HEMOVIGILANCE - AN ANALYSIS OF ADVERSE EFFECTS OF BLOOD DONATION AMONG BLOOD DONORS AND TRANSFUSION REACTIONS AMONG RECIPIENTS IN A TERTIARY-CARE CENTRE

Dissertation submitted to

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum

In partial fulfilment of the requirements for the degree of

M.D in Transfusion Medicine

By,

Dr. Anila Mani

Under the guidance of

Dr. Debasish Gupta

2018 - 2020

DECLARATION BY THE CANDIDATE

*I hereby declare that this dissertation titled "**Hemovigilance - An analysis of adverse effects of blood donation among blood donors and transfusion reactions among recipients in a tertiary-care centre**" is a bonafide and genuine research work carried out by me under the guidance of **Dr. Debasish Gupta**, Professor and Head, Department of Transfusion Medicine, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum*

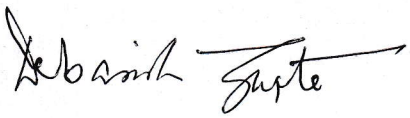
Dr. Anila Mani

*Place: **Trivandrum***

*Date: **30th June 2020***

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation titled ***"Hemovigilance - An analysis of adverse effects of blood donation among blood donors and transfusion reactions among recipients in a tertiary-care centre"*** *is a bonafide research work done by* ***Dr.Anila Mani*** *in partial fulfilment of the requirement for the degree of MD Transfusion Medicine under my guidance and supervision.*



Guide:Dr.Debasish Gupta

Professor& Head

Department of Transfusion Medicine, SCTIMST,Trivandrum

ACKNOWLEDGEMENT

First and foremost, I bow my head to the Almighty for giving me strength, endurance and perseverance which made me capable of carrying out the present work successfully. Words are insufficient to express the love, labour and selflessness that everyone has given and expressed during the last 3 years of tenure in this department.

With deep sense of gratitude, I express my indebtedness to my thesis guide **Prof. (Dr.) Debasish Gupta**, Head, Department of Transfusion Medicine, SCTIMST, Trivandrum for his constant supervision and immense help towards the completion of my work. He has given me his constant support, valuable advices and encouragement towards the progress of my work. It is my immense pleasure to work under the efficient guidance of such a knowledgeable and hard working person with a pleasant personality. I am highly obliged and grateful to him for his time-to-time enquiries about my work and incessant support. I feel myself fortunate to be a student of such a great person without which I would not have been able to finish this work.

I am deeply grateful to **Dr.Mohandoss Murugesan**, Associate Professor, Department of Transfusion Medicine, Malabar Cancer Centre, Thalassery for his expert advice and opinions regarding the thesis.

I am deeply indebted to **Dr.Jayakumar Pillai**, Assistant Professor, Dept. of Biostatistics, Medical College, Trivandrum who helped me with the statistical analysis of the data.

My special thanks to **Mr. Sivaprasad.R** , Senior Medical Records Officer – A , for helping me in data collection and data entry.

I am deeply indebted to **Mr.Ashok Sivasailam,** PhD Scholar, Dept. of Biochemistry, SCTIMST for his valuable and unconditional support.

I take this opportunity to sincerely thank **Dr. Sulochana PV**, Former HOD, Department of Transfusion Medicine SCTIMST, **Dr. Sathyabhama S,** Scientist G,

Department of Transfusion MedicineSCTIMST,for their valuable advice, untiring support and constant encouragement.

I would like to express my gratitude to **Dr. Raj Bharath R** and **Dr. AmitaR**, Associate and Assistant Professors, Department of Transfusion Medicine SCTIMST,for their valuable suggestions and tremendous support.

I am deeply indebted to my senior and junior colleagues – **Dr. VinuRajendran ,Dr.Gayathri AM, Dr.Sreethu Chand** and**Dr.Angel Mary** for the constant and untiring support, freshly brewed ideas and active discussions. I owe my gratitude to all the department staff & students for their constant support.

I take opportunity to thank myparents and family members for their constant support and encouragement. I thank Universal Power for enabling me tocomplete the study without any untoward events.

Last but not the least, I express my deep gratitude to the participants of the study who voluntarily agreed to participate. Without them this research was impossible.

Dr. Anila Mani

ABBREVIATIONS

AABB	American Association of Blood Banks
AFS	Agence Francaise du Sang
AHTR	Acute Hemolytic Transfusion Reaction
ARC	American Red Cross
AST	Aspartate amino transferase
BC	Blood Centre
BNP	B-type natriuretic peptide
BSS	Blood System Secretariat
CDC	Centers for Disease Control and Prevention
CDSCO	Central drugs standard control organization
DART	Danish Registration of Transfusion Risks
DAT	Direct Antiglobulin test
DHTR	Delayed hemolytic transfusion reaction
DMA	Danish Medicinal Agency
DRRF	Donor Reaction Reporting form
DSKI	Danish Society of Clinical Immunology
DSTR	Delayed serological transfusion reaction
DVT	Deep Venous Thrombosis
EBV	Estimated Blood Volume
EC	European Council
FAMHP	Federal Agency for Medicines and Health Products
FFP	Fresh Frozen Plasma
FNHTR	Febrile non-hemolytic transfusion reactions
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HvPI	Hemovigilance Programme of India
IAT	Indirect Antiglobulin test
IBTC	Incorrect Blood Component Transfusion
IBTS	Irish Blood Transfusion Service
IHN	International Hemovigilance Network
IPC	Indian Pharmacopoeia commission
ISBT	International Society of Blood Transfusion
ISTARE	International Database-International Surveillance of Transfusion Associated Reactions and Events
JRC	Japanese Red Cross (JRC)
JRCBSHQ	JRC Blood Service Headquarters
JRCS	Japanese Red Cross Society (JRCS)

LDH	Lactate Dehydrogenase
LOC	Loss of consciousness
LR-RBC	Leuco-reduced Red Blood Cell concentrates
MCE	Major cardiovascular event
MOH	Ministry of Health
NAT	Nucleic acid Amplification Testing
NBS	National Blood Service
NHO	National Hemovigilance Office
NHSN	National Healthcare Safety Network
NIB	National Institute of Biologicals
P-RBC	Packed Red Blood Cell concentrates
PTP	Post -transfusion purpura
PvPI	Pharmacovigilance Program of India
RBTC	Regional Blood Transfusion Centre
RDP	Random Donor Platelets
SDP	Single Donor Platelets
SHOT	Serious Hazards of Transfusion
SOP	Standard Operating Procedures
TACO	Transfusion associated circulatory overload
TAD	Transfusion associated dyspnoea
TAGVHD	Transfusion associated-Graft versus host disease
TAH	Transfusion associated hypotension
TIA	Transient Ischemic Attack
TIR	Transfusion Incidents Reports
TR	Transfusion reaction
TRALI	Transfusion related acute lung injury
TRIP	Transfusion Reactions in Patients
TRRF	Transfusion Reaction Reporting Form
TSO	Transfusion safety officers
TSO	Transfusion Surveillance Officers
TTBI	Transfusion Transmitted Blood stream Infections
TTI	Transfusion Transmitted Infections
UK	United Kingdom
VVR	Vasovagal Reaction

CONTENTS

Topic	Page Numbers
Introduction	1
Aims & Objectives	5
Review of Literature	7
Materials and Methods	44
Results	50
Discussion	92
Summary and Conclusion	103
Limitations of the Study	106
Bibliography	108
Annexure	

INTRODUCTION

Hemovigilance is an important aspect of blood safety which aims at identification, monitoring and prevention of adverse reactions, incidents and adverse events related to blood donation and transfusion for both blood donors and patients (1). Proper analysis of donor complications and transfusion reactions, incidents and events are essential to identify contributing factors. Hemovigilance is an essential tool to understand the clinical consequences of transfusion of blood and blood components, and to develop and implement actions to prevent further recurrence. Hemovigilance is an important part of the quality system for both blood collection and blood transfusion. It implies the various methods for the identification of errors, adverse events and reactions including investigation systems, traceability systems, notification systems and audits of practice.

Hemovigilance may be performed in a hospital to improve blood collection from the blood donor or to improve blood transfusion practices, but this does not create a system. A hemovigilance system comes into existence only when data of adverse transfusion events are collected through an organized network for reporting to a central office where the data are compiled together and analysed by experts and recommendations are made appropriately and further evaluation made for blood safety (2).

Lack of proper awareness and adequate motivation among the people compounded with a fragmented blood transfusion service in our country, often leads to shortage of blood and blood components. Generally, two strategies are adopted to satisfy the demand of blood and blood components –donor recruitment and retention of those donors who are already recruited. Adverse events (AEs) in blood donors can adversely impact our donor recruitment and donor retention (3).

The International Hemovigilance Network (IHN) defines haemovigilance as ‘A set of surveillance procedures covering the whole transfusion chain beginning right from the collection of blood and its components to the follow-up of all recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence’ (IHN). IHN works in co-ordination with the Working Party on Hemovigilance of the International Society of

Blood Transfusion (ISBT) in framing and publishing definitions concerned with major donor and patient-related complications (4, 5)

Hemovigilance has evolved from Pharmacovigilance, which aims at collection and assessment of information in relation to medicinal products. Pharmacovigilance in transfusion medicine deals with plasma derivatives such as Clotting factor concentrates immunoglobulins, albumin, and other plasma fractionated products. Hemovigilance is responsible for blood components like Whole blood, red cell concentrates, platelet concentrates, and fresh frozen plasma. Hemovigilance Program of India was officially launched at the national level on December 10, 2012, as a fundamental constituent of the Pharmacovigilance Program of India (PvPI) (6).

The valuable information obtained through hemovigilance is essential to make appropriate changes in transfusion policies, for improvement in transfusion practices in hospitals and blood transfusion services, to achieve better transfusion standards, to help in creating transfusion guidelines and to improve quality and safety of entire transfusion chain. The eventual goal is to enhance the overall safety of transfusion safety by uncovering and analysing all adverse effects of blood transfusion to correct their cause and to prevent occurrence and recurrence (6).

The recipient hemovigilance should include reporting of unexpected adverse reactions due to blood and/or blood component transfusions and the action taken as a result. This will include all minor and major adverse reactions encountered in blood transfusion including acute and delayed transfusion reactions. Recipient vigilance includes the transfusion reactions associated with the transfusion of various blood components and the corrective measures taken to minimize transfusion related adverse outcome.

The donor hemovigilance should include the systematic reporting of unexpected adverse events and complications in whole blood and blood component donors .These events may be adverse reactions or complications resulting from selection, donation, and management of donors, which may directly harm the donor or influence the quality of the product, thereby putting the recipient at risk. Blood centers should continuously try improving the practices that are followed to create a pleasant donation experience for all donors. To accomplish such a target there should be an effective and comprehensive program to monitor donor complications as the pillar stone of a blood donor safety program.

We as a tertiary care centre aims to study the entire donor related adverse reactions and blood transfusion reactions in the recipient. The donor vigilance will include any adverse reactions in the blood donor from the pre-donation phase to the post-donation phase. Recipient vigilance will include the adverse reactions encountered during and after transfusion of blood and blood components. Donor vigilance is done to improve the donor comfort and safety, so that they get motivated to become a regular non-remunerated voluntary donor and will ensure donor retention. Recipient vigilance will help us to improve the patient safety by adopting safe transfusion practice with improved quality of blood components. This study aims to investigate the various donor and recipient adverse reactions and the overall measures that can be taken to prevent the occurrence of further adverse reactions in future. This study will help us promoting safe blood practices right from the vein of the blood donor to the vein of the transfusion recipient.

AIMS AND OBJECTIVES

The study is carried out with the following aims:

- To analyse the incidence of adverse reactions to blood donation in a tertiary care centre in Kerala.
- To analyse the incidence of transfusion reactions amongst patient population.
- To determine the causative factors for various adverse reactions to blood donation and blood transfusion.

The study is carried out with the following objectives:

- To develop strategies to reduce incidence of donation reaction and transfusion reactions
- To generate evidence-based recommendations for safe blood donation and transfusion practice
- To promote safe blood transfusion practices
- To create awareness amongst healthcare professionals to minimize the adverse donation and transfusion outcome.
- To improve the adverse reaction reporting system to maximize donor and recipient comfort.

REVIEW OF LITERATURE

History

The word ‘hemovigilance’ (he´movigilance in French) was coined in France in and it is derived from the Greek word ‘haema’ (means blood) and the Latin word ‘vigilans’ (means watchful) (7).

The first blood transfusion attempts in the 17th century were attempts to transfuse humans with blood of animals for all kinds of illnesses. However, in 18th century the French King Louis XIV forbade the transfusion of animal blood to humans by law because it was considered to be too dangerous (8). In the 19th century, Henri Leacock and James Blundell pioneered human-human transfusion as a lifesaving therapy for severe blood loss. Blundell, however warned to apply this therapy only as ultimum refugium because it was also dangerous (9)**.** Due to the discovery of anti-coagulation and matching with available techniques blood transfusion became less dangerous in the 20th century. Although it was realized that transfusion was certainly not without risk, data regarding the actual transfusion risk were lacking.

Towards the end of the 1980s, the transmission of infections by blood created the need for a greater awareness on the safety of blood and pioneer work on hemovigilance started in France in 1992 with the set-up of monitoring systems by Blood Transfusion Committees, resulting in a national hemovigilance network in 1994 (10). Hemovigilance is a set of surveillance procedures that covers the whole transfusion chain from the collection of blood from the blood donor and its components to the follow-up of its recipients. Hemovigilance is defined to collect and analyse information on unexpected or undesirable events resulting from the therapeutic use of labile blood products and to prevent its future occurrence and recurrence (11).

Hemovigilance programmes of various countries

Initial hemovigilance programmes came into existence primarily to improve patient safety because of the fact that blood transfusion was identified as one of the major causes for transmissible infections. Later on, there was better understanding that causes of transfusion untoward effects may be found at all levels, from donor selection to the transfusion act. The international hazard surrounding the infection of the blood components by Human Immunodeficiency Virus (HIV) in the 1980s, together with the increasing risk of transfusion

associated Hepatitis C Virus (HCV) led to the development of hemovigilance in many of the countries.(12)

In 1992, the French health authorities undertook a thorough reorganisation of the existing transfusion system in reaction to the trauma of the mismanaged blood affair and at a time when transfusion appeared to be one of the major routes of HCV transmission. One of the innovative advances of the Blood Transfusion Safety Act of 1993 was the advent of haemovigilance. Haemovigilance is a national system of surveillance and alarm, starting right from blood collection to the follow-up of the recipients. The << Agence Francaise du Sang >> (AFS) was entrusted to set forth for the functioning of haemovigilance system, starting in 1994. The aim of Haemovigilance was to detect, gather and analyse all untoward effects of blood transfusion in order to correct their cause and to prevent further recurrence (10).

In French Hemovigilance system, to a network of haemovigilance correspondents, the physicians for every blood centre in every hospitals performing transfusion was entrusted the responsibility to collect reports on transfusion related adverse events and report them to the local health authorities and then to the AFS centralised haemovigilance cell. Regional co-ordinators would supervise the application of haemovigilance. Transfusion Incidents Reports (TIR) are centralised at the AFS level. The AFS haemovigilance aims at revealing trends and providing a better understanding of transfusion morbidity. The AFS also takes initiative and funds prospective studies in haemovigilance (10).

In Japan, the Japanese Red Cross Society (JRCS) recognized the importance of a well-coordinated blood safety system as the very first step in the formation of a blood transfusion organization and founded an established hemovigilance system in 1993 (13). Japanese Red Cross Society (JRCS) is the sole provider of labile blood products, and controls collection, processing and supply of blood products nationwide (14). The Japanese Red Cross (JRC) haemovigilance deals with both adverse reactions and infectious diseases (15).

All cases of suspected adverse reactions and infectious diseases caused by transfusion would be reported to the JRC Blood Service Headquarters (JRCBSHQ) nationwide. All cases of transfusion transmitted infections and adverse reactions be reported. Blood centres would inform the Safety Vigilance Division about the reported cases and also conduct tests such as the irregular antibody test. Nucleic acid amplification testing (NAT) centres conduct tests required for investigating suspected transfusion-transmitted infections and Plasma Fractionation Center investigates reactions related to plasma derivatives. JRCBSHQ

investigates the causal relationship of the adverse event or reaction to transfusion. The results of all possible information gathered in hemovigilance system on reported cases are provided to medical institutions in order to help doctors in charge to make an accurate diagnosis and thereby improving quality and safety of blood products being administered (15)

In United Kingdom (UK), Serious Hazards of Transfusion (SHOT) scheme was established in 1996 as a National confidential reporting system for adverse events among patients. It has introduced an evidence base of transfusion risks that would help to improve patient safety by informed policy decisions, improved standards of hospital transfusion practice, supporting formulation of clinical guidelines, and educating appropriate clinical use of blood among clinicians. The scheme encompassed all labile blood components issued by the four UK blood transfusion services namely National Blood Service [NBS] in England, Scottish National Blood Transfusion Service, Northern Ireland Blood Transfusion Service and the Welsh Blood Service (16).

Participation in SHOT scheme is voluntary and strict confidentiality of individual patients, donors, and reporters were assured. This initiative could encourage all hospitals to establish and support a hospital transfusion team, consisting of a consultant hematologist, a transfusion practitioner, and the blood centre manager. Such teams play a vital role in promoting good transfusion practices and to ensure that all adverse events are recognized, investigated, and reported. A multidisciplinary standing working group and the steering group, undertakes the expert review of case reports. Day to day functioning of SHOT is the responsibility of the national medical coordinator and the scheme manager, who will be supported by a data collection specialist and an administrator based in an NBS blood center. The scheme is funded by the UK blood services (16).

In France, the hemovigilance system was made mandatory by law in 1994 and the system is centralized and nationwide, with legal obligation to notify in written format each and every adverse event related to blood transfusion. In the UK hemovigilance system, SHOT (Serious Hazards of Transfusion) is a national voluntary scheme between professionals to increase the quality and safety of the entire transfusion chain (17).

In 1996 the Dutch Inspectorate of Health being inspired by the United Kingdom’s initiative to establish a reporting system for serious hazards of transfusion enquired from the National Blood Transfusion Council regarding the possibility to develop a national surveillance system of hemovigilance in Netherlands. An independent foundation named TRIP (Transfusion

Reactions in Patients) was formed, which was owned by the professional medical societies engaged in blood transfusion. TRIP was officially launched at the 5th European Hemovigilance Seminar in Amsterdam on February 6-7, 2003.The TRIP office had the aim to anonymously collate, register, analyze and report on the transfusion safety. In addition, TRIP aimed at enhancing the safety of blood transfusion by organising educational programs on safe transfusion practices. The TRIP program closely resembles the British SHOT system, in being a voluntary system and holds the view that the correct and optimal use of blood is important for blood transfusion safety and the prevention of adverse events (18).

The term hemovigilance is not in common practice in the United States. But, the concept of monitoring morbidity and mortality associated with blood transfusion is widely accepted. Transfusion medicine practices in the United States exhibits extensive regulatory oversight of "manufacturing" aspects of blood centering and on the other hand clinical transfusion practice guidelines/ audits provide oversight of "medical and technical" issues. In addition, American Association of Blood centres (AABB) Standards contain requirements for blood issue, issuing blood under emergency situations, and limiting medications that should be added to blood. An entire section includes requirements for detection, reporting, and evaluation of suspected complications of transfusion like immediate, delayed, and infectious disease complications (19).

The content of the Directive 2002/ 98/EC (European Council) certain aspects of haemovigilance in Article 14 on 'traceability' and in Article 15 on 'notification of serious adverse events and reactions'. Article 29 mentions that traceability has to be regulated and there should be an established community procedure for notifying serious adverse reactions and events including the introduction of a common notification format. Traceability needs a unique identification system, and storage of data in relation to complete traceability must be guaranteed for a minimum of 30 years. Notification is essential for any serious reactions (observed during and after transfusion process) and must be notified to the concerned authority if potentially attributable to the quality and the safety of blood components (20).

According to European Directives, Hemovigilance should be considered not only as a surveillance tool of the blood transfusion chain but also to be used as a quality measure to improve quality and safety of the process of blood transfusion. It is the responsibility of the Member States to ensure that all the activities related to the vein-to-vein concept are covered to the same extent (20).

In 1998 by the Danish Society of Clinical Immunology (DSKI), initiated the Danish Registration of Transfusion Risks (DART) in agreement with Danish Medicinal Agency (DMA), which is the official body for registering drug complications. Initially, the DART system was organized as a copy of SHOT in view of making it possible to compare the results from these two systems. An agreement was made with the DMA to initiate the DART system on a voluntary and confidential basis, if the DMA was informed immediately about any appearance of a serious or a new kind of transfusion complication. It was already a legal obligation to report transfusion complications but the rule was that the messages should go directly to the DMA. The implementation of this system was announced to all the directors of the transfusion centers and the report forms were thoroughly explained at a national meeting (21).

Because of the close association between the clinical department and the transfusion center, a transfusion complication will almost always be informed to the centre. As further guarantee, the department should always send a written report back to the center including the description of how the patient reacted to the blood transfusion. Inorder to ensure a 100% return rate of reports, if the report does not arrive within a few days of transfusion, the center will call for it (21).

In case of Ireland, HCV infection of women through infected anti-D immunoglobulin and hemophilia patients who got HIV and HCV infection from infected factor concentrates ensured that hemovigilance would be adopted as a part of transfusion safety. The hemovigilance system in Ireland was launched in October 1999 under the National Hemovigilance Office (NHO) which is based in the Irish Blood Transfusion Service (IBTS). Reports are collected on an anonymously and is staffed by a Consultant Hematologist with two Transfusion Surveillance Officers (TSO), an administrator with an administrative assistant, and is regulated by the Irish Medicines Board (22).

According to the Ireland hemovigilance system, in-depth analysis of individual incidents, along with the review of incidents generates recommendations to improve future transfusion practice. They recommend drawing attention to a systemic approach to eliminate error rather than following a blame culture. Hemovigilance scheme has the capacity to improve overall patient safety which extends well beyond the transfusion process itself if implemented appropriately(22).

The organization of hemovigilance is one of the missions of the Federal Agency for Medicines and Health Products (FAMHP) in Belgium. The purpose of hemovigilance is to assure and improve the quality and safety of the whole blood transfusion chain from the donor to the recipient including the safety of blood collection and the transfusion of blood components. To accomplish this goal, data on serious adverse events and reactions, that may affect the quality of blood and labile blood components or may put the donor or the recipient in danger are recorded and later evaluated. Reporting of the serious adverse reactions and events are mandatory (23).

In Belgium, three years of hemovigilance reporting showed a clear reduction of errors in connection with prescription and sampling leading to cases of incorrect blood component transfusion (IBCT). This was definitely the result of the wide implementation of the procedure of pre-transfusion blood grouping and comparison blood samples of two different blood takings. Hence, hemovigilance data and the appropriate analysis of it have helped to reduce avoidable "wrong blood" transfusions. They proposed that further reduction of human errors will need to be focused on the appropriate utilization of computerized systems (23).

Massachusetts have been using National Healthcare Safety Network (NHSN) to report health care-associated infection data since 2008.The National Healthcare Safety Network (NHSN) is a voluntary, Web-based surveillance system operated by the Centers for Disease Control and Prevention (CDC) that is used by health care facilities in the United States to report patient safety information. Biovigilance section of the NHSN encloses the Hemovigilance Module that is designed to monitor transfusion-related adverse events and reactions. Hospital based transfusion centres that participate can share the data they enter into the system with external agencies, such as patient safety organizations or a state health department, to meet reporting requirements. In addition to this, users are provided access to their own data in a format that allows for comparison with state and national compiled data. The Massachusetts Hemovigilance Module also contains built-in analysis functionality designed for use at the facility level for assessment of reported data to improve transfusion safety and further evaluation of the effectiveness of modifications (24).

Quebec in the year 1998 passed a law creating Hema-Quebec, which is an independent corporation responsible for the manufacture and distribution of blood products, and to establish a Hemovigilance. Inorder to ensure the application of best-practice of standards in transfusion medicine, the Ministry of Health (MOH) also designated a network of 20 regional

hospitals and Transfusion safety officers (TSO) were appointed at the designated hospitals to oversee transfusion activities. A Blood System Secretariat (BSS) was also established at the MOH with to look after the responsibilities for the blood system. Participation in the Quebec hemovigilance system is not mandatory (25).

The hemovigilance system in Quebec monitors both major and minor adverse transfusion reactions, transfusion related incidents such as ‘‘incorrect blood component transfused’’ (IBCT), with or without adverse effects, and near-miss events. All transfusion events associated with administration of both blood components and plasma derivatives are monitored and denominator data on all transfused products are obtained. Data from the Quebec hemovigilance system have proved it useful in sensitizing hospitals to the importance of reporting adverse transfusion events and their prevention (25).

The American Red Cross (ARC) has nearly 7 million blood donors who donate whole blood or apheresis components The ARC has got an established a national hemovigilance program to systematically analyze donor complications. Adverse reactions occurring at the collection site are managed by collection staff, documented on the blood donation record according to a well-defined classification scheme and captured to a central electronic database. Minor or major reactions, with or without injuries are reported by the donor or third parties after the proper management of donation by standard procedures under the supervision of a facility physician, and would be later reported to the national hemovigilance system. The information thereby obtained confirms the overall safety of blood donation and would provide an estimate of risk currently associated with allogeneic whole blood and automated collection procedures (26).

In Germany, the Hemovigilance System is defined by the Medicinal Products Act and the Transfusion Act that came into force in the year 1997. The Medicinal Products Act was amended in 2005 in accordance with EU legislation (Directive 2005/61 EC) with the aim of rapid identification of serious risks related to the blood components at both local and national levels and a rapid initiation of adoption of appropriate risk minimization interventions. Effectively coordinated donor data collection and the proper identification of blood components and recipients by electronic recording with improvement in the quality systems in the blood donation centres and hospitals are important elements for increasing standards of blood product use. After the advent of hemovigilance system, Germany has reached high standards in the safety of blood products (27).

Among developing countries, some emerging economies are making good advancements in developing a structured and well-organized blood transfusion services. Some countries are making attempts to establish a national hemovigilance program. A few countries like South Africa, Malaysia, Thailand and Tunisia have already established hemovigilance program modeled similar to the developed world. Simple basic data collection introduction and later on a comprehensive data collection are implemented as the BTS develops .Various types of models are formulated and implemented to suit the needs of various nations (28).

Currently, on a global scale an International Hemovigilance Network (IHN) is functioning which has originally evolved from European Hemovigilance Network that was founded in 1998. The IHN is intended to initiate and maintain a joint structure related to the safety of blood and labile blood components and of hemovigilance in blood transfusion services and in the field of transfusion medicine throughout the world (29).

The IHN in association with International Society of Blood Transfusion (ISBT) working party on hemovigilance proposed standard definition for hemovigilance system in the year 2011 (4).To further improve the safety of donors and recipients, an international database-International surveillance of transfusion associated reactions and events (ISTARE) has been created (http: //www. ihn-org.com/haemovigilance-databases/istare-2/),where the hemovigilance data can be shared across the whole world. The main goal of ISTARE is to capture all adverse reactions and incidents (events) in recipients of blood and blood products that can certainly, probably, or possibly be attributed to blood transfusion. It also records adverse events in blood donors (29).

In Indian Scenario, Hemovigilance program as an integral part of Pharmacovigilance Program of India (PvPI) at a national level has been launched on December 10, 2012 with a road map of 5 years with four phases. The four phases of Hemovigilance Programme of India (HvPI) are an initiation phase, expansion and consolidation phase, expansion and maintenance phase, and optimization phase (Figure: 1). A core group was constituted to coordinate the activities of hemovigilance between the medical colleges and National Coordinating Centre at Indian Pharmacopoeia commission (IPC) (30). An advisory committee has also been constituted to:

a) Finalize hemovigilance - Transfusion Reaction Reporting Form (TRRF) to be introduced in the country

b) Give expert opinion for collection, collation, and analysis of hemovigilance data and development of the software for the same

c) To monitor the functioning and quality of the data collected by the Adverse Transfusion Reaction Reporting Centres

d) Develop training modules and guidelines for implementation of hemovigilance program under PvPI

e) Develop a roadmap for linking hemovigilance program under PvPI with International Haemovigilance Network.

Sixty medical colleges that are already enrolled under PvPI have been included in the program initially with the intention of an increment to a total of 90 medical colleges by March 2013. The plan was to enroll all hospitals in this program by the year 2016 in order to have a National Centre of Excellence for Hemovigilance at NIB, which will act as a global knowledge platform.

Hemovigilance program has been launched with the following objectives:

1. Monitor transfusion reactions

2. Create awareness among health care professionals

3. Generate evidence-based recommendations

4. Inform Central drugs standard control organization (CDSCO) for safety related regulatory decisions

5. Communicate findings to all key stakeholders

6. Create national and international linkages

The hospitals which are enrolled under hemovigilance program will collect data with respect to adverse reactions associated with blood transfusion and blood product administration in TRRF from their respective Transfusion Medicine departments. The information thereby collected in TRRF will be forwarded to the coordinating Centre National Institute of Biologicals (NIB) through software developed by NIB Information technology division. The data will be consolidated and analyzed to find out trends and provide recommendations regarding best practices and interventions required to improve patient care and transfusion safety. The suggestions and recommendations will be forwarded to the national coordinating

Centre IPC, PvPI for further reporting to Drugs Controller General (India), and then to Central Drugs Standard Control Organization. Those recommendations will be used to create safety related regulatory decisions on blood and labile blood products transfusion that will be communicated to various stake holders (30). (The flow chart of organizational structure is given in Figure: 2)

Hemovigilance includes the proper identification, reporting, investigation and analysis of adverse reactions and events in recipients and blood donors. It also encloses incidents in manufacturing processes, eventually errors and "near-misses". Centres under HvPI are blood centres located in Medical Colleges/ Institutes/ District Hospitals/ Private Hospitals and Stand-alone Blood Centres in India that are registered with the National Coordinating Centre for Haemovigilance Programme of India for reporting the Adverse Reactions that occur during Blood/ Blood Component Transfusion or Blood Product Administration (31).

Haemo-vigil is Software which is being used for HvPI to collect & collate Transfusion Reaction Reports from Centres under HvPI for onward transmission of data to NCC. Software was indigenously developed by NIB & was officially launched on 24thJan, 2013.It is the responsibility of NIB; Coordinating Centre for Hemovigilance Programme of India that the reports received will be kept with strict confidence and protected to the maximum possible extent. Programme staff members are not expected to and will not disclose the reporter's identity in response to a request from the public (31).

Figure No.1: Four phases of Hemovigilance programme of India

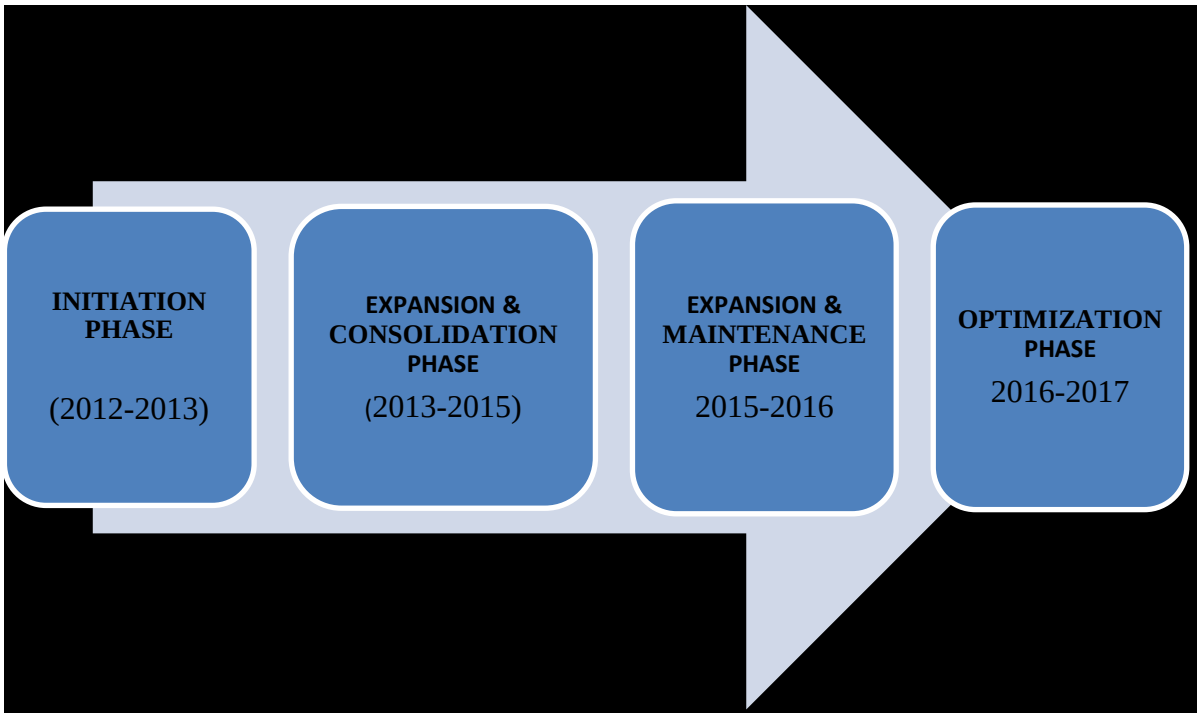
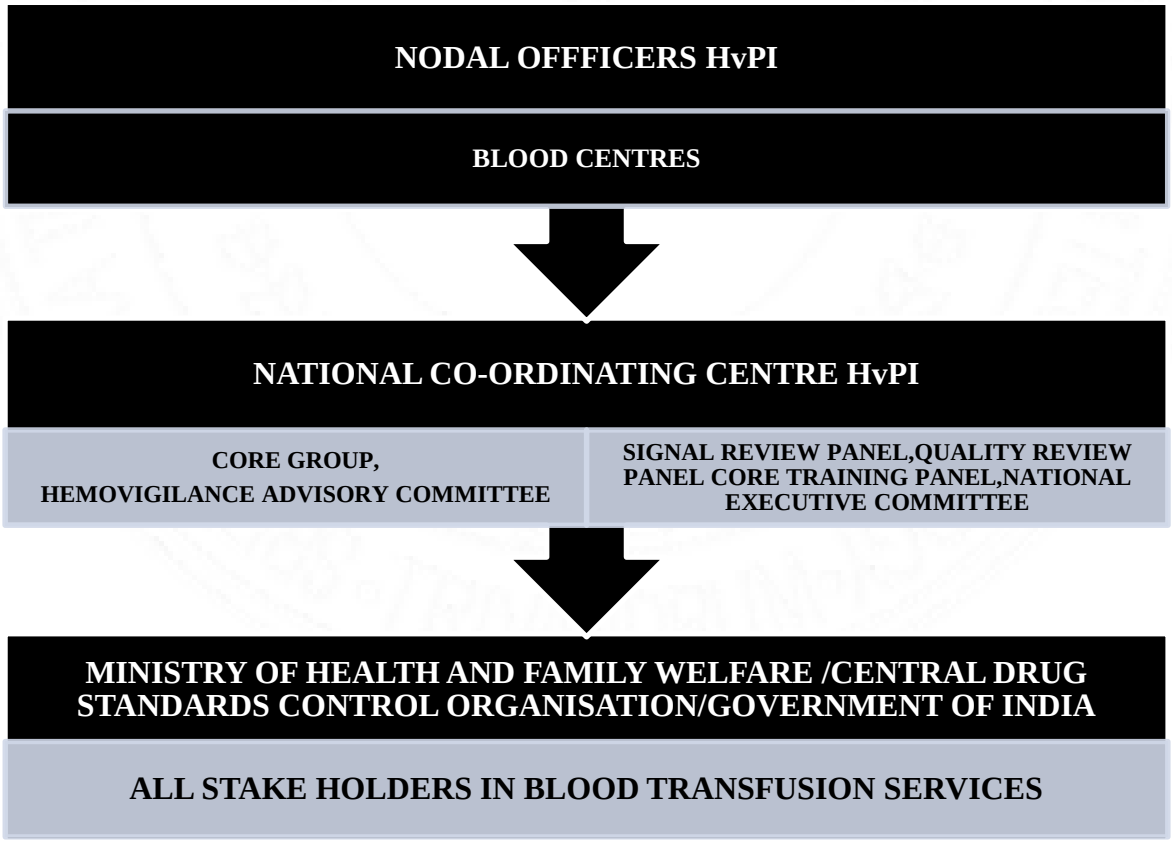


Figure No.2 : Hemovigilance Programme of India – ORGANOGRAM (Organisational structure for flow of HvPI information)



Hemovigilance: Essential Terminologies and Definitions

Errors and adverse events can occur in any aspects of the process of health care and transfusion risks are a small proportion of the risks to which patients are exposed. Therefore, a quality control system for blood transfusion should be a part of a hospital's wider quality management system. Below mentioned definitions are from "Guidance Document of Hemovigilance Programme of India for reporting of adverse transfusion reactions blood transfusion services 2019" (31).

- **Hemovigilance:** A set of surveillance system covering the whole transfusion chain right from the collection of blood and its components to the follow-up of recipients), which is established for compiling and assessing the data on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.(http://www.ihn-org.net)
- **Adverse event :** Any undesirable and unintended occurrence before, during or after transfusion which may be the result of an error or an incident that may or may not result in a reaction.
- **Incident :** When the patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was supposed to be for another patient and may or may not lead to an adverse reaction.
- **Near miss :** Error or deviation from Standard Operating Procedures (SOP) or policies that are made before the start of the transfusion and could have led to a wrongful transfusion or to a reaction in a recipient.
- **Adverse reaction :** Any undesirable response or effect in a patient which is temporally associated with the administration of blood or blood component.
- **Serious Adverse Reaction :** Any untoward response in a donor or in a patient which is associated with the collection or transfusion of blood or labile blood components that is disabling / incapacitating or that can be fatal, life-threatening, or can result in or prolong hospitalization or morbidity.

- **Serious Adverse Event :** Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalization or morbidity.

A well efficient hemovigilance system also detects deviations that do not result in adverse reactions in patients as well as complications in donors (7).

Imputability Levels

Definite (certain): When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion.

Probable (likely): When the evidence is clearly in favour of attributing the adverse event to the transfusion.

Possible: When the evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.

Unlikely (doubtful): When the evidence is clearly in favour of attributing the adverse event to causes other than the transfusion.

Excluded: when there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion.

TRANSFUSION REACTIONS

Definitions and classifications are in accordance with the "Guidance Document of Hemovigilance Programme of India for reporting of adverse transfusion reactions blood transfusion services 2019" (31).

Transfusion reaction: Any untoward or unexpected event or incident with a temporal relationship to blood transfusion is called a transfusion reaction.

Classifications

1. Non -infectious Transfusion Reactions

Hemolytic Transfusion Reactions

- Acute hemolytic transfusion reaction (AHTR)
- Delayed hemolytic transfusion reaction (DHTR)
- Delayed serological transfusion reaction (DSTR)

Non-Hemolytic Transfusion Reactions

- Febrile non-hemolytic transfusion reactions (FNHTR)
- Allergic transfusion reaction / Anaphylaxis
- Transfusion associated-Graft versus host disease (TA-GVHD)
- Transfusion related acute lung injury (TRALI)
- Transfusion associated dyspnoea (TAD)
- Transfusion associated circulatory overload (TACO)
- Transfusion associated hypotension (TAH)
- Post -transfusion purpura (PTP)

- **Other Transfusion Reactions**
  - Hemosiderosis, Hyperkalemia
  - Unclassifiable Complication of Transfusion
- **Errors and Incidents**
  - IBCT, Handling and Storage errors,
  - Near miss events

Infectious Transfusion Reactions

- Transfusion transmitted bacterial infections
- Transfusion transmitted viral infections
- Transfusion transmitted parasitic infections

Table No.1 : Classification of transfusion reactions on the basis of time of onset		
Acute transfusion reactions	**Onset during or within**	**Type of reaction**
	1 hour	TAH
	4 hours	FNHTR, Allergic reaction
	6 hours - 12 hours	TRALI, /TACO
	24 hours	HTR, TAD
Delayed transfusion reactions	**Onset between**	**Type of reaction**
	24 hours - 28 days	DHTR, DSTR
	5 - 12 days	Post transfusion Purpura
	7 - 42 days	TA-GVHD

Table No. 1(A) : Immune Mediated TRs	
I. Acute TR	**II. Delayed TR**
1. Acute hemolytic TR(AHTR) 2. Febrile Non-Hemolytic TR (FNHTR) 3. Allergic TR 4. Anaphylactic TR 5. Transfusion Related Acute Lung Injury(TRALI)	1. Delayed hemolytic TR (DHTR) 2. Allo-immunization 3. Post-transfusion Purpura 4. Transfusion related Graft versus host disease(GvHD) 5. Immunomodulation
Table No. 1(B) : Non-immune mediated TRs	
I. Acute TR	**II. Delayed TR**
1. Hemolytic –Physical/chemical damage to RBCs 2. Bacterial contamination 3. Circulatory overload 4. Coagulopathy: Depletion/dilution of coagulation factors or platelets 5. Air embolism 6. Metabolic citrate toxicity, hyperkalemia, hypokalemia	1. Transfusion associated infections 2. Iron overload

DEFINITIONS AND DIAGNOSIS

1. Hemolytic Transfusion Reactions (HTR):

A hemolytic transfusion reaction is characterized by clinical and laboratory signs of increased red cell destruction produced by blood transfusion. Hemolysis can occur intravascular or extravascular and can be acute or delayed.

1.1 Acute Hemolytic Transfusion Reaction (AHTR):

It has its onset during or within 24 hours of completion of transfusion.

Immune AHTR: AHTR is immune if there is positive serology with ABO incompatible transfusion, incompatible crossmatch, and direct antiglobulin test positive with or without positive antibody screen.

Non–Immune AHTR: AHTR is non-immune if the serology is negative and mechanical/thermal/toxic cause of red cell hemolysis is present.

Clinical signs of red cell destruction: Occurs during, immediately after, or within 24 hours of cessation of transfusion with **any** of the following signs and symptoms - (Table: 2)

Table No.2 : Symptoms and signs of red cell destruction

Symptoms	Signs
• Fever • Chills/rigors • Chest pain • Abdominal pain • Back/flank pain • Nausea/Vomiting • Diarrhoea • Jaundice • Diffuse Bleeding • Dark urine (Cola coloured)	• Facial Flushing • Hypotension • Pallor • Oliguria/anuria

Laboratory features of red cell destruction: Occurs during, immediately after, or within 24 hours of cessation of transfusion with **few** of the following laboratory features- (Table: 3)

Table No. 3 : Laboratory features of red cell destruction	
• Decreased Hemoglobin • Increased Plasma Hemoglobin • Hemoglobinuria • Unconjugated hyperbilirubinemia • Decreased serum haptoglobin • Increased LDH/AST levels • Spherocytosis and fragmented red cells on peripheral blood film	• Deranged renal function tests, serum electrolytes • Positive Direct Antiglobulin test (DAT) for anti-IgG and/or anti-C3 • Decreased fibrinogen, presence of Fibrin Degradation Products

All the above mentioned clinical or laboratory features may not be present in every cases of hemolytic transfusion reactions.

1.2. <u>Delayed Hemolytic Transfusion Reaction (DHTR)</u>:

The transfused recipient develops clinically significant new alloantibodies against red blood cells between 24 hours to 28 days after a blood transfusion despite an initial adequate hemoglobin response.

- Clinical and laboratory features of red cell destruction are usually present but are less severe compared to AHTR
- It may manifest as an inadequate rise of post-transfusion hemoglobin level or unexplained fall in hemoglobin after a transfusion or an unconjugated hyperbilirubinemia.
- Blood group serology usually shows positive direct antiglobulin test and positive antibody screen either due to newly formed alloantibody or pre-existing alloantibody missed on pre transfusion testing.

1.3 <u>Delayed Serological Transfusion Reaction (DSTR)</u>:

It is characterized by the presence of clinically significant alloantibodies against red blood cell antigens which were previously absent with absence of clinical and laboratory features of hemolysis. This can also happen between 24 hours and 28 days after cessation of a transfusion.

The recipient may demonstrate a Positive direct antiglobulin test (DAT) or a Positive antibody screen with newly demonstrated red cell alloantibody. DSTR reactions are not

severe as there are no clinical signs and symptoms. DSTR reactions are not severe as there are no clinical signs and symptoms.

Severity of hemolytic transfusion reactions :

Grade 1 (Non-Severe): The transfusion recipient may have required medical intervention (e.g. symptomatic treatment) but lack of such would not result in permanent damage or any bodily function impairment..

Grade 2 (Severe): The recipient required in-patient hospitalization or prolongation of hospitalization that are directly attributable to the event OR persistent or significant disability or incapacity OR Medical or surgical intervention required precluding permanent damage or impairment of a body function.

Grade 3 (Life threatening): The recipient required major intervention following transfusion in the form of vasopressors, intubation, and transfer to intensive care to prevent death.

Grade 4 (Death): The recipient died following an adverse reaction and the death is possible, probable or definite in relation to transfusion.

If the recipient died of another cause other than blood transfusion, the severity of the reaction should be graded as 1, 2 or 3.

2. Cardio-Respiratory Transfusion reactions:

Pulmonary symptoms are predominant that are characterized by respiratory distress or pulmonary edema due to pulmonary capillary damage produced by blood transfusion. These reactions which include TRALI, TACO and TAD are considered as **primary pulmonary reactions**.

Secondary pulmonary reactions occur in the presence of another transfusion reaction in which lung is not the mainly affected site. These transfusion associated complications include anaphylactic reactions, hemolytic transfusion reactions and Transfusion Transmitted Blood stream Infections (TTBIs).

Grades of severity of all pulmonary transfusion reactions are similar to AHTR.

2.1 Transfusion Related Acute Lung Injury (TRALI):

TRALI is defined as an acute hypoxemia with partial pressure of oxygen (PaO2) /fraction of inspired oxygen (FIO2) ratio of 300 mm Hg or less along with chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e., circulatory overload). Onset of TRALI is abrupt in relation with transfusion.

Definition Criteria

2.1.1 Definite TRALI: There is no evidence of acute lung injury (ALI) prior to initiation of transfusion,

TRALI is diagnosed, if a new onset Acute Lung Injury occurs with the following five criteria:

- Acute onset
- Hypoxemia
    - $Pa0_2/Fi0_2$< 300 mm Hg or
    - Oxygen saturation < 90% on room air or
    - Other clinical evidence
- Bilateral infiltrates on frontal chest radiograph (Chest X-Ray)
- No evidence of left atrial hypertension (i.e. circulatory overload)
- No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion can be established

Table No.4 : Alternate risk factors for ALI

• Direct Lung Injury • Aspiration • Pneumonia • Toxic inhalation • Lung contusion • Near drowning • Indirect Lung Injury	• Severe sepsis • Shock • Multiple trauma • Burn Injury • Acute pancreatitis • Cardiopulmonary Bypass • Drug Overdose

2.1.2 Possible TRALI: If there is presence of temporal relationship of TRALI to an alternate risk factor for Acute Lung Injury.

2.3 Transfusion Associated Circulatory Overload (TACO):

TACO is characterised by infusion volume that cannot be effectively processed by the recipient circulatory system either due to a high infusion rate and/or high infusion volume or an underlying cardiac or pulmonary pathology.

Definition criteria: Patients classified with **TACO** should have an acute or worsening respiratory compromise during or up to 12 hours after completion of transfusion and should exhibit two or more of the criteria:

- Evidence of acute or worsening pulmonary edema based on:
  - **Clinical physical examination** - crackles on lung auscultation, orthopnea and cough, cyanosis and decreased oxygen saturation values in the absence of other specific causes.
  - **Diagnostic Radiographic imaging** - Presence of new or worsening pleural effusions, progressive lobar vessel enlargement, peribronchial cuffing, bilateral Kerley lines, alveolar edema with nodular areas of increased opacity and/or enlarged cardiac silhouette .
- Evidence for cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral edema.
- **Blood pressure monitoring** - Often the arterial pressure is raised with widened pulse pressure. But, hypotension may be a presenting feature among patients in a state of acute cardiac collapse.
- Evidence of fluid overload includes any of the following:
  - a positive fluid balance
  - response to diuretic therapy combined with clinical improvement ,and
  - change in the patient's weight in the peri-transfusion period
- Elevation of B-type natriuretic peptide levels (e.g., BNP or NT-pro BNP) to greater than 1.5 times the pretransfusion value. A normal post-transfusion BNP level is not consistent with a diagnosis of TACO, there should be serial testing of NP levels in the peri-transfusion period may stand helpful identifying TACO.

2.4 Transfusion Associated Dyspnoea:

Demonstrated by presence of respiratory distress within 24 hours of completion of transfusion that does not meet the criteria of TRALI, TACO, or anaphylactic reaction. Respiratory distress should be the most prominent feature and should not be explained by the patient's underlying condition.

2.5 Hypotensive Transfusion Reaction/ Transfusion Induced Hypotension (TIH):

Characterized by hypotension defined as a drop in systolic blood pressure of more than or equal to 30 mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure less than or equal to 80 mm Hg and all other transfusion reactions presenting with hypotension are excluded.

Most reactions occur very rapidly after the start of the transfusion (within a few minutes). Hypotension is usually the sole manifestation but facial flushing and gastrointestinal symptoms can also occur. It is more frequently seen in patients on ACE Inhibitors.

Definition Criteria

The following signs and symptoms are the associated signs and symptoms:

- Hypotension
    - Adults (18 years and older): Drop in systolic BP of greater than or equal to 30 mmHg **or,** Systolic BP less than or equal to 80 mmHg.
    - Infants, children and adolescents (1 year to less than 18 years old): Greater than 25% drop in systolic BP (e.g., drop in baseline systolic BP of 120mmHg to below 90mmHg).
    - Neonates and small infants (less than 1 year old OR any age and less than 12 kg body weight): Greater than 25% drop in baseline value using whichever measurement is being recorded (e.g., mean BP).
- Occurs less than 15 minutes after the start of the transfusion.
- Responds rapidly (within 10 minutes) to cessation of transfusion and supportive treatment.
- All other adverse reactions presenting with hypotension must be excluded.

Severity

Non-Severe: The recipient required no more than discontinuation of transfusion and supportive management and the reaction resulted in no long term morbidity.

Severe: Inpatient hospitalization or prolongation of hospitalization is directly attributable to the reaction, or the reaction has directly led to long term morbidity (e.g. brain damage) and vasopressors were not required.

Life threatening: the recipient required vasopressors for life support

Death: The recipient died as a result of adverse transfusion reaction and Death should be used if possibly, probably or definitely related to transfusion.

3. Systemic Transfusion reactions :

3.1. Febrile Non-hemolytic Hemolytic Transfusion reaction Reaction (FNHTR) :

Fever and/or chills without hemolysis occurring in a recipient during or within 4 hours of completion of transfusion. The most common cause is due to passively transferred cytokines or a reaction of recipient antibodies and leukocytes in the blood product. Blood culture of patient or residual component is performed should be negative. There should not be any laboratory evidence of acute hemolysis.

FNHTR is considered in the presence of one or more of the following signs/symptoms:

- Fever ($\geq 38^{o}$C oral or equivalent and a change of $\geq 1^{o}$C from pre-transfusion value),
- Chills and /or Rigors
- May be accompanied by headache and nausea.

FNHTR occurs during or within four hours following transfusion. Other causes such as hemolytic transfusion reaction, bacterial contamination or underlying condition should be excluded.

FNHTR could be present in absence of fever (chills and/or rigors without fever).

Severity

Grade 1:

- Fever (≥38^{o}C oral and an increase of ≥ 1^{o} C from pretransfusion value)
- Chills/rigors with or without fever
- May be accompanied by headache and nausea.

Grade 2:

- Fever (≥39^{o}C oral and increase of ≥ 2^{o}C from pre-transfusion value)
- With or without chills/rigors
- May be accompanied by headache and nausea.

3.2 Allergic Transfusion reactions and Anaphylaxis:

An allergic reaction present with only mucocutaneous signs and symptoms:

- Morbilliform rash
- Pruritus (itching)
- Urticaria (hives)
- Localized Angioedema
- Generalized flushing
- Edema of lips, tongue and uvula
- Erythema or Edema of Periorbital area
- Conjunctival edema

These may occur during or within 4 hours of cessation of transfusion. This form presents no immediate risk to life of patient and responds quickly to symptomatic treatment like antihistamines or steroids. Hence, this type of allergic reaction is called **'minor allergic reaction'.**

The severe form of Allergic Reaction called as **Anaphylaxis** will additionally involve the cardiovascular and/or respiratory system. In addition to mucocutaneous signs and symptoms, these will also present with any of the following sign and symptoms:

- Respiratory distress (Dyspnoea /Cough)
- Bronchospasm/Wheezing
- Hypoxemia
- Tightness in the throat
- Dysphagia

- Dysphonia
- Hoarseness
- Stridor
- Severe Hypotension (fall of BP beyond 30mm Hg of the original level)

Severity:

Grade 1 / Non-Severe:

No immediate risk to the life of the recipient **and** reaction responds quickly to symptomatic treatment.

Grade 2-4:

An allergic reaction can also involve respiratory and/or cardiovascular systems and present like an anaphylaxis. In addition to mucocutaneous systems, anaphylaxis will have airway compromise or severe hypotension requiring vasopressor treatment or associated symptoms like hypotonia, syncope). The respiratory features may be laryngeal presenting with tightness in the throat, dysphagia, dysphonia, hoarseness, stridor or can be pulmonary that presents with dyspnoea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs occurring during or very shortly following transfusion.

For the purpose of classification, depending on the course and outcome of the reaction as details under grades of severity for AHTR would be **graded as 2 (severe)**, **3 (life-threatening)** OR **4 (death)** .

3.3. Post Transfusion Purpura (PTP):

PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the recipient directed against the Human Platelet Antigen (HPA) system**.**

3.4. Transfusion Associated Graft-vs-Host Disease (TA-GVHD):

TA-GVHD is a clinical syndrome characterized by symptoms of:

- Fever
- Skin rashes : erythematous, maculopapular central eruption that spreads to extremities and in severe cases can progress to generalized erythroderma with or without development of hemorrhagic bullae
- Liver dysfunction, i.e., elevated liver enzymes and elevated bilirubin
- Diarrhea
- Pancytopenia
- Characteristic histological appearance on skin and liver biopsy

TA-GVHD occurs 1-6 weeks following transfusion with no other apparent cause. TA-GVHD diagnosis is further supported by the presence of chimerism.

Severity

Mild: Not Applicable N/A

Severe: Patient had marked symptoms and responded to treatment

Life-threatening: Patient had severe symptoms and required lifesaving treatment (e.g., immunosuppression)

Death: The recipient died as a result of adverse transfusion reaction. Death should be used if death is possibly, probably or definitely related to transfusion.

4. Transfusion transmitted Transmitted Infection (TTI):

These transfusion reactions are characterized by laboratory evidence of a pathogen in the transfusion recipient.

A report is classified as a transfusion-transmitted infection if, following investigations:

- The recipient following transfusion with blood components shows evidence of infection and there was no evidence of infection previously prior to transfusion and no evidence of an alternative source of infection, or
- At least one component received by the infected recipient via transfusion was donated by a donor who had demonstrated the same transmissible infection, or

- At least one component received by the infected recipient demonstrates to contain the agent of infection.

Clinicians investigating suspected viral TTIs should explore all possible risk exposures in parallel with the Blood Transfusion Service investigations, in order to determine the patient's most likely source of infection.

Hence diagnosis of a viral TTI requires the following;

- Documentation of seronegativity of patient in the pre-transfusion sample
- Investigations in both patients and implicated donors
- Exclusion of other modes of transmission
- Viral genotyping in recipient and donor case of doubt /dispute.

Blood Donor Adverse Reactions

Complications related to blood donations are adverse reactions and events that carry a close relationship to blood donation. The 2008 ISBT standard for surveillance of blood donor complications introduced a classification with descriptions of various types of complications (5). The problems encountered with those definitions are:

1. Descriptions were not adequately specific to allow standard classification and comparison of various donor surveillance programs.
2. Descriptions were difficult to apply because they required information that were not easily obtainable in many of the countries.

To review the 2008 definitions, a revision group was convened in 2013 and the propose modifications were to:

1. Provide simple definitions that can be easily applied in a standardised manner.
2. Provide minimal requirements for international comparison that will also satisfy the basic needs of a surveillance program.
3. Provide additional attributes that may be collected nationally if possible that will stay helpful for process improvement by the blood centre, or can lead to relevant research in donor complications.

4. To make standard definitions and match with those used in the American Association of Blood centres (AABB) Donor Hemovigilance System, to permit comparisons and entry of data into an adapted version of the software.

Standards for Surveillance of Complications Related to Blood Donation was formulated by the Working Group on Donor Vigilance of the International Society of Blood Transfusion (ISBT).This was in collaboration with The International Hemovigilance Network and The AABB Donor Hemovigilance Working Group on December 11, 2014.

Complications of blood donation

A. Local Symptoms

A1. Blood outside vessel

- Haematoma
- Arterial puncture
- Delayed bleeding

A2. Arm pain

- Nerve injury/irritation
  - duration < 12 months
  - duration > 12 months
- Other arm pain

A3. Localized infection/inflammation of vein or soft tissues

- Superficial thrombophlebitis
- Cellulitis

A4. Other major blood vessel injury

- Deep Venous Thrombosis (DVT)
- Arteriovenous fistula
- Compartment syndrome
- Brachial artery pseudoaneurysm

B. Generalized symptoms – Vasovagal Reactions

- Vasovagal Reaction, no loss of consciousness (LOC)
- Vasovagal Reaction, loss of consciousness
  - < 60 seconds, no complications
  - ≥ 60 seconds, and/or convulsions or incontinence
    - With injury
    - Without injury

- On collection site
- Off collection site

C. Related to apheresis

- Citrate reactions
- Hemolysis
- Air embolism
- Infiltration

D. Allergic reactions

- Local allergic reaction
- Generalized (anaphylactic) reaction

E. Other serious complications

- Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).
- Myocardial infarction
- Cardiac arrest
- Transient Ischemic Attack (TIA)
- Cerebrovascular accident
- Death

F. Others

Grading of Imputability

The strength of association between donation and complication is:

Definite or certain: When there is conclusive evidence beyond reasonable doubt for the cause of reaction.

Probable or likely: When the evidence is clearly in favour of an association between reaction and blood donation.

Possible: When the evidence is indeterminate for attributing the complication to the donation or there can be an alternative cause of reaction.

Unlikely or doubtful: When the evidence is clearly in favour of attributing the complication to other causes leading to adverse reaction.

Excluded: When there is conclusive evidence beyond reasonable doubt that the complication can be attributed to the causes other than blood donation.

Adverse Donor Reaction Definitions:

A. Complications mainly with local symptoms

These complications are directly caused by the needle insertion. Some among these are characterized by extravasation of blood outside vessels, whereas others are characterized by pain.

A 1. Complications mainly characterized by extravasation of blood outside the vessels.

Hematoma (bruise)

Definition: A hematoma is an accumulation of blood within the tissues outside the blood vessels.

Mechanism: The symptoms are caused by blood spillage out of damaged vessels and accumulation in the soft tissues around. Very large hematomas, infiltrating into the deeper layers of the forearm, put pressure on surrounding tissues and can contribute to other complications such as nerve irritation and nerve injury and rarely compartment syndrome.

Signs and symptoms: Bruising along with discolouration, swelling and localised pain.

Arterial puncture

Definition: Arterial puncture is an accidental puncture of the brachial artery or one of its branches in an attempt of venipuncture for blood donation.

Mechanism: Because of the rapid flow of blood, the risk of large hematoma formation is more and thereby risks of more pain and pressure syndromes.

Signs and symptoms: A bright red colour than usual of the blood being collected with pulsatile needle and tubing. The blood bag fills very fast and there can be weak pain localized to the region around elbow.

Delayed bleeding (re-bleeding) - optional category

Definition: Leakage of blood from the punctured area after the initial hemostasis.

Mechanism: Delayed or re-bleed may be related to pressure not being applied to the correct location or for an inadequate duration, or premature removal of the bandage before proper hemostasis. After the donor has left the site of donation, re-bleeding may be related to heavy lifting or strain to the donor's punctured arm. Donors on certain medications, such as autologous donors on anticoagulants, may be at higher risk to present with delayed or re-bleed.

Signs and symptoms: Sudden spontaneous restart of bleeding from the punctured site, after application of pressure and removal of initial dressing or leakage through the dressing.

A2. Complications mainly characterised with pain

Nerve Injury/irritation

Definition: Accidental injury or irritation of a nerve during the process of venipuncture

Mechanism: A nerve may be injured directly by the needle at the point of insertion or withdrawal, or there may be pressure effect on a nerve due to a hematoma or inflammation of soft tissues around.

Signs and symptoms: Often 'electrical' type of sharp pain that radiate away from the venepuncture site, and/or tingling, burning sensations in the hand, wrist or shoulder area. Symptoms can present immediately when the needle is being inserted or removed. In case of hematoma, pain may not be apparent at the time and may start when the hematoma has

reached a considerable size. Symptoms can get worsened in certain positions or with certain arm movements. In very rare situations, weakness of the arm can develop.

Categories based upon the duration of symptoms:

Symptoms resolving within 12 months: Symptoms usually resolve within days, but can rarely persist for months or even permanent.

Symptoms persisting more than 12 months

Other Painful arm – optional category

Definition: Pain in venipunctured arm is the primary symptom, without any features of nerve irritation or the presence of a hematoma or other complications that are defined and can be painful.

Mechanism: Pain may be related to tissue the injury that is possibly due to hematoma in the deeper layers of tissues.

Signs and symptoms: Pain in the arm, without characteristics of nerve irritation and may be described as an ache or heaviness in the arm. Include all cases where arm pain is the only major symptom, unless a diagnosis of nerve injury/irritation is suspected in the presence of nerve type symptoms recognised by trained staff.

A.3 Localised Infection and Inflammation

Definition: Inflammation along the course of a vein that can progress into localised infection several days post donation. There may be thrombosis in the vein.

Mechanism: Tissue damage can lead to introduction of surface bacteria into the deeper tissues during venipuncture.

Signs and symptoms: Warmth, tenderness, local pain, redness and swelling at the site of puncture. The site and the course of vein may feel tender, firm, and warm to the touch. Fever may also be present.

2 categories:

- **Thrombophlebitis:** The redness, swelling, and tenderness that extend along the course of the vein.

- **Cellulitis:** The redness, swelling and tenderness affect the soft tissues, and are not localised along course of the vein.

A4. Other major blood vessel injury

These rare, but serious conditions and must have to be always be medically diagnosed.

Deep venous thrombosis (DVT)

Definition: Thrombosis of a deep vein in the donor's phlebotomy arm.

Mechanism: Superficial venous thrombosis can sometimes progress into the deeper veins of the donor's arm after blood donation. DVT may even occur rarely without any previous signs and symptoms of superficial thrombosis. The use of oral contraceptives may be an additional risk factor in these donors.

Symptoms and signs: Swelling and pain in the venipunctured arm that may be accompanied by features of superficial inflammation and thrombosis.

Arteriovenous fistula

Definition: Acquired connection between the vein and artery

Mechanism: A channel forms between the punctured vein and artery immediately, or in the process of healing. This can also be seen with arterial puncture.

Signs and symptoms: Pulsatile mass with a palpable thrill and an associated bruit.

Compartment syndrome

Definition: Increased pressure in the compartment of forearm leading to muscle and soft tissue necrosis.

Mechanism: Blood may accumulate in the deeper areas of the forearm, occluding small blood vessels that can result in in tissue necrosis.

Signs and symptoms: Painful movement of the arm with swelling, paraesthesia and sometimes partial paralysis of the arm.

Brachial artery pseudoaneurysm

Definition: Collection of blood outside an artery, contained by adventitia layer of the arterial wall or the surrounding tissues alone.

Mechanism: Blood leakage can occur out of the artery leading to accumulation of blood in the surrounding space after a traumatic arterial puncture.

Signs and symptoms: Pulsatile mass accompanied by pain and paraesthesia, sometimes preceded by a large hematoma following the puncture of artery.

B. Complications mainly with generalized symptoms: Vasovagal Reactions (VVR)

Definition: Generalised feeling of discomfort and weakness that can be accompanied with anxiety, dizziness or nausea which may or may not progress to loss of consciousness .VVR is the most common acute complication associated with blood donation.

Mechanisms: The reaction is mediated by the autonomic nervous system and may also be added up by psychological factors and the volume of blood removed with respect to the total blood volume of the donor.

Signs and symptoms:

- Generalised discomfort
- Weakness
- Anxiety
- Light-headedness/dizziness
- Nausea
- Chills
- Sweating
- Vomiting
- Pallor
- Hyperventilation
- Rapid or a slow pulse

Hypotension and loss of consciousness (LOC) may occur and can be accompanied with bladder or bowel incontinence or convulsive movements or seizures. Reactions may occur before phlebotomy (rare), during phlebotomy or immediately after phlebotomy, when the donor stands up, in the refreshment area, or after the donor has left the collection site. Most reactions occur within 12 hours of phlebotomy. Reactions accompanied with LOC carry a risk of injury, especially if they occur once the donor has left the collection facility (delayed vasovagal reactions).

Vasovagal reactions are divided in two main subgroups:

Without loss of consciousness (LOC) - the donor does not faint

With loss of consciousness (LOC) - the donor faints for a period of time

Subdivision for donors with LOC:

LOC < 60 seconds - without other signs and symptoms

LOC ≥ 60 seconds - or with complications of convulsive movements, urinary or faecal incontinence

Optional subdivision:

With injury - Injury caused by falls or accidents in donors with a vasovagal reaction

Without injury

Location of reaction:

On collection facility - Symptoms occurred before donor has left the donation site

Outside collection facility - Symptoms occurred after donor has left the donation site

C. Allergic reactions

Allergy (local)

Definition: Reddish discolouration or irritated skin at the venipuncture site that can be accompanied with itching.

Mechanism: Reaction can be caused by the irritants in solutions used for disinfection of the arm (such as iodine or chlorhexidine) or in the collection set. Irritation may also occur due to application of the adhesive bandage (**bandage adhesive dermatitis**). An allergic reaction to latex gloves or glove powder can also occur.

Signs and symptoms: Itching and redness can be observed at the venepuncture site, at the site of adhesive bandage, or the entire skin area where disinfectant was used. Allergic reaction can occur soon after blood donation or in the hours to days post blood donation.

Generalised allergic reaction (anaphylactic reaction)

Definition: An anaphylactic type reaction usually starting soon after the procedure is begun and may progress rapidly to cardiac arrest.

Mechanism: These are extremely rare situations characterised by donor sensitivity to ethylene oxide gas used to sterilize some collection kits especially apheresis kits.

Signs and symptoms: Apprehension, anxiety, flushing, swelling of eyes, lips or tongue, cyanosis, cough, wheeze, dyspnoea, chest tightness, muscle cramps, nausea, vomiting, diarrhoea, tachycardia, hypotension, and altered mental status.

D. Other serious complications related to blood donation

Major cardiovascular event (MCE)

- Acute cardiac symptoms (other than myocardial infarction or cardiac arrest)
- Myocardial infarction
- Cardiac arrest
- Transient Ischemic Attack
- Cerebrovascular accident
- Death

Grading of complication severity

Hospitalization: If it can be attributed to the complication and is applicable if a donor is kept in hospital overnight. In situations where a donor is examined, and in some cases given treatment (e.g. suturing, IV fluids, treatment of a fracture) but discharged home are not classified as serious.

Intervention: To prevent permanent damage or impairment of a bodily function or to preclude death (life- threatening complications)

Symptoms: One which causes significant disability or incapacitation following a of blood donation and can persist for more than one year after the blood donation (Long term morbidity)

Death: If it follows as a complication of donation and the death can be possibly, probably or definitely attributed to the donation.

Types and definitions of reactions:

Local reactions –Most of the local reactions like hematoma, arm pain syndromes are not considered to be severe. Severe consequences are separate types of reactions like deep venous thrombosis, arteriovenous fistula or compartment syndromes.

Nerve injury may rarely result in long term morbidity and may be captured by the duration of symptoms.

Systemic reactions - Vasovagal reactions can be characterised as those accompanied with or without LOC. LOC can be again characterised as those with additional symptoms like convulsions, loss of bowel or bladder control and/or duration of more than or equal to 60 seconds). Again VVR can be divided into those reactions that result in injury or not.

Complications that are by their nature itself severe include generalised allergic reactions like anaphylaxis, and all major cardiovascular events.

MATERIALS AND METHODS

This is a one and half year's prospective study which will be conducted by the department of Transfusion Medicine. The department has been designated as a Regional Blood Transfusion Centre (RBTC) by Government of India. As per the directives of National Blood Policy (32), collection of blood from Replacement donors has been totally phased out by Voluntary Non-remunerated blood donors from 1st October, 2016 by our centre.

Hemovigilance Programme of India (HvPI) recommends reporting of all adverse reactions due to blood donation and blood transfusion by the licensed blood centres of India. Accordingly all the blood donors donating blood in our centre during the defined period will be monitored and analysed for donation reactions and all patients receiving blood transfusion in our hospital will be monitored and analysed for transfusion reactions.

A voluntary non-remunerated blood donor who has donated at least three times, the last donation being within the previous year, and continues to donate regularly at least once per year (33). Voluntary blood donors over a period of one year are included in the study. Blood donors attending our outdoor blood donation camps and walk-in donors in blood centre are being provided with a uniformly structured donor questionnaire and consent form approved by government of India in the prescribed format. The questionnaire encloses the donor demographic details, previous blood donation details, donor medical and drug history and a consent form for blood donation and mandatory screening of various transfusion transmissible infections. Voluntary Blood donors are allowed for blood donation only after filling up this questionnaire and signing up the consent.

Every eligible donor (34) was monitored for any adverse reactions encountered during the entire phase of donation – Pre, during and Post donation. Donor adverse reactions include both the acute and delayed reactions. Again these reactions are sub classified into Local and Systemic reactions according to the ISBT 2014 Revised Criteria (5). For the study purpose we have introduced a donor reaction reporting form. This form was filled up by the medical officers who were in charge of the camp or the blood centre. A participant information sheet and an informed consent form were administered to all the donors who developed adverse reaction to make them a part of the study.

The donor reaction reporting form (DRRF) include the demographic details of the donor, previous blood donation history, medical history, signs and symptoms of reactions including recording of vitals like B.P., pulse and the possible causative factors for such different

adverse reactions. This guided us to diagnose the type of donor reaction. Once the donor developed any sort of adverse reactions, he/she would be immediately attended to as per recommended national guidelines and proper management was initiated. Subsequently then the medical officer would fill the above mentioned donor reaction reporting form. After recovery, the donor would be informed about the study undertaken and he/she would be handed over the participant information sheet. After thorough understanding of the details provided, the donor had to sign the informed consent form to make him/her a part of the study.

We would analyse the donor reactions with different parameters like the age, gender, body weight, estimated blood volume, type of donor, phase of donation, previous donation history, venue of donation and seasonal variations. The Estimated Blood Volume (EBV) of the blood donors who developed complications were calculated using Modified Gilcher's Rule of Five (35).

Patients admitted in our hospital and requiring blood and blood component transfusion over a period of one and a half years were the designated subjects of this study. Every patient recommended for blood transfusion by their clinicians, would sign the informed transfusion consent form either themselves or their next of kin. They were explained about the benefits of transfusion as well as possibility of transfusion reaction before they sign the consent for transfusion. After they sign the consent for transfusion, patient / next to kin would be explained about the project and another consent form would be signed by them, in case the patient developed a transfusion reaction. Both these consents were taken simultaneously by blood centre medical officer. The informed consent for blood transfusion is already implemented in our institute. Appropriate bed-side transfusion practices as recommended by national guidelines of government of India are adopted.

Every patient was closely monitored during their transfusion episodes as per the laid down protocols for any sort of adverse reactions. If any patient develops a transfusion reaction, the transfusion would be terminated immediately and blood centre was informed. Blood centre medical officer would immediately attend to the patient and was supposed to have a thorough assessment of the patient status and the component which was presumed to be the cause of the transfusion reaction. Regarding the transfusion reactions, a transfusion reaction reporting form (TRRF) was also formulated. This include, detailed medical and drug history of the patient, previous transfusion history, signs and symptoms of reactions including recording of

vitals like B.P., pulse, respiratory rates and the possible causative factors for such different adverse reactions. The Blood centre medical officer had to fill up the transfusion reaction reporting form.

Various blood samples, blood bag and transfusion sets and urine samples were sent to Transfusion Medicine, Pathology, Microbiology, Biochemistry and Hematology laboratories to assess the cause of transfusion reaction. Various investigations, as already being implemented in our institute, was recommended and conducted by various laboratories, including blood centre to diagnose the transfusion reaction. Accordingly proper management was initiated as per the diagnosis of the adverse reaction and decisions of further transfusions were decided upon. The transfusion reactions were analysed with parameters like age, gender, medical history, previous transfusion history, the component which induced the reaction, time taken for occurrence of reaction from initiation of transfusion, volume of component transfused and others.

Statistical analysis

Numerical data were expressed as mean ± standard deviation and categorical data as frequencies and percentage. Association between categorical variables were analysed using the chi-square test. Continuous variables compared between two group using Student's t-test and with more than two group with ANOVA. All statistical tests were two sided. A p value <0.05 was considered as statistically significant. Data analysis was performed using R software (R version 3.6.2 (2019-12-12)) and SPSS (version 16.0).

After data analysis, an assessment of the donor adverse reactions and transfusion reactions will be made. This will help us to arrive at a definitive conclusion of the various prevailing donor and recipient reactions and their causative factors and the steps that can be initiated to minimize the occurrence of such untoward events in routine blood centre practice.

Our centre is already registered with Hemovigilance Programme of India (HvPI) adopted by Government of India. We are regularly reporting the adverse effects of donation and transfusion to the hemovigilance reporting site. Donor reactions are reported in the Donor Vigil software while Transfusion reactions are reported in Hemovigil software.

Exclusion criteria:

The following exclusion criteria will be adopted for the two sections as follows:

For blood donation related reactions:

1. All type of apheresis donors

2. Autologous blood donors

3. Non-eligible blood donors

4. PRP donors for regenerative medicine

5. Donors not reporting if reaction happens after donors left blood donation premise

For Transfusion reactions,

1. Blood issued to outside hospital for transfusion among their patients

2. Blood units cross-matched but not transfused

3. Patient expired during transfusion and surgery/medical management, but investigations not carried out.

4. Patients lost to follow up

5. All Transfusion transmitted infections like Hepatitis B, Hepatitis C, and HIV etc. Presently, the Hemovigilance Programme of India in their guidelines have not included Transfusion transmitted infections (TTI) like hepatitis B , hepatitis C , HIV etc. in their reporting format.

RESULTS AND ANALYSIS

Blood Donor reactions

We had a total registration of 11642 voluntary blood donors from the time period May 2018 to May 2019. Out of them, we had total whole blood collection of 8180 (70.26%) and 3642 (29.74%) deferrals. Among the total collection, there were 6808 (83.23%) males and 1372 (16.77%) females. Out of the blood donors who donated blood, 3100 (37.90%) were first time donors and 5080 (62.10%) were repeat donors. Among the repeat donors, 1757 (34.59%) were regular repeat donors and 3323 (65.41%) were irregular repeat donors. We had a total of 1542 (18.85%) Blood centre collections and 6638 (81.15%) camp collections. We had a total of 205 camps during the study period and out of this 104 (50.73%) were camp site indoor collections and 101 (49.27%) were in Blood mobile. Out of total collection, 5627 (68.79%) were 350 ml collections and 2553 (31.21%) were 450 ml collections.

We have observed a total of 252 blood donor complications during the period of study. Out of this, 22 (8.73%) adverse reactions were observed during donation at blood centre, while 230 (91.27%) reactions occurred in blood donation camps. Among the camp donations, 141(61.30%) were at outdoor camps and 89 (38.70%) were inside Blood Mobile. All those donors who developed adverse reactions during the process of blood donation were enrolled in the study.

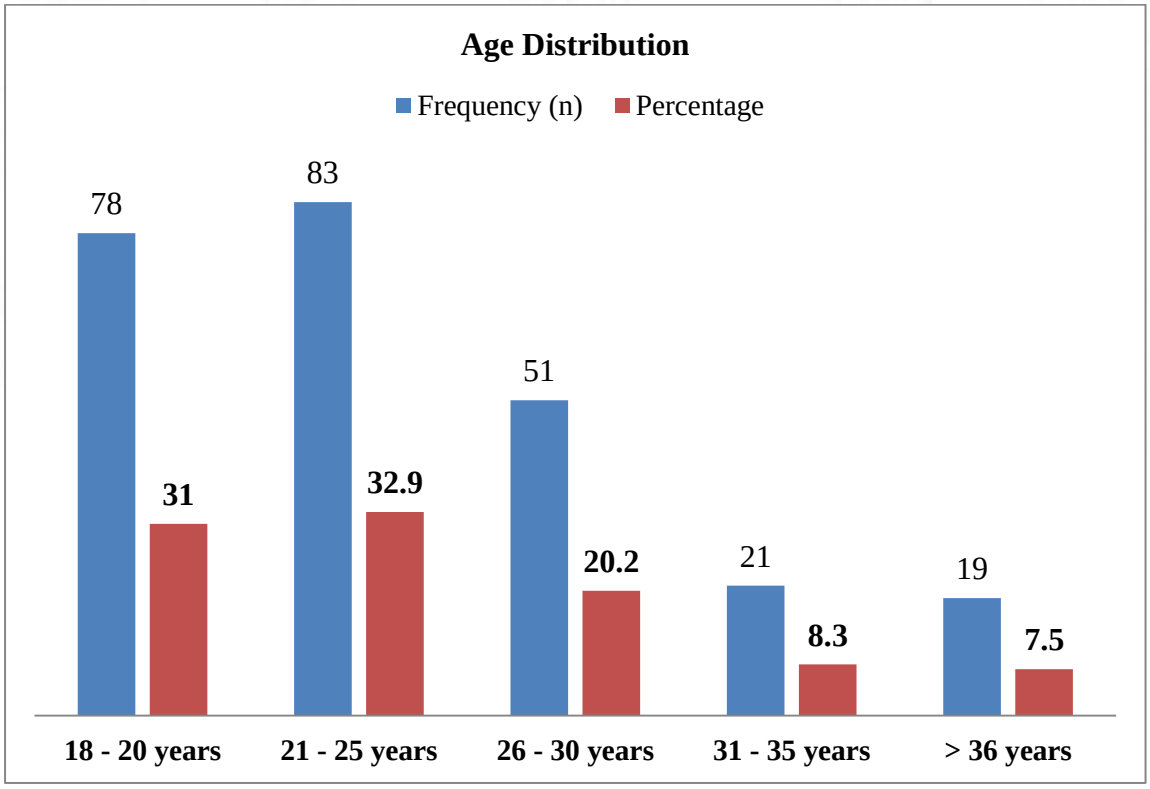
Distribution of age among the study population

Out of 252 participants, 78 (31%) were in between 18-20 years, 83 (32.9%) were in 21-25 years, 51 (20.2 %) were between 26-30 years, 21 (8.3%) were in between 31-35 years and 19 (7.5%) belonged to more than 36 years of age.

Table No. 5 : Distribution of age among the study population

Age (in years)	Frequency (n)	Percentage (%)
18 - 20	78	31
21 - 25	83	32.9
26 - 30	51	20.2
31 - 35	21	8.3
36 +	19	7.5
Total	252	100

Figure No.3: Distribution of age among the study population



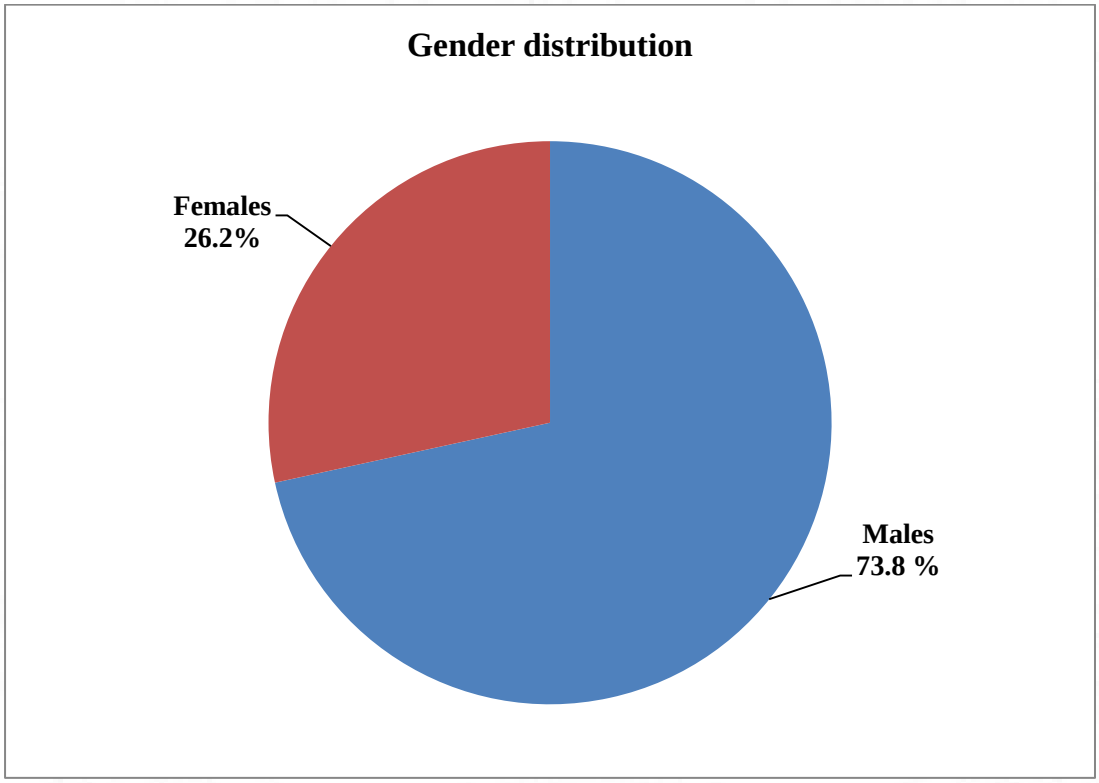
Gender distribution among study population

Out of 252 study participants, 66 (26.2%) were females and 186 (73.8%) were males.

Table No. 6 : Gender distribution among study population

Gender	Frequency (n)	Percentage (%)
Female	66	26.2
Male	186	73.8
Total	252	100

Figure No.4: Gender distribution among study population



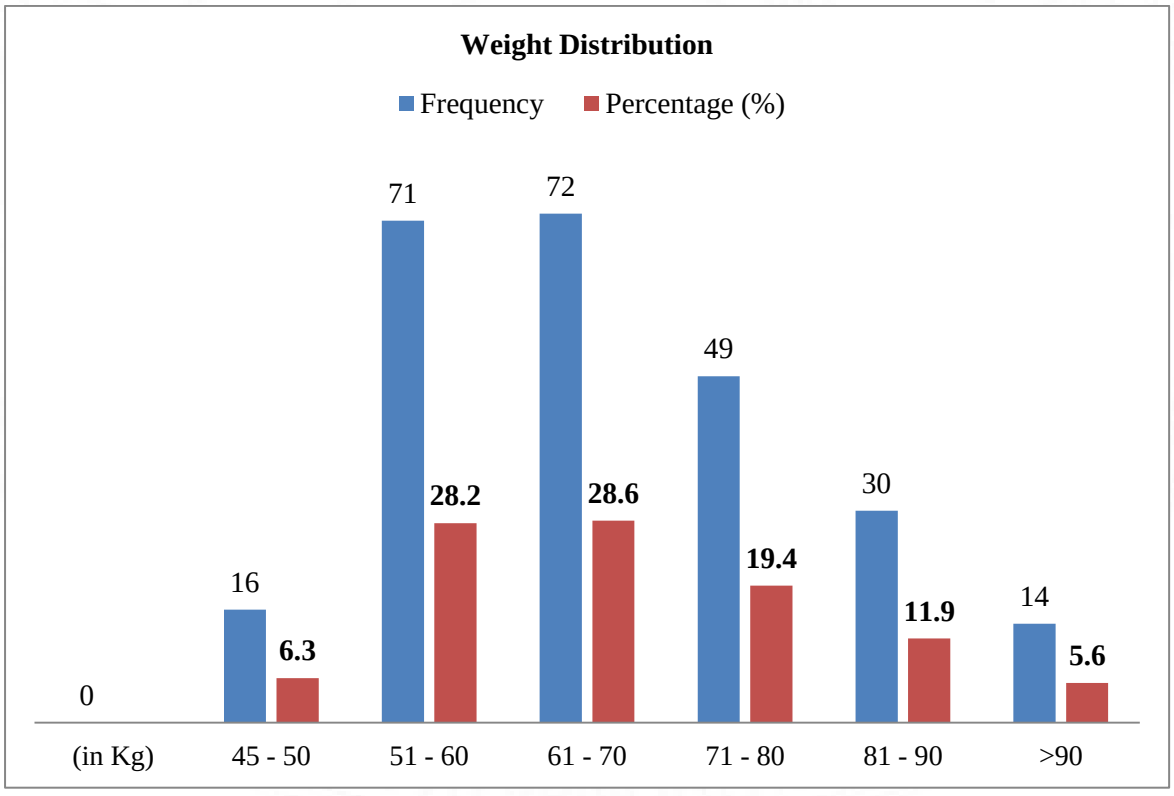
Weight distribution among study population

Out of 252 study participants, 16 (6.3%) had a weight of 45-50 kg, 71(28.2%) had 51-60 kg , 72 (28.6%) were 61-70 kg , 49 (19.4%) were 71-80 kg , 30 (11.9%) were 81-90 kg , 14 (5.6%) were between 90-110 kg weight group.

Table No. 7 : Weight distribution among study population

Weight (in Kg)	Frequency (n)	Percentage (%)
45 - 50	16	6.3
51 - 60	71	28.2
61 - 70	72	28.6
71 - 80	49	19.4
81 - 90	30	11.9
91 - 110	14	5.6
Total	252	100

Figure No.5: Weight distribution among study population



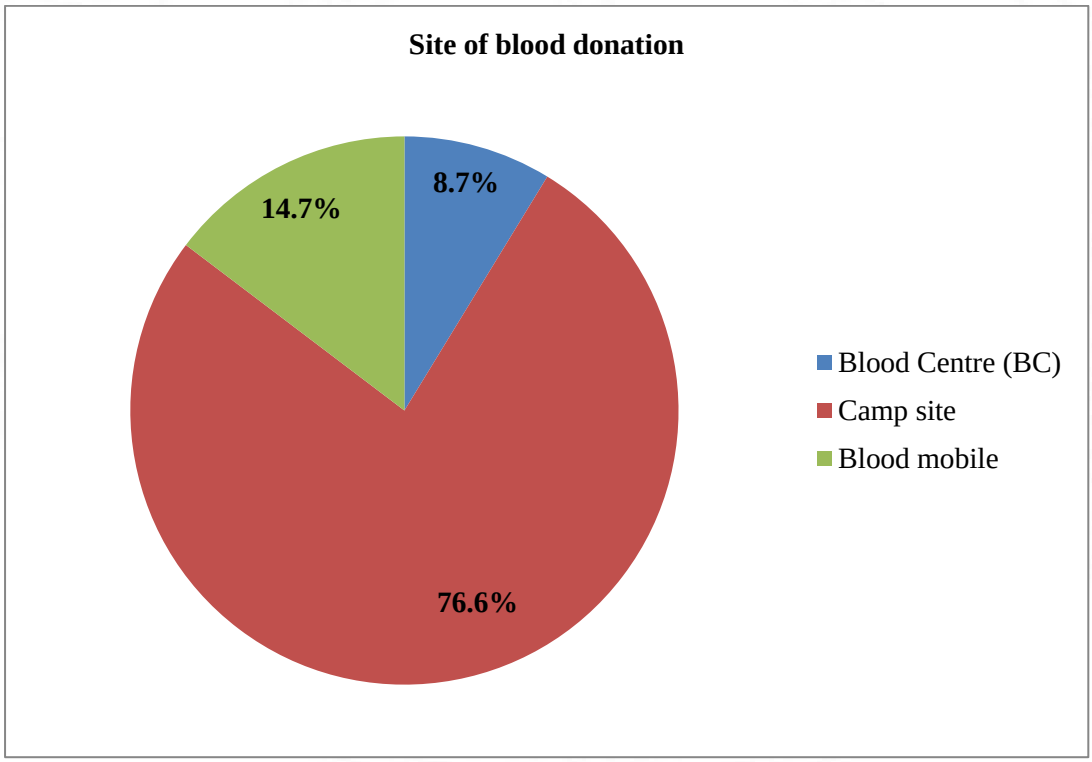
Distribution of site of blood donation and donor complications among study population

Out of total 252 participants, 22 (8.7%) developed complications in blood centre and 193 (76.6%) developed complications in outdoor camp site collections and 37 (14.7%) during blood collection in blood mobile.

Table No.8 : Distribution of site of blood donation and donor complications among study population

Site of blood donation	Frequency (n)	Percentage (%)
Blood centre (BC)	22	8.7
Camp site	193	76.6
Blood mobile	37	14.7
Total	252	100

Figure No.6: Distribution of site of blood donation and donor complications among study population



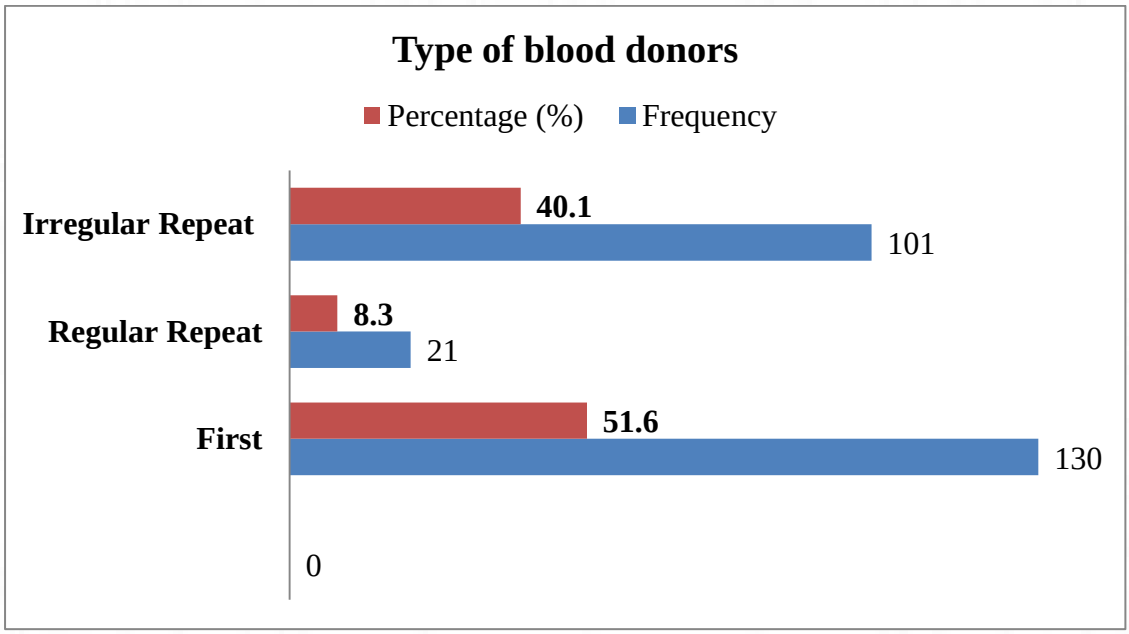
Distribution of type of blood donors among study population

Out of 252 study participants, 130 (51.6%) were first time donors, 21 (8.3%) regular repeat donors and 101 (40.1%) were irregular repeat donors.

Table No.9 : Distribution of type of blood donors among study population

Type of blood donors	Frequency (n)	Percentage (%)
First	130	51.6
Regular Repeat	21	8.3
Irregular Repeat	101	40.1
Total	252	100

Figure No.7: Distribution of type of blood donors among study population



Distribution of Systemic and Local reactions among study population

Among 252 study participants, 36 (14.3%) developed local reactions, 212 (84.1%) developed systemic reactions and 4 (1.6%) developed systemic reactions along with local reactions.

Table No.10 : Distribution of Systemic and Local reactions among study population

Systemic/ Local reactions	Frequency (n)	Percentage (%)
Local	36	14.3
Local + Systemic	4	1.6
Systemic	212	84.1
Total	252	100

Figure No.8: Distribution of Systemic and Local reactions among study population

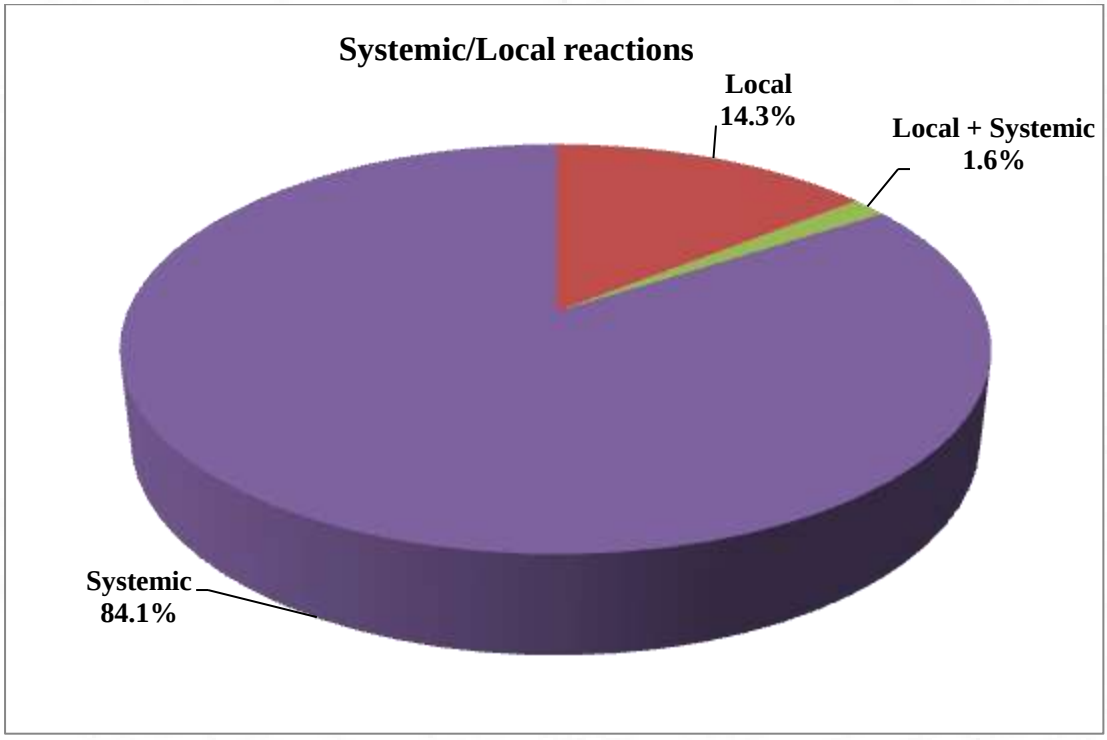


Table No.11 : Distribution of various blood donor complications among study population

Diagnosis	Frequency (n)	Percentage (%)
Local complications		
Delayed bleeding	8	3
Delayed bleeding with hematoma	1	0.4
Failed phlebotomy with bilateral hematoma	1	0.4
Hematoma	25	10
Thrombophlebitis	1	0.4
Systemic complications		
LOC without injury	12	4.8
LOC without injury + seizure (< 60 seconds)	10	4
LOC without injury + headache	1	0.4
LOC without injury + seizure (< 60 seconds) - Delayed vasovagal reaction	1	0.4
Delayed Vasovagal reaction	2	0.8
Hypoglycemia	1	0.4
Vasovagal reactions	185	73.4
Local + Systemic complications		
Arterial puncture+ vasovagal reaction + hematoma	1	0.4
Hematoma followed by vasovagal reaction	2	0.8
LOC without injury + seizure (< 60 seconds) + hematoma	1	0.4
Total	252	100

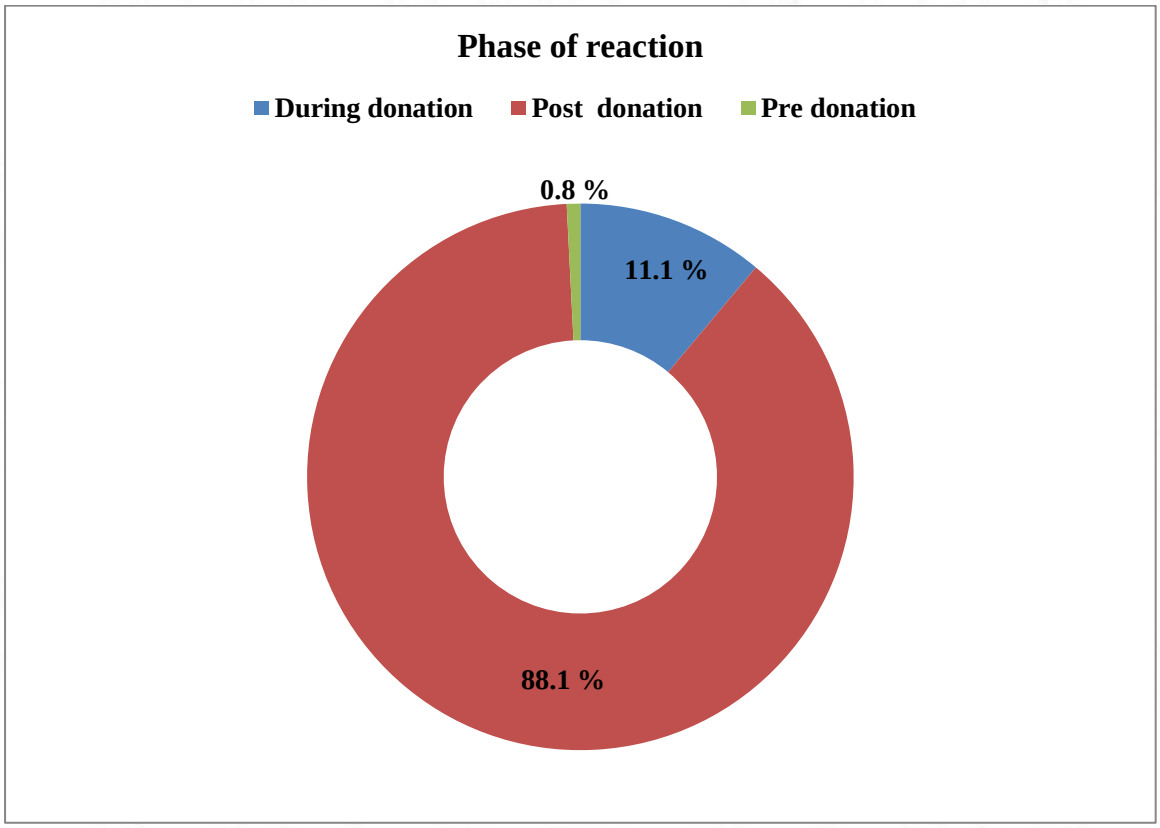
Distribution of phase of reaction among study population

Out of 252 study participants, 28 (11.1%) donors developed complications during blood donation, 222 (88.1%) post-donation and 2 (0.8%) developed pre-donation.

Table No.12 : Distribution of phase of reaction among study population

Phase of reaction	Frequency (n)	Percentage (%)
During donation	28	11.1
Post donation	222	88.1
Pre donation	2	0.8
Total	252	100

Figure No.9: Distribution of phase of reaction among study population



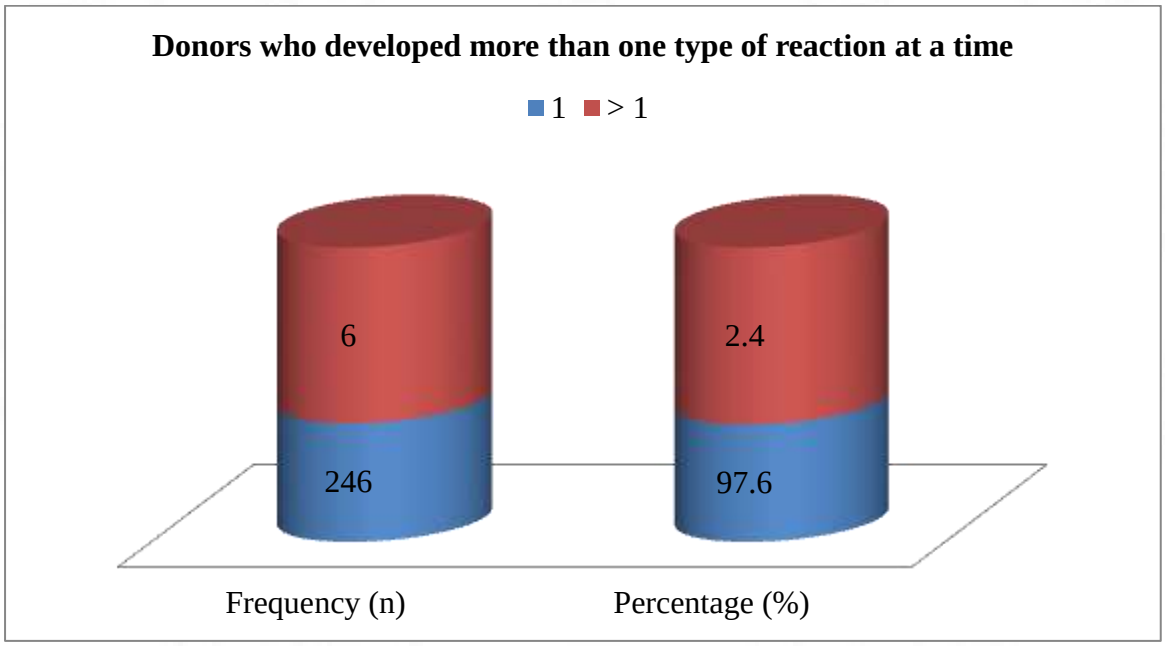
Distribution of donors who developed more than one type of donor complication at a time among study population

Out of 252 study participants, 6 (2.4%) donors developed more than one type of donor complication at a time and 246 (97.6%) of donors developed only one type of complication at a time.

Table No.13: Distribution of donors who developed more than one type of donor complication at a time among study population

Number of complications developed at a time	Frequency (n)	Percentage (%)
1	246	97.6
> 1	6	2.4
Total	252	100

Figure No.10: Distribution of donors who developed more than one type of donor complication at a time among study population



Distribution of number of venipunctures attempted among study population

Out of 252 study participants, more than one venipuncture was attempted in 7 (2.8%) of the blood donors.

Table No.14 : Distribution of number of venipunctures attempted among study population

Number of venipunctures attempted	Frequency (n)	Percentage (%)
1	245	97.2
> 1	7	2.8
Total	252	100

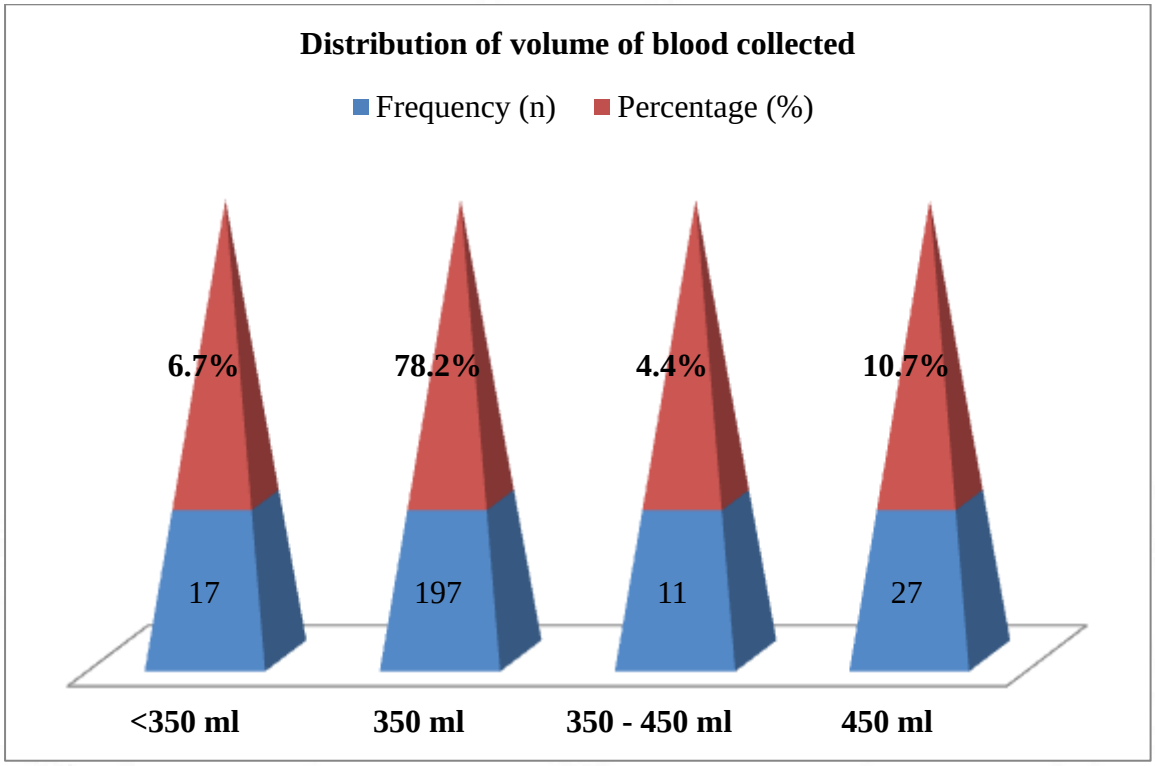
Distribution of volume of blood collected among study population

Out of 252 study participants, less than 350 ml of blood was collected from 17 (6.7%) of donors, 350 ml was collected from 197 (78.2%) donors and more than 350 ml collection was carried out in 38 (15.1%) donors. The volume of blood collected from 11 (4.4%) of the donors who developed complications were in between 350-450 ml and these were under collected 450 ml donations. There were 27 (10.7%) donors who developed donor complications following 450 ml collections.

Table No.15 : Distribution of volume of blood collected among study population

Volume of blood collected (ml)	Frequency (n)	Percentage (%)
<350 ml	17	6.7%
350 ml	197	78.2%
350 - 450 ml	11	4.4%
450 ml	27	10.7%
Total	252	100.0%

Figure No.11: Distribution of volume of blood collected among study population



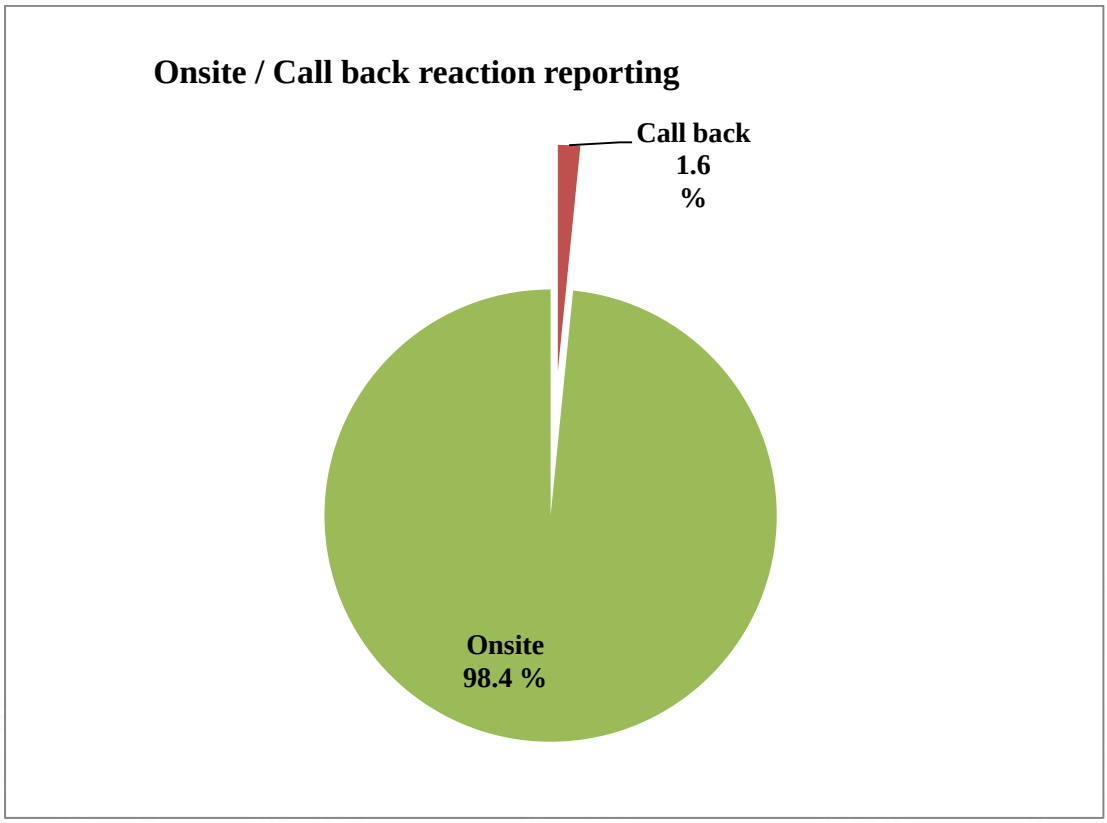
Distribution of Onsite/Call back complication reporting among study population

Out of 252 study participants, 4 (1.6%) donors reported complication by call back to blood centre and 248 (98.4%) were onsite reporting.

Table No.16 : Distribution of Onsite/Call back complication reporting among study population

Onsite/call back complication reporting	Frequency (n)	Percentage (%)
Call back	4	1.6
Onsite	248	98.4
Total	252	100

Figure No.12: Distribution of Onsite / Call back complication reporting among study population



Distribution of donor complications in various months among study population

Out of 252 donor complications, maximum numbers of reactions were observed in the month of May followed by November, September and January. 29 (11.5%) blood donor complications were observed in the month of May and 28 (11.1%) complications were in November. 27 (10.7%) complications were observed in the month of September and 26 (10.3%) in the month of January.

Table No.17: Distribution of donor complications in various months among study population

Number of donor complications in various months	Frequency (n)	Percentage (%)
January	26	10.3
February	17	6.7
March	13	5.2
April	13	5.2
May	29	11.5
June	16	6.3
July	25	9.9
August	20	7.9
September	27	10.7
October	18	7.1
November	28	11.1
December	20	7.9
Total	252	100

Figure No.13: Distribution of donor complications in various months

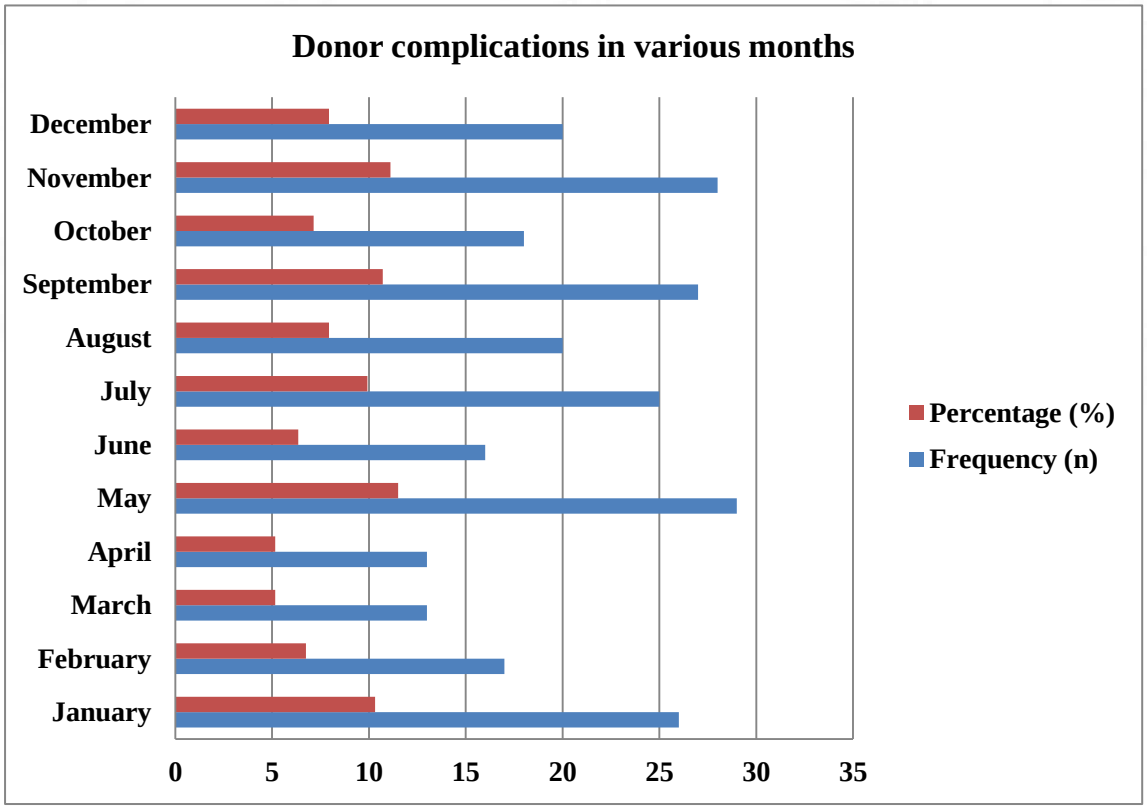


Table No.18: Blood donor details

Blood donor details	(n)	Minimum	Maximum	Mean	SD
Age	252	18	54	24.88	6.581
Weight	252	47	110	68.27	13.336
Estimated Blood Volume	252	2820	7420	4566.94	978.802
Hours of sleep (hours)*	252	2	9	6.958	1.1002
Time of last meal (hours)**	252	2	12	3.85	0.991
Volume of blood collected	250	50	450	352.26	64.561
Time taken for recovery (min)	252	20	480	25.5	32.183
Pre-reaction pulse rate	252	60	98	78.01	10.122
Pre-reaction SBP	250	102	130	117.98	5.39
Pre-reaction DBP	250	60	90	72.29	8.07
Post-reaction pulse rate	252	64	104	83.44	8.945
Post-reaction SBP	252	100	128	115.26	6.48
Post-reaction DBP	252	60	88	68.53	6.973
Time taken for recovery (min)	252	20	480	25.5	32.183

Note:

2 donors developed pre-donation complication. Hence, all the blood donor parameters could not be assessed in them.

*** One donor revealed his sleep duration was 2 hours only after developing donor reaction.**

**** One donor revealed his last meal was 12 hours back only after developing donor reaction.**

Donor Data Analysis

Association between age and gender of the blood donors in development donor complications

Out of the 66 females who developed complications, 34 (51.5%) and 15 (22.7%) were belonging to 18-20 years and 21-25 years respectively. Out of 186 males who developed complications, 44 (23.7 %) and 68 (36.6%) were belonging to 18-20 years and 21-25 years respectively. Hence, a statistically significant association was observed between younger age group and female gender in the development of donor complications.

Table No.19: Association between age and gender of the blood donors in development donor complications

Age	Gender				Total		χ^2	df	p
	Female		Male						
	n	%	n	%	n	%			
18 - 20	34	51.5	44	23.7	78	31	19.781	4	0.001
21 - 25	15	22.7	68	36.6	83	32.9			
26 - 30	8	12.1	43	23.1	51	20.2			
31 - 35	3	4.5	18	9.7	21	8.3			
36+	6	9.1	13	7	19	7.5			
Total	66	100	186	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Association between weight and gender of the blood donors in donor complications

Out of 66 females who developed complications, 11 (16.7%) and 32 (48.5%) had weight of 45-50 kg and 51-60 kg respectively. Out of 186 males who developed complications, only 5 (2.7%) and 39 (21%) had weight of 45-50 kg and 51-60 kg respectively. Hence, a statistically significant association was obtained between body weight less than 60 kg and female gender in the development of blood donor complications.

Table No.20: Association between body weight and gender of the blood donors in donor complications

Body Weight (kg)	**Gender**				**Total**		χ^2	**df**	**p**
	Female		**Male**						
	n	%	n	%	n	%			
45 - 50	11	16.7	5	2.7	16	6.3	45.176	5	<0.001
51 - 60	32	48.5	39	21	71	28.2			
61 - 70	13	19.7	59	31.7	72	28.6			
71 - 80	9	13.6	40	21.5	49	19.4			
81 - 90	1	1.5	29	15.6	30	11.9			
>90	0	0	14	7.5	14	5.6			
Total	66	100	186	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Association between age of blood donors and different types of donor complications

Out of 212 donors who developed systemic complications, 72 (92.3%) ,70 (84.3%) and 41 (80.4%) were in the age group 18-20 years , 21-25 years and 26-30 years respectively. Blood donors less than 25 years of age were found to have more systemic reactions. Hence, a statistical significance was obtained between younger age of blood donation and the development of systemic complications.

Table No.21: Association between age of blood donors and different types of donor complications

Age	Donor complications						Total		χ^2	df	p
	Local		Local + Systemic		Systemic						
	n	%	n	%	n	%	n	%			
18 - 20	6	7.7	0	0	72	92.3	78	100.0			
21 - 25	13	15.7	0	0	70	84.3	83	100.0			
26 - 30	8	15.7	2	3.9	41	80.4	51	100.0			
31 - 35	1	4.8	1	4.8	19	90.5	21	100.0			
36+	8	42.1	1	5.3	10	52.6	19	100.0	24.484	8	0.002
Total	36	14.3	4	1.6	212	84.1	252	100.0			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Association between body weight of blood donors and different types of donor reactions

No statistically significant association was observed between body weight and the development of systemic reactions.

Table No.22: Association between body weight of blood donors and different types of donor reactions

Body Weight (kg)	Donor complications						Total		χ^2	df	p
	Local		Local + Systemic		Systemic						
	n	%	n	%	n	%	n	%			
45 -50	4	11.1	0	0	12	5.7	16	6.3			
51 - 60	7	19.4	2	50	62	29.2	71	28.2			
61 - 70	9	25	0	0	63	29.7	72	28.6			
71 - 80	7	19.4	2	50	40	18.9	49	19.4			
81 - 90	4	11.1	0	0	26	12.3	30	11.9			
91+	5	13.9	0	0	9	4.2	14	5.6	12.688	10	0.242
Total	36	100	4	100	212	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Association between gender of blood donors and different types of donor complications

No statistically significant association was observed between gender of blood donors and various types of donor complications.

Table No.23: Association between gender of blood donors and different types of donor complications

Gender	Donor complications						Total		χ^2	df	p
	Local		Local + Systemic		Systemic						
	n	%	n	%	n	%	n	%			
Female	5	13.9	2	50	59	27.8	66	26.2			
Male	31	86.1	2	50	153	72.2	186	73.8	4.286	2	0.117
Total	36	100	4	100	212	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Association between different types of donor complications and the type of voluntary blood donors

Out of 130 first time donors who developed complications, 119 (91.5%) were systemic reactions. Among repeat donors, 12 (57.1%) of regular repeat donors and 81 (80.2%) of irregular repeat donors developed systemic complications. First time and irregular repeat donors were found to have more systemic complications and statistically significant association was observed between the development of systemic reaction and type of voluntary blood donor.

Table No.24: Association between different types of donor complications and the type of voluntary blood donors

Donor complications	Type of donor						Total		χ^2	df	p
	First		regular		repeat						
	n	%	n	%	n	%	n	%			
Local	9	6.9	7	33.3	20	19.8	36	14.3			
Local + Systemic	2	1.5	2	9.5	0	0	4	1.6	25.208	4	<0.001
Systemic	119	91.5	12	57.1	81	80.2	212	84.1			
Total	130	100	21	100	101	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Association between the age and estimated blood volume of blood donors in donor complications

Out of 252 blood donors who developed donor complications, more donors were belonging to age less than 30 years with an estimated blood volume between 4010.9 and 4858.7. A statistical significance was observed between less than 30 years of age and estimated blood volume in the development of donor complications.

Table No.25: Association between the age and estimated blood volume of blood donors in donor complications

Age	**(n)**	**Estimated Blood Volume (ml)**		**p**
		Mean	SD	
18 - 20	78	4010.9	813.8	<0.001
21 - 25	83	4638.0	911.3	
26 - 30	51	4858.7	990.4	
31 - 35	21	5278.3	841.0	
36+	19	4969.7	930.8	
Total	252	4566.9	978.8	

t-test

Association between the gender and estimated blood volume of blood donors in donor complications

Out of 252 donor complications, 66 females who developed reactions had a mean estimated blood volume ranging between 3748.5 $\pm$ 630.5 ml and 186 males had 4857.4 $\pm$ 914.5 ml. A statistical significance was observed between the gender of blood donors and estimated blood volume in the development of donor complications.

Table No.26: Association between the gender and estimated blood volume of blood donors in donor complications

Gender	**(n)**	**Estimated Blood Volume (ml)**		**p**
		Mean	SD	
Female	66	3748.5	630.5	<0.001
Male	186	4857.4	914.5	
Total	252	4566.9	978.8	

t-test

Association between different types of donor complications and estimated blood volume of blood

No statistical significance was observed between estimated blood volume and systemic complications.

Table No.27: Association between different types of donor complications and estimated blood volume of blood

Donor complications	**(n)**	**Estimated Blood Volume (ml)**		**p**
		Mean	SD	
Local	36	4793.5	1153.1	0.241
Local + Systemic	4	4152.5	901.1	
Systemic	212	4536.3	945.8	
Total	252	4566.9	978.8	

ANOVA test

Association between the site of blood donation and different types of donor complications

No statistical significance was observed between the site of blood donation and different types of donor complications

Table No.28: Association between the site of blood donation and different types of donor complications

Site of donation	**Donor complications**						**Total**		χ^2	**df**	**p**
	Local		**Local + Systemic**		**Systemic**						
	n	%	n	%	n	%	n	%			
BC	6	16.7	1	25	15	7.1	22	8.7	5.705	4	0.222
Camp site	24	66.7	3	75	166	78.3	193	76.6			
Blood mobile	6	16.7	0	0	31	14.6	37	14.7			
Total	36	100	4	100	212	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Association between the volume of blood collected and different types of donor complications

No statistical significance was observed between the volume of blood collected and different types of donor complications

Table No.29: Association between the volume of blood collected and different types of donor complications

Volume of blood collected	Donor complications						Total		χ^2	df	p
	Local		Local + Systemic		Systemic						
	n	%	n	%	n	%	n	%			
<350 ml	5	13.9	0	0	12	5.7	17	6.7			
350 ml	25	69.4	4	100	168	79.2	197	78.2			
>350 ml	6	16.7	0	0	32	15.1	38	15.1	4.652	4	0.325
Total	36	100	4	100	212	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Table No.30: Association between different types of donor complications with the volume of blood collected

Donor complications	(n)	Volume of blood collected		p
		Mean	SD	
Local	35	338.9	89.5	0.403
Local + Systemic	4	350.0	0.0	
Systemic	210	354.6	59.9	

ANOVA test

Association between different types of donor complications and time taken for blood collection

Among 210 systemic complications the mean time of blood collection was 5.37 minutes (±1.26) and among 35 local reactions, the blood collection time was 4.75 minutes (±1.65). A statistical significance was observed between systemic reactions and time taken for blood collection.

Table No.31: Association between different types of donor complications and time taken for blood collection

Donor complications	**(n)**	**Time taken for blood collection (min)**		**p**
		Mean	SD	
Local	35	4.75	1.65	0.036
Local + Systemic	4	5.00	2.16	
Systemic	210	5.37	1.26	

ANOVA test

Association between different types of donor complications and time of last meal

No statistical significance was observed between different types of donor complications and time of last meal

Table No.32: Association between different types of donor complications and time of last meal

Donor complications	**(n)**	**Time of last meal (hours)**		**p**
		Mean	SD	
Local	35	3.92	0.60	0.717
Local + Systemic	4	3.5	0.58	
Systemic	210	3.84	1.05	

ANOVA test

Association between different types of donor complications and hours of sleep

No statistical significance was observed between different types of donor complications and hours of sleep

Table No.33: Association between different types of donor complications and hours of sleep

Donor complications	(n)	Hours of sleep (hours)		p
		Mean	SD	
Local	35	7.19	1.14	0.216
Local + Systemic	4	7.50	0.58	
Systemic	210	6.91	1.10	

ANOVA test

Association between seasonal variations and different types of donor complications

No statistical significance was observed between seasonal variations and different types of donor complications

Table No.34: Association between seasonal variations and different types of donor complications

Season	Donor complications						Total		χ^2	df	p
	Local		Local + Systemic		Systemic						
	n	%	n	%	n	%	n	%			
Summer	3	8.3	0	0	52	24.5	55	21.8	9.013	4	0.061
Rainy	14	38.9	3	75	89	42	106	42.1			
Winter	19	52.8	1	25	71	33.5	91	36.1			
Total	36	100	4	100	212	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Association between seasonal variations and site of blood donation

No statistical significance was observed between seasonal variations and site of blood donation.

Table No.35: Association between seasonal variations and site of blood donation

Season	Site						Total		χ^2	df	p
	BC		Camp		Mobile						
	n	%	n	%	n	%	n	%			
Summer	4	18.2	47	24.4	4	10.8	55	21.8			
Rainy	8	36.4	70	36.3	28	75.7	106	42.1			
Winter	10	45.5	76	39.4	5	13.5	91	36.1	9.013	4	0.061
Total	22	100	193	100	37	100	252	100			

(χ2 – Chi Square, df – degree of freedom, p – p value)

Transfusion Reactions

18124 patients admitted in our hospital over the period of May 2018 to October 2019. Among them 7786 (42.96%) patients were transfused with blood and/or blood components. 5836 patients who received transfusion were adults, while 1950 belong to paediatric age group. Out of 7786 patients transfused, 29 (0.37%) patients developed transfusion reactions. The mean age of the patients who developed adverse reactions were 40.1 $\pm$ 21.9 years. Among these patients, 14 (48.3%) were males and 15 (51.7%) were females. The mean weight of patients who developed adverse reactions were 57.6 $\pm$ 21.6 kg.

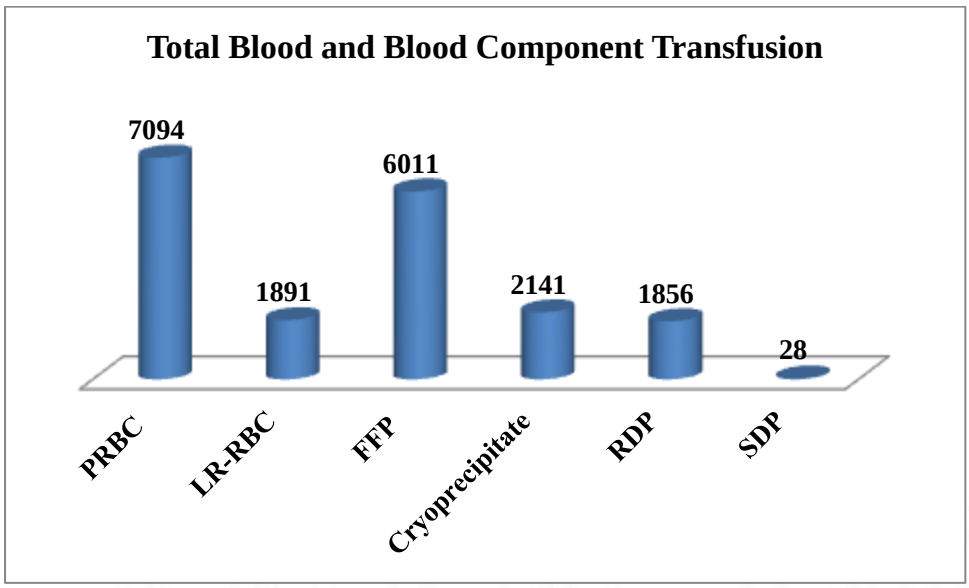
Total blood and blood component transfusion

During the study period, a total of 19021 units of blood component were transfused. Out of that, 7094 (37.30%) were PRBC transfusions and 1891(9.94%) were LR-RBC transfusions. 6011 (31.60%) units of FFP were transfused and 2141 (11.26%) units of cryoprecipitate were transfused. 1856 (9.76%) units of random donor platelets and 28 (0.15%) units of single donor platelets were transfused.

Table No. 36: Total blood and blood component transfusion

Packed Red Cell concentrates (P-RBC)	Leucoreduced-RBC (LR-RBC)	Fresh Frozen Plasma (FFP)	Cryoprecipitate	Random Donor platelets (RDP)	Single Donor Platelets (SDP)	Total blood component transfusion
7094	1891	6011	2141	1856	28	19021
37.30%	9.94%	31.60%	11.26%	9.76%	0.15%	100.00%

Figure.14: Total blood and blood component transfusion



Distribution of blood components that caused transfusion reaction

Out of 7094 PRBC transfusions, 26 units (0.37%) were implicated in various transfusion reactions and out of 1891 LR-RBC transfusions only one unit (0.05%) was implicated in an untoward event. 30 units of FFP (0.50%) were implicated in adverse reactions out of 6011 units transfused and 9 (0.42%) out of 2141 cryoprecipitate transfusion were implicated in adverse reactions. No platelet transfusions were implicated to cause adverse reactions. Out of 19021 blood components that were transfused, only 66 (0.35%) of transfusions resulted in transfusion reactions. Some transfusions reactions were reported in patients who received multi-component transfusions and in such cases we could not point out an isolated causative blood component.

Table No.37: Distribution of blood components that caused transfusion reaction

Blood components that caused transfusion reaction	**No: of units that caused reaction**	**Total units transfused**	**Percentage**
PRBC	26	7094	0.37%
LR-RBC	1	1891	0.05%
FFP	30	6011	0.50%
Cryoprecipitate	9	2141	0.42%
Platelets	0	1884	0.00%
Total	66	19021	0.35%

Figure No.15: Distribution of blood components that caused transfusion reaction

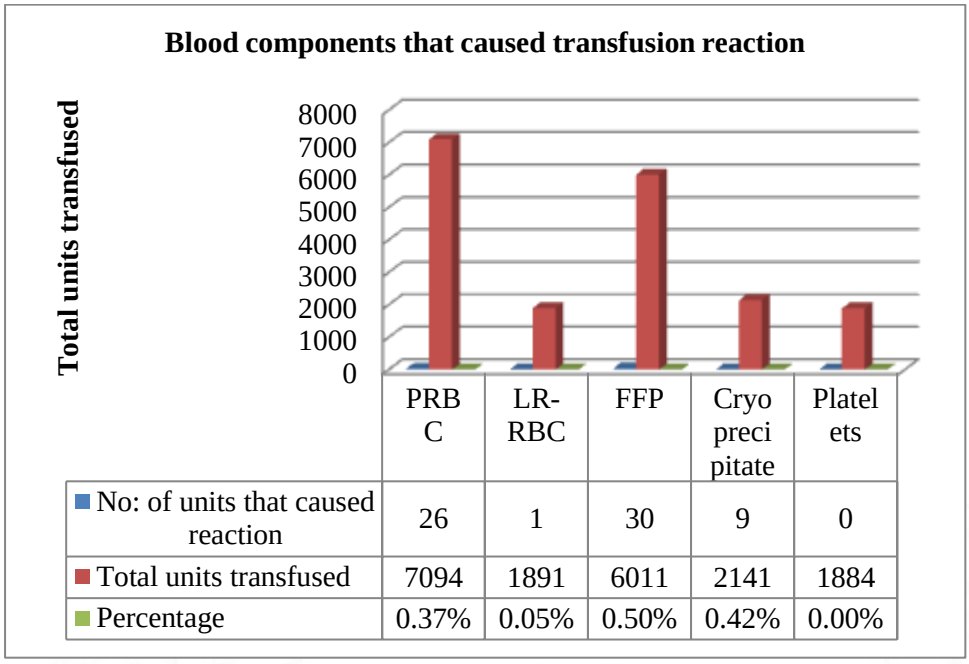


Table No.38: Total number of paediatric patients admitted and Table No.39: Total number of paediatric patients transfused

Admitted	Paediatric cases	Males	Females
CM	2384	2164	220
CS	2084	1886	198
NM	1740	1613	127
NS	2426	2130	296
IR	1916	1661	255
Total	**10550**	**9454**	**1096**

Transfused	Paediatric cases	Males	Females
CM	203	111	92
CS	1072	583	489
NM	274	108	166
NS	353	216	137
IR	48	29	19
Total	1950	1047	903

CM: Cardiomedicine CS: Cardiac Surgery NM: Neuromedicine NS: Neurosurgery

IR: Interventional Radiology

Table No.40: Total number of adult patients admitted and Table No.41: Total number of adult patients transfused

Admitted	Adult cases	Males	Females
CM	4670	3020	1650
CS	2052	1550	502
NM	3091	1755	1336
NS	1660	815	845
IR	1272	745	527
Total	12745	7885	4860

Transfused	Adult cases	Males	Females
CM	553	369	184
CS	2023	1521	502
NM	1460	901	559
NS	1602	787	815
IR	198	109	89
Total	5836	3687	2149

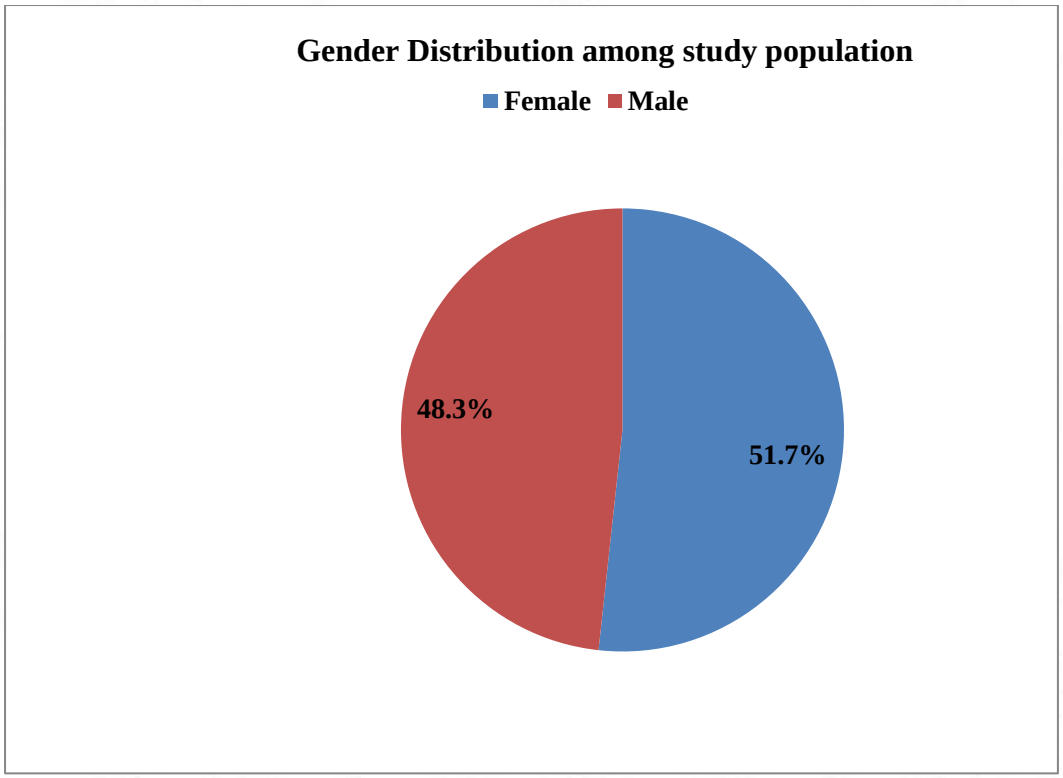
Gender distribution among study population

Among 29 patients who developed transfusion reactions, there were 15 (51.7%) females and 14 (48.3%) males.

Table No.42: Gender distribution among study population

Gender	Frequency (n)	Percentage
Female	15	51.7
Male	14	48.3
Total	29	100

Figure No.16: Gender distribution among study population



Department wise distribution of transfusion reactions

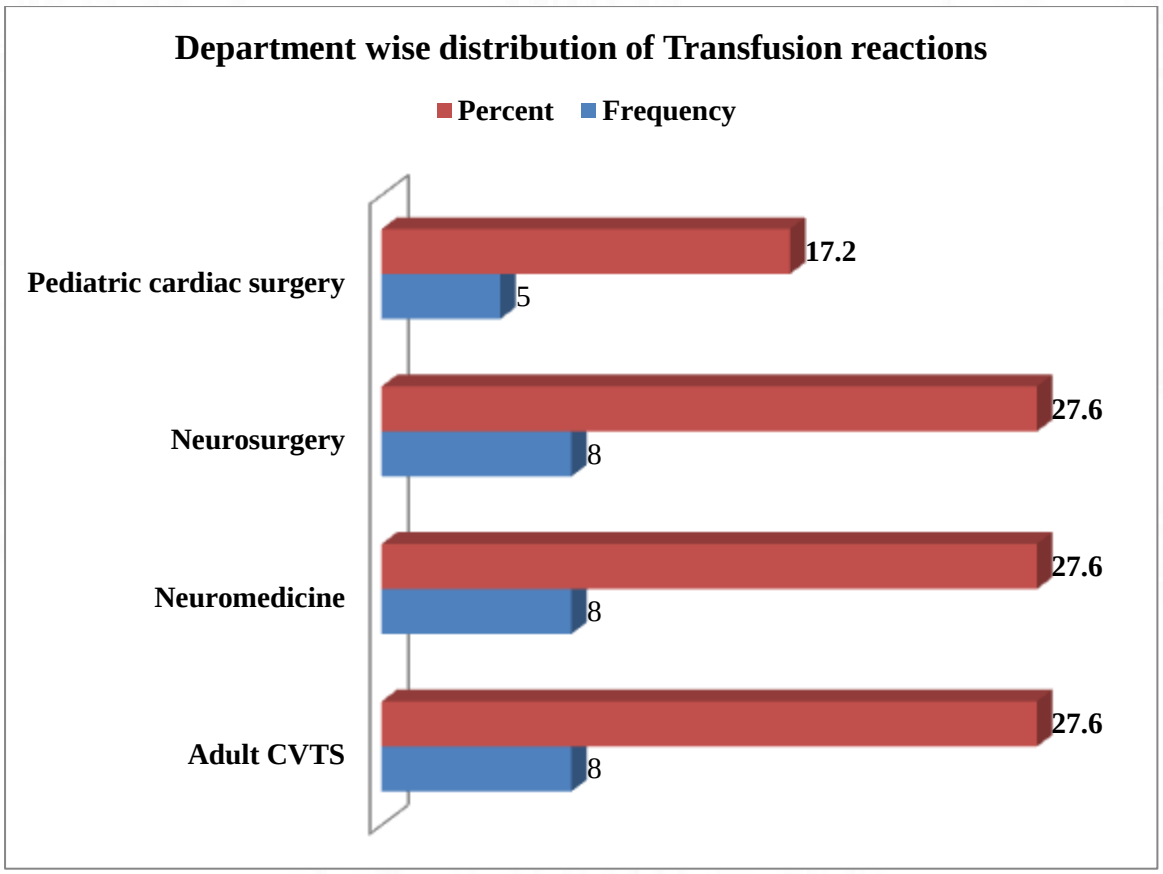
We had 8 adverse reactions each in the departments of adult CVTS (27.6%), Neuromedicine (27.6%) and Neurosurgery (27.6%). There were 5 (17.2%) paediatric cardiac surgery patients who developed transfusion reactions.

Table No.43: Department wise distribution of transfusion reactions

Department	Frequency (n)	Percentage
Adult CVTS	8	27.6
Neuromedicine	8	27.6
Neurosurgery	8	27.6
Paediatric cardiac surgery	5	17.2
Total	29	100

CVTS – Cardiovascular and thoracic surgery

Figure No.17: Department wise distribution of transfusion reactions



Distribution of place of transfusion

We have majority of our transfusions in operation theatres and intensive care units since our hospital is primarily a surgical centre. Hence, we encountered all our adverse transfusion reactions either in operation theatre or in intensive care units (ICU). Out of the total 29 reactions, 6 (20.69%) patients had reactions intraoperative and 23 (79.31%) experienced adverse reactions in various other departmental ICU's.

Table No.44: Distribution of place of transfusion

Place of transfusion	Frequency (n)	Percentage
CHICU	3	10.30
CMICU	1	3.40
CSICU	7	24.10
NMICU	5	17.20
NSICU	4	13.80
NSOT	4	13.80
PSOT	2	6.90
STICU	3	10.30
Total	**29**	**100.00**

Figure No.18: Distribution of place of transfusion

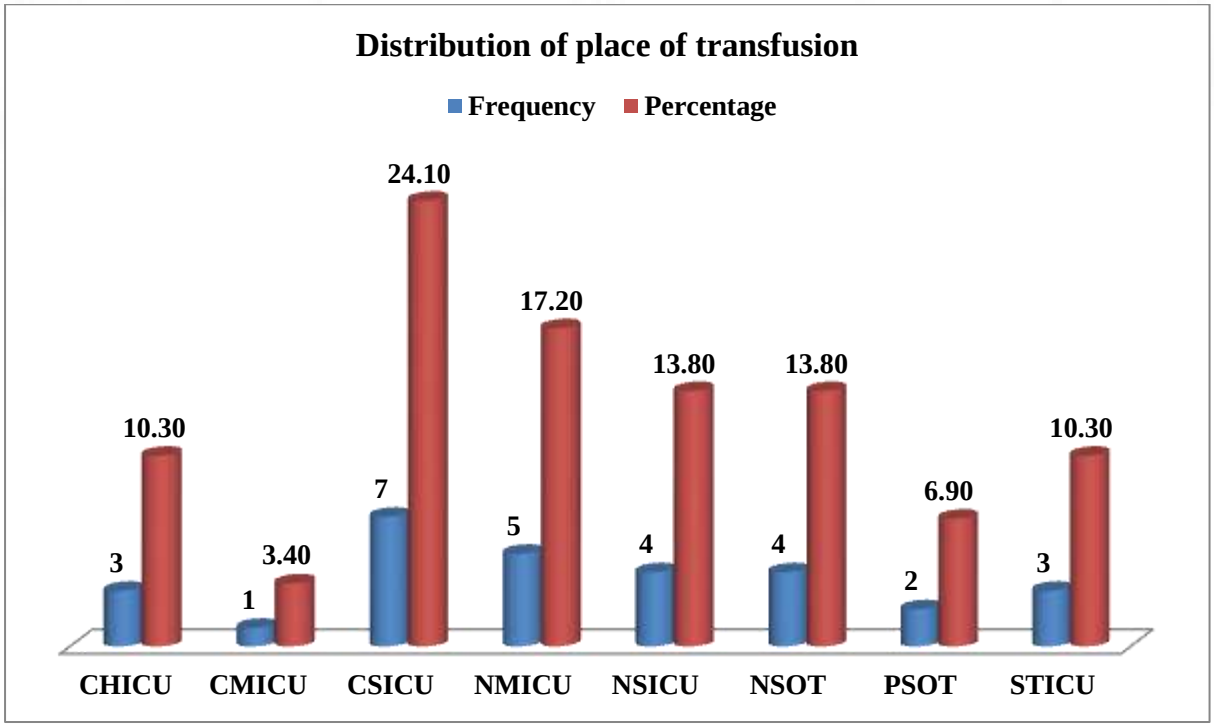
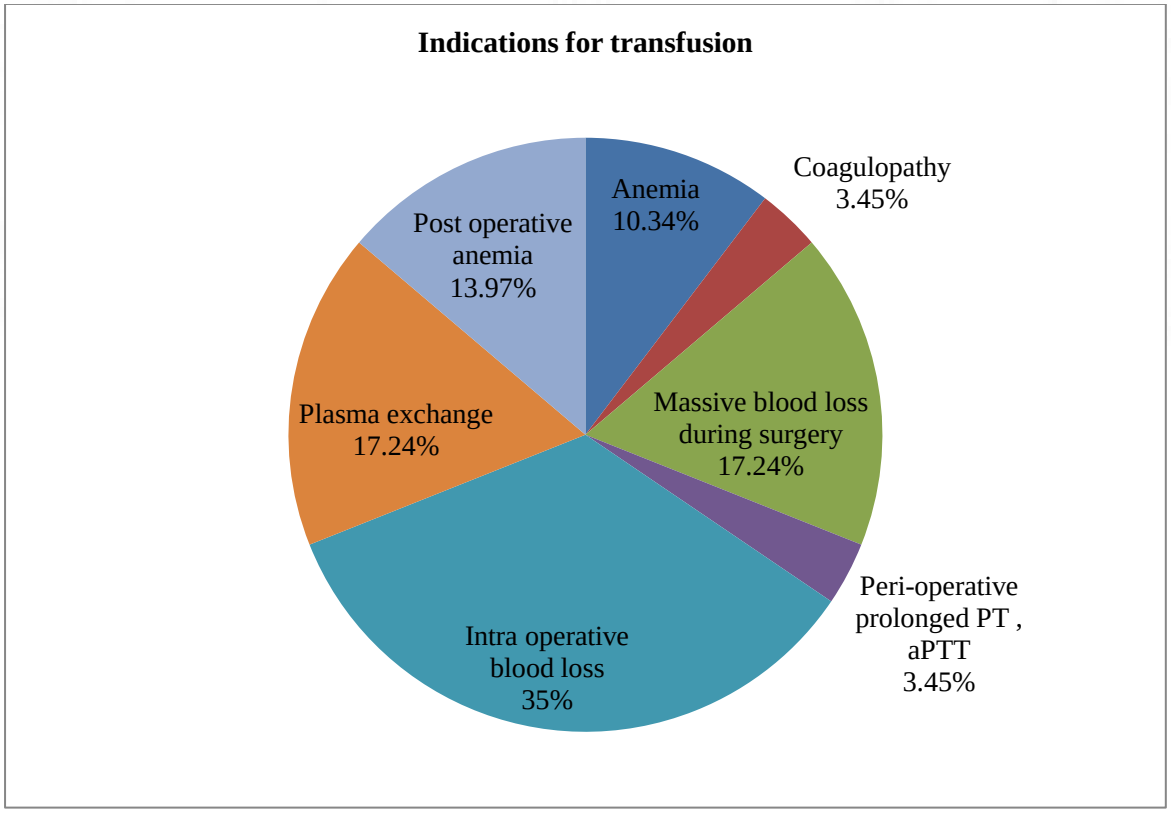


Table No.45: Indications for transfusions

Being predominantly a surgical institute, the usual indications for blood transfusions will be for intraoperative blood loss, massive transfusions and peri-operative anemia correction. We have a well-established therapeutic plasma exchange unit and thereby requiring FFP transfusions also.

Indications for transfusion	Frequency (n)	Percentage
Anemia	3	10.34%
Coagulopathy	1	3.45%
Massive blood loss during surgery	5	17.24%
Peri-operative prolonged PT , aPTT	1	3.45%
Intra operative blood loss	10	34.48%
Plasma exchange	5	17.24%
Post-operative anemia	4	13.79%
Total	29	100.00%

Figure No.19: Indications for transfusions



Whether the patient was under the effect of anaesthesia

14 (48.3%) of the patient were under the influence of anaesthesia at the time of development of transfusion reaction, whereas 15 (51.7%) were not under anaesthesia.

Table No.46: Whether the patient was under the effect of anaesthesia

Under General Anaesthesia	Frequency (n)	Percentage (%)
No	15	51.7
Yes	14	48.3
Total	29	100

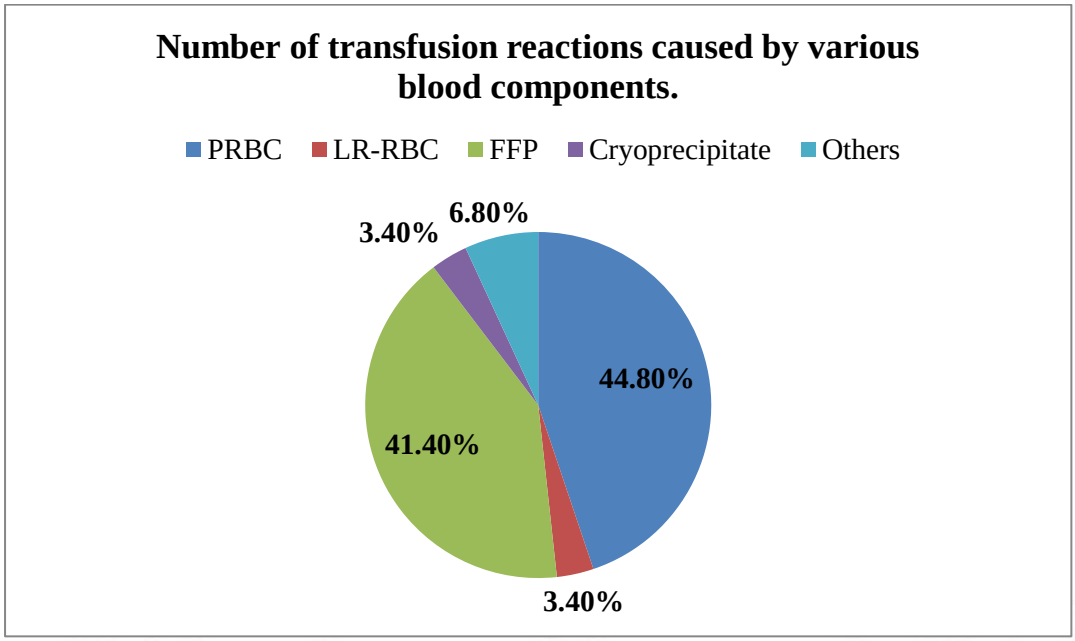
Components that caused transfusion reactions

13 (44.8 %) of the patients who developed adverse transfusion reactions were caused by PRBC followed by 12 (41.40%) patients with reactions caused by FFP. Only one unit of Leucoreduced-RBC and cryoprecipitate were reported to cause transfusion reactions. 6.80% (n=2) of the patients who developed transfusion reactions could not be attributable to an individual blood component as they were transfused with multiple blood components and the transfusion reaction occurred later on.

Table No.47: Number of transfusion reactions caused by various blood components.

Component that caused transfusion reaction	No: of transfusion reactions (n)	Percentage (%)
PRBC	13	44.80
LR-RBC	1	3.40
FFP	12	41.40
Cryoprecipitate	1	3.40
Others	2	6.80
Total	29	100.00

Figure No.20: Number of transfusion reactions caused by various blood components.



Transfusion reactions encountered

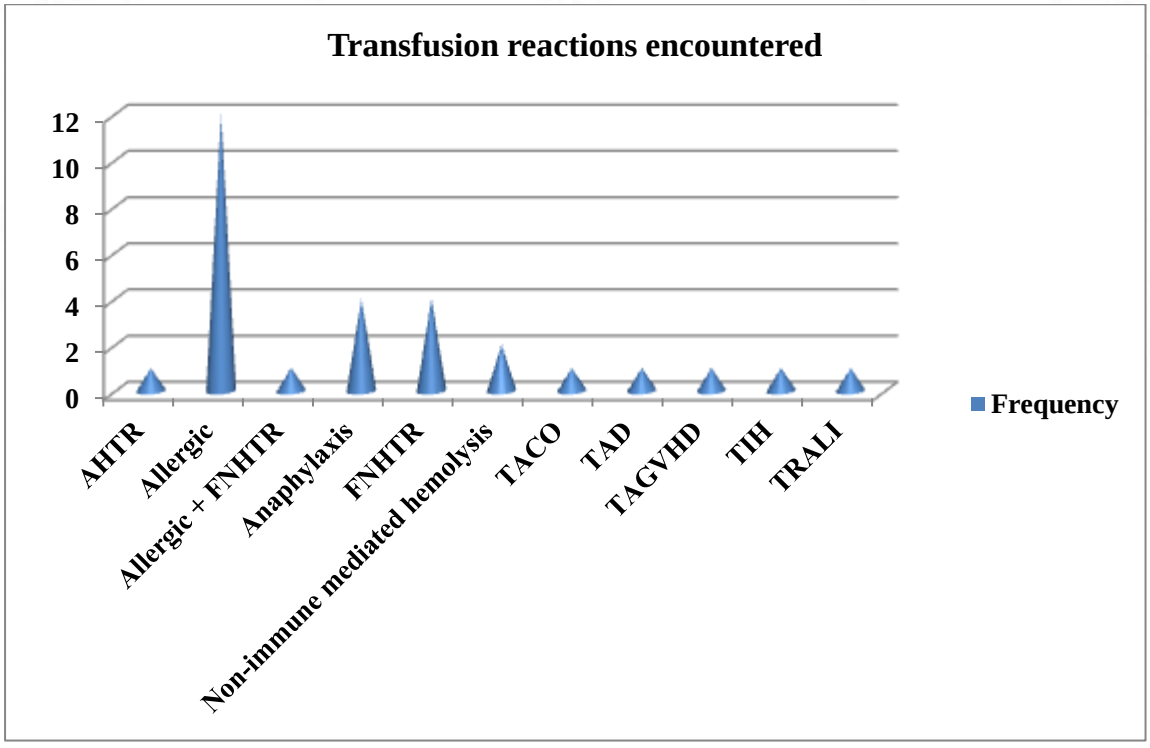
Out of total transfusion reactions that reported, 12 (41. %) were allergic reactions and one allergic reaction was accompanied with FNHTR. We had 4 cases of FNHTR (13.8%) and 4 anaphylaxis (13.8%).We had 2 (6.9%) cases on non-immune AHTR reported and one case each of AHTR, TACO,TRALI,TAD ,TIH and TA-GVHD reported accounting to (3.4 %) each.

Out of the 12 allergic reactions, 8 (0.13%) were due to FFP and 4 (0.06%) due to P-RBC transfusions. All the FNHTR's were associated with PRBC transfusions (4 {0.06%}) units. AHTR and Non- immune mediated AHTR were all associated with PRBC transfusions (3 {0.04%}) units. Out of the 4 anaphylaxis reported, 2 (0.03%) were implicated with isolated FFP transfusions and other 2 occurred in patients who received multi-component transfusions [Figure 21(e)]. One (0.02%) FFP unit was associated with TACO, One (0.05%) LR-RBC unit was associated with TAD and one (0.05%) unit of cryoprecipitate was associated with TIH.TRALI [Figure 21(b, c and d)] and TA-GVHD occurred in patients who were transfused with multiple blood components. One patient developed both allergic reaction and FNHTR; this patient also received multiple components.

Table No.48: Transfusion reactions encountered

Transfusion reactions	Frequency (n)	Out of total transfusion reactions	Out of total transfusions
AHTR	1	3.4%	0.01%
Allergic	12	41.4%	0.15%
Allergic + FNHTR	1	3.4%	0.01%
Anaphylaxis	4	13.8%	0.05%
FNHTR	4	13.8%	0.05%
Non-immune-mediated hemolysis	2	6.9%	0.03%
TACO	1	3.4%	0.01%
TAD	1	3.4%	0.01%
TAGVHD	1	3.4%	0.01%
TIH	1	3.4%	0.01%
TRALI	1	3.4%	0.01%
Total	**29**	**100%**	**0.37%**

Figure No.21 (a): Transfusion reactions encountered



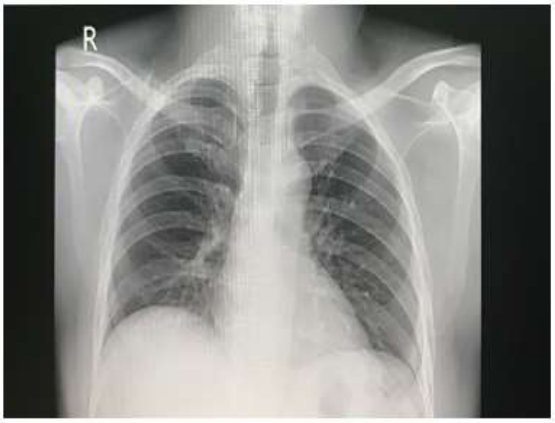


Figure 21 (b) : Normal Chest X-ray

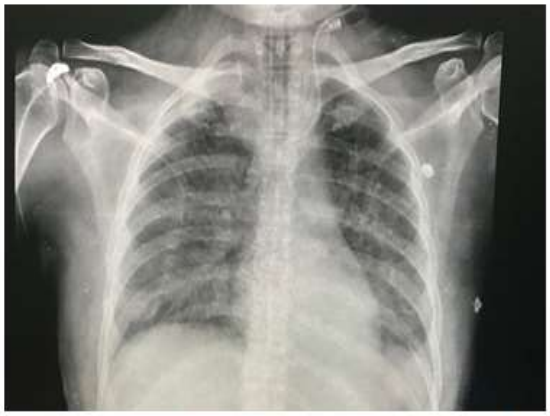


Figure 21 (c) : Chest X-Ray suggestive of TRALI

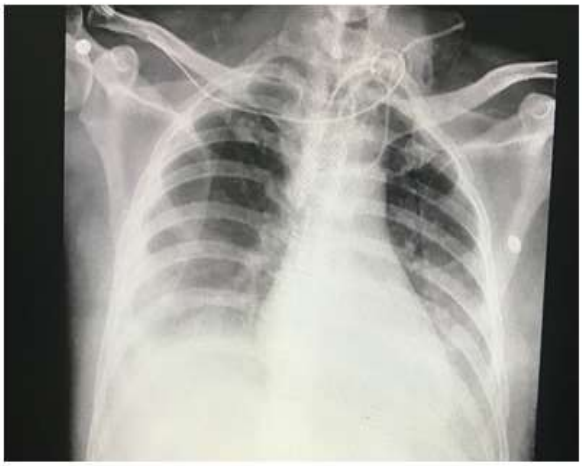


Figure 21 (d) : Chest X-Ray at recovery phase

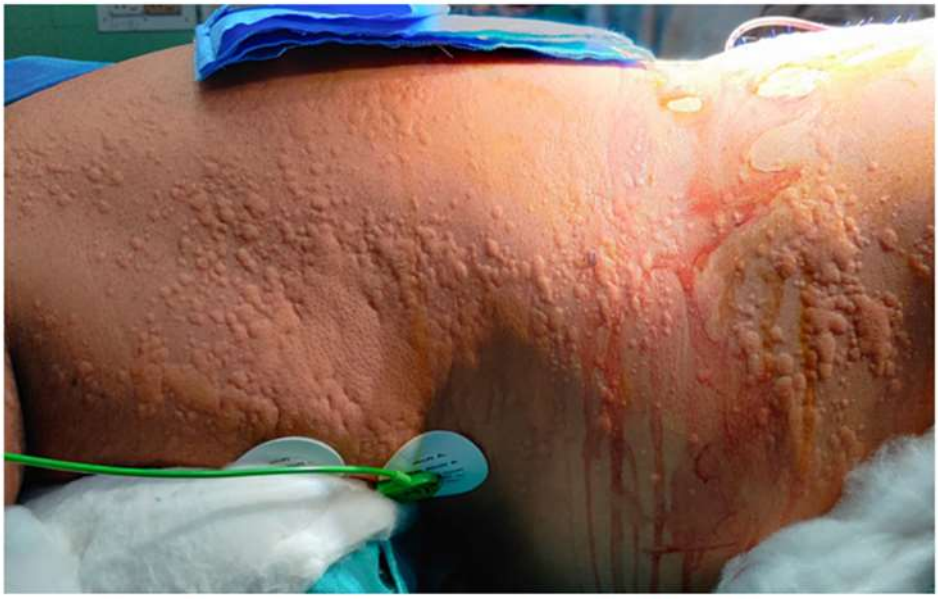


Figure 21(e) : Rashes observed in a patient who developed anaphylaxis

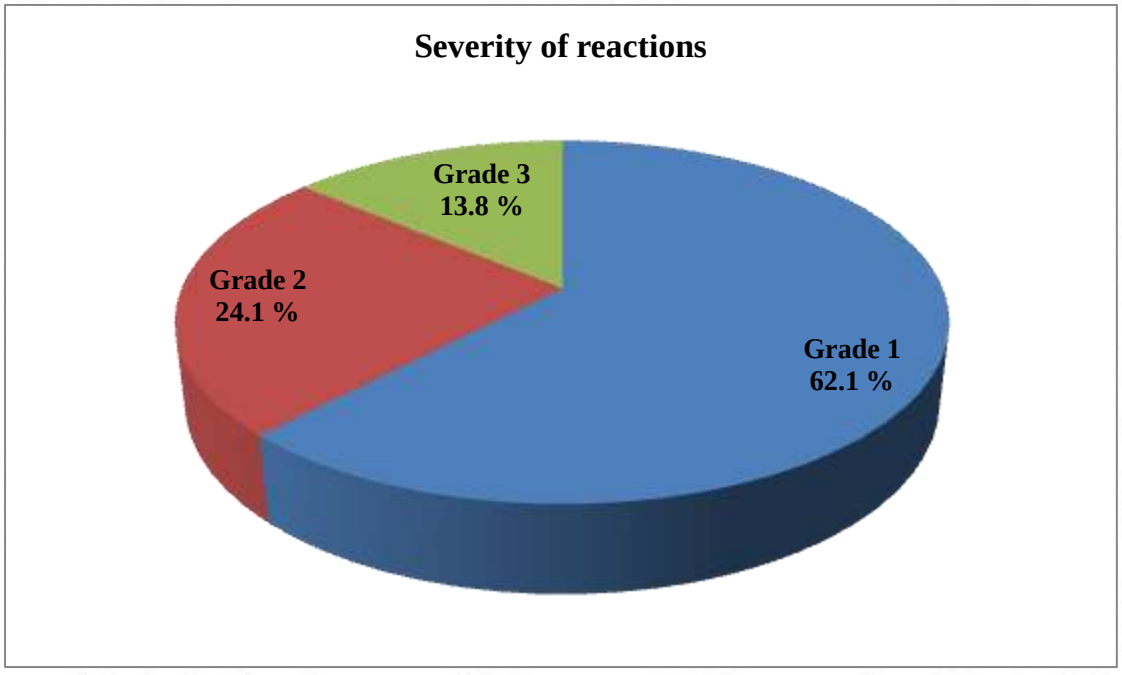
Distribution of severity of transfusion reactions

Out of the 29 transfusion reactions reported, 18 (62.1%) were grade 1 reactions, 7 (24.1%) were grade 2 and 4 (13.8%) were Grade 3 reactions. Not even a single case of Grade 4 reaction was reported and there were no transfusion related mortality.

Table No.49: Distribution of severity of transfusion reactions

Severity of reaction(Grades)	Frequency (n)	Percentage
Grade 1	18	62.1
Grade 2	7	24.1
Grade 3	4	13.8
Grade 4	0	0.0
Total	29	100

Figure No.22: Distribution of severity of transfusion reactions



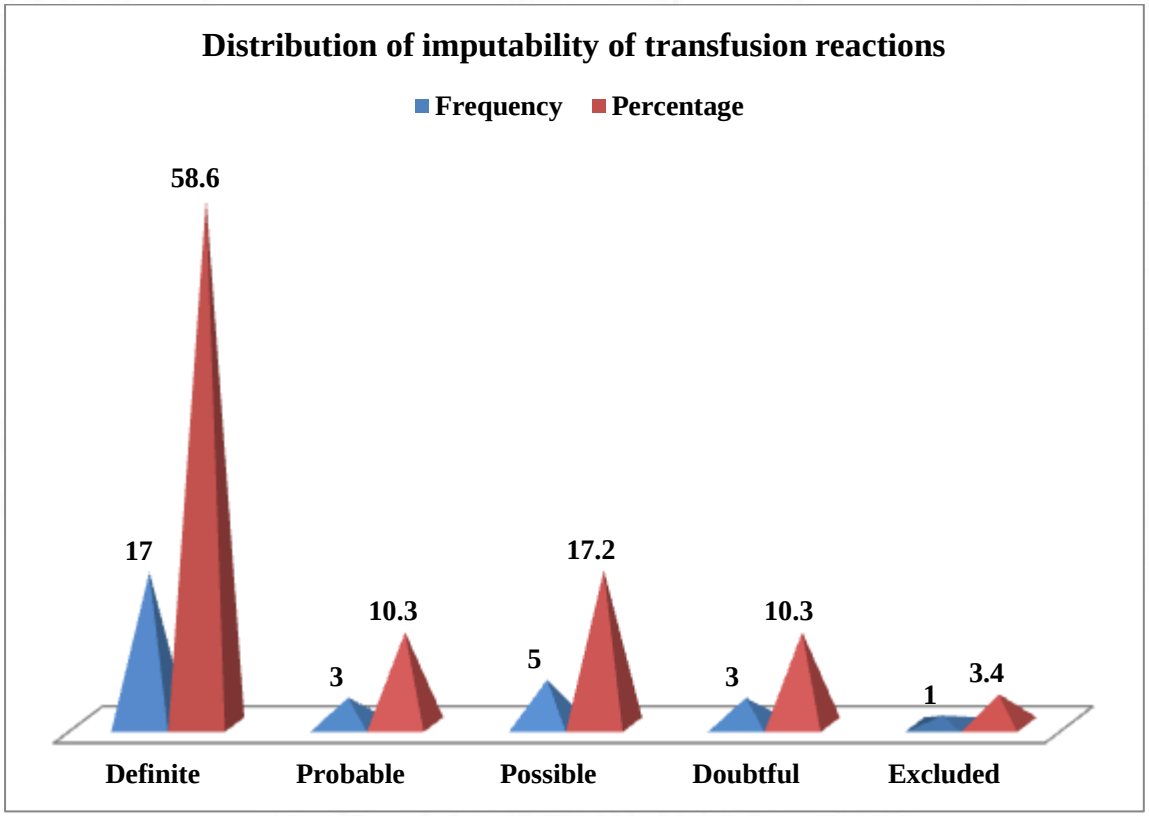
Distribution of imputability of transfusion reactions

Out of the total 29 reactions, 17 (58.6%) carried definite imputability, 3 (10.3%) were probable reactions, 5 (17.2%) were possible reactions, 3 (10.3%) were doubtful reactions and 1 (3.4%) of the reactions were excluded.

Table No.50: Distribution of imputability of transfusion reactions

Imputability	Frequency (n)	Percentage
Definite	17	58.6
Probable	3	10.3
Possible	5	17.2
Doubtful	3	10.3
Excluded	1	3.4
Total	29	100

Figure No.23: Distribution of imputability of transfusion reactions



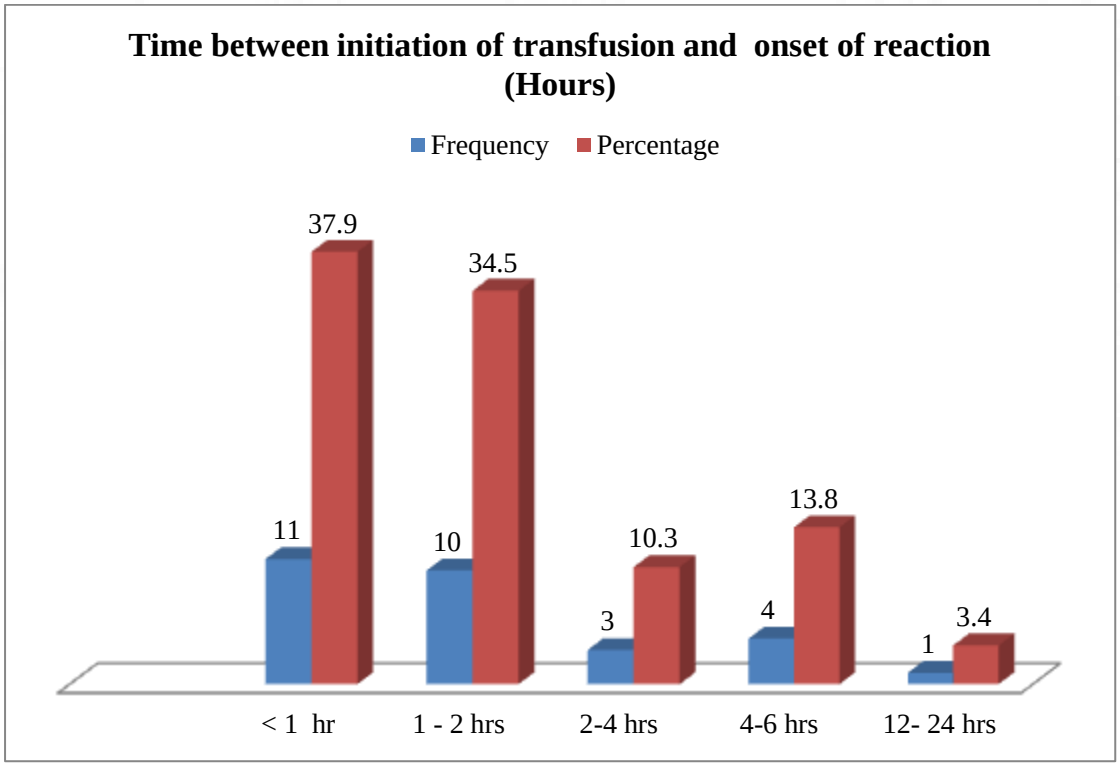
Time between transfusion of transfusion and onset of reaction (Hours)

Out of 29 reported patients, 11 (37.9%) developed reactions within 1 hour of initiation of transfusion and 10 (34.5%) developed within 1-2 hours of transfusion. 4 (13.8 %) patients developed reaction in 4-6 hours of transfusion and 3 developed (10.3%) within 2-4 hours of transfusion. One (3.4%) patient developed reaction only after 12-24 hours of transfusion.

Table No.51: Time between initiation of transfusion and onset of transfusion reaction (Hours)

Time between initiation of transfusion and onset of reaction (Hours)	Frequency (n)	Percentage
< 1 hour	11	37.9
1 - 2 hours	10	34.5
2-4 hours	3	10.3
4-6 hours	4	13.8
12- 24 hours	1	3.4
Total	29	100

Figure No.24: Time between start of transfusion and onset of reaction (Hours)



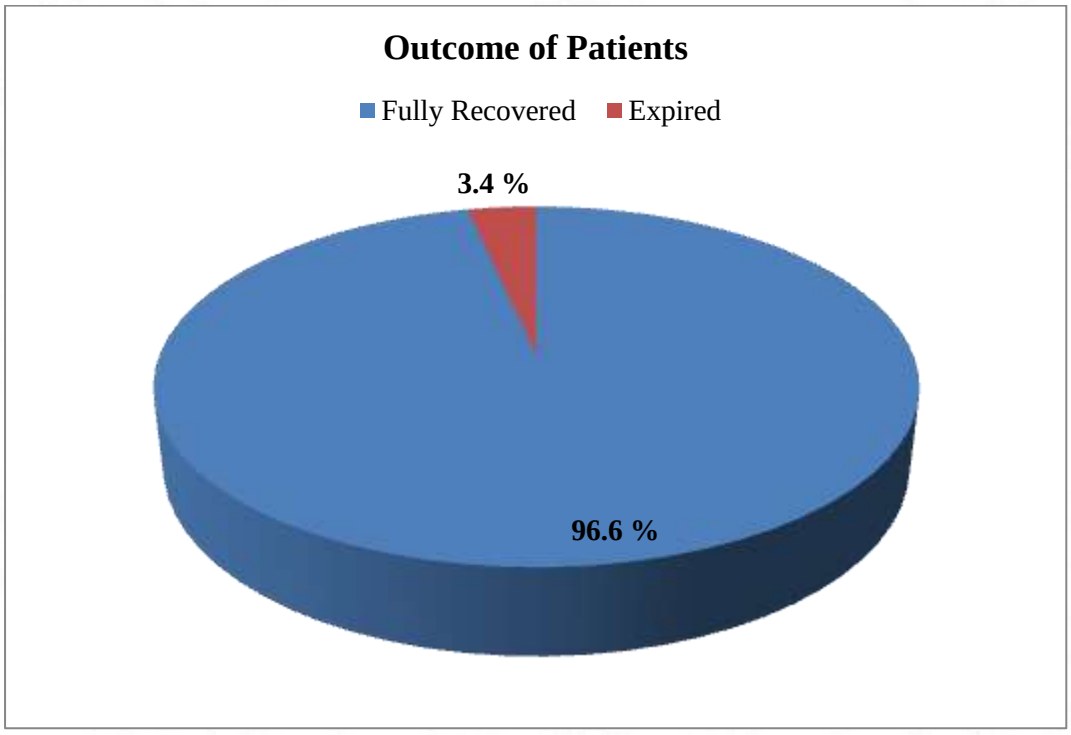
Outcome of patients

Out of 29 patients who developed transfusion reactions, 28 (96.6%) recovered and only one (3.4%) patient expired after 17 days of transfusion due sepsis and was not a transfusion related mortality.

Table No.52: Outcome of patients

Outcome of patients	**Frequency (n)**	**Percentage**
Fully Recovered	28	96.6
Expired (not a transfusion related mortality)	1	3.4
Total	29	100

Figure No.24: Outcome of patients



DISCUSSION

Blood Donor Complications

This is a cross-sectional study, done among 252 voluntary blood donors who developed donor complications as a part of blood donation in the Department of Transfusion Medicine, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala and outdoor blood donation camps organised by the department.

In this study, the most common age group of voluntary blood donors who developed donor complications were 18-25 years. The mean age of study population was 24.88 $\pm$ 6.581 years. The range was 18-54 years.

Among 66 females who developed complications, 34 (51.5%) and 15 (22.7%) belongs to 18-20 years and 21-25 years respectively whereas 186 males who developed complications, 44 (23.7 %) and 68 (36.6%) were between to 18-20 years and 21-25 years respectively. There was a statistically significant association between younger age group and female gender in the development of donor complications in our study. A similar observation was stated in a study by Murphy et al (36) and Goldman et al (37).Younger age of donation and female donors are both significant predictors of vasovagal reactions are also stated in a study by Tondon et al (38).

73.4% of the donor complications were vasovagal reactions that were constituted by pallor, dizziness and sweating and rest of the vasovagal reactions were accompanied by LOC and/or seizures and some of the vasovagal reactions occurred along with local reactions. We had 5.2 % of the vasovagal reactions to be accompanied with LOC without injury and 1.2 % were LOC with seizures but without injury. We had 0.8 % delayed vasovagal reactions and 1.2 % vasovagal reactions accompanied with local complications (arterial puncture and hematoma).

In the present study, we had 3.8 % of donor complications out of total collection and 0.02 % (two donors) of pre-donation reactions out of total registered donors for which these two donors were deferred. A study by Crocco et al (39) has mentioned a convulsive vasovagal reaction rate of 1.2 % which is similar to our study. We have got LOC without injury reaction rate of 5.2 % likewise reported by Smita et al (40). Rajendran et al (41)has reported a case of severe donor reaction with injury also.

10 % of the donors in our study developed hematoma as an isolated complication without any other accompanying systemic or local reactions. This was comparable with 9 to 16 % hematoma prevalence reported in the study by Newman et al (42). We also got an accidental arterial puncture prevalence rate of 0.4 % in one year period and a study by Newman et al (43) has reported 12 such cases in a period of two years and Agnihotri et al has reported one such case (44).

It is observed that female donors with low body weight have encountered more systemic reactions than male donors and this is comparable with a study done by Newman et al (45),who have also found in their study that low body weight was an independent risk factor for development of vasovagal reaction and the their study also had a good number of female participants. Same observations about low body weight and donor complications are also seen in study done by Goleman et al (46). In a study by Tondon et al (38), it is described that weight as such was not the actual risk factor ,but the volume of blood drawn from the donor may predict the reaction rate.

A statistically significant association has been observed between the first time blood donors and increased number of systemic donor complications than in repeat donors or regular donors. A similar observation has been stated in a study by Wiersum et al (47) and Eder et al (48) in which first time donors were found to have more incidence of vasovagal reactions.

We have obtained a statistically significant association between the age and estimated blood volume of donors in the occurrence of blood donor complications as the donors less than 25 years of age with an EBV of less than 4.5 L were found to develop more donor complications. A similar kind of observation has been stated in a study by Rios et al (49) in which blood donors less than 25 years of age with an EBV less than 3.5 L were found to develop more systemic donor reactions. Philip et al (50) and Tomasulo et al (51) in their study also has emphasised on the importance of low blood volume and the consequent occurrence of systemic donor reactions.

Our study has also observed a statistically significant association between females with low estimated blood volume in the occurrence of donor complications. Even though our study could not demonstrate any statistical significance between the occurrence of systemic donor complications and estimated blood volume, other study by Kamel et al (52), has stated low estimated blood volume to be a major risk factor for vasovagal reactions.

Philip et al (50) and Bani et al (53) in their study mentioned that donors with low blood volume, first-time donors, with low weight and female donors had higher absolute donation VVR rates than other donors. Pre-donation hydration has got a beneficial effect on the reduction of systemic complications (54-57).

Even though our study could not demonstrate any statistical significance between seasonal variations and increased incidence of blood donor systemic complications, more number of systemic reactions were observed during the months of May, November, September and January. More donor reactions in the month of May be due to immense heat of summer season and inadequate hydration status of blood donors. In Kerala, September will be rainy season and December and January will be winter season; however, a greater number of systemic complications encountered in these months were due to the poor hydration status of the blood donors during cold season. This assumption was further strengthened by the increased incidence of local complications in winter months due to poor venous access. We could effectively reduce both these complications after proper pre-donation hydration of the blood donors.

We could observe that both systemic and local donor complications were more during rainy and winter months and henceforth, hydration status of the donors play a pivotal role in the decreased incidence of blood donor complications. A study by Ogata et al (58) has shown that in Japan the reaction rates were more during spring season and they have explained this to be because of the fact that spring is the season of climatic change and social stress and thereby more attributing to psychological factors. Another study done by Callahan et al (59) in Wisconsin has shown that their peak incidence of reactions were in the months of April, July and November with relatively lower rates in January and September.

We could not find any statistical significance between the site of blood donation and the increased incidence of blood donor complications. A study by Sachdev et al has shown an increased incidence of donor reactions in blood mobiles during summer season and decreased incidence during winter months (60).

The systemic adverse reaction rates were more among young first time donors, female donors and donors with low estimated blood volume. In order to attain a solution to reduce the reaction rates among those donors; we introduced pre-donation oral hydration with water for all young first-time donors with low estimated blood volume. We made our donor selection procedure much more stringent in such a way that all donors who are at risk of developing

complications are well hydrated prior to the initiation of blood donation and the donors will be distracted by means of continuous verbal communication during the process of blood donation. We initiated training strategies to improve the phlebotomy skills of our phlebotomists to reduce local complications.

Another safety measure we have adopted is a two to one care practice where 2 donors will be taken care by one staff member throughout the donation process and to accomplish this in the camp site donation we have limited the donor couch numbers to be 4 to a maximum number of 5 at a time. Pre-donation hydration will help to reduce the incidence of systemic complications as well local complications like hematoma by establishing a better peripheral venous access. In addition to these, those blood donation camp sites were we anticipate more donor complications like as in Women's colleges or in institutions were more young first time donors are present, before the commencement of blood donation; medical officer in charge of the camp will address the donors and will make them comfortable by making them aware regarding the benefits and Do's and Dont's of blood donation.

Instead of excluding the donors at risk from blood donation, we have included these donors also in blood donation after ensuring the safety measures. Donor deferral is a real demotivating factor which can badly affect donor retention and even donor recruitment at some places. Donor retention is the backbone of voluntary blood donation through which we can sustain more mobilisation of voluntary blood donors to phase out replacement donation gradually. A pleasant donation experience can promote altruism among blood donors and thereby motivating themselves and others to come forward for more donations.

Adverse transfusion reactions

Being primarily a surgical care institute, our transfusions were mainly encircled in operation theatres and intensive care units and because of this reason the transfusion reactions were all encountered during intraoperative blood usage or during post-operative period.

The incidence of acute transfusion reactions can range from 0.4 to 3 % of all transfusions (61), (62). In our study, out of 7786 patients transfused, 29 (0.37%) patients developed transfusion reactions. The most common adverse reaction observed during our study period were allergic reactions (41.4%) followed by FNHTR (13.8%) and 13.8 % of anaphylactic reactions (63, 64).

In our study, 0.15% of the total transfusions resulted in allergic reactions. Here, 0.13% of the total FFP transfusion and 0.06% of the total PRBC lead to allergic transfusion reactions. A study by Tobian et al mentions the incidence of allergic transfusion reactions to be 1-3% (65).Our study is comparable with studies done by Hirayama et al (66) and Savage et al (67) in the rates of allergic transfusion reactions. Even though the commonest reaction in our study was allergic reactions and in our hospital we do not administer any pre-medications, the overall incidence was very less compared to other studies.

FNHTR was the next common adverse reaction observed in our study amounting to 13.8 % of total transfusion reactions and 0.05% of the total blood components transfused. The published incidence rates of FNHTR range from 0.12 % to 0.5 % and for non-WBC-reduced RBCs (68, 69) to between 1.7 % and 31 % for non-WBC-reduced platelets (70, 71). FNHTR incidence rate in our study is comparable with the rates of study by Ezidiegwa et al (72) and Kelley at al (73). Packed red cell concentrates were the culprit blood component in all our reported cases of FNHTR's and 0.06 % of the non-leucoreduced packed red cell concentrate transfusion has led to FNHTR's in our study.

The incidence of reported cases of severe allergic reactions like anaphylaxis were found to be similar to that FNHTR in our study, but the imputabilities of these two types of transfusion reactions were different. The rate of anaphylaxis was 13.8 % of the total transfusion reactions and 0.05 % of the total blood components transfused. Out of the 4 cases of anaphylaxis reported, 2 (0.03%) were following FFP transfusions and 2 cases were reported in patients

with multi-component transfusion where we could not attribute the actual blood component that has produced the reaction.

It was well evident from the current study that not even a single leucoreduced blood component was implicated in allergic reactions and FNHTR's. We could reduce the incidence of FNHTR and allergic transfusion reactions from the reports obtained in the study period by increasing the administration of more leucoreduced blood components for transfusion. Buffy coat reduction is the predominant method of leucoreduction employed in our centre followed by leucofiltration with lab side filters and washing and irradiation in indicated cases. Already in our hospital all platelets that are prepared are buffy coat reduced platelet concentrates.

Pre-storage leucoreduction and reduced incidence of allergic transfusion reactions and FNHTR's are quoted in a large proportion of studies which adopted various leucoreduction techniques to reduce leucocyte associated transfusion reactions (72, 74, 75, 76 and 77). A study by Anderson et al (78) and another by Muylle et al (79) has mentioned the effectiveness of leucoreduced platelet concentrates in the reduced incidence of transfusion reactions.

A study by Callaghan et al (80) has mentioned that the frequency of severe allergic reactions are 7.7 % of total allergic reactions and 1.3 % of total transfusion. It is well known that IgA deficient individuals are prone to develop anaphylactic transfusion reactions (81), in our study IgA estimation was not performed at all. However, those patients who developed anaphylactic reactions received transfusions later on also and those transfusions were uneventful without any premedication. Hence, an IgA deficiency was not suspected in those cases. Moreover, we had only one case of anaphylaxis with definite imputability and one was probable and two had possible imputability.

We have reported one case of acute hemolytic transfusion reaction as a result of ABO mismatched transfusion with definite imputability and 2 cases of non-immune hemolytic transfusion reactions with doubtful imputability. AHTR accounted to 3.4 % of all transfusion reactions and 0.01 % of total transfusions whereas non-immune mediated AHTR accounted to 6.9 % of all reactions and 0.03% of total transfusions. We consider the reporting of non-immune AHTR with doubtful imputability as an achievement in improved transfusion reaction reporting system that has evolved after the introduction of an active hemovigilance surveillance system headed by the Department of Transfusion reaction in our institute.

The ABO incompatible AHTR case that we got in our study was an AHTR that was reported after 12 years in our institute and the incidence of AHTR was nil in our institute for all these years. This occurred as a result of bedside error where wrong blood unit was transfused for wrong patient and since, the blood unit was transfused for intraoperative massive blood loss in a paediatric cardiac surgery patient, anaesthetist could immediately notice dark coloured urine in the Foley's bag. The patient was immediately managed with all adequate emergency salvage measures and the patient recovered. SHOT reports (16) from 1996 to 2004 have reported 44 AHTR's which they have noticed to be due to technical and clerical errors.

Only red cell units were implicated in hemolytic transfusion reactions in our study (82).Though we have rarely administered ABO-incompatible platelet transfusions at lifesaving emergency situations, we have not encountered any hemolytic reactions. But, there are studies which have reported hemolytic transfusion reactions as a result of ABO-incompatible platelet transfusions (83-86).

Following this incident, we have adopted immediate measures to reduce the laboratory side and bed side errors to improve the transfusion safety. We found that in the AHTR case, B Rh (D) patient was wrongly transfused with A Rh (D) negative blood which was issued for another patient the same day morning and the unit was stored in the OT refrigerator as it was not used. Non-immune cases of AHTR were also reported even though those cases were doubtful as a complication of blood transfusion. However; if the cases were actually due to mechanical or thermal hemolysis or if due to prolonged time delay between the issue of blood product and the onset of transfusion, definitely these are preventable causes. A study by Beauregard et al (87) has mentioned various cases and the attributable causes of non-immune hemolysis (82,88).

After these incidents, we have made a strict amendment that no blood units should be stored at the bed side if it is not transfused and the blood units that are not used has to be returned to the blood centre for storage if the quality measures are satisfied. Even at emergency circumstances not more than 2 red cell units will be issued for a patient at any given point of time. In our hospital, the blood units that are issued from the blood centre are received by hospital attenders and not the relatives of the patient, hence we could issue the blood units in a much more responsible manner with proper documentation of the staff who has received the blood unit and whether the blood unit has reached the required place at the right time to the right patient.

One case of possible TRALI was also reported in our study and it occurred in a 38 years old male patient who was massively transfused during his neurosurgery. The very next day morning patient developed hypoxemia and saturation fall with features of pulmonary oedema on chest X-ray. Patient was febrile and was not extubated after surgery. Since the patient was on inotropes, hypotension was not a manifestation. His cardiac function was normal by echocardiography. Since, he was transfused with multiple blood components during surgery, one particular blood component could not be attributed for the causation of the reaction. The patient recovered after 48 hours and was extubated successfully.

In our study, TRALI constituted 3.4 % of the total transfusion reactions and 0.01 % of the total transfusions. TRALI is one of the most common cause of fatal transfusion reactions (89-92).Various hemovigilance networks like SHOT, France, Canada, Denmark and Germany has reported the TRALI percentage of all adverse events from 0.05 % to 7 % (93).

We have got one case of TACO also reported which represented 3.4 % of the transfusion reactions and 0.01 % of the total transfusions which carried definite imputability. This occurred in a 76 year old lady with pre-existing cardiac dysfunction and a study by Menis et al (94) has mentioned the increased incidence of TACO in elderly female patients. TACO is another leading cause of transfusion related mortality (95). The estimated frequency of TACO varies from 1 % in hemovigilance reports to 8 % in post-operative elderly patients and 11 % in critically ill patients (96, 97).TACO is currently the leading cause of transfusion related mortality, accounting for 3 out of 8 deaths in the year 2011 and 6 out of 9 deaths in the year 2012 as per SHOT reports 2012 summary.

We have got one case each of TAD and TIH also. Both of these constituted 3.4 % of the total reactions and 0.01 % of total transfusions. In our study TIH occurred in 7 year old female child in the post- operative period and the child underwent surgical correction for congenital cardiac malformation. The culprit blood product was cryoprecipitate and this was the one and only cryoprecipitate induced transfusion reaction in our study period and carried a possible imputability.

The cause of hypotensive transfusion reactions are believed to be associated with bradykinin metabolism which are found more commonly in patients on Angiotensin converting enzyme inhibitors (98-99). Leucoreduction of blood products can reduce the incidence of hypotensive transfusion reactions (100-102). We have not encountered even a single case of TIH after

administration of leucoreduced blood components. Hypotensive reactions after platelet transfusion has also been mentioned in a study by Hume et al(103) and Mair et al (104).

We have got one case of TAD reported and the culprit blood component was an LR-RBC. This was the one and only transfusion reaction which was reported in association with a leucoreduced blood component in our study. TAD constituted 3.4 % of the total transfusion reactions and 0.01 % of the total transfusions with possible imputability. It was reported in 51 years old female patient with broncho-pneumonia who was admitted following embolic stroke. Towards the end of the transfusion, she developed dyspnoea and there were no findings suggestive of TRALI or TACO. The patient recovered immediately after cessation of transfusion and treatment with bronchodilators and steroids. TAD cases are less frequently reported or often under-reported in majority of the cases (105).

One case of TA-GVHD was also reported in our study period even if the imputability we have excluded. But the reporting was considered as major achievement of our active hemovigilance surveillance system. This occurred in a 26 years old female patient who received 4 units of red cell transfusions during her repeat neurosurgery. She suffered from bilateral frontal lobe glioma for which she was operated before and has received radiotherapy and chemotherapy post procedure. Following recurrence of the tumour she was again operated and received transfusion support that got attributed to the reaction. Within 6 hours of transfusion as per her earlier investigation records, she developed neutropenia, thrombocytopenia. She was immediately reported as TAGVHD by the clinician, but except for the hematology reports there were no features suggestive of TAGVHD. The patient failed to improve and expired after 17 days of TA-GVHD reporting due to sepsis and DIC. It could not be attributed to transfusion related mortality.

TA-GVHD is a rare but life threatening transfusion reaction which can occur even in immuno-competent recipients. In our institute we administer irradiated blood components in all cases where TA-GVHD can become a possible complication and directed donations are completely discouraged. There are many studies which have observed even 100 % mortality rates of TA-GVHD cases (106-109).

Other than TA-GVHD with excluded imputability, we did not come across any other delayed transfusion reactions in the present study. Nineteen cases of DHTR's are reported in a case study by Monaghan et al (110) . Many studies have reported transfusion associated iron overload among multi-transfused group of patients as in cases like thalassemia (111,112).

The hemovigilance active surveillance in our institute will look after all the transfusions that are being administered daily in all areas of blood transfusion and will visits to all patients who have received transfusions for various indications on a routine basis. This has helped us to create a good rapport in between the transfusion medicine, the clinicians, the nursing staff and the patients to improve the bed side transfusion practices which has resulted in the reduced incidence of transfusion reactions in the following years. Eventually the transfusion reaction reporting has progressed to such an extent that now even those cases in which the imputability can be excluded are also being reported.

Reporting of more adverse events enlightened us to take preventive measures against further occurrence and recurrence. All the clerical errors that can possibly raise concern regarding patient safety from the part of blood centre were taken care of by proper documentation and training of staff members. Whenever a transfusion medicine expert makes a visit to the place of were adverse event has occurred, all possible reasons that can be attributed to the causation of such a transfusion reaction will be sought and will give future corrective and preventive advices to both the clinician and the nursing personnel who are in charge of that patient. We don't follow a blame culture in our hospital rather we follow a practice which involves a better understanding between Transfusion medicine and the clinical side thereby promoting increased acceptance of corrective measures.

SUMMARY AND CONCLUSION

This was a prospective observational study which was performed to analyse the causative factors that can lead to complications after blood donation in blood donors and adverse effects of blood transfusion among patients. Such a study was undertaken to achieve the primary goal of reduced incidence of such untoward events among both blood donors and patients.

As far as the blood donation and allied complications are concerned, the inference obtained regarding the various reasons that can lead to blood donor adverse reactions helped us to improve our donor care from the pre-donation area itself. Our study has shown more incidences of adverse reactions among young donors, female gender, donors with low estimated blood volume and first time donors. Instead of excluding those donor populations, we have included them in our donor pool by making them more comfortable by creating more awareness on blood donation by means of pleasant interaction with the donor and pre-hydration of donors who are at risk of developing systemic donor complications. A proper pre-donation and post-donation instruction to restrict lifting of heavy weight with the donated arm and incorporation of well-trained phlebotomy staff has drastically reduced the incidence of hematoma after the study period. Pre-donation hydration has resulted in reduced incidence of systemic reactions in summer months and reduced incidence of hematoma in winter months resulting from dehydration and poor venous access.

Recipient hemovigilance has enhanced the transfusion safety starting from the arm of the donor to the arm of the recipient. Our study has thrown light onto the increased reporting of transfusion reactions thereby incorporating Transfusion Medicine more towards its clinical horizons. Improved reporting system after implementation of active surveillance has helped us to make necessary modifications in the blood component preparation and also steps were taken to minimize clerical and technical errors at both laboratory side and patient side. Our study has shown lesser incidence allergic reactions and FNHTR’s with leucoreduced blood components. We have now accomplished 100 % leucoreduction for all platelet concentrates that are prepared and are moving ahead towards universal leucoreduction.

Hemovigilance reporting has helped us to improve both blood donor safety and transfusion safety. Regular reporting of the adverse donor reactions has led to the increased documentation of all the allied complications not only by the medical officers but also by the staff members. Similarly, on the patient side the transfusion reaction reporting has improved

in such a way that now the reactions with those the imputability that can be excluded are also getting reported. Because of all these reasons, the under reporting of the adverse events have reduced to a greater extend both at donor side and patient side.

LIMITATIONS OF THE STUDY

- In the blood donation point of view, we had only voluntary blood donors in our study as we have 100 % voluntary blood donation in our blood centre. Hence, we could not compare the reaction rates between voluntary-non-remunerated donors and replacement blood donor population.
- Our centre is a super-speciality care centre consisting of only five departments – Departments of Neuromedicine and Neurosurgery, Departments of Cardio-medicine and Cardio-Thoracic -Vascular surgery and Department of Interventional Radiology. We also do not have a trauma care unit. Hence, in the present study we could analyse only the transfusion reactions of patients belonging to these departments.

BIBILOGRAPHY

1. Wood EM, Stevenson L, Bielby L, Wiersum-Osselton JC. Haemovigilance: concepts and frameworks. ISBT Sci Ser. 2014;9(1):86–90.

2. Marwaha N, Singh S, Bisht A. Setting up haemovigilance from the very first step. The Indian perspective. ISBT Sci Ser. 2014;9(1):178–83.

3. Agnihotri N, Marwaha N, Sharma RR. Analysis of adverse events and predisposing factors in voluntary and replacement whole blood donors: A study from north India. Asian J Transfus Sci. 2012;6(2):155–60.

4. Standard P, For D, Of S, Infectious NON, Transfusion A. Working Party on Haemovigilance. Transfusion. 2007;(June).

5. ISBT. Standard for Surveillance of Complications Related to Blood Donation Introduction to the 2014 revised classification. Work Gr Donor Vigil Int Soc Blood Transfus Work Party Haemovigilance [Internet]. 2014;1–15. Available from: http://www.isbtweb.org/fileadmin/user_upload/Donor_Standard_Definitions_Final_2014.pdf

6. Boparai J, Singh S. Hemovigilance: A new beginning in India. Int J Appl Basic Med Res. 2015;5(3):200.

7. De Vries RRP, Faber JC, Strengers PFW. Haemovigilance: An effective tool for improving transfusion practice. Vox Sang. 2011 Jan;100(1):60–7.

8. Bernard J: La legende du Sang. Paris, Ed. Flammarion. 1992.

9. Schmidt PJ, Leacock AG. Forgotten transfusion history: John Leacock of Barbados. Br Med J [Internet]. 2002 [cited 2020 Feb 3];325(7378):1485–7. Available from: https://www.bmj.com/content/325/7378/1485.short

10. Debeir J, Noel L, Aullen JP, Frette C, Sari F, Vo Mai MP, et al. The French haemovigilance system. Vox Sang. 1999;77(2):77–81.

11. Faber JC. Haemovigilance around the world. Vox Sang. 2002;83 Suppl 1:71–6.

12. Lindsay A. Report of the tribunal of inquiry into the infection with HIV and Hepatitis C of persons with haemophilia and related matters Item Type Report [Internet]. 2020 [cited 2020 Feb 7]. Available from: http://hdl.handle.net/10147/78363Findthisandsimilarworksat-http://www.lenus.ie/hse

13. Kato H, Uruma M, Okuyama Y, Fujita H, Handa M, Tomiyama Y, et al. Incidence of transfusion-related adverse reactions per patient reflects the potential risk of transfusion therapy in Japan. Am J Clin Pathol. 2013;140(2):219–24.

14. Odaka C, Kato H, Otsubo H, Takamoto S, Okada Y, Taneichi M, et al. Online reporting system for transfusion-related adverse events to enhance recipient haemovigilance in Japan: A pilot study. Transfus Apher Sci [Internet]. 2013;48(1):95–102. Available from: http://dx.doi.org/10.1016/j.transci.2012.07.008

15. Okazaki H. The benefits of the Japanese haemovigilance system for better patient care. ISBT Sci Ser. 2007;2(2):104–9.

16. Stainsby D, Jones H, Asher D, Atterbury C, Boncinelli A, Brant L, et al. Serious Hazards of Transfusion: A Decade of Hemovigilance in the UK. Transfus Med Rev. 2006;

17. FABER J-C. Hemovigilance: Definition and Overview of Current Hemovigilance Systems. Transfus Altern Transfus Med. 2003;5(1):237–45.

18. Msterdam A, Etherlands THEN, Ague THEH, Etherlands THEN. Hemovigilance System : 2003;5(1):256–9.

19. Menitove JE. Hemovigilance in the United States of America. Vox Sang. 1998;74(S2):447–55.

20. Faber JC. The European Blood Directive: A new era of blood regulation has begun. Transfus Med. 2004;14(4):257–73.

21. Jørgensen J, Taaning E. DART–A Voluntary System of Hemovigilance in Denmark. Transfus Altern Transfus Med. 2003;5(1):260–4.

22. Up S, Scheme H. Scheme in Ireland. 2003;5(1):266–71.

23. Muylle L, Roisin T. Guidelines of the Belgian Hemovigilance Report. 2010;1(2):57–61.

24. Cumming M, Osinski A, O'Hearn L, Waksmonski P, Herman M, Gordon D, et al. Hemovigilance in Massachusetts and the adoption of statewide hospital blood bank reporting using the National Healthcare Safety Network. Vol. 57, Transfusion. 2017. p. 478–83.

25. Robillard P, Nawej KI, Jochem K. The Quebec hemovigilance system: Description and results from the first two years. Transfus Apher Sci. 2004;31(2):111–22.

26. Eder AF, Dy BA, Kennedy JM, Notari IV EP, Strupp A, Wissel ME, et al. The American Red Cross donor hemovigilance program: Complications of blood donation reported in 2006. Transfusion. 2008;48(9):1809–19.

27. Lohmann A, Heiden M, Funk MB. The German Haemovigilance System – reports of serious adverse transfusion reactions between 1997 and 2007. 2009;340–9.

28. Ayob Y. Hemovigilance in developing countries. Biologicals [Internet]. 2010;38(1):91–6. Available from: http://dx.doi.org/10.1016/j.biologicals.2009.10.002

29. Jain A, Kaur R. Hemovigilance and blood safety. Asian J Transfus Sci. 2012;6(2):137–8.

30. Bisht A, Singh S, Marwaha N. Hemovigilance program - India. Asian J Transfus Sci. 2013;7(1):73–4.

31. HVPI guidance document.pdf.

32. National Blood P National Blood P National Blood P National Blood P National Blood Policy olicy olicy olicy olicy National AIDS Control Organisation [Internet]. [cited 2020 Feb 23]. Available from: www.naco.nic.in

33. Organization NAC. Voluntary Blood Donation Programme - An Operational Guideline. Volunt Blood Donation Program - An Oper Guidel. 2007;2:79.

34. Letter reg. guidelines for blood donor selection & referral -2017.pdf.

35. Cummings OT, Morris AA, Enders JR, McIntire GL. Normalizing oral fluid hydrocodone data using calculated blood volume. J Anal Toxicol. 2016;40(7):486–91.

36. Murphy W, Mcsweeney E. Donors and Blood Collection. Pract Transfus Med Third Ed. 2009;39(March):190–9.

37. Goldman M, Fournier E, Cameron-Choi K, Steed T. Effect of changing the age criteria for blood donors. Vox Sang. 2007;92(4):368–72.

38. Tondon R, Pandey P, Chaudhary R. Vasovagal reactions in “at risk” donors: A univariate analysis of effect of age and weight on the grade of donor reactions. Transfus Apher Sci. 2008;39(2):95–9.

39. Crocco A, D'Elia D. Adverse reactions during voluntary donation of blood and/or blood components. A statistical-epidemiological study. Blood Transfus. 2007;5(3):143–52.

40. Resident J, Medicine T, Medical SCB. Adverse Events in Blood Donors & Adoption of Measures to Reduce Such Original Article Adverse Events in Blood Donors & Adoption of Measures to Reduce Such Occurrence. 2018;2(May):1–4.

41. Rajendran V, Nair R, Thaliath G, Gupta D. A case of severe donor reaction leading to grievous injury. Asian J Transfus Sci. 2019 Jan 1;13(1):60–2.

42. Newman BH. Donor reactions and injuries from whole blood donation. Transfus Med Rev. 1997;11(1):64–75.

43. Newman BH. Arterial puncture phlebotomy in whole-blood donors. Transfusion. 2001;41(11):1390–2.

44. Agnihotri N, Chaturvedi YM, Agnihotri A. Arterial Phlebotomy in a Whole Blood Donor and Consequent Adverse Events. Indian J Hematol Blood Transfus [Internet]. 2018;34(3):562–3. Available from: https://doi.org/10.1007/s12288-017-0905-x

45. Newman BH. Vasovagal reaction rates and body weight: Findings in high- and low-risk populations. Transfusion [Internet]. 2003 Jul 22 [cited 2020 Apr 9];43(8):1084–8. Available from: http://doi.wiley.com/10.1046/j.1537-2995.2003.00478.x

46. goleman, daniel; boyatzis, Richard; Mckee A, Perdana. 済無No Title No Title. J Chem Inf Model. 2018;53(9):1689–99.

47. Wiersum-Osselton JC, Marijt-Van Der Kreek T, Brand A, Veldhuizen I, Van Der Bom JG, De Kort W. Risk factors for complications in donors at first and repeat whole blood donation: A cohort study with assessment of the impact on donor return. Blood Transfus. 2014;12(SUPPL.1).

48. Eder AF, Hillyer CD, Dy BA, Notari IV EP, Benjamin RJ. Adverse reactions to allogeneic whole blood donation by 16- and 17-year-olds. JAMA - J Am Med Assoc. 2008;299(19):2279–86.

49. Rios JA, Fang J, Tu Y, Wright DJ, Spencer B, Hillyer CD, et al. The potential impact of selective donor deferrals based on estimated blood volume on vasovagal reactions and donor deferral rates. Transfusion. 2010;50(6):1265–75.

50. Philip J, Sarkar RS, Jain N. A single-centre study of vasovagal reaction in blood donors: Influence of age, sex, donation status, weight, total blood volume and volume of blood collected. Asian J Transfus Sci. 2014 Jan;8(1):43–6.

51. Tomasulo P, Kamel H, Bravo M, James RC, Custer B. Interventions to reduce the vasovagal reaction rate in young whole blood donors. Transfusion. 2011;51(7):1511–21.

52. Kamel H, Tomasulo P, Bravo M, Wiltbank T, Cusick R, James RC, et al. Delayed adverse reactions to blood donation. Transfusion. 2010;50(3):556–65.

53. Bani M, Giussani B. Gender differences in giving blood: A review of the literature. Blood Transfus. 2010;8(4):278–87.

54. France CR, Ditto B, Wissel ME, France JL, Dickert T, Rader A, et al. Predonation hydration and applied muscle tension combine to reduce presyncopal reactions to blood donation. Transfusion. 2010;50(6):1257–64.

55. Murphy W, Mcsweeney E. Donors and Blood Collection. Pract Transfus Med Third Ed. 2009;44(June):190–9.

56. Deepika C, Murugesan M, Shastry S. Effect of pre-donation fluid intake on fluid shift from interstitial to intravascular compartment in blood donors. Transfus Apher Sci [Internet]. 2018;57(1):54–7. Available from: https://doi.org/10.1016/j.transci.2017.11.031

57. Vavic N, Pagliariccio A, Bulajic M, Dinić R, Marinozzi M. Giving blood donors something to drink before donation can prevent fainting symptoms: Is there a physiological or psychological reason? Transfus Apher Sci. 2014;51(1):65–9.

58. Ogata H, Iinuma N, Nagashima K, Akabane T. Vasovagal Reactions in Blood Donors. Transfusion. 1980;20(6):679–83.

59. Callahan R, Edelman EB, Smith MS, Smith JJ. Study of the Incidence and Characteristics of Blood Donor “Reactors.” Transfusion. 1963;3(2):76–82.

60. Sachdev S, Singh L, Marwaha N, Sharma RR, Lamba DiS, Sachdeva P. First report of the impact on voluntary blood donation by the blood mobile from India. Asian J Transfus Sci. 2016;10(1):59–62.

61. Enright H, Davis K, Gernsheimer T, Mccullough JJ, Woodson R. transfusions : experience of the TRAP multicenter clinical trial. 2003;43(October):1545–52.

62. Domen RE, Hoeltge GA. Allergic transfusion reactions: An evaluation of 273 consecutive reactions. Arch Pathol Lab Med. 2003;127(3):316–20.

63. Kumar P, Thapliyal R, Coshic P, Chatterjee K. Retrospective evaluation of adverse transfusion reactions following blood product transfusion from a tertiary care hospital: A preliminary step towards hemovigilance. Asian J Transfus Sci. 2013;7(2):109–15.

64. Geiger TL, Howard SC. Acetaminophen and Diphenhydramine Premedication for Allergic and Febrile Nonhemolytic Transfusion Reactions: Good Prophylaxis or Bad Practice? Transfus Med Rev. 2007;21(1):1–12.

65. Tobian AAR, Savage WJ, Tisch DJ, Thoman S, King KE, Ness PM. Prevention of allergic transfusion reactions to platelets and red blood cells through plasma reduction. Transfusion. 2011;51(8):1676–83.

66. Hirayama F. Current understanding of allergic transfusion reactions: Incidence, pathogenesis, laboratory tests, prevention and treatment. Br J Haematol. 2013;160(4):434–44.

67. Savage WJ, Tobian AAR, Savage JH, Wood RA, Schroeder JT, Ness PM. Scratching the surface of allergic transfusion reactions. Transfusion. 2013;53(6):1361–71.

68. Uhlmann EJ, Isgriggs E, Wallhermfechtel M, Goodnough LT. the Incidence of Transfusion Reactions. 2001;41(August):997–1000.

69. Menitove JE, McElligott MC, Aster RH. Febrile Transfusion Reaction: What Blood Component Should Be Given Next? Vox Sang. 1982;42(6):318–21.

70. Goodnough LT, Riddell J, Lazarus H, Chafel TL, Prince G, Hendrix D, et al. Prevalence of Platelet Transfusion Reactions Before and After Implementation of Leukocyte-Depleted Platelet Concentrates by Filtration. Vox Sang. 1993;65(2):103–7.

71. FERRARA JLM. The febrile platelet transfusion reaction: a cytokine shower. Transfusion. 1995;35(2):89–90.

72. Ezidiegwu CN, Lauenstein KJ, Rosales LC, Kelly KC, Henry JB. Febrile nonhemolytic transfusion reactions: Management by premedication and cost

implications in adult patients. Arch Pathol Lab Med. 2004;128(9):991–5.

73. Kelley DL, Mangini J, Triulzi DJ. T r a n s f u s i o n c o m p l i c a. 2000;40(April):439–42.

74. King KE, Shirey RS, Thoman SK, Bensen-kennedy D, Tanz WS, Al KET. nonhemolytic transfusion reactions to RBCs. Transfusion. 2004;44(January):25–9.

75. Paglino JC, Pomper GJ, Fisch GS, Champion MH, Snyder EL. Platelets After Conversion To Universal Prestorage Leukoreduction. 2004;44(January):16–24.

76. Sanders RP, Maddirala SD, Geiger TL, Pounds S, Sandlund JT, Ribeiro RC, et al. Premedication with acetaminophen or diphenhydramine for transfusion with leucoreduced blood products in children. Br J Haematol. 2005;130(5):781–7.

77. Ibojie J, Greiss M, Urbaniak SJ. Limited efficacy of universal leucodepletion in reducing the incidence of febrile non-haemolytic reactions in red cell transfusion. Transfus Med. 2002;12(6):387–9.

78. Anderson NA, Gray S, Copplestone JA, Chan DC, Hamon M, Prentice AG, et al. A prospective randomized study of three types of platelet concentrates in patients with haematological malignancy: Corrected platelet count increments and frequency of nonhaemolytic febrile transfusion reactions. Transfus Med. 1997;7(1):33–9.

79. Muylle L, Wouters E, Peetermans ME. Febrile reactions to platelet transfusion: The effect of increased interleukin 6 levels in concentrates prepared by the platelet-rich plasma method. Transfusion. 1996;36(10):886–90.

80. Callaghan TA. Transfusion Reactions. Haematol Crit Care A Pract Handb. 2014;86–92.

81. Yu H, Sandler SG. IgA anaphylactic transfusion reactions. Transfus Med Hemotherapy. 2003;30(5):214–20.

82. Strobel E. Hemolytic transfusion reactions. Transfus Med Hemotherapy. 2008;35(5):346–53.

83. Fung MK, Downes KA, Shulman IA. Transfusion of platelets containing ABO-incompatible plasma: A survey of 3156 North American Laboratories. Arch Pathol Lab Med. 2007;131(6):909–16.

84. Josephson CD, Castillejo MI, Grima K, Hillyer CD. ABO-mismatched platelet transfusions: Strategies to mitigate patient exposure to naturally occurring hemolytic antibodies. Transfus Apher Sci [Internet]. 2010;42(1):83–8. Available from: http://dx.doi.org/10.1016/j.transci.2009.10.013

85. Pierce RN, Reich LM. Hemolysis following platelet transfusions from ABO-incompatible donors. Transfusion. 1985;25(1):60–2.

86. McManigal S, Sims KL. Intravascular hemolysis secondary to ABO incompatible platelet products: An underrecognized transfusion reaction. Am J Clin Pathol. 1999;111(2):202–6.

87. Beauregard P, Blajchman MA. Hemolytic and Pseudo-Hemolytic Transfusion Reactions: An Overview of the Hemolytic Transfusion Reactions and the Clinical Conditions That Mimic Them. Transfus Med Rev [Internet]. 1994;8(3):184–99. Available from: http://dx.doi.org/10.1016/S0887-7963(94)70110-3

88. Sahu S, Hemlata, Verma A. Adverse events related to blood transfusion. Indian J Anaesth. 2014;58(5):543–51.

89. Holness L, Knippen MA, Simmons L, Lachenbruch PA. Fatalities caused by TRALI. Transfus Med Rev. 2004;18(3):184–8.

90. Bux J, Sachs UJH. The pathogenesis of transfusion-related acute lung injury (TRALI). Br J Haematol. 2007;136(6):788–99.

91. Wallis JP, Lubenko A, Wells AW, Chapman CE. Single hospital experience of TRALI. Transfusion. 2003;43(8):1053–9.

92. Silliman CC, Fung YL, Bradley Ball J, Khan SY. Transfusion-related acute lung injury (TRALI): Current concepts and misconceptions. Blood Rev [Internet]. 2009;23(6):245–55. Available from: http://dx.doi.org/10.1016/j.blre.2009.07.005

93. Bux J. Transfusion-related acute lung injury (TRALI): A serious adverse event of blood transfusion. Vox Sang. 2005;89(1):1–10.

94. Menis M, Anderson SA, Forshee RA, Mckean S, Johnson C, Holness L, et al. Transfusion-associated circulatory overload (TACO) and potential risk factors among the inpatient US elderly as recorded in Medicare administrative databases during 2011. Vox Sang. 2014;106(2):144–52.

95. Agnihotri N, Agnihotri A. Transfusion associated circulatory overload. Indian J Crit Care Med. 2014;18(6):396–8.

96. Lieberman L, Maskens C, Cserti-Gazdewich C, Hansen M, Lin Y, Pendergrast J, et al. A retrospective review of patient factors, transfusion practices, and outcomes in patients with transfusion-associated circulatory overload. Transfus Med Rev [Internet]. 2013;27(4):206–12. Available from: http://dx.doi.org/10.1016/j.tmrv.2013.07.002

97. Popovsky MA. Pulmonary consequences of transfusion: TRALI and TACO. Transfus Apher Sci. 2006;34(3):243–4.

98. Cyr M, Eastlund T, Blais C, Rouleau JL, Adam A. Bradykinin metabolism. Transfusion. 2001;41(January):136–50.

99. Angell M. The pharmaceutical industry to whom is it accountable? N Engl J Med. 2000;342(25):1902–4.

100. Arnold DM, Molinaro G, Warkentin TE, Ditomasso J, Webert KE, Davis I, et al. That Are Leukoreduced Before Storage. Baseline. 2004;44(September):1361–6.

101. Pagano MB, Ness PM, Chajewski OS, King KE, Wu Y, Tobian AAR. Hypotensive transfusion reactions in the era of prestorage leukoreduction. Transfusion. 2015;55(7):1668–74.

102. Crews WS, Kay JK, Herman JH. Washed RBCs prevent recurrent acute hypotensive transfusion reactions. Am J Clin Pathol. 2014;141(2):285–7.

103. Hume HA, Popovsky MA, Benson K, Classman AB, Hines D, Oberman HA, et al. Hypotensive reactions: A previously uncharacterized complication of platelet transfusion? Transfusion. 1996;36(10):904–9.

104. Mair B, Leparc GF. Hypotensive reactions associated with platelet transfusions and angiotensin-converting enzyme inhibitors. Vox Sang. 1998;74(1):27–30.

105. Karim F, Moiz B, Shamsuddin N, Naz S, Khurshid M. Root cause analysis of non-infectious transfusion complications and the lessons learnt. Transfus Apher Sci [Internet]. 2014;50(1):111–7. Available from: http://dx.doi.org/10.1016/j.transci.2013.10.004

106. Malladi SVS, Paul R, Chandra N, Rao NM, Raju SY. TA-GVHD, a fatal complication

following blood transfusion from a first-degree relative. J Obstet Gynecol India. 2013;63(5):344–6.

107. Capon SM, DePond WD, Tyan DB, Pepkowitz SH, Toyoda H, Cinman AC, et al. Transfusion-associated graft-versus-host disease in an immunocompetent patient. Ann Intern Med. 1991;114(12):1025–6.

108. Anderson KC, Goodnough LT, Sayers M, Pisciotto PT, Kurtz SR, Lane TA, et al. Variation in blood component irradiation practice: Implications for prevention of transfusion-associated graft-versus-host disease. Blood. 1991;77(10):2096–102.

109. Frumin J. Downloaded from anesthesiology.pubs.asahq.org by guest on 01/28/2019. Anesthesiology. 1995;31(4):305–9.

110. Monaghan WP. Delayed Hemolytic Transfusion Reaction: Case Report. Mil Med. 1978;143(2):122–122.

111. Neufeld EJ. Oral chelators deferasirox and deferiprone for transfusional iron overload in thalassemia major: New data, new questions. Blood. 2006;107(9):3436–41.

112. Longo F, Zecchina G, Sbaiz L, Fischer R, Piga A, Camaschella C. The influence of hemochromatosis mutations on iron overload of thalassemia major. Haematologica. 1999;84(9):799–803.

ANNEXURE

ANNEXURE

Technical Advisory Committee (Clinical Studies)

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2018/735 **Date: 24.05.2018**

Project title: HEMOVIGILANCE: AN ANALYSIS OF ADVERSE EFFECTS OF BLOOD DONATION AMONG BLOOD DONORS AND TRANSFUSION REACTIONS AMONG RECIPIENTS IN A TERTIARY CARE CENTRE

Principal Investigator:	
Dr.Anila Mani, Junior Resident, Department of Transfusion Medicine, SCTIMST	Degree: MBBS
Co-Principal Investigator(s)	
Dr. Debasish Gupta, Professor, Department of Transfusion Medicine, SCTIMST	Degree: MBBS, MD.

Members who participated in the TAC meeting on 19/05/2018

Dr. Rupa Sreedhar (Chairperson)
Dr. Prasantakumar Dash
Dr. Sanjay G
Dr. Krishna Kumar K
Dr. Sankara Sarma P
Dr. Sylaja PN
Dr. Ashalatha. R
Dr. Bijulal S
Dr. Jayadevan ER
Dr. Syam K
Dr. Varghese T. Panicker
Dr. K. Shivakumar (Member Secretary)

Dr. Rupa Sreedhar, Dr. Syam K, Dr. Sylaja PN, Dr. Prasantakumar Dash, Dr. Varghese T. Panicker and Dr. Ashalatha. R stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#736,737, 738, 740, 741,743,744, 746, 749, 752).

Risk Classification of the project (Minimum/ Moderate/ High): Minimum

Requirement of DSMB: No

Recommended members of DSMB: Not applicable

Recommendations of TAC:

Recommended for consideration of IEC in the light of the responses received from the investigator
The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.

Signature of the Member Secretary, TAC (Clinical Studies)

Note for IEC

Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-1).

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1224/JUNE-2018

29.06.2018

Dr. Anila Mani
Junior Resident
Department of Transfusion Medicine
SCTIMST, Thiruvananthapuram

Dear Dr. Anila Mani,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "HEMOVIGILANCE: AN ANALYSIS OF ADVERSE EFFECTS OF BLOOD DONATION AMONG BLOOD DONORS AND TRANSFUSION REACTIONS AMONG RECIPIENTS IN A TERTIARY CARE CENTRE" (IEC/1224)" on 16th June, 2018.

The following documents were reviewed:

Original submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 28.05.2018 with check list*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Project Proposal*
5. *Proforma for the Questionnaire*
6. *Patient Information Sheet and Informed Consent Form in English and Malayalam*
7. *CV of Principal Investigator and Co-Principal Investigators*

Revised submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 20.06.2018 with check list*
2. *Copy of IEC Recommendation Letter dated 19.06.2018*
3. *TAC Approval Letter*
4. *IEC Application Form*
5. *Project Proposal*
6. *Blood donor Questionnaire with Consent Form in English and Malayalam*
7. *Donor Reaction Reporting Form*
8. *Transfusion Reaction Reporting Form*
9. *Participant Information Sheet for donors in English and Malayalam*
10. *Participant Information Sheet to recipients in English and Malayalam*
11. *Consent Form for blood transfusion in English and Malayalam*
12. *Informed Consent Forms for recipients in English and Malayalam*
13. *Assent Form for Children in English and Malayalam*
14. *CV of Principal Investigator and Co-Principal Investigators*

The following members of the Ethics Committee were present at the meeting held on 16th June, 2018 at Noshir H Wadia Conference Hall, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
5.	Dr. S S Giri Sankar	LL.M. Ph.D.	Male	Legal Expert	No
6.	Dr. Aneesh V Pillai	BA. LLB (Hons.), LLM, Ph. D, SET (Law)	Male	Legal Expert	No
7.	Mr. Satheesh Chandran	MSW, PGDPM	Male	Lay person/ NGO/ Social Scientist	No
8.	Dr. Harikrishna Varma PR	Ph.D(Materials Science)	Male	Medical Technology	Yes
9.	Dr. P. Manickam	BSMS, MSc (Epid).,PhD	Male	Health Science Expert/ Social Scientist	No
10.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
11.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
12.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
13.	Dr. Anand Kumar A	MD, DM	Male	Clinician	No
14.	Dr. V. Raman Kutty	M D, M Phil, M P H	Male	Health Sciences Expert/Clinician	Yes
15.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:
The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

Plagiarism certificate

URKUND

Entire Document

TITLE

Hemovigilance - An analysis of adverse effects of blood donation among blood donors and transfusion reactions among recipients in a tertiary-care centre

INTRODUCTION Hemovigilance is an important aspect of blood safety which aims at identification, monitoring and prevention of adverse reactions, incidents and adverse events related to blood donation and transfusion for both blood donors and patients (1). Proper analysis of donor complications and transfusion reactions, incidents and events are essential to identify contributing factors. Hemovigilance is an essential tool to understand the clinical consequences of transfusion of blood and blood components, and to develop and implement actions to prevent further recurrence. Hemovigilance is an important part of the quality system for both blood collection and blood transfusion. It implies the various methods for the identification of errors, adverse events and reactions including investigation systems, traceability systems, notification systems and audits of practice. Hemovigilance may be performed in a hospital to improve blood collection from the blood donor or to improve blood transfusion practices, but this does not create a system. A hemovigilance system comes into existence only when data of adverse transfusion events are collected through an organized network for reporting to a central office where the data are compiled together and analysed by experts and recommendations are made appropriately and further evaluation made for blood safety (2). Lack of proper awareness and

URKUND

Document Information

Analyzed document	Thesis - Revised plagiarsm.docx (D73207292)
Submitted	5/29/2020 10:08:00 AM
Submitted by	
Submitter email	amita.rnair@sctimst.ac.in
Similarity	5%
Analysis address	amita.rnair.sctims@analysis.urkund.com

Sree Chitra Tirunal Institute for Medical Sciences and Technology

DEPARTMENT OF TRANSFUSION MEDICINE

Thiruvananthapuram -11 Phone : 2524476

BLOOD DONOR QUESTIONNAIRE

For Office Use Only

Unit Number	Product	Date

Thank you for coming forward to Donate Blood

To ensure your safety as a blood donor and the safety of the patients who will receive your blood, please read the information leaflet provided and answer this questionnaire correctly. If you have any difficulty in filling this form please ask for help from blood centre staff. All details given by you will be kept confidential.

Name.....

Sex :	M / F
Age :	

Date of Birth..... Married /Unmarried/Blood Group.....

Address (Resi.).....

.....Educational Qualification.....Occupation.....

Address (Office).....

Contact Nos : Resi. / Office.....Mobile.....

e-mail : .....

1. Have you donated blood previously ? Yes No

1.1 If yes how many times : 1.2 If yes how many times :

1.3 Did you experience any difficulty or discomfort during previous donations ? Yes No

1.4 Have you ever been advised not to donate blood ? Yes No

2.1 Are you feeling well today ? Yes No

2.2 Have you eaten anything in the last 4 hours ? Yes No

Sleep ☐ Hrs

2.3 After donating blood do you have to engage in heavy work, driving heavy vehicle or work at heights today ? Yes No

2.4 Have you had / have any of the following ? If yes, discuss with the doctor present :

• Allergy	• Kidney Disease	• Endocrine Disease	• Leprosy
• Cancer	• Mental illness	• Diabetes	• Epilepsy
• Fainting Attacks	• Amoebiasis	• Syphilis	• Blood / Bleeding Disorder
• Heart Disease	• Cold / Cough	• Gonorhoea	• Tuberculosis
• Lung Disease	• Liver Disease	• Skin Disease	• Polycythemia
• Asthma	• Fever	• High / Low Blood Pressure	• G-6 PD Deficiency

4 **During past 12 months have you had any of the following ?**

4.1	Received Blood or Blood Components ?	Yes	No
4.2	Any accidents or operations ?	Yes	No
4.3	Received any vaccinations ?	Yes	No
4.4	Bitten by any animal, which can results in rabies ?	Yes	No
4.5	Had Tattooing / Ear piercing or Accupuncture treatment ?	Yes	No
5	Have you had Jaundice ?	Yes	No
5.1	Have you had ever tested positive for Hepatitis B or C ?	Yes	No
5.2	Have you had Close contact with any one *(family / others)* suffering from Jaundice in the last one year	Yes	No
6	Have you had Tuberculosis or Typhoid during the last year ?	Yes	No
7	Have you had Malaria ?	Yes	No
8	Have you had any of the following in the last 6 months ?	Yes	No

Dental Procedure	Yes	No	Measles	Yes	No
Mumps	Yes	No	Chicken Pox	Yes	No
Dengue	Yes	No			

9	Have you taken any medicines in the last 7 days esp aspirin or antibiotic	Yes	No
10	Do you know that you should not blood in the following conditins ?	Yes	No

- If you were found to be positive of HIV, Hepatitis B, C or Syphilis infections
- If you are having multiple sex partners or have engaged in male to male sexual activity.
- If you have ever injected any drug (exp.Narcotics) not prescribed in a qualified doctor.
- If you or your partner is suspected of getting HIV infection.

11.	Do you or your Sexual partner belong to one of the above categories ?	Yes	No
11.1	In the last 6 months have you had night sweats	Yes	No
	Persistent diarrhoea	Yes	No
	Persistent Fever	Yes	No
	Unexplained weight loss	Yes	No
	Swollen Glands	Yes	No

12. In case you are a woman :

a. Are you pregnant or have you had an abortion in the last 6 months ?	Yes	No
b. Have you got a child less than 1 year of age ? Are you breast feeding	Yes	No

BLOOD DONOR INFORMED CONSENT FORM

DONOR CONSENT

- I declare that I have read and understood the information regarding blood donation and answered all the above questions honestly and correctly.
- I also agree to make Blood Products for patient care, by fractionation of Blood Plasma, if not used.
- I agree that the Blood Donated by me voluntarily will be used for the benefit of the patients, in any manner as decided by the Blood Centre.
- I also agree to follow the instructions given to me by the Blood Centre, during and after blood donation and accept the responsibiliity of any consequences of not following those instructions.
- I give my consent to test my Donated Blood for HIV 1 and 2, Syphilis, Hepatitis B and C, Malaria and any other required test in any manner deemed appropriate by the centre.
- I would like to be informed about any abnormal test result : Yes / No

  Mode of communication : Letter Phone Mobile E-mail

I am **WILLING / NOT WILLING** TO DONATE **BLOOD**

ONCE / TWICE / THRICE A YEAR

TO SAVE MANY MORE **HUMAN LIVES**

Donors Signature :.....

(To be signed in front of the interviewing Officer)

Date :.....

FOR OFFICE USE ONLY

MEDICAL ASSESSMENT	Name of Medical Officer	Sign

Donor's Name.....

Weight : .....kgs Hb level:

History Check list :	Feeling well ? / Adequate sleep (>5hrs) ? / Last meal within 4 hrs ? Ever hospitalized ? Current illness or medications.
Examination Check list :	Unhealthy look ? / Palor, icterus ? / Alcohol smell Infected Wounds / Venepuncture site lesions / Lymph node Pulse:.....beats / min BP : .....mm HG Heart :..... Lungs:.....
Counciling points :	Post donation instructions / Making a regular donor Need for follow up for TTI purposes. How to contact for follow up purposes : By a letter By phone By e-mail
Outcome :	Donor accepted Temporary deferral Permanent deferral

Remarks / Reasons for Deferral :

REGISTRATION	**Name of Registering Officer :**	**Date :**
Donor I D No :	Blood Unit No:	Segment No:

Type of Bag : Single Double Triple : Quadruple:

Lot Number Expiry

Blood Collection	**Name of Phlebotomist :**	**Date :**

Check : Donor's Name

Check Donation No : On Donation record / Blood Bags / Specimen Tubes

Start time : .....a.m. / p.m. **Time Taken :** .....mins. **Volume :** .....ml

Bag lot No. Bag expiry date :

Complications : Faint: **Fits:** **Double Prick** **Haematoma :**

Others *(Please specify)*

SF No : Version No.

Sree Chithra Tirunal Institute for Medical Sciences and Technology

DEPARTMENT OF TRANSFUSION MEDICINE

Thiruvananthapuram - 11. Phone : 2524476

Unit Number | Product | Date

രക്തദാനത്തിനായി സ്വയം മുന്നോട്ടു വന്നതിൽ നിങ്ങളെ അഭിനന്ദിക്കുന്നു. നിങ്ങളുടെയും നിങ്ങളുടെ രക്തം സ്വീകരിക്കുന്ന രോഗിയുടേയും സുരക്ഷയ്ക്കുവേണ്ടി താഴെ കൊടുത്തിട്ടുള്ള ചോദ്യാവലിയ്ക്ക് ശരിയായ വിവരങ്ങൾ നല്കുക. ചോദ്യാവലി പൂരിപ്പിക്കുന്നതിൽ എന്തെങ്കിലും സംശയം ഉണ്ടെങ്കിൽ സഹായം അഭ്യർത്ഥിക്കാവുന്നതാണ്. നിങ്ങളെപ്പറ്റിയുള്ള വിവരങ്ങൾ തികച്ചും രഹസ്യവും സുരക്ഷിതവുമായിരിക്കും.

പേര് ..... വയസ് / ജനനതീയതി .....

സ്ത്രീ / പുരുഷൻ അവിവാഹിതൻ / വിവാഹിതൻ / രക്തഗ്രൂപ്പ്

വിദ്യാഭ്യാസ യോഗ്യത ..... ജോലി .....

മേൽവിലാസം : വീട്ടുപേര് / നമ്പർ .....

പോസ്റ്റാഫീസ് : ..... ജില്ല ..... പിൻ .....

ടെലിഫോൺ : ലാൻ ഫോൺ ..... മൊബൈൽ .....

ഇമെയിൽ .....

രോഗിയുടെ പേര് : ആശുപത്രി നമ്പർ :

1. മുൻപ് രക്തദാനം ചെയ്തിട്ടുണ്ടോ ? ഉണ്ട് / ഇല്ല
   ഉണ്ടെങ്കിൽ എത്ര തവണ ..... തൊട്ടുമുൻപ് രക്തദാനം ചെയ്തത് എപ്പോൾ .....
2. മുൻപ് രക്തദാനം ചെയ്തപ്പോൾ എന്തെങ്കിലും അസ്വസ്ഥതകളോ ബുദ്ധിമുട്ടുകളോ അനുഭവപ്പെട്ടിട്ടുണ്ടോ ? ഉണ്ട് / ഇല്ല
   ഉണ്ടെങ്കിൽ അതിന്റെ വിശദാംശങ്ങൾ നൽകുക
3. എപ്പോഴെങ്കിലും രക്തദാനത്തിന് അയോഗ്യനാക്കപ്പെട്ടിട്ടുണ്ടോ ?
4. ഇന്ന് നിങ്ങൾക്ക് ആരോഗ്യവും ഉന്മേഷവും തോന്നുന്നുണ്ടോ ?
5. കഴിഞ്ഞ നാലു മണിക്കൂറിനുള്ളിൽ നിങ്ങൾ ഭക്ഷണം കഴിച്ചതാണോ ?
6. രക്തദാനത്തിനുശേഷം ഇന്ന് നിങ്ങൾക്ക് എന്തെങ്കിലും കഠിനാദ്ധ്വാനം (ഭാരമുള്ള വാഹനം ഓടിക്കുക, ഉയരത്തിൽ നിന്നും ജോലി ചെയ്യുക) ചെയ്യേണ്ടതുണ്ടോ : ഉണ്ട് / ഇല്ല.
7. താഴെ പറയുന്ന എന്തെങ്കിലും രോഗലക്ഷണങ്ങൾ ഉണ്ടായിട്ടുണ്ടെങ്കിൽ, അതിനെപ്പറ്റി ഡോക്ടറുമായി ചർച്ചചെയ്യുക.

- അലർജി
- ശ്വാസകോശരോഗം
- ഡയബെറ്റിസ്
- ത്വക്ക് രോഗങ്ങൾ
- ഗൊണോറിയ
- രക്തം / രക്തവാർച്ച രോഗങ്ങൾ
- ജി.6.പി.ഡി. ഡെഫിഷ്യൻസി
- ക്യാൻസർ
- അസ്തമ (ക്ഷയം ഉൾപ്പെടെ)
- തൈറോയ്ഡ് രോഗങ്ങൾ
- ബോധക്ഷയം, അപസ്മാരം
- പനി, ചുമ, ജലദോഷം
- ചുവന്ന രക്താണുക്കളുടെ ആധിക്യം
- ഹൃദ്രോഗം
- വൃക്ക രോഗങ്ങൾ
- കരൾ രോഗങ്ങൾ
- സിഫിലിസ്
- ഉയർന്ന രക്തസമ്മർദ്ദം

കഴിഞ്ഞ 1 വർഷത്തിനിടയ്ക്ക്

നിങ്ങൾ ചികിത്സയുടെ ഭാഗമായി രക്തമോ ഘടകങ്ങളോ സ്വീകരിച്ചിട്ടുണ്ടോ. ഉണ്ട് / ഇല്ല

എന്തെങ്കിലും ശസ്ത്രക്രിയയോ, അപകടമോ ഉണ്ടായിട്ടുണ്ടോ. ഉണ്ട് / ഇല്ല

ഏതെങ്കിലും പ്രതിരോധ കുത്തിവെയ്പ് എടുത്തിട്ടുണ്ടോ. ഉണ്ട് / ഇല്ല

പേപ്പട്ടി വിഷത്തിനെതിരെ കുത്തിവയ്പ് എടുത്തിട്ടുണ്ടോ ഉണ്ട് / ഇല്ല

ചികിത്സയുടെ ഭാഗമായോ അല്ലാതെയോ (പച്ചകുത്തുക, കാത്തുകുത്തുക, അക്യുപങ്ചർ)

സൂചി കുത്തേണ്ട സാഹചര്യം ഉണ്ടായിട്ടുണ്ടോ. ഉണ്ട് / ഇല്ല

ജയിൽ ശിക്ഷ അനുഭവിച്ചിട്ടുണ്ടോ ? ഉണ്ട് / ഇല്ല

മഞ്ഞപ്പിത്തം ഉണ്ടായിട്ടുണ്ടോ ? ഉണ്ട് / ഇല്ല

ഹെപ്പറ്റൈറ്റിസ് ബി, സി എന്നിവയ്ക്കുള്ള രക്തപരിശോധന ചെയ്തിട്ടുണ്ടോ ഉണ്ട് / ഇല്ല

മഞ്ഞപിത്തബാധയുള്ള വ്യക്തികളുമായി (കുടുംബത്തിലോ, അല്ലാതെയോ)

അടുത്ത് ഇടപഴകാനുള്ള സാഹചര്യം ഉണ്ടായിട്ടുണ്ടോ. ഉണ്ട് / ഇല്ല

കഴിഞ്ഞ മൂന്നു വർഷത്തിനുള്ളിൽ മലമ്പനിക്ക് ചികിത്സിച്ചിട്ടുണ്ടോ ഉണ്ട് / ഇല്ല

കഴിഞ്ഞ 6 മാസത്തിനുള്ളിൽ താഴെ പറയുന്ന എന്തെങ്കിലും ഉണ്ടായിട്ടുണ്ടോ.

1. ദന്തചികിത്സ 2. മണ്ണൻപനി 3. മൂണ്ടിനീർ

4. ചിക്കൻപോക്സ്

കഴിഞ്ഞ ഒരാഴ്ചയ്ക്കുള്ളിൽ നിങ്ങൾ ആന്റിബയോട്ടിക് / ആസ്പിരിൻ തുടങ്ങിയ എന്തെങ്കിലും മരുന്ന് കഴിച്ചിട്ടുണ്ടോ ഉണ്ട് / ഇല്ല

പ്രത്യേകം ശ്രദ്ധിക്കുക

1. നിങ്ങൾ എപ്പോഴെങ്കിലും HIV, Hep. B, C, Syphiils എന്നീ പോസിറ്റീവ് ആയിരിക്കുക.
2. ഒന്നിലധികം ലൈംഗികപങ്കാളികൾ ഉണ്ടാവുക.
3. ലൈംഗിക തൊഴിലാളിയുമായി, ലൈംഗിക ബന്ധത്തിൽ ഏർപ്പെടുക, സ്വവർഗ്ഗ രതിയിൽ ഏർപ്പെടുക.
4. ലഹരി മരുന്ന് കുത്തിവെയ്ക്കുക
5. നിങ്ങൾക്കോ നിങ്ങളുടെ പങ്കാളിക്കോ HIV അണുബാധ ഉണ്ടാകാൻ സാധ്യത ഉണ്ടാവുക.

മുകളിൽ പറഞ്ഞ എന്തെങ്കിലും ഉണ്ടായിട്ടുള്ള വ്യക്തി രക്തദാനം ചെയ്യാൻ പാടില്ല.

കഴിഞ്ഞ 6 മാസത്തിനുള്ളിൽ താഴെപറയുന്ന ലക്ഷണങ്ങൾ നിങ്ങൾക്ക് ഉണ്ടായിട്ടുണ്ടോ.

വിട്ടുമാറാത്ത പനി ഉണ്ട് / ഇല്ല

വിട്ടുമാറാത്ത വയറ്റിളകം ഉണ്ട് / ഇല്ല

ഭാരക്കുറവ് ഉണ്ട് / ഇല്ല

സന്ധിവീക്കം ഉണ്ട് / ഇല്ല

സ്ത്രീ ദാതാവാണെങ്കിൽ

കഴിഞ്ഞ 6 മാസത്തിനിടെ ഗർഭധാരണമോ.

ഗർഭമലസലോ ഉണ്ടായിട്ടുണ്ടോ ഉണ്ട് / ഇല്ല

കുഞ്ഞിനെ മുലയൂട്ടുന്ന അമ്മയാണോ അതെ / അല്ല

ദാതാവിന്റെ സമ്മതപത്രം

- മുകളിൽ തന്നിട്ടുള്ള ചോദ്യാവലി ഞാൻ ശരിയായ രീതിയിൽ മനസ്സിലാക്കുകയും, അവയ്ക്ക കൃത്യ മായും സത്യസന്ധമായും ഉത്തരങ്ങൾ നല്കുകയും ചെയ്തു.

- ഞാൻ സന്നദ്ധമായി നൽകുന്ന രക്തം രോഗികൾക്ക് പ്രയോജനമാകുന്ന വിധത്തിൽ രൂപാന്തരപ്പെ ടുത്തി ഉപയോഗിക്കാൻ രക്തബാങ്കിനെ അനുവദിക്കാൻ എനിക്കു സമ്മതമാണ്.

- രക്തദാനസമയത്തും അതിനുശേഷവും ശ്രദ്ധിക്കേണ്ട കാര്യങ്ങളെ പറ്റിയുള്ള രക്തബാങ്കിന്റെ നിർദ്ദേ ശങ്ങൾ പാലിക്കേണ്ടത്, എന്റെ ഉത്തരവാദിത്വമാണ്. അത് പാലിച്ചില്ലെങ്കിൽ ഉണ്ടായേക്കാവുന്ന ബുദ്ധി മുട്ടുകൾക്ക് ഞാൻ ഉത്തരവാദി ആയിരിക്കും.

- രക്തദാനത്തിലൂടെ ശേഖരിച്ച എന്റെ രക്തം HIV, Hepatitis B, C, Syphilis, Malaria തുടങ്ങിയ പരിശോ ധനകൾക്ക് വിധേയമാക്കുന്നതിനും ഒപ്പം മറ്റ് ആവശ്യമായ പരിശോധനകൾ ചെയ്യുന്നതിനും എനിക്ക് സമ്മതമാണ്.

- രക്തപരിശോധനയുടെ ഫലം അറിയാൻ താല്പര്യം ഉണ്ട് / ഇല്ല.

- എന്നെ ബന്ധപ്പെടേണ്ട രീതി

  കത്ത് മുഖേന

  ഫോൺ

  Mobile phone

  E-mail

വീണ്ടും രക്തദാനം ചെയ്യാൻ ഞാൻ തയ്യാറാണ്. അതെ / അല്ല

ഒപ്പ് :

തീയതി :

For office use only

MEDICAL ASSESSMENT	Name of Medical Officer :	Sign :

Donor's Name : .....

Weight : ..... kgs Hb level : > 12.5 g/dl < 12.5 g/dl

History Check list :	Feeling well ? / Adequate sleep (>5 hrs) ? / Last meal within 4 hrs ? Ever hospitalized ? Current illnesses or medications ;
Examination chek list	Unhealthy look ? / Palor, Icterus ? / Alcohol smell infected wounds / Venepuncture site lesions Pulse : ..... beats/min BP : ..... mmHg Heart : ..... Lungs : .....
Counseling points	Post donation instructions / Making a regular donor Need for follow up for TTI purposes. How to contact for follow up purposes : By a letter By phone By e-mail
Outcome :	Donor accepted Temporary deferral Permanent deferral
Remarks / Reasons for Deferral :	

REGISTRATION	NAME of Registering Officer:	Date :
Donor I.D. No. :	Blood Unit No. :	Segment No. :

Type of Bag : Single Double Triple : Quadruple:

Lot number Expiry

BLOOD COLLECTION	NAME of phlebotomist :	Date :

Check : Donor's Name

Check Donation No. : On Donation record / Blood Bags / Specimen Tubes

Start time : ..... a.m / p.m. **Time Taken :** ..... mins. **Volume :** ..... **ml**

Bag lot No. Bag expiry date :

Complications : Faint : Fits : Double Prick Haematoma :

Others (please specify)

S.F. No. : Version No.

Sree Chitra Tirunal Institute for Medical Sciences and Technology Trivandrum

Department of Transfusion Medicine

Donor Reaction Reporting Form

Donor Details:

Name: **Age:**

Gender:

Weight:

Contact number/Contact details:

Blood Donation and Reaction details:

Date of donation:

Site of donation: Camp/Blood Bank/ Blood Mobile

Venue of donation:

Donor type: first time donor/repeat donor/regular donor

Donation type: whole blood/apheresis

Time of donation:

Time of reaction:

When did the reaction occur?

Pre-Donation / During Donation / Post-Donation

If delayed reaction, specify the exact duration:

Type of reaction:

Number of venipunctures attempted: one/two/more

Whether venipuncture was attempted on both upper limbs: yes / no

Phlebotomy was performed on: central vein / peripheral vein

Blood bag manufacturer:

How the reaction was managed:

Time taken for recovery:

Recovery phase:

Fully recovered/ partially recovered/ Delayed recovery

Volume of blood collected:

Any history of previous adverse reactions during or after blood donation: yes / no

If yes, what type of reaction and how many times?

Brief past medical &treatment history of the donor:

Time of last meal:

Hours of sleep the previous night:

Hydration status of donor: good / fair / poor

<u>Vitals of the donor</u>

Before donation:		**After donation:**	
Pulse:	**BP:**	**Pulse:**	**BP:**

Types Of Adverse Reactions:

1.Localised Reactions:

• **Bruise** • **Bleeding** • **Hematoma** • **Thrombophlebitis** • **Cellulitis**	• **Localised pain/ numbness /tingling along forearm** • **Localised muscle spasm**	• **Pruritis** • **Erythema** • **Urticaria**

2. Allergic Reactions:

A) Localised B) Generalised

3. Vasovagal Reactions:

A) LOC < 60 Sec LOC > 60 Sec without LOC (Loss Of Consciousness)

B) Nausea / Vomiting

C) With Injury without Injury

D) Within Blood Collection Facility or Outside Blood Collection Facility

4. Convulsions:

a) Lasting for >30 sec Lasting for <30 sec

b) With loc without loc

c) Bowel or bladder incontinence

d) Localised or generalised numbness of body

e) Post-ictal confusion

5. Signs and symptoms indicative of any other serious reactions:

• **Nausea** • **Vomiting** • **Headache** • **Chest Pain/Chest tightness** • **Abdominal Pain/Cramps** • **Radiation Of Pain- along neck/jaw/upper limbs/back** • **Dyspnoea** • **Tachycardia** • **Tachypnoea** • **Hoarseness of voice/ stridor** • **Wheezing**	• **Flushing** • **Odema-Localised/Generalised/ Angioedema** • **Hypotension/Hypertension** • **Weakness/Numbness Along One Side Of Body/Generalised** • **Deviation Of Angle Of Mouth** • **Uncontrolled Profuse Bleeding From The Phlebotomy Site**

6. Any other reactions or if the donor develops more than one type of reaction, please specify:

<u>Categorization of the type of reaction:</u>

Mild Moderate Severe Not able to Categorize

<u>Imputability:</u>

Definite / Probable / Possible / Doubtful / Ruled out / Not determined

Name and Signature of the Reporting Person: **Place & Date:**

Sree Chitra Tirunal Institute for Medical Sciences and Technology
Trivandrum – 695011

Participant information sheet for blood donors

Hemovigilance: An analysis of adverse effects of blood donation among blood donors and transfusion reactions among recipients in a tertiary care centre.

Who are the participants of this study?

All the voluntary blood donors who develop adverse reactions just before donation, during blood donation or after blood donation

What is this study about?

This study is directed towards proper reporting, monitoring, assessing the cause and management of blood donor adverse reactions.

How long is the study period?

This will be a one-year long study on all the voluntary blood donors who develop adverse reactions in this one-year period.

What is the need for this study?

This study will help us to find out both the common and uncommon adverse reactions among the blood donors. This will help us to identify and implement the suitable precautions that can be taken in future donations that will minimize the risk of adverse reactions in the donors.

How does this study help the donors?

This study aims to point out all the adverse reactions among the donors, which will aid us to administer the correct treatment and preventive measures. Thus, this study can help us to reduce the adverse reactions as far as possible, thereby ensuring the donor comfort and donor retention. Thereby, providing encouragement to the donors to become regular voluntary blood donors.

What all are the usual donor adverse reactions?

Pain, bleeding, itching, swelling, discoloration and infections at the puncture site.

Then, nausea, vomiting, headache, giddiness, loss of consciousness, fits, allergic reactions, chest pain or discomfort, weakness or numbness along blood donated arm are the usual donor adverse reactions.

How are the usual donor adverse reactions managed?

If the donor develops adverse reactions during donation like severe pain at phlebotomy site, swelling or itching or severe headache, chest pain, nausea or vomiting we will immediately remove the needle and wait for the symptoms to subside and will advise the donor to donate at a later time as per the volume of blood collected during the present donation.

If the donor develops giddiness or loss of consciousness during or after donation, first we will make sure that the needle is removed. Then, will lower the head end and elevate the foot end. Will ask him to cough for 10 times. Will observe the donor for 30 minutes or more depending upon his health status with plenty of oral fluids.

If the donor develops hematoma of the phlebotomy site, initially compression of the site for 10 minutes, then ice pack will be kept for another 7 minutes, thrombophobe gel will be applied afterwards and the donor will be sent home advising weight restriction for that arm with hematoma.

If the donor develops some serious adverse reactions, that will also be managed according to the severity.

Will this study produce any sort of harmful effects to the donors?

No, this is an absolutely safe study and will not produce any harm to the donors. This study is oriented to provide the donors a reaction free donation as far as possible.

If you participate in the study, what will you have to do?

If you wish to take part in this study then you will be provided with an informed consent form, which states that you are voluntarily participating in this study and you can withdraw your permission of being a participant of the study at any time without affecting your usual treatment

or legal rights. After reading this participant information sheet and informed consent form with a thorough understanding of the contents mentioned, you can sign the consent form. After signing the consent form you will become a participant of the study.

Will you have to bear any financial expenses for the study?

No, you will not have to bear any expenses.

Will your personal details will be kept confidential?

The results of this study will be published as a thesis for MD Transfusion Medicine/Medical Journal. But you will not be identified by name in any publication or presentation of results. However, your medical notes will be reviewed by people associated with this study, without your additional permission.

If you have any further questions, please feel free to ask:

Dr.Anila Mani (Tel No: 9656163779) or **Dr.Debasish Gupta** (Tel No: 9020120101).

Name of the Principal Investigator: **Dr.Anila Mani**

Address and contact details:

Junior Resident, Department of Transfusion Medicine,SCTIMST, Trivandrum-695011,

Contact No: 9656163779

Signature of the Principal Investigator:

Date:

Place:

For any clarifications regarding the study's ethics clearance you may contact

Dr. Mala Ramanathan, Member Secretary of the Institute Ethics Committee-SCTIMST.

Phone number: **0471-2524234** and Email**:** **iec.mem.sec@sctimst.ac.in**

ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, തിരുവനന്തപുരം – 695011

രക്ത ദാതാവിന്റെ കാര്യവിവരണപത്രം

രക്തദാന-രക്തസംക്രമണ സംബന്ധമായ ജാഗ്രത (ഹീമോവിജിലൻസ്)- ഒരു ത്രിതല ചികിത്സാകേന്ദ്രത്തിലെ, രക്തദാതാക്കളിലെ രക്തദാനത്തിന്റെയും സ്വീകർത്താക്കളുടെ രക്തസംക്രമണ പ്രതികരണങ്ങളുടെയും, പ്രതികൂല പ്രഭാവങ്ങളുടെ വിശകലനം

- ഈ പഠനത്തിലെ പങ്കാളികളാരെല്ലാം ?

  രക്തദാനത്തിന് തൊട്ടുമുൻപോ, രക്തദാനത്തിനിടയിലോ രക്തദാനം കഴിഞ്ഞതിനുശേഷമോ പ്രതികൂല പ്രതികരണങ്ങളുണ്ടായ എല്ലാ സന്നദ്ധ രക്തദാതാക്കളും

- എന്തിനെപ്പറ്റിയാണ് ഈ പഠനം?

  കൃത്യമായ വിവരം നൽകൽ, നിരീക്ഷണം, രക്തദാതാക്കളിലുണ്ടാകുന്ന പ്രതികൂല പ്രതികരണങ്ങളുടെ കാരണം വിലയിരുത്തലും കൈകാര്യം ചെയ്യലും എന്ന ലക്ഷ്യത്തോടെയാണ് ഈ പഠനം.

- പഠനകാലാവധി യുടെ ദൈർഘ്യം?

  ഈ ഒരുവർഷക്കാലയളവിൽ പ്രതികുല പ്രതികരണങ്ങളുണ്ടാകുന്ന എല്ലാ രക്തദാതാക്കളെയും പഠിക്കുന്ന, ഒരു വർഷം നീളുന്നതാണ് ഈ പഠനം

- ഈ പഠനത്തിന്റെ ആവശ്യമെന്ത്?

  രക്ത ദാതാക്കളിൽ ഉണ്ടാകാവുന്ന, സാധാരണവും അസാധാരണവുമായ പ്രതികൂല പ്രതികരണങ്ങൾ കണ്ടെത്തുന്നതിൽ നമ്മളെ ഈ പഠനം സഹായിക്കും. ഭാവിയിൽ, രക്ത ദാതാക്കളിൽ ഉണ്ടാകാവുന്ന പ്രതികൂല പ്രതികരണങ്ങളുടെ അപായം പരമാവധി കുറക്കാനുള്ള അനുയോജ്യമായ മുൻകരുതലുകൾ ആലോചിക്കാനും നടപ്പിലാക്കാനും ഇത് നമ്മളെ സഹായിക്കും.

- രക്ത ദാതാക്കൾക്ക് ഈ പഠനം എങ്ങിനെ സഹായകമാകും?

  രക്ത ദാതാക്കളിൽ ഉണ്ടാകാവുുന്ന എല്ലാ പ്രതികൂല പ്രതികരണങ്ങളെയും ഈ പഠനം ചൂണ്ടിക്കാണിക്കും. കൃത്യമായ ചികിത്സക്കും പ്രതിരോധ നടപടികളെടുക്കാനും ഇത് സഹായകമാകും. അങ്ങിനെ പ്രതികൂല പ്രതികരണങ്ങൾ സാദ്ധ്യമാകുന്നിടത്തോളം കുറയ്ക്കാൻ ഈ പഠനം സഹായിക്കും അതുവഴി ദാദാക്കളുടെ സ്വാസ്ഥ്യവും ദാതാക്കളായി നിലനിൽക്കുന്നതും ഉറപ്പാക്കാൻ സഹായിക്കും. അത് രക്തദാതാക്കൾക്ക് സ്ഥിരമായി രക്തം ദാനം ചെയ്യാൻ പ്രചോദനമാകും.

- രക്തദാതാക്കളിലുണ്ടാകുന്ന പ്രതികൂല പ്രതികരണങ്ങളെന്തെല്ലാം ?

കുത്തിവയ്ക്കുന്ന സ്ഥലത്തുണ്ടാകുന്ന വേദന, നിറം മാറ്റം, രക്തപ്രവാഹം, ചൊറിച്ചിൽ, വീക്കം, അണുബാധ എന്നിവ. ഓക്കാനം, ഛർദ്ദി, തലവേദന, തലകറക്കം, ബോധം നഷ്ടപ്പെടൽ, അപസ്മാരം, അലർജി, നെഞ്ചുവേദനയോ അസ്വസ്ഥതയോ, സൂചികുത്തിയ കൈയിലുണ്ടാകാവുന്ന ബലക്കുറവോ മരവിപ്പോ എന്നിവയാണ് സാധാരണയായി രക്തദാതാക്കളിലുണ്ടാകുന്ന പ്രതികൂല പ്രതികരണങ്ങൾ.

- രക്തദാതാക്കളിൽ സാധാരണയുണ്ടാകുന്ന പ്രതികൂല പ്രതികരണങ്ങൾ എങ്ങിനെയാണ് കൈകാര്യം ചെയ്യുന്നത്?

കടുത്ത വേദന, വീക്കമോ ചൊറിച്ചിലോ കടുത്ത തലവേദനയോ, നോഞ്ചുവേദന, ഓക്കാനമോ ഛർദ്ദിലോ ഉണ്ടാകുകയാണെങ്കിൽ നമ്മൾ സൂചി മാറ്റുകയും ലക്ഷണങ്ങൾ കുറയുന്നതുവരെ നിരീക്ഷിച്ചിട്ട് ഇപ്പോൾ ശേഖരിച്ച രക്തത്തിന്റെ അളവനുസരിച്ച് കുറച്ചുനാൾ കഴിഞ്ഞ് രക്തം ദാനം ചെയ്യാൻ ദാതാവിനോട് ഉപദേശിക്കകയും ചെയ്യും.

രക്തദാനസമയത്തോ അതിനുശേഷമോ, ദാതാവിന് മയക്കമോ ബോധക്ഷയം ഉണ്ടാകുകയാണെങ്കിൽ, ആദ്യം സൂചി മാറ്റി എന്നുറപ്പാക്കും. എന്നിട്ട് തലയുടെ ഭാഗം താഴ്ത്തുകയും കാലിന്റെ ഭാഗം ഉയർത്തുകയും ചെയ്യും. പത്ത് പ്രാവശ്യം ചുമയ്ക്കാൻ ആവശ്യപ്പെടും. ദാതാവിന്റെ ആരോഗ്യ നിലയനുസരിച്ച് 30 മിനിട്ട് നേരത്തേക്ക് നിരീക്ഷിക്കുകയും ധാരാളം പാനീയം കുടിക്കാൻ നൽകുകയും ചെയ്യും.

രക്തക്കുഴലിൽ മുറിവുണ്ടാക്കുന്ന സ്ഥലത്ത്, ദാതാവിന്റെ കലകളിൽ രക്തം കട്ടപിടിക്കുകയാണെങ്കിൽ തുടക്കത്തിൽ 10 മിനിട്ട് നേരത്തേക്ക് സ്ഥലത്ത് മർദ്ദം ഉപയോഗിക്കും അതിനുശേഷം ഐസ് കട്ട 7 മിനിട്ട് നേരം വയ്ക്കും അതിനുശേഷം ത്രോമ്പോഫോബ് മരുന്ന് പുരട്ടുകയും, കലകളിൽ രക്തം കട്ടപിടിച്ച കൈകൊണ്ട് ഭാരമെടുക്കുന്നത് നിയന്ത്രിക്കാനുപദേശിക്കുകയും ചെയ്യും.

ദാതാവിന് ഗുരുതരമായ പ്രതികൂല പ്രതികരണമുണ്ടായാൽ ഗുരുതരാവസ്ഥക്ക നുസരണമായി കൈകാര്യം ചെയ്യും.

- ഈ പഠനം, രക്തദാതാവിന് ദോഷകരമായ പ്രഭാവങ്ങൾ ഉണ്ടാക്കുമോ?

ഇല്ല. രക്തദാതാവിന് യാതോരുവിധ ദോഷകരമായ പ്രഭാവവും ഉണ്ടാക്കില്ല, ഇത് തികച്ചും സുര ക്ഷിതമായ പഠനമാണ്.

- താങ്കൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നെങ്കിൽ എന്തുചെയ്യണം?

താങ്കൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നെങ്കിൽ താങ്കൾക്ക് കാര്യബോധത്തോടെയുള്ള സമ്മത ത്തിനായുള്ള പത്രിക നൽകും, അതിൽ താങ്കൾ സ്വമേധയായാണ് പങ്കെടുക്കുന്നതെന്നും താങ്കൾക്ക് ഏതു സമയത്തും താങ്കളുടെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങ ളെയോ ബാധിക്കാതെ പങ്കെടുക്കുന്നതിൽ നിന്നും പിൻമാറാമെന്നും പ്രസ്താവിക്കും. ഈ പങ്കാളികൾക്കുള്ള വിവരണപത്രികയും കാര്യബോധത്തോടെയുള്ള സമ്മതപത്രവും വായിച്ച്

സൂചിതമായ സമ്മതത്തെപ്പറ്റി പൂർണ്ണമായി മനസ്സിലാക്കിയശേഷം താങ്കൾക്ക് സമ്മതപത്രത്തിൽ ഒപ്പിടാം.

സമ്മതപത്രം താങ്കൾ ഒപ്പിട്ടശേഷം ഈ പഠനത്തിൽ പങ്കാളിയാകാം.

- ഈ പഠനത്തിനുവേണ്ട് താങ്കൾക്കെന്തെങ്കിലും സാമ്പത്തിക ചിലവുണ്ടാകുമോ?

ഇല്ല. താങ്കൾക്കൊരു ചിലവും വഹിക്കേണ്ടിവരില്ല

- താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കപ്പെടുമോ?

ഈ പഠനത്തിന്റെ ഫലം ഒരു എം. ഡി. ട്രാൻഫ്യൂഷൻ മെഡിസിനുള്ള പ്രബന്ധം/വൈദ്യ ജർണലിൽ പ്രസിദ്ധീകരിക്കും. പക്ഷേ താങ്കളെ പേരുകൊണ്ട് പ്രസിദ്ധീകരണത്തിലോ ഫലങ്ങളുടെ പ്രദർശനത്തിലോ തിരിച്ചറിയാനാവില്ല. എന്നിരുന്നാലും താങ്കളുടെ വൈദ്യ രേഖകൾ പഠനവുമായി ബന്ധപ്പെട്ടയാളുകൾ താങ്കളുടെ വീണ്ടുമുള്ള അനുവാദം കൂടാതെ വിലയിരുത്തും.

താങ്കൾക്ക് കുടുതലെന്തെങ്കിലും ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ഡോ. അനില മണിയോട് ചോദിക്കുക. (ഫോൺ. 9656163779) dranilamani@gmail.com

അല്ലെങ്കിൽ

ഡോ. ദേബശീഷ് ഗുപ്ത (ഫോൺ. 9020120101)

പ്രധാന ഗവേഷകയുടെ പേര്. ഡോ. അനില മണി

മേൽവിലാസവും ബന്ധപ്പെടാനുള്ള വിവരങ്ങളും

ജൂനിയർ റസിഡന്റ്, ട്രാൻസ്ഫ്യൂഷൻ മെഡിസിൻ ഡിപ്പാർട്ട്മെന്റ്, SCTIMST തിരുവനന്തപുരം 695011,

ബന്ധപ്പെടാനുള്ള നമ്പർ 9656163779 ഇമെയിൽ. dranilamani@gmail.com

പ്രധാന ഗവേഷകയുടെ ഒപ്പ്

തീയതി

സ്ഥലം

പഠനത്തിന്റെ നൈതീക അനുവാദസംബന്ധമായ എന്തെങ്കിലും വിശദീകരണമാവശ്യമെങ്കിൽ താങ്കൾക്ക് ബന്ധപ്പെടാവുന്നത് ഡോ. മാല രാമനാഥൻ (മെമ്പർ സെക്രട്ടറി, എത്തിക്സ് കമ്മിറ്റി SCTIMST), ഫോൺ. 04712524234. ഇമെയിൽ. iec.mem.sec@sctimst.ac.in

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum

CONSENT FORM FOR TRANSFUSION OF BLOOD / BLOOD COMPONENTS

Patient Name: _____

IP Number: _____ Ward/Bed No: _____

Blood transfusion is a life saving medical procedure. Blood can be given as "whole blood" or as components such as: Red cells, Platelets, Plasma and Cryoprecipitate.

1. I /My patient have been informed of the transfusion options available and expected benefits of transfusion of blood and / or components.
2. I /My patient agree to the administration of blood and / or components in the interest of proper medical care.
3. I /My patient understand that blood / blood components to be administered have been prepared and tested in accordance with rules established by National Regulation. However, there is still a very small chance that an adverse reaction can occur such as: fever with or without chills and rigor, itching and hives, which are treatable. Rarely an unpredictable life threatening event can also occur.
4. I/My patient have been informed that despite mandatory screening for blood borne infections such as HIV, Hepatitis B, Hepatitis C, Syphilis and Malaria, by approved standard diagnostic kits, the risk of acquiring these infections is not totally eliminated.
5. I/My patient have had the opportunity to ask questions about transfusions, alternatives to transfusion, risk of not transfusing, the procedures to be used and the relative risks and hazards involved.
6. I/My patient believe that I have been sufficiently informed to make a decision to give consent for transfusion of blood / blood components.
7. I/My patient have been informed and explained the above in a language that I/my patient understand.

AUTHORIZATION BY PATIENT

Signature/Thumb impression of Patient

Name of the Patient: _____

Signature/Thumb impression of Witness

Name of Witness: _____

Date:_____

Doctor: _____

Designation: _____

PATIENT'S ATTENDANT/NEXT OF KIN

The patient is unable to give consent because _____
And I_____ (name / relationship to patient), therefore consent for the patient. I acknowledge that I have had an opportunity to discuss this procedure, as stated above, with my physician, physician designee and hereby consent to this procedure.

Signature/Thumb impression

Name of the Patient attendant/Next of kin: _____

Signature/Thumb impression

Name of Witness: _____

Date: _____

Doctor: _____

Designation: _____

ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, തിരുവനന്തപുരം – 695011

രക്ത/രക്തഘടകങ്ങളുടെ സംക്രമണത്തിനായുള്ള സമ്മതപത്രം

പഠനശീർഷകം. രക്തദാന-രക്തസംക്രമണ സംബന്ധമായ ജാഗ്രത (ഹീമോവിജിലൻസ്)- ഒരു ത്രിതലചികിത്സാകേന്ദ്രത്തിലെ, രക്തദാതാക്കളിലെ രക്തദാനത്തിന്റെയും സ്വീകർത്താക്കളുടെ രക്തസംക്രമണ പ്രതികരണങ്ങളുടെയും, പ്രതികൂല പ്രഭാവങ്ങളുടെ വിശകലനം.

രോഗിയുടെ പേര്..... ആശുപത്രി നമ്പർ.....വാർഡ്/ബെഡ് നമ്പർ.....

ജീവൻരക്ഷാപരമായ ഒരു ചികിത്സാ നടപടിയാണ് രക്തസംക്രമണം. രക്തം, മുഴുവനുമായോ ചുവന്നരക്താണുക്കൾ, പ്ളേറ്റ്ലറ്റുകൾ, പ്ളാസ്മ, ക്രയോപ്രസിപ്പിറ്റന്റ് എന്നീ ഘടകങ്ങളായോ നൽകാം.

1. എനിക്ക്/എന്റെ രോഗിക്ക് രക്തസംക്രമണത്തിന്റെ വ്യത്യസ്ഥ രീതികളെപ്പറ്റിയും രക്തത്തിന്റെ/ രക്തഘടകങ്ങളുടെ സംക്രമണത്തിൽ പ്രതീക്ഷിക്കുന്ന നേട്ടങ്ങളെപ്പറ്റി അറിയിച്ചിട്ടുണ്ട്.
2. വേണ്ടുംവിധമുള്ള വൈദ്യപരിചരണത്തിന്റെ താത്പര്യർത്ഥം രക്തം/ രക്തഘടകങ്ങൾ നൽകാൻ ഞാൻ/എന്റെ രോഗി സമ്മതിച്ചിട്ടുണ്ട്.
3. നൽകുന്ന രക്ത/രക്തഘടകങ്ങൾ തയാറാക്കുകയും പരിശോധിക്കുകയും ചെയ്യുന്നത് ദേശീയ നിയന്ത്രണങ്ങൾക്ക് അനുസരണമായാണെന്ന് ഞാൻ/എന്റെ രോഗി മനസ്സിലാക്കുന്നു. രക്തം/ രക്തഘടകങ്ങൾ നൽകുമ്പോൾ കുളിര്/വിറയൽ എന്നിവയോടുകൂടിയോ അല്ലാതെയോ ഉള്ള പനി, ചൊറിച്ചിൽ, തൊലി ചുവന്നുതടിക്കൽ എന്നീ ചികിത്സക്കാവുന്ന, പ്രതികൂലമായ പ്രതികരണങ്ങൾക്ക് ചെറിയ സാദ്ധ്യതയുണ്ട്. അപൂർവ്വമായി അപ്രതീക്ഷിതമായ ജീവനുഭീഷണിയാകാവുന്ന സംഭവങ്ങളും ഉണ്ടായേക്കാം എന്ന് ഞാൻ/എന്റെ രോഗി മനസ്സിലാക്കുന്നു.
4. നിർബന്ധമായുള്ള രക്തപരിശോധനനടത്തിയാലും, രക്തജന്യമായ എച്ച് ഐ വി, ഹെപ്പറ്റൈറ്റിസ് ബി, സിഫിലിസും മലേറിയയും തുടങ്ങിയ അണുബാധകളുടെ സാദ്ധ്യതകൾ പൂർണ്ണമായും ഒഴിവാക്കാനാകില്ലെന്നും എന്നെ/എന്റെ രോഗിയെ അറിയിച്ചിട്ടുണ്ട്.
5. രക്തസംക്രമണത്തെപ്പറ്റിയും, രക്തസംക്രമണേതരമാർഗ്ഗങ്ങളെപ്പറ്റിയും സംക്രമണം നടത്താതിരുന്നലുള്ള അപകടത്തെപ്പറ്റിയും, ചെയ്യുന്ന നടപടിയെപ്പറ്റിയും സാപേക്ഷികമായ അപകടസാദ്ധ്യതകളെപ്പറ്റിയും ചോദ്യങ്ങൾ ചോദിക്കാൻ എനിക്ക്/എന്റെ രോഗിക്ക് അവസരമുണ്ടായി.
6. രക്തം/ രക്തഘടകങ്ങൾ സംക്രമണം ചെയ്യുന്നതിനുള്ള സമ്മതം നൽകാൻ തീരുമാനിക്കുന്നതിനാവശ്യമായ വിവരങ്ങൾ ലഭിച്ചു എന്ന് ഞാൻ/എന്റെ രോഗി വിശ്വസിക്കുന്നു.
7. എനിക്ക്/എന്റെ രോഗിക്ക് മനസ്സിലാകുന്ന ഭാഷയിൽ മുകളിൽപറഞ്ഞ വിവരങ്ങൾ വിശദീകരിച്ചു തന്നു.

രോഗി അധികാരപ്പെടുത്തിയയാളുടെ

ഒപ്പ്/ വിരലടയാളം

രോഗിയുടെ പേര്

തീയതി

സ്ഥലം

ഒപ്പ്/ വിരലടയാളം

സാക്ഷിയുടെ പേര്

തീയതി

സ്ഥലം

ഡോക്ടർ

ഔദ്യോഗിക പദവി

രോഗിയുടെ ശുശ്രൂഷകൻ/അടുത്ത ബന്ധു

..... നാൽ രോഗിക്ക് സമ്മതം നൽകാൻ ശേഷിയില്ല. ആകയാൽ ഞാൻ..... (പേര്/രോഗിയുമായുള്ള ബന്ധം) രോഗിക്കുവേണ്ടി സമ്മതം നൽകുന്നു. മുകളിൽ പറഞ്ഞപോലെ ഈ നടപടിയെപ്പറ്റി ഡോക്ടർ നിയോഗിച്ചയാളോട് ചർച്ചചെയ്യാൻ അവസരം കിട്ടിയെന്നത് സമ്മതിച്ചുകൊണ്ട് ഇതിനാൽ ഈ നടപടിക്ക് അനുവാദം നൽകുന്നു.

ഒപ്പ്/വിരലടയാളം

രോഗിയുടെ ശുശ്രൂഷകൻ/അടുത്ത ബന്ധുവിന്റെ പേര്

തീയതി

സാക്ഷിയുടെ പേര്

തീയതി

സ്ഥലം

ഡോക്ടർ

ഔദ്യോഗിക പദവി

Sree Chitra Tirunal Institute For science and Technology
Trivandrum, 11

Department of Transfusion Medicine

Transfusion Reaction Reporting Form

Patient/Recipient Details:

Hos No:

Name:

Age: **Date of Birth / / (mm/dd/yy)**

(optional)

Gender: **Weight:**

Contact Details:

Admitting or Primary diagnosis:

Indication for transfusion:

Relevant Severe co-morbidities (if applicable):

Current Medications:

List transfusion history BEFORE reaction:

List transfusion history AFTER reaction:

Any history of previous transfusion reactions (type and date):

Blood /Blood Component(S) & Reaction Information

Blood Bag Manufacture Company	Blood Component that caused Reaction	Volume of Blood Transfused	Date & Time of start of Transfusion	Date & Time of Transfusion Reaction	Date & Time of Stoppage of Transfusion

Vital signs of the patient:

Vitals	Pre-Transfusion	During Transfusion	Post Transfusion
Pulse Rate			
Blood Pressure			
Respiratory Rate			
Temperature			
Sp02			

Symptoms/signs at time of reaction – tick mark all that apply

SYMPTOMS
Nausea
Vomiting
Pain at infusion site
Pruritis
Abdominal pain/cramps
Diarrhoea
Chest pain
Substernal pain
Chest tightness
Back pain
Headache
Anxiety
Impending doom

Signs	
Loss of consciousness	Tachycardia
Flushing	Arrythmia
Erythema	Hypotension
Urticaria	Hypertension
Fever	Jugular venous distension
Chills/Rigors	Widened pulse pressure
Cough	Shock
Dyspnoea	Cardiac arrest
Wheezing	Edema – pulmonary /pedal
Tachypnoea	Angioedema
Hoarseness/Stridor	Oliguria
Orthopnoea	DIC
Hypoxemia	
Cyanosis	

Allergic/Anaphylactic [1] **TRALI [2]** **TACO [3]** **Septic Transfusion Reaction [4]**

Treatment and Clinical Course

Treatment	Administered ?? (Yes Or No)	Responded To Treatment (Yes Or No)
Acetaminophen		
Antihistamines		
Bronchodilators		
Diuretics		
Epinephrine		
Steroids		
Oxygen Supplementation		
Intubation/Ventillator support		

Others (specify):

Current Status of the patient:

i) Returned to pre-transfusion status

ii)Still requires support related to transfusion reaction

iii)Expired (Transfusion related fatality)

Other/Unknown

Suspected Bacterial Contamination

Whether the suspected components were returned to the blood bank? Yes No

On reinspection does the component present any abnormalities (e.g. clumps, discoloration, hemolysis)?

Yes No: Describe if yes:

Suspected component – Source used: Bag Segment Not done

Gram stain performed:

Negative Positive Pending Not done

Result (organism):

Culture performed:

Negative Positive Pending Not done

Result (organism):

Patient's pre-transfusion blood culture: Negative Positive Pending Not done

Date/Time: / / (mm/dd/yy)

Result (organism):

Patient's post-transfusion blood culture result Negative Positive Pending Not done

Date/Time: / / (mm/dd/yy) Result (organism identified if positive):

Does the patient have history of fever or any other infection related to his/her underlying medical condition? No Yes

Was the patient on antibiotics at the time of transfusion? No Yes, Name:

Is the patient currently being treated with antibiotics? No Yes, Name:

Did the patient have an absolute neutropenia (neutrophil less than 500 per µl) prior to transfusion? □ No □ Yes

Suspected transfusion reaction categorization

Reaction: **1] Allergic/Anaphylactic** **2] TRALI** **3] TACO**

4] Septic Transfusion Reaction **5] Others:**

Severity: **Mild** **Moderate** **Severe** **Life Threatening** **Death**

Imputability: **Definite** **Probable** **Possible** **Doubtful** **Ruled out** **Not Determined**

Name & Signature of the Reporting Person:

Date & Place:

Sree Chitra Tirunal Institute for Medical Sciences and Technology
Trivandrum – 695011

Participant information sheet for blood transfusion recipients

Hemovigilance: An analysis of adverse effects of blood donation among blood donors and transfusion reactions among recipients in a tertiary care centre.

Who are the participants of this study?

All the patients who develop transfusion reactions during or after transfusion of blood or blood components.

What is this study about?

This study is directed towards proper reporting, monitoring, assessing the cause and management of transfusion reactions in the patients.

How long is the study period?

This will be a one-year long study on all those patients who will develop adverse reactions in this one-year period.

What is the need for this study?

This study will help us to find out both the common and uncommon adverse reactions among the recipients. This will help us to think and implement the apt precautions that can be taken in future donations and transfusions which will make the risk of adverse reactions among the patients to the least possible extent.

How does this study help the patients?

This study aims to point out all the adverse reactions among the transfusion recipients, which will aid us to administer the correct treatment and preventive measures. Thus, this study can help us to reduce the adverse reactions as far as possible, thereby ensuring the patient safety.

What all are the usual recipient adverse reactions?

Pain, itching or swelling at the infusion site.

Nausea,vomiting,sweating,palpitation,fever with or without chills and rigor,breathlessness,chest pain or chest discomfort, abdominal pain or diarrhea, reduced urine output or black colored urine. Then fall in blood pressure or elevation of blood pressure, generalized oedema or oedema of both the legs of the face. Sometimes transfusion reactions can even lead to life threatening reactions and even in death.

How the usual recipient adverse reactions are managed?

If the recipient develops any adverse reactions during transfusion, the transfusion will be immediately stopped and appropriate treatment according to the protocol will be administered.

Will this study produce any sort of harmful effects to the recipient?

No, this is an absolutely safe study and will not produce any harm to the recipients. This study is oriented to provide the recipients a reaction free transfusion.

If you participate in the study, what will you have to do?

If you wish to take part in this study then you will be provided with an informed consent form, which states that you are voluntarily participating in this study and you can withdraw your permission of being a participant of the study at any time without affecting your usual treatment or legal rights. After reading this participant information sheet and informed consent form with a thorough understanding of the contents mentioned, you can sign the consent form. After signing the consent form you will become a participant of the study.

Will you have to bear any financial expenses for the study?

No, you will not have to bear any expenses.

Will your personal details will be kept confidential?

The results of this study will be published as a thesis for MD Transfusion Medicine/Medical Journal. But you will not be identified by name in any publication or presentation of results.

However, your medical notes will be reviewed by people associated with this study, without your additional permission.

If you have any further questions, please feel free to ask:

Dr.Anila Mani (Tel No: 9656163779) or**Dr.Debasish Gupta** (Tel No: 9020120101).

Name of the Principal Investigator:**Dr.Anila Mani**

Address and contact details:

Junior Resident, Department of Transfusion Medicine, SCTIMST, Trivandrum-695011,

Contact No: 9656163779

Signature of the Principal Investigator:

Date:

Place:

For any clarifications regarding the study's ethics clearance you may contact
Dr. Mala Ramanathan, Member Secretary of the Institute Ethics Committee-SCTIMST.
Phone number:**0471-2524234** and Email**: iec.mem.sec@sctimst.ac.in**

ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, തിരുവനന്തപുരം – 695011

രക്തസംക്രമണം സ്വീകരിച്ചുകൊണ്ട് പങ്കാളികളാകുന്നവർക്കുള്ള കാര്യവിവരണപത്രം

രക്തദാന-രക്തസംക്രമണ സംബന്ധമായ ജാഗ്രത (ഹീമോവിജിലൻസ്)- ഒരു ത്രിതല ചികിത്സാകേന്ദ്രത്തിലെ, രക്തദാതാക്കളിലെ രക്തദാനത്തിന്റെയും സ്വീകർത്താക്കളുടെ രക്തസംക്രമണ പ്രതികരണങ്ങളുടെയും, പ്രതികൂല പ്രഭാവങ്ങളുടെ വിശകലനം ഈ പഠനത്തിലെ പങ്കാളികളാരെല്ലാം.

- ഈ പഠനത്തിലെ പങ്കാളികളാരെല്ലാം ആണ്?

  രക്തം/രക്തഘടകങ്ങളുടെ സംക്രമണസമയത്തോ അതിനുശേഷമോ സംക്രമണ പ്രതികരണങ്ങളുണ്ടാകുന്ന എല്ലാ രോഗികളും.

- എന്തിനെപ്പറ്റിയാണ് ഈ പഠനം?

  കൃത്യമായ വിവരം നൽകൽ, നിരീക്ഷണം, രോഗികളിലുണ്ടാകുന്ന രക്തസംക്രമണ പ്രതികരണങ്ങളുടെ കാരണം വിലയിരുത്തലും കൈകാര്യം ചെയ്യലും എന്ന ലക്ഷ്യത്തോടെയാണ് ഈ പഠനം.

- പഠനകാലാവധിയുടെ ദൈർഘ്യം?

  ഈ ഒരുവർഷക്കാലയളവിൽ രക്തസംക്രമണ പ്രതികൂല പ്രതികരണങ്ങളുണ്ടാകുന്ന എല്ലാ രോഗികളെയും പഠിക്കുന്ന, ഒരു വർഷം നീളുന്നതാണ് ഈ പഠനം

- ഈ പഠനത്തിന്റെ ആവശ്യമെന്ത്?

  രോഗികളിൽ ഉണ്ടാകുന്ന, സാധാരണവും അസാധാരണവുമായ പ്രതികൂല പ്രതികരണങ്ങൾ കണ്ടെത്തുന്നതിൽ നമ്മളെ ഈ പഠനം സഹായിക്കും. ഭാവിയിൽ, രക്തംസ്വീകരിക്കുന്നവരിൽ ഉണ്ടാകാവുന്ന പ്രതികൂല പ്രതികരണങ്ങളുടെ അപായം പരമാവധി കുറക്കാനുള്ള അനുയോജ്യമായ മുൻകരുതലുകൾ ആലോചിക്കാനും നടപ്പിലാക്കാനും ഇത് നമ്മളെ സഹായിക്കും.

- രക്തം സ്വീകരിക്കുന്നവർക്ക് ഈ പഠനം എങ്ങിനെ സഹായകമാകും?

  രക്ത സ്വീകരിക്കുന്നവർക്ക് ഉണ്ടാകാവുന്ന എല്ലാ പ്രതികൂല പ്രതികരണങ്ങളെയും ഈ പഠനം ചൂണ്ടിക്കാണിക്കും. കൃത്യമായ ചികിത്സക്കും പ്രതിരോധ നടപടികളെടുക്കാനും ഇത് സഹായകമാകും. അങ്ങിനെ പ്രതികൂല പ്രതികരണങ്ങൾ സാദ്ധ്യമാകുന്നിടത്തോളം കുറയ്ക്കാൻ ഈ പഠനം സഹായിക്കും. അതുവഴി സ്വീകർത്താക്കളുടെ സുരക്ഷ ഉറപ്പാക്കാനാകും.

- രക്ത സ്വീകർത്താക്കളിൽ സാധാരണയുണ്ടാകുവന്ന പ്രതികൂല പ്രതികരണങ്ങൾ എന്തെല്ലാം?
  കുത്തിവയ്ക്കുന്ന സ്ഥലത്തുണ്ടാകുന്ന വേദന, ചൊറിച്ചിൽ അല്ലെങ്കിൽ വീക്കം. ഓക്കാനം, ഛർദ്ദിൽ, വിയർപ്പ്, കിതപ്പ്, കുളിര്/വിറയൽ എന്നിവയോടുകൂടിയോ അല്ലാതെയോ ഉള്ള പനി, ശ്വാസംകിട്ടായ്ക, നെഞ്ച് വേദനയോ അസ്വസ്ഥതയോ, വയറു വേദനയോ വയറിളക്കമോ, മൂത്രം പോകുന്നതിൽ കുറവ് അല്ലെങ്കിൽ മൂത്രത്തിന്റെ നിറവ്യത്യാസം. രക്തസമ്മർദ്ദം കുറയുയോ വർദ്ധിക്കുകയോ ചെയ്യുക. പൊതുവായോ കാലുകളിലും മുഖത്തുമോ ഉള്ള വീക്കം എന്നിവയുണ്ടായേക്കാം. ചിലപ്പോൾ രക്തസംക്രമണ പ്രതികരണങ്ങൾ ജീവനു ഭീഷണിയാകുന്ന നിലയിലുള്ളതോ മരണം സംഭവിക്കുന്നതോ ആകാം.

- രക്ത സ്വീകർത്താക്കളിൽ സാധാരണയുണ്ടാകുന്ന പ്രതികൂല പ്രതികരണങ്ങൾ എങ്ങിനെ കൈകാര്യം ചെയ്യും?

  രക്ത സ്വീകർത്താക്കളിൽ എതെങ്കിലും പ്രതികൂല പ്രതികരണങ്ങൾ രക്തസംക്രമണസമയത്തോ അതിനുശേഷമോ ഉണ്ടായാൽ രക്തസംക്രമണം ഉടൻ നിർത്തുകയും അനുയോജ്യമായ നടപടിക്രമമനുസരിച്ചുള്ള ചികിത്സ നൽകുകയും ചെയ്യും.

- ഈ പഠനം സ്വീകർത്താവിന് ദോഷകരമായ പ്രഭാവങ്ങൾ ഉണ്ടാക്കുമോ?

ഇല്ല. സ്വീകർത്താവിന് യാതോരുവിധ ദോഷകരമായ പ്രഭാവവും ഉണ്ടാക്കില്ല, ഇത് തികച്ചും സുരക്ഷിതമായ പഠനമാണ്.

- താങ്കൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നെങ്കിൽ എന്തുചെയ്യണം?

താങ്കൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നെങ്കിൽ താങ്കൾക്ക് കാര്യബോധത്തോടെയുള്ള സമ്മതത്തിനായുള്ള പത്രിക നൽകും, അതിൽ താങ്കൾ സ്വമേധയായാണ് പങ്കെടുക്കുന്നതെന്നും താങ്കൾക്ക് ഏതു സമയത്തും താങ്കളുടെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ പങ്കെടുക്കുന്നതിൽ നിന്നും പിൻമാറാമെന്നും പ്രസ്താവിക്കും. ഈ പങ്കാളികൾക്കുള്ള വിവരണപത്രികയും കാര്യബോധത്തോടെയുള്ള സമ്മതപത്രവും വായിച്ച് സൂചിതമായ സമ്മതത്തെപ്പറ്റി പൂർണ്ണമായി മനസ്സിലാക്കിയശേഷം താങ്കൾക്ക് സമ്മതപത്രത്തിൽ ഒപ്പിടാം.

സമ്മതപത്രം താങ്കൾ ഒപ്പിട്ടശേഷം ഈ പഠനത്തിൽ പങ്കാളിയാകാം.

- ഈ പഠനത്തിനുവേണ്ടി താങ്കൾക്കെന്തെങ്കിലും സാമ്പത്തിക ചിലവുണ്ടാകുമോ?

ഇല്ല. താങ്കൾക്കൊരു ചിലവും വഹിക്കേണ്ടിവരില്ല

- താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കപ്പെടുമോ?

ഈ പഠനത്തിന്റെ ഫലം ഒരു എം. ഡി. ട്രാൻഫ്യൂഷൻ മെഡിസിനുള്ള പ്രബന്ധം/വൈദ്യ ജർണലിൽ പ്രസിദ്ധീകരിക്കും. പക്ഷേ താങ്കളെ പേരുകൊണ്ട് പ്രസിദ്ധീകരണത്തിലോ ഫലങ്ങളുടെ

ഫലങ്ങളുടെ പ്രദർശനത്തിലോ തിരിച്ചറിയാനാവില്ല. എന്നിരുന്നാലും താങ്കളുടെ വൈദ്യ രേഖകൾ പഠനവുമായി ബന്ധപ്പെട്ടയാളുകൾ താങ്കളുടെ വിണ്ടുമുള്ള അനുവാദം കൂടാതെ വിലയിരുത്തും

താങ്കൾക്ക് കൂടുതലെന്തെങ്കിലും ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി **ഡോ. അനില മണിയോട്** ചോദിക്കുക. (ഫോൺ. 9656163779) dranilamani@gmail.com

അല്ലെങ്കിൽ

ഡോ. ദേബശീഷ് ഗുപ്ത (ഫോൺ. 9020120101)

പ്രധാന ഗവേഷകയുടെ പേര്. **ഡോ. അനില മണി**

മേൽവിലാസവും ബന്ധപ്പെടാനുള്ള വിവരങ്ങളും

ജൂനിയർ റസിഡന്റ്, ട്രാൻസ്ഫ്യൂഷൻ മെഡിസിൻ ഡിപ്പാർട്ട്മെന്റ്, SCTIMST തിരുവനന്തപുരം 695011,

ബന്ധപ്പെടാനുള്ള നമ്പർ 9656163779

പ്രധാന ഗവേഷകയുടെ ഒപ്പ്

തീയതി

സ്ഥലം

പഠനത്തിന്റെ നൈതീക അനുവാദസംബന്ധമായ എന്തെങ്കിലും വിശദീകരണമാവശ്യമെങ്കിൽ താങ്കൾക്ക് ബന്ധപ്പെടാവുന്നത് **ഡോ. മാല രാമനാഥൻ** (മെമ്പർ സെക്രട്ടറി, എത്തിക്സ് കമ്മിറ്റി SCTIMST, ഫോൺ. 04712524234. ഇമെയിൽ. iec.mem.sec@sctimst.ac.in

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum -695011

Department of Transfusion Medicine

Informed Consent Form

Participant's name:

Date of Birth / Age (in years):

I_____, declare that:

I/My patient have understood the information provided to me/us by the Investigator regarding the study "Hemovigilance: An analysis of adverse effects of blood donation among blood donors and transfusion reactions among recipients in a tertiary care centre".

- I/We have clarified any doubts that I had in mind regarding the proposed study.
- I/We also understand that participation in this study is entirely voluntary and that I/my patient am/is free to withdraw permission to continue to participate in this study at any time without affecting my usual treatment or my legal rights.
- I/We also understand that I/my patient will not have to bear any financial expenses for the study purpose.
- I/We understand that the study staff and Institutional Ethics Committee members will not need my permission to look at my health records even if I withdraw from the study. I agree to this access.
- I/We understand that my/our patient identity will not be revealed in any information released to third parties or medical publications.
- I/We voluntarily agree to take part in this study.
- I/We have been provided with the contact numbers of the principle investigator, in case I/We want to know more about the study and participants rights.
- I/We received a copy of this signed informed consent form.

Signature / Thumb impression
Of the Patient / Legally acceptable representative:
Name:
Date:

Name of witness:
Relation to participant:
Signature:
Date:

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked are answered.

Name and signature of person obtaining consent (For Principal Investigator)

Date:
Place:

Witness:

For any clarifications regarding the study's ethics clearance you may contact:

Dr. Mala Ramanathan, Member Secretary of the Institutional Ethics Committee-SCTIMST.
Phone number: **0471-2524234** and Email: **iec.mem.sec@sctimst.ac.in**

ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, തിരുവനന്തപുരം – 695011

ട്രാൻസ്ഫ്യൂഷൻ മെഡിസിൻ ഡിപ്പാർട്ട്മെന്റ്

കാര്യബോധത്തോടെയുള്ള സമ്മതപത്രം

പങ്കെടുക്കുന്നയാളുടെ പേര്

ജനനതീയതി/വയസ്സ്(വർഷത്തിൽ)

ഞാൻ..... പ്രസ്താവിക്കുന്നതെന്തെന്നാൽ

- രക്തദാന-രക്തസംക്രമണ സംബന്ധമായ ജാഗ്രത (ഹീമോവിജിലൻസ്)- ഒരു ത്രിതല ചികിത്സാകേന്ദ്രത്തിലെ, രക്തദാതാക്കളിലെ രക്തദാനത്തിന്റെയും സ്വീകർത്താക്കളുടെ രക്തസംക്രമണ പ്രതികരണങ്ങളുടെയും, പ്രതികൂല പ്രഭാവങ്ങളുടെ വിശകലനം എന്ന പഠനസംബന്ധിയായി ഗവേഷകർ എനിക്ക്/എന്റെ രോഗിക്ക് നൽകിയ വിവരങ്ങൾ മനസ്സിലാക്കി. [ ]
- എനിക്ക്/ഞങ്ങൾക്ക് പഠനസംബന്ധമായി ഉണ്ടായ സംശയങ്ങൾ പരിഹരിച്ചു [ ]
- എന്റെ/ഞങ്ങൾക്ക് ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയായാണെന്നും അനുവാദം എനിക്ക്/ ഞങ്ങൾക്ക് ഏതുസമയത്തും ചികിത്സയെയും നിയമപരമായ അവകാശങ്ങളെയും ബാധിക്കാതെ പിൻവലിക്കാൻ അവകാശമുണ്ടെന്നും മനസ്സിലാക്കുന്നു. [ ]
- പഠനാവശ്യത്തിനായി സാമ്പത്തിക ചിലവുകൾ എനിക്ക്/ഞങ്ങൾക്ക് ഉണ്ടാവില്ലെന്നും ഞാൻ/ഞങ്ങൾ മനസ്സിലാക്കുന്നു. [ ]
- ഞാൻ/ഞങ്ങൾ ഈ പഠനത്തിൽനിന്നും പിൻമാറിയാലും പഠനം നടത്തുന്നവർക്കും സ്ഥാപനത്തിലെ നൈതീകകമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ/എന്റെ രോഗിയുടെ ആരോഗ്യരേഖകൾ പരിശോധിക്കുന്നതിന് എന്റെ/ഞങ്ങളുടെ അനുവാദം ആവശ്യമില്ലെന്ന് ഞാൻ/ഞങ്ങൾ മനസ്സിലാക്കുന്നു. അതിനോട് ഞാൻ/ഞങ്ങൾ അതിനോട് യോജിക്കുന്നു. [ ]
- എന്നെ/എന്റെ രോഗിയെ തിരിച്ചറിയാനുതകുന്ന വിവരങ്ങൾ ഒന്നും മറ്റുള്ളവർക്ക് നൽകുകയോ പ്രസിദ്ധീകരിക്കുകയോ ചെയ്യില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
- ഞാൻ/ഞങ്ങൾ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു [ ]

- എനിക്ക്/ഞങ്ങൾക്ക് പഠനത്തെപ്പറ്റിയോ പങ്കാളിയുടെ അവകാശങ്ങളെപ്പറ്റിയോ കൂടുതൽ അറിയണമെങ്കിൽ പ്രധാനഗവേഷകയെ ബന്ധപ്പെടാനുള്ള നമ്പർ നൽകിയിട്ടുണ്ട്
- സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു കോപ്പി എനിക്ക്/എന്റെ രോഗിക്ക് കിട്ടി [ ]

പങ്കെടുക്കുന്നയാളുടെ/ നിയമപരമായി അംഗീകൃതമായ പ്രതിനിധിയുടെ ഒപ്പ് (തള്ളവിരലടയാളം)
.....തീയതി..... ഒപ്പിട്ടയാളുടെ പേര്.....

സാക്ഷിയുടെ ഒപ്പ്.....
പങ്കെടുക്കുന്നയാളുമായുള്ള ബന്ധം.....
തീയതി.....
സാക്ഷിയുടെ പേര് .....

(സമ്മതം വാങ്ങുന്നയാൾ)

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണപദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേരു്..... ഒപ്പും.....

പഠനത്തിന്റെ നൈതീക അനുവാദസംബന്ധമായ എന്തെങ്കിലും വിശദീകരണമാവശ്യമെങ്കിൽ താങ്കൾക്ക് ബന്ധപ്പെടാവുന്നത് ഡോ. മാല രാമനാഥൻ (മെമ്പർ സെക്രട്ടറി, എത്തിക്സ് കമ്മിറ്റി SCTIMST, ഫോൺ. 04712524234. ഇമെയിൽ. iec.mem.sec@sctimst.ac.in

Sl No :	Donor number:	Age	Gender	Weight	Estimated Blood Volume (ml)	Site of donation	Type of donor	Type of donation	Phase of reaction	Time duration					Time taken for recovery (min)	Volume of blood collected	Time taken for blood collection (min)	Onsite/call back by donor	Pre-pulse rate	Pre-SBP	Pre-DBP
										Date of donation	Time of donation	Time of reaction	Date of recovery	Time of recovery							
1	159929	21	M	78	5460	BC	repeat	WB	during	15-05-2018	11.40 am	11.45 am	15-05-2018	12.30 pm	45	450	5	Onsite	78	124	74
2	160016	29	M	58	4060	BC	repeat	WB	post	18-05-2018	10.01 am	10.20 am	18-05-2018	10.45 am	20	350	7	Onsite	90	110	60
3	160373	32	M	74	5180	BC	regular	WB	post	04-06-2018	12.35 pm	12.43 pm	04-06-2018	1.20 pm	20	350	2	Onsite	68	120	62
4	160375	32	M	74	5180	BC	repeat	WB	post	04-06-2018	1.30 pm	1.34 pm	04-06-2018	2.45 pm	90	350	3	Onsite	64	120	80
5	160644	54	M	86	6020	BC	regular	WB	post	14-06-2018	10.28 am	10.37 am	14-06-2018	11.30 am	25	350	4	Onsite	82	126	88
6	160644	50	M	77	5390	BC	regular	WB	during	14-06-2018	10.35 am	10.37 am	14-06-2018	11.30 am	30	150	2	Onsite	84	120	60
7	160940	21	F	63	4095	BC	repeat	WB	post	22-06-2018	11.40 am	11.50 am	22-06-2018	12.20 pm	20	350	7	Onsite	82	128	68
8	160949	19	M	66	4620	BC	First	WB	post	22-06-2018	12.40 pm	12.50 pm	22-06-2018	1.30 pm	20	350	6	Onsite	78	120	64
9	163142	21	F	55	3575	BC	First	WB	post	01-10-2018	9.30 am	10.35 am	01-10-2018	11.15 am	30	350	8	call back	74	110	70
10	169821	32	M	85	5950	BC	repeat	WB	post	02-11-2018	10.30 am	10.45 am	02-11-2018	11.15 am	20	450	5	Onsite	86	118	72
11	163869	37	F	52	3120	BC	repeat	WB	post	05-11-2018	3.45 pm	4.00 pm	05-11-2018	5.00 pm	40	350	5	Onsite	84	130	74
12	164347	36	F	70	4550	BC	repeat	WB	post	29-11-2018	11.40 am	11.50 am	29-11-2018	12.30 pm	20	350	5	Onsite	72	120	78
13	164306	27	M	87	6090	BC	repeat	WB	post	28-11-2018	11.10 am	11.15 am	28-11-2018	11.45 am	20	450	5	Onsite	72	122	76
14	164303	24	M	110	6600	BC	repeat	WB	post	28-11-2018	10.45 am	11.00 am	28-11-2018	11.30 am	30	350	6	Onsite	92	110	74
15	164404	30	M	80	5600	BC	repeat	WB	post	01-01-2019	8.50 am	9.00 am	01-01-2019	9.30 am	20	350	4	Onsite	98	108	80

16	165019	42	M	69	4830	BC	repeat	WB	post	05-01-2019	12.45 pm	12.55 pm	05-01-2019	4.00 pm	180	350	5 Onsite	72	120	70
17	165145	28	M	96	6720	BC	repeat	WB	post	14-01-2019	1.10 pm	1.20 pm	14-01-2019	2.00 pm	30	450	4 Onsite	84	118	80
18	165221	23	M	63	4410	BC	repeat	WB	post	15-01-2019	4.35 pm	4.47 pm	15-01-2019	5.20 pm	20	350	7 Onsite	86	110	70
19	165500	35	M	90	6300	BC	first	WB	post	28-01-2019	1.05 pm	1.22 pm	28-01-2019	2.05 pm	40	450	6 Onsite	90	110	70
20	167171	20	M	52	3380	BC	repeat	WB	post	29-04-2019	8.31 am	8.43 am	29-04-2019	9.30 am	20	350	4 Onsite	62	112	70
21	167172	22	M	82	5740	BC	first	WB	during	29-04-2019	8.35 am	8.40 am	29-04-2019	9.15 am	20	385	5 Onsite	66	114	70
22	169945	36	M	85	5950	BC	repeat	WB	post	23-09-2019	3.40 pm	3.48 pm	23-09-2019	4.30 pm	20	350	5 Onsite	72	116	68
23	159721	32	M	75	5250	camp	repeat	WB	post	03-05-2018	12.10 pm	12.25 pm	03-05-2018	1.00 pm	20	450	8 Onsite	78	120	64
24	159728	29	M	76	5320	camp	repeat	WB	post	03-05-2018	12.20 pm	12.35 pm	03-05-2018	1.10 pm	20	350	6 Onsite	88	128	62
25	159705	26	M	69	4830	mobile	repeat	WB	post	02-05-2018	1.00 pm	1.15 pm	02-05-2018	1.45 pm	20	450	7 Onsite	74	124	64
26	159995	25	M	74	5180	mobile	repeat	WB	post	17-05-2018	12.10 pm	12.14 pm	17-05-2018	1.00 pm	30	350	6 Onsite	86	112	64
27	160006	27	M	53	3710	mobile	first	WB	post	17-05-2018	12.50 pm	1.00 pm	17-05-2018	1.30 pm	20	350	7 Onsite	92	114	62
28	160014	24	M	63	4410	mobile	first	WB	post	17-05-2018	1.40 pm	1.50 pm	17-05-2018	2.15 pm	20	350	6 Onsite	94	118	72
29	160188	26	F	75	4875	camp	first	WB	post	24-05-2018	1.10 pm	2.00 pm	24-05-2018	2.45 pm	40	350	5 Call back	96	120	80
30	160174	31	M	94	6580	camp	first	WB	during	24-05-2018	12.45 pm	12.47 pm	24-05-2018	1.25 pm	20	150	2 Onsite	82	120	60
31	160163	24	M	68	4760	camp	first	WB	post	24-05-2018	12.30 pm	12.40 pm	24-05-2018	1.10 pm	20	350	7 Onsite	88	118	74
32	160216	28	F	65	4225	camp	first	WB	post	25-05-2018	12.15 pm	12.35 pm	25-05-2018	1.05 pm	20	350	8 Onsite	74	120	60
33	160255	24	M	58	4060	camp	first	WB	post	29-05-2018	11.15 am	11.25 am	29-05-2018	12.10 pm	20	350	4 Onsite	82	122	62
34	160340	26	M	60	4200	camp	first	WB	post	30-05-2018	1.00 pm	1.10 pm	30-05-2018	1.40 pm	20	350	4 Onsite	68	126	66

35	160453	26	M	65	4550	camp	repeat	WB	during	06-06-2018	1.30 pm	1.33 pm	06-06-2018	2.00 pm	20	350	3 Onsite	66	128	76
36	160681	26	F	56	3640	camp	first	WB	post	14-06-2018	10.45 am	10.55 am	14-06-2018	11.25 am	20	350	5 Onsite	68	118	60
37	160413	19	F	50	3000	mobile	first	WB	post	05-06-2018	1.00 pm	1.15 pm	05-06-2018	2.00 pm	20	350	5 Onsite	72	116	64
38	160411	28	M	69	4830	mobile	first	WB	post	05-06-2018	12.50 pm	1.05 pm	05-06-2018	1.30 pm	20	350	5 Onsite	74	112	62
39	160408	18	F	60	3900	mobile	first	WB	during	05-06-2018	12.30 pm	12.45 pm	05-06-2018	2.00 pm	30	350	5 Onsite	76	120	70
40	160393	19	F	48	2880	mobile	repeat	WB	post	05-06-2018	11.45 am	12.00 pm	05-06-2018	12.45 pm	45	350	7 Onsite	88	124	74
41	160387	20	F	50	3000	mobile	first	WB	post	05-06-2018	10.30 am	10.40 am	05-06-2018	11.15 am	20	350	5 Onsite	84	120	78
42	160889	32	M	104	6240	camp	repeat	WB	post	21-06-2018	10.30 am	10.45 am	21-06-2018	11.30 am	30	450	5 Onsite	92	114	72
43	161077	19	M	69	4830	camp	first	WB	post	29-06-2018	2.15 pm	2.25 pm	29-06-2018	3.00 pm	30	350	6 Onsite	98	128	74
44	161062	19	M	63	4410	camp	repeat	WB	post	29-06-2018	1.20 pm	1.30 pm	29-06-2018	2.00 pm	20	350	6 Onsite	94	124	76
45	161160	38	M	60	4200	camp	repeat	WB	post	04-07-2018	12.30 pm	12.43 pm	04-07-2018	1.35 pm	30	450	6 Onsite	88	126	76
46	161180	37	M	110	6600	camp	repeat	WB	during	05-07-2018	11.20 am	11.23 pm	05-07-2018	11.55 pm	30	200	3 Onsite	84	124	78
47	161184	32	M	103	6180	camp	repeat	WB	during	05-07-2018	11.45 am	11.41 am	05-07-2018	12.30 am	30	350	5 Onsite	86	128	72
48	161182	43	M	81	5670	camp	repeat	WB	during	05-07-2018	12.05 pm	12.07 pm	05-07-2018	1.00 pm	45	250	2 Onsite	88	122	76
49	161124	19	F	50	3000	mobile	first	WB	post	03-07-2018	12.35 pm	12.45 pm	03-07-2018	1.30 pm	30	350	6 Onsite	74	118	74
50	161134	44	M	90	6300	mobile	repeat	WB	post	04-07-2018	10.10 am	10.15 am	04-07-2018	10.45 am	20	350	9 Onsite	76	122	62
51	161204	29	M	70	4900	camp	repeat	WB	post	05-07-2018	10.40 am	10.50 am	05-07-2018	11.25 am	20	450	7 Onsite	82	128	68
52	161206	21	M	60	4200	camp	first	WB	post	06-07-2018	10.45 am	10.52 am	06-07-2018	11.30 am	20	350	6 Onsite	92	124	74

53	161238	22	M	76	5320	camp	first	WB	post	07-07-2018	11.25 am	11.35 am	07-07-2018	12.10 am	20	350	5 Onsite	80	112	76
54	161296	19	F	66	4290	mobile	first	WB	post	10-07-2018	1.18 pm	1.30 pm	10-07-2018	2.00 pm	20	350	5 Onsite	84	112	68
55	161297	19	F	55	3575	mobile	first	WB	post	10-07-2018	1.30 pm	1.34 pm	10-07-2018	2.00 pm	20	350	4 Onsite	86	114	62
56	161298	19	F	58	3770	mobile	first	WB	post	10-07-2018	1.30 pm	1.45 pm	10-07-2018	2.30 pm	30	350	5 Onsite	90	120	70
57	161353	21	M	83	5810	mobile	first	WB	post	13-07-2018	11.22 am	11.30 am	13-07-2018	12.00 pm	20	350	7 Onsite	82	120	72
58	161364	23	M	55	3850	mobile	first	WB	post	13-07-2018	12.30 pm	12.40 pm	13-07-2018	1.20 pm	20	350	5 Onsite	62	112	60
59	161466	23	M	85	5950	camp	repeat	WB	post	19-07-2018	11.40 am	11.48 am	19-07-2018	12.30 pm	20	350	5 Onsite	68	114	64
60	161469	34	F	66	4290	camp	repeat	WB	post	19-07-2018	11.55 am	12.02 pm	19-07-2018	12.30 pm	20	350	5 Onsite	72	114	70
61	161476	31	M	70	4900	camp	repeat	WB	post	19-07-2018	12.35 pm	12.55 pm	19-07-2018	1.30 pm	20	450	7 Onsite	70	120	70
62	161426	23	F	52	3120	camp	repeat	WB	post	18-07-2018	12.00 pm	12.10 pm	18-07-2018	1.00 pm	20	350	5 Onsite	74	122	68
63	161604	18	M	84	5880	camp	first	WB	post	24-07-2018	3.30 pm	3.36 pm	24-07-2018	4.10 pm	30	350	5 Onsite	76	102	70
64	161657	30	M	77	5390	camp	repeat	WB	post	26-07-2018	12.12 pm	12.20 pm	26-07-2018	1.00 pm	30	350	5 Onsite	80	110	68
65	161706	19	F	57	3705	camp	first	WB	post	26-07-2018	12.20 pm	12.30 pm	26-07-2018	1.00 pm	30	350	5 Onsite	82	114	70
66	161690	19	F	62	4030	camp	first	WB	post	27-07-2018	11.15 am	12.05 pm	27-07-2018	12.45 pm	30	350	6 Call back	86	118	62
67	161709	18	M	55	3850	camp	first	WB	post	27-07-2018	12.25 pm	12.45 pm	27-07-2018	1.00 pm	20	350	6 Onsite	84	114	64
68	161720	21	M	55	3850	camp	repeat	WB	post	27-07-2018	1.00 pm	1.10 pm	27-07-2018	1.50 pm	30	350	5 Onsite	68	108	60
69	161758	21	M	80	5600	camp	repeat	WB	post	31-07-2018	12.45 pm	12.55 pm	31-07-2018	1.30 pm	30	450	6 Onsite	70	112	62
70	161832	23	M	72	5040	camp	first	WB	post	02-08-2018	12.35 pm	12.45 pm	02-08-2018	1.20 pm	20	350	5 Onsite	60	114	64
71	161941	25	M	68	4760	mobile	first	WB	during	08-08-2018	11.20 am	11.23 am	08-08-2018	12.00 pm	20	250	3 Onsite	62	104	60
72	161963	28	M	65	4550	camp	first	WB	post	08-08-2018	12.35 pm	12.45 pm	08-08-2018	1.15 pm	20	350	5 Onsite	66	108	62
73	161971	30	M	60	4200	camp	first	WB	post	08-08-2018	1.05 pm	1.15 pm	08-08-2018	2.00 pm	30	350	5 Onsite	88	110	64

74	161989	22 M	83	5810	mobile	repeat	WB	post	10-08-2018	10.35 am	11.10 am	10-08-2018	12.00 pm	30	450	6 Onsite	86	128	68
75	162028	25 F	47	2820	mobile	first	WB	post	13-08-2018	12.05 am	12.22 am	13-08-2018	1.00 pm	20	350	8 Onsite	90	124	66
76	162074	19 M	55	3850	camp	first	WB	post	14-08-2018	11.45 am	11.55 am	14-08-2018	12.30 pm	20	350	5 Onsite	92	110	66
77	162079	18 M	78	5460	camp	first	WB	post	14-08-2018	12.15 pm	12.30 pm	14-08-2018	1.00 pm	20	350	7 Onsite	80	112	66
78	162157	25 F	60	3900	mobile	repeat	WB	post	17-08-2018	12.30 pm	12.40 pm	17-08-2018	1.15 pm	20	350	5 Onsite	82	108	62
79	162152	28 M	70	4900	mobile	repeat	WB	post	17-08-2018	12.15 pm	12.22 pm	17-08-2018	1.10 pm	20	450	6 Onsite	80	104	64
80	162120	25 M	55	3850	mobile	repeat	WB	post	17-08-2018	10.30 am	10.38 am	17-08-2018	11.10 am	20	350	6 Onsite	70	112	68
81	162196	28 M	95	6650	camp	repeat	WB	post	20-08-2018	12.35 pm	12.38 pm	20-08-2018	1.05 pm	20	350	3 Onsite	72	120	70
82	162208	22 M	75	5250	camp	repeat	WB	post	21-08-2018	10.05 am	10.15 am	21-08-2018	10.55 am	20	450	5 Onsite	80	122	70
83	162243	25 M	81	5670	camp	first	WB	post	21-08-2018	12.10 pm	12.18 pm	21-08-2018	1.00 pm	20	350	5 Onsite	82	124	72
84	162255	32 M	73	5110	camp	repeat	WB	post	21-08-2018	1.00 pm	1.10 pm	21-08-2018	2.00 pm	20	450	5 Onsite	86	120	80
85	162266	27 M	77	5390	camp	repeat	WB	post	21-08-2018	10.02 pm	10.10 pm	21-08-2018	11.00 pm	20	350	5 Onsite	66	122	82
86	162288	19 M	56	3920	camp	first	WB	post	24-08-2018	12.10 pm	12.12 pm	24-08-2018	1.00 pm	30	350	2 Onsite	68	114	68
87	162300	28 M	70	4900	camp	first	WB	post	29-08-2018	10.35 am	10.45 am	29-08-2018	11.15 am	30	350	7 Onsite	80	116	64
88	162310	24 M	64	4480	camp	first	WB	post	29-08-2018	11.30 am	11.30 am	29-08-2018	12.00 pm	30	350	5 Onsite	82	120	80
89	162345	24 M	70	4900	camp	repeat	WB	post	30-08-2018	10.57 am	11.10 am	30-08-2018	12.00 pm	30	450	5 Onsite	86	124	82
90	162388	24 M	77	5390	mobile	repeat	WB	post	01-09-2018	11.35 am	11.50 am	01-09-2018	12.30 pm	20	350	7 Onsite	72	116	84
91	162374	25 M	76	5320	mobile	repeat	WB	post	01-09-2018	10.30 am	10.47 am	01-09-2018	11.30 am	25	450	6 Onsite	74	118	68
92	162449	21 M	60	4200	camp	first	WB	post	04-09-2018	12.40 pm	1.00 pm	04-09-2018	1.30 pm	20	350	5 Onsite	82	124	72
93	162432	23 M	88	6160	camp	repeat	WB	post	04-09-2018	11.15 am	11.30 am	04-09-2018	12.00 pm	20	450	5 Onsite	84	128	80
94	162470	27 M	65	4550	camp	first	WB	post	05-09-2018	11.00 am	11.07 am	05-09-2018	11.35 am	20	350	6 Onsite	98	114	66
95	162558	19 F	55	3575	camp	first	WB	post	07-09-2018	12.30 pm	12.37 pm	07-06-2018	1.05 pm	20	350	5 Onsite	96	116	64
96	162550	19 F	60	3900	camp	repeat	WB	post	07-09-2018	11.45 am	12.00 pm	07-09-2018	12.30 pm	20	350	5 Onsite	84	118	62
97	162548	20 F	60	3900	camp	repeat	WB	post	07-09-2018	11.40 am	11.45 am	07-09-2018	12.30 pm	20	350	5 Onsite	66	118	66

98	162547	19	F	57	3705	camp	first	WB	post	07-09-2018	11.35 am	11.45 am	07-09-2018	12.30 pm	20	350	6 Onsite	64	120	80
99	162546	19	F	50	3000	camp	first	WB	post	07-09-2018	11.40 am	12.10 pm	07-09-2018	1.00 pm	30	350	8 Onsite	60	122	82
100	162628	26	F	54	3240	camp	first	WB	post	12-09-2018	11.00 am	11.40 am	07-09-2018	12.20 pm	20	350	6 Onsite	66	124	84
101	162682	19	M	74	5180	camp	first	WB	post	13-09-2018	11.45 am	11.56 am	13-09-2018	12.30 pm	20	350	5 Onsite	64	110	68
102	162681	19	M	78	5460	camp	first	WB	post	13-09-2018	11.40 am	11.50 am	13-09-2018	12.30 pm	20	350	5 Onsite	66	114	68
103	162674	19	M	84	5880	camp	first	WB	post	13-09-2018	11.05 am	11.11 am	13-09-2018	1.30 pm	90	350	5 Onsite	72	116	66
104	162670	20	M	95	6650	camp	first	WB	post	13-09-2018	10.40 am	10.50 am	13-09-2018	11.30 am	20	350	6 Onsite	74	106	64
105	162669	19	F	55	3575	camp	first	WB	post	13-09-2018	10.50 am	10.57 am	13-09-2018	11.30 am	20	350	5 Onsite	70	110	68
106	162695	18	F	51	3060	camp	first	WB	post	13-09-2018	12.45 pm	12.51 pm	13-09-2018	1.30 pm	20	350	5 Onsite	80	120	68
107	162697	18	F	55	3575	camp	first	WB	post	13-09-2018	1.00 pm	1.10 pm	13-09-2018	2.00 pm	20	350	6 Onsite	84	120	70
108	162764	22	M	55	3850	camp	first	WB	post	13-09-2018	1.48 pm	2.05 pm	13-09-2018	2.35 pm	25	350	5 Onsite	82	124	74
109	162711	20	M	55	3850	camp	repeat	WB	post	14-09-2018	10.54 am	11.03 am	14-09-2018	11.35 am	20	350	6 Onsite	86	128	76
110	162823	26	M	65	4550	camp	first	WB	post	15-09-2018	1.30 pm	1.40 pm	15-09-2018	2.15 pm	20	350	7 Onsite	74	120	78
111	162780	32	M	76	5320	camp	first	WB	post	15-09-2018	10.50 am	10.58 am	15-09-2018	11.30 am	20	350	5 Onsite	76	122	80
112	162852	19	F	57	3705	mobile	first	WB	post	17-09-2018	12.35 pm	12.48 pm	17-09-2018	1.15 pm	20	350	7 Onsite	80	124	82
113	162840	20	F	65	4225	mobile	first	WB	post	17-09-2018	12.35 pm	12.47 pm	17-09-2018	1.40 pm	20	350	6 Onsite	88	128	84
114	163051	27	F	55	3575	camp	first	WB	post	26-09-2018	11.30 am	11.37 am	26-09-2018	12.10 pm	20	350	5 Onsite	80	122	86
115	162982	34	M	84	5880	camp	repeat	WB	post	25-09-2018	10.25 am	10.26 am	25-09-2018	11.00 am	20	350	5 Onsite	94	114	88
116	163198	20	M	65	4550	camp	first	WB	during	03-10-2018	12.15 pm	12.17 pm	03-10-2018	1.00 pm	30	350	2 Onsite	90	116	88
117	163420	23	M	70	4900	camp	repeat	WB	post	12-10-2018	12.45 pm	12.55 pm	12-10-2018	1.35 pm	20	350	5 Onsite	70	120	90
118	163271	27	M	64	4480	mobile	first	WB	post	06-10-2018	12.40 pm	12.50 pm	06-10-2018	1.35 pm	20	350	5 Onsite	74	120	88

119	163448	19	M	59	4130	camp	repeat	WB	post	15-10-2018	11.05 pm	11.30 pm	15-10-2018	12.00 pm	20	350	7 Onsite	76	122	86
120	163441	24	M	95	6650	camp	repeat	WB	post	15-10-2018	11.05 am	11.30 am	15-10-2018	12.00 pm	20	450	8 Onsite	82	114	70
121	163283	21	F	54	3510	mobile	first	WB	post	08-10-2018	10.50 am	10.57 am	08-10-2018	11.30 am	20	350	5 Onsite	74	116	66
122	163384	19	M	55	3850	mobile	repeat	WB	during	20-10-2018	12.45 pm	12.49 pm	20-10-2018	1.20 pm	20	200	4 Onsite	76	120	70
123	163587	25	M	85	5950	mobile	repeat	WB	during	20-10-2018	12.55pm	1.00 pm	20-10-2018	1.30 pm	20	200	5 Onsite	90	122	78
124	163612	41	M	81	5670	camp	regular	WB	post	21-10-2018	11.00 am	11.10 am	21-10-2018	11.45 am	20	450	5 Onsite	92	124	76
125	163628	20	M	60	4200	camp	regular	WB	during	23-10-2018	10.43 am	10.44 am	23-10-2018	11.15 am	20	50	1 Onsite	96	126	74
126	163633	20	F	75	4875	camp	first	WB	post	23-10-2018	11.05 am	11.11 am	23-10-2018	12.00 pm	20	350	5 Onsite	98	114	78
127	163647	21	F	68	4420	camp	first	WB	post	23-10-2018	12.10 pm	12.20 pm	23-10-2018	8.00 pm	480	350	5 Onsite	66	118	76
128	163649	20	F	48	2880	camp	first	WB	post	23-10-2018	12.30 pm	12.35 pm	23-10-2018	1.00 pm	20	350	5 Onsite	72	120	74
129	163673	28	M	87	6090	mobile	regular	WB	during	24-10-2018	11.30 am	11.31 am	24-10-2018	12.00 pm	20	350	1 Onsite	70	122	72
130	163690	30	M	72	5040	mobile	repeat	WB	post	24-10-2018	1.10 pm	1.17 am	24-10-2018	1.50 pm	20	350	4 Onsite	62	124	78
131	163709	40	F	71	4615	camp	regular	WB	post	26-10-2018	11.35 am	11.50 am	26-10-2018	12.35 pm	30	350	7 Onsite	72	110	80
132	163732	18	M	76	5320	camp	repeat	WB	post	29-10-2018	11.20 am	11.26 am	29-10-2018	12.00 pm	20	350	5 Onsite	76	112	70
133	163835	30	M	106	7420	camp	repeat	WB	during	01-11-2018	12.55 pm	12.56 pm	01-11-2018	1.30 pm	20	50	1 Onsite	80	116	60
134	163908	22	M	68	4760	camp	first	WB	post	08-11-2018	10.44 am	10.50 am	08-11-2018	11.30 am	20	350	6 Onsite	84	118	66
135	163883	19	M	50	3500	camp	first	WB	post	07-11-2018	12.15 pm	12.25 pm	07-11-2018	1.00 pm	20	350	6 Onsite	86	120	70
136	163887	19	M	63	4410	camp	first	WB	post	07-11-2018	12.13 pm	12.25 pm	07-11-2018	1.00 pm	20	350	5 Onsite	94	122	76
137	163887	19	M	54	3780	camp	first	WB	post	09-11-2018	12.58 pm	1.10 pm	09-11-2018	1.35 pm	20	350	5 Onsite	90	124	78

138	163955	35	M	85	5950	mobile	regular	WB	post	10-11-2018	10.35 am	10.45 am	10-11-2018	11.15 am	20	450	6 Onsite	82	114	74
139	163961	29	M	66	4620	mobile	first	WB	post	10-11-2018	12.15 pm	12.25 pm	10-11-2018	1.00 pm	20	350	5 Onsite	70	116	66
140	163968	24	M	62	4340	mobile	first	WB	during	10-11-2018	12.40 pm	12.50 pm	10-11-2018	1.20 pm	20	350	4 Onsite	74	118	68
141	163994	23	M	84	5880	camp	first	WB	post	12-11-2018	12.05 pm	12.15 pm	12-11-2018	12.50 pm	20	350	6 Onsite	74	120	80
142	163989	26	F	57	3705	camp	first	WB	post	12-11-2018	12.00 pm	12.15 pm	12-11-2018	12.45 pm	20	350	4 Onsite	72	124	68
143	163971	22	M	68	4760	camp	first	WB	post	12-11-2018	10.25 am	10.32 am	12-11-2018	10.45 am	20	350	4 Onsite	80	122	66
144	164009	22	M	73	5110	camp	first	WB	post	13-11-2018	10.15 am	10.28 am	13-11-2018	11.00 am	20	350	4 Onsite	80	120	72
145	164080	20	M	82	5740	camp	repeat	WB	post	16-11-2018	12.15 pm	12.25 pm	16-11-2018	1.00 pm	20	350	5 Onsite	72	124	76
146	164077	18	F	47	2820	camp	repeat	WB	post	16-11-2018	12.00 pm	12.15 pm	16-11-2018	12.45 pm	20	350	6 Onsite	84	116	78
147	164071	19	F	50	3000	camp	first	WB	post	16-11-2018	10.30 am	10.40 am	16-11-2018	11.10 am	20	350	5 Onsite	86	128	88
148	164066	20	F	63	4095	camp	first	WB	post	16-11-2018	11.00 am	11.19 am	16-11-2018	11.50 am	20	350	6 Onsite	88	120	88
149	164153	19	F	54	3510	camp	first	WB	post	21-11-2018	10.15 am	10.26 am	21-11-2018	11.00 pm	20	350	6 Onsite	94	120	80
150	164156	19	F	48	2880	camp	first	WB	post	21-11-2018	10.25 am	10.30 am	21-11-2018	11.00 pm	20	350	5 Onsite	88	122	86
151	164167	18	F	55	3300	camp	first	WB	post	21-11-2018	11.15 am	11.25 am	21-11-2018	12.00 pm	20	350	6 Onsite	64	120	84
152	164171	18	F	76	4560	camp	first	WB	post	21-11-2018	11.25 am	11.35 am	21-11-2018	12.00 pm	20	350	5 Onsite	68	122	82
153	164306	27	F	87	5220	mobile	repeat	WB	post	28-11-2018	11.00 am	11.15 am	28-11-2018	11.45 am	20	450	7 Onsite	94	110	78
154	164303	24	M	110	6600	mobile	repeat	WB	during	28-11-2018	10.45 am	10.48 am	28-11-2018	11.30 am	20	250	3 Onsite	96	112	76
155	164347	36	M	70	4200	camp	first	WB	post	29-11-2018	11.40 am	11.45 am	29-11-2018	12.15 pm	20	350	5 Onsite	84	114	76
156	164387	30	M	80	4800	camp	repeat	WB	post	01-12-2018	8.50 am	8.56 am	01-12-2018	9.20 am	20	350	5 Onsite	80	120	78
157	164465	25	F	75	4500	camp	repeat	WB	post	04-12-2018	11.30 am	11.35 am	04-12-2018	12.00 pm	20	350	4 Onsite	80	122	66
158	164471	22	M	60	3600	camp	repeat	WB	during	04-12-2018	11.40 am	11.42 am	04-12-2018	12.15 pm	20	150	2 Onsite	82	110	78
159	164476	20	M	75	4500	camp	first	WB	post	04-12-2018	12.20 pm	12.26 pm	04-12-2018	1.00 pm	20	350	5 Onsite	86	114	64
160	164478	23	M	79	4740	camp	repeat	WB	post	04-12-2018	12.50 pm	12.56 pm	04-12-2018	1.30 pm	20	350	5 Onsite	88	114	66

161	164479	21	F	70	4200	camp	repeat	WB	post	04-12-2018 1.05 pm	1.15 pm	04-12-2018 1.45 pm	20	350	6 Onsite	90	120	80
162	164480	28	M	61	3660	camp	repeat	WB	post	04-12-2018 1.10 pm	1.16 pm	04-12-2018 1.45 pm	20	350	5 Onsite	92	120	82
163	164481	21	F	60	3600	camp	repeat	WB	post	04-12-2018 1.20 pm	1.27 pm	04-12-2018 2.00 pm	20	350	6 Onsite	94	124	84
164	164448	23	M	63	3780	camp	first	WB	post	03-12-2018 12.10 pm	12.20 pm	03-12-2018 1.00 pm	20	350	7 Onsite	70	112	66
165	164568	28	M	60	3600	camp	repeat	WB	post	07-12-2018 11.15 am	11.22 am	07-12-2018 12.00 pm	20	350	5 Onsite	76	110	68
166	164578	42	M	81	4860	camp	regular	WB	post	07-12-2018 12.40 pm	12.47 pm	07-12-2018 1.20 pm	20	350	6 Onsite	74	120	80
167	164627	19	F	55	3300	camp	repeat	WB	post	10-12-2018 12.40 pm	12.55 pm	10-12-2018 1.30 pm	20	350	5 Onsite	62	122	84
168	164607	18	M	66	3960	camp	first	WB	post	10-12-2018 11.00 am	11.10 am	10-12-2018 12.00 pm	20	350	7 Onsite	60	106	66
169	164700	26	M	60	3600	camp	repeat	WB	post	13-12-2018 12.20 pm	12.25 pm	13-12-2018 1.00 pm	20	350	4 Onsite	64	114	88
170	164777	19	F	72	4320	camp	first	WB	post	19-12-2018 3.00 pm	3.10 pm	19-12-2019 3.45 pm	20	350	5 Onsite	66	108	66
171	164747	19	F	76	4560	camp	first	WB	post	20-12-2018 11.35 am	11.45 am	20-12-2018 12.15 pm	20	350	6 Onsite	60	116	68
172	164835	22	M	68	4080	camp	repeat	WB	post	26-12-2018 12.02 pm	12.10 pm	26-12-2018 1.00 pm	20	350	5 Onsite	62	112	86
173	164885	18	M	64	3840	camp	first	WB	post	28-12-2018 10.35 am	10.44 am	28-12-2018 11.15 am	20	350	5 Onsite	64	120	86
174	164887	19	M	64	3840	camp	first	WB	post	28-12-2018 10.40 am	10.50 am	28-12-2018 11.30 am	20	350	5 Onsite	80	124	88
175	164915	19	M	62	3720	camp	first	WB	post	28-12-2018 1.00 pm	1.10 pm	28-12-2018 1.40 pm	20	350	6 Onsite	82	118	66
176	164996	48	M	60	3600	camp	regular	WB	post	04-01-2019 11.55 am	11.59 am	04-01-2019 12.30 pm	20	350	5 Onsite	80	120	80
177	165023	20	M	62	3720	camp	repeat	WB	post	05-01-2019 12.12 pm	12.22 pm	05-01-2019 1.00 pm	20	350	7 Onsite	86	120	84
178	165069	24	M	65	3900	camp	regular	WB	post	09-01-2019 1.05 pm	1.17 pm	09-01-2019 2.00 pm	20	350	8 Onsite	84	124	80
179	165072	21	M	59	3540	camp	first	WB	during	09-01-2019 1.25 pm	1.27 pm	09-01-2019 2.00 pm	20	150	2 Onsite	90	120	86
180	165138	28	M	62	3720	camp	first	WB	during	11-01-2019 11.10 am	11.13 am	11-01-2019 12.00 pm	20	200	3 Onsite	92	118	60
181	165200	22	M	73	4380	camp	repeat	WB	post	15-01-2019 12.00 pm	12.07 pm	15-01-2019 12.30 pm	20	450	5 Onsite	80	118	66

182	165177	20	M	63	3780	camp	repeat	WB	post	14-01-2019	1.15 pm	1.22 pm	14-01-2019	1.45 pm	20	350	6 Onsite	66	110	64
183	165263	18	M	60	3600	camp	first	WB	post	18-01-2019	11.00 am	11.08 am	18-01-2018	11.35 am	20	350	4 Onsite	60	120	80
184	165278	19	M	63	3780	camp	first	WB	post	18-01-2018	12.15 pm	12.22 pm	18-01-2018	12.50 pm	20	350	7 Onsite	62	120	82
185	165286	18	M	53	3445	camp	first	WB	during	18-01-2019	12.50 pm	12.54 pm	18-01-2019	1.20 pm	20	330	5 Onsite	64	120	82
186	165308	25	M	72	5040	camp	repeat	WB	during	21-01-2019	11.10 am	11.17 am	21-01-2019	11.50 am	35	450	7 Onsite	66	124	84
187	165358	29	M	79	5530	camp	repeat	WB	post	22-01-2019	11.00 am	11.07 am	22-01-2019	11.35 am	20	350	5 Onsite	68	126	80
188	165363	22	F	54	3240	camp	first	WB	post	22-01-2019	11.00 am	11.09 am	22-01-2019	11.35 am	20	350	6 Onsite	72	110	64
189	165391	30	M	81	5670	camp	regular	WB	post	22-01-2019	2.35 pm	2.43 pm	22-01-2018	3.10 pm	20	350	5 Onsite	74	112	66
190	165406	20	M	70	4900	camp	repeat	WB	post	23-01-2019	11.40 am	11.46 am	23-01-2019	12.30 pm	30	450	6 Onsite	76	118	68
191	165328	24	M	66	4620	camp	repeat	WB	post	19-01-2019	12.40 pm	12.44 pm nxt day	25-01-2019	9.00 am	6 days	350	6 Call back over phone	80	126	80
192	165468	22	M	53	3445	camp	repeat	WB	post	25-01-2019	11.50 am	11.57 am	25-01-2019	12.30 pm	20	350	5 Onsite	84	120	66
193	165477	21	M	70	4900	camp	first	WB	post	25-01-2019	12.30 pm	12.32 pm	25-01-2019	1.00 pm	20	100	2 Onsite	86	122	82
194	165523	26	M	80	5600	camp	first	WB	post	29-01-2019	12.15 pm	12.25 pm	29-01-2019	1.00 pm	20	350	6 Onsite	88	124	84
195	165545	21	M	60	4200	camp	repeat	WB	post	30-01-2019	11.45 am	11.55 am	30-01-2019	12.25 pm	20	350	5 Onsite	90	120	86
196	165571	25	M	75	5250	camp	first	WB	post	31-01-2019	10.15 am	10.25 am	31-01-2019	11.00 am	20	450	6 Onsite	84	114	60
197	165674	27	M	75	5250	camp	repeat	WB	post	04-02-2019	1.15 pm	1.20 pm	04-02-2019	2.00 pm	20	450	5 Onsite	82	116	66
198	165670	27	M	89	6230	camp	first	WB	post	04-02-2019	12.45 pm	12.55 pm	04-02-2019	1.25 pm	20	450	7 Onsite	80	110	64
199	165659	21	M	58	4060	camp	first	WB	during	04-02-2019	12.05 pm	12.08 pm	04-02-2019	1.00 pm	20	350	3 Onsite	90	114	62

200	165656	26	M	55	3575	camp	first	WB	during	04-02-2019	11.45 am	11.50 am	04-02-2019	1.00 pm	45	350	5 Onsite	84	120	80
201	165645	21	M	50	3250	camp	repeat	WB	post	04-02-2019	11.10 am	11.20 am	04-02-2019	11.50 am	20	450	6 Onsite	76	122	82
202	165773	18	M	53	3445	camp	first	WB	during	08-02-2019	1.20 pm	1.24 pm	08-02-2018	2.00 pm	20	350	4 Onsite	94	116	68
203	165823	19	M	50	3250	camp	first	WB	post	12-02-2019	12.40 pm	12.50 pm	12-02-2019	1.30 pm	20	350	5 Onsite	74	110	66
204	165820	24	M	63	4410	camp	repeat	WB	post	12-02-2019	12.25 pm	12.40 pm	12-02-2019	1.20 pm	30	350	6 Onsite	78	112	60
205	165808	25	M	94	6580	camp	regular	WB	during	12-02-2019	11.10 am	11.12 am	12-02-2019	11.40 am	20	100	2 Onsite	64	106	64
206	165805	22	F	51	3060	camp	repeat	WB	post	12-02-2019	10.40 am	10.50 am	12-02-2019	11.30 am	20	350	5 Onsite	74	120	80
207	166040	18	M	70	4900	camp	first	WB	post	22-02-2019	11.40 am	11.54 am	22-02-2019	12.30 pm	20	350	5 Onsite	68	122	80
208	165905	34	M	85	5950	camp	repeat	WB	post	15-02-2019	10.10 am	10.24 am	15-02-2019	12.00 pm	120	450	7 Onsite	90	116	62
209	165967	22	M	75	5250	camp	first	WB	post	19-02-2019	11.00 am	11.18 am	19-02-2019	12.00 pm	20	450	5 Onsite	68	118	64
210	165977	23	M	100	6000	camp	first	WB	post	19-02-2019	12.00 pm	12.06 pm	19-02-2019	12.30 pm	20	400	6 Onsite	64	120	80
211	166057	40	M	78	5460	camp	repeat	WB	post	26-02-2019	10.40 am	10.47 am	26-02-2019	11.20 am	20	450	6 Onsite	88	122	84
212	166065	19	M	68	4760	camp	regular	WB	post	26-02-2019	11.15 am	11.27 am	26-02-2019	12.00 pm	20	450	6 Onsite	84	118	68
213	166076	19	M	50	3250	camp	repeat	WB	post	26-02-2019	12.05 pm	12.10 am	26-02-2019	12.40 pm	20	350	5 Onsite	82	120	80
214	166177	25	M	62	4340	camp	repeat	WB	post	05-03-2019	11.15 am	11.20 am	05-03-2019	11.45 am	20	350	5 Onsite	64	122	80
215	166166	23	M	63	4410	camp	regular	WB	post	05-03-2019	10.40 am	10.50 am	05-03-2019	11.20 am	20	350	5 Onsite	62	120	80
216	166267	33	F	65	4225	camp	first	WB	post	08-03-2019	10.45 am	10.51 am	08-03-2019	11.25 am	20	350	6 Onsite	66	118	60

217	166296	38	F	73	4745	camp	first	WB	post	08-03-2019	10.45 am	11.01 am	08-03-2019	11.30 am	20	350	7 Onsite	62	116	66
218	166435	21	M	65	4550	camp	first	WB	post	15-03-2019	1.00 pm	1.10 pm	15-03-2019	1.50 pm	20	350	4 Onsite	64	120	80
219	166414	21	M	60	4200	camp	first	WB	post	15-03-2019	11.10 am	11.20 pm	15-03-2019	12.00 pm	20	350	5 Onsite	72	122	82
220	166411	28	M	59	4130	camp	first	WB	post	15-03-2019	10.50 am	11.10 am	15-03-2019	12.00 pm	20	350	6 Onsite	76	114	60
221	166474	30	M	90	6300	camp	regular	WB	post	19-03-2019	11.58 am	12.13 pm	19-03-2019	12.38 pm	20	350	5 Onsite	78	116	66
222	166461	50	F	67	4355	camp	repeat	WB	post	19-03-2019	10.45 am	10.56 am	19-03-2019	11.30 am	20	350	5 Onsite	62	120	82
223	166530	26	M	66	4620	camp	regular	WB	post	20-03-2019	12.10 pm	12.20 pm	20-03-2019	12.45 pm	20	350	6 Onsite	64	122	68
224	166630	19	M	56	3920	camp	first	WB	post	23-03-2019	12.36 pm	12.50 pm	23-03-2019	1.20 pm	20	350	7 Onsite	66	110	60
225	166693	27	M	107	6420	camp	first	WB	post	28-03-2019	11.35 am	11.45 pm	23-03-2019	12.15 am	20	350	5 Onsite	68	122	76
226	166780	29	M	85	5950	camp	first	WB	post	25-03-2019	2.30 pm	2.37 pm	25-03-2019	3.10 pm	20	350	5 Onsite	76	118	66
227	166840	24	M	70	4900	camp	first	WB	post	03-04-2019	12.30 pm	12.40 pm	03-04-2019	1.15 pm	20	450	6 Onsite	78	114	68
228	166843	22	M	70	4900	camp	first	WB	post	03-04-2019	12.50 pm	1.03 pm	03-04-2019	1.30 pm	20	450	5 Onsite	80	120	80
229	166856	20	M	72	5040	camp	first	WB	post	03-04-2019	2.25 pm	2.32 pm	03-04-2019	3.00 pm	20	350	5 Onsite	82	120	80
230	166864	19	M	52	3640	camp	first	WB	post	03-04-2019	3.00 pm	3.10 pm	03-02-2019	3.45 pm	20	350	5 Onsite	84	120	80
231	166903	35	M	71	4970	camp	repeat	WB	post	04-04-2019	2.30 pm	2.37 pm	04-04-2019	3.05 pm	20	350	5 Onsite	86	114	68
232	166895	24	F	60	3900	camp	first	WB	post	04-04-2019	12.40 pm	12.50 pm	04-04-2019	1.20 pm	20	350	6 Onsite	60	116	62
233	166995	22	F	80	5200	camp	regular	WB	post	11-04-2019	12.40 pm	12.50 pm	11-04-2019	1.20 pm	20	350	6 Onsite	68	116	64
234	167002	26	F	53	3180	camp	repeat	WB	post	11-04-2019	2.35 pm	2.47 pm	11-04-2019	3.30 pm	20	350	6 Onsite	64	112	66
235	167126	28	M	70	4900	camp	repeat	WB	post	25-04-2019	12.28 pm	12.35 pm	25-04-2019	1.00 pm	40	350	6 Onsite	66	110	60
236	167119	22	M	58	4060	camp	repeat	WB	post	25-04-2019	11.25 am	11.37 am	25-04-2019	12.10 pm	20	350	7 Onsite	84	116	62
237	167201	22	M	68	4760	camp	first	WB	post	29-04-2019	12.18 pm	12.25 pm	29-04-2019	1.00 pm	20	350	6 Onsite	90	120	80

238	167246	32	M	68	4760	camp	repeat	WB	post	02-05-2019	10.59 am	11.07 am	02-05-2019	11.35 am	20	350	7 Onsite	92	122	82
239	167321	24	M	65	4550	camp	first	WB	during	04-05-2019	1.15 pm	1.16 pm	04-05-2019	1.45 pm	20	50	1 Onsite	60	116	66
240	167381	19	M	50	3250	camp	first	WB	post	07-05-2019	1.25 pm	1.40 pm	07-05-2019	2.05 pm	20	350	6 Onsite	64	118	68
241	167356	19	M	76	5320	camp	first	WB	post	07-05-2019	11.50 pm	12.05 pm	07-05-2019	12.30 pm	20	350	6 Onsite	62	112	64
242	167393	25	M	55	3850	camp	repeat	WB	post	08-05-2019	10.10 pm	10.17 pm	08-05-2019	10.45 pm	20	350	6 Onsite	72	116	66
243	167403	32	M	73	5110	camp	regular	WB	post	08-05-2019	10.45 am	10.55 am	08-05-2019	11.25 pm	20	350	7 Onsite	62	118	66
244	167407	22	F	49	2940	camp	first	WB	post	08-05-2019	10.55 am	11.05 am	08-05-2019	11.30 am	20	350	5 Onsite	78	120	80
245	167523	20	F	56	3640	camp	first	WB	post	14-05-2019	11.40 am	11.50 am	14-05-2019	12.20 pm	20	350	5 Onsite	80	122	80
246	167563	36	F	66	4290	camp	first	WB	post	16-05-2019	10.55 am	11.05 am	16-05-2019	11.30 am	20	350	5 Onsite	82	124	82
247	167583	27	M	72	5040	camp	regular	WB	post	16-05-2019	12.25 am	12.40 pm	16-05-2019	1.15 pm	20	350	7 Onsite	88	112	66
248	167755	34	F	53	3180	camp	repeat	WB	post	24-05-2019	10.53 am	11.05 am	24-05-2019	11.30 am	20	350	6 Onsite	60	116	68
249	167861	34	M	62	4340	camp	regular	WB	post	30-05-2019	10.55 am	11.15 am	30-05-2019	11.40 pm	20	350	4 Onsite	62	108	64
250	167897	21	M	86	6020	camp	repeat	WB	post	31-05-2019	10.35 am	10.45 am	31-05-2019	11.15 am	20	350	5 Onsite	78	120	80
251		23	M	64	4480	camp	first	WB	Pre								Onsite	90	118	68
252		20	F	53	3180	camp	first	WB	Pre								Onsite	94	120	70

WB - Whole Blood
BC - Blood Centre

Post-pulse rate	Post-SBP	Post-DBP	Diagnosis	Systemic/ Local reactions	Type of reaction	Diagnosis
82	110	60	LOC + seizure	Systemic	LOC with seizure < 60 sec giddiness and sweating	LOC + seizure
96	112	64	vasovagal reaction	Systemic	post donation	vasovagal reaction
72	118	60	Arterial puncture+ vasovagal reaction + hematoma	Local + Systemic	arterial puncture followed by giddines and hematoma	Arterial puncture+ vasovagal reaction + hematoma
72	122	78	Hypoglycemia	Systemic	immediately post donation donor developed generalised shivering	Hypoglycemia
86	124	82	Delayed bleeding	Local	prolonged oozing from puncture site	Delayed bleeding
88	120	60	hematoma	Local	hematoma over punctue site after start of donation	hematoma
86	120	64	vasovagal reaction	Systemic	giddiness and sweating post donation	vasovagal reaction
78	114	62	vasovagal reaction	Systemic	pallor giddiness and sweating post donation	vasovagal reaction
78	108	68	Delayed Vasovagal reaction	Systemic	giddiness and sweating post donation	Delayed Vasovagal reaction
88	114	70	vasovagal reaction	Systemic	giddiness and sweating post donation	vasovagal reaction
90	122	70	Delayed bleeding	Local	prolonged oozing from puncture site	Delayed bleeding
76	122	74	vasovagal reaction	Systemic	gidinness and pallor	vasovagal reaction
78	116	70	vasovagal reaction	Systemic	giddiness and sweating post donation	vasovagal reaction
94	108	72	vasovagal reaction	Systemic	giddiness and sweating post donation	vasovagal reaction
100	106	76	vasovagal reaction	Systemic	giddiness post donation	vasovagal reaction

74	120	64	Delayed bleeding	Local	developed prolonged oozing post donation which got controlled only after 3 hours	Delayed bleeding
86	116	74	Delayed bleeding	Local	developed prolonged oozing post donation for almost 30 minutes post donation	Delayed bleeding
88	110	64	hematoma	Local	developed small hematoma post donation	hematoma
94	104	62	LOC + Seizure	Systemic	developed dizziness followed by LOC < 60 sec and seizures.	LOC + Seizure
70	104	66	vasovagal reaction	Systemic	developed dizziness post donation	vasovagal reaction
72	110	72	vasovagal reaction	Systemic	developed dizziness during donation	vasovagal reaction
76	112	64	vasovagal reaction	Systemic	developed diziness post donation	vasovagal reaction
84	114	68	vasovagal reaction	Systemic	developed dizziness post donation	vasovagal reaction
92	126	64	Delayed bleeding	Local	developed prolonged oozing for more than 20 min post donation	Delayed bleeding
78	110	64	vasovagal reaction	Systemic	developed dizziness and sweating post donation	vasovagal reaction
88	106	68	LOC + Seizure	Systemic	post donation developed LOC and seizures lasting less than < 60 sec	LOC + Seizure
94	104	66	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
96	120	80	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
100	102	88	LOC + seizure - Delayed vasovagal reaction	Systemic	post donation donor left the donation site after refreshment after 30 minutes she developed nausea followed by LOC with seizures lasting < 60 sec.Reaction occcured outside blood collection facility	LOC + seizure - Delayed vasovagal reaction
86	110	64	vasovagal reaction	Systemic	developed dizziness and sweating after 2 min of start of donation.Stopped donation immediately	vasovagal reaction
92	112	88	vasovagal reaction	Systemic	developed pallor sweating and giddiness post donation	vasovagal reaction
78	118	66	vasovagal reaction	Systemic	developed reaction post 10 min of donation	vasovagal reaction
86	120	64	vasovagal reaction	Systemic	post 10 min donation developed reaction	vasovagal reaction
72	120	62	vasovagal reaction	Systemic	post donation 5 min developed reaction	vasovagal reaction

74	120	80	vasovagal reaction	Systemic	after 3 min of initiation of donation he developed pallor and fatigue.Immediately stopped donation	vasovagal reaction
70	110	66	vasovagal reaction	Systemic	5 min post donation he developed reaction	vasovagal reaction
74	120	68	vasovagal reaction	Systemic	post 10 min donation developed reaction	vasovagal reaction
76	116	70	vasovagal reaction	Systemic	post 10 min donation developed reaction	vasovagal reaction
80	122	80	hematoma	Local	first was failed phlebotomy on right hand and hematoma developed at puncture site and left side puncture was successful.	hematoma
94	128	82	hematoma	Local	developed hematoma at puncture site post donation	hematoma
96	124	84	vasovagal reaction	Systemic	developed giddiness and sweating post donation	vasovagal reaction
98	116	70	LOC + seizure	Systemic	10 min post donation he developed LOC with seizure < 60 sec	LOC + seizure
102	122	76	vasovagal reaction	Systemic	post 10 min donation developed reaction	vasovagal reaction
98	120	80	vasovagal reaction	Systemic	post 10 min donation developed reaction	vasovagal reaction
90	120	82	LOC	Systemic	immediately post donation he ddeveloped giddiness with LOC < 60 sec.	LOC
90	122	82	hematoma	Local	during donation developed hematoma over puncture site.Donation immediately stopped	hematoma
92	124	80	hematoma	Local	developed hematoma on right arm immediately after puncture.Hence punctured left side which was successful.	hematoma
94	126	80	hematoma	Local	initially puntured on right side centre vein,failed phlebotomy and hematoma developed.Then puntured on left side vein ,that also low flow.	hematoma
78	120	80	vasovagal reaction	Systemic	developed dizziness and sweating post donation	vasovagal reaction
78	124	60	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
84	120	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
94	118	82	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction

84	118	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
86	110	64	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
88	120	66	vasovagal reaction	Systemic	towards end of donation donor developed giddiness.Immediately donation stopped.	vasovagal reaction
94	122	80	Delayed bleeding	Local	prolonged oozing from punture site for more than 20 min post donation	Delayed bleeding
86	116	80	vasovagal reaction	Systemic	post donation developed reaction	vasovagal reaction
64	118	70	vasovagal reaction	Systemic	post donation developed reaction	vasovagal reaction
76	104	70	vasovagal reaction	Systemic	post donation developed reaction	vasovagal reaction
74	118	74	vasovagal reaction	Systemic	post donation developed reaction	vasovagal reaction
74	110	76	vasovagal reaction	Systemic	post donation developed reaction	vasovagal reaction
76	104	74	vasovagal reaction	Systemic	post donation developed reaction	vasovagal reaction
80	100	72	LOC	Systemic	immediately post donation developed LOC < 60 sec	LOC
86	104	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
84	108	72	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction
86	120	68	Delayed Vasovagal reaction	Systemic	40 min post donation donor developed giddiness and sweating.He donated and left camp site and developed reaction outside blood collection facility	Delayed Vasovagal reaction
88	112	66	hematoma	Local	developed hematoma at puncture site post donation	hematoma
72	112	62	hematoma	Local	first puncture on right arm failed and hematoma developed.Punture left arm and was successful	hematoma
76	104	68	vasovagal reaction	Systemic		vasovagal reaction
68	108	60	vasovagal reaction	Systemic	developed hematoma at puncture site post donation	vasovagal reaction
66	114	60	vasovagal reaction	Systemic	after 3 min of initiation of donation he developed pallor and dizziness.Immediately stopped donation	vasovagal reaction
72	112	62	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90	114	64	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction

90	108	66	LOC + seizure	Systemic	developed LOC < 60 sec with seizures after 30 min of donation	LOC + seizure
92	120	66	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
94	104	68	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
86	108	62	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
84	102	60	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
88	108	62	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
78	110	70	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
80	116	72	vasovagal reaction	Systemic	developed giddiness after 3 min of start of donation.Donation was discontinued immediately	vasovagal reaction
88	114	74	vasovagal reaction	Systemic	developed giddiness and sweating post donation	vasovagal reaction
86	108	72	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
90	110	78	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
72	120	80	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
74	106	64	LOC + seizure	Systemic	developed seizures lasting < 60 sec after 2 min of start of donation.Immediately donation discontinued.	LOC + seizure
82	118	62	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
86	124	70	Hematoma	Local	developed hematoma at puncture site post donation	Hematoma
88	110	78	LOC + seizure	Systemic	post donation giddinesss followed by LOC with seizures < 60 sec	LOC + seizure
80	100	80	vasovagal reaction	Systemic	developed giddiness and sweating post donation	vasovagal reaction
82	104	66	Delayed bleeding with hematoma	Local	prolonged oozing with hematoma over puncture site	Delayed bleeding with hematoma
84	116	70	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
88	120	70	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
104	104	68	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
102	112	62	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90	120	64	vasovagal reaction	Systemic	post donation developed pallor and giddiness	vasovagal reaction
74	116	66	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction

72	118	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
74	104	66	LOC	Systemic	post donation after 15 min she developed LOC < 60 sec in the refreshment area	LOC
68	120	78	hematoma followed by vasovagal reaction	Local + Systemic	developed rebleeding after 30 min of donation and seeing the bleed developed giddiness	hematoma followed by vasovagal reaction
70	112	64	vasovagal reaction	Systemic	developed giddiness and sweating post donation	vasovagal reaction
72	108	64	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction
78	100	62	LOC	Systemic	immediately post donation donor had mild dizziness.Relieved and was sitting in refreshment area.After 15 min of sitting in refreshment area he developed LOC< 60 sec.After that he was not able to get up due to continued dizziness.	LOC
80	102	62	vasovagal reaction	Systemic	developed giddiness post donation	vasovagal reaction
80	114	66	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
86	114	64	vasovagal reaction	Systemic	post donation developed dizziness and sweating	vasovagal reaction
88	116	68	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90	118	66	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
92	120	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
80	122	74	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
88	114	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
84	126	80	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90	110	74	LOC	Systemic	15 min post donation developed LOC < 60 sec	LOC
88	114	74	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
104	118	74	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
94	110	74	LOC	Systemic	after 2 min of start of donation ,donor developed LOC< 60 sec.Immediatley donation discontinued	LOC
74	114	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
78	112	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction

82	120	64	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
86	110	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
82	110	66	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
80	118	60	vasovagal reaction	Systemic	4 min of start of donation donor developed giddiness.Donation immediately stopped.	vasovagal reaction
96	120	64	vasovagal reaction	Systemic	developed giddiness after 5 minutes of start of donation	vasovagal reaction
98	118	60	hematoma	Local	developed hematoma over puncture site post donation	hematoma
100	120	70	vasovagal reaction	Systemic	developed sweating and light headedness	vasovagal reaction
102	112	64	vasovagal reaction	Systemic	developed giddiness immediately post donation	vasovagal reaction
74	116	60	vasovagal reaction	Systemic	post donation donor developed headache	vasovagal reaction
76	114	62	vasovagal reaction	Systemic	post donation donor developed giddiness	vasovagal reaction
80	124	70	hematoma	Local	first prick on one arm failed and hematoma developed.Hence,pricked on other arm which was successful	hematoma
78	120	70	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction
78	114	60	hematoma followed by vasovagal reaction	Local + Systemic	post donation donor developed hematoma over puncture site and after 5 minutes she developed sweating and lightheadedness	hematoma followed by vasovagal reaction
82	116	64	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
84	116	60	failed phlebotomy with bilateral hematoma	Local	initially punctured on right arm,phlebotomy failed and hematoma developed.Punctured on the left arm that also phlebotomy failed and hematoma formed.Both were side veins	failed phlebotomy with bilateral hematoma
88	122	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90	124	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
98	118	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
94	120	74	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction

88	118	68	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
78	118	62	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
78	122	62	hematoma	Local	first phlebotomy on right arm failed and hematoma formed.Hence,left arm punctured and successful phlebotomy.	hematoma
80	116	64	vasovagal reaction	Systemic	post donation developed pallor and giddiness	vasovagal reaction
88	116	62	vasovagal reaction	Systemic	post developed giddiness and sweating	vasovagal reaction
86	120	66	vasovagal reaction	Systemic	post developed giddiness and sweating	vasovagal reaction
86	124	70	vasovagal reaction	Systemic	post developed giddiness and sweating	vasovagal reaction
78	118	60	vasovagal reaction	Systemic	post developed giddiness and sweating	vasovagal reaction
88	112	62	vasovagal reaction	Systemic	post developed giddiness and sweating	vasovagal reaction
90	120	80	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
92	116	68	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
96	114	66	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90	114	70	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction
72	122	68	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction
74	124	70	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction
98	112	70	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction
100	104	68	vasovagal reaction	Systemic	3 minutes after start of donation developed giddiness.Needle immediately withdrawn.	vasovagal reaction
90	106	62	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
86	122	74	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
86	114	66	vasovagal reaction	Systemic	post developed giddiness and sweating	vasovagal reaction
84	104	64	LOC + seizure	Systemic	developed LOC with seizures < 60 sec after 2 minutes of start of donation	LOC + seizure
90	120	70	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
92	118	66	Delayed bleeding	Local	25 minutes post donation developed delayed bleeding while donor was tieing shoes.	Delayed bleeding

96	124	80	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
94	114	66	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
96	110	70	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
76	118	66	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
78	102	60	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
78	112	70	vasovagal reaction	Systemic	post donation developed giddiness and sweating after 15 min of donation	vasovagal reaction
72	108	62	LOC	Systemic	,donor developed giddiness and LOC < 60 sec	LOC
74	102	66	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
72	104	80	Hematoma	Local	post donation developed hematoma	Hematoma
70	118	62	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
68	120	70	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
78	120	82	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
70	124	80	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
82	114	64	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
88	116	66	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
88	122	80	LOC	Systemic	post donation developed giddiness and LOC < 60 sec	LOC
90	116	68	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
92	120	80	Delayed bleeding	Local	post donation developed prolonged bleeding for more than 20 minutes from the puncture site	Delayed bleeding
94	116	60	vasovagal reaction	Systemic	after 2 min of start of donation donor developed pallor and sweating with dizziness.Donation immediately stopped	vasovagal reaction
96	120	60	vasovagal reaction	Systemic	after 3 min of start of donation donor developed giddiness pallor and sweating	vasovagal reaction
88	122	66	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction

74	112	62	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
74	124	80	vasovagal reaction	Systemic	post donation developed giddiness and pallor	vasovagal reaction
74	114	64	vasovagal reaction	Systemic	post donation developed giddiness and pallor towards end of donation	vasovagal reaction
76	116	66	vasovagal reaction	Systemic	donor developed giddiness.Immediately donation stopped. towards end of donation	vasovagal reaction
72	120	84	vasovagal reaction	Systemic	donor developed giddiness.Immediately donation stopped.	vasovagal reaction
78	124	82	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
82	112	60	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
78	114	64	vasovagal reaction	Systemic	post donation developed giddiness and sweating towards end of donation	vasovagal reaction
84	120	68	LOC + seizure	Systemic	donor developed LOC with seizures < 60 sec.Donation immediately stopped.	LOC + seizure
84	120	80	thrombophlebitis	Local	one day post donation,donor developed thrombopblebitis at the puncture site.After donation, punture site was absolutely clean.	thrombophlebitis
86	122	66	vasovagal reaction	Systemic	post donation developed giddiness and sweating after 2 min of start of donation donor developed pallor and sweating with dizziness.Donation	vasovagal reaction
90	114	64	vasovagal reaction	Systemic	immediately stopped	vasovagal reaction
92	118	62	hematoma	Local	post donation developed hematoma	hematoma
94	112	66	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
88	118	60	hematoma	Local	post donation developed hematoma	hematoma
88	128	70	hematoma	Local	post donation developed hematoma	hematoma
84	112	62	vasovagal reaction	Systemic	post donation developed giddiness and sweating during donation donor developed	vasovagal reaction
94	108	66	hematoma	Local	hematoma.Needle withdrawn and donation stopped.	hematoma

88	102	62	LOC + seizure + hematoma	Local + Systemic	towards end of donation donor developed giddiness followed by LOC with seizures < 60 seconds.After 15 min again he developed giddiness followed by hematoma over puncture site.	LOC + seizure + hematoma
80	116	66	Hematoma	Local	post donation developed hematoma	Hematoma
102	102	60	LOC	Systemic	post donation developed LOC < 60 sec	LOC
80	112	62	hematoma	Local	post donation developed hematoma	hematoma
84	114	62	hematoma	Local	post donation developed hematoma	hematoma
74	108	62	hematoma	Local	during donation developed hematoma over puncture site.Donation immediately stopped	hematoma
78	118	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
84	120	70	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
94	108	66	LOC	Systemic	developed LOC< 60 sec post donation,afterwards he was not able to get up due to giddiness	LOC
72	110	62	vasovagal reaction	Systemic	poat donation developed giddiness and sweating	vasovagal reaction
70	116	64	vasovagal reaction	Systemic	towards end of donation donor developed giddiness	vasovagal reaction
92	120	84	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
90	112	62	LOC + seizure	Systemic	towards end of donation donor developed LOC with seizures < 60 sec.	LOC + seizure
88	120	80	hematoma	Local	post donation developed hematoma	hematoma
72	124	82	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
70	120	78	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
78	126	62	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction

74	122	66	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
74	124	80	vasovagal reaction	Systemic	post donation developed sweating and giddiness	vasovagal reaction
78	126	78	vasovagal reaction	Systemic	post donation developed giddiness and sweating	vasovagal reaction
84	120	64	LOC + headache	Systemic	post donation after 15 min he developed giddiness followed by LOC < 60 sec in the refreshment area.He was made to lie down and he developed nausea and continued giddiness.After sometime donor developed severe headache.	LOC + headache
82	110	64	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
72	112	66	hematoma	Local	post donation developed hematoma	hematoma
70	114	64	hematoma	Local	post donation developed hematoma	hematoma
72	118	64	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
78	102	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
82	112	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
84	108	62	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
86	114	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
88	110	74	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90	122	80	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
92	118	64	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
68	120	64	LOC	Systemic	post donation developed LOC < 60 sec	LOC
74	122	62	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
78	120	66	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
70	116	62	LOC	Systemic	post donation developed LOC < 60 sec	LOC
88	118	62	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
94	118	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction

96	116	64	vasovagal reaction	Systemic	post donation developed giddiness	vasoval reaction
70	112	62	vasovagal reaction	Systemic	Donor had failed phlebotomy ,following which immediately he developed giddiness and sweating.	vasovagal reaction
68	120	70	vasovagal reaction	Systemic	post donation donor developed giddiness	vasovagal reaction
64	118	66	vasovagal reaction	Systemic	post donation donor developed giddiness	vasovagal reaction
78	120	70	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
68	126	68	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
80	128	80	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
86	126	80	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
84	122	82	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90	108	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
72	104	62	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
68	112	64	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
80	116	60	vasovagal reaction	Systemic	post donation developed giddiness	vasovagal reaction
90			vasovagal reaction	Systemic	post Hemoglobin prick fainting	vasovagal reaction
94			vasovagal reaction	Systemic	post Hemoglobin prick fainting	vasovagal reaction

Comment	Whether more than one reaction at a time	No of venipunctures attempted	Phebotomy site	Whether both arms punctured	Time of last meal (hours)	Hours of sleep (hours)	Comment	H/o previous reaction	No: of previous reactions	Type of previous reaction	H/o any regular medications	Recovery phase	Imputability
after 5 minutes of start of donation donor developed reaction.Donation stopped and immediately needle withdrawn	no	1	centre	no	4	3	initially told 6 hours sleep ,later after reaction only revealed 3 hours	no	nil	nil	no	Fully recovered	definite
10 min post donation developed reaction	no	1	centre	no	4	7		no	nil	nil	no	Fully recovered	definite
donor had a rapid collection of 350 ml blood in 2 min,bright red colored.	yes	1	centre	no	3	8	Phlebotomist was newly recruited staff.	no	nil	nil	no	Fully recovered	definite
donor lied that he had breakfast and skipped breakfast	no	1	side vein	no	12	6	donor was given sugar containing oral fluids,still he was feeling dizzy.Hence,IV DNS was transfused.Then he got stabilised	no	nil	nil	no	Fully recovered	definite
	no	1	centre	no	3	7		no	nil	nil	no	Fully recovered	definite
	no	1	side vein	no	4	6	ice compression given and applied thrombophobe and settled	no	nil	nil	no	Fully recovered	definite
	no	1	side vein	no	3	8		no	nil	nil	no	Fully recovered	definite
	no	1	centre	no	4	9		no	nil	nil	no	Fully recovered	definite
she developed reaction post 1 hour donation.She left blood bank and was in outside blood collection facility when she developed reaction	no	1	centre	no	3	8	made to lie down reassured and rehydrated	no	nil	nil	no	Fully recovered	definite
developed sweating and dizziness	no	1	centre	no	4	9		no	nil	nil	no	Fully recovered	definite
had prolonged bleeding from puncture site for more than 30 min post donation	no	1	centre	no	3	7	applied pressure and ice compression,gave tight banding	yes	1	Delayed bleeding after donation	no	Fully recovered	definite
	no	1	side vein	no	4	9		no	nil	nil	no	Fully recovered	definite
	no	1	side vein	no	4	8		no	nil	nil	no	Fully recovered	definite
slept only 4.5 hours previous night and lied to be 6 hours	no	1	centre	no	4	4.5		no	nil	nil	no	Fully recovered	definite
	no	1	centre	no	5	9		no	nil	nil	no	fully recovered	definite

no	1	centre	no	4	9	applied pressure,cold compression, tincture iodine and later tight bandaging	yes		2	prolonged oozing after donation	no	fully recovered	definite
no	1	side vein	no	4	8	applied pressure,cold compression, tincture iodine and later tight bandaging	no	nil	nil		no	fully recovered	definite
no	1	side vein	no	4	9		no	nil	nil		no	fully recovered	definite
no	1	centre	no	2	4	made to lie down,hydrated well and reassured	no	nil	nil		no	fully recovered	definite
no	1	centre	no	4	6		no	nil	nil		no	fully recovered	definite
no	1	centre	no	5	8		no	nil	nil		no	fully recovered	definite
no	1	side vein	no	5	6		no	nil	nil		no	fully recovered	definite
no	1	side vein	no	3	6		no	nil	nil		no	fully recovered	definite
no	1	centre	no	4	8	tight compression and ice	no	nil	nil		no	fully recovered	definite
no	1	centre	no	5	8		no	nil	nil		no	fully recovered	definite
no	1	centre	no	4	5	made to lie down and seizure and LOC resolved spontaneosly	no	nil	nil		no	fully recovered	definite
no	1	centre	no	4	9		no	nil	nil		no	fully recovered	definite
no	1	side vein	no	5	6		no	nil	nil		no	fully recovered	definite
no	1	centre	no	5	7	made to lie down and head end lowered & foot end elevated and sprinkled water.Recovered immediately	no	nil	nil		no	fully recovered	definite
no	1	side vein	no	5	8		no	nil	nil		no	fully recovered	definite
no	1	centre	no	4	6		no	nil	nil		no	fully recovered	definite
no	1	side vein	no	4	7		no	nil	nil		no	fully recovered	definite
no	1	centre	no	3	8		no	nil	nil		no	fully recovered	definite
no	1	side vein	no	4	7		no	nil	nil		no	fully recovered	definite

no	1	side vein	no	5	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	3	8	no	nil	nil	no	fully recovered	definite
no	2	both side veins	yes	4	5	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	3	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	5	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	5	no	nil	nil	no	fully recovered	definite
no	1	centre	no	5	8	no	nil	nil	no	fully recovered	definite
no	2	both side veins	yes	4	5	no	nil	nil	no	fully recovered	definite
no	2	centre and side vein on other hand	yes	3	4	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite

no	1	side vein	no	3	7		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	5	6		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	6	made to lie down and recovered spontaneously	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	2	both centre veins	yes	5	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	5	8		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	5	8		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	6		no	nil	nil	no	fully recovered	definite

no	1	centre	no	5	6	made to lie down and sprinkled water and immediately recovered	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	3	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6		no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	5		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	3	7		no	nil	nil	no	fully recovered	definite
yes	1	centre	no	4	7	ice compression and tight bandaging given ,along with thrombophobe oinment	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	3	6		no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1	centre	no	5	6		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite

	no	1	centre	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7	made to lie down and recovered immediately	no	nil	nil	no	fully recovered	definite
	yes	1	centre	no	4	7	gave ice compression and made to lie down	no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	4	8		no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
After LOC only donor revealed the fact that he slept only for 2 hours and skipped breakfast	no	1	centre	no	12	2	made to lie down and rehydrated,but since he was not getting stabilised infused 2 units of IV DNS.Got stabilised	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	6		no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	6		no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	3	6		no	nil	nil	no	fully recovered	definite
	no	1	centre	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	4	6		no	nil	nil	no	fully recovered	definite
	no	1	centre	no	3	8		no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7		no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	8		no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	3	7	made to lie down and recovered immediately	no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	4	8		no	nil	nil	no	fully recovered	definite
	no	1	center	no	4	7		yes		2 vasovagal reaction	no	fully recovered	definite
	no	1	center	no	3	7	recovered spontaneously when donation stopped	no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	4	8		yes		1 vasovagal reaction	no	fully recovered	definite
	no	1	centre	no	3	7		no	nil	nil	no	fully recovered	definite

no	1 centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	8	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	3	7	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	3	6	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	6	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	8	no	nil	nil	no	fully recovered	definite
no	2 both side veins	yes	3	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7	yes		1 vasovagal reaction	no	fully recovered	definite
yes	1 side vein	no	3	8	no	nil	nil	no	fully recovered	definite
no	1 centre	no	3	6	no	nil	nil	no	fully recovered	definite
no	2 both side veins	yes	4	7	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	5	no	nil	nil	no	fully recovered	definite
no	1 centre	no	5	8	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	6	no	nil	nil	no	fully recovered	definite

no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	8	no	nil	nil	no	fully recovered	definite
no	2	both side veins	yes	4	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	7	yes	1	vasovagal reaction	no	fully recovered	definite
no	1	centre	no	4	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	6	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	yes	1	vasovagal reaction	no	fully recovered	definite
no	1	centre	no	6	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	9	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	6	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	7	no	nil	nil	no	fully recovered	definite

no	1	side vein	no	4	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	7	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	5	7	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	9	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	3	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	centre	no	3	8	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	applied pressure and ice compression,gave tight banding	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	4	6	no	nil	nil	no	fully recovered	definite
no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1	side vein	no	3	5	no	nil	nil	no	fully recovered	definite

	no	1	side vein	no	4	6	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	2	9	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	3	7	no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	4	9	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	3	6	no	nil	nil	no	fully recovered	definite
Donor contacted blood centre via phone.Reassured and adviced to report back to blood bank.Reported to blood bank and apllied thrombophobe oinment and adviced hygiene over the puncture site	no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	6	no	nil	nil	no	fully recovered	definite
After reaction only he revealed that he slept for only 2 hours the previous night.	no	1	centre	no	4	2	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	3	6	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	4	9	no	nil	nil	no	fully recovered	definite
	no	1	centre	no	4	7	no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	3	6	no	nil	nil	no	fully recovered	definite
	no	1	side vein	no	4	7	no	nil	nil	no	fully recovered	definite

yes	1 centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	3	6	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	6	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	8	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	6	IV 500 ml saline infused since he had continued giddiness	no	nil	nil	no	fully recovered	definite
no	1 centre	no	3	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	6	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	3	7	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	7	no	nil	nil	no	fully recovered	definite
no	1 centre	no	3	7	no	nil	nil	no	fully recovered	definite
no	1 side vein	no	4	6	no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	8	no	nil	nil	no	fully recovered	definite

	no	1 centre	no	6	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	4	9		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	4	7		no	nil	nil	no	fully recovered	definite
After reaction only he revealed that he slept for only 4 hours the previous night.	yes	1 centre	no	4	4	Made to lie down and because of continued giddiness,infuse 500 ml NS .Then given tablet ranitidine and paracetamol.	no	nil	nil	no	fully recovered	definite
	no	1 centre	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	4	8		no	nil	nil	no	fully recovered	definite
	no	1 side vein	no	6	9		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	2	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	2	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	4	7		no	nil	nil	no	fully recovered	definite
	no	1 side vein	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	4	6		no	nil	nil	no	fully recovered	definite
	no	1 side vein	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	4	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	4	9		no	nil	nil	no	fully recovered	definite
	no	1 side vein	no	4	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	3	7		no	nil	nil	no	fully recovered	definite
	no	1 centre	no	4	7		no	nil	nil	no	fully recovered	definite

no	1 centre	no	3	6		no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	8		no	nil	nil	no	fully recovered	definite
no	1 side vein	no	3	7		no	nil	nil	no	fully recovered	definite
no	1 centre	no	3	6		no	nil	nil	no	fully recovered	definite
no	1 side vein	no	3	7		no	nil	nil	no	fully recovered	definite
no	1 centre	no	4	7		no	nil	nil	no	fully recovered	definite
no	1 centre	no	2	7		no	nil	nil	no	fully recovered	definite
no	1 centre	no	3	6		no	nil	nil	no	fully recovered	definite
no	1 centre	no	2	7		no	nil	nil	no	fully recovered	definite
no	1 side vein	no	3	7		no	nil	nil	no	fully recovered	definite
no	1 centre	no	2	7		no	nil	nil	no	fully recovered	definite
no	1 centre	no	3	7		no	nil	nil	no	fully recovered	definite
no			2	7						fully recovered	definite
no			3	8						fully recovered	definite

Sl No:	Hosp no:	Age	Gender	Weight	Place of transfusion	Diagnosis / Procedure do	Department	Indication for transfusion	Any significant comorbidity / History	under General Anasthesia (GA) / Sedation / On Ventillator	Component caused reaction	volume transfused (ml)	Volume comment
1	451097	18	M	55	NMICU	Transverse myelitis	Neuromedicine	Plasma exchange	nil	tracheostomy	FFP	80	
2	449950	79	F	70	CSICU	Aortic valve replacement	Adult CVTS	Perioperative anemia	Diabetes mellitus	no	PRBC	200	
3	437781	38	M	67	NSOT	Rt.jugular foramen tumour	Neurosurgery	Massive blood loss during surgery	no	yes and later tracheostomy	12 RBC,17 FFP,2 Cryo,8 platelets	> 4000	massive transfusion with all blood components
4	331189	7	F	18	CHICU	Repair of Double outlet right ventricle	Pediatric cardiac surgery	Perioperative use	Congenital cyanotic heart disease	no	Cryoprecipitate	5	
5	8804890	51	F	65	STICU	Embolic stroke+bilateral bronchopneumonia+coagulopathy+anemia	Neuromedicine	Anemia	Cardiac failure+hypotesnion	intubated	LR-RBC	180	
6	274468	50	M	70	NSICU	Temporal lobe cyst excision	Neurosurgery	Perioperative anemia	Temporal lobe epilepsy	tracheostomy	PRBC	230	
7	451778	26	F	65	NSOT	Bilateral malignant frontal glioma	Neurosurgery	Perioperative anemia	Previuosly received radiotherapy 1 year back after first surgery and was on chemotherapy	intubated	PRBC		Blood counts were checked in the immediate post-op period due to coagulopathy and severe bleeding.,4 units of PRBC got transfused during surgery
8	456137	2	F	8	CHICU	Pulmonary Artery Banding	Pediatric cardiac surgery	Perioperative anemia	Ventricular septal defect	no	PRBC	30	

9	343408	18	M	58	PSOT	Single ventricle Pathology Repair	Pediatric cardiac surgery	Massive blood loss during surgery	Congenital cyanotic heart disease	yes during surgery	PRBC	30		
10	430345	2	M	8	PSOT	Atrial Septal defect with Pulmonary Vein re-routing	Pediatric cardiac surgery	Intraoperative usage	nil	yes during surgery	PRBC and FFP 1 unit each	50 ml each	during reaction patient was on Bypass pump and RBC and FFP was flowing via pump	
11	456077	58	M	68	CSICU	Coronary Artery Bypass surgery	Adult CVTS	Post operative anemia	Hypertension	no	PRBC	220		
12	454781	33	F	79	NSOT	Meningioma - excision	Neurosurgery	Massive blood loss during surgery	nil	yes during surgery	FFP	190		
13	462748	53	M	60	NMICU	Chronic inflammatory demyelinating polyneuropathy	Neuromedicine	Plasma exchange	nil	no	FFP	130		
14	459494	52	M	80	CSICU	Coronary Artery Bypass surgery	Adult CVTS	Perioperative use	Post surgery patient developed mild Acute kidney injury with s.creatinine 2.3 .	no	PRBC	170		
15	452192	59	M	80	CSICU	Coronary Artery Bypass surgery - Dialysis Post surgery	Adult CVTS	Post operative anemia	Diabetes mellitus,Hypertension and CKD	intubated	PRBC	15		

16	466161	26	F	55	NSICU	Pineal gland tumor-surgery done	Neurosurgery	Peri-operative prolonged PT, aPTT	patient was on some ayurvedic medication for 2 weeks for headache prior to surgery and was on hormone tablets for oligomenorrhoea for 5 months prior to surgery.Allergic Rhinitis	no	FFP	180	
17	342144	76	F	80	STICU	Cardioembolic stroke,coagulopathy,malena,Severe anemia	Neuromedicine	Severe anemia	Diabetes mellitus Hypertension Old myocardial infarction with cor pulmonale and Old stroke with anasarca and heart failure	Tracheostomy	FFP	30	
18	467290	2	F	10	CHICU	Tetrology of Fallot - Surgery	Pediatric cardiac surgery	Post operative anemia	Congenital cyanotic heart disease	intubated	PRBC	100	
19	467288	68	F	60	STICU	Cerebrovascular accident	Neuromedicine	Anemia	Hypertension Diabetes mellitus	no	PRBC	100	
20	446074	49	M	45	CSICU	Peripheral vascular occlusive surgery - surgery	Adult CVTS	Perioperative use	Diabetes mellitus Hypertension	no	FFP	230	
21	9607192	31	F	42	NMICU	Neuromyelitis Optica	Neuromedicine	Plasma exchange		no	FFP	200	
22	458899	56	M	87	NMICU	Chronic inflammatory demyelinating polyneuropathy	Neuromedicine	Plasma exchange	Diabetes mellitus,chronic liver disease,hypoalbuminemia	no	FFP	180	
23	472427	49	M	70	CSICU	Coronary Atery Bypass surgery	Adult CVTS	Perioperative use		no	PRBC	160	
24	471002	50	F	60	NMICU	Myasthenia Gravis - in myasthenic crisis	Neuromedicine	Plasma exchange	Diabetes mellitus	intubated	FFP	150	after transfusion of 5 units of FFP

25	471910	17	M	60	NSOT	Chiari malformation - surgery done	Neurosurgery	Massive blood loss during surgery	nil	under GA	PRBC	180	180 ml was transfused in 5 minutes via pressure pump due to blood loss
26	468462	62	F	60	NSICU	Post CVA - Decompressive craniectomy done	Neurosurgery	Perioperative use	old ischemic CVA,Diabetes mellitus,Hypertension on dual antiplatelet therapy	no	FFP	180	after transfusion of 4 units of FFP
27	466995	39	F	70	NSICU	Vestibular schwanoma	Neurosurgery	Massive blood loss during surgery	nil	under GA	FFP	120	patient received massive transfusion for massive hemorrhage
28	317571	41	F	55	CMICU	Rheumatic mitral regurgitation with Atrial Fibrillation - on oral anticoagulants	Adult CVTS	Coagulopathy	nil	no	FFP	130	
29	473155	52	F	65	CSICU	Dual valve Repair	Adult CVTS	Post operative anemia	nil	no	PRBC	10	

PRBC - Packed red blood cells

FFP - Fresh frozen plasma

Cryo - Cryoprecipitate

LR-RBC - Leucoreduced red blood cells

FNHTR - Febrile non-hemolytic transfusion reaction

TAD - Transfusion associated dyspnoea

TIH - Transfusion induced hypotension

TAGVHD - Transfusion associated graft versus host disease

TRALI - Transfusion related acute lung injury

TACO - Transfusion associated cardiac overload

AHTR - Acute hemolytic transfusion reaction

pulse rate /min

Features of reaction	Date of transfusion	Time of transfusion	Date of reaction	Time of reaction	Date of stoppage	Time of stoppage	Time btw onset of transfusion & reaction (Hours)	Reaction comment	Date of recovery	Time of recovery	Medicines given for treatment	pre reaction	during
itching - head and face	13-05-2018	2.30 pm	13-05-2018	2.48 pm	13-05-2018	2.50 pm	< 1 hr	after 15 min of start of transfi	13-05-2018	4.20 pm	antihistamine and steroids	52	78
chills and rigors with rise in temperature	31-05-2018	4.30 pm	31-05-2018	8.45 pm	31-05-2018	8.00 pm	4-6 hrs	after 30 min of stoppage of transfusion	31-05-2018	9.45 pm	antipyretics and antihistamines	69	70
hypoxemia & pulmonary oedema	11-06-2018	3.00 pm	13-06-2018	6.30 am	12-06-2018	9.00 pm	12- 24 hrs	transfused massively on day of surgery and nxt day for re-exploration.Noticed hypoxemia nxt day morning	18-06-2018	9.00 pm	oxygen,steroids bronchodilators antibiotics and other supportive measures	96	108
hypotension	23-07-2018	5.00 pm	23-07-2018	5.03 pm	23-07-2018	5.06 pm	< 1 hr	Just after the onset of transfusion, there was sudden onset of hypotension	23-07-2018	5.45 pm	stopped transfusion and put IV NS	123	122
dyspnoea	24-07-2018	2.50 pm	24-07-2018	4.43 pm	24-07-2018	4.45 pm	1 - 2 hrs	towards end of transfusion she developed sudden onset dyspnoea and got relieved on bronchodilators and steroids and other supportive measures	24-07-2018	5.45 pm	Immediately diuretic was given and brochodilators and steroids were given	128	124
Developed rise in temperature during transfusion	23-07-2018	5.00 pm	23-07-2018	9.05 pm	24-07-2018	8.30 pm	4-6 hrs	after 15min of stoppage of transfusion developed fever	24-07-2018	10.00 pm	antipyretics and antihistamines	72	74
severe neutropenia and thrombocytopenia	07-08-2018	11.30 am	07-08-2018	5.30 pm	07-08-2018	4.20 pm	4-6 hrs	4 units of RBC got transfused due to intraoperative bleed. She was shifted to icu and has sent CBC ,then noticed severe neutropenia nd thrombocytopenia	dint recover	dint recover	G-CSF and all blood products including 3 SDP and 15 RDP	90	120
erythema over face and neck with pruritis	13-09-2018	12.30 pm	13-09-2018	3.05 pm	13-09-2018	3.06 pm	4-6 hrs	after 30 ml of transfusion patient developed reaction	13-09-2018	4.30 pm	antihistamine and steroids	122	130

tachycardia,tachypnoea ,dark coloured urine in foleys bag	06-09-2018	2.30 am	06-09-2018	2.32 am	06-09-2018 2.33 am	< 1 hr	Immediately after start of Aneg blood for B+ patient wrongly at bedside	06-09-2018	3.00 am	continous normal saline infusion + lasix and other supportive measures	78	120
hypotension and destauration with urticaria and erythema of chest and abdomen	12-09-2018	7.20 pm	12-09-2018	7.45 pm	12-09-2018 7.46 pm	< 1 hr	patient developed reaction after 30 minutes of transfusion via pump at the time of weaning using protamine sulphate	12-09-2018	9.15 pm	oxygen,brochodilators,steroids ,antihistamine and ionotropes	88	108
isolated single erythematous patch over right hypochondrium without itching	05-10-2018	10.30 am	05-10-2018	1.45 pm	05-10-2018 1.30 pm	2-4 hrs	10 minutes after complete transfusion developed reaction	05-10-2018	2.30 pm	antihistamines	84	86
tachypnoea,tachycardia,hypotension,hypoxemia	09-11-2018	2.20 pm	09-11-2018	2.25 pm	09-11-2018 2.26 pm	< 1 hr	towards the end of the surgery, after 15 minutes of start of FFP	09-11-2018	2.45 pm	antihistamine ,steroids adrenaline and Normal saline	86	98
generalised urticaria	02-01-2019	6.48 pm	02-01-2019	7.10 pm	02-10-2019 7.13 pm	< 1 hr	after 30 minutes of start of transfusion developed reaction	02-01-2018	8.40 pm	anthistamines and steroids	80	82
found hyperkalemia in ABG while the sample was drawn from central line when blood was flowing through peripheral line.Patient was asypmtomatic	04-01-2019	8.00 am	04-01-2019	10:00 AM	04-01-2019 10.01 am	1 - 2 hrs	Hyperkalemia and S.pottasium 6.5 was accidental finding on ABG. Post-op ABG aws taken as a routine investigation.But,during transfusion nurse has drawn the sample from the other line .	04-01-2019	2.30 pm	stopped transfusion and repeated pottasium after 4 hours & found normal	114	108
Blood was flowing in central line but got blocked after 10 ml of transfusion and it came into notice only after 2 hours ,then icu nurse flushed and connected to next central line portal and patient immediately developed tachycardia hypotension and fever	20-01-2019	1.30 pm	20-01-2019	3.00 pm	20-01-2019 3.15 pm	2-4 hrs		20-01-2018	5.30 pm	stopped transfusion immediately	93	110

generalised pruritis and urticaria	06-03-2019	12.30 pm	06-03-2019	1.30 pm	06-03-2019	1.30 pm	1 - 2 hrs	2 units of FFP were transfused unevenful,third unit of FFP toward the end of complete transfusion developed reaction	06-03-2019	2.15 pm	stopped transfusion and antihistamines and steroids given	78	96
severe dyspnoea during transfusion with tachypnoea, tachycardia, hypoxemia and hypotension	14-03-2019	2.45 am	14-03-2019	3.30 am	14-03-2019	3.31 am	1 - 2 hrs	patient got admitted at night and was on tracheostomy during admission,patient developed reaction after 30 ml of RBC transfusion	14-03-2019	4.30 am	stopped transfusion and gave lasix steroids bronchodilataors and morphine,patient was put on ionotropic support later	109	123
Developed rashes over face and abdomen	26-03-2019	10:00 PM	26-03-2019	1.00 am	26-03-2019	2.00 am	2-4 hrs	developed reaction after 1 hour of completion of transfusion	26-03-2019	3.00 am	antihistamines and steroids	79	78
Developed rise in temperature during transfusion	02-04-2019	2:00 PM	02-04-2019	3:00 PM	02-04-2019	3.01 pm	1 - 2 hrs	developed reaction after 1 hour of start of transfusion	02-04-2019	4.00 pm	antipyretics and antihistamine	69	144
generelised urticaria	06-05-2019	6:00 PM	06-05-2019	6.45 pm	06-05-2019	6.30 pm	< 1 hr	developed reactionafter 15 min of stoppage of transfusion	06-05-2019	7.30 pm	antihistamines and steroids	116	118
generalised itching and rashes over face and hands and flushing	13-05-2019	6.10 pm	13-05-2019	8.10 pm	13-05-2019	7.10 pm	1 - 2 hrs	developed reaction after 1 hour of transfusion of 3 units of FFP	13-05-2019	9.00 pm	antihistamines and steroids	70	78
generalised pruritis and rashes	03-07-2019	5.45 pm	03-07-2019	6.50 pm	03-07-2019	6.05 pm	1 - 2 hrs	toward the end of transfusion of 5th unit of FFP,developed reaction	03-07-2018	7.15 pm	antihistamines and steroids	65	66
generalised pruritis and rashes	10-07-2019	3.30 pm	10-07-2019	5.00 pm	10-07-2019	5.01 pm	1 - 2 hrs	toward the end of transfusion developed reaction	10-07-2019	6.30 pm	antihistamines and steroids	101	100
generalised rashes with chills and rise in temperature	19-07-2019	8.15 pm	19-07-2019	9.15 pm	19-07-2019	8.30 pm	1 - 2 hrs	after 30 minutes after stoppage of 5th unit of FFP patient developed reaction	10-07-2019	10.30 pm	antihistamines and steroids	86	124

urticaria, tachypnoea,desaturation and hypotension	26-08-2019	5.30 pm	26-08-2019	5.33 pm	26-08-2019	5.34 pm	< 1 hr	developed reaction after 3 minutes of transfusion	26-08-209	6.30 pm	antihistamines and steroids and double dose adrenaline	88	130
generalised pruritis and rashes	03-09-2019	7.00 pm	03-09-2019	8.05 pm	03-09-2019	8.00 pm	1 - 2 hrs	after 5 minutes of complete transfusion of 4 units of FFP developed reaction	03-09-2019	9.30 pm	antihistamines and steroids	88	86
hypoxemia , hypotension angioodema	10-09-2019	6.55 pm	10-09-2019	7.00 pm	10-09-2019	7.01 pm	< 1 hr	it was the 4th FFP the patient received during surgery	10-09-2019	8.45 pm	antistamines, steroids bronchodilators and adrenaline	98	100
generalised pruritis and urticaria	09-10-2019	7.20 pm	09-10-2019	7.35 pm	09-10-2019	7.36 pm	< 1 hr	had reaction within 20 minutes of start of 2nd FFP	09-10-2019	8.45 pm	antihistamines and steroids	128	118
chills and rigors, no rise in temperature	13-10-2019	2.55 pm	13-10-2019	3.00 pm	13-10-2019	3.01 pm	< 1 hr	developed reaction after 5 minutes of starting transfusion	13-10-2019	4.30 pm	antipyretics and antihistamine	78	78

ıute		BP mmHg			Temperature °F			Respiratory rate /minute			SpO2 (%)					
post	whether on ionotrope during reaction	pre	during	post	pre	during	post	Whether on ventillator during reaction	pre	during	post	pre	during	post	Any other signs	Responded to treatment	h/o previous reactions	h/o transfusions in past
76	no	100/60	100/65	110/70	98.6	98.6	98.6	yes	18	18	18	100	100	100	normal transfusion reaction work up	yes	no	yes
109	no	114/58	112/41	109/87	98.6	98.6	99.6	no	22	23	26	97	98	98	normal transfusion reaction work up	yes	no	yes
104	yes	120/88	100/50	112/72	98.6	98.6	98.6	yes	18	19	18	97	86	93	Chest Xray- S/O pul oedema	yes	no	yes
123	no	95/62	50 /0	96/62	98.6	98.6	98.6	no	21	22	21	75	76	76	normal transfusion reaction work up	yes	no	yes
123	yes	140/93	140/94	138/93	98.6	98.6	98.6	yes	33	34	35	93	94	94	chest xray- no pulmonary oedema, Echo - normal cardiac function	yes	no	no
98	no	130/90	134/88	132/88	98.6	98.6	103	yes	19	19	18	100	100	100	normal transfusion reaction work up	yes	no	yes
118	no	110/60	100/50	100/60	98.6	98.6	98.6	yes	22	30	28	100	99	100	chest xray - no pulmonary oedema,but later developed sepsis and coagulopathy,DIC and mucocutaneous and systemic bleed	no	no	yes
150	no	96/56	84/59	113/90	98.6	98.6	98.6	no	24	24	23	94	94	94	normal transfusion reaction work up	yes	no	yes

123	no	120/60	60/0	80/50	98.6	98.6	98.6	yes	28	28	28	93	94	96	tachycardia,hypotension ,tachypnoea and dark colored urine,bleeding from surgical site	yes	no	yes
110	no	110/77	80/48	120/68	98.6	98.6	98.6	yes	29	29	28	94	86	96	hypotension, saturation fall and rashes	yes	no	no
84	no	110/80	115/68	110/66	98.6	98.6	98.6	no	18	19	18	94	94	94	normal transfusion reaction work up	yes	no	no
80	no	110/88	60/0	120/82	98.6	98.6	98.6	yes	22	30	22	100	90	100	normal transfusion reaction work up	yes	no	no
83	no	130/90	120/80	122/71	98.6	98.6	98.6	no	18	18	19	100	100	100	normal transfusion reaction work up	yes	no	no
90	no	145/73	128/63	130/90	98.6	98.6	98.6	no	18	18	18	100	100	100	normal peripheral smear and all transfusion reaction work up normal	yes	no	yes
98	no	98/62	83/40	90/60	98.6	100	98.6	yes	20	21	20	100	100	100	peripheral semar ,LDH,post transfusion reaction work up were all normal,serum pottasium normal	yes	no	yes

82	no	93/57	120/72	120/81	98.6	98.6	98.6	no	16	18	16	100	100	100	normal transfusion reaction work up	yes	no	no
114	no	107/51	86/50	133/67	98.6	98.6	98.6	yes	22	34	23	96	80	97	echo showed severe LV dysfunction ,ches xray was taken next day morning which dint reveal features of pulmonary oedema,but post transfusion echo showed pulmonary oedema	yes	no	no
91	no	111/61	101/61	120/74	98.6	98.6	98.6	yes	21	22	22	65	66	67	normal transfusion reaction work up	yes	no	yes
72	no	153/69	160/70	150/70	98.6	99.9	98.6	no	20	30	21	100	100	100	tachycardia,tachypnoea	yes	no	no
108	no	113/60	112/64	164/78	98.6	98.6	98.6	no	23	24	24	100	100	100	normal transfusion reaction work up	yes	no	yes
84	no	89/63	89/64	90/68	98.6	98.6	98.6	no	22	24	22	100	100	100	normal transfusion reaction work up	yes	no	yes
68	no	140/78	138/83	142/74	98.6	98.6	98.6	no	20	20	20	100	100	100	normal transfusion reaction work up	yes	no	yes
102	no	101/65	108/66	108/60	98.6	98.6	98.6	no	18	19	18	100	100	100	normal transfusion reaction work up	yes	no	yes
84	no	130/80	110/60	110/70	98.6	99	98.6	yes	23	22	21	100	100	100	normal transfusion reaction work up	yes	no	yes

98	no	110/72	50/30	100/70	98.6	98.6	98.6	yes	22	32	28	100	84	98	normal transfusion reaction work up	yes	no	no
88	no	140/90	138/88	142/86	98.6	98.6	98.6	no	18	19	19	100	100	100	normal transfusion reaction work up	yes	no	yes
110	no	97/50	72/44	100/62	98.6	98.6	98.6	yes	21	22	21	100	94	99	Increase in airway pressure with desaturation , EtCO2 increased and hypotension .Normal transfusion reaction work up	yes	no	yes
116	no	117/80	116/81	115/81	98.6	98.6	98.6	no	18	19	20	100	100	100	normal transfusion reaction work up	yes	no	yes
68	no	120/66	133/76	123/6	98.6	98.6	98.6	no	22	20	22	100	100	100	normal transfusion reaction work up	yes	no	no

	h/o repeated reactions				Blood culture						
h/o transfusions post reaction	prior to current transfusion	post current transfusion	Status of patient	whether patient already had fever prior to transfusion	Positive blood culture pre /post transfusion	Organism grown	Component caused reaction	Transfusion reaction	Severity of reaction(Grades)	imputability	Remarks
yes	no	no	recovered fully	no	no	no	FFP	Allergic	1	Definite	
no	no	no	recovered fully	no	no	no	PRBC	FNHTR	1	probable	It can be a postop day -acute inflammatory reaction too
no	no	no	recovered fully	no	no	no	12 RBC,17 FFP,2 Cryo,8 platelets	TRALI	3	possible	proBNP not checked but cardiac function was normal with normal Echo- no vol overload. 2 blood units that got transfused were from female blood donors, one being a parous woman
no	no	no	recovered fully	no	no	no	cryoprecipitate	TIH	2	possible	Already cyanotic heart disease patient on treatment
no	no	no	recovered fully	no	no	no	LR-RBC	TAD	2	possible	patient already had co-morbidities including pre-existing poor pulmonary function
no	no	no	recovered fully	no	no	no	PRBC	FNHTR	1	probable	It can be a postop day -acute inflammatory reaction too
yes	no	no	Expired after 17 days	no	post op day blood culture positive	Klebsiella pneumonia	PRBC	TAGVHD	3	Excluded	Patient already had blood counts towards the lower range of reference standards due to chemotherapy.TAGVHD unlikely immediately post transfusion as it usually a delayed transfusion reaction
yes	no	no	recovered fully		no	no	PRBC	Allergic	1	Definite	

yes	no	no	recovered fully	no	no	no	PRBC	AHTR	3	Definite	Samples were sent after 16 hours to blood bank for work up, so DCT was negative and free plasma hemoglobin was normal,peripheral smear showed fragmented RBC's,LDH was elevated , indirect hyperbilirubineamia ,all clerical errors were ruled out,Culprit bag was not sent and by mistake got discarded in OT
no	no	no	recovered fully	no	no	no	PRBC and FFP 1 unit each	Anaphylaxis	2	possible	patient was given protamine sulphate also prior to reaction for heparin reversal .Protamine is notorious to produce severe allergic reactions
no	no	no	recovered fully	no	no	no	PRBC	Allergic	1	Doubtful	it was an isolated small erythematous patch accidently noticed during dressing change
no	no	no	recovered fully	no	no	no	FFP	Anaphylaxis	2	possible	There were no skin rashes
yes	no	no	recovered fully	no	no	no	FFP	Allergic	1	Definite	
yes	no	no	recovered fully	no	no	no	PRBC	Non-immune mediated hemolysis	1	Doubtful	There were no features of hemolysis in peripheral smear and post transfusion sample plasma was clear with normal LDH.Patient also had Acute kidney injury due to post-surgery
yes	no	no	recovered fully	no	yes	post transfusion day 4 MRSA	PRBC	Non-immune mediated hemolysis	2	Doubtful	There is a chance that lysed RBC got transfused, since RBC might have got lysed in the tubing due to stagnation for 2 hours,but lab parameters doesn't suggest hemolysis

no	no	no	recovered fully	no	no	no	FFP	Allergic	1	Definite	
yes	no	no	recoverd fully	no	no	no	FFP	TACO	3	Definite	pro BNP was not done since patient was admitted with already established cardiac failure and ischemic changes .Hence, there can be pre-existing elevated pro-BNP
no	no	no	recoverd fully	no	no	no	PRBC	Allergic	1	Definite	
no	no	no	recovered fully	no	no	no	PRBC	FNHTR	1	Definite	
yes	no	no	recovered fully	no	no	no	FFP	Allergic	1	Definite	
yes	no	no	recovered fully	no	no	no	FFP	Allergic	1	Definite	
yes	no	no	recoverd fully	no	no	no	FFP	Allergic	1	Definite	
no	no	no	recovered fully	no	no	no	PRBC	Allergic	1	Definite	
yes	no	no	recovered fully	no	no	no	FFP	Allergic + FNHTR	1	Definite	

no	no	no	recovered fully	no	no	no	PRBC	Anaphylaxis	2	Definite	
no	no	no	recovered fully	no	no	no	FFP	Allergic	1	Definite	
yes	no	no	recovered fully	no	no	no	FFP	Anaphylaxis	2	Probale	patient also developed Severe cerebral oedema during surgery,hence its not sure whether hypotension and hypoxemia were due to brain stem compression
yes	no	no	recovered fully	no	no	no	FFP	Allergic	1	Definite	
yes	no	no	recovered fully	no	no	no	PRBC	FNHTR	1	Definite	