The role of blood transfusion in the occurrence of surgical site infection amongoperated patients at Muhimbili Nationalhospital, Dar Es Salaam.

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MMed (General Surgery) Dissertation
Muhimbili University of Health and Allied Sciences
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MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)
SCHOOL OF MEDICINE
DEPARTMENT OF SURGERY

THE ROLE OF BLOOD TRANSFUSION IN THE OCCURRENCE OF SURGICAL SITE INFECTION AMONG OPERATED PATIENTS AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM

By

Abdiaziz Sheikh Mohammed, MD

A Dissertation submitted in (partial) fulfillment of the Requirement for the Degree of Masters of Medicine (General Surgery) of the

Muhimbili University of Health and Allied Sciences
October, 2018.

CERTIFICATION

The undersigned certify that he has read and hereby recommend for acceptance for examination by the Muhimbili University of Health and Allied Sciences a dissertation entitled; ***The role of blood transfusion in the occurrence of surgical site infection among operated at Muhimbili National Hospital, Dar es salaam,*** in partial fulfillment of the requirements for the degree of Master of Medicine (Surgery) of Muhimbili University of Health and Allied Sciences.

_____

Dr Larry Akoko

Supervisor

_____

Date

DECLARATION AND COPYRIGHT

I, Abdiaziz S Mohammed, declare that this **dissertation** is my own original work, and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature……. Date……...

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DEDICATION

This thesis work is dedicated to my wives and children who have been a steady foundation of support and encouragement during the challenges of graduate school and life. I am truly thankful for having you in my life.

This work is also dedicated to my dear parents, **Rukia Yusuf** and **Mohamed HajiYusuf**, who have always loved me unreservedly and whose excellent examples have taught me to work hard for the things that I aspire to achieve.

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ABSTRACT

Background

Several studies have shown that allogeneic blood transfusions can induce clinically significant Immunosuppression referred to as transfusion-associated immunomodulation (TRIM). TRIM has been linked to an improved clinical outcome in the setting of renal allograft transplantation. TRIM-associated effects include an increased rate of cancer recurrence and of post-operative bacterial infection.

This study was carried out to determine the prevalence and factors associated with Surgical Site Infection among post-operative surgical patients following exposure to blood transfusion in the surgical units of Muhimbili National Hospital.

Methodology

A nested case control study was carried out at the surgical units of Muhimbili National Hospital from May through December 2017. The study involved two groups of post-operative patients (i.e. those who were transfused and those post operatives who had not been exposed to blood transfusion) admitted to the surgical wards. Study subjects were recruited conveniently until the desired sample size was achieved. A well-structuredquestionnaire containing socio-demographic characteristics, patient's preoperative, perioperative and postoperative information was administered to study subjects who met the inclusion criteria and consented to participate in the study. Data was checked for completeness, coded and entered into SPSS version 22. Frequencies, proportions and measures of central tendency and measure of dispersion were calculated. Odds ratio was used as a measure of association.

Results

A total of 200-study participants were recruited during the study period. The median age was 47.5 years with a range of 12 to 94 years. Majority of respondents were female (53%) while age group 45 year and above constituted 57%. More than half of the study respondent had HB level of 11 g/dl and above.

With regards to hospital stay, 58% stayed less than 7 days. 93 study respondents (47%) were transfused during surgery with more females transfused compared to males (58% vs. 42%) while age group 45 years and above had the highest cases of those who were transfused. Twelve percent of those who were transfused developed surgical site infection.

There was nearly equal number of males (9) and females (8) participants who developed surgical site infection with participants in the age group above 45 years, those with Hb level below 11g/dl and participants with hospital stay more than seven (7) days having developed more cases of surgical site infection.

Conclusion

This study has failed to reject the null hypothesis hence but has shown a possible increased risk for SSI among patients receiving BT. Although many studies have shown the association between BT and overall infection, there is scant literature on the association between BT and specific infections. Low hemoglobin, which is related to BT, was however shown to have significant increased risk for occurrence of SSI. Similarly, prolonged hospital stay was also found to have increased risk of SSI development. Smoking was however found to be the most important factor in the occurrence of SSI in our cohort of patients. Due to frequent complications seen in transfused patients, a more restrictive transfusion practice may be safe and efficient. Patients undergoing BT were more likely to experience complications and that the triggering level of Hb and target of transfusion should be restricted.

Recommendations

- Further studies that are surgery specific to assess the role of blood transfusion influence on surgical site infection.
- Counseling the surgical patients on cessation of smoking at least two weeks before surgery to scale down on the adverse effects of cigarette smoke on wound healing.
- Adhere to established guideline in preoperative preparation to optimize postoperative outcomes.

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ABBREVIATIONS

ASA	American Society of Anesthesiologists
CDC	Centre for Disease Control and Prevention
HIV/AID	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
TRIM	Transfusion associated immune-modulation
SOPs	Standard Operating Procedures
SPSS	School of Public Health and Social Sciences
SSI	Surgical Site Infections
WHO	World Health Organization
RBC	Red Blood Cells
MOF	Multiple Organ Failure
UTI	Urinary Tract Infection
MOD	Multiple Organ Dysfunction
WBC	White Blood Cells
ABT	Allogenic Blood Transfusion
TPE	Therapeutic Plasma Exchange
POD	Post operative Blood Transfusion
BT	Blood transfusion

1.0 INTRODUCTION

The CDC definition describes three levels of SSI:
Superficial incisional, affecting the skin and subcutaneous tissue. These infections may be indicated by localized (Celsian) signs such as redness, pain, heat or swelling at the site of the incision or by the drainage of pus.

Deep incisional, affecting the fascial and muscle layers. These infections may be indicated by the presence of pus or an abscess, fever with tenderness of the wound, or a separation of the edges of the incision exposing the deeper tissues.

Organ or space infection, which involves any part of the anatomy other than the incision that is opened or manipulated during the surgical procedure, for example joint or peritoneum. These infections may be indicated by the drainage of pus or the formation of an abscess detected by histopathological or radiological examination or during re-operation. Organ infection is not included within the scope of this guideline.

In this study, the first two levels of definitions shall apply for the convenience of the investigator and uniformity of the findings viz-postoperative infection within 30 days with clinical evidence of purulent discharge associated with pain and tenderness over the surgical site.

Surgical Site infections are the most frequently reported infections of all nosocomial infections among hospital patients. Among surgical patients, Surgical Site Infections were the most common nosocomial infections and the rate is higher in sub-Saharan Africa.
Surgical site infection is a type of healthcare-associated infection in which a wound infection occurs after an invasive (surgical) procedure. Other types of healthcare-associated infections that mainly affect surgical patients are postoperative respiratory and urinary tract infections,

bacteraemias (including methicillin-resistant *Staphylococcus aureus* infections and intravascular cannula infections) and antibiotic-related diarrhoeas (particularly *Clostridium difficile* enteritis) (2).

Surgical site infections have been shown to compose up to 20% of all of healthcare-associated infections. At least 5% of patients undergoing a surgical procedure develop a surgical site infection (2).

A surgical site infection may range from a spontaneously limited wound discharge within 7–10 days of an operation to a life-threatening postoperative complication, such as a sternal infection after open-heart surgery.

Most surgical site infections are caused by contamination of an incision with microorganisms from the patient's own body during surgery. Infection caused by microorganisms from an outside source following surgery is less common.

The majority of surgical site infections are preventable. Measures can be taken in the pre-, intra- and postoperative phases of care to reduce risk of infection.

Surgical site infections can have a significant effect on quality of life for the patient. They are associated with considerable morbidity and extended hospital stay. In addition, surgical site infections result in a considerable financial burden to healthcare providers. (1).

1.2 LITERATURE REVIEW

Blood transfusion has been recognized as a significant risk factor for minor and major complications in non-pancreatic surgeries. Janssen et al. reported(1) that the odds ratio for exposure to allogeneic blood transfusion in patients undergoing lumbar spine surgery was 2.6 for any postoperative infection. Xiao H et al also found that perioperative blood transfusion was an independent risk factor (OR = 2.71) for postoperative infectious complications after radical gastrectomy in patients with gastric cancer. However, Sutton et al. found that blood transfusion was not associated with the increased rate of infectious complications. Therefore, retrospective clinical study was conducted to investigate risk factors related to serious infections in an attempt to reduce postoperative infectious complications. Multiple factors including age, gender, body mass index (BMI), nutritional screening scores (NRS-2002), clinical presentation, preoperative laboratory findings and biliary drainage procedures, type of resection, operative blood loss, red blood cell transfusion, and histopathological findings were analyzed in the 212 patients who underwent pancreaticoduodenectomy and revealed that blood transfusion was found to be an independent risk factor associated with postoperative infections. The results of this study indicated that patients who received blood transfusion had a 3.2 times higher risk of developing serious infections than those without. The study results also show that although patients with serious infections almost had the same volume of blood loss as those without, a larger percentage of patients (61.7 vs. 38.4 %) received blood transfusion in the serious infection group than in the non-infection group. Furthermore, considering the volume of blood transfused, 21.6 % of patients with serious infections had blood transfusions of more than 2 units, while only 11.5 % of patients without serious infections had more than 2 units of blood transfusion. Except for transfusion errors (i.e., receiving the wrong blood) and transfusion-transmissible infections, increased risk of infections after blood transfusion is thought to be a result of transfusion-related Immunosuppression. Transfusions increase suppressor T cell activity and inhibit natural killer cell activity. (1)

Allogeneic blood transfusions are known to have important immunomodulatory effects. More than 100 studies have now been published regarding the transfusion of blood products and the risk of postoperative infection. Unfortunately, small cohorts and retrospective design limit modern interpretation. Further confounding the issue is the fact that early studies often used whole blood, which is rarely used now. In addition, currently produced packed erythrocyte units contain less than 10% plasma and less than 5% leukocytes versus units produced in the 1970s. Finally, the hemorrhage that often necessitates transfusion has itself been shown to increase infectious risk. Regardless, many recent prospective studies have linked perioperative transfusion to infection in multiple surgical populations including cardiac surgery, orthopedic surgery, trauma and colorectal surgery. Although these studies imply that the transfusion of blood products increases the risk of infection, some studies have not noted an increased risk, and others have argued that the effect of transfusion is minor. Nevertheless, the risk of infection with transfusion can be decreased using autologous blood donation versus allogenic blood. In fact, in most studies, the infection rates with autologous blood approach those of patients who did not have transfusion. This point lends further evidence to the causal relation between allogeneic packed erythrocyte transfusions and the risk of infection. This issue has generated an impressive amount of literature, discussion, and argument. There is no doubt that transfusion has an immunomodulatory effect, but the true clinical impact and the most effective methods of prevention are still hotly debated. (2)

Perioperative blood product transfusions cause substantial alterations to the anti-inflammatory/pro-inflammatory milieu in the recipient. Administration of stored blood products may be more deleterious than fresh products from the inflammatory-immunomodulatory perspective. Recent data in animal models suggest that old red cells, rather than leucocytes or soluble fractions, may be responsible for tumor promoting effects. The net result of the transfusion of blood products in the recipient is immunodepression, although the extent and clinical significance of this phenomenon are not yet certain. Because of the growing evidence indicating that the presence of circulating tumor cells are linked to

prognosis, studies showing no association between cell saver utilization and cancer recurrence should be accepted with caution. The best clinical evidence to date associating perioperative blood transfusions with cancer recurrence is in colorectal cancer. Whether blood transfusion also increases recurrence risk for other cancers is unclear because of the paucity of well-conducted randomized controlled trials that have addressed this question.(3)

Intraoperative blood loss necessitates the transfusion of allogeneic blood to avoid perioperative anemia, itself identified as an independent risk factor in perioperative morbidity and mortality. However, there exist consequential trade-offs between the risks and benefits of allogeneic blood transfusion versus anemia in terms of their effects on perioperative outcomes. Although the adverse effects of allogeneic blood transfusion on postoperative infection in the context of spine surgery have been demonstrated, the low power and uncontrolled potential confounds of many of these studies has limited the interpretation of their data This systematic review failed to find a consistent association between allogeneic transfusion and SSI in patients undergoing spinal surgery. However, the studies were all retrospective with a high or moderately high risk of bias. To understand the nature of the association between allogeneic blood transfusion and subsequent infection in spine surgery, appropriately designed and controlled prospective studies of sufficient power (n ¼ 2400) are required.(4)

Although blood transfusions are regarded as essential in many surgical procedures, they carry significant risks, including: transfusion reactions, receipt of infectious agents, contaminated red blood cells, and compromised immunity. Our finding related to the association between blood transfusion and SSIs is in agreement with other recent reports that it is an independent risk factor for postoperative bacterial infection (odds ratio=1.18, P=0.007), SSI, and post-injury multiple-organ failure. Interestingly, the occurrence of wound infections appears to increase incrementally with each unit of blood transfused, and is also greater if the blood has been in storage for 21 days or more or has been depleted of nitric oxide.(5)

Blood transfusion is the mainstay therapy for moderate-to severe perioperative anemia; however, administration of blood products is associated with poor outcomes in patients with and without cancer. In those with cancer, blood transfusions can directly (via soluble factors) and indirectly (via transfusion related immune modulation) induce proliferation and spread cancer cells present at sites of minimal residual disease (tumor margins and dormant tumors). After transfusions, there is an increase in the concentrations of local (tumor microenvironment) and circulating pro-inflammatory cytokines and prostaglandin E, which tilt the balance toward immune suppression. At the cellular level, there is a reduction in the function of natural killer cells; a decrease in the proliferation of CD4+, CD8+ T cells, and B lymphocytes; induction of T regulatory cells; and a decrease in maturation and antigen presenting activity of dendritic cells, which also contributes to a diminished immune function.(6)

Multivariable analysis showed independent predictors of SSI included ankle-brachial index <0.35 (odds ratio [OR], 1.53; 95% confidence interval [CI], 1.03-2.30, P < .04), transfusion >2 units (OR, 3.30; 95% CI, 2.17-5.02; P < .001), and procedure time >220 minutes (OR, 2.11; 95% CI, 1.05-4.23; P < .04). (7)

Blood transfusion in the setting of non-cardiac surgery is associated with increased risk of 30-day mortality and pulmonary, septic, wound, and thromboembolic complications. The increased risk of mortality and morbidity associated with blood transfusion was present after adjusting for patient demographics, functional status, comorbidities and surgical complexity. Blood transfusion did not appear to be protective in patients with cardiovascular disease. (8)
Although blood transfusions were associated with surgical blood loss and duration of surgery, which could act as confounding variables, neither of these factors was significantly associated with postoperative infection, suggesting an independent relationship between transfusion and postoperative infection. Allogeneic transfusion is a significant predictor of postoperative infection, maintaining a dose–response relationship, even if only one unit of blood is

transfused. Accumulated evidence shows that allogeneic transfusions have a profound negative effect on the immune system. This negative effect implies an increase in the recurrence of surgically resected tumors and the frequency of postoperative infections. Allogeneic plasma, allogeneic white blood cells (WBCs) and substances that accumulate in blood components during storage have been implicated in the pathogenesis of TRIM. An association between ABT and perioperative infection has been clearly established from multiple observational studies. Such an association persists after statistically adjusting for the effects of multiple confounding factors considered by the authors. However, with an observational design, researchers can only control the effects of confounding factors that are known and can be measured, and can therefore be introduced into a multivariate analysis. (9)

The significant association of perioperative BT with infections strongly suggests a causal relationship between the two events, according to the hypothesis that allogeneic BT induces a non-specific immunodepression which would favor postoperative infective complications. The mechanisms by which BT may cause immunodepression concern cell-mediated immunity and the function of macrophages, decreasing their migration toward chemotactic stimuli and/or inducing an increased production of PGE2.(10)

The association between perioperative allogeneic blood transfusion and the possibility of increased risk of post-operative bacterial infection following surgery has been reported in many observational studies. The available studies have been summarized elsewhere and indicate a possible association between allogeneic blood transfusion and post-operative infection. Until recently, the various observational studies reporting an association between allogeneic blood transfusions and increased risk for post-operative infection were not adjusted for the effects of severity of illness and/or for the various risk factors for post-operative infection at specific sites. Recently there have been three large observational studies reported in which the authors attempted to adjust for many of the potential confounding variables. Thus, Carson et al. conducted a retrospective cohort study of 9,598 consecutive patients with hip fractures, who underwent surgical repair between 1983 and 1993, at twenty hospitals across the US. The primary outcome variable was serious bacterial infection defined as

bacteremia, pneumonia, deep wound infection, or septic arthritis/osteomyelitis. The adjusted relative risk of serious post-operative infection associated with allogeneic transfusions was calculated to be 1.43 (95% CI, 1.16 to 1.78; 0.001). Similarly, Chang et al. analyzed a database of 1,349 patients, undergoing elective colorectal surgery for various diseases of the colon or rectum at 11 Canadian University hospitals. Ten prognostic variables were found to be associated with both transfusion and post-operative wound infection, with the final regression model adjusting for four of these confounders. In this study, allogeneic blood transfusions were found to be a significant independent predictor of post-operative wound infection (OR 1.18; 95% CI, 1.05 to 1.33; /0.007). Finally, Vamvakas and Carven reported a retrospective cohort study of 416 consecutive patients admitted to one hospital for coronary artery bypass surgery. The outcome variable was limited to post-operative wound infection, or pneumonia, and adjustment was made for the effects of chronic systemic illness and specific risk factors for wound infection and/or pneumonia. In this latter study the adjusted risk of post-operative infection or pneumonia increased by 6% per unit of allogeneic RBCs and/or platelets transfused (/0.0284), or by 43% per patient receiving a mean transfusion dose of 7.2 units of RBCs and/or platelets .There have been 7 RCTs reported that have compared the incidence of post-operative infection between recipients of buffy-coat-reduced RBCs, standard allogeneic RBCs, or whole blood; with recipients of autologous, WBC-reduced buffy-coat reduced allogeneic RBCs, or whole blood. These seven studies are statistically very heterogeneous. Thus, when all seven studies were considered together, to be included in a potential meta-analysis, the probability that the disagreements about the findings might have arisen by chance was smaller than 1 per 10,000. Two studies reported a signify PB Cant (0.05) TRIM effect, two studies PB reported a marginally significant (/0.10) TRIM effect and three studies did not detect any TRIM effect. More importantly, the variation in the results of these 7 RCTs range from a 7.3-fold increase in the risk of post-operative infection to no effect. The various characteristics of these seven studies are extensively examined elsewhere and the final conclusion is that these seven studies do not show unanimity of a TRIM effect and thus cannot be combined in a meta-analysis. (11)

Many observational studies and multiple randomized controlled trials have described the potential association between transfusion and an increased risk of postoperative SSI. This association has been noted with a variety of surgical procedures (colorectal, general abdominal, orthopedic, trauma, head and neck, and cardiothoracic surgery. Donated WBCs have been implicated as a source of transfusion-induced Immunosuppression. Results of these randomized clinical trials have failed, however, to provide a consensus answer to the association between transfusion and postoperative infection. The occurrence of TRIM, seen particularly in recipients of allogeneic transfusions of WBC-containing blood products, has been supported by animal and human studies. (12)

Preoperative anaemia is an emerging concern in patients undergoing surgery. This has been also been attributed to the increased need for perioperative transfusions in the anaemic subject, which are also independently associated with adverse postoperative outcomes even when as low as one unit of packed red blood cells (pRBC) is administered intraoperatively.(13)

Several studies have pointed out allogeneic blood transfusion as an independent risk factor for SSI after total joint arthroplasty, including Total hip replacement. Transfusion of allogeneic blood is considered to induce immunomodulation to the recipient, due to the presence of white blood cells (WBC) above a critical level .However, even transfusion of WBC-filtered allogeneic blood has been found to independently increase the risk of infection after THA. Preoperative autologous blood donation, regional anesthesia, and prevention of excessive intraoperative blood loss can reduce the need or allogeneic blood transfusion and therefore the risk of developing SSI. (14)

Surgical site infection presents as a significant problem that limits the potential benefits of surgical interventions. A case-control study including 49 patients with SSI and 105 patients without SSI was performed. Demographics, clinical characteristics, laboratory information, medical and surgical data were compared between groups. Significant elements were

subsequently brought into logistic regression analysis for further identification. Patients with SSI exhibited higher tobacco usage rate ($p = 0.03$), lower preoperative hemoglobin ($p = 0.02$) and pre-albumin level ($p = 0.02$). Bowel penetration instead of stricture was more frequent in patients with SSI ($p = 0.04$). Longer duration of operation ($p = 0.03$) and higher intraoperative lactate level ($p = 0.02$) were observed in patients with SSI. Logistic analysis identified that preoperative pre albumin (95% CI: 0.2~0.7; OR = 0.5; $p = 0.03$), duration of operation (95% CI: 2.3~9.5; OR = 3.8; $p = 0.03$) and intraoperative lactate level (95% CI: 1.7~7.2; OR = 3.4; $p = 0.04$) were associated with postoperative surgical site outcome.(15)

Intra- and/or post-operative, not pre-operative, BT was found to be associated with an increased risk for postoperative infectious complication. (16)

1.3 STATEMENT OF THE PROBLEM

Surgical site infection is among the frequent causes of undesirable events in post-operative patients, the situation being worse in the low income settings. For instance, in Tanzania, the trend of surgical site infection is on the rise. Despite marked improvements in the status of operating rooms, modes of sterilization, and surgical skills, surgical site infection remains a major challenge.

Several risk factors are associated with surgical site infection viz; duration of operation, comorbidities, smoking, hospital stay and of interest in this study blood transfusion status.In Tanzania, no tangible studies have been done about to determine the influence of blood transfusion on the development of surgical site infection.

1.4 RATIONALE

This study was conducted in an attempt to determine the influence of blood transfusion on the occurrence of SSI among post-operative patients and provide an insight on the need to control the said factors associated with surgical site infection and of importance, the need to review blood transfusion practices in this setting with the aim to reduce the trends of surgical site infection in the operated patients.

1.5 CONCEPTUAL FRAMEWORK

Independent variables included the preoperative factors via; age, comorbidities, hospital stay, previous use of antibiotics, cigarette smoking, malnutrition and Immunosuppression, type and duration of elective surgery, antimicrobial prophylaxis, while the dependent variable was surgical site infection.

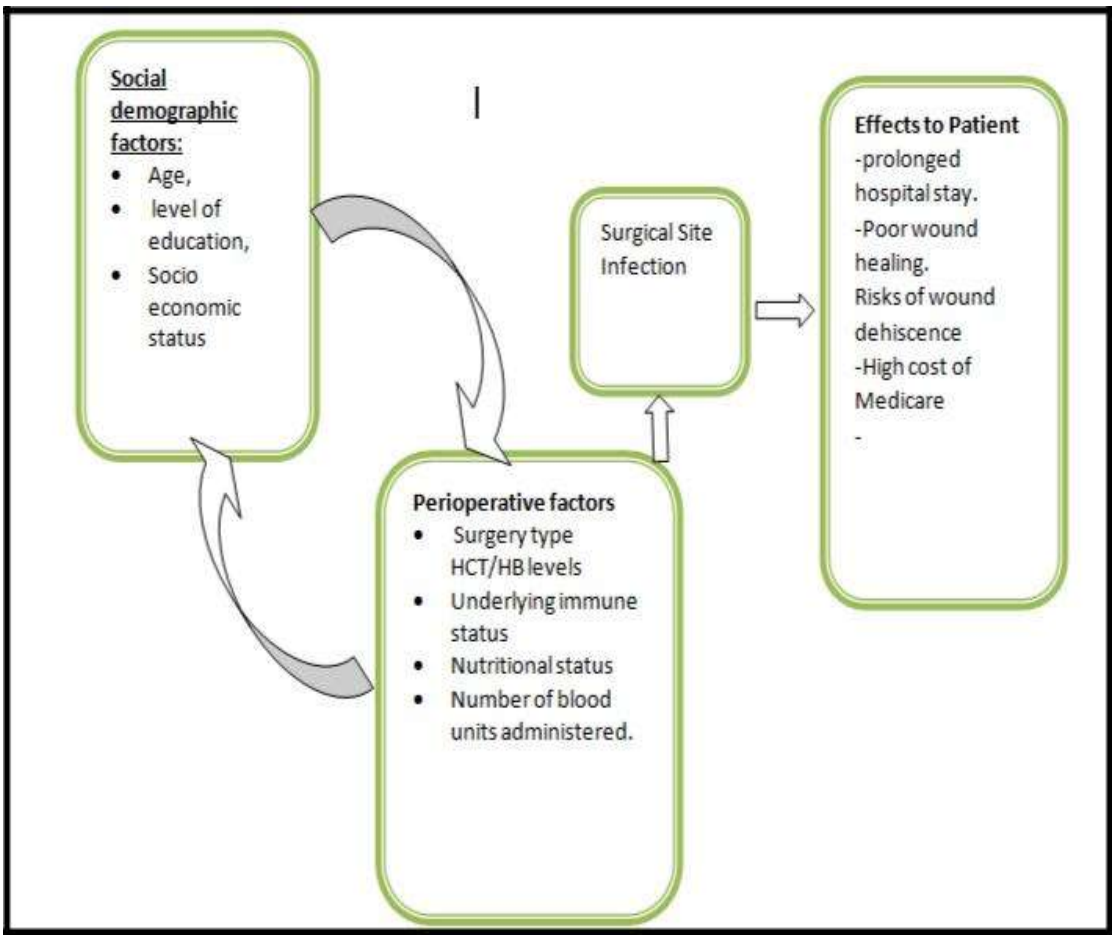


Figure 1: Conceptual Framework

Source; Personal diagram created by Dr Abdiaziz.

1.6 RESEARCH QUESTIONS

What was prevalence and factors associated with SSI among postoperative surgical patients exposed to blood transfusion?

1.7 HYPOTHESIS

HO: Blood transfusion does not influence the occurrence of surgical site infection.

H1: Blood transfusion influences the occurrence of surgical site infection.

1.8 BROAD OBJECTIVES

To explore the prevalence and factors associated with SSI among of post-operative surgical patients following exposure to blood transfusion in the surgical units of Muhimbili National Hospital.

1.8.1 SPECIFIC OBJECTIVES

To determine the prevalence of SSI among post-operative patients following blood transfusion.

To assess clinical, demographical and nutritional factors associated with SSI among post-operative surgical patients following blood transfusion.

2.0 METHODOLOGY

2.1 STUDY DESIGN

This was a case control study that was carried out in the surgical units of Muhimbili National Hospital between May 2017 to December 2017.

2.2 STUDY AREA

We carried out a case-control study at the surgical units of Muhimbili National Hospital from May through December 2017. This is the largest hospital in the country and serves as a teaching hospital to Muhimbili University of Health and Allied Sciences (MUHAS) located in Dare es salaam, the commercial capital of Tanzania. It has over 22 operating rooms with probably the highest transfusion rates and cancellations due to blood shortages. Patients were categorized as cases (those that received blood) and controls (those that did not receive blood). The decision to transfuse or not to transfuse was made by the treating team and not by the researcher

2.3 STUDY PERIOD

The study was conducted from May 2017 –December 2017.

2.4 STUDY POPULATION

The study involved post-operative elective surgical patients who were admitted at the surgical unit at Muhimbili National Hospital during the study period.

2.5 INCLUSION CRITERIA

i. Age $\geq$ 11 years.
ii. Elective surgery.
iii. Prophylactic Antibiotics administered.
iv. Consented to participate in the study.

2.6 EXCLUSION CRITERIA

i. Died either before developing surgical site infection.
ii. Died before completion of 30 day follow up period.
iii. Critically ill to consent or emergency case.

2.7 SAMPLE SIZE

Sample size of 200 patients with 100 in the blood transfusion group was needed to detect 2.5% risk in the occurrence of surgical site infection at power 80%, α 5% with the ratio of the unexposed to the exposed at 1.

2.8 METHODS

In the study, postoperative wounds were manually inspected daily during the in-patient stay and at every follow up visit. Follow up visits were conducted at two weeks and four weeks post discharge. Surgical site infection was considered to have developed when there was evidence of pain, redness, swelling, discharge or when an attending physician said so.

2.9 RECRUITMENT

Convenient, consecutive patients undergoing elective surgery were recruited till the desired sample size was achieved**.**

2.10 DATA COLLECTION

Participants were recruited during the perioperative time (within 24 hours following elective surgery). A structured standard questionnaire containing the below variables was administered. Predictor variables; hospital stay, duration of surgery, hemoglobin levels, age, sex, diabetes, hypertension, HIV infection, cigarette smoking, transfusion status. Outcome variables; surgical site infection.

2.11 DATA ENTRY, CLEANING AND ANALYSIS

Data was checked for completeness, then coded, and entered into SPSS version 22 for analysis. Categorical variables were summarized into proportions while continuous variables were summarized into means and medians with standard deviation and interquartile range. Variables were compared for matching between those that received blood transfusion versus those that did not. The groups were considered comparable with no difference as was statistically significant with P- value > 0.005. The difference in the occurrence of surgical site infection between the transfused and those not transfused was significant when the P-value was < 0.005.

2.12 ETHICAL CONSIDERATIONS

This study was approved by MUHAS institutional research board and MNH research and consultancy committee written informed consent was obtained from all participants. Patients were independently managed by their physicians, even when SSI had developed as per hospital protocols. Decision to transfuse or not was also with the attending doctor. All collected information was kept confidential before and after the study. Patient data was de-identified at the completion of data collection.

2.13 STUDY LIMITATIONS

Failure to collect information on wound class and ASA classification was a serious omission. How these two important determinants of SSI occurrence influenced our results thus remains unknown.

3.0 RESULTS

3.1 Descriptive analysis

200 study participants were recruited during the study period. The median age was 47.5 years with a range of 12 to 94 years. Majority of respondents were female (53%) while age group 45 year and above constituted 57%. More than half of the study respondent had HB level of 11 g/dl and above. In regards to hospital stay, 58% stayed less than 7 days (Table 1).

Table 1: Socio-demographic and clinical characteristic of study respondent, Surgical Unit, Muhimbili Hospital, 2018

Variable	Numbers	Percent
Sex		
Male	95	47
Female	105	53
Age group (years)		
<25	10	5
25-44	75	37
≥45	115	57
Hb level g/dl		
<11	67	33
≥11	133	67
Hospital stay (days)		
<7	116	58
≥7	84	42
Diabetes		
Yes	11	5
No	189	95
Hypertension		
Yes	16	8
No	184	92
HIV/AIDS		
Yes	33	17
No	167	83
Smoking		
Yes	63	32
No	147	68
Surgical SI		
Yes	17	9
No	183	91

Table 2: Socio-demographic and clinical characteristic of study respondent stratified by transfusion status, Surgical Unit, Muhimbili Hospital, 2018.

Variable	No. n (%) N=107	Yes n (%) N=93	P-value
Sex			
Male	55 (50)	40 (42)	0.234
Female	52 (50)	53 (58)	
Age group (years)			
<25	6(6)	4(4)	0.864
25-44	41(38)	34(37)	
≥45	60(56)	55(59)	
Hospital stay (days)			
<7	66 (62)	49 (53)	0.231
≥7	41 (38)	43(47)	
Diabetes			
Yes	7 (7)	4 (4)	0.488
No	100 (93)	89(96)	
Hypertension			
Hypertensive	8 (7)	8 (9)	0.769
Not hypertensive	99 (93)	85 (91)	
HIV/AIDS			
Positive	16 (15)	17 (18)	0.50
Negative	91 (85)	76 (82)	
Smoking			
Yes	33 (31)	30 (32)	0.829
No	74 (69)	63 (68)	

Of the 200-study respondents who were recruited 93 (47%) were transfused during surgery. More females were transfused compared to male (58% vs. 42%) while age group 45 years and above had the highest number of those who were transfused. Twelve percent of those who were transfused developed surgical site infection however there was no much different in regards to hospital stay after surgery among those who were transfused. The mean hospital stay was 1.4days.(Table 2).

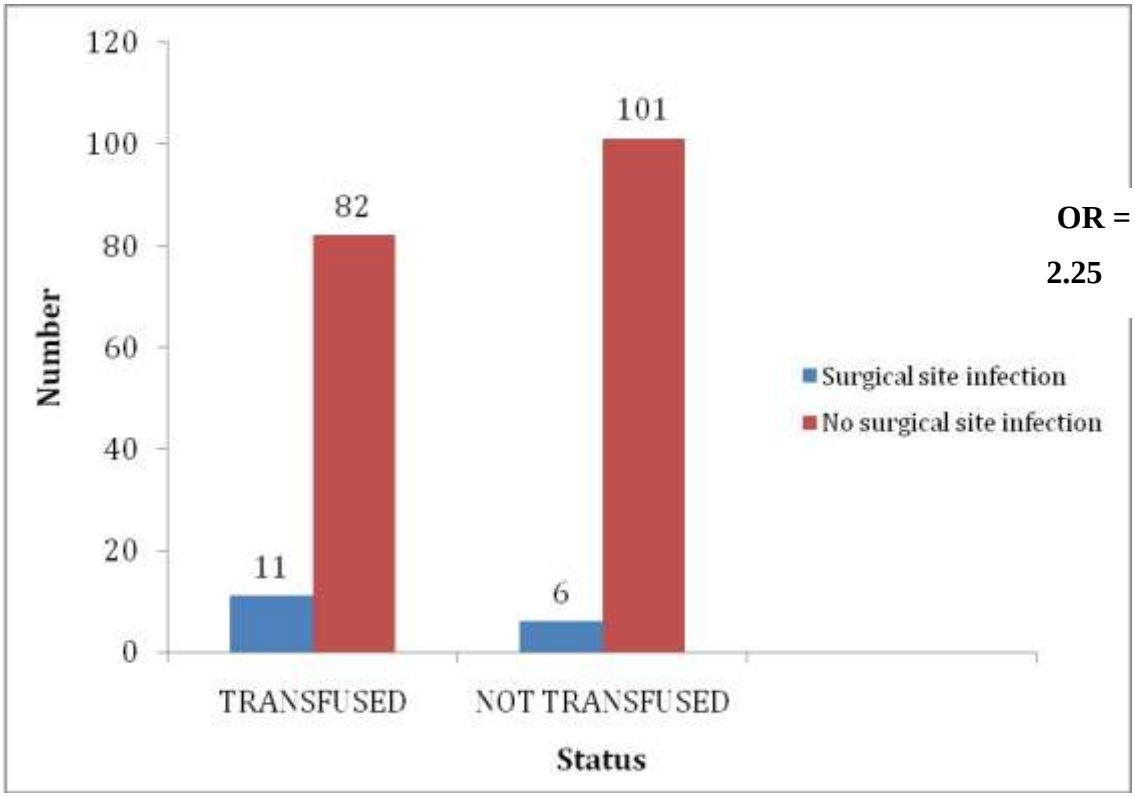


Figure 2: Blood transfusion status by surgical site infection among operated patients.

There was no difference in the proportion of surgical site infection by transfusion status (Figure 1).

Table 3: Factors associated with surgical site infection among post-operative patients, Muhimbili National Hospital, surgical unit, 2018.

	Surgical Site Infection					
Variable	**Yes**	**No**	**COR (95% CI)**	**P value**	**AOR (95% CI)**	**P value**
Sex						
Male	9	86	1.24 (0.46-3.4)	0.63	1.29(0.45-3.70)	0.63
Female	8	97				
Age group (years)						
<45	8	77				
≥45	9	106	1.22 (0.45-3.31)	0.69	1.63(0.57-4.64)	0.35
Hb level g/dl						
<11	11	56	**4.15** (1.46-11.8)	**0.004***	4.20 (1.47-11.6)	**0.004***
≥11	6	127				
Hospital stay (days)						
≥7	11	73	**3.3** (1.10-9.93)	0.025	3.29 (1.08-10.03)	**0.03***
<7	5	110				
Diabetes						
Yes	1	10	1.08 (0.13-8.99)	0.94	0.96 (0.10-8.90)	0.97
No	16	173				
Hypertension						
Yes	3	13	2.8 (0.71-11.01)	0.12	4.24(0.05-1.03)	0.05
No	14	170				
HIV/AIDS						
Yes	5	28				
No	12	155	2.30 (0.75-7.05)	0.13	2.83 (0.87-9.2)	0.080
Smoking						
Yes	8	55				
No	9	128	2.06 (0.75-5.64)	0.14	2.28 (0.81-6.42)	0.11
Blood transfusion						
Yes	11	82	2.20 (0.80-6.36)	0.116	2.18 (0.73- 5.96)	0.10
No	6	101				

COR- Crude Odds Ratio, AOR-Adjusted Odd Ratio

Several risk factors for surgical site infection were assessed during the study period. The odd of developing surgical site infection was 3.3 times higher among those who stayed seven or more days after surgical procedure as compared to those who stayed less than seven days. Hence, hospital stay duration ≥ 7days was independently associated with surgical site infection. The other variable that's was significantly associated with surgical site infection included hemoglobin of less than 11g/dl (AOR 4.15, 95% CI 1.47-11.6).The odd of developing surgical site infection was 2.2 times higher among those who reported to have been transfused however the association was not statistically significant (Table **3).**

4.0 DISCUSSION

This is one of the pioneer studies carried out to determine the role of blood transfusion in the occurrence of surgical site infection among operated patients at the surgical units of MNH.The study aim was to determine the influence of blood transfusion on SSI among post-operative surgical patients in the surgical units of Muhimbili National Hospital.

Surgical Site Infection (SSI) was found to occur at a rate of 12% in this study among elective cases. This is considered high as these are patients who should have been well optimized by thorough preparations before their surgery unlike if they were to be emergent cases. However, this figure is within the rates reported from other studies, and lower than that from similar settings. Most studies in Africa and other developing continents, the incidence of SSI is high at 16.4%. For instance in Ethiopia, SSI rates were found at 10.6% whereas in a private hospital in Kenya incident rates of 7.0% were found and the overall SSI rate in Nepal and Tanzania was 23% and 26%, respectively. This contrasts with the overall SSI rate in other regions like mainland China which is at 4.5% and that in Seoul, South Korea, at 3.3% and that in the US at 2-3%. (17). The occurrence of SSI in our setting might still be high as detection is passive after discharge from the hospital unlike in High Income countries where follow up is active with most SSI being diagnosed post discharge. Patients in our setting might consider superficial SSI as of less significance and report to lower facilities for wound care without mechanisms of reporting back to the treating facility. If we were to address the issue of SSI, a more robust approach is needed to detect them including an understanding of all its risk predictors which was the focus of our present study.

This might be one of the few studies that have examined the role of Blood Transfusion (BT) in the causation of SSI. There was a more than 2 fold increased rates of SSI among patients that received BT but failed to reach significant levels. This might be due to the design issues with the study with mixed cases and none consideration NNIS score. BT is a common practice in our set up among surgical patients due to our low threshold to transfuse and none adherence to

International recommendations on hemoglobin cut off values for elective surgery. It is known that BT is related to suppression of immunity through Transfusion Related Immune Modulation (TRIM) but how this plays to affect surgical wounds outcome has not received much attention. Few studies that have examined the role of BT in occurrence of SSI have reported contradicting results with one suggesting no effect and the other an increased risk (1, 9). This call for more studies preferable surgery-type-specific to reduce confounders associated with mixed cases designs and well controlled environments. Patients receiving BT might be having significant comorbidities that could as well lead to the occurrence of SSI. The hemoglobin cut offs at BT might also play significant role in wound healing that might not be influenced by perioperative BT.

Low hemoglobin level before surgery was found to have significant association with the occurrence of SSI. This might explain the increased risk among patients on BT as normal levels of oxygen delivery might not return immediately following BT due to effect of cold storage and deactivation of 2, 3 - DPG in the stored blood. Reduced Hb may cause disorder in surgical and traumatic tissue oxygenation and it can embitter ischemia and inflammation that is base of wound infection. Various studies have shown that, oxygen transferred by Hb is involved in all steps of wound healing including inflammation, granulation, neo angiogenesis, and tissue modeling. Therefore it is not surprising that reduced oxygen supply is a major driver of pathogenesis of wound infections. In particular, wound infections are maintained due to this hypoxic status of the surrounding tissue (18). Another factor that had significant influence of SSI was prolonged duration in the hospital pre-operatively. A number of studies have reported preoperative hospital stay as an important risk factor for SSI. A study from Serbia reports a difference in the duration of preoperative stay among those with and without SSI as 9.12 and 5.25 days, respectively. In another study, it is suggested that preoperative stay correlates with comorbidity and severity of illness (19).

Cigarette smoking was shown to have 13-fold increased odds for developing SSI among our cohort. But proportion of smokers was small giving the wider confidence interval. Smoking has been shown to be an independent risk factor for SSI. Smoking delays the healing of SSIs by causing local and systemic vasoconstriction. This results in tissue hypoxia and hypovolemia, an environment conducive to SSI (17). The mechanism of wound healing involves a cascade of interconnected cellular and molecular events for the occurrence of resurfacing and tissue reconstruction. Cigarettes have vasoconstrictor substances, which may impair the patient's circulation, since it reduces the diameter of vessels, restricting blood supply, which can trigger the death of some cells. The presence of this condition may predispose the individual to be infected and therefore have his hospital discharge delayed. Preoperative smoking cessation for four weeks or longer has several benefits to the patient, because it significantly reduces surgical site infections, delays in healing, suture dehiscence, hernias and fistulas (20). Some physiological factors may be involved: inadequate blood supply to the tissue, which can lead to necrosis; decreased inflammatory response and healing damage through oxidative mechanisms; deficiency in the proliferative phase of wound healing; and, altered collagen metabolism. This is similar to Zhang et al (1) findings and long held belief with strong scientific backing of the role of nicotine on leukocyte migration. AT MNH, there is no strong smoking cessation policy before elective major surgeries and this could explain the high risk observed.

5.0 CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

This study has failed to reject the null hypothesis hence but has shown a possible increased risk for SSI among patients receiving BT. Low hemoglobin, which is related to BT was however shown to have significant increased risk for occurrence of SSI. Similarly, prolonged hospital stay was also found to have increased risk of SSI development. Smoking was however found to be the most important factor in the occurrence of SSI in our cohort of patients.

5.2 RECOMMENDATION

- Further studies that are surgery specific to assess the role of blood transfusion influence on surgical site infection.
- Counseling the surgical patients on cessation of smoking at least two weeks before surgery to scale down on the adverse effects of cigarette smoke on wound healing.
- Adhere to established guideline in preoperative preparation to optimize postoperative outcomes.
- Active follow up on cases.

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APPENDICES

APPENDIX NO. 1Informed Consent Form (English Version)

ID No……

Consent to participate in the study on the **ROLE OF BLOOD TRANSFUSION IN THE OCCURRENCE OF SURGICAL SITE INFECTION AMONGTHE OPERATED PATIENTS** in thesurgical units at Muhimbili National Hospital, Dar -es -salaam- Tanzania.

Hello, pleasure to share with you! My names are Dr **Abdiaziz Sheikh Mohammed**, a postgraduate student pursuing Med Surgery at MUHAS, researching onthe outcomes of blood transfusion among postoperative patients in the surgical units of Muhimbili National Hospital, Dar- es- salaam, Tanzania.

Purpose of the study:

To compare postoperative outcomes among the surgical patients who are transfused and those not subjected to transfusion in the surgical units of Muhimbili National Hospital, Dar-es-salaam between May 2017 –Dec 2017.

What Participation Involves:

Should you allow me to recruit you in my study, you shall be interviewed with the aid of questionnaires, some detailed information on social demographic characteristics, past medical history and physical examination shall be requested. You may be subjected to some laboratory and radiological investigations to help us ascertain whether you are affected by the blood transfusion during the period of the surgery.

Confidentiality:

All delicate information you shall avail us and recorded on the questionnaires shall be safely confined into computers soft copies for the ease of storage and analysis with special code

number. The information obtained from you shall be treated with utmost confidentiality. Your details shall not be utilized during data analysis and report development.

Risks:

As the researcher, I wish to cause no harm whatsoever during your participation in this study. Any samples taken shall be only to ascertain that your health status is updated.

Rights to Withdraw and Alternatives:

Participation in this study is not obligatory but rather informed decision. Should you wish not to participate in the study or decide to stop participating in the study, you shall still be privileged enjoy healthcare services that any other patient shall receive this hospital. You may opt to drop out of the study at will anytime you wish so despite having given your consent. Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefits to which you are otherwise entitled.

Benefits:

If you agree to take part in this study, you will benefit by knowing the result of culture and sensitivity pattern of a collected specimen, and whenever there are culture positive results, appropriate medications will be prescribed and you will be advised accordingly.

Cost:

No payment will be requested from you as a fee to participate in this study.

In Case of Injury:

The researcher does not anticipate that any harm will occur to you or your child because of participation in this study. However, if any physical injury resulting from participation in this research should occur, we shall provide you or your child with medical treatment according to the current standard of care in Tanzania.

Whom to Contact:

If you ever have questions about this study, you should contact the study Principal Investigator, DrAbdiaziz S Mohammed, Resident; surgery at Muhimbili University of Health and Allied Sciences, P.O.Box 65001, Dar es salaam. Email address: abucamir@gmail.com, Mobile No: +255624717626.

If you have further clarifications, you may contact Dr BRUNO SUNGUYA, Chairperson, Senate Research and Publications Committee, P.O. Box 65001, Dar es Salaam. Tel: 2150302-6.

Agreement of Participation

I, ……..., identification number……, have read thecontents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant/guardian…….

Signature of witness (if participant cannot read) ……..

Signature of research assistant……

Date of signing consent…….

KIAMBATISHO NO.2 FomuyaRidhaa (Swahili Version)

ID No……

Ridhaa ya kushiriki katika utafiti juu ya visababishi vya maambukizi kufuatiya opareshenihasw akwa wale wagonjwa waliochangiwa damu muda wa opareshenikatika wodi za upasuaji Hospitali ya Taifa, Muhimbili.

Salamu! Jina langu ni Dk. Abdiaziz S. Mohammed, mwanafunzi wa Shahada ya Uzamili katika Chuo Kikuu cha Afya na Sayansi za Tiba, Muhimbili (MUHAS). Nafanya utafiti juu ya visababishi vya maambukizi katika vidonda vya wagonjwa waliofanyiwa upasuaji haswa wale waliochangiwa damu nyakati za opareshenikatika wodi za upasuaji Hospitaliya Taifa Muhimbili.

Madhumuni ya utafiti:

Kujua visababishi vya maambukizi katika vidonda vya wagonjwa waliofanyiwa upasuaji katika wodi za upasuaji Hospitali ya Taifa Muhimbili.

Jinsi ya kushiriki:

Kama utakubali kushiriki, utahojiwa maswali machache kuhusu matatizo haya na utaombwa kutolewa sampuli ya usaha kwa ajili ya uchunguzi zaidi.

Utunzajisiri:

Taarifa zote zitakazo kusanywa zitatunzwa kwa siri kwa kutumia herufi na nambari badala ya jina la mgonjwa.

Madhara/Athari:

Mtafiti hatarajii kutakuwa na madhara yoyote yanayotegemewa kutokana na utafiti huu.
Wakati mwingine maumivu kidogo yanaweza kutokea wakati wa kuchukua sampuli.

Uhuru wa kushiriki:

Kushiriki katika utafiti huu ni hiari yako. Kama utachagua kutokushiriki katika utafiti huu utaendelea kupokea huduma zote kama kawaida kutoka hospitali hii. Una we Kuacha kushiriki katika utafiti huu wakati wowote, hata kama baada ya kutoa idhini yako.

Faidazautafiti:

Kama utashiriki katika utafiti huu, maambukizo ya vidonda vya operesheni yatachunguzwa na kama kutakuwa maambukizi, matibabu stahili utapatiwa na utapatiwa ushauri itakapo takiwa kufanya hivyo.

Gharama:

Hakuna malipo yoyote utakayotozwa kama ada ya kushiriki katika utafiti huu.

Taarifa/Mawasiliano:

Endapo utahitaji kupata maelezo zaidi au taarifa yoyote kuhusu utafiti huu, wasiliana na DktAbdiaziz S Mohammed, Chuo Kikuu cha Afya na Sayansi za Tiba, Muhimbili, S.L.P 65001, Dar es Salaam. Barua pepe: abucamir@gmail.com. Simu ya Mkononi: +255624717626.

Kama utakuwa na maswali kuhusu haki yako kama mshiriki, unaweza wasiliana na, Dr BRUNO SUNGUYA ,Mwenyekiti wa kamati ya Utafiti na machapisho, S.L.P 65001, Dar es Salaam. Simu Nambari: 2150302-6.

Kukubali Kushiriki

Mimi……,mwenye nambari ya ushiriki……,

Nimeelezwa na nimesoma yaliyomo katika fomu hii, maswali yangu yamejibiwa Nimekubali kushiriki katika utafiti huu.

Sahihi ya Mshiriki/Mlezi……

Sahihi ya Shahidi (kama Mshiriki / Mlezi hajui kusoma)……

Sahihi ya Mtafiti Msaidizi……..

Tarehe ya Ridhaa……..

APPENDIX NO.3 Questionnaire (English Version)

BLOOD TRANSFUSION RELATED SSI AMONG POSTOPERATIVE PATIENTS INTHE SURGICAL UNITS OF MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM.

1. IDENTIFICATION DETAILS:

CODE NO:

ID NO……..

Hospital Reg. No……..

Date of interview…...……

Surgical ward/ Unit.

(a) General Surgery Firm I

(b) General Surgery Firm II

II. DEMOGRAPHIC DATA:

Age in years

Sex…….1). MALE

III.Hemoglobin level before surgery:

A. PREOPERATIVE FACTORS:

1). < 25 years

2). 25 – 44 years

3). > 45 years

2).FEMALE

Preoperative Diagnosis

Surgical Site Infection 1). YES 2). NO

Pre-existing illness

a). Diabetes Mellitus 1). YES 2). NO

b)Hypertension1). YES 2). NO

c). HIV/AIDS 1). YES 2). NO

d) History of cigarette smoking 1). YES 2). NO

B.INTRAOPERATIVE FACTORS:

Surgery performed

a). Hernia repair 1). YES 2). NO

b). Cholecystectomy 1). YES 2). NO

c). Exploratory laparotomy 1). YES 2). NO

d). Splenectomy 1). YES 2). NO

e). Colostomy 1). YES 2). NO

f). Hepatobiliary Surgery 1). YES 2). NO

h). Small bowel resections 1). YES 2). NO

j).Pancreatic Resections 1). YES 2). NO

k).By- pass biliary surgery). 1. YES 2). NO

l). Colorectal Surgery 1). YES 2). NO

m).Gastric Surgery 1). YES 2). NO

p).Duration of hospital Stay 1). < 7 Day 2). ≥ 7 Days

q) Operation duration1).< 3 hours, 2). ≥ 3 hours

r) Transfused 1) YES, 2) NO