



St. Paul Hospital Millennium Medical College Graduate Study Program

ASSESSMENT OF BLOOD TRANSFUSION PRACTICE IN EMERGENCY DEPARTMENTS.

A research proposal submitted to Department of Emergency Medicine and Critical Care

Dr. Alem Abera EMCC-R3

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ASSESSMENT OF BLOOD TRANSFUSION PRACTICE IN THE EMERGENCY
DEPARTMENT OF ADDIS ABABA BURN, EMERGENCY AND TRAUMA HOSPITAL
AND ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE: THREE MONTH
PROSPECTIVE CROSS SECTIONAL STUDY

A research proposal submitted to the department of Emergency Medicine and Critical Care
Presented in Partial fulfillment of the Requirements for the Degree of specialty training; St. Paul
Hospital Millennium Medical College

By: Dr. Alem Abera Oli

Emergency medicine and critical care Resident

Advisors:

Dr. Etsegenet Aklog

Assistant Professor of Emergency Medicine and Critical care

Saint Paul's Hospital Millennium Medical College.

Dr. Desalegn

Assistant Professor of Emergency Medicine and Critical care

Saint Paul's Hospital Millennium Medical College

Summary

Problem statement: Blood transfusion is a lifesaving procedure with particular significance in the emergency department for the resuscitation of the critically ill and bleeding patient. In our country there is lack of hospital specific transfusion guideline and also the lack of assessment of the practice of blood transfusion in terms of demographics and common risk factors that require transfusion.

Objectives: The objective of this study is to assess the practice of transfusion of blood products in the emergency department of AaBET hospital and St. Paul's hospital Millennium Medical College, Addis Ababa, Ethiopia

Methods: This research will use cross-sectional observational method to access all patients transfused in the ED of the above stated hospitals by using a structured questionnaire to be filled by attending physician. And the results will be analysed by using statistical analysis.

Time frame: June1 to August 31 2020, GC.

Estimated budget: 27,791.40 Birr

Conflict of interest: None

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Table of Contents

Summary	3
Acknowledgement	4
List of Tables	6
1. Introduction.....	8
1.1 Background.....	8
1.2 Statement of the problem	9
1.3 Significance of the study.....	11
2. Literature review.....	12
3. Objective of the study	17
3.1 General.....	17
3.2 Specific	17
4. Methods and materials	18
4.2 Study design.....	18
4.3 Study period.....	18
4.4 Source population and Study population	18
4.5 Inclusion and exclusion criteria	19
4.5.1 Inclusion criteria	19
4.5.2Exclusion criteria	19
4.6 Sample size determination	19
4.7 Study variable	19
4.6.1 Dependent variable	19
4.6.2. Independent variable	19
4.8 Operational Definition	20
5. Data collection tools and procedures	20
5.1 Data collection procedure	20
5.2 Data quality control.....	21
5.3 Data analysis.....	21
5.4 Ethical consideration.....	21
5.5 Dissemination of result	Error! Bookmark not defined.
6. Tentative Work plan	21
7. Budget breakdown	22
7. References.....	24
9. Annex.....	28
9.1 Questionnaire	28

List of Tables

Table of tentative work plan

Table of budget breakdown

List of acronyms and abbreviations

AaBET- Addis Ababa Burn, Emergency and Trauma hospital

aPTT- activated

BP- Blood pressure

ED- Emergency department

FFP- Fresh frozen plasma

HIC- High income country

Hgb/HCT- Hemoglobin/ hematocrit

ICU- Intensive Care Unit

IDA- Iron deficiency anemia

INR- International Normalized Ratio

LMIC- Low- and middle income country

OR- Operating rooms

PLT- Platelet

PRBC- Packed red blood cells

PR- Pulse rate

PT- Prothromin time

RR- Respiratory rate

SPHMMC – Saint Paul’s Hospital Millennium Medical College

WB- Whole blood

WHO- World Health Organization

1. Introduction

1.1 Background

Blood product transfusion plays a crucial role in the resuscitation of the critically ill or injured patient in the ED by improving the oxygen carrying capacity, increasing intravascular volume, correction of coagulopathies and/or improving overall homeostasis. In order to select the most appropriate blood product for use in ED, the physician must consider the cause of the deficit, severity of the symptoms, likelihood of ongoing hemorrhage, tissue oxygen requirement and the patient ability to compensate for the decreased oxygen carrying capacity which in turn is influenced by the age of the patient, underlying medical condition and their hemodynamic status.

Even if the benefit of transfusion practice in the emergency department is invaluable, like any other medication has infrequent, yet very significant, complications associated with it like increased risk of infection, alloimmunization, infection transmission and transfusion reactions.

Blood transfusion therapy that is included on the World Health Organization (WHO) list of essential medications. Blood is a scarce product that must be utilized in a safe and appropriate manner to ensure its sustainability. [1]

Since the beginning of the practice of transfusion, it has undergone significant changes based on the current knowledge and technology availability from the liberal used in the earlier time to the current more restrictive strategies to ensure the safety of the patient and proper utilization of blood products. With the introduction of evidence based transfusion guidelines and strategies for improved blood utilization has been shown to be cost effective. [2]

In order to ensure adequate supply and appropriate transfusion principle, the concept of patient blood management(PBM) was introduced by WHO in 2005. It is a patient-focused, evidence-based and systematic approach to optimize the management of patient and transfusion of blood products for qualitative and effective patient care. The three pillars of PBM are the optimization of hematopoiesis, minimization of blood losses, and optimization of tolerance to anemia. It is designed to improve patient outcomes through the safe and rational use of blood and blood products and by minimizing unnecessary exposure to blood products. [3]

1.2 Statement of the problem

The National Blood Service had been governed by the Ethiopian Red Cross since its inception in 1969, there are currently 24 regional blood banks available to increase the blood collection from capacity of 20,000 to 130,000 units of whole blood per year by 2015 starting from 2012 [4] In Ethiopia as disclosed by the National blood Bank on September 2015 around 87,000 units of blood were collected, although the country needs 200,000 annually.

In AaBET hospital a total of 3478 units of blood product was requested in the past six month with 36.4% of it being from ED, OR and ICU and total amount of 1219 units of blood products were transfused with 701(57.5%) of it being utilized in the ED, OR and ICU. This shows a major uptake of the blood products by the ED, ICU and OR that could affect the management of the patients. While in SPHMMC during the past six months a total of 948 unit of blood product was requested from the adult ED while 581 units were transfused.

In high-income countries, transfusion is most commonly used for supportive care in cardiovascular and transplant surgery, massive trauma, and therapy for solid and hematological malignancies, meanwhile In low- and middle-income countries it is more often used to treat pregnancy-related complications and severe childhood anemia [5] In sub-Saharan Africa, blood transfusion is critical to the treatment of diverse pathologies including malaria associated anemia, obstetric hemorrhage, and trauma. [6]

Anemia affects about one-third of the world population with deleterious clinical and economic impact. Iron Deficiency Anemia is a common cause anemia in patients presenting to the emergency department and is often treated with RBC transfusion. [7] .

Currently in a more restrictive transfusion strategy is being recommended in patients with hemoglobin level less than 7g/dl be the trigger for initiation of RBC transfusion for patients are hemodynamically stable even critically ill patient with no previous heart disease or undergoing major surgery. With the endpoint for transfusion being hemoglobin level above 7g/dl. But for patients with acute coronary syndrome, orthopedic surgery and cardiac surgery the recommendation is the trigger of hemoglobin less 8 g/dl. [8] [9].

While studies from high-income countries support restrictive blood transfusion thresholds in medical patients. In LMIC where the etiologies of anemia and baseline health states differ greatly; the appropriateness of current blood transfusion guidelines is not clear. [10]

Worldwide, injuries account for approximately five million mortalities annually, with 90% occurring in LMIC. Bleeding is the second leading cause of death, 30% to 40% of overall mortality after major trauma of which 7% is considered preventable, and is considered the predominant cause of preventable death after hospital admission. [11]

Acute bleeding may cause early death through exsanguination or secondary hypoperfusion and coagulopathy, which can precipitate multiple organ dysfunction and later mortality. In order to prevent these complications early recognition of blood loss, control of bleeding and restoration of circulating volume are critical to the management of hemorrhagic shock, and transfusion of blood components is a key intervention. Currently in high income countries(HIC) recommendation is to start the patient with FFP:PRBC: PLT of 1:1:1 so as to achieve faster hemostasis [12] [13]. However, access to a safe and adequate blood supply remains an enduring public health challenge in much of Sub-Saharan Africa and LMIC. [14] [15] There is a paucity of high-quality data to inform appropriate use of blood transfusion therapies in LMIC injury care due volume of available emergency blood appears inadequate for injury care, and doesn't consider the need for other causes of acute hemorrhage (e.g. gastric, gynecological, etc.) and no international consensus guidelines to inform the care of injured patients. [15] The. Furthermore, lack of other blood components (i.e. plasma and platelets) presents a challenge in this low-resourced setting. [16]

Lack of updated and current evidence-based transfusion guidelines and lack of awareness about clinical use of blood among physician can be proposed to be the possible contributing factors in the inappropriate clinical use of blood products in our country too.

1.3 Significance of the study

The practice of blood transfusion is daily activity in the ED and appropriate and safe transfusion which starts in the ED will improve the outcome of the patient. To date there is no data for the current transfusion triggers and endpoint which have been used to guide the resuscitation of critically ill patient and those with trauma in the ED.

Additionally, this will be baseline assessment of the current trends will be a stepping stone for the implementation of further improvement strategies.

2. Literature review

Blood transfusion is an essential component of health care, which saves millions of lives each year. Every second, someone in the world is in need of blood for surgery, trauma, severe anemia or complications of pregnancy [17]

In the emergency department the primary aim of blood transfusion is to attain hemodynamic stability and prevent complications in the critically ill and trauma patients with underlying anemia, thrombocytopenia and/ or coagulation abnormalities. This is attained by developing understanding on the current and evidence based guidelines.

Problem to proper utilization arises because the guidelines are based on expert recommendations from randomized control trials and observation [18] . The use of this current recommendations to be generalized to developing countries is unknown. [10]

Despite the prevalence of IDA in the general population clinical guidelines for identifying and managing it in the ED are lacking. Patients presenting to the ED with iron deficiency anemia are under recognized and over-transfused. While blood transfusion can be a life-saving therapy in acutely hemorrhagic patients with symptomatic hemodynamic instability, in cases of chronic well compensated anemia a different approach should be applied based on Patient Blood Management principles. [19] [20]

The current trend of PBM which focuses on alternative to transfusion like oral iron therapy and intravenous iron therapy are getting more focus for use in the ED. There is increasing evidence that intravenous iron maybe superior to oral iron alone for many patients and in some circumstances, maybe be superior to red blood cell transfusion. [21] Although clinical history may strongly suggest the diagnosis of IDA laboratory evaluation with low iron stores and hypochromic microcytic red cells are its hallmarks are not routinely done in the ED. [19] In hemodynamically stable patient with IDA, blood transfusion should be the exception rather than the rule. Currently the AABB is recommending that transfusion is not recommended for IDA in a hemodynamically stable patient irrespective of their hemoglobin level. [9] [8] [18]

In an international review of the appropriateness of PRBC transfusion in various scenarios, the International Consensus Conference on Transfusion Out-comes observed that 59% of transfusions were inappropriate, 29% were uncertain, and only 12% were appropriate. [22] In a

2017 multicenter cross-sectional observational study of 5 regional hospitals in Spain which assessed the appropriateness of RBC transfusion indications, according to the pre-transfusion Hgb and patient characteristics and transfused volume in adult patients who attended ED over a period of three months. It identified the underlying pathologies as hemato-oncological diseases (24%), bleeding due to antiplatelet (20%) or anticoagulation (20%) therapy, chronic kidney disease (15%), chronic heart failure (13%), and chronic liver disease (8%). Prescription was found to be inappropriate in 21.4% (197/908) of all episodes. With over-transfusion in 45% (232/516) of the appropriate prescription and 21.5% (197/908) in those without appropriate indication and 41% (584/1433) RBC units unnecessarily transfused. Which in comparison to 1997 study to evaluate the appropriateness of RBC transfusion in ED of a Spanish hospital which found 44% as appropriate shows significant improvement in the appropriateness reflecting the influence of clinical guidelines on the physicians decision- making. [22]

Similarly, in 2019 an observational, cross-sectional study was done in the La Paz University Hospital and the Hospital of Salamanca, Spain, to reassess the suitability of the indication for transfusing RBC and the volume transfused in ED which studied a total of 381 patients excluding those with massive hemorrhage and patients with plasma and platelet transfusion. Only 54.9% (209/381) of the prescriptions for transfusion were considered appropriate, with significant differences according to the indication. Of the 209 patients with an appropriate prescription, 143(68.4%) received an improper volume of blood components (over transfusion). [23]

In 2015 a retrospective study at Legnano General Hospital, northern Italy, the general prevalence and the treatment policy of anemic patients referring to the Emergency Department was assessed by studying the full blood cell count data from patients admitted to the ED for any reason. In a group of 22,329 patients the overall prevalence of anemia was 27.5% (6144 patients) severe anemia of 1.6%. Among the anemic patients, 281 / 6144 (4.6%) were transfused. The applied transfusion policy showed an overall good level of appropriateness (74.5% of transfusion episodes) but the appropriateness of the administered red blood cell mass was low (8.8%), due to over-transfusion (104 patients out of 114; 91.2%). [24]

In the same setting from 2018 to 2019 pre and post study on alternatives to reduces red blood cell unit transfusion in the Emergency Department by using early intravenous iron administration

was done. It evaluated 226 anemic patients in the pre-protocol phase and 267 patients as the post-protocol group. The appropriateness of transfusion therapy and administered PRBC volume improved from 68.8% to 90.0% and from 13.3 to 87.0% in the two observed periods. With respect to hemoglobin value, 108 of 162 patients (67.1%) received intravenous iron with hemoglobin below 8.0 g/dl and 26 of 106 (24.5%) in the hemoglobin range of from ≥ 8.0 to < 9.0 g/dl. And clear tendency to reduce hospitalization in the post-protocol phase (38.8 vs 63.8%) was observed. [19]

A retrospective study at four centers in the Calgary Zone from 2014-2018 Alberta which reviewed the number of RBC transfusions that were given in emergency department and the proportion of which were potentially avoidable. Out of 8651 patient with iron deficiency anemia 990 (11.4%) of them received transfusions; of these 71.8% were indicated while 28.1% were potentially avoidable. Out of the transfusions that were indicated, 32.3% were given to patients with a hemoglobin < 7 g/dL and 67.7% were given to patients with a hemoglobin > 7 g/dL but who were hemodynamically unstable. While out of the transfusions that were potentially avoidable, the highest number were given to those with hemoglobin 7.1-8 g/dl. The potentially avoidable transfusion rates from 2014 to 2018 showing the rate has decreased since the release of the guidelines. [25] A significant percentage of ED blood product transfusions are discordant with guideline recommendations. [26]

With regards to our country a retrospective study in Black Lion Hospital, Addis Ababa from September 2009 to August 2010 which assessed blood and blood component utilization studied 361 transfused study subjects and 856 units of blood were transfused with the mean of 2.37 units per recipient showing whole blood was most commonly transfused to 307 (85%) patients, and the combination of two blood products was administered to 27 (7.5%) patients. Plasma was transfused only for a single patient (0.3%). It also assessed patients who did not clinically improve, and 66.2% were those transfused with whole blood. Significant associations were found between the overall improvement status of patients with the type of blood and blood product administered. [27]

In cross sectional study at Black Lion Hospital 2016 of blood requisition, transfusion practice and factors associated with transfusion in elective surgical procedure which included all 242 elective surgical patients 55 (22.7%) of patients were transfused with 107 (20.4%) units of the

prepared blood giving cross-match to transfusion ratio of 4.9, transfusion probability (%T) 22.7% and transfusion index of 0.44. It also determined that independent predictors of perioperative blood transfusion were being neurosurgery (craniotomy), hemoglobin <11.0 g/dl and intraoperative blood loss of >15 % [28]

A retrospective study in SPHMMC gynecology- obstetrics department in 2016 show a total of 532 units of blood being requested for cross-matching for the 265 patients who underwent hysterectomies with a total of 74 units. The results of the study showed that for most of the elective hysterectomies performed at SPHMMC, the level of blood utilization was minimal and there is significant over ordering of blood and associated wastage of resources. [29]

These study demonstrates that a simple algorithm preceded by educational initiatives can lead to a better, safer and cost-saving utilization of blood products, in accordance with Patient Blood Management principles. [19]

For any actively bleeding trauma patient the goal is to restore oxygen supply to tissue but In 2012 to 2013 randomized study at 12 trauma centers in Huston, Texas on assessing deficiencies associated with the classic definition of massive transfusion(MT), the concepts of critical administration threshold(CAT) and resuscitation intensity(RI) were developed to better quantify the overall severity of illness and predict the need for transfusions and early mortality. Patients randomized in the Pragmatic, Randomized Optimal Platelet and Plasma Ratios (PROPPR) trial. Of 680 patients, 301 patients met MT definition, 521 were CAT, and 445 were RI4+. Of those that died, 23% never reached MT threshold, but allwere captured by CAT+ and RI4+. It concluded that CAT was best sensitive and RI had better specificity and good negative and positive predictive value. [12]

In a retrospective study in trauma unit at Red Cross War Memorial Children's Hospital, Cape Town, South Africa of 2009 to 2014 done to review the protocol adherence to blood transfusion thresholds in 144 pediatric trauma patients age 0 - 13 years who received a blood transfusion. Hemoglobin transfusion thresholds was defined as 10 g/dl for neurotrauma patients and patients requiring skin grafting or a musculocutaneous flap (group 1). All other trauma patients had an hemoglobin transfusion threshold of 7 g/d (group 2). The mean age 5.2 years. The mean

hemoglobin increase after transfusion was 3.5 g/dl. Adherence to the transfusion hemoglobin threshold protocol was 96.7% for group 1 v. 34.0% for group 2. [30]

In Sacramento, California from 2019 which had developed its own of the pediatric trauma transfusion guideline based on expert opinion in which the parameters for the initiation of transfusion will be evidence of ongoing hemorrhage and /or hemodynamic instability. And also 20:10:5 ml/Kg of PRBC: FFP: PLT be used in the resuscitation if resuscitation with crystalloid is unresponsive, while avoid permissive hypotension. Also RBC transfusion be started at hemoglobin level below 6g/dl unless unstable or bleeding. [31]

In a 2019 global systematic review of 194 publications including 190 studies on the use of platelet transfusion in thrombocytopenic patient stated that the most common indications for platelet transfusion was prophylactically to prevent spontaneous bleeding with approximately 30% for the treatment during active bleeding. Which also reviewed that the real world evidence of platelet transfusion generally increased the platelet count which varied by patient characteristics but this does not always translate into a clinically significant risk in the reduction of risk of bleeding [32]. It also showed that the outcome and threshold for platelet transfusion varies based on the underlying etiology.

3. Objective of the study

3.1 General

To assess the current transfusion practice in the ED

3.2 Specific

To review the clinical indications and the demographics of transfusion in the ED

To review the current triggers and endpoints transfusion being applied

To review the pattern and efficiency of blood ordering and blood utilization

To identify the current problems or short comings associated with transfusion

4. Methods and materials

4.1 Study setting

This study will be conducted at SPHMMC adult ED and AaBET hospital ED.

SPHMMC is the second largest hospital in the country, more than 2000 patients visit the hospital per day. The adult emergency department is covered 24 hours a day by an Emergency medicine and critical care-led team consisting of an attending physician and residents from departments of emergency medicine, internal medicine, general surgery, radiology and various other sub-specialties as well as interns. In this hospital various types of cases are seen on daily bases excluding the trauma patients and patients with neurosurgical and orthopedic related complaints.

AaBET hospital is part of Saint Paul's Hospital Millennium Medical College. It is the first Emergency and Trauma hospital in Ethiopia. It is a place where department of emergency medicine and critical care, neurosurgery, orthopedics surgery and plastic surgery departments works as a unit in the management of cases.

4.2 Study design

A descriptive cross-sectional study will be conducted at the two emergency departments

4.3 Study period

From June 1 to August30 2020 GC

4.4 Source population and Study population

Source population- all patients seen in the ED during the study period

Study population-All the patients that were transfused at the ED during the study period will be included in the study

4.5 Inclusion and exclusion criteria

4.5.1 Inclusion criteria

Patient transfused with any blood product in the ED

4.5.2 Exclusion criteria

Pediatric patients transfused for other indications than trauma related complications

Pregnant and postpartum patients transfused for indications other than trauma related complications

4.6 Sample size determination

All patients that will be transfused during the study period.

4.7 Study variable

4.6.1 Dependent variable

Amount of each blood product transfused

Post transfusion

Vital signs- heart rate, blood pressure, respiratory rate and oxygen saturation

Laboratory results- hemoglobin/hematocrit, platelet, PT,PTT, INR others

Transfusion complication

Achieved endpoint of transfusion

4.6.2. Independent variable

Age

Sex

Indication for transfusion

Co-existing disease

Number of units ordered

Types of blood product ordered

Goal of transfusion planned

Pre-transfusion

Vital signs- heart rate, blood pressure, respiratory rate and oxygen saturation

Laboratory results- hemoglobin/hematocrit, platelet, PT,PTT, INR others

4.8 Operational Definition

Blood product- Any therapeutic substance prepared from human blood.

Anemia- hemoglobin < 13g/dl in males and 12mg/dl in females

Severe <7g/dl

Thrombocytopenia- platelet count < 150,000cells/microliter

Mild- 100,000 -150,000

Moderate – 50,000-99,000

Severe <50,000/microliter

MT of 10 U or greater red blood cell (RBC) in 24 hours, replacement of 50% of blood volume within 3 hours or ongoing transfusion during rapid bleeding like >150mL/minute

CAT+, 3 U or greater RBC in the first hour; and

RI, total products in the first 30 minutes (1 U RBC, 1 U plasma, 1000 mL crystalloid, 500 mL colloid each valued at 1 U

5. Data collection tools and procedures

5.1 Data collection procedure

Data collection will ensue after the research committee has approved the proposal and the questionnaire has been pre-tested on selected individuals to ascertain the legibility and the

completeness. The questionnaire will be filled by the attending physician at the time of the transfusion with the data to be filled for every patient in the emergency department that has been transfused during the study period

5.2 Data quality control

To avoid observational bias the questionnaires will be filled not containing the name of the collector and the results will be cross checked with the transfusion details in the patient card and the registry at the blood bank.

5.3 Data analysis

Data will be entered Descriptive statistics including frequency distribution, mean, standard deviation, percentages and interquartile range (25th –75th) will be used to describe the different quantitative data). Qualitative data will be compared using the chi-square test and quantitative data using the unpaired Student t test or the Mann-Whitney nonparametric test when appropriate. P value of <0.05 will be taken as statically significant. The collected data will be entered into EPI INFO 7, processed and analyzed by using SPSS version 25 statistical software

5.4 Ethical consideration

In order to ensure anonymity the confidential detail of the patient will not be recorded into the questionnaire like the name of the patient

6. Tentative Work plan

S.N	Activities	Responsible body	Time frame							
			March	April	May	June	July	August	September	October

1.	Proposal development and submission to advisors	Principal investigator								
2	Feedback from advisor	Advisor and Principal investigator								
3	Approval and proposal defense									
4	Questionnaire testing and duplication	Principal Investigator								
5	Training data collectors and data collection									
6	Data entry analysis	Principal Investigator								
7	Finalization and final comment from advisor	Advisors and principal investigator								
8	Final Paper submission	Principal Investigator								

7. Budget breakdown

S.N	List of items	Number	Qualification	Payment(birr)	Total
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1	Personnel				
	Data collectors	6	Physician	50birr/questionnaire (minimum of 400 questionnaire)	20,000
	Data collectors training	6	Physician	600(100 birr/individuals)	600
2	Supplies				
	Pen	10	8	10	80
	Pencil	Each	8	5	40
	Sharpener		4	7	28
	Duplication Paper	Ream	20	100birr/ream	2000
	Printing service	Page 3	1200 pages	1birr/page	3600
	Note book		6	20	120
	Contingency 5%				1323.40
Total cost					Birr 27,791.40

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9. Annex

9.1 Questionnaire

1) Hospital AaBET SPHMMC

2) Patient identification

MRN

Age

Sex

3) Reason for presentation/ transfer to the emergency

4) Diagnosis of the patient

5) Indication for transfusion

6) Any chronic medical condition

7) Pre-transfusion

i) Laboratory results

- ◆ Patient blood group
- ◆ Hgb/HCT
- ◆ Platelet count
- ◆ PT/INR
- ◆ aPTT
- ◆ Others

ii) Vital signs

- ◆ BP
- ◆ PR
- ◆ RR
- ◆ Temp
- ◆ Oxygen Saturation

iii) Type of blood requested and amount

- ◆ Whole blood
- ◆ PRBC
- ◆ FFP
- ◆ Platelet

iv) Goal of transfusion

8) Transfusion

i) Time elapsed between request and start of transfusion

ii) Type of blood patient transfused with and unit

iii) Whole blood

- ◆ PRBC
- ◆ Platelet
- ◆ FFP

iv) Any medication given at the start or end of transfusion

v) Time elapsed during transfusion

9) Post transfusion

i) Vital signs

- ◆ BP
- ◆ PR
- ◆ RR
- ◆ TEMP
- ◆ Oxygen Saturation

ii) Laboratory results

- ◆ Hgb/Hct
- ◆ Platelet
- ◆ PT/INR
- ◆ APTT
- ◆ Others

10) Any discrepancy between the requested and transfused amount of blood product

- ◆ Yes
- ◆ No

11) if yes to Question no 10, reason

- a) patient was transferred before completion
- b) the condition improved
- c) the requested product was not available
- d) other, please state,

12) Any adverse reactions.

- ◆ Yes
- ◆ No

13) If yes, please state below

14) Any difficulty or problem during or prior to transfusion process