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Incidence and Risk Factors of Acute Transfusion Reactions among Adult Transfused Patients at Worabe Comprehensive Specialized Hospital, Silte Zone, Central Ethiopia

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This is to certify that the thesis prepared by Shemsu Kedir, entitled “Incidence and Risk Factors of Acute Transfusion Reactions among Adult Transfused Patients at Worabe Comprehensive Specialized Hospital, Silte Zone, Central Ethiopia and submitted in partial fulfillment of the requirements for a Master of Science Degree in Clinical Laboratory Sciences (Hematology and Immunohematology), complies with the regulations of the university and meets the accepted standards with respect to originality and quality.

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Table of Content

Contents

Acknowledgement i
Table of Content ii
List of Figures iv
List of Tables v
Abbreviations and Acronyms vi
Abstract viii
1. Introduction 1
1.1. Background 1
1.2. Statement of the Problem 3
1.3. Significance of the Study 5
2. Literature Review 6
3. Study Objective 12
3.1. General objective 12
3.2. Specific objectives 12
4. Methods and Materials 13
4.1. Study setting and study period 13
4.2. Study Design 13
4.3. Population 13
4.3.1. Source population 13
4.3.2. Study population 13
4.4. Eligibility criteria 13
4.4.1. Inclusion criteria 13
4.4.2. Exclusion criteria 13
4.5. Study Variables 14
4.5.1. Dependent variables 14
4.5.2. Independent variables. 14
4.6. Sample size calculation and Sampling technique 14
4.6.1. Sample size determination 14
4.6.2. Sampling Techniques 15
4.7. Socio-Demographic and Clinical Data Collection Procedures 15
4.8. Sample Collection and Laboratory Examinations 16
4.8.1. Pre-transfusion sample collection: 16

4.8.2. Post- transfusion samples collection: 16
4.8.3. Blood culture procedures: 16
4.9. Data Quality Management 17
4.10. Data Analysis 18
4.11. Operational Definitions 18
4.12. Ethical Consideration 19
4.13. Dissemination of Result 19
5. Results 20
5.1. Socio-demographic characteristic of study participants 20
5.2. Clinical characteristics of study participants 20
5.3. Blood Component Type, Characteristics of Transfused Blood, and 22
Blood Group of Transfused Patients 22
5.4. Transfusion reactions and associated factors 23
5.5. Comparison of Pre- and Post-Transfusion Hematological Parameters among Patients Who Developed Acute Transfusion Reactions 26
6. Discussion 27
7. Strength and Limitation of the Study 32
7.1 Strength of the study 32
7.2 Limitations of the study 32
8. Conclusion 33
9. Recommendations 33
10. References 35
ANNEX I: English version participant information sheet 40
ANNEX II. Amharic version participant information sheet 42
ANNEX III- Consent form (English version) 44
ANNEX IV- Amharic version consent form 44
ANNEX V. Materials and Reagents 45
ANNEX VI: Laboratory procedures and principles 46
ANNEX VII: Questionnaire/data collection checklist form (English version) 53
ANNEX VIII- Questionnaire (Amharic version) 57
ANNEX-IX. Declaration sheet 62

List of Figures

Figure 1:-Conceptual framework……..……11

Figure 2: Blood group of transfused patients at WCSH from January 15, 2026 to April 15, 2026…….…….23

List of Tables

Table 1: Socio-Demographic Characteristics of Transfused Participants at WCSH from January 15, 2026 to April 15, 2026…….…… 20

Table 2: Clinical Characteristics of Transfused Patients at WCSH from January 15, 2026 to April 15, 2026…….…….……21

Table 3: Type and Characteristics of Transfused Blood Component with Frequency of Transfused Patients at WCSH from January 15, 2026 to April 15, 2026……22

Table 4: Incidence and Type of Transfusion Reaction among Adult Transfused Patients at WCSH from January 15, 2026 to April 15, 2026……..…….24

Table 5: Bivariable and Multivariable Binary Logistic Regression Analysis of Associated Factors of ATRs among Adult Transfused Patients at WCSH from January 15, 2026 to April 15, 2026…….……25

Table 6: Comparison of Pre- and Post-Transfusion Selected Hematological Parameters among Patients Who Developed ATR at WCSH from January 15, 2026 to April 15, 2026……26

Abbreviations and Acronyms

AAU	Addis Ababa University
ABO	ABO blood group system
AHG	Antihuman-Globulin
AHR	Acute Hemolytic Reaction
AOR	Adjusted Odds Ratio
ATR	Acute Transfusion Reaction
CBC	Complete Blood Count
CI	Confidence Interval
COR	Crude Odds Ratio
DAT	Direct Anti-Globulin Testing
DMLS	Department of Medical Laboratory Sciences
EDTA	Ethylene Di-Amine Tetra-Acetic Acid
FFP	Fresh Frozen Plasma
FNHTR	Febrile Non-hemolytic Transfusion Reaction
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen
IQR	Interquartile Range
IRB	Institutional Review Board.
ISTARE	International Surveillance of Transfusion-Associated Reactions and Events
K3-EDTA	Tri-Potassium Ethylene Di-Amine Tetra Acetic Acid
OR	Odds Ratio
PI	Principal Investigator
PLT	Platelets
PRBCs	Packed Red Blood Cells
RBC	Red Blood Cells
Rh	Rhesus factor

Rh D	Rhesus blood group system (D antigen)
SOP	Standard Operating Procedure
SPSS	Statistical Package for the Social Sciences
TACO	Transfusion-Associated Circulatory Overload
TRALI	Transfusion-Related Acute Lung Injury
TSB	Trypticase Soy Broth
US	United States
WB	Whole Blood
WCSH	Worabe Comprehensive Specialized Hospital

Abstract

Background: Acute adverse transfusion reactions (ATRs) are adverse events that occur within 24 hours of blood transfusion and contribute to transfusion-related morbidity and mortality. In Ethiopia, data on ATR incidence and associated factors are limited, and no studies have been published from central Ethiopian region.

Objectives: To determine the incidence and associated risk factors of ATRs among adult blood transfused patients at Worabe Comprehensive Specialized Hospital (WCSH), Silte zone, central Ethiopia.

Methods: An institution-based prospective study was conducted at WCSH. A total of 239 adult transfused patients who received whole blood or blood components were selected using consecutive sampling technique. ATRs were defined as any adverse reaction occurring within 24 hours of transfusion and were assessed by clinical monitoring and laboratory investigations. Accordingly, socio-demographic and clinical data were collected using structured questionnaires and checklists. Pre-transfusion blood and urine samples were collected to determine baseline Complete Blood Count (CBC), ABO/Rh blood group, Direct Antiglobulin Test (DAT) and urine hemoglobin. Post-transfusion blood and urine sample also collected from patients suspected for ATR to perform post transfusion CBC, ABO/Rh, re-cross-match, DAT, blood culture and urine hemoglobin. CBC testing was performed using the MINDRAY BC 6800 PLUS hematology analyzer, at WCSH hematology laboratory. Cross-matching was performed using the immediate-spin method. Suspected cases underwent repeat testing. Data were analyzed using SPSS Version 27. Descriptive statistics, bivariable and multivariable logistic regression, and Wilcoxon Signed-Rank test were used, with p-value <0.05 considered significant.

Results: The incidence of ATR was 7.1% (95%CI: 3.8- 10.4%). Febrile non-hemolytic reaction (FNHTR) was the predominant reaction type (58.8%), followed by allergic reactions (35.3%) and transfusion-related acute lung injury (TRALI, 5.9%). History of abortion (AOR=6.59; 95%CI: 1.22 -35.50), blood storage duration ≥14 days (AOR= 9.34; 95% CI: 1.35- 64.67) and transfusion of ≥3 units of blood (AOR= 8.82; 95% CI: 1.60- 48.72) were significantly associated with ATR. Among patients who developed ATR, RBC count increased significantly from 2.20 $\times 10^{12}$/L 2.71 $\times 10^{12}$/L (p = 0.001), hemoglobin increased from 6.5 g/dL to 8.3 g/dL (p = 0.001), and platelet count increased from 106 $\times$ 10^9/L to 110 $\times 10^9$/L (p = 0.014), while WBC count showed no significant change from 5.04$\times$ 10^9/L to 4.99 $\times 10^9$/L (p = 0.201).

Conclusion: ATRS were relatively common among adult transfused patients at WCSH, predominantly FNHTR and allergic reactions. Abortion history, prolonged blood storage and multiple-unit transfusion were important risk factors. Strengthening hemovigilance and improving transfusion practices are recommended.

Keywords: acute transfusion reaction, blood transfusion, hemovigilance, Ethiopia.

1. Introduction

1.1. Background

Blood transfusion is the process of transferring whole blood or blood components from one person to another of the same species in order to restore blood volume, correct anemia, treat coagulation defects, or support patients during critical illness or surgery (1). In modern medicine, blood transfusion is a common lifesaving treatment used for the management of severe anemia, major hemorrhage, trauma, surgery, hematological disorders, and obstetric complications (2–4). The transfusion can be whole blood (WB) or blood components, including packed red blood cells (PRBCs), platelets (PLT), fresh frozen plasma (FFP), and plasma derivatives, according to the patient's clinical needs (5). WB is mainly advised for acute blood loss requiring replacement of both red blood cells (RBCs) and plasma. PRBCs are transfused to treat anemia and improve oxygen-carrying capacity. PLT transfusion can be utilized to treat bleeding associated with thrombocytopenia or platelet abnormality, while FFP is transfused to replace coagulation factors for the patients with bleeding disorders or coagulation abnormalities. Blood components have different storage conditions and shelf lives; WB can be stored for up to 21–35 days at 1–6°C and PRBCs for up to 21–42 days at 1–6°C depending on the preservative and additive solution used, platelet concentrates are stored at 20–24°C with continuous agitation for up to 5–7 days, and FFP is stored at −18°C or below for up to one year. The use of blood components rather than whole blood allows more efficient utilization of donated blood and enables targeted therapy for specific clinical indications (6–8).

Although blood transfusion is an essential medical treatment that plays a life-saving role, it is also potentially hazardous procedure that should be given only when the clinical benefits to the patient clearly outweigh the potential risks. Blood transfusion reactions (BTRs) are adverse effects that occur during or after blood transfusion in the transfused patients (9,10). BTRs are classified as acute, manifesting within 24 hours of transfusion, or delayed, occurring after 24 hours (11). Patients experiencing acute transfusion reactions (ATR) may develop allergic or anaphylactic reactions, transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), febrile non-hemolytic transfusion reaction (FNHTR), and acute

hemolytic transfusion reaction (AHR) bacterial contamination-related sepsis, isolated hypotension, and other less common reactions (12,13).

The prevalence, type and severity of transfusion reactions are affected by several factors, including recipient's sex and age (14), underlying clinical condition, storage time of the transfused blood, number of transfused units, and prior transfusion or pregnancy history (15,16). Furthermore, multi-transfused patients and multiparous women are at a higher risk for febrile and immune-mediated reactions, whereas aged patients and those with cardiac and vascular disorder are more susceptible to volume overload related complications (17). Notably, non-infectious transfusion reactions are estimated to occur about 1000 times more frequently than transfusion-transmitted infections (8).

Common clinical signs and symptoms of a transfusion reaction include changes in circulation (e.g. increased bleeding, hypertension or hypotension, tachycardia); immune-related reactions (e.g. itching, flushing, fever, chills or rigors, urticarial); respiratory manifestations (e.g. coughing, wheezing, dyspnea, or new infiltrates on chest X-ray); Other symptoms can include anxiety, unexplained discomfort, back or chest pain, pain at the intravenous infusion site or along the vein (11).

The assessment of an acute transfusion reaction relies on both clinical investigations (including history, physical examinations and vital signs), and laboratory findings, including complete blood count (CBC), ABO and Rh grouping, compatibility testing, direct anti-globulin test (DAT), microbiological tests for bacterial contamination, detection of urine hemoglobin, and measurement of serum bilirubin. Microscopic evaluation of RBCs may reveal spherocytes (extravascular hemolysis) or schistocytes (intravascular hemolysis) (5).

Despite the lifesaving benefits of blood transfusion, maintaining an adequate and safe blood supply remains challenging in many developing countries because of limited voluntary blood donation, inadequate infrastructure, and resource constraints. In addition, shortages of equipment, blood component preparation facilities, and trained personnel contribute to the continued use of whole blood transfusion, limiting the maximal use of blood components and potentially affecting transfusion safety (18–20). Therefore, strengthening blood transfusion services, promoting component therapy, and improving hemovigilance systems are essential to enhance transfusion safety and patient outcomes.

1.2. Statement of the Problem

ATRs are among the most severe complications associated with transfusion, and their magnitude is not similar across countries (19). Data obtained from the VigiBase global safety database in 2021, showed that adverse reactions related to blood and blood components (whole blood, red blood cells, platelets and fresh frozen plasma) accounted for 10.9% of all reported drug-related adverse reactions, whereas plasma-derived medicines and recombinant blood products accounted for 88.4% and 0.7%, respectively (21). In 2009 a nationwide assessment of blood collection and usage conducted in the United State (US) reported that there were over 60,000 transfusion reactions, from these approximately 16,000 were severe transfusion reactions (22).

As documented by the International Hemovigilance Network Database (ISTARE) from 2012 to 2016 showed that, 25% of reported ATR cases were serious, including 368 deaths and 284 transfusion-transmitted infections. Among the reported transfusion-transmitted infections bacterial infections accounted for the largest proportion (187 cases), followed by viral infections (84 cases), and parasitic or fungal infections (13 cases), with a death report of nine cases. Although respiratory complications associated with transfusion, such as TACO, TRALI and transfusion-associated dyspnea, constituted for 8.3% of the total ATRs, they were responsible for a larger proportion of serious reactions (20.1%) and more than half of all transfusion-related deaths (52.2%) (23). These adverse events contribute to significant morbidity, mortality, as well as socio-economic burden for patients and for the health service infrastructure (9).

Although respiratory adverse reactions represented only a small proportion (8.3%) of all transfusion reactions, they were responsible for a much larger proportion of serious reactions (20.1%) and more than half of all transfusion-related deaths (52.2%). This indicates that respiratory transfusion reactions are relatively uncommon but are among the most severe and potentially fatal transfusion complications.

The magnitude of ATRs also varies considerably across different regions of the world. In Europe and other non-African countries, the rate of ATRs range from 0.23% to 4.41%, with the lowest rate documented in the US (0.23%) and the highest in Belgaum, India (4.41%) (24,25). On the other hand, in sub-Saharan Africa, ATR rates are generally higher, ranging from 2.6% in the Democratic Republic of the Congo to 11.8% in Nigeria (26,27). In Ethiopia, the incidence of

ATR ranges from 5.2% to 10.0%, with a predominant proportion of the reactions being FNHTR and allergic reactions (15,28).

In the industrialized world, the provision and safety of blood are generally well implemented, supported by robust blood bank systems and hemovigilance programs. In contrast however, many African countries, including Ethiopia, face challenges such as limited access to safe blood, inadequate screening and blood safety protocols, and weak hemovigilance implementation (20,26). In most developing nations, including Sub-Saharan Africa, WB is the predominant transfused blood and the majority of the ATRs occur due to whole blood transfusion (29). For example, a study conducted in Zimbabwe reported that approximately 68.4% of acute transfusion reactions occurred following whole blood transfusion (30); and provision of unsafe or poorly monitored transfusion practices render blood safety a major public health concern. Generally, ATRs are well recognized transfusion-related adverse events associated with higher rates of morbidity and mortality, as well as socioeconomic effects at both individual and community levels (15,31).

Overall, while acute transfusion reactions are known to be a widespread problem in Ethiopia, there is limited concrete, locally generated data on their incidence and associated factors, particularly in central Ethiopia. To the best of our knowledge, no study has assessed the incidence and risk factors of ATRs among adult transfused patients at Worabe Comprehensive Specialized Hospital (WCSH). Therefore, this study aims to investigate the incidence and associated risk factors of ATRs among adult blood transfused patients at Worabe Comprehensive Specialized Hospital (WCSH), from January 15, 2026 to April 15, 2026, thereby contributing to safer blood transfusion practices and strengthening transfusion-reaction surveillance system at the hospital.

1.3. Significance of the Study

The findings of this study will have important implications at multiple levels.

At the clinical level, identifying the incidence and predictors of acute transfusion reactions will assist healthcare providers in early recognition, appropriate management, and prevention of ATRs. This will help reduce delays in diagnosis, improve patient monitoring, and enhance patient safety during blood transfusion.

At the institutional level, the results will support Worabe Comprehensive Specialized Hospital in strengthening its blood transfusion practices and hemovigilance system. The study will inform the development and updating of standard operating procedures (SOPs) for transfusion monitoring, early detection of reactions and reporting of adverse transfusion reactions. It may also guide training programs and the design of transfusion reaction recording forms tailored to the hospital setting.

For the policy makers and further researcher, the study will provide locally generated evidence that can inform regional and national blood safety programs in Ethiopia. The findings may be used to adjust transfusion guidelines, improve hemovigilance reporting and prioritize risk reduction strategies such as component therapy, better blood storage practices, and closer monitoring of high risk patients. Furthermore, the results will contribute to the existing scientific literature on transfusion related complications and can serve as baseline for future multicenter and longitudinal studies in Ethiopia and similar resource-limited settings.

2. Literature Review

In spite of the growing public awareness about the risks and complications of blood transfusion, which has resulted in stricter procedures in donor selection, infectious disease screening, blood component preparation, and transfusion practices, blood transfusion remains correlated with notable adverse events. The frequency of these adverse events typically decreases as greater care is taken during preparation and supervision of each transfusion (21,23).

In developed countries, transfusion safety is closely monitored through structured hemovigilance programs, which enable accurate detection and prevention of transfusion related complications. A retrospective study of U.S. elderly in-patients undergoing transfusion from 2011 to 2012 included 4, 336, 338 transfusion stays and recorded 2,517 FNHTR diagnoses, giving an overall rate of 58.0 FNHTRs from 100, 000 transfusions. According to the report FNHTR rates were influenced by age, sex, type of blood components, and number of blood units transfused. Higher rate of reactions were observed with platelet and red blood cell transfusions. The occurrence of FNHTR were significantly associated with transfusing higher number of blood units, females sex, transfusion history and hematological malignancies (32).

In the United Kingdom, the Serious Hazard of Blood Transfusion (SHOT) report documented 3,214 incidents of transfusion reactions in 2020. Of these, majority of the reactions (81.6%) were attributed to human and procedural mistakes. The reported morbidities were mainly due to AHR, TRALI, TACO, transfusion associated infections, transfusion of wrong blood components, and ABO incompatibility. On the other hand, transfusion-related mortalities were mainly due to TACO and delayed transfusion reactions (33).

Hemovigilance in developing Asian countries has improved in recent years but remains limited by reporting gaps and infrastructure constraints (34). A study undertaken in India between 2013 and 2015, included 3,455 units of whole blood and component transfusions, reported 32 ATRs (0.92%). According to the study the most dominant type of transfusion reaction reported was allergic reactions (65.6%), that were seen more frequently with transfusion of packed RBC and whole blood. The second dominant type of reaction reported was FNHTR (28.1%), observed more frequently with transfusion of PRBCs. The occurrence of transfusion reaction were not recorded due to platelet transfusion (35).

A retrospective study of adverse transfusion reactions was conducted at the India All Institute of Medical Sciences during 2007 to April 2012. The study reported that overall 380,658 blood units were provided by the blood bank, of these 196 transfusion reactions were recorded. Allergic reaction (55.1%), and FNHTR (35.7%) was the most frequent type of adverse reaction encountered. Other less commonly reported transfusion reactions include, anaphylactoid reactions (5.1%), Acute non-immune AHTRs (2.6%), TACO (0.5%), TRALI (0.5%), and delayed hemolytic transfusion reactions (0.5%) (36).

Another cross-sectional study was conducted from 2014 to 2015 among patients who received blood and blood components in obstetrics department of tertiary healthcare facility in Belgaum, India. The study included 204 women who received blood or blood products. The incidence of transfusion reactions was 4.41% (9 women), out of these three women encountered a sever transfusion reaction in the form of TRALI, whereas the rest 6 women encountered minor transfusion reactions in the form of urticarial rash and chills (25).

A 5 year hospital based retrospective study was carried out at a Tertiary Care Center in Bangladesh from 2016 to 2020. The study reported that, overall 39,070 blood units were transfused, and the magnitude of ATR was 0.24%. The reactions were mainly observed among females and patients with age of more than 60 years. The commonest type of ATR encountered was FNHTR, followed by allergic reaction. Among ATR encountered patients majority of them showed a symptom of rigor and chills. The occurrence of ATR was markedly elevated with PRBC transfusion (62.1%) and among patients with history of previous transfusion (66.3%) (37).

A study conducted at a teaching hospital in Kermanshah, Iran, from 2010 to 2012 among adult inpatients requiring blood transfusion. The study showed that from a total of 6,238 blood units transfused, the prevalence of ATR was 0.94% (59 patients). The most frequent reaction type reported was allergic reactions (49.2%), followed by FNHTR (37.2%). while the remaining reaction type reported were pain at the site transfusion and hypotension each accounted for 6.8% of reaction cases (38).

Another study carried out at Tel Aviv University, Israel, in 2008, included 242 elderly patients who received 382 blood units. The occurrence of adverse transfusion reactions was 11% (40 patients). From the patients who developed ATR; Fever, shortness of breath, vomiting and chills

accounted for 29 (72%), four (10%), three (8%) and three (8%) cases respectively. No death report were observed during the study period due to blood transfusion reaction (39).

Across Africa, data on transfusion reactions remain scarce because of weak hemovigilance systems, limited laboratory capacity, and under-reporting. Reports from sub-Saharan Africa are particularly limited due to underdeveloped hemovigilance infrastructure. For example, a study in Nigeria by Baffa *et al.* reported an ATR incidence of 3.6%, of which 3.3% were FNHTRs and 0.3% were acute allergic reactions. (40).

A seven week-prospective study was carried out at a national referral hospital in Uganda, 2014. A total of 507 transfusions were analyzed, of which the occurrence of ATR was 9.6% (49 cases). Regarding the type of ATR 24 FNHTR, 7 allergic reaction, 5 hypertension, 3 hypotension, 3 TACO, 2 AHR, and 5 others was identified (41).

A retrospective study of all blood transfusions given to pregnant women at Federal Medical Centre Azare, Nigeria from January to December 2012, showed that 1,602 pregnant women received blood transfusion out of 15,213 deliveries. The occurrence of ATRs was 26.3% of transfused patients. The most common type of reaction reported was FNHTR (47.7%) followed by allergic urticarial reactions (24.5%). The study reported that ATR occurrence was significantly associated with storage duration of the blood units and history of prior transfusion. However, there was no statistically significant difference observed among reactions following cross matched ABO compatible blood versus uncross matched but ABO compatible blood (42).
by the blood bank, of these 196 transfusion reactions were recorded

A study conducted across all Eritrean hospitals in 2020 using ten-year historical data showed that, a total of 87,655 blood units were provided, of these 37 adverse transfusion reactions were reported (0.42 per 1,000 transfusions). The median patient age was 27 years (IQR: 23), and most reactions occurred in females (68%). Nearly all reactions were acute, primarily FNHTR (37.8%) followed by allergic reactions (29.7%), anaphylactic reactions (10.8%), or non-ABO hemolytic transfusion reactions (8.1%). About 24.3% of reported reactions were classified as serious, and two cases were fatal (43).

Coming to Ethiopia, a cross-sectional study was carried out at Felege Hiwot Comprehensive Referral Hospital, Bahir Dar, in 2019, founded the proportion of ATR among transfused patients was 5.2%. The most common types of reaction reported was allergic reactions (65%) followed by FNHTR (30%). prior transfusion history, abortion history, storage duration of the blood units, and receiving ≥3 blood units showed statistically significant association with ATR (15).

A similar study conducted at Jimma University Medical Center in 2020 reported an ATR incidence of 5.7%, with FNHTR accounting for 63.6% and allergic reactions for 36.4%. The majority of reactions were mild clinical manifestations (27.3%). Significant predictors included prior transfusion (OR≈ 3.3), blood stored ≥ 13 days (OR≈ 3.85), history of abortion (OR≈ 4.2), and receipt of more than three blood units (OR≈ 3.9) (44).

An institution-based cross-sectional study done at Debre Markos Comprehensive Specialized Hospital, Ethiopia, 2022 found ATR in 12 (6.6%) patients. The study revealed statistically significant association of ATR with abortion history, patients with history of prior transfusion, storage of blood units above 20 days, and the number of blood units transfused (45).

A study was conducted at Bishoftu General Hospital, Oromia, Ethiopia, in 2023. The incidence of ATR was 5.6%. The most common reaction was febrile non-hemolytic transfusion reaction (48%), followed by allergic reactions (36%). There was significant association of ATR with previous transfusion history (AOR=5.42), abortion history (AOR=4.3), longer storage time (AOR=4.6), and receipt of more than three blood units (AOR=5.1) (46).

Anothers study was carried out at Tikur Anbessa Specialized Hospital between September and November 2022, included 210 participants. The majority of study participants aged 18 to 40 years, the most common blood group was O Rh “D+”. PRBCs were given in 74.8% of cases. The incidence of ATR was 10%, occurring in 19.6% of patients with platelet transfusions and 7% with PRBC transfusions, and while none of patients who received FFP transfusion developed ATR. The most frequently encountered reactions were FNHTR and urticaria. ATRs were significantly associated with female sex, autoimmune disease, and ABO-incompatible platelet transfusion (28).

In general, across all regions of the world, acute transfusion reactions remain a significant cause of transfusion-related morbidity, with febrile non-hemolytic transfusions and allergic reactions being the most common. Global data also show that organized hemovigilance reduces the risk of ATR through early detection and improved reporting (23). However, studies from Africa and Ethiopia reveal persistent under-reporting and methodological inconsistencies. The absence of published data from central Ethiopia limits evidence based monitoring of transfusion safety in the region. Therefore, this study aims to fill that gap by assessing the incidence and risk factors of acute transfusion reactions among adult transfused patients at Worabe Comprehensive Specialized Hospital.

Conceptual framework

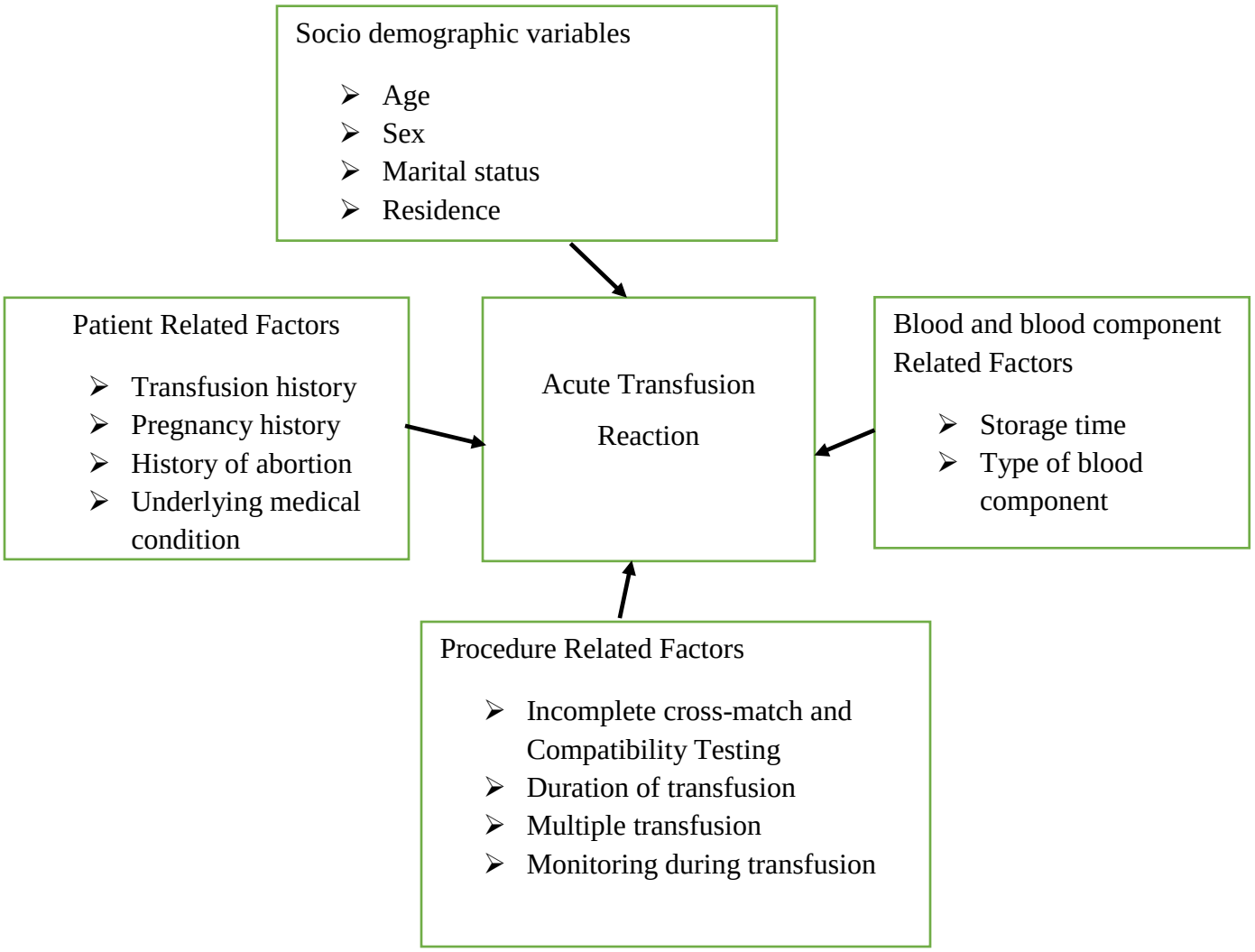


Figure 1:-Conceptual framework.

This framework is prepared after referring different literatures (5,7,14,26,47).

3. Study Objective

3.1. General objective

- To determine the incidence and associated risk factors of acute transfusion reactions among adult blood transfused patients at Worabe Comprehensive Specialized Hospital, Silte zone, from January 15, 2026 to April 15, 2026.

3.2. Specific objectives

- To determine the incidence and types of acute transfusion reactions among adult blood transfused patients at Worabe Comprehensive Specialized Hospital.
- To identify the risk factors associated with acute transfusion reactions among adult blood transfused patients at Worabe Comprehensive Specialized Hospital.

4. Methods and Materials

4.1. Study setting and study period

The study was conducted at Worabe Comprehensive Specialized Hospital (WCSH) from January 15, 2026 to April 15, 2026. The hospital is located in Worabe town, the administrative capital of Silte zone, in the central Ethiopian region, approximately 176 km southwest of Addis Ababa, the capital city of Ethiopia. WCSH is a tertiary level hospital established in 2014. It serves as a referral center for health centers, primary hospitals and general hospitals within the district and neighboring areas. The hospital provides secondary and tertiary services in major departments including Internal Medicine, Obstetrics and Gynecology, Psychiatry, Surgery, Emergency Medicine, and Pediatrics. On average, the hospital performs approximately 300 blood transfusions per-month.

4.2. Study Design

An institution-based prospective study was conducted at Worabe Comprehensive Specialized Hospital (WCSH).

4.3. Population

4.3.1. Source population

All adult patients (≥18 years) who receive blood transfusions at WCSH.

4.3.2. Study population

All adult patients who receive blood transfusions at WCSH during the study period and meet the inclusion criteria, as well as those who voluntarily consent to participate in the study.

4.4. Eligibility criteria

4.4.1. Inclusion criteria

All adult patients (≥18 years) receiving blood transfusion services at WCSH and who voluntarily consent to participate in the study.

4.4.2. Exclusion criteria

The following patients were excluded from the study:

- Unconscious or critically ill patients at the time of transfusion.

- Patients who require blood transfusion during or within 24 hours after major surgery or while under anesthesia.
- Patients undergoing hemodialysis.

4.5. Study Variables

4.5.1. Dependent variables

- Occurrence of acute transfusion reaction-

4.5.2. Independent variables.

- Socio-demographic factors: age, sex, residence, and marital status.
- History of prior transfusion
- Known allergies to blood and blood products.
- History of pregnancy
- Gravidity (number of pregnancies)
- History of abortion
- Primary diagnosis/reason for transfusion
- Transfusion related factors: Type of blood product transfused, storage duration of blood product, and number of blood units transfused.

4.6. Sample size calculation and Sampling technique

4.6.1. Sample size determination

The sample size is calculated using a single population proportion formula:

$$n = \frac{Z^2 p (1-p)}{d^2}$$

Where:

- n = required sample size
- Z = Z value (1.96 for 95% confidence level)
- P = 0.1 (10%, estimated proportion of ATR, from Temesgen *et al*., 2023, Addis Abeba) (28).
- d = 0.04 (margin of error, 4%)

$$n = \frac{(1.96)^2 \times 0.1(0.9)}{(0.04)^2} \qquad n = 217$$

Considering a 10% non-response rate: $N_{final} = 217 \times 1.10 \sim 239$

Therefore, the total sample size required for this study was 239 adult blood transfused patients.

4.6.2. Sampling Techniques

A consecutive sampling technique was employed during the data collection period. This approach involved including all eligible adult patients who received blood transfusion at WCSH and met the inclusion criteria during the study period. This method ensures that every eligible participant is included until the desired sample size is reached. It is appropriate for hospital-based studies where the population flow is continuous and the occurrence of acute transfusion reactions (ATRs) is not expected to vary by season (15).

4.7. Socio-Demographic and Clinical Data Collection Procedures

Socio-demographic data and past medical history including prior transfusion history, previous pregnancies, known allergies to blood products and abortion history were collected using structured questionnaires by trained nurses.

Baseline vital signs including body temperature, respiratory rate, pulse rate, blood pressure, as well as oxygen saturation level were measured by nurses after the patient had rested for at least 5 minutes and recorded on a data collection checklist form. During transfusion, the vital signs were monitored within 15 minutes after the initiation of the transfusion, and then every 30 minutes until the completion of the transfusion. Following the transfusion, vital signs were monitored for 24 hours at 4-hour intervals. At the same time, patients were also physically evaluated and examined for signs and symptoms of ATRs, including fever, rigors/chills, itching/urticarial, nausea, vomiting, tachycardia, restlessness, dyspnea, anxiety, and headache.

In addition, data regarding the transfusion details such as primary diagnosis, type of blood component transfused, blood group of donor and recipient, storage of blood units, number of units transfused, presence of acute transfusion reactions and types of ATR were gathered from the patient charts and the laboratory registration logbooks using structured checklist sheets by trained nurses and medical laboratory professionals. Medical doctors evaluated and confirmed the suspected cases of acute transfusion reactions, managed affected patients, and classified reactions based on clinical and laboratory findings.

4.8. Sample Collection and Laboratory Examinations

4.8.1. Pre-transfusion sample collection:

Prior to transfusion, blood and urine samples were collected by medical laboratory professionals from each patient to establish baseline laboratory values. Pre-transfusion CBC, ABO/Rh blood group and DAT results were obtained from the patient's medical record when available. For patients without these results, the tests were conducted on the pre-transfusion samples collected for cross-matching. CBC testing was performed using the MINDRAY BC 6800 PLUS, at WCSH hematology laboratory before the cross-match procedure was performed. Initial cross-matching was performed using the immediate-spin method to confirm compatibility. Additionally, 3 mL urine specimen was collected in a clean container to assess pre-transfusion urine hemoglobin using a urine strip test.

4.8.2. Post- transfusion samples collection:

For patients who developed clinical signs suggestive of an acute transfusion reaction (ATR), medical laboratory professionals collected post-transfusion blood and urine samples after verification of patient identity and blood unit labels. A 5 mL of post-transfusion blood was collected, of which 3 mL was added to a blood culture bottle and 2 mL was placed in a K_2-EDTA tube for post-transfusion CBC, malaria screening, ABO/Rh regrouping, re-cross-matching, and DAT. A 3 mL urine specimen was collected for post-transfusion hemoglobin determination followed by microscopic examination to rule out hematuria. The donor blood samples were similarly tested for blood culture, regrouping, and cross-matching. In addition, for suspected ATR cases, pre- and post-transfusion samples were re-cross-matched using the polyclonal antihuman globulin (AHG) technique (standard cross-matching). The DAT was performed on post-transfusion washed red blood cells using polyclonal anti-human globulin reagent (containing anti-IgG and anti-complement antibodies) to detect in-vivo sensitization of red cells. All samples were checked for correct labeling, hemolysis, and clotting before analysis.

4.8.3. Blood culture procedures:

All blood cultures were performed aseptically by medical microbiologists in a Class II biosafety cabinet at the WCSH Medical Microbiology Laboratory. The cultures were incubated in Trypticase Soy Broth (TSB) at 35–37°C for 24 hours and examined for signs of bacterial growth such as turbidity and hemolysis. Subcultures were then made on Blood Agar, Chocolate Agar,

and MacConkey Agar plates, which were monitored for up to five days. If no growth was observed at the end of this period, the result was reported as negative.

4.9. Data Quality Management

To ensure the accuracy and reliability of the study data, several quality management measures was implemented:

1. **Laboratory sample consistency**

Pre- and post-transfusion samples were analyzed using the same instruments to avoid instrumental variation. Acceptance criteria for collected samples like non-clotting, non-hemolysis, and sufficient sample volume were strictly checked. All samples were labeled with identical identification codes on both the sample container and the request form to prevent mix-ups.

2. **Laboratory procedure adherence**

The laboratory test results were maintained to a high standard by following to the manufacturer's instructions and SOPs throughout the process of all laboratory tests. Low, normal, and high quality control materials were used for the hematology analyzer, according to the protocol of the laboratory. To reduce background carryover effects of the machine, background readings were obtained daily. Prior to analyzing patient samples the expiration date of reagent were strictly checked. Quality control for blood culture was maintained by checking media sterility, ensuring proper bottle condition, using strict aseptic collection techniques, monitoring incubator temperature daily, and verifying results with control organisms and senior technologist review. In addition, for urine analysis, reagent strips were checked daily for expiration and integrity, and microscopic findings were cross-checked by a second technologist when abnormal results appear.

3. **Questionnaire reliability**

The questionnaires and checklists in English were translated into the Amharic language, and subsequently retranslated back into English to ensure the accuracy and reliability of the data. To maintain the quality of data, the check list was pretested on 5% (15) of the sample at Silti Primary Hospital, and necessary modifications were made before the main data collection.

4. **Training and supervision**

The data collector nurses and medical laboratory professionals received training on the objective of the study and proper data collection techniques. The principal investigator supervised the data collection process and checked the completed checklists daily for completeness and consistency.

5. **Data management and confidentiality**

All collected data was cleaned, verified and entered before analysis to ensure accuracy and reliability. Participants' test results and other personal information was handled confidentially and used solely for research purposes through the use of unique identification codes.

4.10. Data Analysis

All collected data first reviewed for completeness, cleaned, sorted, and coded on a daily basis, then entered into Statistical Package for the Social Sciences (SPSS) version 27 for statistical analysis.

Descriptive statistics was used to summarize participants' socio-demographic and clinical characteristics. The results were presented in tables, figures, and narrative form using frequencies and percentages.

Bivariable and multivariable logistic regression analyses were performed to determine the association between independent variables and acute transfusion reaction. Variables with a p-value less than 0.25 in the bivariable analysis were included in the multivariable model, which was fitted using the backward stepwise likelihood method. In addition, Pre- and post-transfusion hematological parameters among patients who developed ATR were compared using the Wilcoxon Signed-Rank test after assessment of normality using the Shapiro-Wilk test.

A p-value < 0.05 was considered statistically significant in the final model. The strength of association was interpreted using odds ratios (ORs) with 95% confidence intervals (CIs).

4.11. Operational Definitions

Acute Transfusion Reaction (ATR): any adverse reaction occurring within 24 hours during or after a blood transfusion.

Adult patients: patients whose age is more than or equal to 18 years.

Incidence of ATR: the number of ATR cases observed among blood transfused patients during the study period.

Blood transfusion: the administration of blood or blood components for therapeutic purposes.

Hemovigilance: a set of surveillance procedures that encompass the entire chain of blood transfusion, from the donation and processing of blood and blood components, through their provision and transfusion for patients, including post-transfusion follow-up.

4.12. Ethical Consideration

This study was performed after the proposal was reviewed and ethically approved by the Departmental Ethics and Research Committee of the Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University. A support letter was submitted to Worabe Comprehensive Specialized Hospital to get permission to conduct the study.

All participants were informed about the purpose and aim of the study. Written informed consent was acquired from each participant for the use of their clinical data and their blood samples. Patient confidentiality, equity of services, and the interests of patients were strictly maintained throughout the study.

Moreover, all the study participants were informed of their full right to participate or refuse from participating in the study without any effect on the clinical care they receive at the hospital. All international and institutional research ethics guidelines were strictly obeyed during the study process. All data collected during the study were treated with strict confidentiality and used solely for the purpose of this study.

4.13. Dissemination of Result

The findings of this research will be submitted to the Department of Medical Laboratory Sciences (DMLS) for public defense in the presence of DMLS staff and students. The final approved thesis will be submitted to Addis Ababa University, College of Health Sciences; Department of Medical Laboratory Sciences and a copy of the report will be provided to Worabe Comprehensive Specialized Hospital.

Furthermore, the study finding will be shared with the Ministry of Health, Central Ethiopia Health Bureau, and other relevant hospitals to support improvements in blood transfusion safety and patient care.

The result will also be disseminated through publication in peer reviewed local and international journals and presented at workshops, seminars and scientific conferences to reach the wider medical and academic community.

5. Results

5.1. Socio-demographic characteristic of study participants

A total of 239 study participants were included in the study. Of these, 131(54.8%) were females. The majority of the study participants were married 149 (62.3%), followed by single participants 70 (29.3%). Regarding residence, most participants, 180 (75.3%), were from rural areas. In terms of age distribution, the largest group, 104 (43.5%), was aged 18–30 years, and the median age of the study participants was 35 years (interquartile range (IQR): 26–47 years) (Table 1).

Table 1: Socio-Demographic Characteristics of Transfused Participants at WCSH from January 15, 2026 to April 15, 2026.

Variables		**Frequency**	**Percentage (%)**
Sex	Male	108	45.2
	Female	131	54.8
Marital status	Single	70	29.3
	Married	149	62.3
	Divorced	13	5.4
	Widowed	7	2.9
Age	18-30	104	43.5
	31-40	56	23.4
	41-50	31	13.0
	51-60	18	7.5
	≥61	30	12.6
Residence	Urban	59	24.7
	Rural	180	75.3

5.2. Clinical characteristics of study participants

Of the 239 participants, 158 (66.1%) had no prior transfusion history, while 81(33.9%) had been transfused previously, with most of them receiving one or two previous transfusions. Among the 131 female participants, 102 (77.9%) had a history of pregnancy; of these, 26 (25.5%) reported a history of abortion, which had most commonly occurred once in 18 women (69.2%).

Hematological conditions were the leading indication for transfusion (95, 39.7%), followed by maternal complications (55, 23.0%) and trauma, orthopedic or surgical causes (37, 15.5%) (Table 2).

Table 2: Clinical Characteristics of Transfused Patients at WCSH from January 15, 2026 to April 15, 2026.

Characteristics		**Frequency**	**Percentage (%)**
History of transfusion	Yes	81	33.9
	No	158	66.1
Previous number of transfusions:	One	35	43.2
	Two	35	43.2
	Three or more	11	13.6
History of pregnancy	Yes	102	77.9
	No	29	22.1
Number of gravida	One	49	48.0
	Two	18	17.6
	Three or more	35	34.3
History of abortion	Yes	26	25.5
	No	76	74.5
Frequency of abortion	One	18	69.2
	Two	3	11.5
	Three or more	5	19.2
Indication for transfusion	Maternal complications	55	23.0
	Trauma/orthopedic/surgical	37	15.5
	Chronic disease	36	15.1
	Hematological conditions	95	39.7
	Gastrointestinal bleeding	11	4.6
	Others	5	2.1

5.3. Blood Component Type, Characteristics of Transfused Blood, and Blood Group of Transfused Patients

Overall, 404 blood units were transfused to 239 patients, with a mean of 1.69 units per patient (1.72 for males vs 1.66 for females). Most patients were transfused with whole blood (non-leukocyte reduced), 180 (75.3%), followed by packed red blood cells (non-leukocyte reduced), 32 (13.4%), while other components such as platelets and plasma were used less frequently. Among transfused whole blood and PRBC units, 136 (60.7%) had a storage duration of less than 14 days, while 88 (39.3%) were stored for ≥14 days. Nearly half of the transfusions, 118 (49.4%), were completed within 30–60 minutes, and the majority of patients 135 (56.5%), received one unit of blood (Table 3).

Table 3: Type and Characteristics of Transfused Blood Component with Frequency of Transfused Patients at WCSH from January 15, 2026 to April 15, 2026.

Characteristics		**Frequency of transfused patients**	**Percentage (%)**
Type of Blood Component Transfused:	Whole blood	180	75.3
	PRBC	32	13.4
	platelets	10	4.2
	Plasma (FFP)	5	2.1
	Whole blood and PRBC	9	3.8
	Whole blood and PLT	3	1.3
Storage Duration of Transfused Blood (whole blood and PRBC)	<14 days	136	60.7
	≥14 days	88	39.3
Time Taken for Transfusion	Less than 30 minutes	28	11.7
	30–60 minutes	118	49.4
	More than 60 minutes	93	38.9
Number of Blood Units Transfused:	One	135	56.5
	Two	62	25.9
	Three or more	42	17.6

Concerning the blood group of study participants, O Rh “D+” was the predominant blood group 96 (40.17%), followed by A Rh “D+” 65 (27.20%), while AB Rh “D-” was the least common blood group 2 (0.84%) among transfused patients (Figure 2).

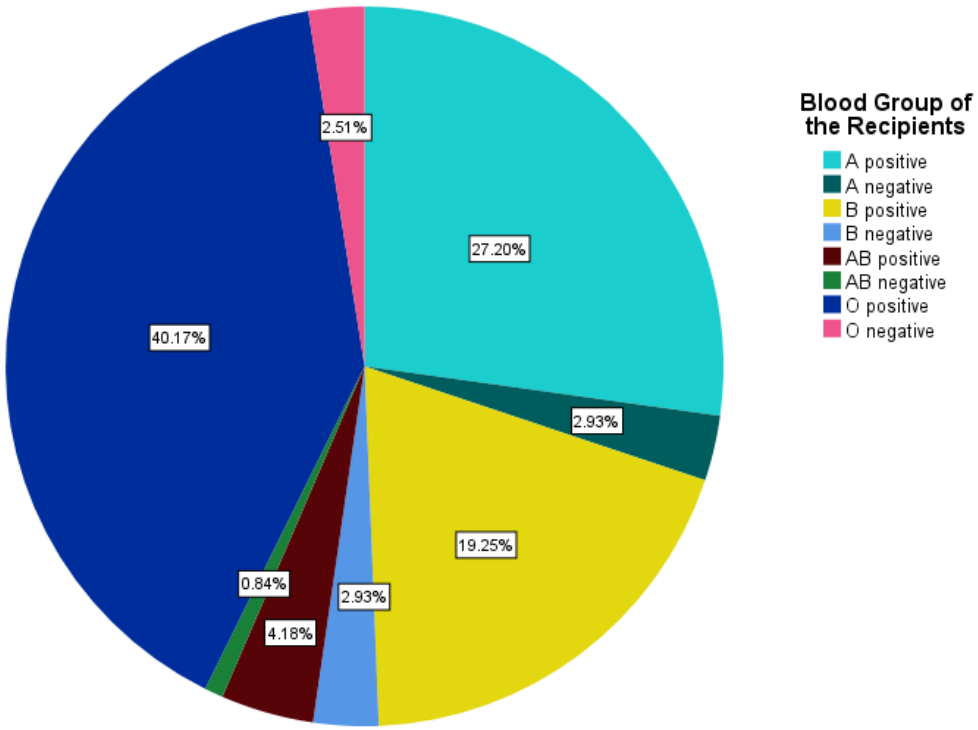


Figure 2: Blood group of transfused patients at WCSH from January 15, 2026 to April 15, 2026.

5.4. Transfusion reactions and associated factors

A total of 239 patients received blood and blood components, and the overall incidence of acute transfusion reaction (ATR) was 17 (7.1%; 95% CI: 3.8-10.4%). Among those who developed reactions, FNHTR was the commonest type, occurring in 10 patients (58.8%), followed by allergic reactions in 6 patients (35.3%). A small proportion experienced transfusion-related acute lung injury (TRALI) in 1 patient (5.9%) (Table 4).

Table 4: Incidence and Type of Transfusion Reaction among Adult Transfused Patients at WCSH from January 15, 2026 to April 15, 2026.

Incidence of Reaction and Type		Frequency	Percentage (%)
Transfusion reaction occurrence	Yes	17	7.1
	No	222	92.9
Reaction type	FNHTR	10	58.8
	Allergic reaction	6	35.3
	TRALI	1	5.9

Key: FNHTR, Febrile Non-Hemolytic Transfusion Reaction; TRALI, Transfusion-Related Acute Lung Injury

The magnitude of transfusion reactions was higher among females (8.4% vs 5.6%), urban residents (10.2% vs 6.1%), and patients aged ≥41 years (7.5% vs 6.9%). Higher rates were also seen in those with prior blood transfusions (14.8% vs 3.2%), or prior transfusion reactions (11.1% vs 7.0%), and in females with pregnancy history (8.8% vs 6.9%) or abortion history (23.1% vs 3.9%). Additionally, reactions were more common in patients who received ≥ 3 units (19.0% vs 4.6%), blood stored for ≥ 14 days (15.9% vs 2.2%), and whole blood (8.3% vs 3.4%).
In bivariate logistic regression analysis, ATR was significantly associated with transfusion history (COR = 5.32; 95%CI: 1.81-15.70), abortion history (COR = 7.30; 95%CI: 1.68-31.80), blood stored ≥ 14 days (COR = 8.39; 95%CI: 2.33-30.13), and transfusion ≥ 3 units of blood (COR: 4.92; 95% CI = 1.77-13.63). In the multivariate logistic regression model, after adjustment for confounding factors, the following remained significantly associated with ATR: abortion history (AOR = 6.59; 95% CI: 1.22-35.50, P = 0.029), storage duration ≥ 14 days (AOR = 9.34; 95% CI: 1.35-64.67, P = 0.024) and number of transfused units ≥3 units of blood (AOR = 8.82; 95% CI: 1.60– 48.72, P = 0.013) (Table 5).

Table 5: Bivariable and Multivariable Binary Logistic Regression Analysis of Factors Associated with ATRs among Adult Transfused Patients at WCSH from January 15, 2026 to April 15, 2026.

Variable		ATR		COR (95% CI)	AOR (95% CI)
		Developed n (%)	Not-Developed n (%)		
Sex (n=239)	Male	6(5.6)	102(94.4)	1	
	Female	11(8.4)	120(91.6)	1.56 (0.56-4.36)	
Age (year) (n=239)	18 −40	11(6.9)	148(93.1)	1	
	≥41	6(7.5)	74(92.5)	1.09 (0.388-3.065)	
Residence (n=239)	Urban	6(10.2)	53(89.8)	1.74 (0.61-4.93)	
	Rural	11(6.1)	169(93.9)	1	
Blood component (n=239)	Whole blood	15(8.3)	165(91.7)	2.59 (0.58-11.68)	5.30 (0.38-74.54)
	Others	2(3.4)	57(96.6)	1	1
Transfusion history (n=239)	Yes	12(14.8)	69(85.2)	5.32 (1.81-15.7)	3.66 (0.54-24.84)
	No	5(3.2)	153(96.8)	1	1
Previous transfusion reaction	Yes	1 (11.1)	8(88.9)	1.67 (0.20-14.21)	
	No	16(7.0)	214(93.0)	1	
Pregnancy history (n=131)	Yes	9(8.8)	93(91.2)	1.31 (0.27-6.41)	
	No	2(6.9)	27(93.1)	1	
Abortion history (n=102)	Yes	6(23.1)	20(6.9)	7.30 (1.68-31.8)	**6.59 (1.22-35.50)**
	No	3(3.9)	73(96.1)	1	**1**
Storage time (n=224)	<14	3(2.2)	133(97.8)	1	**1**
	≥14	14(15.9)	74(84.1)	8.39 (2.33-30.13)	**9.34 (1.35-64.67)**
Transfused units (n=239)	< 3 units	9(4.6)	188(95.4)	1	**1**
	≥ 3 units	8(19.0)	34(81.0)	4.92 (1.77-13.63)	**8.82 (1.60-48.72)**

5.5. Comparison of Pre- and Post-Transfusion Hematological Parameters among Patients Who Developed Acute Transfusion Reactions

Pre- vs post-transfusion hematological parameters among patients who developed ATR showed statistically significant increases in RBC count, hemoglobin (Hgb) level, and platelet count following transfusion. The median RBC count increased from 2.20 $\times 10^{12}$/L (IQR: 1.87–2.90) pre-transfusion to 2.71 $\times 10^{12}$/L (IQR: 2.09–2.99) post-transfusion ($p = 0.001$). Similarly, the median Hgb level increased from 6.5 g/dL (IQR: 5.9–7.4) pre-transfusion to 8.3 g/dL (IQR: 6.8–9.2) post-transfusion ($p = 0.001$). Platelet count also demonstrated a statistically significant increase from a median of 106 $\times 10^9$/L (IQR: 50–150) to 110 $\times 10^9$/L (IQR: 54–156.5) following transfusion ($p = 0.014$). However, there was no significant difference was seen in WBC count between pre- and post-transfusion measurements ($p = 0.201$) (Table 6).

Table 6: Comparison of Pre- and Post-Transfusion Selected Hematological Parameters among Patients Who Developed ATR at WCSH from January 15, 2026 to April 15, 2026.

Hematologic parameter	**Pre-transfusion Median (IQR)**	**Post-transfusion Median (IQR)**	**P-value**
RBC ($\times 10^{12}$/L)	2.20 (1.87–2.90)	2.71 (2.09–2.99)	0.001
Hgb (g/dL)	6.5 (5.9–7.4)	8.3 (6.8–9.2)	0.001
WBC ($\times 10^9$/L)	5.04 (3.52–6.65)	4.99 (3.69–6.68)	0.201
Platelet ($\times 10^9$/L)	106 (50–150)	110 (54–156.5)	0.014

6. Discussion

Blood transfusion is an important therapeutic intervention used for the management of severe anemia, trauma, surgical conditions, hematological disorders, and obstetric complications (2,4). It is also observed in the current study that patients transfussed with blood products has an overall improvemenet in blood parameters including RBC, Platelet count, and Hgb levels. Despite its lifesaving role, transfusion is associated with different adverse reactions ranging from mild allergic manifestations to severe life-threatening complications. ATRs remain a major concern in transfusion practice, particularly in developing countries where hemovigilance systems and leukocyte reduction practices are limited (9,20). Therefore, this study assessed the incidence of ATR and its associated factors among adult transfused patients at Worabe Comprehensive Specialized Hospital.

In the current study, the incidence of ATR among adult transfused patients was 7.1% (95% CI: 3.8-10.4%). This finding is comparable with studies conducted in Uganda (9.6%), Belgaum, India (4.41%), Bahir Dar, Ethiopia (5.2%), Debre Markos, Ethiopia (6.6%) (15,25,41,45). However, the current incidence was higher than studies done in Bangladesh (0.24%), India (0.92%), Iran (0.94), and Nigeria (3.6%) (35,37,38,40). The possible reason for this variation may be related to differences in transfusion practices, study settings, hemovigilance systems, sample size, and blood component processing methods (6,11,19,23). In many developed countries, leukocyte-reduced blood components and strict national hemovigilance systems are routinely practiced, which significantly reduce the occurrence of ATRs (38). In contrast, most transfused blood in the current study was non-leukocyte reduced whole blood, which may contain leukocyte-derived cytokines and inflammatory mediators capable of triggering transfusion reactions (16).

On the other hand, the current incidence was lower than studies conducted in Israel (11%) and Nigeria (26.3%) (39,42). The discrepancy may be attributed to differences in study populations and clinical characteristics. For instance, the Israeli study mainly involved elderly patients with a median age of 82 ± 9 years, which may explain the higher incidence observed (39). However, the participants in our study had a median age of 35 years old (IQR ± 21 years). Similarly, the Nigerian study focused on pregnant women and obstetric complications. In addition, most of the transfusions were given to women with incomplete abortion and placenta previa with fetal-

maternal hemorrhage that may be linked with the occurrence of ATR (42). This may also increase the likelihood of alloimmunization and subsequent transfusion reactions (48).

Regarding the types of ATR observed in this study, FNHTR was the most common type, accounting for 58.8% of the total reactions, followed by allergic reactions (35.3%) and TRALI (5.9%). This finding is consistent with studies conducted in the United States, Nigeria, Bangladesh, Uganda, Eritrea, Ethiopia (Bishoftu, Jimma) (37,40,41,43,44,46,49) where FNHTR was reported as the predominant transfusion reaction. However, the current result differs from studies conducted in, Iran, India, Bahir Dar (Ethiopia) and Debre Markos (Ethiopia) (15,35,38,45) where allergic reactions were more frequently reported. The possible justification for such difference may be due to variations in transfusion practices, blood component utilization, patient characteristics, sample size, and reaction reporting systems (6,11,19,23).

The predominance of FNHTR in the current study may be explained by the transfusion of non-leukocyte reduced blood products. FNHTR commonly occurs due to antibodies of the recipient reacting against donor leukocytes or due to cytokines released from leukocytes during blood storage. Cytokines such as interleukin-1, interleukin-6, and interleukin-8 accumulate progressively during storage and can provoke fever, chills, and rigors following transfusion. Since leukocyte reduction was not routinely practiced in the current study setting, sensitization may have contributed to the higher occurrence of FNHTR (11,13).

Allergic reactions were the second most common ATR identified in our study. Such reactions occur mainly due to recipient immunoglobulin E (IgE) or non-IgE mediated hypersensitivity responses against donor plasma proteins (albumin, complement components, IgG, and IgA) or other soluble allergens (50). The patients presented with signs of hypersensitivity, such as itching, rash (urticarial), wheezing, and flushing. The use of plasma-containing whole blood products in the present study could have contributed to the occurrence of allergic reactions, as the majority of the transfusions were whole blood in the current study (75.3%). This suggests the importance of promoting component therapy and leukocyte reduction practices to minimize transfusion-related complications.

One patient developed TRALI accounting for 5.9% of the total ATR. Similar findings have been documented in previous studies conducted in Belgaum (25), India (36), and in Ethiopian

hospitals (45,46). The patient presented with respiratory distress during transfusion and bilateral infiltrates on chest x-ray. TRALI may occur due to anti-human leukocyte antigen (HLA) or anti-neutrophil antibodies of the donor reacting with recipient leukocytes, leading to pulmonary endothelial damage, capillary leakage, pulmonary edema, and acute respiratory distress (51). Although TRALI was uncommon in this study, its occurrence highlights the importance of close monitoring of transfused patients during and after transfusion.

No cases of AHR, transfusion associated sepsis or TACO were recorded in this research. This may be because of the relatively small sample size compared to other studies done in different study parts of the world. For instance, A single case of TACO, one case of TRALI and five cases of AHTR were documented by Kumar P. *et al* from 380,658 units of transfusion (36).

The present study demonstrated that the incidence of reaction was higher among females compared to males (8.4% vs 5.6%). Similar findings have been documented in previous studies (28,32,37,44,45). The possible explanation may be related to pregnancy or abortion-associated alloimmunization among females. This is corroborated with our data where a history of abortion was 6.59 times more likely to develop ATR compared to those without abortion history (AOR = 6.59; 95% CI: 1.22–35.50). This finding is similar with previous studies conducted in U.S.A (32), Ethiopia (15,44–46). Exposure to fetal antigens during pregnancy can stimulate antibody production against leukocyte, platelet, or red cell antigens, which have a higher likelihood of causing adverse reactions during blood transfusions (48). In addition, the higher HLA diversity in African population would likely exacerbate the sensitization for alloimmunization (52,53).

The incidence of ATR was also higher among patients with previous transfusion history compared to those without previous transfusion exposure (14.8% vs 3.2%). Although in this study the association was not statistically significant in multivariable analysis, similar findings have been documented in studies conducted in Ethiopia (44–46), Nigeria (40,42), and USA (32). Repeated exposure to donor blood antigens may sensitize the immune system and lead to production of antibodies against specific blood cell antigens (RBCs, WBCs, and PLTs). Consequently, subsequent transfusions may trigger immune-mediated transfusion reactions such as FNHTR

Another significant factor associated with ATR was storage duration of blood products. Patients who received blood stored for ≥14 days were 9.34 times more likely to develop ATR compared to those transfused with blood stored for less than 14 days (AOR = 9.34; 95% CI: 1.35–64.67). Studies performed in North-Western Nigeria (40), North-Eastern Nigeria (42) and Ethiopia (15,44,45) have reported similar findings. Prolonged blood storage results in biochemical, biomechanical, and immunological alterations collectively referred to as "storage lesions." During storage, leukocytes release cytokines and inflammatory mediators, while RBCs undergo structural as well as metabolic changes that may affect their viability and increase recipient inflammatory responses. These changes may increase the likelihood of FNHTR and allergic reactions among recipients of long-stored blood (54).

The number of transfused blood units was also significantly associated with ATR occurrence. This study showed patients who received more than two units of blood had 8.82 times higher odds of developing ATR compared with those who received fewer than three units. This finding is in agreement with studies done in Ethiopia (15,45), and the United States (32). Multiple transfusions expose recipients to greater amounts of donor leukocytes, cytokines, antibodies, and soluble plasma proteins, thereby increasing the probability of immune sensitization and transfusion-related complications. Furthermore, repeated transfusions may promote alloantibody formation, increasing the risk of immune-mediated reactions in future transfusions (8).

In the current study, post-transfusion RBC count, hemoglobin level, and platelet count showed statistically significant increase compared with pre-transfusion values among patients who developed ATR. This finding may reflect the expected hematologic improvement following transfusion, despite the occurrence of ATR. The increase in hemoglobin and RBC count is biologically plausible because transfusion directly increases circulating red blood cells and oxygen-carrying capacity. Similarly, the significant increase in platelet count may be attributed to the transfusion of platelet-containing blood components (6,55). However, no significant difference was showed in WBC count before and after transfusion. This may be because transfusion is not primarily intended to increase leukocyte count, and leukocyte changes may be influenced by inflammatory or immunologic responses associated with transfusion reactions (7,56).

Overall, the findings of the present study indicate that ATR remains a potential clinical problem among adult transfused patients at Worabe Comprehensive Specialized Hospital. The predominance of FNHTR and allergic reactions, together with the significant association of ATR with abortion history, prolonged blood storage duration, and multiple transfusions, highlights the need for strengthening hemovigilance systems, improving blood storage and transfusion practices, encouraging component therapy, and ensuring close monitoring of transfused patients before, during, and after blood transfusion.

7. Strength and Limitation of the Study

7.1 Strength of the study

This study has several important strengths. First, the study included both clinical assessment and laboratory investigations for suspected transfusion reactions, which improved the reliability of reaction identification and classification. Second, standardized data collection procedures and regular patient follow-up were used to minimize missing information and enhance data quality. Moreover, blood cultures were done as part of the differential diagnosis to rule out transfusion associated sepsis.

7.2 Limitations of the study

Despite these strengths, this study had some limitations. First, the study was conducted in a single hospital setting with a relatively small sample size (n = 239), which may limit the generalizability of the findings to other healthcare institutions. Second, the study focused only on acute transfusion reactions occurring within 24 hours after transfusion and did not assess delayed transfusion reactions. Third, advanced immunohematological investigations including antibody screening and antibody identification for non-ABO alloantibodies were not performed. Fourth, the transfused blood units were not-leukocyte reduced, limiting comparison between leukocyte-reduced and non-leukocyte-reduced products. In addition, the relationship between the independent variables and specific types of ATR was not examined in detail because the number of patients who developed the clinical outcome of interest, ATR, was minimal (n = 17) for several variables.

8. Conclusion

The present study showed that acute transfusion reactions were relatively common among adult transfused patients at Worabe Comprehensive Specialized Hospital. The incidence of ATR was 7.1% (95% CI: 3.8- 10.4%). FNHTR was the most common type of ATR, followed by allergic reactions. The study identified abortion history, prolonged blood storage duration of transfused blood (≥14 days), and transfusion of three or more blood units as significant risk factors for ATR. Post-transfusion RBC count, hemoglobin level, and platelet count showed statistically significant increase compared with pre-transfusion values among patients who developed ATR. However, statistically significant change was not observed in WBC count before and after transfusion.

9. Recommendations

For Worabe Comprehensive Specialized Hospital (WCSH) Management or CEO

- Strengthen routine monitoring of patients before, during, and after blood transfusion to enable early detection and prompt management of ATRs.
- Strengthen hospital-based hemovigilance and transfusion reaction reporting systems to ensure complete documentation, timely feedback, and improvement of transfusion safety.
- Encourage the use of blood component therapy (packed red blood cells, platelets, plasma) instead of whole blood whenever clinically appropriate.
- Minimize transfusion of prolonged stored blood products whenever feasible.
- Ensure proper documentation of transfusion history, pregnancy history, abortion history, and previous transfusion reactions before every transfusion to identify high risk patients and plan safer transfusion strategies.

For Blood Bank and Laboratory Professionals

- Implement strict blood storage and inventory management practices to reduce the duration of blood storage and minimize the use of older units.

- Promote leukocyte reduction practices when resources are available to minimize transfusion reactions.
- Strengthen compatibility testing and ensure strict adherence to standard transfusion procedures for blood grouping, cross matching, and component preparation.
- Provide regular training for healthcare professionals on identification, management, and reporting of transfusion reactions to improve clinical preparedness and reporting quality.

For Healthcare Professionals

- Closely monitor patients receiving multiple transfusions and those with previous abortion or transfusion history, since they are at higher risk of developing ATRs.
- Immediately stop transfusion and initiate appropriate clinical management whenever a transfusion reaction is suspected, and ensure prompt communication with blood bank and laboratory team.

For Researchers and Academic Institutions

- Future studies should include advanced immunohematological investigations (e.g., non-ABO antibody screening and identification) and the assessment of delayed transfusion reactions.
- Additional research should evaluate the impact of leukocyte-reduced blood products on the occurrence of ATRs in Ethiopia.

For Public Health and Policy Makers

- Strengthen regional and national hemovigilance systems to improve reporting and policy response.
- Promote national training programs on safe transfusion practice and adverse reaction reporting.

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ANNEX I: English version participant information sheet

Title of the Research: Incidence and Risk Factors of Acute Transfusion Reaction Among Adult Transfused Patients at Worabe Comprehensive Specialized Hospital, Silte Zone, Central Ethiopia

Name of Principal Investigator: Shemsu Kedir

Advisors:

I. Dr Mikiyas Negash (PhD.)
II. Mintewab Hussein (Msc.)
III. Dr Fedlu Jenfa (MD, Internist)

Name of the organization: Addis Ababa university, college the health sciences and department of the medical laboratory science

Introduction: This information sheet is prepared for the aim of explaining the research that you are asked to join with research participant. This information sheet describes about the research.

Aim of the study: to determine the incidence and associated risk factors of acute transfusion reaction among blood transfused adult patients at Worabe Comprehensive Specialized Hospital, Silte zone, central Ethiopia

Procedure: If the participants are agreed to take part in the study, clinical nurse will give verbal or written information about the study and participants will sign on consent form. Participants are kindly requested to give the correct information about them and the necessary measurements will be performed by the assigned nurse. 3 mL of blood specimens will be collected from each patient in K3-EDTA test tube for pre-transfusion test. In addition, if ATR is suspected about 5mL of blood will be collected. About 3mL of urine will be collected in a clean urine cup container for urine analysis before and after transfusion.

Risk and discomfort: Participating in this research will not cause more discomfort than is required you could go through for routine examination. If there is any discomfort, we shall offer you necessary medical treatment. The amount of blood taken from each volunteer throughout the study period is 3ml (and 5mL if ATR is suspected) and 3mL of urine which will not affect your health.

Benefits: If you are participating in this study, there may not be direct benefit to you but your participation is likely to help us an important input to find the incidence of acute transfusion reaction and associated factors among adult transfused patients and if the medical examination reveals any abnormalities that need immediate treatment, I will inform you and link to hospital or other health facilities

Incentives and payment for participating in the study: You will not be provided with any direct incentives for your participation in this study. But the cost for your medical examination will be covered.

Confidentiality: All information about the patients will be kept confidential. The name of participant will be coded. The information sheet that links the coded number to patient name will be locked inside a computer and it will not be revealed to anyone except your physician and the principal investigator.

Right to refuse or withdraw: You have full right to withdraw from participating in the study at any time before and after consent without explaining the reason and not respond to some or all the questions. Your decision will not affect your right to get health service you are supposed to get otherwise.

Contact Address

If you have any question or concern, you can contact Shemsu Kedir at any time using the following address:

Shemsu Kedir, MSc student at Addis Ababa University, college of Health sciences and department of Medical Laboratory Sciences.

Shemsu Kedir
Tel: 09-80-20-69-44
Email: shemsukedir646@gmail.com
Addis Ababa, Ethiopia

THANK YOU VERY MUCH!!!

ANNEX II. Amharic version participant information sheet

(ለጥናቱ ተሳታፊዎች የሚሰጥ መረጃ)

የጥናቱ ርዕስ: ፈጣን የደም መውሰድ አላስፈላጊ ምልክቶች መጠን ና ተያያዥ መንስኤ በወራቤ ኮምፕሬንሲቭ ስፔሻላይዝድ ሆስፒታል ደም ከተሰጣቸው አዋቂዎች መካከል

ተመራማሪ፡ ሽምሱ ከድር

አማካሪዎች፡

1. ዶክተር ሚኪያስ ነጋሽ (PhD.)
2. ምንትዋብ ሁሴን (MSc.)
3. ዶክተር ፈድሉ ጀንፋ (MD, Internist)

የተቋሙስም፡-አድስ አበባ ዩኒቨርሲቲ፣ ጤና ሳይንስ ኮሌጅ ፣ሜዲካል ላቦራቶሪ ትምህርት ክፍል

መግቢያ፡-ይህ የማብራሪያ ቅፅ አሁን እርስዎ እንዲሳተፉ የምንጠይቀዎትን ምርምር ጥናት የሚያብራራ ነው፡፡ በዚህ ጥናት ለመሰሳተፍ ከመወሰንዎ በፊት ይህንን ቅፅ መረጃ ሰብሳቢዎቹ በሚያነቡበት ጊዜና በዚህ ጥናት መሳተፍ ከጀመሩ በኃላ በማንኛውም ጊዜ ጥያቄ ካለዎት መጠየቅ ይችላሉ፡፡

የጥናቱ ዓላማ፡- ፈጣን የደም መውሰድ አላስፈላጊ ምልክቶች መጠን ና ተያያዥ መንስኤ በወራቤ ኮምፕሬንሲቭ ስፔሻላይዝድ ሆስፒታል ደም ከተሰጣቸው አዋቂዎች መካከል መግለፅ።

የጥናቱ ሂደት፡ በዚህ ጥናት ለመሳተፍ ፍቃደኛ ከሆኑ ከጤናዎ ሁኔታ ጋር የተያያዙና ሌሎች የግል መረጃዎችን እንዲሰጡ ይጠየቃሉ፡፡ በመቀጠልም 3 ሚሊ መጠን ያለው የደም ናሙና (በተጨማሪ ደም ሲተላለፍ የህመም ምልክት ካለ 5 ሚሊ መጠን ያለው የደም ናሙና) እና 3 ሚሊ መጠን ያለው የውሃ ሽንት ናሙና ለተጠቀሰዉ ዓላማ እንድንወስድ ይጠየቃሉ፡፡

ከጥናቱ ጋር የተያያዘ ጉዳት/አለመመቸት፡ እርስዎ በዚህ ጥናት ውስጥ በመሳተፈዎ ለከፋ ጉዳት የሚጋለጡበት ሁኔታ አይኖርም፡፡ደም በሚወሰድበት ወቅት አነስተኛ ህመም ሊሰማወት ይችላል፡፡ ነገርግን እነዚህ ሁኔታዎች የከፋ ጉዳት የሚያስከትሉ አይደሉም፡፡ ምናልባት ከዚህ ጋር በተያያዘ ማንኛውም ዓይነት ህመም ካጋጠመዎት፣ አስፈላጊውን

የሕክምና እንክብካቤ እንሰጥዎታለን። በተጨማሪም የውሃ ሽንት ናሙና መውሰድ ምንም አይነት የጤና ጉዳት አያስከትልም።

በጥናቱ የመሳተፍ ጥቅም፡ ምንም አይነት የገንዘብ ጥቅም ባይኖረውም ከጥናቱ በሚገኘዉ ዉጤት ለማወቅ እና ተጠቃሚ እንዲሆኑ ይጠቅማል። ኣላማው በፈጣን የደም መውሰድ አላስፈላጊ ምልክቶች የሚመጣውን ህመም እና ሞት ለመቀነስ ይረዳል ።።

ክፍያ፡ በዚህ ጥናት በመሳተፍዎ እርሶ የሚያገኙት ምንም ሌዩ ክፍያ የለም፡ ነገርግን እርስዎ በዚህ ጥናት ላይ በመሳተፍዎ ነፃ ፈጣን የደም መውሰድ አላስፈላጊ ምልክቶች ምርመራ ያገኛሉ።

የጥናቱ ተሳታፊዉ መብት፡ በጥናቱ ላይ ለመሳተፍ ባይስማሙ ምንም አይነት ቅጣት የማያስከትል ሲሆን ማንኛውም እርሰዎ ሊያገኙ የሚገባውን ህክምናና ተያያዥ መብት የማያሳጣ መሆኑን እናረጋግጣለን።።

የጥናቱ መረጃዎች ምስጥራዊነት፡ እርሰዎን በተመለከተ የምንናገኘውን መረጃ በጥናቱ ወቅትም ሆነ ከዚያ በኃላ ባሉት ጊዜያት እንዲሁም ከጥናቱ የተገኘው መረጃ ሚስጥራዊነት የሚጠበቅ ሲሆን መረጃዎቹም የሚያዙት በስምሳይሆን በልዩ ኮድ ነው።። ይኸው መረጃ በጥንቃቄ የሚያዝና የተፈቀደለት ተመራማሪ እና ለህክምና ባለሙያዉ ብቻ ይህም እጅግ አስፈላጊ በሆነ ጊዜ ብቻ ካልሆነ በስተቀር ለሌላ ለማንም ሰው አይሰጥም።። ማንኛውም ከርስዎ ጋር የተያያዘ ውጤት በልዩ ኮድ ብቻ የሚያዝ ሲሆን ውጤቱም ለሳይንሳዊ ዓላማ ብቻ ስም በማይገልፅ ሁኔታ እንዲታተም ይደረጋል።።

ስለ ጥናቱ መረጃ ማግኘት ቢፈልጉ፡ ጥናቱን በተመለከተ ግልጽ ያልሆነ ማንኛዉንም ጥያቄ ካለዎት ነፃ ሆነው ከዚህ በታች ባለው አድራሻ መጠየቅ ይችላሉ።።

ሸምሱ ከድር

ስልክ: 09-80-20-69-44

ኢሜል: shemsukedir646@gmail.com

አድስ አበባ ,ኢትዮጵያ

በጣም እናመሰግናለን!

ANNEX III- Consent form (English version)

I confirm that, as I give consent to participate in the study, it is with a clear understanding of the objectives and conditions of the study and with recognition of my right to withdraw from the study if I change my idea. I have been given the necessary information about the research. I have also been assured that I can withdraw my consent at any time without penalty or loss of benefits. The proposal is explained to me in the appropriate language I understand. I_____ do here by give consent to Dr. /Mr. /Mrs. /Miss _____to include me in the proposed research.

Participant code _____

Participant (signature) _____date_____

Name of the data collector_____

Data collector (signature) _____date_____

ANNEX IV- Amharic version consent form

ከላይ የተፃፈውን የመረጃ ቅፅ አንብቤ የጥናቱ ዓላማና ጥቅም በግልጽ ተረድቻለሁ በማንኛውም ጊዜ ከጥናቱ ያለምንም ችግርና መንገላታት መውጣት እንደምንችል ተገልያልኛል፡፡ ከዚህም በተጨማሪ የጥናቱን ዓላማ በሚገባኝ ቋንቋ ተረድቻለሁ፡፡ በዚህ መሠረት ያለጥናት ቡድኑ አባላት ተፅዕኖ በሙሉ ፈቃደኝነት በዚህ ጥናት ውስጥ በመሣተፍ የሚጠበቅብኝን አስተዋፅዎ ለማበርከት በፊርማዬ አረጋግጣለሁ፡፡ እኔ _____በዚህ ጥናት ውስጥ እንዲያካተቱኝ ለዶ/ር/አቶ/ወ/ሮ/ወ/ሪት _____ ፈቃገኛ መሆኔን እረጋግጣለሁ።

የተሳታፊው የሚስጥር ቁጥር ----------

የተሳታፊው ፊርማ ----------ቀን ----------

የመረጃ ሰብሳቢው ስም ----------

የመረጃ ሰብሳቢው ፊርማ ----------ቀን ----------

ANNEX V. Materials and Reagents

1. Materials and Equipments

The following materials and equipment were used during data and specimen collection, laboratory investigations, and documentation:

Sample collection materials:

- EDTA tubes, sterile syringes (fitted with needle), cotton, gloves, face mask, bandage, tourniquet.

Urine Analysis materials:

- Clean urine cups, urine dipsticks, microscope slides, cover slips, and applicator sticks.

Laboratory consumables and equipment:

- Petri-dishes, blood culture bottles, conical centrifuge tubes, and pipettes with tips.

Laboratory instruments:

- Microscope, CBC machine, centrifuge, biological safety cabinet level 2, incubator and Bunsen burner.

Other materials:

- A4 paper, pens, notebooks, and data recording forms for documentation.

2. Reagents

The following reagents were used for blood grouping, cross-matching, microbiological culture, and hematological analysis during the study:

General laboratory reagents:

- 70 % alcohol, bleach, normal saline, 20% albumin, and distilled water.

Blood grouping and serological reagents:

- Anti-A, anti-B and anti-D monoclonal antibodies; anti-human globulin reagent,

Hematology analyzer reagents:

- LN Lyse, LD Lyse, LH Lyse, FN dye, FD dye, diluent, and probe cleanser (for CBC machine operation).

Microbiological culture media:

- Trypticase Soy Broth (TSB), blood agar, chocolate agar, and MacConkey agar.

Reagents for Gram staining:

- Crystal violet, Gram's iodine, 95% ethyl alcohol/acetone, safranine, immersion oil (for microscopic examination).

ANNEX VI: Laboratory procedures and principles

Procedure for venous blood sample collection

1. Remove the syringe from its protective wrapper and the needle from the cap
2. Assemble them allowing the cap to remain covering the needle until use.
3. Attach the needle so that the bevel faces in the same direction as the graduation mark on the syringe
4. Check to make sure: the needle is sharp; the syringe moves smoothly; there is no air left in the barrel
5. Identify the right patient and allow him/her to sit comfortably preferably in an armchair stretching his/her arm. Explain the procedure to the patient to gain informed consent.
6. Explain the procedure to the patient to gain informed consent and reassure the patient
7. Apply the tourniquet
8. Prepare the arm by swabbing the antecubital fossa with a gauze pad or cotton moistened with 70% alcohol.
9. Grasp the back of the patient's arm at the elbow and anchor the selected vein by drawing the skin slightly taut over the vein
10. Using the assembled syringe and needle, enter the skin first and then the vein
11. insert the needle properly into the vein
12. The plunger is drawn back to create suction pressure to draw the blood
13. The tourniquet should be released the moment blood starts entering the syringe
14. After drawing the required blood sample, apply a ball of cotton to the puncture site and gently withdraw the needle.
15. Instruct the patient to press on the cotton
16. Dispense the blood in to EDTA anticoagulated test tube. Invert 8-10 times for EDTA tube
17. Label the tubes with patient's name, hospital identification number
18. Re-inspect the venipuncture site to ascertain that the bleeding has stopped.
19. Do not let the patient until the bleeding stops
20. If bleeding does not stop apply band aid
21. Bid farewell to the patient with smile.

Procedure for blood culture

1. Collect blood sample as mentioned above. In addition, follow aseptic technique (use sterile equipment, sterile glove, Class II biosafety cabinet and maintain proper hand hygiene), to prevent contamination
2. Using alcohol swab disinfect the rubber stopper of the culture bottle
3. Transfer the blood sample in to the blood culture bottle containing enrich media (Tryptic Soya broth)
4. Label the culture bottle with patient's name, hospital identification number
5. Fill the laboratory requestion form
6. Incubated the blood culture at 35–37°c for 24 hrs.
7. Examined for the presence of bacterial growth like turbidity and hemolysis
8. At the end of 24 hrs sub-inoculate into blood agar, chocolate agar and MacConkey agar
9. The result will be reported as negative if there is no growth at the end of 5 days.

Procedure for Gram Staining

1. Use clean slides frosted on one end. Label slides appropriately using pencil, prepare smears according to type of specimen being processed. Sufficient materials must be applied to the slide so that chances for detecting and distinguishing microorganisms are maximized; however, avoid too thick smears. As a guideline, newspaper print should be visible through the smear.
2. Place a drop of sterile normal saline on slide. Transfer a small portion of colony from solid media with a sterile applicator stick or inoculating loop. Mix gently to emulsify.
3. Air dry slides on a flat surface before fixation.
4. Pass air-dried slides two or three times through a flame. Do not overheat to avoid distortions.
5. Allow slide to cool before staining.
6. Flood the fixed smear with crystal violet for 60 seconds.
7. Decant crystal violet and rinse slide gently with running tap water.
8. Rinse off excess water with Gram's iodine, and then flood the slide with Gram's iodine for 60 seconds.

9. Rinse off Gram's iodine gently with flowing tap water.
10. Decolorize with 95% ethyl alcohol/acetone until most of the crystal violet is removed in thin areas 15-30 second (length of decolorizing time depends on thickness of smear).
11. Rinse with tap water and drain off excess water.
12. Flood with Safranin and allow to remain for 60 seconds.
13. Remove excess safranin with a gentle flow of tap water.
14. Drain slide and air dry in an upright position.
15. Place a drop of immersion oil on the slide.
16. Examine using oil immersion (100x) objective.
17. Focus using coarse and fine adjustment knobs until objects are in focus..
18. Result Reporting of Gram reaction
    - Gram positive : deep violet
    - Gram negative : pink or red

Procedure for Determination of Hemoglobin in Urine

I. Chemical Examination of Urine for Hemoglobin Determination

1. Dip the test end of strip into a well-mixed specimen of urine and remove immediately.
2. After 30 seconds compare the test area with the color chart provided.
3. Report as indicated on the color chart (the color of the test spot for hemoglobin turns blue).

The test strip cannot differentiate between hemoglobinuria and hematuria. Hematuria can be distinguished from hemoglobinuria by a microscopic examination

II. Procedure for Microscopic Examination of Urine

1. Mix the urine specimen
2. Transfer about 10 ml of urine into a labelled centrifuge tube.
3. Centrifuge the specimen at a medium speed (from 1500 – 2000 rpm) for 3-5 minutes
4. Discard the supernatant by quick inversion of the tube
5. Re suspend the sediment that is at the bottom of the tube by tapping the tube by fingers

6. Take the sediment by Pasteur pipette from the tube and transfer a drop into the clean and dry slide.
7. Apply cover slide on the urine sediment that is on the slide.
8. Put on the microscope and look under 10x objective of the microscope.
9. Change the objective in to 40x objective. Look for the presence of RBCs which appear in the fresh sample as intact, small and faint yellowish discs, darker at the edges

Red blood cells are not usually present in normal urine.

Interpretation;

If the urine sample is positive in chemical examination of urine for hemoglobin and RBCs present in microscopic examination of urine this indicates hematuria a condition when intact red blood cells are present in the urine indicate bleeding somewhere in the urinary tract. or other normal physiological disturbances.

If the urine sample is positive in chemical examination of urine for hemoglobin and RBCs absent (<5 RBCs/HPF) in microscopic examination of urine this indicates hemoglobinuria (the presence of free Hemoglobin in the urine occur in severe intravascular hemolysis).

Procedure for DAT

1. Add 1 drop of 2-5% cell suspension patient cells
2. Add drop of Polyspecific AHG (Coombs reagent) to the tube, mix and Centrifuge
3. Examine for agglutination with an optical aid

Interpretation:

- Agglutination: positive DAT, there are incomplete antibodies attached to RBCs in vivo
- No agglutination: negative DAT, there is no incomplete antibody attached to RBCs in vivo

Immediate-Spin Compatibility Testing to Demonstrate blood Compatibility

1. Label a clean test tube with patient and donor identifiers.
2. Add 2 drops of recipient serum/plasma into the tube**.**
3. Add 1 drop of donor 2–5% red cell suspension (prepared by washing and suspending donor RBCs in saline).

4. Gently mix the contents.
5. Centrifuge for 1 minute at 1000 rpm (or according to lab SOP).
6. Gently tap the tube to resuspend the cell button.
7. Inspect the tube for visible agglutination or hemolysis using adequate light.
8. Interpretation
    - Agglutination or hemolysis constitutes a positive (incompatible) test result.
    - A smooth suspension of red cells after re-suspension of the red cell button constitutes a negative result and indicates a compatible immediate spin cross-match (6).

Procedure for standard cross-match method

1. Take 3 small tubes mark them 1,2 and 3, and add to each the following
    - ✓ **Tube 1**: 1volume of patient's serum; 1volume of 3-5% donor's red cells
    - ✓ **Tube 2**: 1 volume of 20% bovine albumin; 1volume of patient's serum; 1volume of 3-5% donor's red cells
    - ✓ **Tube 3**: 3 volumes of patent's serum; 1volume of 20-30% suspension of donor's cells 2.
2. Incubate tube 1 at RT for 30 min and Tube 2 for 30 minutes at 37^0C. Incubate tube 3 for 15 minutes at 37^0C.
3. After incubation, remove tube 3 and wash the cells three times with clean saline to make sure that all the non-bounded globulins are removed from the cells and make a 5% saline suspension of the washed cells in a tube. To one volume of red cell deposit add 2 volumes of antihuman globulin (Coombs) Reagent.
4. Remove tube 1 and 2 and centrifuge with tube 3 for one minute at 1000 rpm
5. Examine the tube for hemolysis macroscopically and microscopically for agglutination.

Result interpretation

If there is no hemolysis or agglutination is seen in tube 1, 2 or 3, the blood is compatible and can be issued with the completed cross-match label.

If there is agglutination or hemolysis in any of the tubes, the blood is incompatible, and must not be issued for the patient.

Procedure for Blood grouping (slide method)

1. Prepare necessary reagents and labeled slide in to three sections; A, B, and D
2. Place one drop of anti-A in the A section of the slide; one drop of anti-B in the B section and one drop of anti-D in the D section
3. Add one drop of blood in to each section
4. Mix the contents of each division, using clean applicator stick for each.
5. Mix for 2-3 minutes read the results and decide the blood group.

Interpretation:

- The blood group is A if agglutination with anti-A, the blood group is B if agglutination with anti-B, the blood group is AB if agglutination with anti-A and anti-B, the blood group is O if there is no agglutination with anti-A and anti-B.
- The blood is Rh positive if agglutination with anti-D; However, if there is no agglutination with anti-D perform test tube method for Rh grouping.

Test tube method of Rh blood grouping

1. Prepare a red blood cell suspension with a concentration of 2–5%.
2. Label two test tubes. Mark the first tube as “D” and add two drops of anti-D reagent.
3. Mark the second tube as “A” and add one drop of Rh control (albumin).
4. Add one drop of the 2–5% red cell suspension to each tube.
5. Mix the contents thoroughly, then centrifuge at 2500 rpm for 1 minute.
6. Gently shake each tube to loosen the cell button and check for agglutination. Record the reaction strength.
    - Any degree of agglutination in the anti-D tube shows Rh-positive.
    - The control tube should show a smooth suspension with no agglutination.
7. Set aside all samples that are weakly reactive (+/–) or negative for a Du test.
8. Incubate these weakly reactive or Rh-negative samples and the control at 37°C for 30 minutes.
9. Wash the cells in both tubes 3–4 times with normal saline.
10. Add one drop of polyspecific anti-human globulin (Coombs reagent) to each tube and mix.
11. Centrifuge again at 2500 rpm for 30 seconds.

12. Gently resuspend the cell button and examine for agglutination.
13. Interpretation:
    - Positive: Agglutination present in the anti-D tube and absent in the control.
    - Negative: No agglutination in either the test or control tubes.

Daily Workflow for MINDRAY BC 6800 PLUS Auto-hematology analyzer

1. Before starting check reagents, waste level, tubing, pressure, and wash solution.
2. Turn on analyzer and computer, then open the software.
3. Run daily QC sample (three level controls).
4. Verify QC results are within acceptable limits; troubleshoot if not.
5. Confirm system status parameters are normal.
6. Mix and load whole-blood samples in rack or aspirate samples in open-tube mode.
7. Run samples and remove tubes after completion.
8. Review results and print/export reports.
9. Shut down software and power off analyzer and computer

ANNEX VII: Questionnaire/data collection checklist form (English version)

Addis Ababa University, college of health sciences, department of medical laboratory sciences

Study Title: Incidence and Risk Factors of Acute Transfusion Reaction among Adult Transfused Patients at Worabe Comprehensive Specialized Hospital

Instructions: This questionnaire contains a question, which is pertinent to the research objectives. You are kindly requested to answer all as much as possible and carefully by filling the blank spaces and encircling one appropriate choice from the alternatives given.

Participant Identification

Participant serial number _____ Identification code_____

Participant address_____ Phone number_____ Date: _____

Ward: ☐ Medical ☐ Surgical ☐ Gyn/Obs ☐ Emergency ☐ Others: _____

Part I: Socio-Demographic Information

1. Sex ☐ Male ☐ Female
2. Age (years)_____
3. Marital status ☐ Single ☐ Married ☐ Divorced ☐ Widowed
4. Residence ☐ Urban ☐ Rural

Part II: Medical and Transfusion History

1. Primary diagnosis / indication for transfusion_____
2. History of previous transfusion ☐ Yes ☐ No
3. If yes, number of previous transfusions ☐ 1 ☐ 2 ☐ ≥3
4. History of known allergy or prior transfusion reaction ☐ Yes ☐ No
5. Pregnancy history (females only) ☐ Yes ☐ No
6. If yes, gravida: ____
7. History of abortion (females only) ☐ Yes ☐ No
8. If yes, number: ____
9. Pre-transfusion Clinical Status: ☐ Stable ☐ Not stable

Part III: Transfusion Details

1. Blood group of the donor_____
2. Blood group of the recipient_____
3. Type of blood component transfused ☐ Whole blood ☐ PRBC ☐ Platelet ☐ plasma (FFP) ☐ cryoprecipitate
4. Number of units transfused ☐ 1 ☐ 2 ☐ 3 ☐ ≥4
5. Storage duration the blood (days)_____
6. Duration of transfusion ☐ <30 min ☐ 30–60 min ☐ >60 min
7. Cross-match compatibility result ☐ Compatible ☐ Incompatible

Part IV: Vital Signs and Clinical Monitoring

Time of measurement	Temp (°C)	Pulse (bpm)	BP (mmHg)	Resp Rate (/min)	SpO_2 (%)	Liver size	Remarks / Signs of ATR
Before transfusion							
15 min after start							
30 min after start							
Every 30 min until end							
4hrs after end							
8hrs after end							
12hrs after end							
16hrs after end							
20hrs after end							
24hrs after end							

Transfusion starting time_____ Transfusion ending time_____

If any abnormal sign observed, tick below:

☐ Fever ☐ Chills/Rigors ☐ Rash/Urticaria ☐ Pruritus ☐ Dyspnea ☐ Chest pain ☐Nausea/Vomiting ☐ Tachycardia ☐ Hypotension ☐ Restlessness ☐ Headache ☐ Itching ☐ Anxiety ☐ Others: _____

Part V: Laboratory Data

Pre-Transfusion Tests

1. CBC result Hb: _____ g/dL RBC: _____x10^{12}/ul WBC: _____x10^{9}/ul PLT: ____x10^{9}/ul
2. ABO/Rh grouping ABO: ___ Rh: ___
3. Cross-match ☐ Compatible ☐ Incompatible
4. Urine Hb (strip) ☐ Positive ☐ Negative
5. DAT ☐ Positive ☐ Negative

Post-Transfusion Tests (for suspected ATRs)

1. CBC result Hb: _____ g/dL RBC: _____x10^{12}/ul WBC: _____x10^{9}/ul PLT: ____x10^{9}/ul
2. ABO/Rh re-grouping ABO: ___ Rh: ___
3. Re-cross-match ☐ Compatible ☐ Incompatible
4. DAT (post) ☐ Positive ☐ Negative
5. Urine Hb (post) ☐ Positive ☐ Negative
6. Blood culture (recipient sample) ☐ Growth ☐ No growth Organism: _____
7. Blood culture (donor unit) ☐ Growth ☐ No growth Organism: _____

Part VI: Assessment of Transfusion Reaction

1. Clinical suspicion of ATR ☐ Yes ☐ No
2. If yes, type of reaction ☐ FNHTR ☐ Allergic ☐ AHR ☐ TRALI ☐ TACO ☐ Bacterial contamination ☐ Others: _____
3. If yes for (1),Severity ☐ Mild ☐ Moderate ☐ Severe ☐ Fatal
4. Physician confirmation ☐ Yes ☐ No

5. Does management given? ☐ Yes ☐ No
6. If yes management given_____
7. Outcome after 24hrs ☐ Recovered ☐ Under observation ☐ Died ☐ Unknown

Name of Data Collector _____ Sign_____ Date_____

ANNEX VIII- Questionnaire (Amharic version)

የመጠይቅ ቅፅ / የመረጃ መሰብሰቢያ ቅፅ

አድስ አበባ ዩኒቨርሲቲ፣ጤና ሳይንስ ኮሌጅ፣ሜዲካል ላቦራቶሪ ትምህርት ክፍል

መመሪያ፡-ይህ መጠይቅ በውሰጡ ከጥናቱ ዓላማ ጋር የተያያዙ ጥያቄዎችን ይዟል እርሰዎም ትክክለኛዉን መልስ እንድሰጡን በትህትና እነጠይቆታልን፡፡ በታቻለዎ መጠን በጥንቃቄ ባዶቦታዎችን በመሙላት ወይም ከተሰጡት አማራጮች ውስጥ ተገቢ የሆኑትን መልሶችን ያክብቡ ካልሆነ ጥያቄው ሲነበብለዎት ትክክለኛዉን መልሰ ይናገሩ፡፡

የተሳታፊ ተራ ቁጥር----------የተሳታፊ መለያ ኮድ----------

አድራሻ---------- ስልክ ቁጥር----------

ደም የተሰጠበት ክፍል: ☐ ድንገተኛ ☐ የወሊድ ወይም የማህፀን ክፍል ☐ የውስጥ ደዌ ህክምና ክፍል

☐ ቀዶ ህክምና ክፍል ☐ሌላ: _____

ክፍል1፡ የማህበራዊና ስነ-ህዝብ ባህሪያት

1. **ዕታ ☐ ወንድ ☐ ሴት**
2. **ዕድሜ በዓምት _____**
3. **የጋብቻ ሁኔታ ☐ ያላገባ/ች ☐ ያገባ/ች ☐ የተፋቱ ☐ በሞት የተለየ/ች**
4. **የሚኖሩበት አካባቢ ☐ ገጠር ☐ ከተማ**

ክፍል II: የህክምና መረጃ

1. **የመጀመሪያ ሕመም / ደም የተሰጠበ ምክንያት :_____**
2. **ከዚህ በፊት ደም ወስደዋል? ☐ አዎ ☐ አይደለም**
3. **ምላሽዎ አዎ ከሆነ ☐ አንዴ ☐ ሁለት ግዜ ☐ ሶስት እና ከዚያ በላይ**
4. **ከዚህ በፊት ደም ሲሰጡት ህመም አጋጥመውታል? ☐ አዎ ☐ አይደለም**

5. ከዚህ በፊት እርግዝና ነበር (ለሴት) ☐ አዎ ☐ አይደለም
6. ምላሽዎ አዎ ከሆነ ☐ አንዴ ☐ ሁለት ግዜ ☐ ሶስት እና ከዚያ በላይ
7. ከዚህ በፊት የእርግዝና መቁዋረጥ (ውርጃ) አጋጥመውታል? (ለሴት) ☐ አዎ ☐ አይደለም
8. ምላሽዎ አዎ ከሆነ ☐ አንዴ ☐ ሁለት ግዜ ☐ ሶስት እና ከዚያ በላይ
9. ደም ከመሰጠቱ በፊት የታማሚ የህይወት ምልክት ሁኔታ ☐ የማይቀያየር ☐ የሚቀያየር

ክፍልIII: የደም ማስተላለፍ መረጃ

1. ደም ለታማሚ የተሰጠበት ቀን_____
2. የተሰጠው ደም የደም ቡድን_____
3. የታማሚ የደም ቡድን_____
4. የተሰጠው የደም አይነት ☐ ሙሉ ደም (Whole blood) ☐ Packed red blood cells ☐ ፕላትሌት (platelets) ☐ፕላዝማ (FFP) ☐ክራዮ (cryoprecipitate)
5. የተላለፈው ዳም ብዛት ☐ አንድ ☐ ሁለት ☐ ሶስት ☐ አራትና ከዚያ በላይ
6. የተሰጠው ደም ምን ያህል ግዜ ቆይተዋል (ቀን)_____
7. ደም ሲተላለፍ ምን ያህል ሰአት ፈጀ? ☐ ከ 30 ደቂቃ በታች ☐ ከ 30-60 ደቂቃ ☐ ከ 60 ደቂቃ በላይ
8. የክሮስማች ውጤት: ☐ ተመጣጣኝ ☐ ያልተመጣጠነ

ክፍል IV: የህክምና ክትትል እና ቫይታል ምልክቶች

ጊዜ	የሙቀት መጠን T(°C)	የልብ ምት (በደቂቃ)	የደም ግፊት (mmHg)	የአተነፋፈስ ፍጥነት (በደቂቃ)	SpO2 (%)	የጉበት መጠን	ማስታወሻ (የATR ምልክት)
ደም ማስተላለፍ							

ከመጀመሩ በፊት							
ደም መተላለፍ ከመጀመረበት 15 ደቂቃ በኋላ							
ደም መተላለፍ ከመጀመረበት 30 ደቂቃ በኋላ							
በየ 30 ደቂቃ እስከመጨረሻ							
ከ4 ሰዓት በኋላ							
ከ8 ሰዓት በኋላ							
ከ12 ሰዓት በኋላ							
ከ16 ሰዓት በኋላ							
ከ20 ሰዓት በኋላ							
ከ24 ሰዓት በኋላ							

ደም መተላለፍ የመጀመረበት ሰኣት_____ የቆመበት ሰኣት _____

የተገኙ ምልክቶች (ካሉ): ☐ ትኩሳት ☐ ብርድ/ማንቀጥቀጥ ☐ ቆዳ ሽፍታ ☐ እብጠት ☐ መተንፈስ ችግር ☐ የደም ግፊት መቀነስ ☐ ማቅለሽለሽ/ማስታወክ ☐ የደረት ህመም ☐ የልብ ምት ፍጥነት መጨመር ☐ የማጨናነቅ ስሜት ☐ የራስ ህመም ☐ ሌሎች: _____

ክፍል V: የላቦራቶሪ መረጃ

ደም መሰጠት ከመጀመሩ በፊት (Pre-Transfusion)

1. የ CBC ውጤት Hb: _____ g/dL RBC: _____x10^{12}/ul WBC: _____x10^{9}/ul PLT: ____x10^{9}/ul
2. ABO/Rh: ___ / ___
3. Cross-match: ☐ ተመጣጣኝ ☐ ያልተመጣጠነ
4. የሽንት Hb: ☐ አለ ☐ የለም
5. DAT: ☐ አለ ☐ የለም

ደም ከተላለፈ በኋላ (የህመም ምልክት ላላቸው)

1. የ CBC ውጤት Hb: _____ g/dL RBC: _____x10^{12}/ul WBC: _____x10^{9}/ul PLT: ____x10^{9}/ul
2. ዳግም ABO/Rh: ___ / ___
3. ዳግም Cross-match: ☐ ተመጣጣኝ ☐ ያልተመጣጠነ
4. DAT: ☐ አለ ☐ የለም
5. የሽንት Hb: ☐ አለ ☐ የለም
6. የታካሚ የደም ካልቸር ውጤት: ☐ እድገት ኣለ ☐ እድገት የለም የኦርጋኒዝም (ዘአካል) ስም____
7. የደም ሰጪ ካልቸር ውጤት: ☐ እድገት ኣለ ☐ እድገት የለም የኦርጋኒዝም (ዘአካል) ስም____

ክፍል VI: የደም መተላለፍ ህመም ምላሽ ግምገማ

1. የATR ጥርጣሬ: ☐ አለ ☐ የለም
2. ምላሽዎ ኣዎ ከሆነ የህመም አይነት: ☐ FNHTR ☐ አለርጂ ☐ AHR ☐ TRALI ☐ TACO ☐ ባክቴሪያ ብክለት ☐ ሌሎች: _____
3. ምላሽዎ ኣዎ ከሆነ (1) ደረጃ: ☐ ቀላል ☐ መካከለኛ ☐ ከባድ ☐ ሞት
4. የሐኪም ማረጋገጫ: ☐ አለ ☐ የለም
5. ሕክምና ተደርጎለታል? ☐ አዎ ☐ ኣይደለም
6. ምላሽዎ ኣዎ ከሆነ የተደረገ ሕክምና: _____
7. ውጤት (24 ሰዓት በኋላ): ☐ ዳነ ☐ በሕክምና ሂደት ላይ ☐ ሞተ ☐ አይታወቅም

የመረጃ ሰብሳቢ ስም: _____**ፊርማ:** _____
ቀን:_____

ANNEX-IX. Declaration sheet

The undersigned declares that this M.Sc. thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been duly acknowledged.

MSc. Candidate: Shemsu Kedir Signature _____ Date_____

Approval of Advisors

Dr Mikiyas Negash (PhD.): Signature _____Date_____

Mintewab Hussein (MSc.): Signature _____Date_____

Dr Fedlu Jenfa (MD, Internist): Signature _____Date_____