
</tbody>
</table>
DISCUSSION:

The mean (SD) Hb of the study population was 13.57 (2.25) g/dl with a range of 9 to 17 g/ dl. This shows that clinicians were less likely to schedule for elective surgeries with low hemoglobin levels. In similar transfusion studies for cardiac surgery, lower hemoglobin values were tolerated by the clinicians pre-operatively (16,41). In one of these studies (16), 21% of the patients admitted for cardiac and thoracic surgery had a hematocrit of less than 30%, which is expected to affect transfusion indices and practices in the end. The mean pre-operative Hb from a study by Gatheru in 2012 for all surgical procedures done at KNH was 11.2 g/dl (25). He further reported that the lowest value that clinicians were comfortable scheduling a patient for theatre at the institution was 10 g/ dl. There was no statistically significant difference of the pre-operative hemoglobin level, age and weight between males and females.

Females had a significantly higher blood request than males, probably because they underwent procedures that had higher C/T ratios. Pre-operative Hb and age of the study participants did not affect blood ordering. The length of procedure significantly predicted red blood cell transfusion, such that for every extra minute that was spent in a procedure, there was loss of 9.409 ml of blood. Age, gender, weight and the level of pre-operative Hb of the study participants however, did not affect how blood was utilized for the various procedures. This was contrary to a report by the British Society of anesthesiologists clinical practice guidelines, in which these variables were shown to predict blood transfusion (27). It also contrasted with two other studies done to determine factors predicting blood transfusion for cardiac and vascular surgery in which longer procedures, the female gender, low hemoglobin, increasing age and low body mass index were associated with more transfusions (42,43).

This contrast was the case partly because of the differences in sample sizes of the studies, with ours having fewer study participants and even fewer cardiac surgeries. In addition, 96% of the study participants from our study had a preoperative Hb of >10 g/ dl, meaning that this variable probably did not affect blood transfusion as was the case for the other studies with much lower pre-operative values. Furthermore, K.N.H lacks protocols for blood transfusion peri-operatively and this has been shown to affect transfusion behavior amongst clinicians. With the lack of such guidelines, some clinicians have been shown to tolerate anemia and blood loss intra-operatively more than others, resulting in fewer transfusions as opposed to allowing the patient’s physiological need for it dictate red blood cell transfusion (41). Age was not a
predictor of blood transfusion for our study probably because there was normal distribution and there were no extremes of age which has been shown to predict blood transfusion (44,45).

As expected, the length of procedures affected the C/T ratio, the transfusion probability and index. The C/T ratio for procedures that took less than 180 minutes was significantly high at 4.6, which is way above the recommended value of 2. This signifies significant blood wastage for these procedures which is further supported by a very low transfusion probability of 27%. With a transfusion index of 0.45, then it signifies that probably such relatively short procedures may not require a blood crossmatch. Rather, a Group and Save would suffice. On the other hand, there was no blood wastage for procedures which took longer than 180 minutes with a normal C/T ratio of 1.92. The reverse was true in a recent study done for cardiac surgeries. The C/T ratio was 1.70 and 4.12 for procedures which took <180 minutes and > 180 minutes respectively, with the transfusion probability increasing from 30.7 % to 71.1% (16).

Blood requests ranged from 0 to 6 pints and 44 % of the study participants received a blood request. Only 50% of these patients received a blood transfusion. Out of the 120 units crossmatched, only 57 were transfused intraoperatively, giving a C/T ratio of 2.1:1. This meant that 47.6% of the blood that was cross-matched was transfused. This is just marginally above the recommended ratio of 2:1 which compares well with a study done by Mugenya in 1993 where the C/T ratio of vascular and cardiothoracic procedures was 2.45 (46). There were more oesophagectomies in our study, probably due to the rise in oesophageal cancer in recent times in Sub-Saharan Africa (47). There were no open-heart surgeries recorded from the Mugenya study, which was done 23 years ago. Even though it was possible to do open heart surgeries at this time, the department and the surgical arts of the procedure at the hospital were still young hence not many were done (48). Similarly, The C/T ratio for vascular, and cardiothoracic procedures from a hospital in India was 1.9, which compared well with that from our study (49).

The transfusion probability and transfusion index for all procedures combined was 59% and 1.3 respectively. A transfusion probability of less than 30% is indicative of blood wastage which meant that there was appropriate blood utilization for the procedures combined. Transfusion indices for the individual procedures differed. Single cardiac valve replacement had a C/T ratio of 1.48 which is globally acceptable. This, associated with a transfusion probability of 100 %, it shows that blood was well utilized for open heart surgery at the institution.
Three vascular procedures were recorded. AAA graft repair, AV fistula fashioning and venous stripping for varicose veins. C/T ratios for the three were 1.57, 1 and 3 respectively which meant that there was wastage of blood for varicose vein stripping as opposed to the other two. On the contrary, the average C/T ratio of vascular surgeries combined from an Iranian study was high at 17:1 (18). This points to massive blood wastage. Three thoracic procedures were recorded; Oesophagectomy for cancer of the oesophagus, decortication for empyema thoracis and pneumonectomy. Each of the three procedures had higher than normal C/T ratios of 3.87, 2.7 and 2.5 respectively.

A transfusion index of less than 0.3 indicated that the specific procedure doesn’t require blood to be cross-matched (16). This was the case for AV fistulas and venous stripping. For these two, it is recommended that a group and save be done, so in the case that blood is needed, an emergency cross-match can be done within 10 minutes and blood availed to the operating theatre in time.

A Maximum Surgical Blood Ordering Schedule (MSBOS) was calculated from the transfusion index for each procedure (21). It was estimated from the study, that at the Kenyatta National Hospital, the following units of blood should be cross-matched for the specific procedures: 5 units of blood are needed for single cardiac valve replacement, 3 units for AAA repair, 2 units for pneumonectomy, and 1 pint each for oesophagectomy and decortication. Only a G & S would be needed for AV Fistula and venous stripping. The recommended units of blood for AAA from a referral hospital in India was 1.5 (49). This was because abdominal aneurysms at this center were repaired using endo-vascular techniques, which resulted in lesser blood transfusions than ours which were open (50). 1 unit was recommended at the same center for single cardiac valve replacement, and only a G & S in a cardiac center in Florida (13), probably due to the use of more advanced cell-salvage techniques during open heart surgery in both centers.

In a study done with an attempt to review the surgical blood ordering schedule at John Hopkins Hospital, the C/T ratios for open heart and thoracic procedures was 2:1 and 6:1 respectively. Oesophagectomy had a C/T ratio of 6:1 and an MSBOS of 2 units. AV fistula had a C/T ratio of 3.8:1 and only a group and save was recommended. AAA had a C/T ratio of 1.5:1 and 4 units recommended (28). An MSBOS algorithm from the institution is attached in (Appendix VI).
CONCLUSION:

This study shows that there was appropriate blood utilisation for cardiac, vascular and thoracic surgery at the Kenyatta National Hospital. Individual procedures however, had differing practices, with single cardiac valve replacement having the least blood wastage and thoracic procedures having the highest.

While age, gender, weight and preoperative haemoglobin didn’t affect blood utilisation practices, longer procedures led to more blood loss and more transfusions.

Finally, we can conclude that at the Kenyatta National Hospital, 5 units of blood are needed for single cardiac valve replacement, 3 units for AAA repair, 2 units for pneumonectomy, and 1 pint each for oesophagectomy and decortication. Only a G & S is needed for AV Fistula and venous stripping. This would ensure appropriate blood use.

RECOMMENDATIONS

We recommend that the MSBOS developed above be adopted by the Kenyatta National Hospital’s thoracic and cardiovascular department. This will guide appropriate application and use of blood and blood products, a reduction in the cost of production and storage of these products, and a reduction in the cancellation rates for these procedures.

We further recommend that the laboratory should determine the blood group, do ABO and Rhesus typing and screen for atypical red blood cell antibodies of the patient’s blood and serum for AVF fashioning and varicose vein stripping, for which only a G & S is recommended by the algorithm. A negative antibody would then signify the need for an immediate spin cross match which should be done in a period not exceeding 10 minutes to enable availability of blood as fast as possible intra-operatively.

The staff in the cardiothoracic unit should be trained on the algorithm and the model should be used to create MSBOS for all the other surgical departments.

We also note that the algorithm should not be used without consideration of the individual patients’ clinical conditions.
REFERENCES:


46. Mugenya GW. (University of Nairobi. Towards establishing a MSBOS at the Kenyatta National Hospital. Thesis. 1995;


APPENDICES:
APPENDIX I: INFORMED CONSENT FORM

This informed consent form has four parts:

1. Information Sheet (to share information about the research with you).
2. Certificate of Consent (for signatures if you agree to take part).
3. Assent form for children 13-17 years of age.
4. Statement by the researcher/person taking consent.

You will be given a copy of the full Informed Consent Form.

PART 1: INFORMATION SHEET

Introduction.

My name is Dr. Daniel Kibicho, a resident in General Surgery at the University of Nairobi. I am conducting a research on the blood ordering and utilisation practices for elective thoracic, cardiac and vascular surgery at the Kenyatta National Hospital with an aim at establishing a Maximum Surgical Blood Ordering Schedule. I am going to give you information about the research that want to carry out and invite you to be in my study. You don’t need to make that decision today. In case of any questions please feel free to ask.

Purpose of the research.

Blood is an important component of surgery. During an operation, blood may be required if significant blood loss is encountered or anticipated. However, blood is a very scarce resource and its transfusion is not without adverse effects in some cases.

It is not uncommon that the clinician will request for blood for an operation depending on his anticipation for blood loss, or on his fears and past experiences. This should however not be the case. Certain protocols guided by studies such as this should exist for every hospital to guide blood requests and utilisation.

Our study aims to collect data from patients like you, with your consent, to enable us find out the blood ordering and utilisation practices for thoracic, cardiac and vascular surgery at the Kenyatta National Hospital with an aim to develop a protocol.
Voluntary participation

Participation in this study is entirely on voluntary basis. Whether you choose to participate or not, all the services you expect to receive will be the same with no bias whatsoever. Any patient above the ages of 13yrs is free to participate in this study.

Procedures and protocol

If you wish to participate in this study you will be given a questionnaire to fill. You will then proceed to theatre for the scheduled operation as advised by the clinician. The surgery will continue as scheduled and no further input will be required of the participant. All information required for the questionnaire will be filled from data available from the patient’s theatre records and file.

Confidentiality

Your results will be held with utmost confidentiality and will only be released to a third party if given a written consent.

Risks

There are no foreseen risks of taking part in this study.

Benefits

Information gotten from this study will help us to develop a guideline for the appropriate use of blood and blood products for thoracic, cardiac and vascular surgery at the Kenyatta National Hospital which will aid to inform policy at the hospital.

Who to contact

If you wish to ask questions later, you may contact the primary investigator;

Dr Daniel Kibicho

Department of Surgery, University of Nairobi

P.O. Box 15369-00400

Nairobi.

Cell phone number, 0723 973983
If you have any ethical concerns, you may contact:

Secretary, UoN/KNH-ERC,

P.O. Box 201723- 00202

KNH Nairobi

Tel 020-726300-9

Email: KNHplan@Ken.Healthnet.org

PART II

Certificate of consent (for participants above 18 years of age)

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Signature of participant …………………………………………………

Date ………………………………………………………………………

If Non- literate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Signature of witness …………………………………………………

Date ………………………………………………………………………

Thumb print of participant
Certificate of Consent by patient’s guardian (For participants below 18yrs of age).

I……………………………………………………freely give consent of my child/ kin to take part in the study conducted by Dr Daniel K Kibicho, the nature of which has been explained to me. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care being given to my child or my proxy. The results of the study may directly be of benefit to my child or my kin and other patients.

Signature of guardian/ next of kin……………………………
Date……………………………………………………………

Statement by a witness if the guardian or proxy is illiterate:

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness………………………………………………
Signature of witness…………………………………………
Date……………………………………………………………

PART III

Assent form for participants 13- 17 years of age.

My name is Dr Daniel K Kibicho and I am doing a study about the ‘Blood ordering and utilisation practices for thoracic, cardiac and vascular surgery at the Kenyatta National Hospital.’
Data collected from this study will help us develop a protocol for better and efficient use of blood for these surgical procedures. If you would like, you can participate in this study.

If you decide you want to participate in my study, your parent or guardian will be asked some personal questions, and required to go through a questionnaire with me or my research assistant.

Data will be collected from your laboratory tests and no physical examination is necessary. There are no risks involved in this study and you, your parent or guardian will not incur any extra costs for participating in this study.

Other people will not know if you are participating in this study. Your answers and your progress will be kept private. When I tell other people about my research, I will not use your name, so no one can tell who I am talking about.

Your parents or guardian have to say if it will be okay for you to be in the study. After they decide, you will get to choose if you want to do it too. If you don’t want to be in this study, you will not get into any trouble. You can stop being in the study at any time.

My telephone number is 0723 973983. You can call me if you have questions about the study or if you decide you do not want to be in the study any more.

I will give you a copy of this form in case you want to ask questions later.

Sign this form only if you:

- Have understood what you will be doing for this study.
- Have had all your questions answered.
- Have talked to your parent(s)/ legal guardian about this study, and
- You have agreed to take part in this research.

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

Your signature       Name       Date

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

Name of Parent(s) or Legal Guardian(s)
PART IV

Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate better understanding of the blood ordering and utilisation practices for elective thoracic, cardiac and vascular surgery at the KNH with an at the establishment of an MSBOS.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Name of the researcher/ person taking consent _____________________________

Signature of researcher/ person taking consent _____________________________

Date _____________________________
APPENDIX II: RIDHAA KIDATO

Hii ridhaa kidato ina sehemu nne:

1. Taarifa karatasi (habari kuhusu utafiti)
2. Hati ya idhini (kwa ajili ya kutiwa saini)
3. Fomu ya usajili kwa washiriki wa umri kati ya miaka kumi na tatu na kumi na saba.
4. Ujumbe kutoka kwa mtafiti.

Utapewa nakala ya fomu ridhaa.

Sehemu ya kwanza: Maelezo

Utangulizi:


Madhumuni ya utafiti

Damu ni muhimu kwa upasuaji wowote. Wakati wa upasuaji, damu huitajikwa wakati mtu amepoteza damu kwa kiasi kikubwa au wakati kuvunja damu kunatarajiwa. Hata hivyo, damu ni rasilimali adimu sana na kuongezewa damu kuna adhari mbaya katika baadhi ya kesi.

Ni kawaida kuwa daktari ataitisha damu kwa ajili ya upasuaji akitegemea kutarajia kwa kupoteza damu, au kwa hofu yake na uzoevu wa zamani. Lakini kuna baadhi ya itifaki zinazofaa kuongoza utumizi wa damu katika upasuaji wowote ule.

Utafiti wetu una lengo la kukusanya takwimu kutoka kwa washiriki kama wewe, kwa idini yake, ili kutuwezesha kujua jinsi damu inavyoagizwa na kutumika kwa upasuaji wa kifuwa, moyo na mishipa katika Hospitali ya Taifa ya Kenyatta kwa lengo la keundeleza itifaki.

Ushiriki wa hiari
Kushiriki katika utafiti huu ni kwa hiari yako. Kama utachagua kushiriki au la, huduma zote unazotarajia kupokea zitakuwa sawa bila mapendeleo yoyote. Mgonjwa yeyote juu ya umri wa miaka kumi na mitatu anaweza kushiriki katika utafiti huu.

**Taratibu na itifaki**

Kama ungependa kushiriki katika utafiti huu, utapewa dodoso ambayo utaijaza kwa ukamilifu na kisha utaendelea na opereshi uliyopangiwa kwa ushauri wa daktari. Hakuna pembejeo Zaidi itatakiwa kwako kama mshiriki. Taarifa zote zinazohitajika kwa dodoso zitajazwa kutoka kwa takwimu zilizopo kutoka kwa rekodi za kila mgonjwa.

**Usiri**

Taarifa zozote zilozotea wakati wa utafiti zitawekwa kwa siri. Mpelezi mkuu na wasimamizi wake pekee wakuwa na fursa ya kuweka taarifa. Wakati wa uchambuzi wa data, jina yake itaondolewa kwa kufanya aina mia aina kwa mgonjwa kwa motokeo yake ili kulinda usiri wako.

**Hatari**

Hakuna hatari inayotabiriwa ya kushiriki katika utafiti huu.

**Faida**

Taarifa itakayopatikana kwa mgonjwa kwa utafiti huu itasaidia kuendeleza mwongozo kwa ajili ya matumizi sahihi ya damu kwa upasuaji wa kifua, moyo na mishipa katika Hospitali ya taifa ya Kenyatta. Hii itasaidia sera katika hospitali.

**Mawasiliano**

Ukitaka kuuliza maswali baadaye, unaweza kuwa na mshiriki na mapelezi mkingo; Daktari Daniel Kibicho

Idara ya upasuaji, Chuo kikuu cha Nairobi

S.L. Posta 15369-00400

Nairobi.

Namba ya simu, 0723 973983

Kama una matatizo yoye ya kimaadili, unaweza kweli na mshiriki na:

Katibu mkuu, UoN/ KNH-ERC,
S.L. Posta 2011723- 0020

KNH Nairobi

Namba ya simu 020-726300-9

Barua pepe:

KNHplan@KEn.Healthnet.org

Sehemu ya Pili:

Hati Ridhaa

Nimeisoma nakala hii na nimepewa nasafi ya kuuliza maswali na yamejibiwa kwa ukamilifu. Nakiri hiari ya kushiriki katika utafiti huu.

Sahihi ya mshiriki ........................................................................................................

Tarehe ............................................................................................................................

Kwa wasioweza kusoma na kuandika.


Jina la shahidi .........................

Sahihi la shahidi .......................

Tarehe ........................................

Alama ya kidole

Hati ridhaa itakayojazwa na mlezi wa mshiriki aliye chini ya miaka kumi na nane.

Mimi ..............................................................natoa ridhaa ya mtoto wangu/ jamaa wangu kushiriki katika utafiti unaofanywa na daktari Daniel K Kibicho, kwa jinsi ambayo nimeelezewa. Nimefahamishwa na kuelewa kuwa ushiriki wangu ni kwa hiari na pia naelewa

Saini ya mlinzi/ jamaa ........................................

Tarehe ...........................................

**Tamko la shahidi kama mlezi au wakala hajui kusoma au kuandika:**

Nimeshuhudia kuwa mshiriki amesomewa fomu ya idhini na amekuwa na nafasi ya kuuliza maswali. Nathibisha pia kuwa ametoa ridhaa kwa uhuru.

Jina la shahidi.................................................................

Saini ya shahidi ..............................................................

Tarehe .................................................................

**Sehemu ya tatu:**

**Fomu ya usajili kwa wshiriki kati ya miaka kumi na tatu na kumi na saba.**

Jina langu ni Dr Daniel K Kibicho na mimi nafanya utafiti kuhusu uagizaji na utumiaji wa damu kwa upasuaji wa kifua, roho na mishipa katika hospitali ya kitaifa ya Kenyatta.

Takwimu zitakazokusanywa kutoka kwa utafiti huu zitasaidia kuendeleza itifaki kwa matumizi bora ya damu kwa ajili ya taratibu hizi za upasuaji.

Kama ungependa, unaweza kushiriki katika utafiti huu. Na ukiamua kushiriki katika utafiti wangu, mzazi au mlezi wako atatakiwa baadhi ya maswali binafsi kwa njia ya dodoso.

Takwimu zitakusanywa kutoka kwa vipimo za damu na hakuna uchunguzi Zaidi utafanyiwa. Hakuna hatari ya kushiriki katika utafiti huu na wewe, mzazi au mlezi wako hamtakuwa na garama yoyote ya ziada kwa kushiriki katika utafiti huu.

Hakuna mtu mwingine atakayejua kama wewe ni mshiriki katika utafiti huu na majibu yako yatawewa binafsi. Jin alako halitatumika wakati taarifa za utafiti huu zitakapotolewa.

Unaweza kuacha kuwa katika utafiti wakati wowote ule. Namba yangu ya simu ni 0723 973983. Unaweza kunipigia simu ikiwa utakuwa na swali lolote kuhusu utafiti au ukiamua kushiriki.

Utapewa nakala ya fomu hii kama utataka kuuliza maswali baadaye. Tia saini yako kwenye fomu hii tu kama wewe:

- Umeelewa nia ya utafiti huu.
- Umejibiwa maswali yako yote kuhusu utafiti huu.
- Umeongea na mzazi au mlezi wako kuhusu utafiti huu, na
- Umekubali kushiriki katika utafiti huu.

........................................................................................................................................
Sahihi yako jina lako tarehe
........................................................................................................................................
Jina la mzazi/ wazazi/ au mlezi/ walezi
.................................................................................................................................
Sahihi ya mtafiti jina la mtafiti tarehe
........................................................................................................................................

Sehemu ya nne:

Ujumbe kutoka kwa mtafiti:

Nimesomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuataayo:

- Kutoshiriki au kujitaa wenyewe utafiti huu hakutadhuru kupata kwake kwa matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu yanaweza chapishwa kusaidia uagizaji na mazoea ya matumizi ya damu kwa upasuaji wa kifua, moyo na mishipa katika hospitali kuu ya Kenyatta na kwa kutengeneza sera mwafaka.

Nadhibitisha kwamba mshiriki alipewa nafasi ya kuuliza maswali kuhusu utafiti huu, na kwamba nimeyajibu maswali yote kwa usahihi na kwa kadri ya uwezo wangu. Pia nadhibitisha kwamba mshiriki hajashurutishwa kutoa idhini, na kuwa amepewa ridhaa kwa uhuru na kwa hiari. Mshiriki amepewa Nakala yah hii fomu ya ridhaa.

Jina la mtafiti ………………………………………………………………………..

Saini ya mtafiti ………………………………………………………………………...

Tarehe ………………………………………………………………………………….

APPENDIX III: QUESTIONNAIRE FORM

Study Number: …………….. Patient’s IP Number…………………………

Patient’s initials………………

Part A: Biodata

1. Age in years: _________

2. Gender: ___________

Part B: Pre-operative information.

1. Weight (Kg): __________

2. Pre-operative Haemoglobin level (g/dl): __________

3. Pre-operative Haematocrit (%): __________

4. Is the patient on anti-coagulants?

Yes _______ No _______

If yes, for how long ……………………………………….

5. Does the patient have a coagulopathy?

Yes _______ No _______

6. Has blood been requested for the operation?
Yes  
No  

If Yes, How many pints?

7. How many pints of blood were cross-matched pre-operatively?

8. Is this the primary surgery or a re-operation?

Primary surgery  
Re-operation  

Part C: Intra-operative data.

1. What is the estimated blood loss prior to surgery?

2. Is there a predicted risk of major bleeding prior to surgery?

Yes  
No  

3. What is the calculated blood loss during the operation?

4. What type of procedure was done?

5. Was blood transfused during the operation?

Yes  
No  

If the answer is Yes, answer question 6. If No, move to question 7.

6. How many pints were transfused?

7. What was the length of the procedure (minutes)?

8. Was Cardio-Pulmonary Bypass (CPB) used?

Yes:  
No  

9. If Yes, what was the Cardio-Pulmonary Bypass time?