National Blood Transfusion Service of Sri Lanka

ANNUAL HAEMOVIGILANCE REPORT

2023

VOLUME 12

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ACKNOWLEDGEMENTS

- All the Consultant Transfusion Physicians, Medical Officers, Nursing Officers, Medical Laboratory Technologists, Public Health Inspectors and other supportive staff of NBC and NBTS of Sri Lanka
- Medical Officer In-Charge and the staff of HIU, National Blood Center, Colombo 5, Sri Lanka
- Photo credits to Dr Saman de Silva (for the cover page)

FORWARD

Message from The Director - National Blood Transfusion Service

Dr E. A. L. C. K. Edirisinghe

I take the privilege of conveying this message through the 12th Volume of National Haemovigilance Report published by the national Haemovigilance Unit of National Blood Transfusion Service.

NBTS, as any other institute, is working towards a common goal, i.e. ensuring the adequacy, safety and quality of blood and blood components throughout the transfusion chain from the donor to recipient, as a team consisting of team managers and administrative officers, subject experts, technical personnel as well as other supportive staff.

The main objective of all these efforts is to ensure safe blood transfusion.

The National Haemovigilance Unit strengthens this process through providing data on adverse reactions related to donor, process and recipient haemovigilance, encouraging the NBTS staff to learn through mistakes and avoid occurrences and recurrences of similar incidents.

To optimize this reporting process, several advancements of the reporting system has been introduced by the National Haemovigilance Unit, in collaboration with the Health Informatics Unit of the NBTS. Where as, the continued support of the NBTS staff by prompt updating of data and the system has inevitably contributed to succeed this team effort. Extending my sincere gratitude to all those, I add this last note, the accountability and responsibility at every stage will ensure a “Meaningful Free Health” to all the people in the country.

Message from the Consultant In-Charge

National Haemovigilance Unit, NBTS

Dr. Senarath Jayasekara - Consultant Transfusion Physician

In assuring the quality and safety of blood transfusion process, the National Haemovigilance System plays a vital role to identify the deviations from standard practices as well as to guide the process towards minimizing errors. Shouldering this national responsibility, the National Haemovigilance Unit collects, analyzes and thus presents the data that all our NBTS staff provided throughout the year 2023.

It is encouraging to see the improvement of reporting status of haemovigilance data, for which I would like to pay my gratitude to all the staff members of NBTS who contributed. At the same time I would like to draw your attention to the number of group-incompatible transfusions, which we should put further effort to minimize. And also, when reporting adverse reactions providing relevant details promptly and adequately will ensure complete analysis of the relevant incidents as well as enhance the accuracy of arrived conclusions. Moreover, I invite all the NBTS staff to use this publication as a learning tool to improve our practices to ensure safe blood transfusion to all.

ABBREVIATIONS

Abbreviation	Meaning
ACE Inhibitors	Angiotensin-Converting Enzyme Inhibitors
AHTR	Acute Haemolytic Transfusion Reactions
AP	Apheresis
ATR	Adverse Transfusion Reactions
BSH	British Society for Haematology
Cryo	Cryoprecipitate
DAT	Direct Antiglobulin Test
DHTR	Delayed Haemolytic Transfusion Reactions
ETU	Emergency Treatment Unit
FFP	Fresh Frozen Plasma
FNHTR	Febrile Non-Haemolytic Transfusion Reactions
Hb	Haemoglobin
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HDU	High Dependency Unit
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen
HNA	Human Neutrophil Antigen
HV	Haemovigilance
ICU	Intensive Care Unit
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
LDH	Lactate Dehydrogenase
MP	Malaria Parasites
NBTS	National Blood Transfusion Service
NHU	National Haemovigilance Unit
OT	Operating Theatre
PLT	Platelets
QMS	Quality Management Section
RBC	Red Blood Cells
RCC	Red Cell Concentrate
SHOT	Serious Hazards of Transfusion
TACO	Transfusion Associated Circulatory Overload
TAD	Transfusion Associated Dyspnoea
TAH	Transfusion Associated Hypotension
TAS	Trasfusion Associated Sepsis
TPHA	Treponema Pallidum Haemagglutination
TPPA	Treponema Pallidum Particle Agglutination
TRALI	Transfusion Related Acute Lung Injury
TTI	Transfusion Transmitted Infections
VDRL Test	Venereal Disease Research Laboratory (VDRL) Test
WHO	World Health Organization

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CHAPTER 01

INTRODUCTION

INTRODUCTION

1.1 NATIONAL BLOOD TRANSFUSION SERVICE OF SRI LANKA

National Blood Transfusion Service of Sri Lanka is a centrally coordinated special campaign under the Ministry of Health. Being the sole supplier of blood and blood products to all state hospitals and most of the private hospitals, the NBTS ensures the quality, safety, adequacy and cost effectiveness of the blood supply and related laboratory, clinical, academic and research services in accordance with national requirements and WHO recommendations.

Starting from a single room located at General Hospital Colombo, the NBTS has expanded into 24 cluster centers and 112 hospital-based blood banks, over six decades. Out of them, 106 centers were in the functioning status in 2023.

Today, the NBTS maintains its blood stock exclusively from voluntary non-remunerated blood donors. All donor units are being tested to prevent transfusion transmitted infections, inside the modern laboratories in the cluster centers. The processed blood and blood components are being stored under optimal conditions at all the centers, and efficiently exchanged depending on the demand, through the coordination of National Blood Center, as the head quarters of NBTS.

In addition, all the adverse events related to the steps in the entire transfusion chain are actively monitored through the national haemovigilance system, maintained by the National Haemovigilance Unit.

1.2 NATIONAL HAEMOVIGILANCE UNIT

Established in 2009 at the National Blood Centre, the national haemovigilance system operates through data collected from all the blood banks island-wide, regarding the donor-related, process-related and recipient-related adverse events as well as near-miss events. Under the direct supervision of Consultant Transfusion Physician-In-Charge of NHU, the medical officers analyse the collected data, and preventive and corrective measures are taken accordingly.

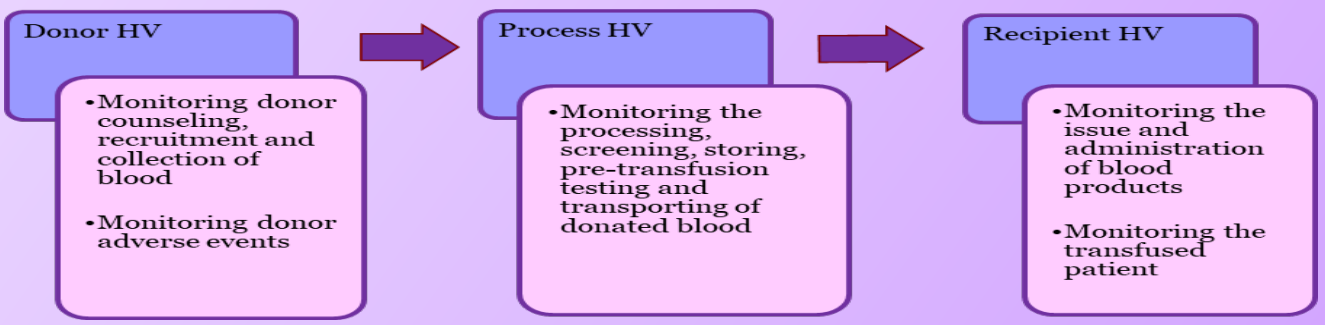


Figure 1.1 : Components of the Haemovigilance System

Thus collected data is finally compiled as the Annual Haemovigilance Report, which ultimately used as an educational tool and a self teaching guide.

CHAPTER 02

HAEMOVIGILANCE OVERVIEW

HAEMOVIGILANCE OVERVIEW

Adverse transfusion reactions reported under Recipient Haemovigilance, comprises a major portion of the reports received to NHU, other than the donor adverse events reports, incident reports on processing errors and near-miss reports.

In 2023, NHU received 3067 adverse transfusion reaction reports, 10016 donor reaction reports, 35 reports on processing related incidents and 36 Near-Miss event reports. The total collection in 2023 was 466 061, while total component issues was 844 182.

Table 2.1 shows total collections, total component issues and total number of ATR reported over past five years.

Year	Total Collection	Total Component Issues	Total Number of ATR
2023	466 061	844 182	3067
2022	424 127	788 712	2716
2021	385 054	726 972	2866
2020	397 833	736 885	3797
2019	444 515	757 175	4300

Table 2.1 : Yearly Comparison of Total Collections, Total Component Issues and Total ATR

The number of ATR reports received as well as the total collection and total component issues in 2023 have increased when compared to 2022. 2023 figures indicate a 12.9% growth of ATR than 2022.

Figure 2.1 is a descriptive illustration of the above data.

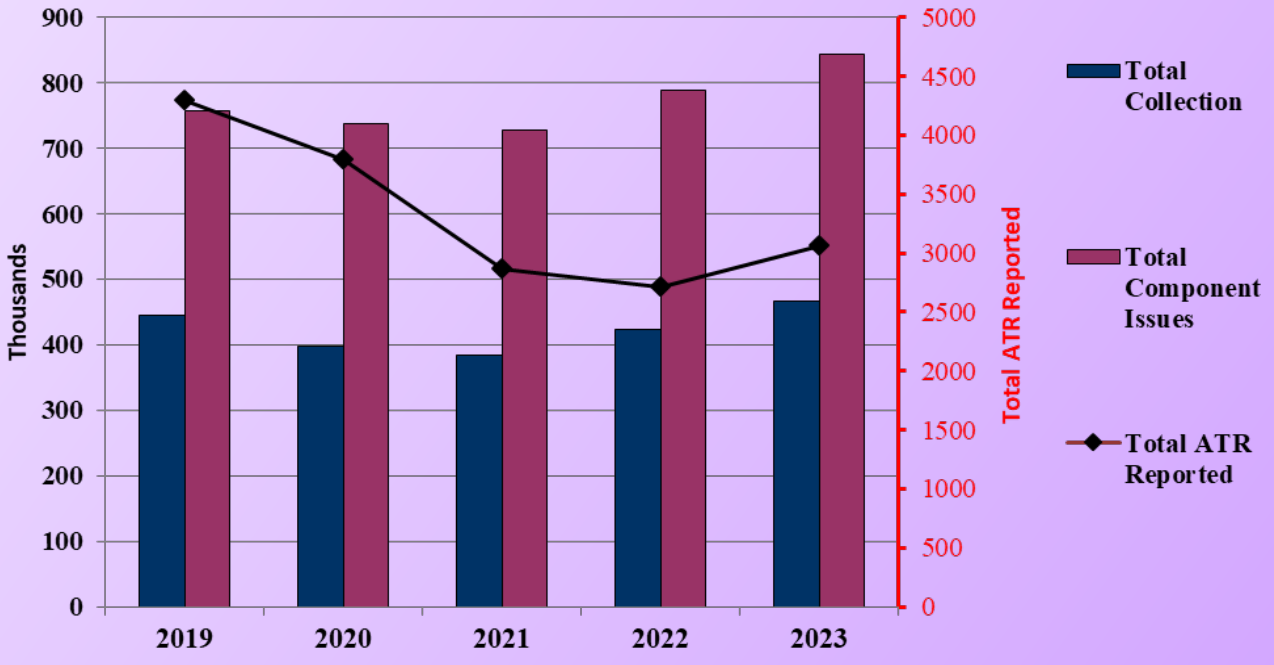


Figure 2.1 : Yearly Comparison of Total Collections, Total Issues and Total ATR

In 2023, number of total component issues per 1000 population has markedly increased while the number of ATR per 1000 component issues also show ascending trend.

Figure 2.2 illustrates the above data.

(Projected population : Source - www.statistics.gov.lk)

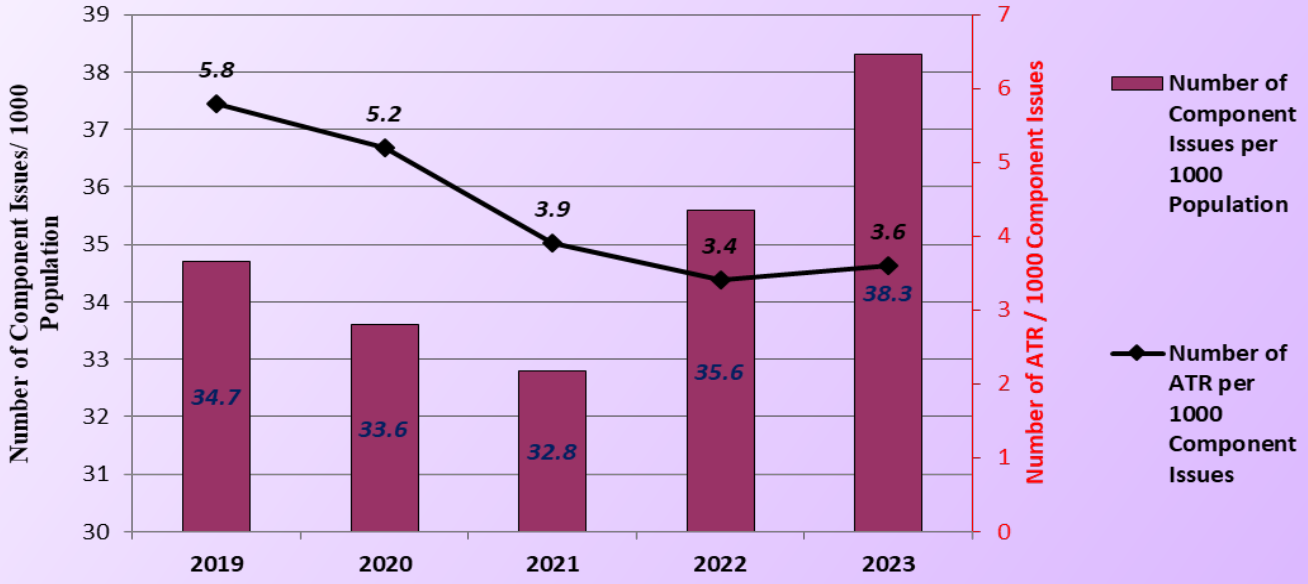


Figure 2.2 : Yearly Comparison of Total Component Issues, Population and Number of ATR

* As the accurate data on total number of transfusions is not available, total number of component issues is considered to assess the population risk of exposure to transfusions and development of adverse reactions.

As mentioned earlier, the total number of blood components issued in 2023 is **844 182**.

Figure 2.3 illustrates the numbers of each component type issued annually from 2019 to 2023.

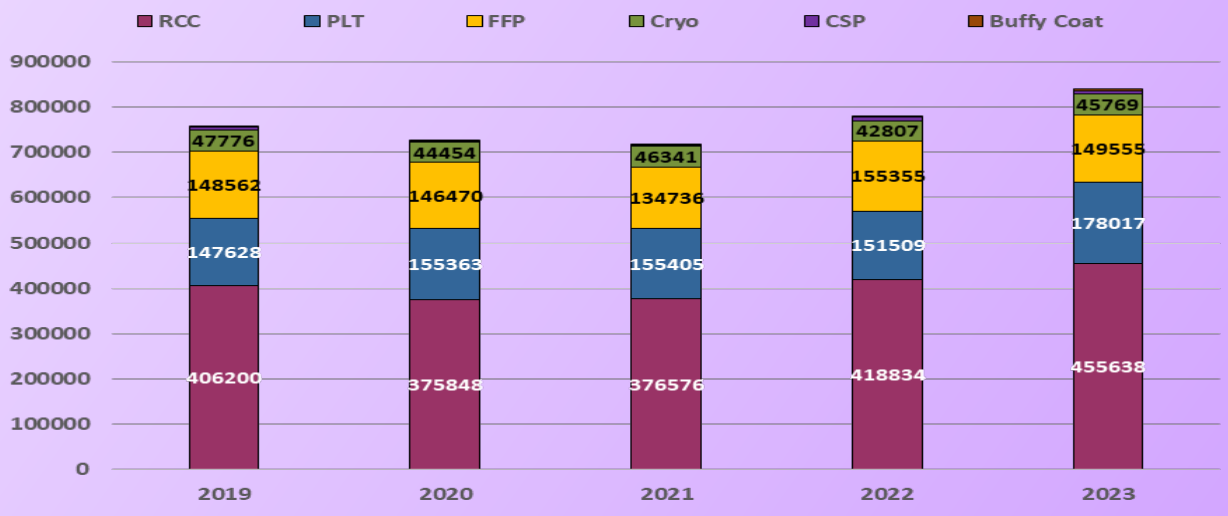


Figure 2.3 : Yearly Comparison of Individual types of Component Issues

CHAPTER 03

ADVERSE TRANSFUSION REACTIONS

3.0 ADVERSE TRANSFUSION REACTIONS

3.1 Definition

An adverse event is an undesirable and unintended occurrence before, during or after transfusion of blood or blood component which may be related to the administration of the blood or component. It may be the result of an error or an incident and it may or not result in a reaction in a recipient.

3.2 Overview

Out of 3067 ATR reports received in 2023, 2716 (88.6 %) were assigned an imputability of possible, probable or certain and will be analyzed in the rest of Chapter 3. The remaining 351 (11.4 %) reports were of low imputability (not assessable and excluded or unlikely), a slightly lower proportion than previous year (Figure 3.2.1-1). These reports have been excluded from further analysis.

3.2.1 Imputability

NHU applies the following SHOT definitions and scores for imputability when assessing reports.

IMPUTABILITY		
N/A	Not assessable	When there is insufficient data for imputability assessment
0	Excluded or Unlikely	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components or where the evidence is clearly in favour of alternative causes
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or where there may be alternative causes
2	Likely / Probable	When the evidence is clearly in favour of attributing the adverse reactions to the blood or blood component
3	Certain	When there is conclusive evidence beyond reasonable doubt attributing the adverse reactions to the blood or blood component

Table 3.2.1-1 : SHOT Definitions for Imputability

Figure 3.2.1-1 compares yearly trends of imputability.

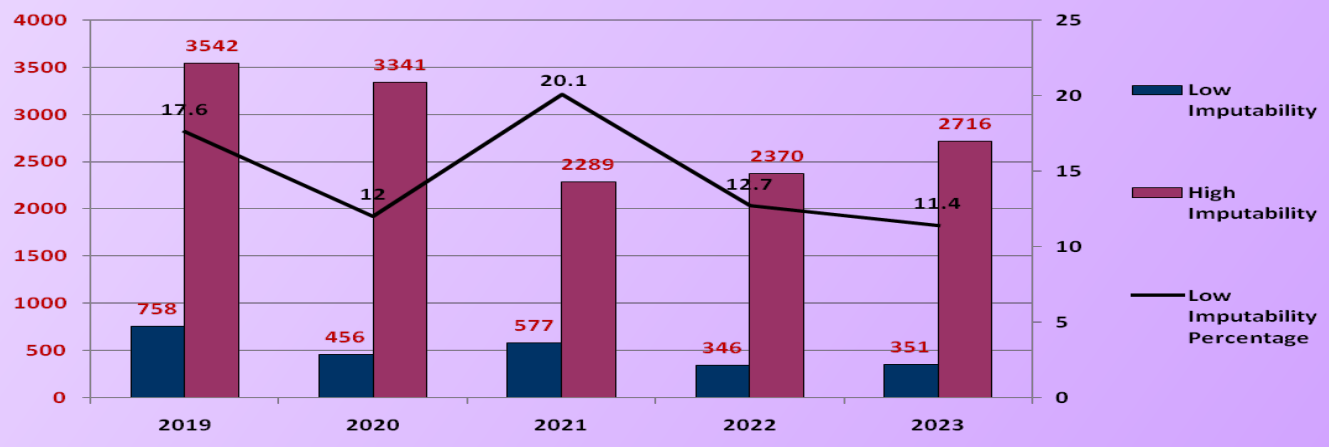


Figure 3.2.1-1: Yearly Comparison of ATR Reports with Reference to Imputability

3.3 Haemovigilance Data 2023—Adverse Transfusion Reactions At A Glance

ATR TYPE Major Reactions	NUMBER	PERCENTAGE (%)
ABO and Rh Incompatible Transfusions	17	0.55 %
Other AHTR	4	0.13 %
TRALI	6	0.20 %
TACO	205	6.68 %
TAD	53	1.73 %
Anaphylaxis	54	1.76 %
Bacterial Contamination	2	0.07%
Deaths Following Transfusions	5	0.16 %
Minor Reactions	**NUMBER**	**PERCENTAGE (%)**
FNHTR	1159	37.79 %
Allergic Reactions	1105	36.03 %
FNHTR + Allergic Reactions	49	1.60 %
Hypotensive Reactions	23	0.75 %
Imputability	**NUMBER**	**PERCENTAGE (%)**
Excluded & Unlikely	304	9.91 %
Not Assessable	47	1.53 %
Near Miss Events	**NUMBER**	**PERCENTAGE (%)**
Ward Errors	24	0.79 %
Laboratory Errors	9	0.29 %
Paper Based Errors	1	0.03 %
Total	**3067**	**100.00%**

Table 3.3-1 : Adverse Transfusion Reactions At A Glance

Majority of ATR belongs to FNHTR and Allergies, which are categorized as minor reactions.

3.3.1 Adverse Transfusion Reactions Types

Below 3.3.1-1 Table depicts the total numbers and relevant percentages of some of the selected major ATRs over past four years.

ATR Type	2020	2021	2022	2023
ABO and Rh Incompatibility	**24**	**14**	**20**	**17**
	0.63 %	0.49 %	0.74 %	0.55%
TRALI	**10**	**9**	**3**	**6**
	0.26 %	0.31 %	0.11 %	0.20%
TACO	**393**	**215**	**232**	**205**
	10.35 %	7.51 %	8.54 %	6.68%
TAD	**94**	**34**	**86**	**53**
	2.48 %	1.19 %	3.17 %	1.73%
ANAPHYLAXIS	**27**	**27**	**47**	**54**
	0.71 %	0.94 %	1.73 %	1.76%

Table 3.3.1-1: Yearly Comparison of Selected ATRs

Figure 3.3.1-1 is a graphical representation of the above data.

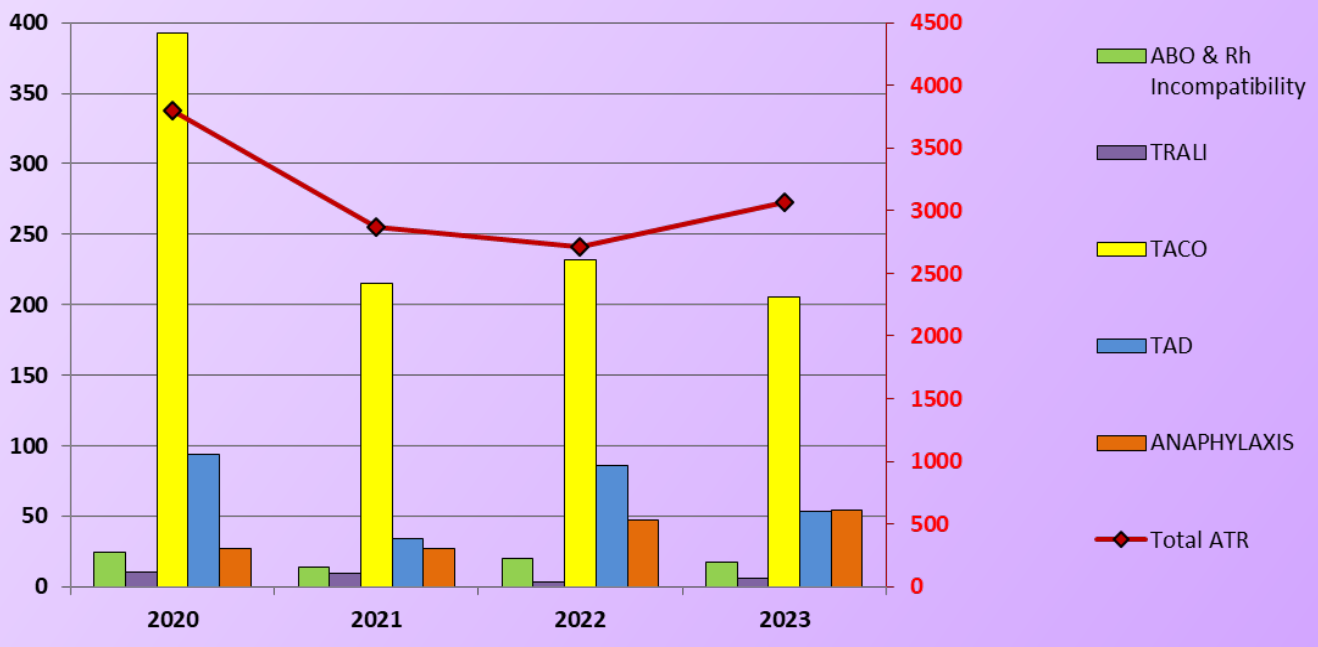


Figure 3.3.1-1 : Yearly Trends of selected ATRs

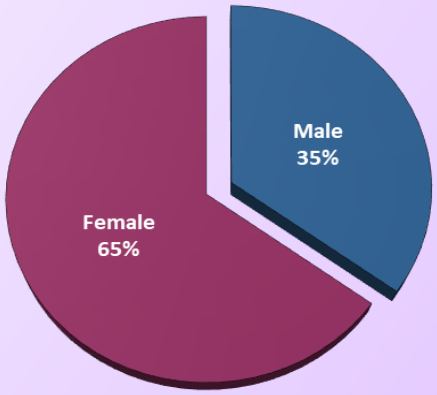
3.4 Febrile Non-Haemolytic Transfusion Reactions (FNHTR)

3.4.1 Definition

Febrile-type reaction (simple febrile reactions associated with chills and/or rigors or other inflammatory symptoms, or involving a 2°C temperature rise over baseline, or an absolute temperature of 39°C) occurring at any time up to 24 hours following a transfusion of a blood component.

3.4.2 FNHTR Data Analysis

FNHTR continue to be the most frequently reported adverse transfusion reaction over the past five years.



There was a total of 1159 (37.79 % of total ATR), where 756 female recipients and 403 male recipients developed FNHTR in 2023. (Figure 3.4-1)

Figure 3.4-1 : FNHTR 2023 on Gender Basis

Out of the FNHTR reported, 927 were due to RCC transfusions, 23 were due to FFP transfusions, 32 were due to platelet transfusions and 177 were due to other components. (Figure 3.4-2)

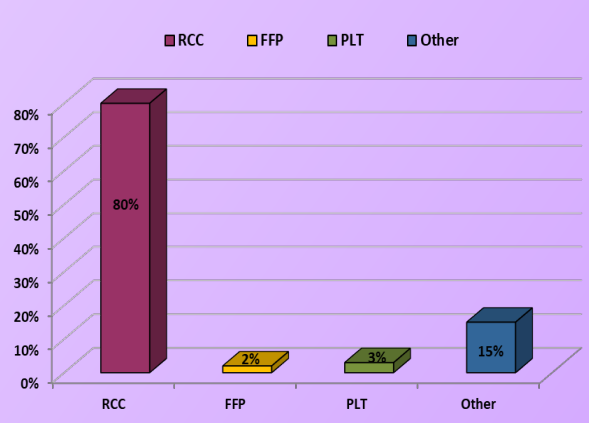


Figure 3.4-2 : FNHTR 2023 Based on Transfused Component

41% of total male recipients who developed adverse reactions, and 44% of female recipients with adverse reactions, developed FNHTR.

When considering the component transfusions, 47% of RCC, 8% of FFP, 22% of PLT and 61% of other component transfusions with adverse reactions developed FNHTR.

3.5 Allergic Transfusion Reactions

3.5.1 Definition

Allergic type transfusion reactions occurring at any time up to 24 hours following a transfusion of a blood component. An allergic reaction may present only with mucocutaneous signs and symptoms:

- ◊ Morbilliform rash with pruritus
- ◊ Urticaria (hives)
- ◊ Localized angioedema
- ◊ Edema of lips, tongue and uvula
- ◊ Periorbital pruritus, erythema and edema
- ◊ Conjunctival edema

In this form it usually presents no immediate risk to life of patient and responds quickly to symptomatic treatment like anti-histamine or steroid medications. This type of allergic reaction is called 'minor allergic reaction' in many hemovigilance systems.

3.5.2 Allergic Transfusion Reactions Data Analysis

During 2023, 1105 (36.03%) of the adverse reaction reports were classified as allergic reactions.

Of these, 400 were in male recipients while 705 were in female recipients. (Figure 3.5-1)

Out of the allergies reported, 740 were due to RCC transfusions, 207 were due to FFP transfusions, 84 were due to platelet transfusions and 74 were due to other components. (Figure 3.4-2)

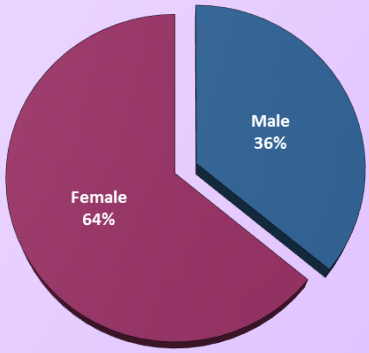


Figure 3.5-1 : Allergic Reactions 2023 On Gender Basis

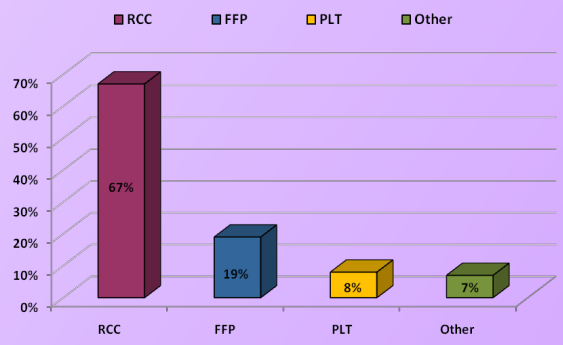


Figure 3.5-2 : Allergic Reactions 2023 Based on Transfused Component

41% of total male recipients who developed adverse reactions, and 41% of female recipients with adverse reactions, developed allergic reactions.

When considering the component transfusions, 37% of RCC, 76% of FFP, 58% of PLT and 25% of other component transfusions with adverse reactions developed allergic reactions.

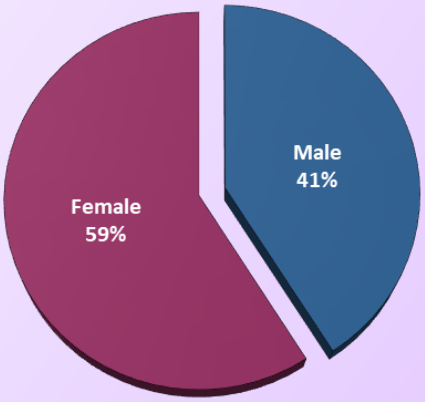
3.6 Reactions with Both Allergic and Febrile Features

3.6.1 Definition

Reactions with both febrile and allergic features occurring at any time up to 24 hours following a transfusion of a blood component.

3.6.2 Reactions with both Allergic and Febrile Features—Data Analysis

During 2023, 49 (1.60 %) of the adverse reaction reports were classified as FNHTR + Allergic Reactions.



Out of 49 FNHTR + allergic reactions reported, 20 were in male recipients while 29 were in female recipients. (Figure 3.6-1)

Figure 3.6-1 : FNHTR + Allergic Reactions 2023 on Gender Basis

Out of the FNHTR + allergic reactions reported, 34 were due to RCC transfusions, 6 were due to FFP transfusions, 5 were due to platelet transfusions and 4 were due to other components. (Figure 3.6-2)

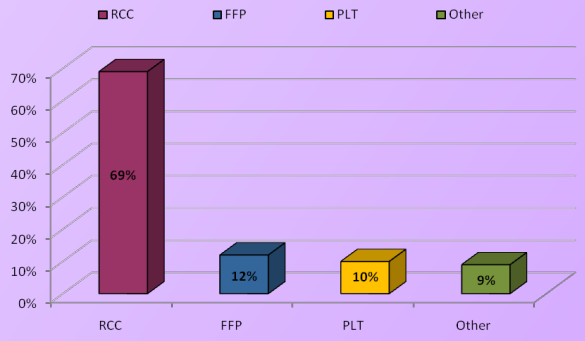


Figure 3.6-2 : FNHTR + Allergic Reactions 2023 Based on Transfused Component

2% of total male recipients who developed adverse reactions, and 1.7% of female recipients with adverse reactions, developed FNHTR + allergic reactions .

When considering the component transfusions, 1.7% of RCC, 2.2% of FFP, 3.5% of PLT and 1.4% of other component transfusions with adverse reactions developed FNHTR + allergic reactions.

3.7 Anaphylaxis

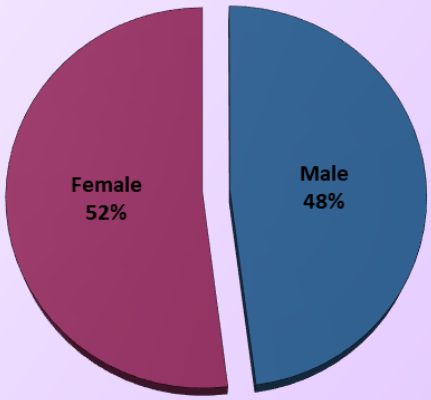
3.7.1 Definition

Severe, life-threatening, generalised or systemic hypersensitivity reaction with rapidly developing airway AND/OR breathing AND/OR circulation problems, usually associated with skin and mucosal changes.

In anaphylaxis, in addition to mucocutaneous systems there is airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs during or very shortly after transfusion.

3.7.2 Anaphylactic Reactions —Data Analysis

During 2023, 54 (1.76 %) of the adverse reaction reports were classified as Anaphylactic Reactions.



Out of them, 26 were in male recipients while 28 were in female recipients. (Figure 3.7-1)

Figure 3.7-1 : Anaphylactic Reactions 2023 on Gender Basis

Additionally, 28 of reported Anaphylactic reactions were due to RCC transfusions, 11 were due to FFP transfusions, 8 were due to platelet transfusions and 7 were due to other components. (Figure 3.7-2)

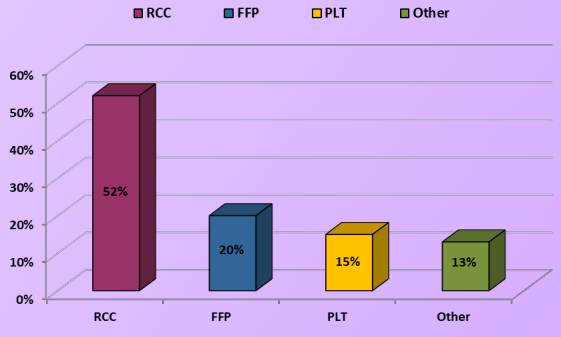


Figure 3.7-2 : Anaphylactic Reactions 2023 Based on Transfused Component

2.7% of total male recipients who developed adverse reactions, and 1.6% of female recipients with adverse reactions, developed anaphylactic reactions .

When considering the component transfusions, 1.4% of RCC, 4% of FFP, 5.6% of PLT and 2.4% of other component transfusions with adverse reactions developed anaphylactic reactions.

3.8 Transfusion Associated Hypotension (TAH)

3.8.1 Definition

This reaction is characterized by hypotension defined as a drop in systolic blood pressure of ≥ 30 mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure ≤ 80 mm Hg.

Most reactions do occur very rapidly after the start of the transfusion (within minutes). This reaction responds rapidly to cessation of transfusion and supportive treatment. This type of reaction appears to occur more frequently in patients on ACE inhibitors. Hypotension is usually the sole manifestation but facial flushing and gastrointestinal symptoms may occur. All other categories of adverse reactions presenting with hypotension, especially allergic reactions, must have been excluded. The underlying condition of the patient must also have been excluded as a possible explanation for the hypotension.

3.8.2 Transfusion Associated Hypotension - Data Analysis

During 2023, 23 (0.75%) of the adverse reaction reports were classified as Transfusion Associated Hypotensive Reactions. Of these, 10 were in male recipients while 13 were in female recipients. (Figure 3.8-1)

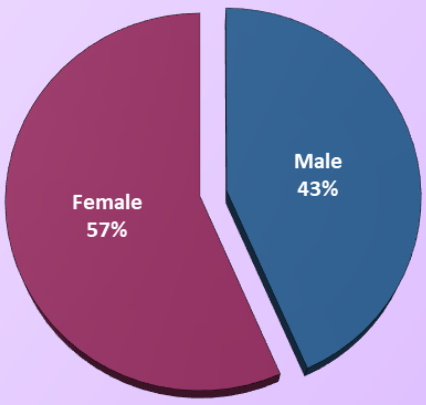


Figure 3.8-1 : TAH Reactions 2023 On Gender Basis

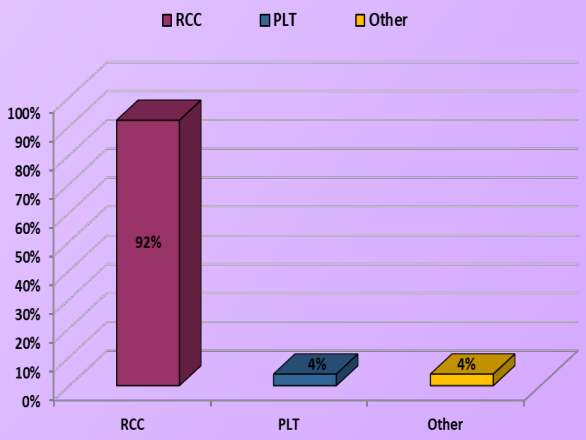


Figure 3.8-2 : TAH Reactions 2023 Based on Transfused Component

Additionally, 21 of the reported Hypotensive reactions were due to RCC transfusions, 1 was due to platelet transfusion and 1 was due to other components. (Figure 3.8-2)

3.9 Pulmonary Complications

3.9.1 Transfusion Related Acute Lung Injury (TRALI)

3.9.1.1 Definition

Acute dyspnoea with hypoxia and clear evidence of pulmonary oedema on imaging

- Occurring during or within 6 hours of transfusion
- The patient's respiratory state in the last 12 hours is considered as stable or improving.
- AND circulatory overload (i.e., objective or supporting evidence of left atrial hypertension) is not thought to be the major contributor to the reaction

3.9.1.2 Overview

Transfusion-related acute lung injury (TRALI) is a serious and potentially fatal complication of blood product transfusion in which a patient develops rapid onset lung injury and non-cardiogenic pulmonary edema due to activation of immune cells in the lungs. It is a clinically diagnosed syndrome, and can be severe enough to be life-threatening. TRALI has been caused by many types of blood components, including red cell concentrates (even those that are leucoreduced), plasma, platelet concentrates, platelets collected by apheresis (AP) and, rarely, intravenous immunoglobulin. If TRALI is suspected, the transfusion should be stopped. Patient management is supportive as there are no specific therapeutic interventions. Nevertheless, almost all patients will require some form of oxygen supplementation to maintain acceptable oxygen saturations.

3.9.1.3 TRALI - Data Analysis

During 2023, 6 (0.2 %) of the adverse reaction reports were classified as TRALI.

Clinically suspected TRALI incidents are further investigated in the HLA Laboratory of National Blood Center, for identification of HLA and HNA antibodies.

Accordingly, out of the 6 incidents, two were reported as antibody positive and other four were decided as clinically suggestive even though laboratory evidence were inconclusive. (Figure 3.9.1-1)

And also, none of the TRALI incidents have occurred in recipients less than 12 years of age.

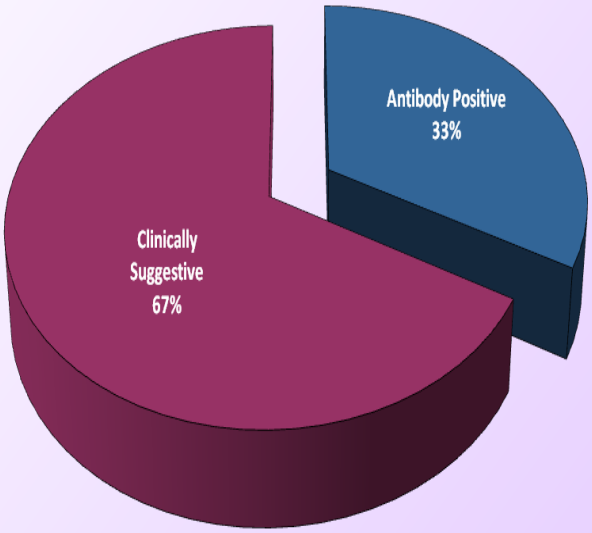


Figure 3.9.1-1 : TRALI 2023
Based on Serology

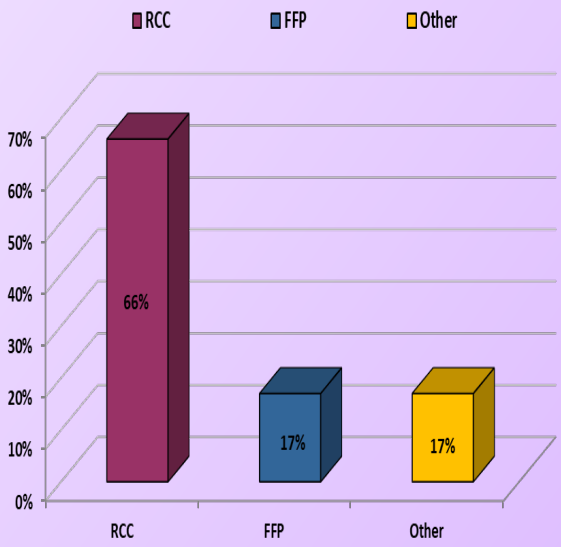


Figure 3.9.1-2 : TRALI 2023
Based on Transfused Component

In addition, 4 of the reported Hypotensive reactions were due to RCC transfusions, 1 was due to FFP transfusion and 1 was due to other components. (Figure 3.9.1-2)

3.9.1.4 Transfusion Related Acute Lung Injury—Case History

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Galle

Transfusion related acute lung injury (TRALI) is a life threatening complication of transfusion and it is a significance cause of transfusion associated morbidity and mortality. TRALI is clinically indistinguishable from acute lung injury or acute respiratory distress syndrome due to other causes. Both adults and children affect with similar rates. Recurrence of TRALI is extremely rare. All kind of blood components including red cells with or without additive solution, platelets, granulocytes, plasma, cryoprecipitate, IVIg and even autologous transfusion have been associated with the development of TRALI.

Onset of symptoms usually occurs within or during 2 hours of transfusion episode; but can be up to 6 hours later. TRALI manifests as acute respiratory distress due to non-cardiogenic pulmonary oedema and is characterized by symptoms and signs of dyspnoea, cyanosis, hypotension, fever and pulmonary oedema. The diagnosis of TRALI is mainly clinical. Full blood count might show a transient drop of neutrophil and monocyte counts. Chest radiography may show white opacities throughout in both lungs. As there is no specific therapeutic intervention available, treatment is largely supportive to allow lung injury to subside. Nearly all affected patients need some form of oxygen supplementation. Some of them need ventilator support for several days. Lung infiltrates usually resolve within 96 hours.

The pathogenesis of TRALI is complex and yet to be understood. Currently, it is described as a **two-hit model**, where the first hit represents the underlying clinical condition of the recipient and the second hit is conveyed by components in the transfused blood product such as anti-leucocyte and/or endothelium-reactive antibodies or other biological response modifiers. Among the patient factors, hypoxia, old age, recent surgery, cytokine therapy, sepsis and massive transfusion have been suggested as predisposing factors. Symptoms are thought to be result from the interaction of specific leucocyte antibodies or other modifiers with leucocytes and/ or pulmonary endothelium of the transfusion recipient. Both epithelial and endothelial injury occurs and the alveolar spaces are filled with fluid and proteinaceous materials due to increased permeability resulting dyspnoea and cyanosis.

Human Leucocyte antigen (HLA) antibodies, both class I and class II, and antibodies to Human Neutrophil antigens (HNA) have been implicated in developing TRALI. Usually, antibodies are donor-derived. Sometime, the donor leucocytes might react with recipient-derived antibodies or antibodies presence in a second transfusion. The TRALI caused by the later mechanisms are named as “reverse TRALI”. Anti-HLA and anti-HNA antibodies present in multiparous women is a common cause for developing TRALI. Higher rate of HLA sensitization has been demonstrated with increasing the number of pregnancies. Once it is established that leucocyte antibodies present in multiparous women leads to develop TRALI, blood services in UK initiated to obtain transfusable plasma units predominantly from male donors since 2003. This practice dramatically reduced the reported cases of TRALI in UK. Thus, it is now widely practiced among transfusion services worldwide. Furthermore, female donors are checked for the presence of HLA antibodies before recruiting for apheresis donations.

A case of TRALI developed following red cell transfusion from a multiparous woman is described below.

TRALI—Case History Cont.

A 27-year-old, primi antenatal mother with low haemoglobin level was admitted to the hospital for blood transfusion at 28 weeks of POA. Prior to the admission, she has had symptoms of respiratory tract infection for three days. She had been transfused once for symptomatic anemia several years ago.

On admission, her Hb was 7.3g/dL and one unit of red cell concentrate was administered over 3 hours. Fifteen minutes following the completion of blood transfusion, patient developed fever, tachycardia and hypotension. Saturation was dropped from 100% to 75% on room air. Chest X-ray revealed bilateral consolidations, mainly in the middle and lower zones. Full blood count showed high WBC count with neutropenia. Transfusion reaction investigation findings were compatible with pre-transfusion results.

Patient was symptomatically treated and transferred to ICU for ventilation. Blood pressure was maintained within normal range without inotropes. During the incidence, Fetal Heart Sound (FHS) had been reduced and the absence of FHS was detected in Ultrasound scan done in the next day morning. The dead fetus was delivered by laparotomy 9th day following the incident. Patient fully-recovered over next few days and transferred back to the ward.

Being suspected for TRALI, HLA investigation workup was initiated. The implicated blood donor was a multiparous woman. HLA typing and anti-leucocyte antibody screening of the patient and the donor were performed at the Histocompatibility laboratory of National Blood Center. HLA typing was done using Luminex microbead-based molecular typing assay. HLA (class I and II) and Human Neutrophil Antigen (HNA) antibody screening/ identification were performed by Luminex Microbead-based assays. Results were tabulated and analyzed for the presence or absence of cognate anti-leucocyte antibodies. Due to practical difficulties, HLA crossmatch test was not performed.

The donor was positive for HLA Class I and Class II antibodies with over 90% PRA positivity. Additionally, anti-HNA-1a and -1c antibodies were also detected. Cognate antibodies for recipient's HLA Class I and Class II antigens were identified in the donor's sample confirming the diagnosis of TRALI. Since facilities were not available, HNA typing was not performed. HLA class I antibodies were detected in the recipient's serum too.

During the acute phase of the illness, washed red cells were transfused to the patient for stabilizing Hb prior to the laparotomy. Meanwhile, leucodepleted red cells were recommended for future transfusions. The donor was counseled and advised to refrain from blood donations.

3.9.2 Transfusion Associated Circulatory Overload (TACO)

3.9.2.1 Definition

Required criteria (A and/or B)

A. Acute or worsening respiratory compromise and/or

B. Evidence of acute or worsening pulmonary oedema based on:

◊ clinical physical examination, and/or

◊ radiographic chest imaging and/or other noninvasive assessment of cardiac function

Additional criteria

C. 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 oedema

D. Evidence of fluid overload including any of the following: a positive fluid balance; clinical improvement following diuresis

E. Supportive result of a relevant biomarker, e.g., an increase of B-type natriuretic peptide levels (BNP) or N-terminal-pro brain natriuretic peptide) NT-pro BNP to greater than 1.5 times the pre-transfusion value

3.9.2.2 TACO - Data Analysis

During 2023, 205 (6.68 %) of the adverse reaction reports were classified as Transfusion Associated Circulatory Overload. And only one of them have occurred in recipients less than 12 years of age.

Out of 205 TACO reported, 83 were in male recipients while 122 were in female recipients. (Figure 3.9.2-1)

Where as 19 of the reported TACO were emergency transfusions while 181 were not emergency and 5 were not mentioned. (Figure 3.9.2-2)

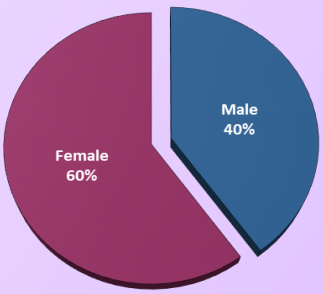

Figure 3.9.2-1 : TACO 2023 On Gender Basis

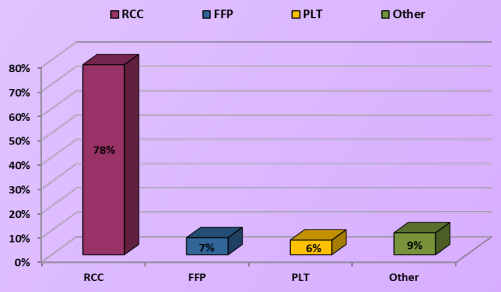

Figure 3.9.2-2 : TACO 2023 Based on Transfused Component

Additionally, 160 of reported TACOs were due to RCC transfusions, 14 were due to FFP transfusions, 12 were due to platelet transfusions and 19 were due to other components. (Figure 3.9.2-2)

8.5% of total male recipients who developed adverse reactions, and 7.1% of female recipients with adverse reactions, developed TACO.

When considering the component transfusions, 8.1% of RCC, 5.1% of FFP, 8.3% of PLT and 6.5% of other component transfusions with adverse reactions developed TACO.

3.9.3 Transfusion Associated Dyspnoea (TAD)

3.9.3.1 Definition

TAD is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO or allergic reaction. Respiratory distress in such cases should not be explained by the patient's underlying condition.

3.9.3.2 TAD - Data Analysis

During 2023, 53 (1.73 %) of the adverse reaction reports were classified as Transfusion Associated Dyspnoea. And only one of them have occurred in recipients less than 12 years of age.

Out of 53 TAD reported, 17 were in male recipients while 36 were in female recipients. (Figure 3.9.3-1)

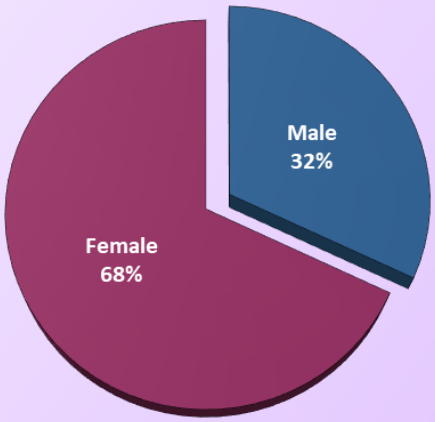

Figure 3.9.3-1 : TAD 2023
On Gender Basis

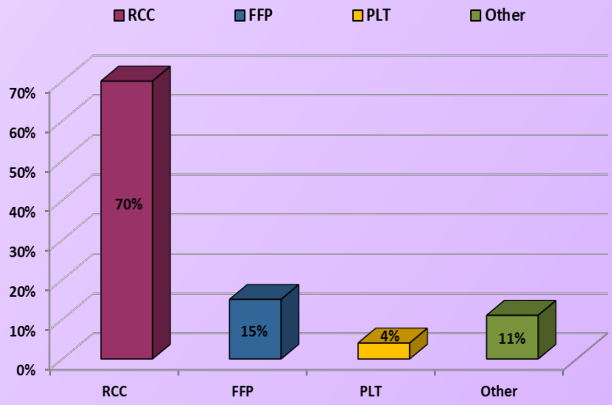

Figure 3.9.3-2 : TAD 2023
Based on Transfused Component

Additionally, 37 of reported TAD were due to RCC transfusions, 8 were due to FFP transfusions, 2 were due to platelet transfusions and 6 were due to other components. (Figure 3.9.3-2)

1.7% of total male recipients who developed adverse reactions, and 2.1% of female recipients with adverse reactions, developed TACO.

When considering the component transfusions, 1.9% of RCC, 2.9% of FFP, 1.4% of PLT and 2.1% of other component transfusions with adverse reactions developed TACO.

3.10 Acute Haemolytic Transfusion Reactions (AHTR)

3.10.1 Definition

AHTRs are defined as fever and other symptoms/signs of haemolysis within 24 hours of transfusion; confirmed by one or more of the following:

- ◊ Failure to increment or Hb drop to lower than pre-transfusion levels
- ◊ Rise in LDH
- ◊ Rise in bilirubin
- ◊ Positive DAT
- ◊ Incompatible cross match not detectable pre-transfusion

Acute hemolytic transfusion reactions (AHTRs) occur when preformed recipient antibodies bind to transfused RBC antigens resulting in antigen-antibody complex formation. This complex formation activates the complement cascade and causes intravascular haemolysis.

Most commonly, AHTRs are severe reactions due to ABO incompatibility. This occurs when transfused RBC antigens are incompatible with the recipient's plasma (e.g., group A RBCs into group O recipient) or, less commonly, when transfused plasma contains antibodies against the recipient's RBC antigens (e.g., group O plasma into group A recipient).

AHTRs can also be associated with antigen-antibody complex formation outside of the ABO system.

Lastly, RBC destruction may be a result of mechanical haemolysis.

3.10.2 AHTR Data Analysis

In 2023, 19 Acute Haemolytic Transfusion Reactions were reported. Out of them, sixteen (16) were due to ABO Incompatible transfusions, one was due to Rh Incompatible Transfusion and two (2) were due to other causes.

Additionally, two incidents of administrating incorrect blood packs were reported. Both were not blood group-incompatible and the transfusions were quit immediately hence no reactions were developed.

When compared to previous years, the total number of reported AHTR is more or less similar to that of 2022. (*Table 3.3.1-1)*

Out of them, two ABO incompatible transfusions had ended up in fatality.

Out of the two other AHTR, one was of a female recipient and due to non immunological haemolysis, and the other one was of a male recipient and Anti Le^b was detected in pre and post transfusion samples. Both were above 12 years of age.

Out of the 17 ABO and Rh Incompatible transfusions reported, 5 were in male recipients while 12 were in female recipients. (Figure 3.10.2-1)

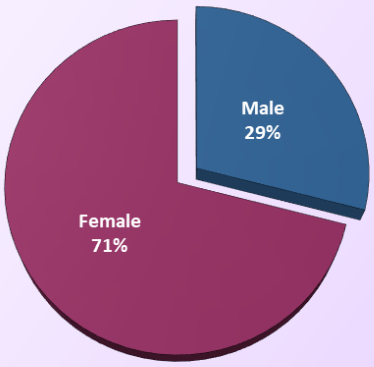

Figure 3.10.2-1 : ABO & Rh Reactions 2023 On Gender Basis

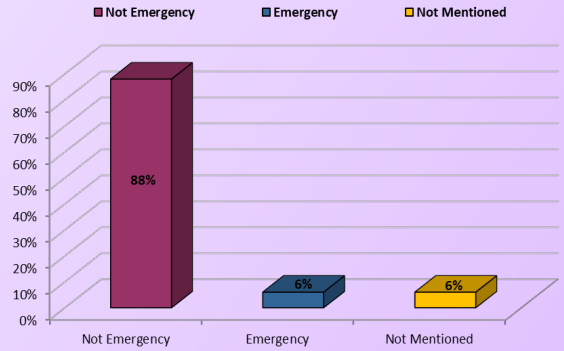

Figure 3.10.2-2 : ABO & Rh Reactions 2023 Based on Urgency of Transfusion

And also 1 of them was emergency transfusion while 15 were not and 1 was not mentioned. (Figure 3.10.2-2)

When analyzing data on the location of error, 11 have occurred in the ward set up while 3 in Blood Banks and 3 were having errors in both locations. (Figure 3.10.2-3)

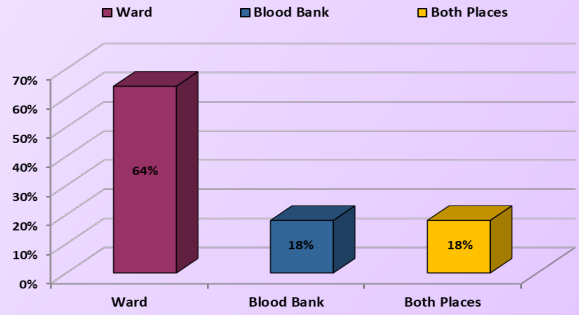

Figure 3.10.2-3 : ABO & Rh Reactions 2023 Based on Location of Error

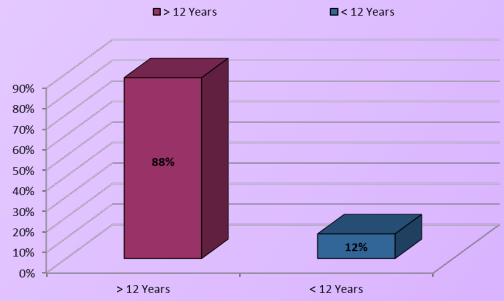

Figure 3.10.2-4 : ABO & Rh Reactions 2023 on Age Basis

And also, 15 of the ABO and Rh Incompatible transfusions have occurred in recipients more than 12 years of age while 2 have occurred in recipients less than 12 years of age. (Figure 3.8-4)

In addition, all of the reported reactions were due to ABO or Rh Incompatible RCC transfusions.

According to the analysis, the types of errors detected were as follows.

Blood Bank Errors

- ◊ Testing errors / sample swapping
- ◊ Incorrect interpretation of test results
- ◊ Documentation errors/ clerical errors
- ◊ Issuing errors
- ◊ Not practicing second sampling

Ward Errors

- ◊ Sample collection and labelling errors
- ◊ Incorrect patient identification and administration
- ◊ Incorrect method of practicing second sample
- ◊ Reconnecting the erroneous blood pack to the correct patient as soon as the error was detected, leading to contamination

3.11 Transfusion Associated Sepsis (TAS)

3.11.1 Definition

Transfusion associated sepsis is suspected if, following investigation the recipient had evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion, and no evidence of an alternative source of infection.

Plus: Either at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection. Or at least one component received by the infected recipient was shown to contain the agent of infection.

Sources of bacteria in blood components includes contamination from skin organisms of the donor at the phlebotomy site due to ineffective skin disinfection, transient bacteremia in donors and rarely contamination during handling and processing of components.

Bacterial contamination is more likely in components stored at room temperature such as platelets.

Clinical features include:

- Fever (temperature rise from baseline of ≥1.5 ^{o}C)
- Rigors
- Nausea/ vomiting/ diarrhoea
- Tachycardia (≥120 bpm or change from baseline of ≥40 bpm)
- Hypotension or hypertension (fall/ rise in systolic blood pressure of ≥30 mmHg)
- Haemolysis
- Shock
- Multiple organ failure during or immediately after the transfusion

3.11.2 Transfusion Associated Sepsis (TAS) - Data Analysis

Two(2) TAS were reported in 2023 (0.07%), and following the relevant post transfusion investigations one incident was confirmed while the other incident was inconclusive due to inadequacy of supportive evidences.

Both incidents had occurred in male recipients, above 12 years of age, and were not emergency transfusions of LRRC.

In the inconclusive incident culture of the blood pack was positive for Coagulase negative Staphylococcus Spp. while the recipient was negative and he had already been on antibiotics for an ongoing sepsis.

In the other incident cultures of both the blood pack and recipient were positive for pseudomonas Spp.

3.12 Deaths Following Transfusions

3.12.1 Overview

In 2023, 17 deaths were reported following transfusion of blood components. Out of them, only 5 were related to transfusions.

The reasons for the deaths were reported as follows.

1. Following ABO Incompatibility — 2
2. Possible TRALI—2
3. Possible TACO—1

Rest of the reported deaths were included in the imputable category—excluded or unlikely as they were either not directly related to transfusion/ having other co-morbidities.

3.12.2 Data Analysis of Deaths Following Transfusions

Out of the 5 deaths considered, 3 were female recipients while 2 were male recipients. (Figure 3.12.2-1)

In addition, 3 of the reported deaths were following RCC transfusions, 1 was following FFP transfusion and 1 was following other component transfusion. (Figure 3.12.2-2)

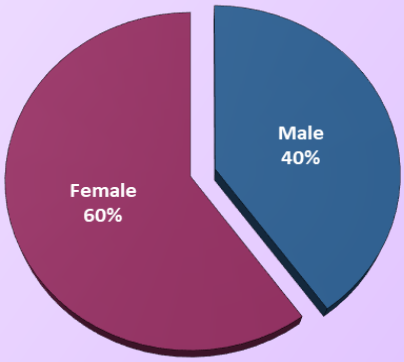

Figure 3.12.2-1 : Deaths 2023 On Gender Basis

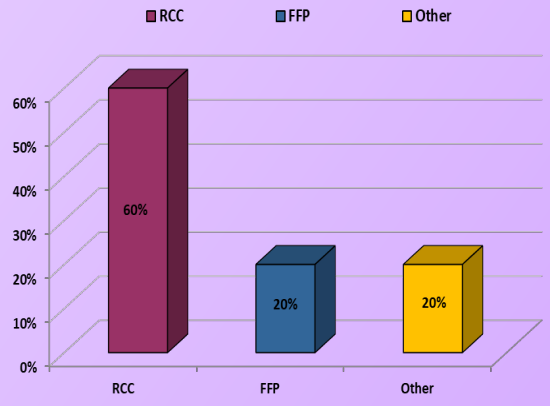

Figure 3.12.2-2 : Deaths 2023 Based on Transfused Component

Furthermore, all of them were not emergency transfusions .

3.13 Transfusion Transmitted Infections (TTI)

3.13.1 Overview

Following blood transfusions, there is a risk of transfusion transmitted infections (TTI), which is minimized through current advanced screening technologies.

In Sri Lanka, each and every donor unit is being screened for five major infectious agents, decided according to the prevalence in Sri Lankan community. They are, Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Syphilis and Malaria.

3.13.2 TTI - Data Analysis

Following Table 3.13-1 summarizes the TTI Data of the donated blood units over past five years.

Year	HIV Screening +ve	HIV Confirmed +ve	Hep B Repeat Reactive	Hep C Repeat Reactive	VDRL Reactives	TPPA/ TPHA Positives	MP Positives
2019	694	44	528	804	1344	119	0
2020	533	34	252	613	960	96	0
2021	422	56	751	495	1496	153	1
2022	1196	60	221	354	2296	143	0
2023	1327	71	208	449	1398	211	0

Table 3.13-1 : Yearly Comparison of TTI Data

Following Figure 3.13-1 is a graphical illustration of the above data, plotted against the total units tested.

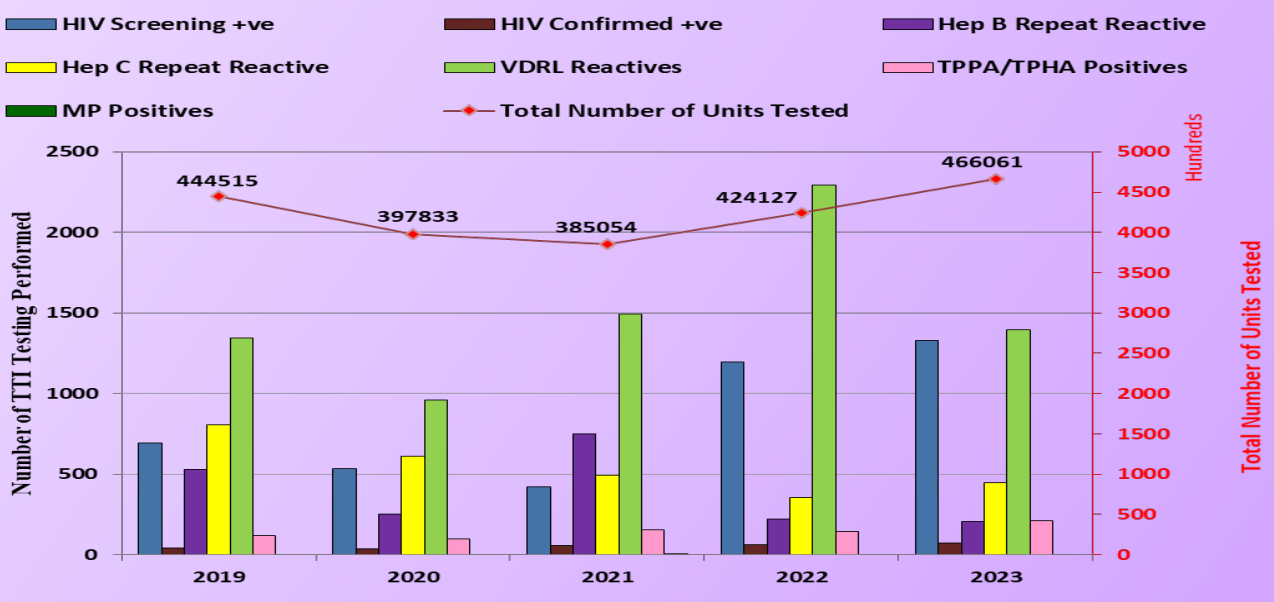

Figure 3.13-1 : Yearly Comparison of TTI Test Results Against Total Units Tested

CHAPTER 04

Donor Haemovigilance

4.0 Donor Haemovigilance

4.1 Overview

Donor Haemovigilance includes monitoring donor counseling , recruitment and collection of blood as well as reporting of unexpected adverse events in whole blood and component donors and the action taken as a result. These events may be adverse reactions or complications resulting from donation, selection and management of donors, which may directly harm the donor or influence the quality of the product, there by putting the recipient at risk.

4.2 Data Analysis - Donor Deferrals

During 2023, a total of 55542 donors were deferred in Mobile, In-house and Apheresis donations. Out of them, 19033 (34%) were due to low Hb and 6590 (12%) were due to medical Reasons. Table 4.2-1 summarizes the donor deferral causes over past five years.

Cause	2019	2020	2021	2022	2023
TTI	1097	974	1098	1945	3352
Medical	21171	9233	4505	5729	6590
Low Hb	12241	11783	10134	13977	19033
Low Wt	1735	1401	673	911	624
Travel	1270	741	447	1184	2621
Other	5512	13867	15896	16040	23322
Total	**43026**	**37999**	**32753**	**39786**	**55542**

Table 4.2-1 : Yearly Comparison of Donor Deferral Causes

When analysing the donor deferral causes, the deferrals due to low Haemoglobin level has a marked increase than previous years.

Figure 4.2-1 illustrates the above data.

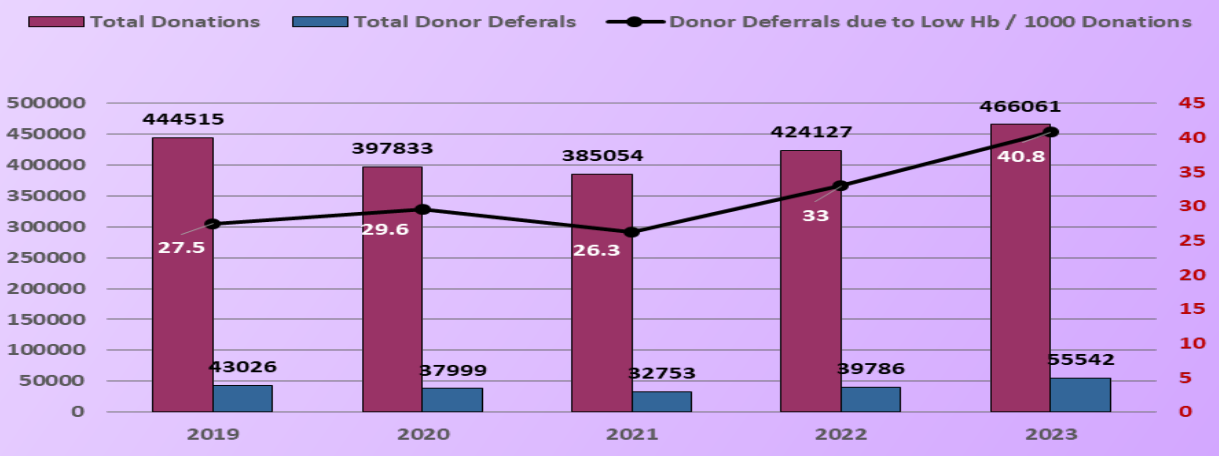

Figure 4.2-1 : Yearly Comparison of Total Donations, Total Donor Deferrals and Deferrals due to Low Hb per 1000 Donations

4.3 Data Analysis - Donor Adverse reactions

In 2023, a total of 10016 donor adverse reactions were reported in Mobile, In-house and Apheresis donations. Where as, early faints is the most common donor adverse reaction reported over past four years. (Table 4.3-1)

Reaction	2020	2021	2022	2023
Vomiting	502	600	530	630
Faints (Early)	12033	4866	5154	7566
Faints (Late)	592	296	515	837
Haematoma	52	33	63	65
Pain (Donating arm)	30	5	15	41
Numbness	8	0	15	13
Arterial Puncture	0	0	4	0
Convulsions	167	179	132	229
Other	483	2569	2569	635
Total	**13867**	**7948**	**8997**	**10016**

Table 4.3-1 : Yearly Comparison of Donor Adverse Reactions

In 2023, number of total donor adverse reactions per 1000 donations remains static as previous two years.

Figure 4.3-1 illustrates the above data.

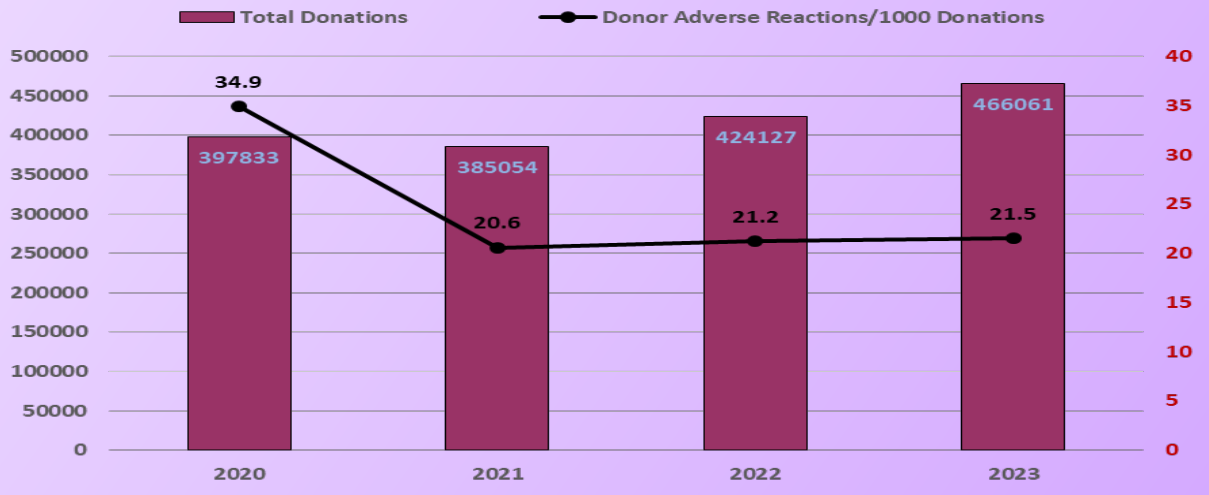

Figure 4.3-1 : Yearly Comparison of Donor Adverse Reactions per 1000 Donations

Additionally, 6 incidents related to blood collection and platelet apheresis procedures were reported to the QMS in 2023.

CHAPTER 05

Process Haemovigilance

5.0 Process Haemovigilance

5.1 Overview

Process Haemovigilance comprises of monitoring the processing, screening, storing, pre-transfusion testing and transporting of donated blood, focused on minimizing the deviations from the standard procedures in order to ensure safe and quality blood transfusion.

5.2 Data Analysis

Below Table 5.2-1 summarizes the incidents reported to Quality Management Section under the category of Process Haemovigilance in 2023.

Incident Category	No of Incidents Reported
PLT AP Machine/Procedure Related Errors	6
Component Processing Errors/ Procedure failure	10
Component Labeling Errors	5
Blood Component Transportation Related Errors	1
Blood Transfusion Related Incidents	1
Incidents Related to Patients Blood Sample Collection for Testing Procedures	1
End Product Quality Related Errors	5
Total	**29**

Table 5.2-1 : Summary of the Incidents on Process Haemovigilance 2023

CHAPTER 06

Near Miss Events

6.0 Near Miss Events

6.1 Definition

A near miss is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrong transfusion or a reaction in a recipient if transfusion had taken place.

6.2 Data Analysis of Near Miss Events

During 2023, there were 34 (1.11 %) near miss events reported to NHU. Table 6.2-1 summarizes the reported near miss events.

Error	Total Number
Blood sample taken from wrong patient	21
Testing done with wrong sample	2
Testing done correctly, but wrong documentation – Detected prior to issue	1
Wrong compatibility report/detected before transfusion	2
Pack grouping error	4
Required special product not requested and past history of positive antibody reports not considered in DT request – detected at blood bank prior to issue	1
Blood sample and DT request form sent to blood bank with wrong BHT – Detected prior to acceptance	1
Labelling error leading to swapping of samples – detected prior to transfusion	1
Wrong group mentioned in previous documents (Paper Base Errors)	1
Total	**34**

Table 6.2-1 : Summary of the Near Miss Events 2023

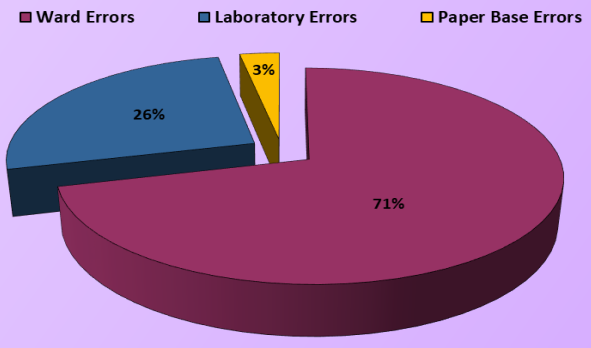

Figure 6.2-1 : Near Miss Events 2023 - Based on the Location of Error

Message From The National Haemovigilance Unit

When summarizing the available data, total number of reported ATR shows slight increase in 2023 (12.9 % increase than 2022). At the same time, total collection and total component issues have marked the highest values over past five years in 2023.

In 2023, number of component issues per 1000 population is 38.3, the highest value for past five years, while the number of ATR per 1000 component issues is 3.6, slightly higher than 2022 (3.4).

Considering the major ATR, there were 17 ABO and Rh Incompatible transfusions in 2023, which is slightly less than 2022.

Numbers of reported TRALI were 6 and anaphylactic reactions were 54, both being higher than 2022.

Two transfusion associated sepsis incidents were reported in 2023, unlike the previous years.

Only a few incidents were reported as DHTR, either due to missed-detection and under-reporting or else owing to antibody screening at pre-transfusion cross-match. However, due to the inadequacy of supportive clinical and/or laboratory evidence, they were attributed to other incident categories.

Under the minor ATRs, FNHTR is the most frequently reported ATR for the past five years.

Regarding donor Haemovigilance, 10016 donor adverse reactions were reported, with a comparatively significant increase than 2022.

The Haemovigilance Unit of NBTS shoulders the national responsibility of identifying and preventing occurrences or recurrences of transfusion-related adverse events, to increase the safety, efficacy and efficiency of blood transfusion, covering the entire transfusion chain from donor to recipient. This process needs accurate and reliable data analysis for the implementation of corrective and preventive measures.

Therefore, spotlight on the following factors would be determining to succeed that task.

1. Prompt and accurate reporting of the adverse events with adequate and relevant details
2. Be updated and follow the standard definitions
3. Strictly adhere to the transfusion guidelines
4. Cross-check on the performed tests and documentation, as much as possible
5. Emphasize on the implementation and adherence to pre-transfusion blood group verification by second sampling
6. Learn from the Near Miss Events and Incident Reports

Last but not least, the continued support of all the members of the National Blood Transfusion Service to achieve the goal of continued quality improvement of the transfusion chain through corrective and preventive actions to improve donor and patient safety, improve transfusion appropriateness and reduce wastage, is highly appreciated with gratitude .

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National Haemovigilance Unit of Sri Lanka

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