



KEMENTERIAN KESIHATAN MALAYSIA
PUSAT DARAH NEGARA

NATIONAL HAEMOVIGILANCE COORDINATING CENTRE,
PUSAT DARAH NEGARA

HAEMOVIGILANCE REPORT 2022-2023

NATIONAL TRANSFUSION MEDICINE SERVICE IN MALAYSIA



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Pusat Darah Negara
Ministry of Health Malaysia



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Ministry of Health Malaysia

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National Haemovigilance Coordinating Centre Pusat Darah Negara
Jalan Tun Razak
50400 Kuala Lumpur, Malaysia
Tel: 03-2613 2688
Fax: 03-26980362
Web: <http://www.pdn.gov.my>

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WRITING AND EDITORIAL GROUP

ADVISOR

- : DR. MOHAMMAD MASRIN BIN MD ZHRIN**
Transfusion Medicine Consultant
Head of Transfusion Medicine Service
Director, Pusat Darah Negara

HEAD OF DIVISION

- : DR. IDALESWATI NOR MOHAMED**
Transfusion Medicine Consultant
Head of Division
National Surveillance and Assessment
Pusat Darah Negara

HEAD OF SECTION

- : DR. FARAHIN BINTI AMAT TAMIYES**

HEAD OF UNIT

- : DR. AZRATUL FARHAN BT CHE ABD GHANI**
DR. NUR IZZATI BT IZHAR

MEMBERS

- : DR. NITHIYAA A/P BALA**
DR. NUR NADIRA BINTI ABD RAHIM
DR. SERJITSRUUP KAUR JUDGE
DR. THAYANI A/P SIVASAMBU
ENCIK YUSANI AMIR BIN JAAFAR
PUAN SHAHRATULHASHIMA BT RASHID



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We would like to extend our deepest appreciation to all the blood banks across Malaysia for their unwavering dedication in submitting haemovigilance data, which has been pivotal in shaping this publication as a key resource for advancing transfusion practices and patient safety.

Our sincere thanks go to the Director of the National Blood Centre for his steadfast support and invaluable leadership throughout the development of this important initiative.

We are also deeply grateful to the Director of the Medical Development Division, Ministry of Health Malaysia, for granting permission to publish and ensure the accessibility of this report on Ministry of Health official platform, signify its critical role in enhancing haemovigilance efforts and elevating the quality of transfusion services nationwide.

FOREWORD

Haemovigilance is a critical aspect of patient safety. With the publication of fourth biennial Haemovigilance Report 2022-2023 by National Haemovigilance Coordinating Centre, it reflects on ongoing dedication and commitment towards enhancing the safety and efficacy of blood transfusions.

The advancement of transfusion medicine demands meticulous data collection and analysis to identify trends, evaluate risks, and implement evidence-based enhancement in transfusion practices. This is where the role of hemovigilance comes into play whereby the fundamental purpose of hemovigilance is to ensure better quality in the transfusion chain

by addressing issues with corrective and preventive actions. A range of findings and proposed recommendations have been outlined herein based on the data analysis of the events and incidents reported to the National Haemovigilance Coordinating Centre. It is hope that this report provides clarity on our current state of hemovigilance in Malaysia.

Special thanks are extended to the National Haemovigilance Coordinating Centre for their dedication and effort in producing this report. May this publication serve as a source of information and exchange for all everyone engaged in the field of transfusion.

YBHG. DATO' DR. MOHD AZMAN YACOB

Director
Medical Development Division
Ministry of Health Malaysia



PREFACE



The Haemovigilance Report 2022-2023 acts as an essential reference for medical professionals in Ministry of Health (MOH) facilities nationwide to supply safe and adequate blood supply. This haemovigilance report highlights the advancements and improvements made over the past year in our monitoring and response to adverse events related to blood transfusions.

Effective hemovigilance is a shared responsibility that involves the active participation of hospitals, whose contributions are critical to upholding the safety of blood transfusions. The increase in report submissions over the years has been notably encouraging. This report highlights the key findings

from the data submitted by hospitals in identifying critical areas in transfusion process and areas for continued improvement. It plays an indirect role in enhancing awareness and increasing vigilance to ensure the safety of transfused blood.

I would like to thank and congratulate all the contributors and the National Haemovigilance Coordinating Centre in the creation of this report. May this report act as a practical guide for all those involved in the transfusion process, contributing to enhanced patient safety. We welcome any suggestions and feedback that will help us to enhance and provide a higher quality of service.

DR. MOHAMMAD MASRIN BIN MD ZAHRIN

Head of National Transfusion Medicine Service

Director

Pusat Darah Negara



EXECUTIVE SUMMARY

The Haemovigilance Report for 2022-2023 provides an in-depth analysis of transfusion-related incidents, highlighting key findings, trends, and challenges faced in ensuring safe and effective blood transfusions in Malaysia. Haemovigilance, the systematic monitoring and reporting of transfusion-related adverse events, plays a critical role in ensuring that blood transfusions are not only effective but also safe for both donors and recipients. In Malaysia, the National Haemovigilance Coordinating Centre (NHCC) under Pusat Darah Negara (PDN) has been leading this effort, as demonstrated in this report.

The role of haemovigilance in transfusion medicine is essential, as it encompasses the entire transfusion chain—from donor selection and blood collection to the transfusion of blood products to patients. According to the World Health Organization (WHO), haemovigilance aims to continuously improve the quality of the transfusion chain through corrective and preventive measures, ultimately enhancing donor and patient safety and reducing wastage.

One of the most important achievements in this report is the increased participation in haemovigilance reporting, with 6,951 reports analysed in 2022 and 7,356 in 2023. This reflects a stabilization in reporting, signifying a commitment to blood transfusion safety across Malaysian healthcare institutions. However, inconsistencies in monthly reporting, particularly underreporting, remain a concern. As a result, starting in 2024, haemovigilance reporting is included as a key performance indicator (KPI) for the Transfusion Medicine Service to ensure greater consistency and adherence to reporting protocols.

Adverse transfusion reactions (ATRs) continued to be the most frequently reported incidents, accounting for over 60% of adverse events. Mild allergic reactions and febrile non-haemolytic transfusion reactions (FNHTR) were the most common, while a prominent rise in transfusion-associated circulatory overload (TACO) cases raised concerns due to its severe complications. This trend highlights the importance of implementing risk-reduction strategies to identify at-risk patients before transfusion.



The report also shown a decline in transfusion errors, with 46 Incorrect Blood Component Transfused (IBCT) cases and 256 Near Misses (NMs) reported in 2022, dropping to 39 IBCTs and 230 NMs in 2023, despite an increase in total number of transfusion. Most errors occurred during sample taking, labelling, and component selection, often due to failures in patient identification and non-compliance with Standard Operating Procedures (SOPs). The 2022-2023 report provides a more detailed analysis by introducing individual chapters on specific transfusion errors such as Right Blood Right Patient (RBRP), Handling and Storage Errors (HSE) and Avoidable, Delayed, Under or Over Transfusion (ADU). These dedicated chapters emphasize the importance of focusing on each error category, helping to identify the root causes and implement targeted interventions. The report recommends enhancing staff training, supervision, and the use of technology such as the Blood Bank Information System (BBIS) to reduce human errors, particularly in busy environments like general wards and emergency departments. Clinical audits and ongoing education for healthcare professionals are also critical to ensuring sustained improvements in transfusion safety.

On the donor side, the most frequently reported adverse events were vasovagal reactions and hematomas. These findings emphasize the need for continuous training for phlebotomists and better post-donation care to enhance the donor experience and reduce adverse donor reactions. The report also emphasises donor seroconversion as a critical area of concern, with syphilis, HIV, and HBV being the most common causes. Male donors aged 20-39 and those with fewer than five donations were found to be at higher risk, highlighting the need for better donor education and awareness to prevent the transmission of infections through blood transfusions.

Several key recommendations emerge from this report. First, addressing inconsistencies in haemovigilance reporting is crucial to obtaining a complete and accurate understanding of transfusion safety across the country. Ensuring that all hospitals submit reports, even when no adverse events occur, will provide a more comprehensive picture. Additionally, improving transfusion practices, such as strengthening patient identification procedures and handling one sample at a time, can significantly reduce the risk of transfusion errors. Managing at-risk patients more effectively, particularly those prone to severe ATRs like TACO, is another priority. For donor care, implementing better post-donation support and minimizing adverse reactions such as vasovagal episodes are essential. Continuous education for healthcare providers, both in transfusion and donation, will help reduce adverse events. Lastly, enhancing donor education and public awareness about the importance of blood safety, particularly regarding the self-declaration of at-risk behaviours, will further contribute to preventing transfusion-transmitted infections.



In conclusion, the 2022-2023 Haemovigilance Report reaffirms the importance of a robust haemovigilance system in ensuring the safety and efficacy of blood transfusions in Malaysia. The evidence provided in this report are crucial for guiding the implementation of preventive measures and quality improvements across the transfusion chain. With continuous vigilance, strengthened protocols, and a commitment to haemovigilance, Malaysia's healthcare system can continue to improve outcomes for both donors and patients.

DR. IDALESWATI NOR MOHAMED

Transfusion Medicine Consultant
National Surveillance and Assessment
Pusat Darah Negara



TABLE OF CONTENTS

CHAPTER 1:		1
Introduction		
1.1	National Haemovigilance Coordinating Centre (NHCC)	2
1.2	Objectives	2
1.3	Definition of Hemovigilance	2
1.4	Post Covid-19 Pandemic Recovery	3
1.5	Reporting Process and Data Analysis Limitations	3
1.6	Reporting Steps of An Adverse Event to NHCC	3
CHAPTER 2:		5
Participation of Haemovigilance Reporting		
2.1	Overview Of Haemovigilance Reporting	6
2.2	Type of Adverse Events	7
2.3	Reported No Cases of Adverse Events (AE)	8
2.4	Participation to Haemovigilance Reporting	11
2.5	Total Number of Reported Adverse Event	27
CHAPTER 3:		31
Transfusion Error		
3.1	Definition of Errors	32
3.2	Incidence of Error Reported by Hospital Blood Banks under the Ministry of Health	33
3.3	Critical Control Point (CCP)	35
	3.3.3.1 Request	36
	3.3.3.2 Sample Taking/ Labelling	38
	3.3.3.3 Sample Receipt	40
	3.3.3.4 Testing	42
	3.3.3.5 Component Selection	44
	3.3.3.6 Component Labelling, Availability and Handling and Storage Errors	46



3.3.3.7	Component Collection	48
3.3.3.8	Prescription	49
3.3.3.9	Administration	50
3.4	Error in Critical Control Points in the Transfusion Process	53
3.5	Error Locations in the Transfusion Process	54
3.6	Category of Staff Involved	58
3.7	Wrong Component Transfused (WCT) and Specific Requirement Not Met (SRNM) in relation to CCP	59
3.8	Imputability	63
CHAPTER 4: Right Blood Right Patient (RBRP)		65
4.1	Definition of RBRP	66
4.2	Incidence	66
CHAPTER 5: Handling And Storage Errors (HSE)		69
5.1	Definition of HSE	70
5.2	Incidence	70
CHAPTER 6: Avoidable, Delayed, Under Or Overtransfusion (ADU)		73
6.1	Definition of HSE	74
6.2	Incidence	74
CHAPTER 7: Incident		75
7.1	Definition of Incident	76
7.2	Incidence	76
7.3	Contributing Factors	77
7.4	Recommendations	78



CHAPTER 8:		79
Adverse Transfusion Reaction		
8.1	Definitions of Adverse Transfusion Reaction (ATR)	80
8.2	Overview of Adverse Transfusion Reaction (ATR) Reports	80
8.3	Types of Adverse Transfusion Reaction (ATR) Reported	81
8.4	Adverse Transfusion Reactions Reports According to types of Reaction	82
	8.4.1 Febrile, Allergic, Hypotensive Reactions (FAHR)	82
	8.4.2 Pulmonary Complications of Transfusion Reaction	84
	8.4.3 Transfusion-Associated Graft-Versus-Host Disease (Ta-GvHD)	91
	8.4.4 Haemolytic Transfusion Reaction (HTR)	91
	8.4.5 Uncommon Complications of Transfusion	92
	8.4.6 Transfusion-Transmitted Infection (TTI)	94
	8.4.7 Post Transfusion Purpura (PTP)	94
8.5	Type Of Blood Component Transfused And ATR Complication	95
8.6	Incidence of Implicated Blood Components in 10,000 Blood Components Transfused	95
8.7	Types of Adverse Events Associated with Leucofiltered Red Blood Cell (RBC)	96
CHAPTER 9:		97
Adverse Donor Reaction		
9.1	Definition	98
9.2	Overview of Adverse Donor Reaction (ADR) Reporting	98
9.3	Types of Adverse Donor Reactions (ADR)	99
	9.3.1 Vasovagal Reactions (VVR)	100
	9.3.2 Hematoma	105
	9.3.3 Delayed Bleeding	108
	9.3.4 Other Arm Pain	109
	9.3.5 Arterial Puncture	110
	9.3.6 Citrate Reaction	111
	9.3.7 Nerve injury/ irritation	112
	9.3.8 Local Allergic Reaction	114
	9.3.9 Thrombophlebitis/ Cellulitis	115
	9.3.10 Deep Vein Thrombosis	115
	9.3.11 Arteriovenous Fistula	115



9.3.12 Compartment Syndrome	116
9.3.13 Brachial Artery Pseudoaneurysm	116
9.3.14 Hemolysis	116
9.3.15 Air Embolism	117
9.3.16 Generalized (Anaphylactic) Reaction	117
9.3.17 Other Serious Complications related to Blood Donation	117
9.3.18 Others	120
CHAPTER 10: Seroconvert Donors	121
10.1 Definition	122
10.2 Lookback Recall Procedure	122
10.3 Method Of Reporting	123
10.4 Seroconvert Donor Reports	123
10.5 Part 1 with Post Donation Counselling (PDC) Report	125
10.6 Human Immunodeficiency Virus (HIV)	126
10.7 Hepatitis B Virus (HBV)	130
10.8 Hepatitis C	134
10.9 Syphilis	138
10.10 Co-Infection Of TTIs	142
10.11 Summary and Recommendations	146
REFERENCES	149



FIGURES

Figure 2.1	Number of Haemovigilance Reports Received from 2010 – 2023	6
Figure 2.2	Number of Adverse Transfusion Reaction (ATR), Incorrect Blood Component Transfused (IBCT), Near Misses (NM), Incident, Adverse Donor Reaction (ADR) and Seroconvert Donors (SD) reported to NHCC from 2016 – 2023	7
Figure 2.3.1	Number of Reported No Case of Adverse Events (ATR, IBCT, NM, Incident, ADR And SD) Reported in 2022 and 2023	8
Figure 2.3.2a	Number of Reported No Case of Adverse Events (ATR, IBCT, NM, Incident, ADR and SD) by States in 2022	9
Figure 2.3.2b	Number of Reported No Case of Adverse Events (ATR, IBCT, NM, Incident, ADR and SD) by States in 2023	10
Figure 3.2.1a	Incidence of IBCT and Number of Blood Components Transfused by State in MOH Hospitals, 2022 and 2023	34
Figure 3.2.1b	Incidence of Near Misses and Number of Blood Components Transfused by State in MOH Hospitals, 2022 and 2023	34
Figure 3.3	Critical Control Point in the Transfusion Process	35
Figure 3.4	Critical Control Point in the Transfusion Process where IBCT/NM Occurred in 2022-2023	54
Figure 3.5.2	Error in Ward in 2022 - 2023	55
Figure 3.5.3	Error in Blood Bank in 2022 - 2023	57
Figure 3.6.1	Category of Staff Involved in 2022 - 2023	58
Figure 3.7.1a	Sub-categorisation of IBCT in 2022 - 2023	60
Figure 3.7.1b	Critical Control Point where Error Occurred on Type of IBCT (WCT and SRNM) in 2022	60
Figure 3.7.1c	Critical Control Point where Error Occurred on Type of IBCT (WCT and SRNM) in 2023	61
Figure 3.7.2a	Critical Control Point where Near Miss Occurred leading to Probable WCT and Probable SRNM in 2022	62
Figure 3.7.2b	Critical Control Point where Near Miss Occurred leading to Probable WCT and Probable SRNM in 2023	62
Figure 4.2.1a	RBRP: Detected Post-transfusion in 2022 - 2023	66
Figure 4.2.1b	RBRP: Detected Pre-transfusion in 2022 – 2023	67
Figure 4.2.1c	RBRP - Incident in 2022 – 2023	67
Figure 4.2.3	The PLEDGE aide memoire	68
Figure 5.2	Handling and Storage Errors (HSE) in 2022 - 2023	71
Figure 6.2	ADU Reports in 2022 - 2023	74



FIGURES

Figure 7.2	Total Number of Incidents Reported in 2022 - 2023	77
Figure 8.4.1.2	Number of Reported Cases of Allergic, Febrile, Mixed Allergic/ Febrile and Hypotensive Reactions in 2022 - 2023	83
Figure 8.4.2.2	Total Number of Cases of Pulmonary Complications in 2022 - 2023	87
Figure 8.4.4.2	Number of Cases of Haemolytic Transfusion Reaction in 2022 - 2023	92
Figure 8.4.5.2	Number of Cases of UCT in 2022 - 2023	93
Figure 8.4.5.3	Outcome of Adverse Transfusion Reaction (UCT) in 2022 - 2023	93
Figure 8.5	Total Number of Blood Component Transfused and Implicated with ATR in 2022 - 2023	95
Figure 8.6	Incidence of ATR per 10,000 Blood Components Transfused	95
Figure 8.7	Types of ATR associated with Filtered Red Blood Cell in 2022 - 2023	96
Figure 9.2	Rate of ADR per 10,000 blood collection from 2016 – 2023	98
Figure 9.3.1.2	Category of VVR in 2022 - 2023	100
Figure 9.3.1.3	VVR Report based on Gender in 2022 – 2023	101
Figure 9.3.1.4	VVR Report based on Age in 2022 – 2023	101
Figure 9.3.1.5	VVR Report based on Weight in 2022 – 2023	102
Figure 9.3.1.6	VVR Report based on Frequency of Donation in 2022 – 2023	102
Figure 9.3.2.2	Total Number of Hematoma in 2022 – 2023	105
Figure 9.3.2.3a	Hematoma Report based on Gender in 2022 – 2023	106
Figure 9.3.2.3b	Hematoma Report based on Age in 2022 – 2023	106
Figure 9.3.2.3c	Hematoma Report based on Weight in 2022 – 2023	106
Figure 9.3.3.2	Total Number of Delayed Bleeding in 2022– 2023	108
Figure 9.3.4.2	Total Number of Other Arm Pain in 2022 – 2023	109
Figure 9.3.5.2	Total Number of Arterial Puncture in 2022 – 2023	110
Figure 9.3.6.2	Total Number of Citrate Reaction in 2022 – 2023	111
Figure 9.3.7.2	Total Number of Nerve Injury/ Nerve Irritation in 2022 – 2023	113
Figure 9.3.8.2	Total Number of Local Allergic Reaction in 2022 – 2023	114
Figure 9.3.17.2	Total Number of Other Serious Complications Related to Blood Donation in 2022 – 2023	118
Figure 10.4.1	Total Number of Seroconvert Donor Report Received from 2016 – 2023	123



FIGURES

Figure 10.6.2	Total Number of HIV Seroconvert Donors in 2022 - 2023	126
Figure 10.6.4	Demographic Distribution and Risk Factors for HIV seroconvert Donors in Part 1 in 2022 – 2023	128
Figure 10.6.5	Outcome of Blood Products and Recipient of Seroconvert Donors for HIV in 2022 - 2023	129
Figure 10.7.2	Total Number of Hepatitis B Seroconvert Donors in 2022 -2023	131
Figure 10.7.4	Demographic Distribution and Risk Factors for Hepatitis B Seroconvert Donors in Part 1 in 2022 - 2023	132
Figure 10.7.5	Outcome of Blood Products and Recipient of Seroconvert Donors for HBV in 2022 – 2023	133
Figure 10.8.2	Total Number of Hepatitis C Seroconvert Donors in 2022-2023	134
Figure 10.8.4	Demographic Distribution and Risk Factors for Hepatitis C Seroconvert Donors in Part 1 in 2022 - 2023	136
Figure 10.8.5	Outcome of Blood Products and Recipient of Seroconvert Donors for HCV in 2022 – 2023	137
Figure 10.9.2	Total Number of Syphilis Seroconvert Donors in 2022- 2023	138
Figure 10.9.4	Demographic Distribution and Risk Factors for Syphilis Seroconvert Donors in Part 1 in 2022 – 2023	140
Figure 10.9.5	Outcome of Blood Products and Recipient of Seroconvert Donors for Syphilis in 2022 - 2023	141
Figure 10.10.2	Total Number of Co-infection TTI Seroconvert Donors in 2022 - 2023	143
Figure 10.10.4	Demographic Distribution and Risk Factors for Co-infection Seroconvert Donors in Part 1 in 2022 – 2023	144
Figure 10.10.5	Outcome of Lookback and Recall for Co-infection Seroconvert Donors in 2022 – 2023	145
Figure 10.11	Seroconvert Donor Summary 2022 and 2023	148



TABLES

Table 2.4.3.1	Participation in Patient Haemovigilance Reporting	12
Table 2.4.3.2	Participation in Donor Haemovigilance by the Collection Center	21
Table 2.5.1	Number of Patient Haemovigilance Reports Submitted by States in 2022 - 2023	27
Table 2.5.2	Rate of Adverse Events per 10,000 Blood Components Issued by States in 2022 – 2023	28
Table 2.5.3	Number of Donor Haemovigilance Reports Submitted by States in 2022 – 2023	29
Table 2.5.4	Rate of Adverse Donor Reaction per 10,000 Blood Collection by States in 2022 – 2023	30
Table 3.3.3.1	Request Error in 2022 – 2023	36
Table 3.3.3.2	Sampling/Labelling Error in 2022 – 2023	39
Table 3.3.3.3	Receipt and Registration Error in 2022 – 2023	40
Table 3.3.3.4	Testing Error in 2022 – 2023	42
Table 3.3.3.5	Component Selection Error in 2022 – 2023	44
Table 3.3.3.6	Component Labelling, Availability and Handling & Storage Errors in 2022 – 2023	46
Table 3.3.3.7	Component Collection Error in 2022 – 2023	48
Table 3.3.3.8	Prescription Error in 2022– 2023	49
Table 3.3.3.9	Administration Error in 2022– 2023	51
Table 3.3.4	Miscellaneous in 2022 – 2023	52
Table 3.8.1	Imputability	63
Table 3.8.2	Clinical Outcomes by Imputability for IBCT cases in 2022 - 2023	64
Table 8.2	Total Number of Adverse Transfusion Reaction Reported	80
Table 8.3	Incidence of ATR based on Type of Reaction in 2022 & 2023	81
Table 8.4.1.1	Definitions of FAHR (<i>Adopted from SHOT Report 2021</i>)	82
Table 8.4.1.4	Outcome of Adverse Transfusion Reaction - FAHR in 2022 - 2023	83
Table 8.4.2.1	SHOT Criteria for Assessment of TRALI Cases (<i>Adopted from SHOT Report 2020</i>)	85
Table 8.4.2.3	Summary of Reported TRALI Cases in 2022 and 2023	87
Table 8.4.2.4	Outcome of Adverse Transfusion Reaction - Pulmonary Complications (2022 and 2023)	88
Table 8.4.2.5	TACO Pre-transfusion Risk Assessment (Adopted from SHOT Report 2023)	89
Table 8.4.2.6	Comparison table to assist with pulmonary reaction classification (Adopted from SHOT Report 2022)	90
Table 8.4.4.3	Outcome of Adverse Transfusion Reaction - HTR in 2022 - 2023	92
Table 9.3	Types of ADR in 2022 – 2023	99
Table 10.4.3	Total number of Seroconvert Donor Reporting	124
Table 10.5	Part 1 with PDC: Seroconvert Donor Demographic Characteristics according to Transfusion Transmissible Infection (TTI)	125



ABBREVIATIONS (A to Z)

ADR	Adverse Donor Reaction	MSP	Multiple Sexual Partners
ADU	Avoidable/ Delayed/ Undertransfused	NAT	Nucleic Acid Testing
AMT	Applied Muscle Tension	NBC	National Blood Centre
ANC	Antenatal Care	NHCC	National Haemovigilance Coordinating Centre
ARDS	Acute Respiratory Distress	NHSBT	National Health Service Blood and Transplant
ATR	Adverse Transfusion Reaction	NM	Near miss
BBIS	Blood Bank Information System	NRR	No Report Received
CCP	Critical Control Point	NSN	Negeri Sembilan
CDC	Centers for Disease Control and Prevention	OT	Operation Theatre
CME	Continuous Medical Education	PAC	Patient Admission Centre
CPPT	Cryoprecipitate	PBM	Patient Blood Management
CSUP	Cryosupernatant	PC	Packed Cell
DHTR	Delayed Haemolytic Transfusion Reaction	PDC	Post Donation counselling
ED	Emergency Department	PHG	Pahang
ER	Emergency Room	PLS	Perlis
FEFO	First Expiry, First Out	PLT	Platelet
FFP	Fresh Frozen Plasma	PNG	Penang
FNHTR	Febrile Non-Haemolytic Transfusion Reaction	PRBC	Packed Red Blood Cell
GSH	Group, Screen and Hold	PRK	Perak
GXM	Group and Crossmatch	PPK	Pembantu Perawatan Kesihatan
HBV	Hepatitis B Virus	RBC	Red Blood Cell
HCV	Hepatitis C Virus	RCA	Root Cause Analysis
HIV	Human Immunodeficiency Virus	RBRP	Right Blood Right Patient
HLA	Human Leukocyte Antigen	SBH	Sabah
HNA	Human Neutrophil Antigen	SD	Seroconvert Donors
HO	House Officer	SGR	Selangor
HSE	Handling and Storage Error	SN	Staff Nurse
HTC	Hospital Transfusion Team	SOP	Standard Operating Procedure
HTR	Haemolytic Transfusion Reaction	SRNM	Specific Requirement Not Met
IBCT	Incorrect Blood Component Transfused	SWK	Sarawak
ICPS	International Classification for Patient Safety	TACO	Transfusion Associated Circulatory Overload
ICU	Intensive Care Unit	TAD	Transfusion Associated Dyspnoea
IPK	Institut Perubatan Khas	TAT	Turn-around-time
IT	Information Technology	TE	Transfusion Error
IVDU	Intravenous Drug Used	TRALI	Transfusion Related Acute Lung Injury
JHR	Johor	TRG	Terengganu
KDH	Kedah	TTI	Transfusion Transmittable Infection
KK	Klinik Kesihatan	TTP	Thrombotic Thrombocytopenic Purpura
KKIA	Klinik Kesihatan Ibu dan Anak	UCT	Uncommon complications of transfusion
KTN	Kelantan	UNI	University
LR	Labour Room	VVR	Vasovagal reaction
MLK	Melaka	WB	Whole Blood
MLT	Medical Laboratory Technologists	WBIT	Wrong Blood in Tube
MO	Medical Officer	WCT	Wrong Component Transfused
MOH	Ministry of Health	WHO	World Health Organisation
MPSG	Malaysian Patient Safety Goals	WNOT	Wrong Name on Tube
MSM	Men Sex with Men	WPK	Wilayah Persekutuan



CHAPTER 1

INTRODUCTION



CHAPTER 1

INTRODUCTION

1.1 NATIONAL HAEMOVIGILANCE COORDINATING CENTRE (NHCC)

1.1.1 Established in 2003 under the governance of the National Blood Centre, the National Haemovigilance Coordinating Centre (NHCC) has implemented a comprehensive haemovigilance system that records and analyses an adverse event in the entire blood transfusion chain, from donor to recipient. This system has significantly enhanced transfusion safety in Malaysia over the years.

1.1.2 The NHCC is responsible for the reporting and verification of haemovigilance related adverse events. To accurately classify these events, further information is sometimes required to determine the type, imputability, and severity of the adverse event. The NHCC has previously published three biennial reports:

- Haemovigilance Report 2016-2017
- Haemovigilance Report 2018-2019
- Haemovigilance Report 2020-2021

This fourth haemovigilance report compiles adverse events related to the transfusion chain occurring from 1st January 2022 to 31st December 2023.

1.2 OBJECTIVES

1.2.1 In alignment with Goal 6 of the Malaysian Patient Safety Goals (MPSG), the NHCC, in collaboration with the Patient Safety Council, is committed to safeguarding the transfusion of blood and blood products. The core elements of a safe and high-quality transfusion program include ensuring universal access to safe, high-quality, and efficacious blood and blood products. This vision and mission guide our efforts to present evidence-based reports to promote advancements in Transfusion Medicine Services in Malaysia.

1.3 DEFINITION OF HAEMOVIGILANCE

1.3.1 Haemovigilance encompasses a series of surveillance procedures that monitor the entire transfusion process, from blood donation and processing to transfusion and patient follow-up. It involves the reporting, investigation, and analysis of adverse events related to blood donation, processing, and transfusion, with the goal of preventing recurrence (WHO).



1.4 POST COVID-19 PANDEMIC RECOVERY

1.4.1 In 2022, blood transfusion services experienced a recovery in blood collection and usage, as healthcare services resumed their regular pace following the COVID-19 pandemic.

1.4.2 The NHCC has observed a significant increase in the number of reports received in 2022-2023 compared to 2021.

1.5 REPORTING PROCESS AND DATA ANALYSIS LIMITATIONS

1.5.1 This report addresses adverse events related to the transfusion chain from blood collection to blood administration. The final submission deadline for reports have reverted to the standard deadline of 31st March on the following year.

1.5.2 Reports are reviewed and classified as verified or pending if additional information is required. Reporters are required to resubmit necessary details within the designated period. A verified report contains sufficient details for NHCC to proceed with data analysis. In 2022, 6951 cases were analyzed, and in 2023, 7356 cases were analyzed.

1.6 REPORTING STEPS OF AN ADVERSE EVENT TO NHCC

1.6.1 The table below provides an overview of the reporting process to NHCC.



Who is reporting?

All hospitals in Malaysia that provide blood transfusion services.
(MOH / Special Medical Institution / University Hospitals / Private Hospitals).

When to report?

Reports must be sent on a monthly basis to NHCC. The reporting year's reports must be submitted by March 31st of the following year.

How to report?

Hospitals with BBISv2

Submit monthly summary of adverse event reported and each cases reported via respective modules in BBIS:

- a) Module Hemovigilance
- b) Module Seroconvert

Non BBISv2 Hospitals

Submit monthly summary of adverse event reported and each cases reported using hardcopy form respectively:

- a) Reporting form for Transfusion Related Adverse Events (BTS/HV/3/2016)
- b) Reporting form for Adverse Donor Reaction (BTS/DV/2/2016)
- c) Reporting form for Seroconvert Donor Notification Part 1 and Part 2 (BTS/SC/1/2016)

What happen to these reports?

Hospitals with BBISv2

Reports submitted are reviewed and verified by NHCC personnel. The reporter might need to provide more details to an incomplete report.

Non BBISv2 Hospitals

Reports submitted are entered, reviewed and verified by NHCC personnel. The reporter might need to provide more details to an incomplete report.

What happens next?

Verified reports are presented and discussed during NBC's quarterly technical meeting.

Urgent actions are recommended to improve donor and patient safety when warranted.

Production of Hemovigilance Report and online publication on the MOH website.



CHAPTER 2

PARTICIPATION OF HAEMOVIGILANCE REPORTING



CHAPTER 2

PARTICIPATION OF HAEMOVIGILANCE REPORTING

2.1 OVERVIEW OF HAEMOVIGILANCE REPORTING – Figure 2.1

2.1.1 The haemovigilance reporting has shown an upward trend from 2010 to 2018, with reports increasing annually to a peak of 6792 in 2018. However, there was a decline in the number of reports received in 2019 due to the change of the final date of reports accepted by NHCC from the end of June to end of March of the following year, starting from March 2020. The COVID-19 pandemic in 2020 led to a notable rise to 7338 reports, reflecting heightened monitoring. Subsequent years saw stabilization around 6639 in 2021 and 6951 in 2022, indicating adaptation to pandemic conditions. By 2023, reports remained steady at 7356.

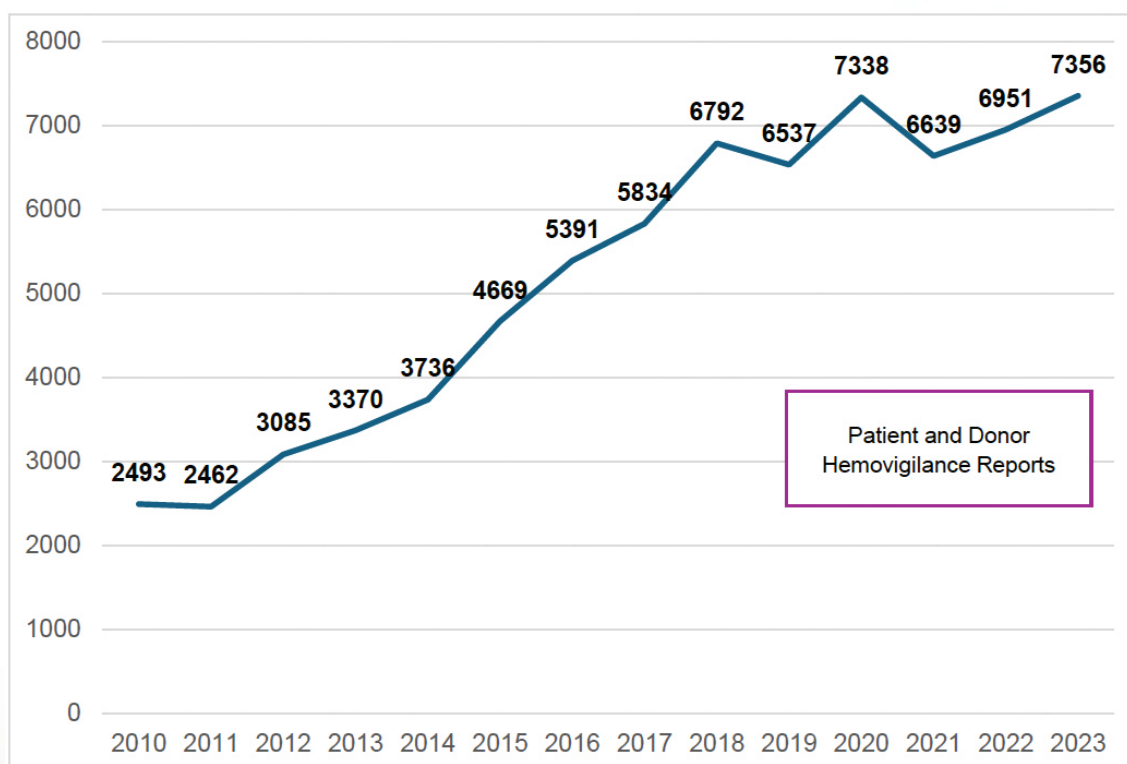


Figure 2.1: Number of Haemovigilance Reports Received from 2010 – 2023



2.2 TYPE OF ADVERSE EVENTS – Figure 2.2

2.2.1 Patient haemovigilance reports, comprising Adverse Transfusion Reactions (ATR), Incorrect Blood Component Transfusions (IBCT), Near Misses (NM), and incidents, accounted for 61% of total reports received in 2022 and 64% in 2023. Among these, ATRs constituted 89% of patient haemovigilance reports in 2022 and over 92% in 2023. IBCT reports were the least frequent, comprising of 1% in 2022 and 0.8% in 2023.

2.2.2 Donor haemovigilance reports, which include Adverse Donor Reactions (ADR) and seroconverted donors (SD), represented 39% of total reports received in 2022 and 36% in 2023. ADRs accounted for 88% of donor haemovigilance reports in 2022 and 87% in 2023.

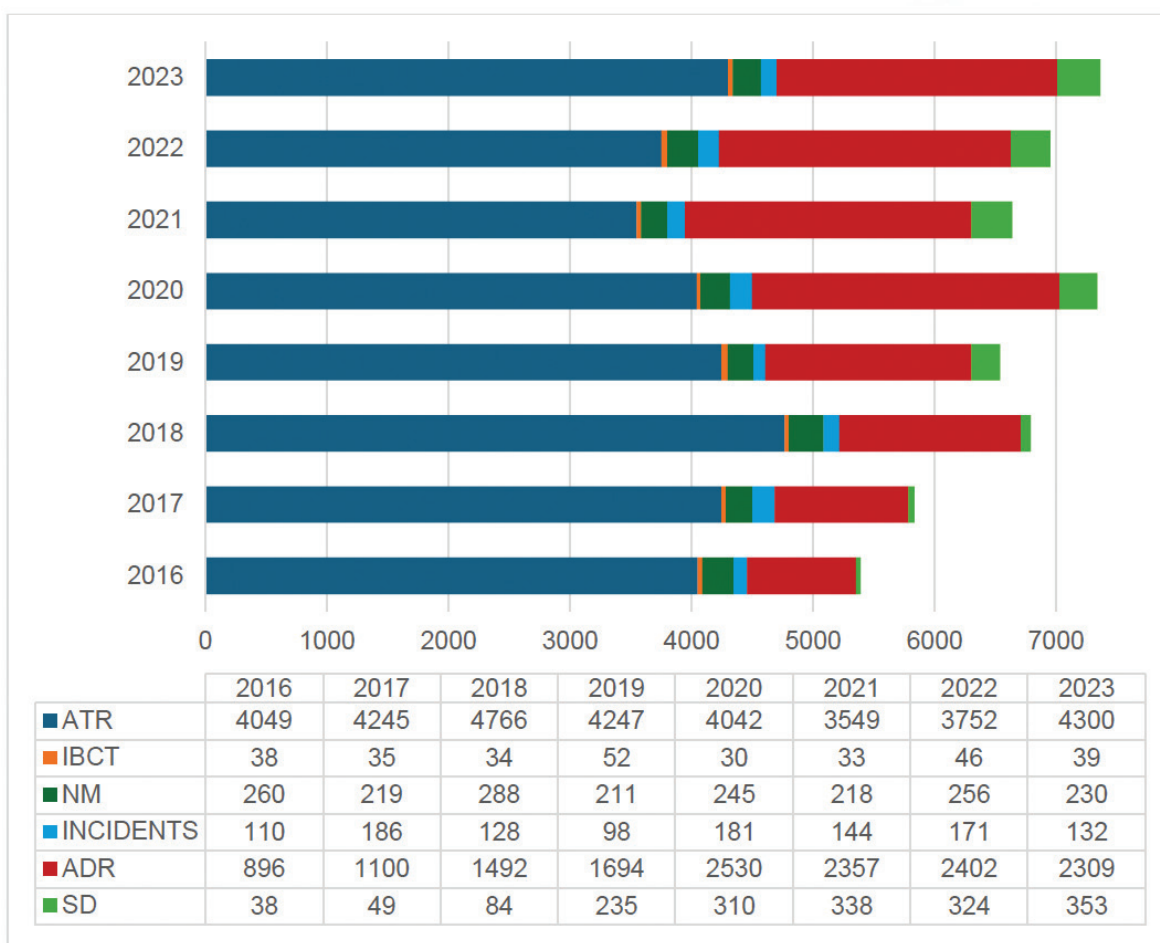


Figure 2.2: Number of Adverse Transfusion Reaction (ATR), Incorrect Blood Component transfused (IBCT), Near Misses (NM), Incident, Adverse Donor Reaction (ADR) and Seroconvert Donors (SD) reported to NHCC from 2016 – 2023



2.3 REPORTED NO CASES OF ADVERSE EVENT (AE) – Figure 2.3.1, 2.3.2a, 2.3.2b

2.3.1 NHCC also captured data on instances where no adverse events (AEs) occurred for Adverse Transfusion Reactions (ATR), Incorrect Blood Component Transfusions (IBCT), Near Misses (NM), Incidents, Adverse Donor Reactions (ADR), and Seroconvert Donors (SD). These instances were categorized as “Reported No Cases of Adverse Events” to distinguish them from cases where no reporting occurred. This ensures clarity in reporting, distinguishing between true absence of AEs and non-participation in reporting by hospitals. Notably, IBCT and seroconverted donors were frequently reported as having no cases in both years.

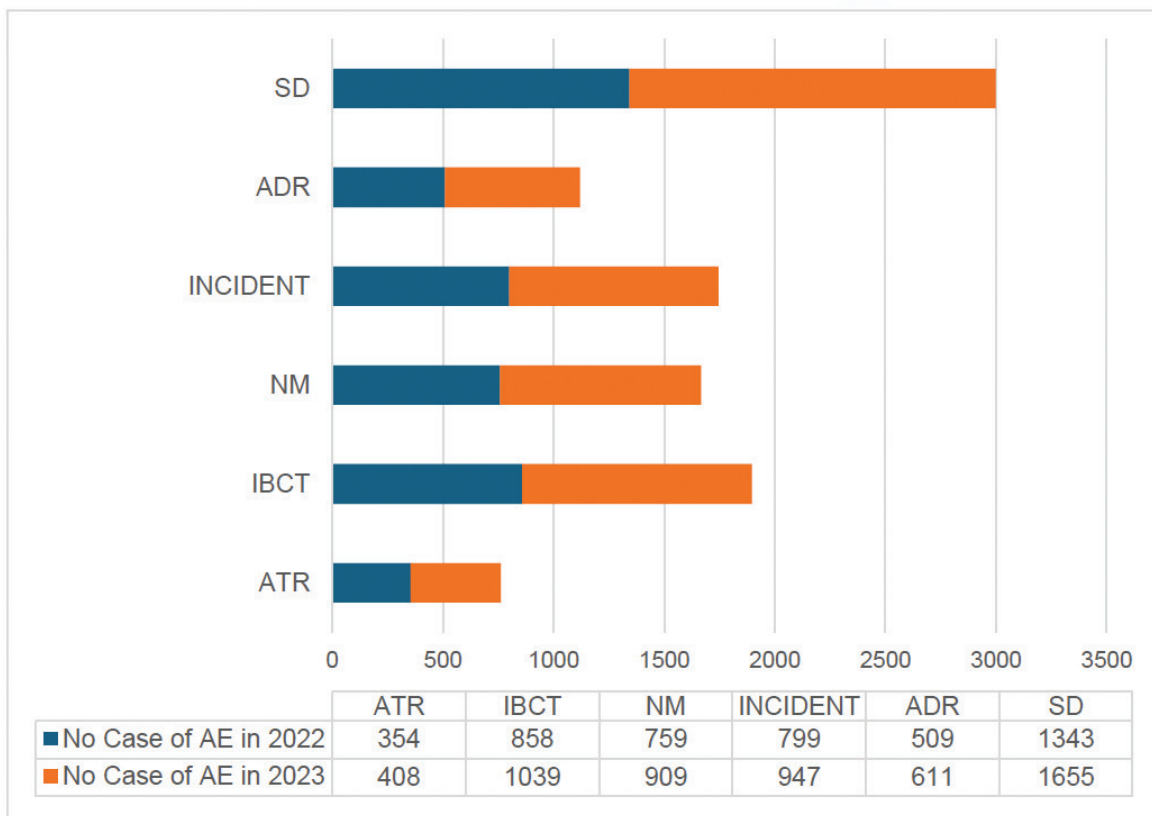


Figure 2.3.1: Number of Reported No Case of Adverse Events (ATR, IBCT, NM, Incident, ADR and SD) Reported in 2022 and 2023

2.3.2 Total number of reported No Case of Adverse Event depends on total number of hospitals in each state and their participation of reporting. However, this data did not reflect the general participation of all hospitals throughout the year as it did not capture incomplete participation or no participation. All hospitals were encouraged to include data of no cases upon report submission.

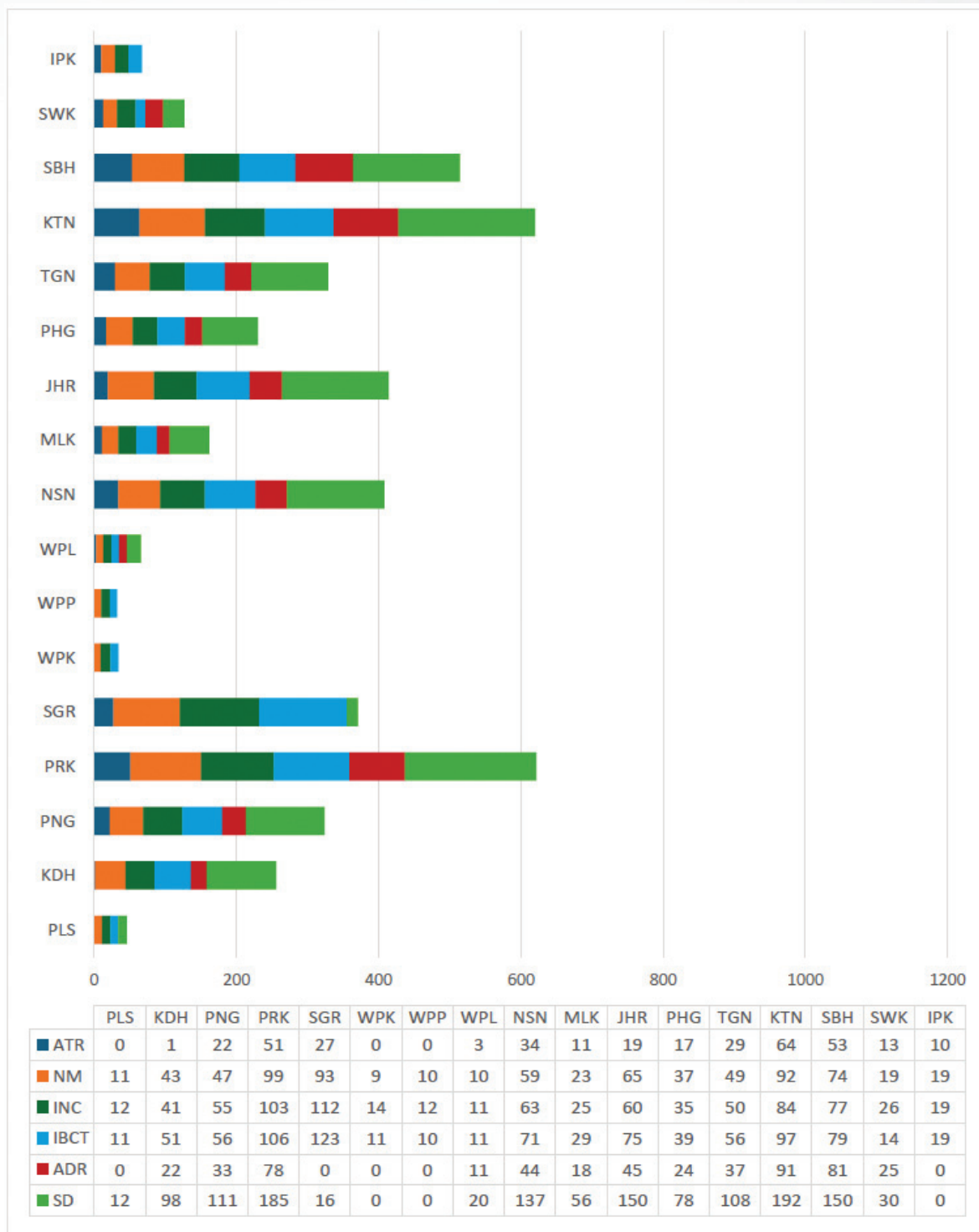


Figure 2.3.2a: Number of Reported No Case of Adverse Events (ATR, IBCT, NM, Incident, ADR and SD) by States in 2022

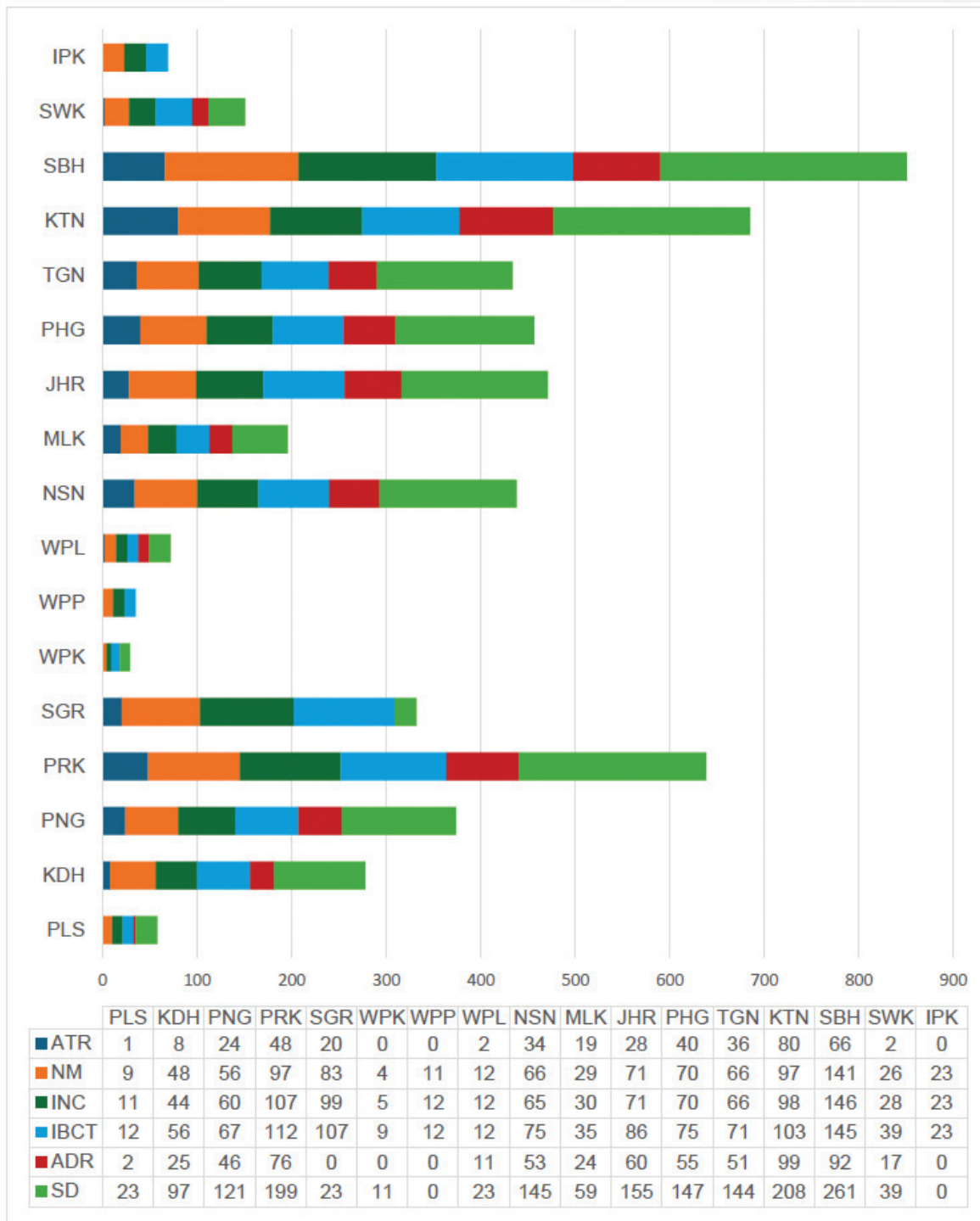


Figure 2.3.2b: Number of Reported No Case of Adverse Events (ATR, IBCT, NM, and Incident, ADR and SD) by States in 2023



2.4 PARTICIPATION TO HAEMOVIGILANCE REPORTING

- 2.4.1** Haemovigilance reporting is participated in by blood banks from government hospitals, private hospitals, university hospitals, military hospitals, and institutions. Hospitals must send a monthly summary of adverse events to NHCC using the Haemovigilance Monthly Report (Appendix 1). This assists NHCC in monitoring participation and improving data accuracy.
- 2.4.2** Depending on the reports provided to NHCC for the reporting year, hospitals are categorized into three participation groups. 'No report received' (NRR) refers to hospitals that did not submit any reports throughout the entire year. Hospitals that submitted their reports in full for the entire reporting year are categorized as 'complete', while those that submitted reports for one or more months of the reporting year are categorized as 'incomplete'.
- 2.4.3** In 2023, there was increased participation in haemovigilance reporting compared to 2022. Wilayah Persekutuan Kuala Lumpur, Pulau Pinang, Kelantan and Terengganu have achieved complete participation for two consecutive years.
- 2.4.4** The table below shows the general participation in haemovigilance reporting across Malaysia. It is hoped that this information could help blood banks understand their level of haemovigilance reporting compared to other blood banks with similar capacity.



2.4.3.1 PARTICIPATION IN PATIENT HAEMOVIGILANCE REPORTING – Table 2.4.3.1

PERLIS (PLS)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
1	Perlis	Hospital Tuanku Fauziah Kangar	State Hospital		*		*		*		

KEDAH (KDH)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
2	Kedah	Hospital Sultanah Bahiyah, Alor Setar	State Hospital	*		*			*		
3		Hospital Sultan Abdul Halim, Sg Petani	Major Specialist		*	*			*		
4		Hospital Kulim	Major Specialist		*	*			*		
5		Hospital Langkawi	Minor Specialist		*		*		*		
6		Hospital Baling	Non Specialist		*		*			*	
7		Hospital Yan	Non Specialist		*				*		*
8		Hospital Jitra	Non Specialist		*		*			*	
9		Hospital Sik	Non Specialist		*		*				*
10		Hospital Kuala Nerang	Non Specialist		*				*		*



PULAU PINANG (PNG)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
11	PULAU PINANG (PNG)	Hospital Pulau Pinang	State Hospital	*		*			*		
12		Hospital Seberang Jaya	Major Specialist	*		*			*		
13		Hospital Bukit Mertajam	Minor Specialist		*	*			*		
14		Hospital Kepala Batas	Minor Specialist		*	*			*		
15		Hospital Sungai Bakap	Non Specialist		*	*			*		
16		Hospital Balik Pulau	Non Specialist		*	*			*		

PERAK (PRK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
17	Perak	Hospital Raja Permaisuri Bainon, Ipoh	State Hospital	*		*			*		
18		Hospital Taiping	Major Specialist	*		*			*		
19		Hospital Teluk Intan	Major Specialist		*	*			*		
20		Hospital Kuala Kangsar	Minor Specialist		*	*			*		
21		Hospital Slim River	Minor Specialist		*	*			*		
22		Hospital Seri Manjung	Minor Specialist	*		*			*		
23		Hospital Gerik	Minor Specialist		*				*		*
24		Hospital Parit Buntar	Non Specialist		*				*		*
25		Hospital Batu Gajah	Non Specialist		*		*			*	
26		Hospital Kampar	Non Specialist		*				*		*
27		Hospital Tapah	Non Specialist		*		*			*	
28		Hospital Selama	Non Specialist		*		*				*
29		Hospital Changkat Melintang	Non Specialist		*		*			*	
30	Hospital Sungai Siput	Non Specialist		*		*			*		



SELANGOR (SGR)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
31	Selangor	Hospital Tengku Ampuan Rahimah, Klang	State Hospital	*		*				*	
32		Hospital Kajang	Major Specialist		*	*			*		
33		Hospital Ampang	Major Specialist		*	*			*		
34		Hospital Selayang	Major Specialist		*	*			*		
35		Hospital Sungai Buloh	Major Specialist		*	*			*		
36		Hospital Serdang	Major Specialist		*	*			*		
37		Hospital Shah Alam	Major Specialist		*	*			*		
38		Hospital Banting	Non Specialist		*	*			*		
39		Hospital Kuala Kubu Baru	Non Specialist		*		*		*		
40		Hospital Tanjung Karang	Non Specialist		*		*			*	
41		Hospital Tengku Ampuan Jemaah, Sabak Bernam	Non Specialist		*		*		*		
42		Hospital Orang Asli, Gombak	Non Specialist		*				*		*
43		Hospital Cyberjaya	Non Specialist		*		*		*		

WILAYAH PERSEKUTUAN (WPK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
44	Wilayah Persekutuan	Hospital Kuala Lumpur	State Hospital	*		*			*		
45		Hospital Tuanku Azizah	Major Specialist	*		*			*		
46		Hospital Putrajaya	Major Specialist		*	*			*		
47		Hospital Labuan	Minor Specialist		*	*			*		



NEGERI SEMBILAN (NSN)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
48	Negeri Sembilan	Hospital Tuanku Jaafar, Seremban	State Hospital	*		*			*		
49		Hospital Tuanku Ampuan Najihah, Kuala Pilah	Major Specialist		*	*			*		
50		Hospital Tampin	Minor Specialist		*	*				*	
51		Hospital Port Dickson	Minor Specialist		*	*				*	
52		Hospital Jelebu	Non Specialist		*				*	*	
53		Hospital Jempol	Non Specialist		*		*			*	
54		Hospital Rembau	Non Specialist		*		*			*	

MELAKA (MLK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
55	Melaka	Hospital Melaka	State Hospital	*		*			*		
56		Hospital Alor Gajah	Non Specialist		*		*		*		
57		Hospital Jasin	Non Specialist		*		*		*		



JOHOR (JHR)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
58	Johor	Hospital Sultanah Aminah, Johor Bahru	State Hospital	*		*			*		
59		Hospital Sultan Ismail, Johor Bahru	Major Specialist		*	*			*		
60		Hospital Pakar Sultanah Fatimah, Muar	Major Specialist		*	*			*		
61		Hospital Sultanah Nora Ismail, Batu Pahat	Major Specialist	*		*			*		
62		Hospital Segamat	Major Specialist		*	*				*	
63		Hospital Enche' Besar Hajah Khalsom, Kluang	Minor Specialist		*			*	*		
64		Hospital Kota Tinggi	Minor Specialist		*		*			*	
65		Hospital Pontian	Non Specialist		*			*			*
66		Hospital Mersing	Non Specialist		*			*		*	
67		Hospital Tangkak	Non Specialist		*			*			*
68	Hospital Maharaja Tun Ibrahim, Kulai	Non Specialist		*	*				*		



PAHANG (PHG)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
69	Pahang	Hospital Tengku Ampuan Afzan, Kuantan	State Hospital	*			*			*	
70		Hospital Sultan Haji Ahmad Shah, Temerloh	Major Specialist	*		*			*		
71		Hospital Pekan	Minor Specialist		*			*			*
72		Hospital Kuala Lipis	Minor Specialist		*		*		*		
73		Hospital Bentong	Minor Specialist		*		*			*	
74		Hospital Raub	Non Specialist		*			*		*	
75		Hospital Jerantut	Non Specialist		*		*			*	
76		Hospital Jengka	Non Specialist		*			*	*		
77		Hospital Muadzam Shah	Non Specialist		*		*			*	
78		Hospital Sultanah Kalsom Cameron Highland	Non Specialist		*				*		*
79		Hospital Rompin	Non Specialist		*				*		*



TERENGGANU (TGN)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
80	Terengganu	Hospital Sultanah Nur Zahirah, Kuala Terengganu	State Hospital	*		*			*		
81		Hospital Kemaman	Major Specialist		*	*			*		
82		Hospital Dungun	Major Specialist		*	*			*		
83		Hospital Besut	Non Specialist		*	*			*		
84		Hospital Hulu Terengganu	Non Specialist		*	*			*		
85		Hospital Setiu	Non Specialist		*	*			*		

KELANTAN (KTN)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
86	Kelantan	Hospital Raja Perempuan Zainab II, Kota Bharu	State Hospital	*		*			*		
87		Hospital Kuala Krai	Major Specialist		*	*			*		
88		Hospital Tanah Merah	Major Specialist		*	*			*		
89		Hospital Gua Musang	Minor Specialist		*	*			*		
90		Hospital Machang	Non Specialist		*	*			*		
91		Hospital Tumpat	Non Specialist		*	*			*		
92		Hospital Pasir Mas	Non Specialist		*	*			*		
93		Hospital Tengku Anis, Pasir Puteh	Non Specialist		*	*			*		
94		Hospital Jeli	Non Specialist		*	*			*		



SABAH (SBH)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
95	Sabah	Hospital Queen Elizabeth I, Kota Kinabalu	State Hospital		*	*			*		
96		Hospital Queen Elizabeth II, Kota Kinabalu	Major Specialist	*		*			*		
97		Hospital Duchess of Kent, Sandakan	Major Specialist	*		*			*		
98		Hospital Tawau	Major Specialist	*		*			*		
99		Hospital Beaufort	Minor Specialist		*		*		*		
100		Hospital Keningau	Minor Specialist		*		*		*		
101		Hospital Lahad Datu	Minor Specialist		*				*	*	
102		Hospital Kota Marudu	Minor Specialist		*				*		*
103		Hospital Kota Belud	Non Specialist		*				*		*
104		Hospital Kudat	Non Specialist		*				*		*
105		Hospital Papar	Non Specialist		*				*		*
106		Hospital Ranau	Non Specialist		*		*		*		
107		Hospital Semporna	Non Specialist		*		*			*	
108		Hospital Tambunan	Non Specialist		*				*		*
109		Hospital Tenom	Non Specialist		*		*		*		
110		Hospital Sipitang	Non Specialist		*				*	*	
111		Hospital Beluran	Non Specialist		*				*		*
112	Hospital Kinabatangan	Non Specialist		*				*		*	
113	Hospital Kuala Penyu	Non Specialist		*				*		*	
114	Hospital Kunak	Non Specialist		*				*		*	
115	Hospital Pitas	Non Specialist		*		*			*		
116	Hospital Tuaran	Non Specialist		*		*			*		
117	Hospital Wanita dan Kanak-kanak, Likas	Major Specialist		*	*				*		



SARAWAK (SWK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
118	Sarawak	Hospital Umum Sarawak	State Hospital	*		*			*		
119		Pusat Jantung Sarawak	Major Specialist		*				*		*
120		Hospital Sibul	Major Specialist	*		*			*		
121		Hospital Miri	Major Specialist	*		*			*		
122		Hospital Bintulu	Major Specialist		*		*		*		
123		Hospital Sri Aman	Minor Specialist		*		*				*
124		Hospital Limbang	Minor Specialist		*				*		*
125		Hospital Sarikei	Minor Specialist		*				*	*	
126		Hospital Kapit	Minor Specialist		*				*		*
127		Hospital Mukah	Minor Specialist		*				*		*
128		Hospital Serian	Non Specialist		*				*		*
129		Hospital Lundu	Non Specialist		*				*		*
130		Hospital Saratok	Non Specialist		*				*		*
131		Hospital Kanowit	Non Specialist		*				*		*
132		Hospital Marudi	Non Specialist		*				*		*
133		Hospital Lawas	Non Specialist		*				*		*
134		Hospital Bau	Non Specialist		*				*		*
135		Hospital Simunjan	Non Specialist		*				*		*
136		Hospital Betong	Non Specialist		*				*		*
137		Hospital Daro	Non Specialist		*				*		*
138	Hospital Rajah Charles Brooke Memorial	Non Specialist		*				*		*	
139	Hospital Dalat	Non Specialist		*		*				*	

INSTITUT PERUBATAN KHAS (IPK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
140	Institut Perubatan Khas	Institut Kanser Negara	Special Medical Institution		*	*			*		
141		Institut Jantung Negara	Special Medical Institution		*		*		*		



2.4.3.2 PARTICIPATION IN DONOR HAEMOVIGILANCE BY THE COLLECTION CENTER – Table 2.4.3.2

PERLIS (PLS)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
1	Perlis	Hospital Tuanku Fauziah Kangar	State Hospital		*	*			*		

KEDAH (KDH)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
2	Kedah	Hospital Sultanah Bahiyah, Alor Setar	State Hospital	*		*			*		
3		Hospital Sultan Abdul Halim, Sg Petani	Major Specialist		*	*			*		
4		Hospital Kulim	Major Specialist		*	*			*		
5		Hospital Langkawi	Minor Specialist		*		*		*		
6		Hospital Baling	Non Specialist		*		*			*	
7		Hospital Yan	Non Specialist		*			*			*
8		Hospital Jitra	Non Specialist		*		*			*	
9		Hospital Sik	Non Specialist		*		*				*
10		Hospital Kuala Nerang	Non Specialist		*			*			*

PULAU PINANG (PNG)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
11	PULAU PINANG (PNG)	Hospital Pulau Pinang	State Hospital	*		*			*		
12		Hospital Seberang Jaya	Major Specialist	*		*			*		
13		Hospital Bukit Mertajam	Minor Specialist		*	*			*		
14		Hospital Kepala Batas	Minor Specialist		*	*			*		
15		Hospital Sungai Bakap	Non Specialist		*	*			*		



PERAK (PRK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
16	Perak	Hospital Raja Permaisuri Bainon, Ipoh	State Hospital	*		*			*		
17		Hospital Taiping	Major Specialist	*		*			*		
18		Hospital Teluk Intan	Major Specialist		*	*			*		
19		Hospital Kuala Kangsar	Minor Specialist		*	*			*		
20		Hospital Slim River	Minor Specialist		*	*			*		
21		Hospital Seri Manjung	Minor Specialist	*		*			*		
22		Hospital Gerik	Minor Specialist		*				*		*
23		Hospital Parit Buntar	Non Specialist		*				*		*
24		Hospital Batu Gajah	Non Specialist		*		*			*	
25		Hospital Kampar	Non Specialist		*				*		*
26		Hospital Tapah	Non Specialist		*		*			*	
27		Hospital Selama	Non Specialist		*		*				*
28		Hospital Changkat Melintang	Non Specialist		*		*			*	
29		Hospital Sungai Siput	Non Specialist		*		*			*	

SELANGOR (SGR)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
30	Selangor	Hospital Tengku Ampuan Rahimah, Klang	State Hospital	*		*			*		

WILAYAH PERSEKUTUAN (WPK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
31	Wilayah Persekutuan	Pusat Darah Negara	Special Medical Institution	*		*			*		
32		Hospital Labuan	Minor Specialist		*	*			*		



NEGERI SEMBILAN (NSN)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
33	Negeri Sembilan	Hospital Tuanku Jaafar, Seremban	State Hospital	*		*			*		
34		Hospital Tuanku Ampuan Najihah, Kuala Pilah	Major Specialist		*	*			*		
35		Hospital Tampin	Minor Specialist		*	*			*		
36		Hospital Port Dickson	Minor Specialist		*	*			*		

MELAKA (MLK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
37	Melaka	Hospital Melaka	State Hospital	*		*			*		

JOHOR (JHR)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
38	Johor	Hospital Sultanah Aminah, Johor Bahru	State Hospital	*		*			*		
39		Hospital Sultan Ismail, Johor Bahru	Major Specialist		*	*			*		
40		Hospital Pakar Sultanah Fatimah, Muar	Major Specialist		*	*			*		
41		Hospital Sultanah Nora Ismail, Batu Pahat	Major Specialist	*		*			*		
42		Hospital Segamat	Major Specialist		*	*				*	
43		Hospital Enche' Besar Hajah Khalsom, Kluang	Minor Specialist		*				*	*	
44		Hospital Kota Tinggi	Minor Specialist		*		*			*	
45		Hospital Pontian	Non Specialist		*				*		*
46		Hospital Mersing	Non Specialist		*				*	*	
47		Hospital Tangkak	Non Specialist		*				*		*
48		Hospital Maharaja Tun Ibrahim, Kulai	Non Specialist		*	*				*	



PAHANG (PHG)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
49	Pahang	Hospital Tengku Ampuan Afzan, Kuantan	State Hospital	*			*			*	
50		Hospital Sultan Haji Ahmad Shah, Temerloh	Major Specialist	*		*			*		
51		Hospital Pekan	Minor Specialist		*			*			*
52		Hospital Kuala Lipis	Minor Specialist		*		*		*		
53		Hospital Bentong	Minor Specialist		*		*			*	
54		Hospital Raub	Non Specialist		*			*		*	
55		Hospital Jerantut	Non Specialist		*		*			*	
56		Hospital Jengka	Non Specialist		*				*	*	
57		Hospital Sultanah Kalsom Cameron Highland	Non Specialist		*				*		*

TERENGGANU (TGN)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
58	Terengganu	Hospital Sultanah Nur Zahirah, Kuala Terengganu	State Hospital	*		*			*		
59		Hospital Kemaman	Major Specialist		*	*			*		
60		Hospital Dungun	Major Specialist		*	*			*		
61		Hospital Besut	Non Specialist		*	*			*		
62		Hospital Hulu Terengganu	Non Specialist		*	*			*		

KELANTAN (KTN)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
63	Kelantan	Hospital Raja Perempuan Zainab II, Kota Bharu	State Hospital	*		*			*		
64		Hospital Kuala Krai	Major Specialist		*	*			*		
65		Hospital Tanah Merah	Major Specialist		*	*			*		
66		Hospital Gua Musang	Minor Specialist		*	*			*		
67		Hospital Machang	Non Specialist		*	*			*		
68		Hospital Tumpat	Non Specialist		*	*			*		
69		Hospital Pasir Mas	Non Specialist		*	*			*		
70		Hospital Tengku Anis, Pasir Puteh	Non Specialist		*	*			*		



SABAH (SBH)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBIsv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
71	Sabah	Hospital Queen Elizabeth I	State Hospital		*	*			*		
72		Hospital Queen Elizabeth II	Major Specialist	*		*			*		
73		Hospital Duchess of Kent, Sandakan	Major Specialist	*		*			*		
74		Hospital Tawau	Major Specialist	*		*			*		
75		Hospital Beaufort	Minor Specialist		*		*		*		
76		Hospital Keningau	Minor Specialist		*		*		*		
77		Hospital Lahad Datu	Minor Specialist		*			*	*		
78		Hospital Kota Marudu	Minor Specialist		*			*			*
79		Hospital Kota Belud	Non Specialist		*			*			*
80		Hospital Kudat	Non Specialist		*			*			*
81		Hospital Papar	Non Specialist		*			*			*
82		Hospital Ranau	Non Specialist		*		*		*		
83		Hospital Semporna	Non Specialist		*		*			*	
84		Hospital Tambunan	Non Specialist		*			*			*
85		Hospital Tenom	Non Specialist		*		*		*		
86		Hospital Sipitang	Non Specialist		*			*	*		
87		Hospital Beluran	Non Specialist		*			*			*
88		Hospital Kinabatangan	Non Specialist		*			*			*
89		Hospital Kuala Penyu	Non Specialist		*			*			*
90		Hospital Kunak	Non Specialist		*			*			*
91		Hospital Pitas	Non Specialist		*		*			*	
92		Hospital Tuaran	Non Specialist		*		*			*	



SARAWAK (SWK)

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
93	Sarawak	Hospital Umum Sarawak	State Hospital	*		*			*		
94		Pusat Jantung Sarawak	Major Specialist		*				*		*
95		Hospital Sibul	Major Specialist	*		*			*		
96		Hospital Miri	Major Specialist	*		*			*		
97		Hospital Bintulu	Major Specialist		*		*		*		
98		Hospital Limbang	Minor Specialist		*				*		*
99		Hospital Sarikei	Minor Specialist		*				*	*	
100		Hospital Kapit	Minor Specialist		*				*		*
101		Hospital Mukah	Minor Specialist		*				*		*
102		Hospital Serian	Non Specialist		*				*		*
103		Hospital Lundu	Non Specialist		*				*		*
104		Hospital Saratok	Non Specialist		*				*		*
105		Hospital Kanowit	Non Specialist		*				*		*
106		Hospital Marudi	Non Specialist		*				*		*
107		Hospital Lawas	Non Specialist		*				*		*
108		Hospital Bau	Non Specialist		*				*		*
109		Hospital Simunjan	Non Specialist		*				*		*
110		Hospital Betong	Non Specialist		*				*		*
111	Hospital Daro	Non Specialist		*				*		*	

OTHERS

No.	Satetes	Hospital	Hospital Category	Mode of Reporting		Report submission 2022			Report submission 2023		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
112	Non MOH	Hospital Angkatan Tentera Darat Tuanku Mizan	MOD		*				*		*
113	Private	Loh Guan Lye, Penang	Private		*	*			*		



2.5 TOTAL NUMBER OF REPORTED ADVERSE EVENT – Table 2.5.1, 2.5.2, 2.5.3, 2.5.4

2.5.1 Patient haemovigilance contains data on ATR, IBCT, near miss and incident. Total number of reports submitted by states for patient haemovigilance as shown below:

YEAR	2022				2023			
	STATE	ATR	IBCT	NM	Incident	ATR	IBCT	NM
PLS	136	1	1	0	79	0	3	0
KDH	320	7	37	16	342	2	24	11
PNG	272	8	26	8	298	4	17	8
PRK	340	4	14	10	397	3	10	3
SGR	521	4	42	18	526	8	36	14
WPK	343	2	7	23	331	2	25	10
NSN	196	0	9	6	179	1	15	9
MLK	168	1	8	5	158	1	11	4
JHR	369	9	16	25	482	3	24	27
PHG	156	2	6	7	155	1	5	3
TGN	147	1	15	18	217	1	8	10
KTN	115	2	11	22	140	6	6	12
SBH	208	0	14	7	402	3	8	7
SWK	172	3	15	2	279	1	14	6
IPK	79	0	0	0	107	0	0	0
MOD	2	0	0	0	6	0	0	0
UNI	123	1	30	4	124	1	22	8
PVT	85	1	5	0	78	2	2	0
Total	3752	46	256	171	4300	39	230	132

Table 2.5.1: Number of Patient Haemovigilance Reports Submitted by States in 2022 – 2023



2.5.2 The rate of adverse event per 10,000 blood components issued in Malaysia increased from 66 in 2022 to 68 in 2023.

YEAR	2022			2023		
STATE	Total Component Issued	No. of Adverse Event	Rate/10000 component Issued	Total Component Issued	No. of Adverse Event	Rate/10000 component Issued
PLS	8917	138	155	8566	82	96
KDH	45860	380	83	50145	379	76
PNG	38250	314	82	40046	327	82
PRK	51080	368	72	53410	413	77
SGR	91908	585	64	96602	584	60
WPK	40974	375	92	42659	368	86
NSN	30648	211	69	33744	204	60
MLK	21062	182	86	20634	174	84
JHR	66746	419	63	70867	536	76
PHG	27422	171	62	28584	164	57
TGN	23508	181	77	25807	236	91
KTN	28080	150	53	28649	164	57
SBH	69039	229	33	77933	420	54
SWK	40637	192	47	44778	300	67
Total	584131	3895	67	8566	4351	70

Table 2.5.2: Rate of Adverse Event per 10,000 Blood Components Issued by states in 2022 – 2023



2.5.3 Donor haemovigilance contain data on adverse donor reaction and seroconvert donor. Total number of reports submitted by states for donor haemovigilance as shown below:

YEAR	2022		2023	
STATE	ADR	Seroconvert (Part 1 + Part 2)	ADR	Seroconvert (Part 1 + Part 2)
PLS	57	0	56	1
KDH	118	39	114	28
PNG	371	28	424	17
PRK	327	30	249	34
SGR	44	14	51	1
WPK	658	54	591	78
NSN	78	6	45	4
MLK	42	5	38	3
JHR	176	23	123	56
PHG	41	7	44	19
TGN	85	3	76	4
KTN	17	7	12	11
SBH	199	69	352	64
SWK	189	39	134	33
Total	2402	324	2309	353

Table 2.5.3: No. of Donor Haemovigilance Reports Submitted by States in 2022 – 2023



2.5.4 The rate of adverse donor reaction per 10,000 blood collection in Malaysia decreased from 33 in 2022 to 30 in 2023.

YEAR	2022			2023		
STATE	Total Blood Collection	No. of ADR	Rate/10000 Blood Collection	Total Blood Collection	No. of ADR	Rate/10000 Blood Collection
PLS	9795	57	58	9503	56	58
KDH	50755	118	23	55830	114	20
PNG	43814	371	85	47714	424	89
PRK	61958	327	53	63024	249	40
SGR	29357	44	15	30296	51	17
WPK	203819	658	32	207240	589	28
WPL	2133	0	0	2321	2	9
NSN	24372	78	32	26114	45	17
MLK	30730	42	14	28663	38	13
JHR	75450	176	23	78408	123	16
PHG	30522	41	13	30684	44	14
TGN	22759	85	37	24899	76	31
KTN	24666	17	7	27540	12	4
SBH	72881	199	27	79509	352	44
SWK	54097	189	35	57127	134	23
Total	737108	2402	33	768872	2309	30

Table 2.5.4: Rate of Adverse Donor Reaction per 10,000 Blood Collection by States in 2022 – 2023

*1. This data only includes government hospital blood banks



CHAPTER 3

TRANSFUSION ERROR





CHAPTER 3

TRANSFUSION ERROR

3.1 DEFINITION OF ERRORS

3.1.1 According to the Malaysian fourth edition Transfusion Practice Guideline, an incorrect blood component transfused (IBCT) occurs when a patient is transfused with blood or blood components that do not meet the required standards or that are intended for another patient. In contrast, a near miss (NM) event refers to an error that if undetected could result in the determination of a wrong blood group, or issue, collection, or administration of an incorrect, inappropriate, or unsuitable blood or blood component, but which was recognized before the erroneous transfusion took place. This definition aligns with the UK's Serious Hazards of Transfusion (SHOT) framework, which categorizes IBCT into two subcategories:

a. Wrong component transfused (WCT)

Where a patient was transfused with a blood component of an incorrect blood group, or which was intended for another patient and was incompatible with the recipient, which was intended for another recipient but happened to be compatible with the recipient, or which was other than that prescribed e.g., platelets instead of red cells.

b. Specific requirements not met (SRNM)

Where a patient was transfused with a blood component that did not meet their specific requirements, for example irradiated components, human leucocyte antigen (HLA)-matched platelets when indicated, antigen-negative red cell units for a patient with known antibodies, red cells of extended phenotype for a patient with a specific clinical condition (e.g. haemoglobinopathy), or a component with a neonatal specification where indicated. (This does not include cases where a clinical decision was taken to knowingly transfuse components not meeting the specification in view of clinical urgency).

In this report, near misses and actual errors are analyzed together, as it is important to view near misses as warning events that require prompt action to prevent future errors.



3.2 INCIDENCE OF ERROR REPORTED BY HOSPITAL BLOOD BANKS UNDER THE MINISTRY OF HEALTH – Figure 3.2.1a, 3.2.1b

In 2022, there were 256 NMs and 46 IBCTs, compared to 230 NMs and 39 IBCTs in 2023. During these years, the total number of blood components transfused was 584,131 in 2022 and 622,424 in 2023. The incidence of IBCT remained low, with less than 1 in 10,000 blood components transfused for both years. The incidence of NMs per 10,000 blood components transfused decreased from 4.4 in 2022 to 3.7 in 2023, indicating an improvement in safety measures.

3.2.1 INCIDENCE OF NEAR MISSES AND IBCT REPORTED BY HOSPITAL BLOOD BANKS UNDER MINISTRY OF HEALTH (MOH) – Figure 3.2.1a, 3.2.1b

- 3.2.1.1** In 2022, the total number of blood components transfused across various states ranged from approximately 8,917 to 91,908 units. By 2023, these numbers increased, with the transfusion volumes ranging from 8,566 to 96,602 units, indicating a general rise in the demand for blood components across most states.
- 3.2.1.2** In 2022, Johor reported the highest number of IBCT cases with 9 incidents, while other states reported between 0 and 8 cases. By 2023, there was a noticeable increase in IBCT cases in some states, with Selangor reporting 8 cases and Kelantan 6 cases compared to 4 cases and 2 cases respectively in 2022. Potential issues in the transfusion process that may require further investigation and corrective actions needs to be performed.
- 3.2.1.3** In 2022, Selangor reported the highest number of near misses at 42, with other states reporting between 1 and 37 cases. In 2023, while some state, such as Selangor, saw a slight decrease in near misses (down to 36 cases), others, like Wilayah Persekutuan, saw an increase, with near misses rising to 25 cases. This indicates that while some progress has been made in certain areas, ongoing challenges in the blood transfusion process persist in others.

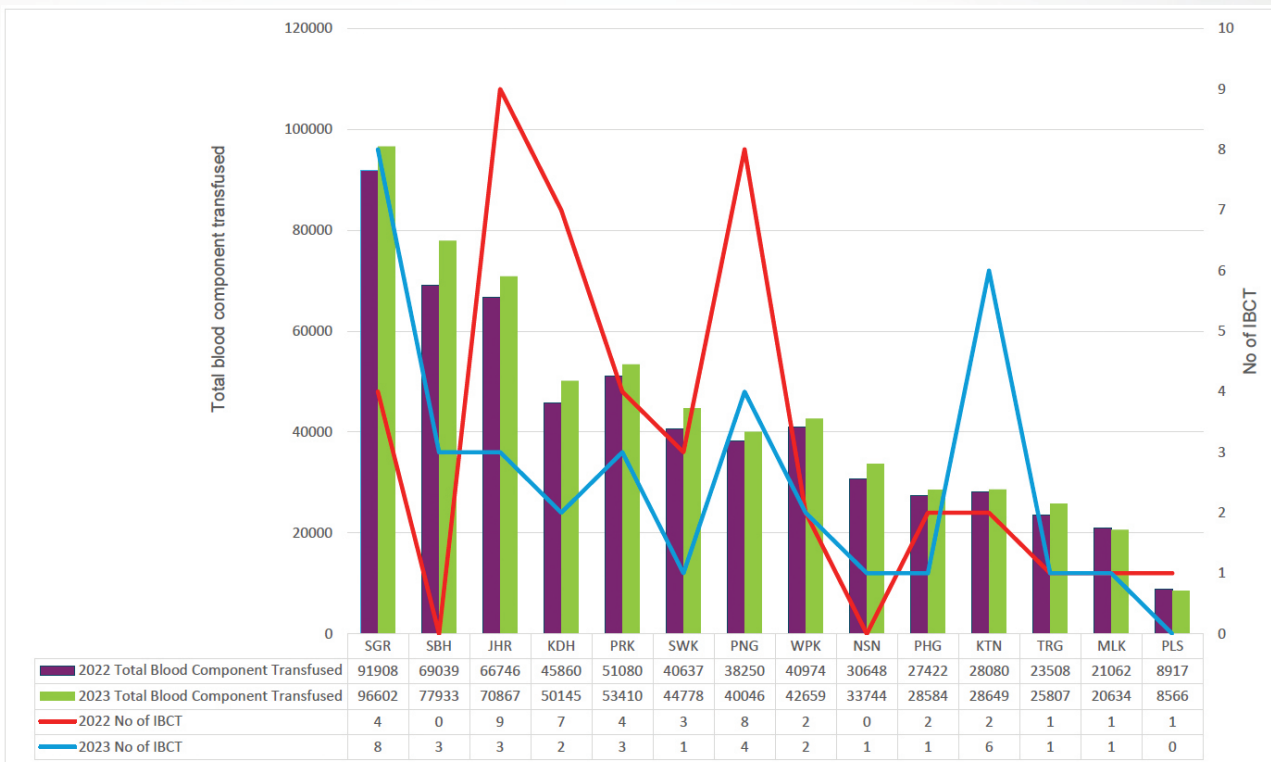


Figure 3.2.1a: Incidence of IBCT and Number of Blood Components Transfused by State in MOH Hospitals, 2022 and 2023

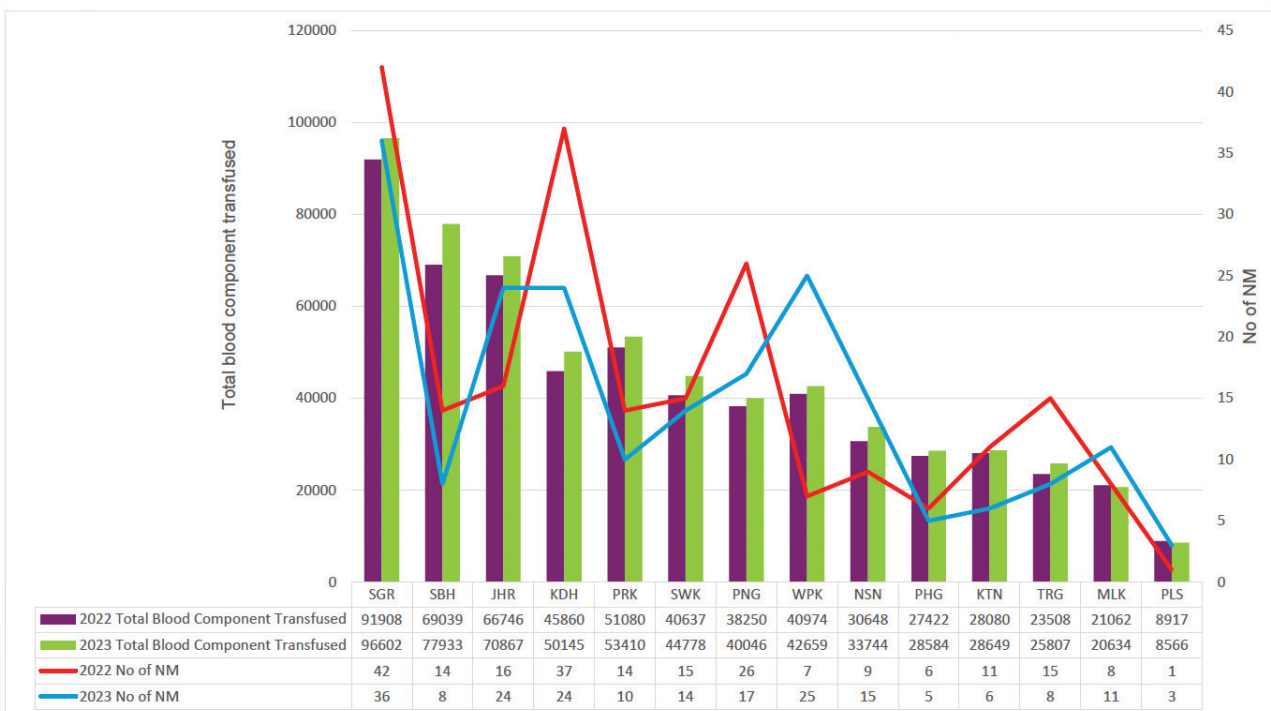


Figure 3.2.1b: Incidence of Near Misses and Number of Blood Components Transfused by State in MOH Hospitals, 2022 and 2023

3.3 CRITICAL CONTROL POINT (CCP) – Figure 3.3

3.3.1 A critical control point, as defined by National Health Service Blood and Transplant United Kingdom (NHSBT UK), is a step in a process that, if it went wrong, would result in a negative or undesirable consequence. To avoid an undesirable incident during the transfusion procedure, it is essential to make sure that no crucial processes go wrong. The Serious Hazard of Transfusion (SHOT) report, which identified nine crucial points where mistakes might happen anywhere in the transfusion process, was adopted by NHCC. This presents an opportunity to identify the system’s weaknesses, rectify them, and enhance current standard operating procedures (SOP).

3.3.2 The errors that happened throughout the blood transfusion process, from the patient’s request through the administration of blood components, were all categorised, analysed and discussed according to the CCP.

The nine-step transfusion pathway

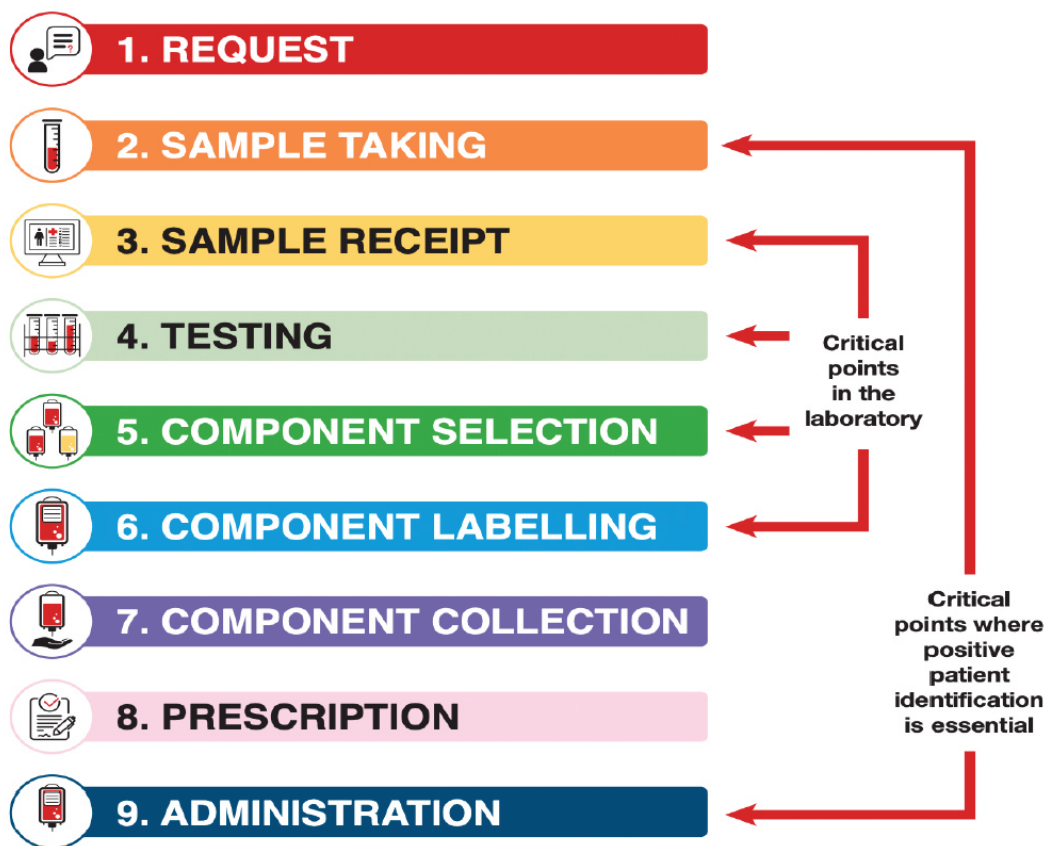


Figure 3.3: Critical Control Point in the Transfusion Process



3.3.3 Critical Control Point (CCP) in the Transfusion Process

3.3.3.1 REQUEST – Table 3.3.3.1

3.3.3.1.1 The first step in the transfusion process, after deciding to transfuse, is the request for a blood transfusion. This request must include the type of blood component needed and the patient’s core identifiers for the selection and release of components.

3.3.3.1.2 In 2022, there were 28 errors related to blood transfusion requests, which decreased to 23 in 2023. These errors comprised 22 NM and 6 IBCT in 2022, compared to 21 NM and 2 IBCT incidents in 2023. The majority of these errors were due to incorrect patient information, such as misspelled names, incorrect ID numbers, and wrong blood groups entered on the GSH form, accounting for 82.1% (23 cases) of the errors in 2022 and 78.2% (18 cases) in 2023.

Errors related to a lack of knowledge and awareness of specific requirements were minimal, contributing to only 3.57% (1 IBCT case) in 2022 and 4.3% (1 NM case) in 2023. Other errors, making up 14.3% (4 cases) in 2022 and 17.3% (4 cases) in 2023, involved issues like requesting the wrong components—such as FFP instead of platelets in all IBCT cases—and errors in patient identification or incorrect blood product requests in NM cases. Despite the overall decrease in errors, the data highlights ongoing challenges in ensuring accurate patient information and appropriate blood component requests.

STEP 1: REQUEST ERRORS	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=22	N=6	N=21	N=2
1a) Request (incorrect transcription/patient information)	20	3	18	0
1a) Request (incorrect transcription/patient information)	0	1	1	0
1a) Request (incorrect transcription/patient information)	2	2	2	2

Table 3.3.3.1: Request Error in 2022 – 2023



3.3.3.1.3 Contributing factors:

According to the root cause analysis (RCA) report, the main causes of errors were:

- a. Team factors: Issues with written communication and risky behaviour, such as assuming information and not seeking clarification.
- b. Incomplete clinical information: Missing details on request forms.
- c. Lack of knowledge and awareness: Insufficient understanding of blood transfusion requirements.
- d. Lack of manpower: Many healthcare facilities are overburdened with excessive patient loads.
- e. Non-compliance with SOP: Failure to adhere to standard operating procedures.

3.3.3.1.4 Recommendations:

- a. Supervision and monitoring: Superiors should ensure that housemen in training do not take shortcuts and are encouraged to ask for assistance when needed.
- b. Ongoing training and education: Implement continuing medical education (CME) to address knowledge gaps and ensure SOP compliance.
- c. Regular clinical audits: Conduct audits to enhance the standard of care and ensure adherence to SOP.
- d. Increase manpower: Ensure adequate staffing in healthcare facilities to manage patient loads effectively.
- e. Strengthen communication: Improve written communication and encourage staff to seek clarification when in doubt.
- f. Improve request form accuracy: Ensure all clinical information is complete and accurate on request forms.



3.3.3.2 SAMPLE TAKING / LABELLING – Table 3.3.3.2

3.3.3.2.1 During the collection of a blood sample for pre-transfusion testing and the administration of blood to the patient, it is crucial to correctly identify the patient. One patient and one trained, competent, and authorized staff member must participate in a single, uninterrupted procedure for collecting the patient's blood sample and filling out the sample's information.

3.3.3.2.2 The minimal requirements for sample tube information include the patient's core identities (name, ID number, and hospital registration number), the date and time the sample is taken, and the identity of the staff member taking the sample. The person who took the sample must promptly label the sample tubes at the patient's bedside.

3.3.3.2.3 Sampling and labeling errors can cause significant harm and are classified as:

- a. Wrong Blood in Tube (WBIT): The sample may have been taken from the incorrect patient and labelled for the intended recipient.
- b. Wrong Name on Tube (WNOT): The sample has been taken for the intended recipient but labelled with another patient's information.

In blood banks, these errors are often found during pre-transfusion testing. If there is a disagreement between the patient's current blood group sample and their previous record, the root cause of the ABO discrepancy will be investigated.

3.3.3.2.4 NHCC received 209 NM events and 11 IBCT cases in 2022, and 187 NM events and 8 IBCT cases in 2023.

- a. In 2022, 48.2% (n=106) and 41.5% (n=81) in 2023 were due to failure to conduct a positive patient identification during blood taking.
- b. 20.5% (n=45) in 2022 and 20% (n=39) in 2023 were due to multiple personnel involved during sample taking.
- c. Pre-labeling samples elsewhere and/or not doing the procedure continuously accounted for 31.3% (n=69) in 2022 and 38.5% (n=75) in 2023.

Despite sample and labeling errors frequently occurring at the clinical site, IBCT only results if the patient has no prior transfusion record with the blood bank.



STEP 2: SAMPLE / LABELLING ERRORS	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=209	N=11	N=187	N=8
2a) Positive patient identification was not performed	102	4	77	4
2b) More than one person involved in blood taking (Sample not labelled by the person taking the blood)	42	3	36	3
2c) Pre-labelled sample/form. Sample was not labelled at the bedside	65	4	74	1

Table 3.3.3.2: Sampling/ Labelling Error in 2022 – 2023

3.3.3.2.5 Contributing factors:

The RCA report noted the following frequent causes of these errors:

- a. Work/Environmental Factors: Insufficient staff, high workload, busy and noisy environments, insufficient breaks, and building design issues. For instance, in COVID wards, samples taken by staff in PPE were passed to staff in clean areas.
- b. Personal Staff Factors: Non-compliance with SOPs, distractions, fatigue, and unsafe behaviours like assuming and not seeking clarification.
- c. Team Factors: Insufficient oversight or monitoring.

3.3.3.2.6 Recommendations:

- a. Adequate staffing, training, and monitoring are necessary to address staffing issues identified in many of the reported instances. All areas involved in transfusion require adequate staffing at all times.
- b. To address non-compliance with SOPs, housemen should receive training on blood-taking protocols and transfusion safety early in their postings.
- c. Periodic clinical audits are recommended to enhance quality and SOP adherence.
- d. Strengthen the involvement of the Hospital Transfusion Committee (HTC). HTC should act as a liaison between clinical and blood bank activities, providing solutions, feedback, education, and best practices to ensure that transfusion practices align with national standards.



3.3.3.3 SAMPLE RECEIPT – Table 3.3.3.3

3.3.3.3.1 Proper sample receipt and registration at the blood bank are crucial for ensuring the right investigation is conducted for the right patient with the right sample at the right time. The data on the request form must match the sample's label to avoid errors. The failure to recognise the patient's transfusion history at this step will result in an error.

3.3.3.3.2 In 2022, there were no near misses reported for this step. However, in 2023, two near misses occurred involving blood bank personnel:

- a. Near miss 1: A sample was switched during registration, and the discrepancy in the automated machine's result went unnoticed.
- b. Near miss 2: An MLT supplied the wrong packed cell based on given names rather than full names and failed to match other identifiers.

Additionally, in 2022, there was one incident of incorrect blood component transfusion (IBCT) where blood bank staff mistakenly registered the patient's name in BBIS, leading to blood being supplied twice. Despite discrepancies between the GXM form and the PPDK card, the correct blood was ultimately given to the patient. In 2023, there have been no IBCT incidents related to this step.

STEP 3: SAMPLE RECEIPTS & REGISTRATION ERROR	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=0	N=1	N=2	N=0
Incorrect sample receipt and registration at blood bank/ patient's previous history not being checked or entered/ error during relabelling of patient's sample / switching patient's blood samples, etc.	0	1	2	0

Table 3.3.3.3: Receipt and Registration Error in 2022 – 2023



3.3.3.3.3 Contributing factors:

The RCA report identified the following contributing factors:

- a. Work/Environmental Factors: Inadequate staff, heavy workload, cluttered and noisy surroundings, insufficient breaks.
- b. Individual Staff Factors: Failure to adhere to SOPs due to fatigue and stress.
- c. Team Factors: Lack of supervision and monitoring.

3.3.3.3.4 Recommendations:

- a. Staffing and Workload: Address the issue of inadequate staffing and high workload by analysing staffing needs and restructuring shifts to accommodate peak times.
- b. Adherence to SOPs: Superiors should perform periodic checks and remind staff to adhere to SOPs despite heavy workloads to reduce the risk of errors.
- c. Patient Historical Data: Always check patient historical data to detect discrepancies and verify with patient demographic data.
- d. Identifier Verification: Ensure all important identifiers are fully matched at every level of checking to prevent transfusion errors.
- e. Training and Supervision: Enhance staff training on SOPs and increase supervision to ensure compliance and accuracy in sample handling.
- f. Work Environment: Improve the work environment by reducing clutter and noise and ensuring staff have adequate breaks to reduce fatigue and stress.



3.3.3.4 TESTING – Table 3.3.3.4

3.3.3.4.1 Proper pre-transfusion testing, in line with local and national guidelines, ensures the safe provision of blood components. Accurate results for blood group, antibody screening, and antibody identification are crucial. The process should not be interrupted until findings are transcribed into the blood bank information system (BBIS). Errors can be procedural, interpretational, transcriptional, or technical.

- a. Procedural errors include:
 - b. Wrong procedure performed
 - c. Incorrectly performed or omitted steps
 - d. Unidentified clinically significant antibody
 - e. Unperformed antibody identification after a positive screen
 - f. Blood components issued without second-person verification
- b. Interpretation errors occur when the procedure is correct, but results (e.g., ABO grouping, Rh D typing) are interpreted incorrectly.
- c. Transcription errors happen when test results are correctly obtained but wrongly recorded in the GXM form or BBIS.
- d. Technical errors involve IT issues, such as system failures.

3.3.3.4.2 There were 22 near-miss (NM) cases reported in two years:

- a. 2022: 11 NMs (4 procedural, 1 interpretation, 6 transcription, 0 technical)
- b. 2023: 11 NMs (3 procedural, 6 interpretation, 2 transcription, 0 technical)

There were 11 IBCT cases involving testing errors:

- a. 2022: 4 IBCTs (3 procedural, 0 interpretation, 1 transcription, 0 technical)
- b. 2023: 7 IBCTs (3 procedural, 1 interpretation, 3 transcription, 0 technical)

No technical errors caused IBCTs in either year.

STEP 4: TESTING ERROR	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=11	N=4	N=11	N=7
4a) Procedural error	4	3	3	3
4b) Interpretation error	1	0	6	1
4c) Transcription error	6	1	2	3
4d) Technical error	0	0	0	0

Table 3.3.3.4: Testing Error in 2022 – 2023



3.3.3.4.3 Contributing factors:

- a. Blood bank personnel switched samples, misread results, or misinterpreted blood group results.
- b. Lack of second verification before blood release or transfusion.
- c. Incorrect use of anti-AB instead of anti-D.
- d. Issuance of incompatible or DCT-positive packed cells.
- e. Shortcuts due to understaffing and high workload.

3.3.3.4.4 Recommendations:

- a. Standardise Protocols: Hospitals should update SOPs for ABO and Rh grouping, adding a second verification step, such as preparing a new red cell suspension or having a different individual verify the blood grouping.
- b. Staff Training: Provide intensive retraining and continuous CME to staff.
- c. Supervision: Conduct regular close observation of technical staff by supervisors.
- d. Automation: Consider automating blood grouping and antibody screening in high-workload blood banks to reduce manual errors and improve work quality.
- e. Historical Records: Address the issue of unavailable patient historical blood bank records by implementing strategies like two independent sample processes for ABO blood grouping for patients without historical records and sharing patient transfusion data between hospitals.
- f. Expand BBIS Systems: Sharing patient transfusion data between hospitals.
- g. Work Environment: Improve work environment conditions to reduce stress and errors.
- h. Regular Audits: Conduct regular audits to ensure adherence to updated protocols and identify areas for improvement.
- i. Incident Reporting: Encourage prompt and accurate reporting of near misses and errors to facilitate continuous improvement.



3.3.3.5 COMPONENT SELECTION – Table 3.3.3.5

3.3.3.5.1 This step ensures that the correct components together with the specific requirements are selected to comply with the patient’s requirements and the clinical request.

3.3.3.5.2 Component selection-related NM were reported in 5 cases in 2022 and 4 cases in 2023. All of the cases were caused by blood bank personnel selecting the incorrect blood component not fulfilling specific requested requirements, or issuing blood intended for another patient.

There were 17 cases of IBCT over two years:

- a. 2022: 9 IBCTs, including wrong blood groups, incorrect components, incorrect phenotypes, and one case of expired paedipack issued for transfusion.
- b. 2023: 8 IBCTs, including failure to supply phenotype blood, wrong components, and one case of expired blood component issued for transfusion.

STEP 5: COMPONENT SELECTION ERROR	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=5	N=9	N=4	N=8
5a) Wrong blood group/ Component / Specific requirement requested not selected / wrong blood issued to patient/ unscreened blood	5	8	4	7
5b) Expired blood component issued	0	1	0	1

Table 3.3.3.5: Component Selection Error in 2022 – 2023



3.3.3.5.3 Contributing factors

- a. Lapses in concentration among blood bank personnel.
- b. Lack of knowledge on selecting non-red cell components.
- c. System limitations allowing staff to override incompatibility prompts.
- d. Substandard inventory management causing expired blood release.
- e. Failure to follow SOP.

3.3.3.5.4 Recommendations

- a. Staff Training: Regular retraining and annual competency tests to improve staff knowledge.
- b. Adequate Staffing: Prioritize staffing requests for understaffed blood banks to reduce stress and errors.
- c. System Upgrades: Upgrade blood banking systems in hospitals that lack them.
- d. Interim Measures: Implement systematic strategies to mitigate errors in hospitals without blood banking information systems.
- e. Inventory Management: Adhere to the “first expiry, first out” (FEFO) principle to prevent expired blood from being used.
- f. Error Reporting: Encourage prompt reporting and analysis of near-misses and errors to facilitate continuous improvement.
- g. Regular Audits: Conduct regular audits to ensure adherence to protocols and identify areas for improvement.
- h. Enhanced Supervision: Increase supervision and checks to ensure compliance with SOPs.



3.3.3.6 COMPONENT LABELLING, AVAILABILITY & HANDLING AND STORAGE ERRORS – Table 3.3.3.6

3.3.3.6.1 The correct component needs to be labelled with the correct four (or five) key patient identifiers, accessible and available for the time required. If this is not attainable then the clinical area needs to be informed. It is essential that only one patient’s component is labelled at a time to prevent transposed labels. All blood components need to be handled and stored in the correct way as defined in the guidelines.

3.3.3.6.2 There were 5 reports received involving this step in 2022 of which 3 NM and 2 IBCT meanwhile there were only 2 cases of NM in 2023, no IBCT reported. The 5 cases of NM were due mishandling of blood product, failure to label the blood component with the correct patient identifiers, mislabelling of the recipient card with wrong blood group and lastly due to wrong PPDK card attached to the correct blood bag. Meanwhile, the 2 cases of IBCT in 2022 were due to wrong blood bags were supplied to patients due to blood card switched at the blood bank counter.

STEP 6: COMPONENT LABELLING, AVAILABILITY AND HANDLING AND STORAGE	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=3	N=2	N=2	N=0
6a) Failure to label the blood component with the correct patient identifiers.	2	2	2	0
6b) Failure to handle and store blood components correctly	1	0	0	0
6c) Others	0	0	0	0

Table 3.3.3.6: Component Labelling, Availability and Handling & Storage Errors in 2022 – 2023



3.3.3.6.3 Contributing factors

- a. Task Factor: Lack of protocol detailing critical information and instructions (e.g., “attend one patient at a time”).
- b. Team Factors: Inadequate supervision to ensure SOP compliance.
- c. Staff Factor: Insufficient knowledge and non-compliance with policies and procedures.
- d. Workload: Insufficient staff and high workload leading to procedural shortcuts.
- e. Technology Factor: Weakness in the laboratory information system (LIS) requiring manual data entry, increasing transcription errors.

3.3.3.6.4 Recommendations:

- a. Staffing and Workload: Increase staffing levels and restructure shifts to accommodate high workload periods.
- b. SOP Revision: Update SOPs to include specific instructions such as “attend one patient at a time”.
- c. Periodic Checks: Superiors should perform regular checks and reminders to ensure adherence to SOPs, especially during high workload periods.
- d. Cross-Checking Culture: Promote a culture of cross-checking details on GXM forms, blood cards, and blood bags between ward staff and MLTs.
- e. Staff Training: Provide retraining and annual competency tests, incorporating visual aids and targeted parameters for checks.
- f. Error Reporting: Encourage prompt reporting and analysis of near-misses and errors for continuous improvement.
- g. Regular Audits: Conduct regular audits to ensure protocol adherence and identify improvement areas.
- h. Enhanced Supervision: Increase supervision and checks to ensure compliance with SOPs.



3.3.3.7 COMPONENT COLLECTION – Table 3.3.3.7

3.3.3.7.1 Correct component collection requires following proper procedures, ensuring the component meets clinical requests and collection slip requirements. Laboratory personnel must verify all components before issuing to clinical personnel.

3.3.3.7.2 No IBCT cases reported in both years. There were 4 cases of NM reported in 2022 and 1 in 2023. Four cases of NM were due to ward personnel not checking blood bag details against laboratory labels. One case involved switching of PPKD card between two blood bags belonging to the same patient. As only one unit of blood was used, the error was only discovered during cancellation of unused blood bags in the blood bank.

STEP 7: COMPONENT COLLECTION ERROR	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=4	N=0	N=1	N=0
7a) Blood component not collected or received by trained, competent, and authorized staff.	0	0	0	0
7b) Failure to check patient's core identifiers and component details against laboratory-generated label	4	0	1	0

Table 3.3.3.7: Component Collection Error in 2022 – 2023

3.3.3.7.3 Contributing factors:

Non-compliance with SOP by ward personnel, not cross-checking patient information against the laboratory label on the blood bag.



3.3.3.7.4 Recommendations:

- a. Continuous Training: Regular training and CME sessions to remind staff of SOP importance and the need to transfuse blood within 30 minutes of issue.
- b. Positive Identification: Ensure positive patient identification at every transfusion stage by checking patient identifiers (first name, last name, date of birth, unique ID) on both the blood bag and the patient to avoid discrepancies.
- c. Supervision: Increase supervision and monitoring of staff compliance with SOPs during blood component collection and transfusion.
- d. Audit and Feedback: Conduct regular audits of component collection procedures and provide feedback to staff to improve adherence to protocols.

3.3.3.8 PRESCRIPTION – Table 3.3.3.8

3.3.3.8.1 Although the prescription may be written at different points in the transfusion process, it must be completed and checked before the final administration step. It should include the patient’s core identifiers, the component to be transfused, the date, volume or number of units, rate of transfusion, and any other clinical instructions. It must be signed by the authorizer.

3.3.3.8.2 No cases of NM or IBCT were documented for either year.

STEP 8: PRESCRIPTION ERROR	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=0	N=0	N=0	N=0
Blood transfusion not authorized by trained staff/failure to document specific clinical requirements	0	0	0	0

Table 3.3.3.8: Prescription Error in 2022– 2023

3.3.3.8.3 Contributing factors:

No cases reported involving this step.

3.3.3.8.4 Recommendations:

- a. Reinforce Protocols: Regularly reinforce the importance of completing and checking transfusion prescriptions as per protocol.
- b. Training: Ensure all staff are trained and aware of the necessary components of a transfusion prescription.
- c. Periodic Reviews: Conduct periodic reviews to ensure compliance with prescription procedures.



3.3.3.9 Administration – Table 3.3.3.9

- 3.3.3.9.1 The final opportunity to prevent errors is during administration. Qualified healthcare staff must perform the final bedside check. The component blood group must match the patient, and the donation barcode, blood group, and expiration date on the component pack must match the laboratory label. Any specific clinical requirements, such as leukodepletion or irradiation, must also be met before transfusion.
- 3.3.3.9.2 In 2022 and 2023, there was 1 reported case of NM involving administration error each year. Additionally, 12 IBCT cases were reported in 2022, and 14 IBCT cases were reported in 2023. Among these, a total of 6 IBCT cases and 1 NM case in both years were attributed to the failure of a final administration check at the bedside. For instance, in one of the NM case, the error happened during haemodialysis because medical officer and the staff nurse performing the blood administration were distracted by numerous referrals and family inquiries. This distraction led to non-compliance with SOP for blood administration at various checkpoints. The error was detected when the transfusion was withheld due to a blocked transfusion set filter caused by blood clots from a previous packed cell transfusion. There were also 20 IBCT cases reported cumulatively due to failure to check patient's core identifiers and details of the component collected against the details on the laboratory-generated label attached to the blood bag. In the majority of cases, staff members failed to verify patient identities and cross-check between the PPDK card, blood bag, and patient.
- 3.3.3.9.3 On the other hand, there was 1 case of NM in 2022 reported under 'Others', where during the transfer of a patient from a district to a tertiary hospital with packed cells, a staff nurse inadvertently brought along the incorrect GXM form. This form had been previously used for a cryoprecipitate transfusion for the same patient. Consequently, the packed cell unit was attached to the wrong GXM form and could not be used for the patient.



STEP 9: ADMINISTRATION ERROR	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=1	N=12	N=1	N=14
9a) Final administration check not done at bedside	0	4	1	2
9b) Failure to check patient's core identifiers and component details against laboratory label	0	8	0	12
9c) Others (requirement not met)	1	0	0	0

Table 3.3.3.9: Administration Error in 2022– 2023

3.3.3.9.4 Contributing factors:

These are among the contributing factors that were identified:

- a. Individual/Staff Factors: Lack of knowledge, non-compliance with SOP, unsafe behaviour, not asking for clarification.
- b. Team Factors: Ineffective leadership, lack of supervision, poor communication between clinical and blood bank staff.
- c. Failure in Positive Patient Identification (PPI): Not done at the bedside, or not verified by two staff members due to workload and lack of manpower.

3.3.3.9.5 Recommendations:

- a. Positive Patient Identification (PPI): Must be done at every step, verifying the patient identifiers on the blood bag and the recipient before transfusion. Two-step verification by two different staff members at the bedside is required.
- b. Verification of Details: Patient details must match the laboratory-generated label on the blood bag.
- c. Training: Housemen must complete training in safe transfusion before being off-tagged in the department.
- d. Regular Supervision: Ensure continuous supervision and adherence to SOP despite workload.
- e. Effective Communication: Improve communication between clinical and blood bank staff to prevent errors.



3.3.4 Miscellaneous – Table 3.3.4

3.3.4.1 Errors are categorized as miscellaneous if they do not relate to any of the nine transfusion process steps or if the root cause is inconclusive due to insufficient information, such as when the patient is deceased or discharged when the error is discovered.

3.3.4.2 In 2022, there was 1 near miss (NM) and 1 IBCT case, both involving registration errors. In both cases, registration staff incorrectly registered patient names despite correct identification being provided. In 2023, one incomplete report was received where patient details on the blood sample did not match the blood request form, but no further investigation was conducted.

MISCELLANEOUS	NM 2022	IBCT 2022	NM 2023	IBCT 2023
	N=1	N=1	N=1	N=0
10a) Error not associated with the nine steps	1	1	0	0
10b) Inconclusive	0	0	1	0

Table 3.3.4: Miscellaneous in 2022 – 2023

3.3.4.3 Contributing factors:

Errors at the registration counter due to not using official identification documents or lack of an ID card reader, leading to manual entry errors.

3.3.4.4 Recommendations:

- a. Registration Policy: Hospitals must have a clear and well-documented policy and procedure for patient registration. This ensures accurate enrolment of patient information and prevents errors that could delay treatment.
- b. Use of Identification Tools: Implement the use of identification card readers at registration counters to reduce manual entry errors.
- c. Training: Ensure staff are trained to follow the registration procedures accurately and verify patient details carefully.



3.4 ERROR IN CRITICAL CONTROL POINTS IN THE TRANSFUSION PROCESS - Figure 3.4

3.4.1 In 2022, there were a total of 302 reported cases of transfusion errors, consisting of 256 NMs and 46 IBCTs. By 2023, the total number of transfusion errors decreased to 269, which included 230 NMs and 39 IBCTs. Additionally, in 2023, NHCC received an incomplete report from a state hospital.

3.4.2 Clinical/Ward Errors:

The number of reported errors in the clinical area was 267 in 2022 (237 NMs and 30 IBCTs) and decreased to 235 in 2023 (211 NMs and 24 IBCTs). Sampling and labelling errors were the most frequent, with 220 reports in 2022 and 195 in 2023. These errors mainly involved Wrong Blood in Tube (WBIT) or Wrong Name on Tube (WNOT). ABO discrepancies detected during pre-transfusion testing due to differences between current and historical blood group records have prompted investigations.

3.4.3 Blood Bank Errors:

In 2022, blood bank errors accounted for 35 cases, including 19 NMs and 16 IBCTs. Component selection errors were most common, with 15 cases (42.8%), involving incorrect component selection, wrong blood group, or specific requirements such as phenotype blood. In 2023, there were 33 cases, with 18 NMs and 15 IBCTs. Testing errors were predominant in 2023, accounting for 18 cases (54.5%), and included procedural, interpretation, and transcription errors.

3.4.4 Hospital admission error:

In 2022, there were 2 cases (1 NM and 1 IBCT) due to registration errors during hospital admission.

3.4.5 Inconclusive:

In 2023, there was one inconclusive NM case due to the absence of a Root Cause Analysis (RCA) report.

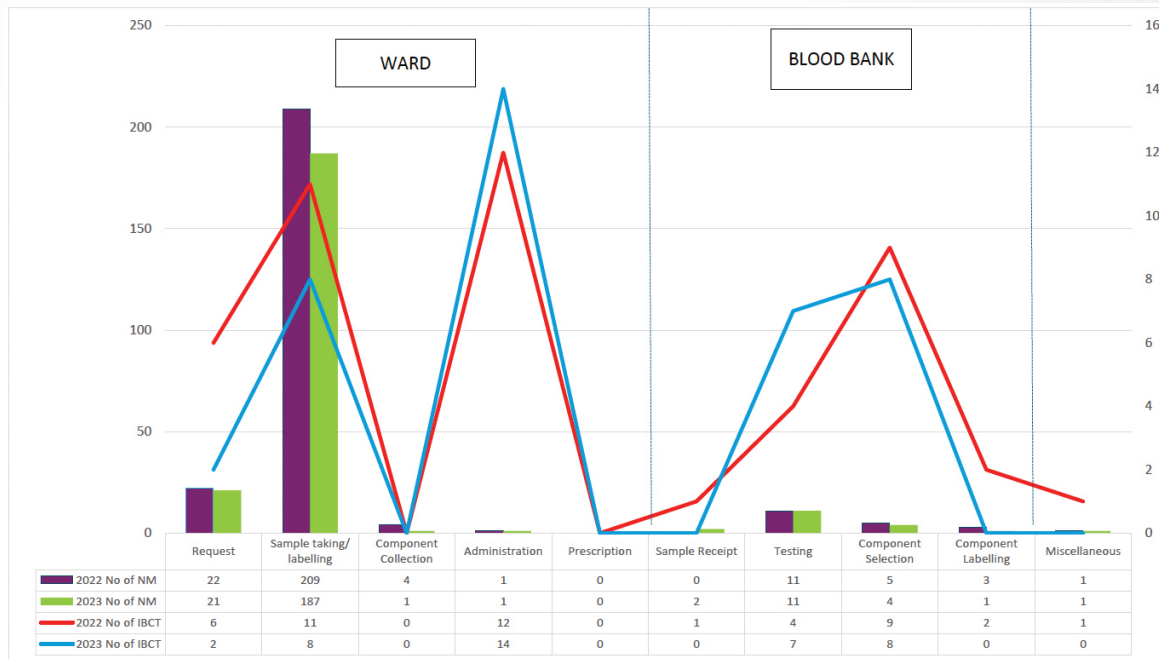


Figure 3.4: Critical Control Point in the Transfusion Process where IBCT/NM Occurred in 2022-2023

3.5 ERROR LOCATIONS IN THE TRANSFUSION PROCESS – Figure 3.5.2, 3.5.3

3.5.1 Errors in the transfusion process can occur in various locations within the clinical setting or the blood bank. These locations are categorized based on the nature of the workplace. The analysis focuses on the clinical area and the blood bank, highlighting specific locations where errors were most prevalent.

3.5.2 Clinical Area

3.5.2.1 General Ward and ED/PAC:

The General Ward had the highest number of near misses and IBCTs in both years. ED / PAC saw an increase in near misses but a decrease in IBCTs from 2022 to 2023.

- a. General Ward: In 2022, there were 189 NMs and 18 IBCTs reported. In 2023, these numbers decreased to 166 NMs and 17 IBCTs.
- b. Emergency Department (ED) / Patient Admission Centre (PAC): Near misses increased from 30 in 2022 to 34 in 2023. IBCTs decreased from 9 to 4 over the same period.



3.5.2.2 Operation Theatres (OT) and Labour Rooms (LR)

Errors in OT/LR remained relatively low and consistent.

- a. Near misses in OT/LR slightly decreased from 9 in 2022 to 8 in 2023.
- b. IBCTs remained constant at 2 for both years.

3.5.2.3 Intensive Care Units (ICU/NICU)

Errors in ICU/NICU remained relatively low and consistent.

- a. ICU/NICU recorded 7 near misses in 2022, which decreased to 3 in 2023. No IBCTs were recorded in these units for both years.
- b. Errors were mainly due to non-adherence to SOPs involving multiple individuals in sample collection and labelling.

3.5.2.4 Other locations:

The daycare ward and registration counter reported 1 near miss each in 2022, with no cases reported in 2023. There was 1 IBCT case each in 2022 and 2023 in the Scope Room, due to a lack of positive patient identification before transfusion.

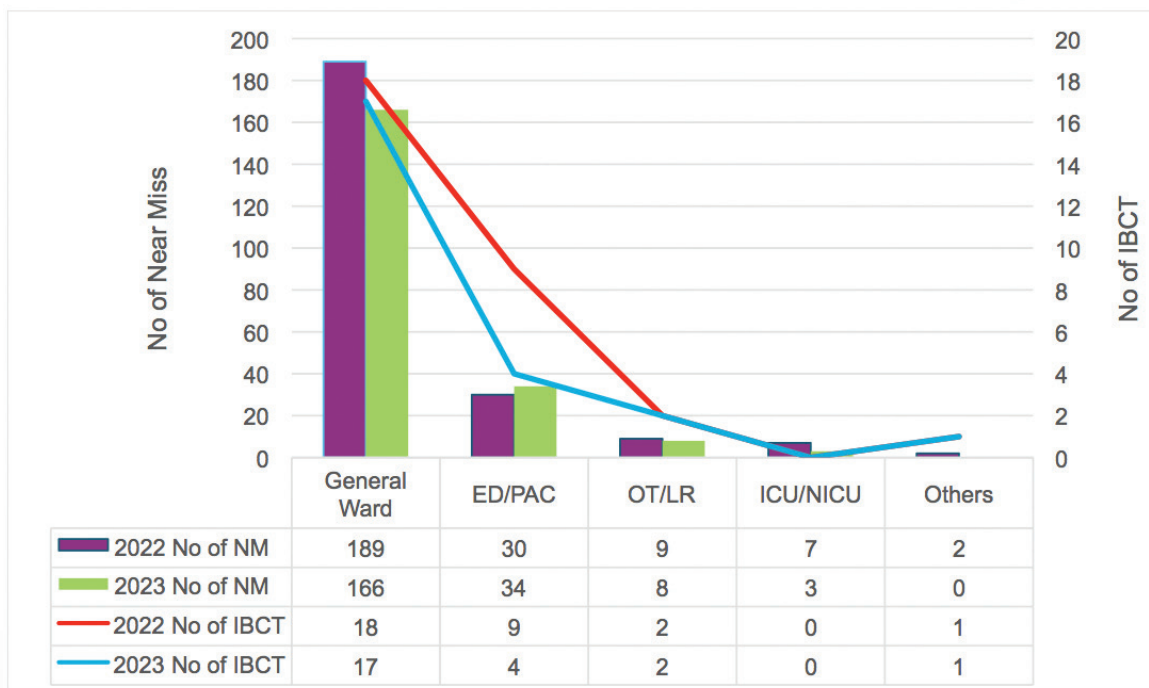


Figure 3.5.2: Error in Ward in 2022 - 2023



3.5.3 Blood Bank

3.5.3.1 When the procedure is done correctly, blood transfusions are very safe and efficient. However, errors in sample receipt and registration, which frequently result in discrepancies in patient information, could lead to errors in the blood bank. Over in testing errors, errors could be mostly because of procedural error in the pre-transfusion testing procedure, in which procedures are completed incorrectly or omitted, and the other cause is where wrong interpretation of blood group/Rh antibody identification. Last but not least, technical errors like BBISv2 data migration or BBISv2 error occur when the incorrect transcription of blood group, Rh, antibody, or barcode is encountered. Errors over blood banks can also be due to component selection errors where a wrong blood group/component/ specific requirement was requested but not selected/unscreened blood was selected and issued to the patient. Lastly, component labelling in which there is a failure to label the blood component with the correct patient identifiers, availability and handling and storage errors where there is a failure to handle and store blood components in the correct way as defined in the guidelines.

3.5.3.2 The blood bank reported 35 transfusion errors in 2022 and 33 in 2023. Clinical sites reported higher IBCT cases (30 in 2022 and 24 in 2023) compared to the blood bank (16 in 2022 and 15 in 2023).

3.5.3.3 Clinical Transfusion Department (CTD) / Immunohaematology (IH):

There were 15 cases of IBCT in 2022 and 14 cases in 2023 over at CTD. Out of these in 2022, 3 were due to procedural errors, 1 transcription error, 1 registration error, 8 component selection error and 2 error due to failure to label the blood component with the correct patient identifiers. Meanwhile in 2023, 3 procedural errors, 1 interpretation error, 3 transcription error and 7 of component selection error.



3.5.3.4 Inventory:

There was 1 near miss and 1 IBCT in 2022, while in 2023, no near misses were reported, and 1 IBCT occurred due to component selection errors involving expired blood.

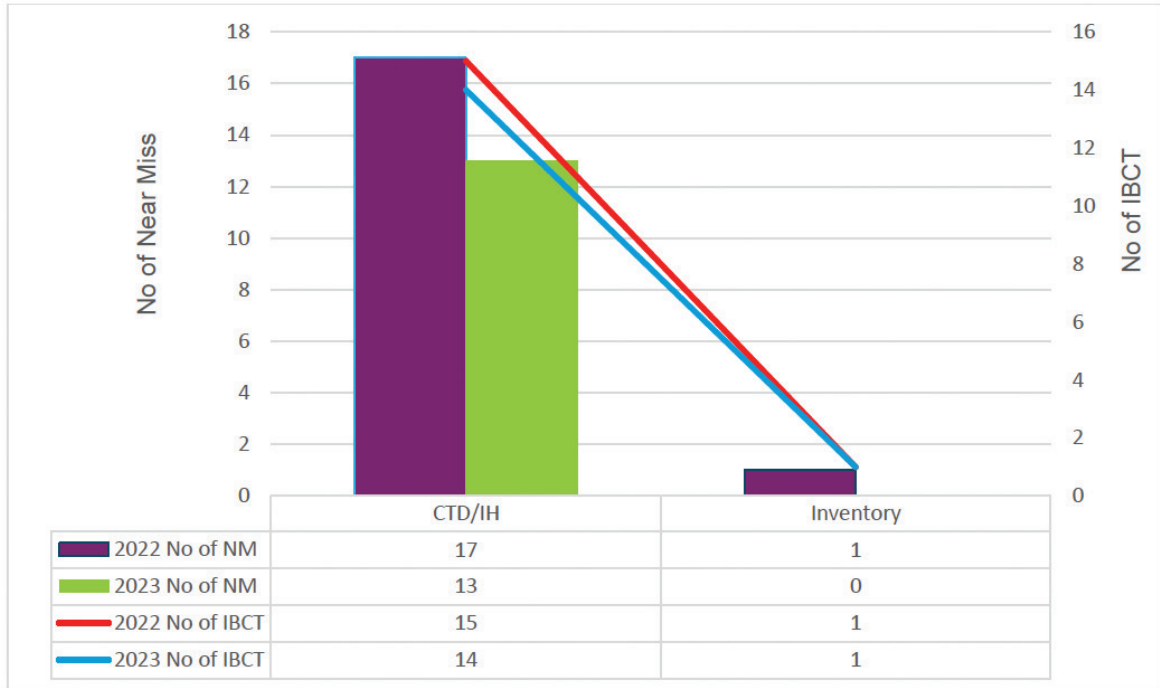


Figure 3.5.3: Error in Blood Bank in 2022 – 2023



3.6 CATEGORY OF STAFF INVOLVED – Figure 3.6.1

3.6.1 The majority of hospital staff involved in NM and IBCT incidents over both years were house officers (HOs), accounting for 73.4% of the total incidents. The high percentage of involvement by HOs can be attributed to their training status and their primary responsibility for blood collection in the ward. The workload and exhaustion faced by HOs often result in deviations from SOPs. It is then followed by MLTs whom contributed to 12.3 %, MO 8.4%, SN 4.5% and other category of hospital personnel by 1.4%.

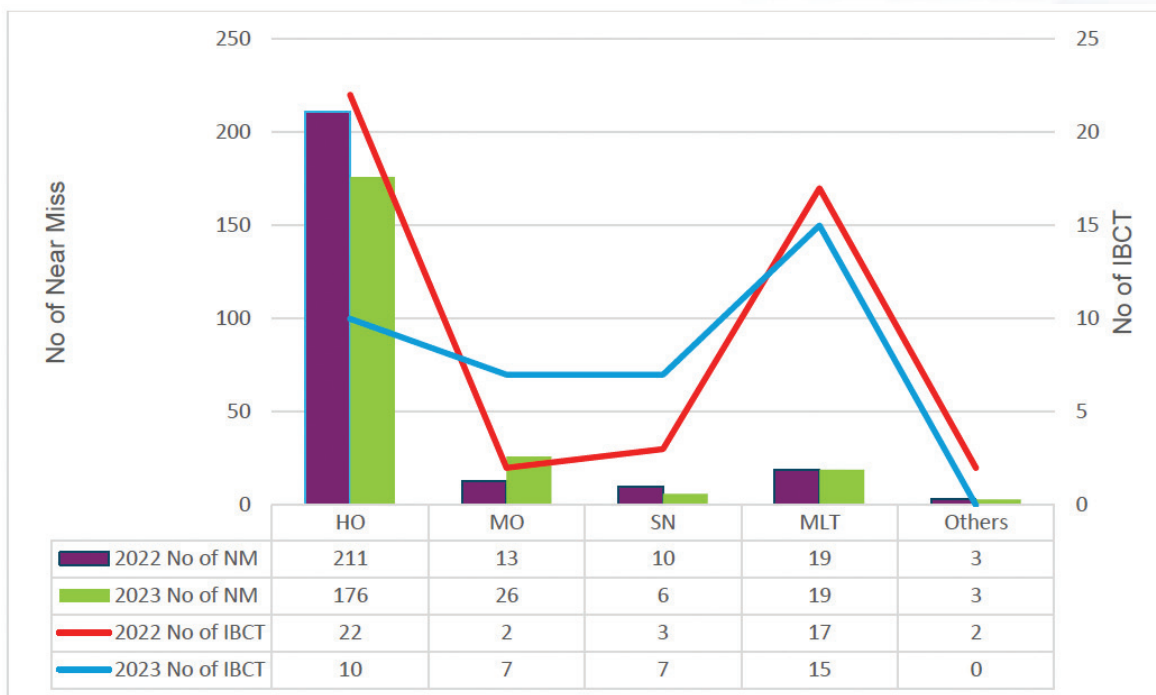


Figure 3.6.1 Category of Staff Involved in 2022 – 2023



3.7 WRONG COMPONENT TRANSFUSED (WCT) AND SPECIFIC REQUIREMENT NOT MET (SRNM) IN RELATION TO CCP

3.7.1 IBCT – Figure 3.7.1a, 3.7.1b, 3.7.1c

3.7.1.1 In 2022, out of 46 IBCT cases reported, 38 patients were transfused with the wrong components while 2 patients were transfused with blood in which specific requirements were not met. Despite 38 patients receiving the wrong blood components, only three developed a haemolytic transfusion reaction. Two patients experienced symptoms of dyspnoea, chest tightness, and back pain without evidence of haemolysis. Additionally, three patients developed fever with chills and rigors, and another two patients had allergic reactions. Fortunately, all other patients showed no signs or symptoms of a transfusion reaction. There were also 5 cases of RBRP detected post-transfusion in 2022 and 1 under HSE which would be elaborated further in their respective chapters.

3.7.1.2 In 2023, out of 39 IBCT cases reported, 34 reports involving the transfusion of wrong components and 3 cases of SRNM. Among these incidents, three patients exhibited evidence of haemolytic transfusion reactions, two developed a fever, one experienced a severe allergic reaction, and another patient developed chest pain but recovered well afterwards. The remaining patients did not show any significant reactions. Other than that there were also one case of RBRP detected post-transfusion, one case of HSE in 2023 reported that would also be elaborated their respective chapters later.

3.7.1.3 The most common errors leading IBCT in both 2022 and 2023 occurred within clinical settings, with sample taking and administration errors being the primary causes, respectively. Among the notable contributing factors in the clinical setting were instances of non-compliance with standard operating procedures (SOP), including failure to perform positive patient identification, involvement of multiple individuals in blood sampling, or not labelling samples at the bedside. Additionally, a lack of awareness or understanding of the policy regarding final administration checks conducted at the bedside also contributed to these incidents.

3.7.1.4 Lack of training, non-compliance to SOP and poor supervision were associated with an increased risk of errors that may jeopardise patient's safety. NHCC emphasises all blood banks to review the training provided to clinical staff and underscores the critical importance of adhering strictly to SOP during the blood transfusion process.

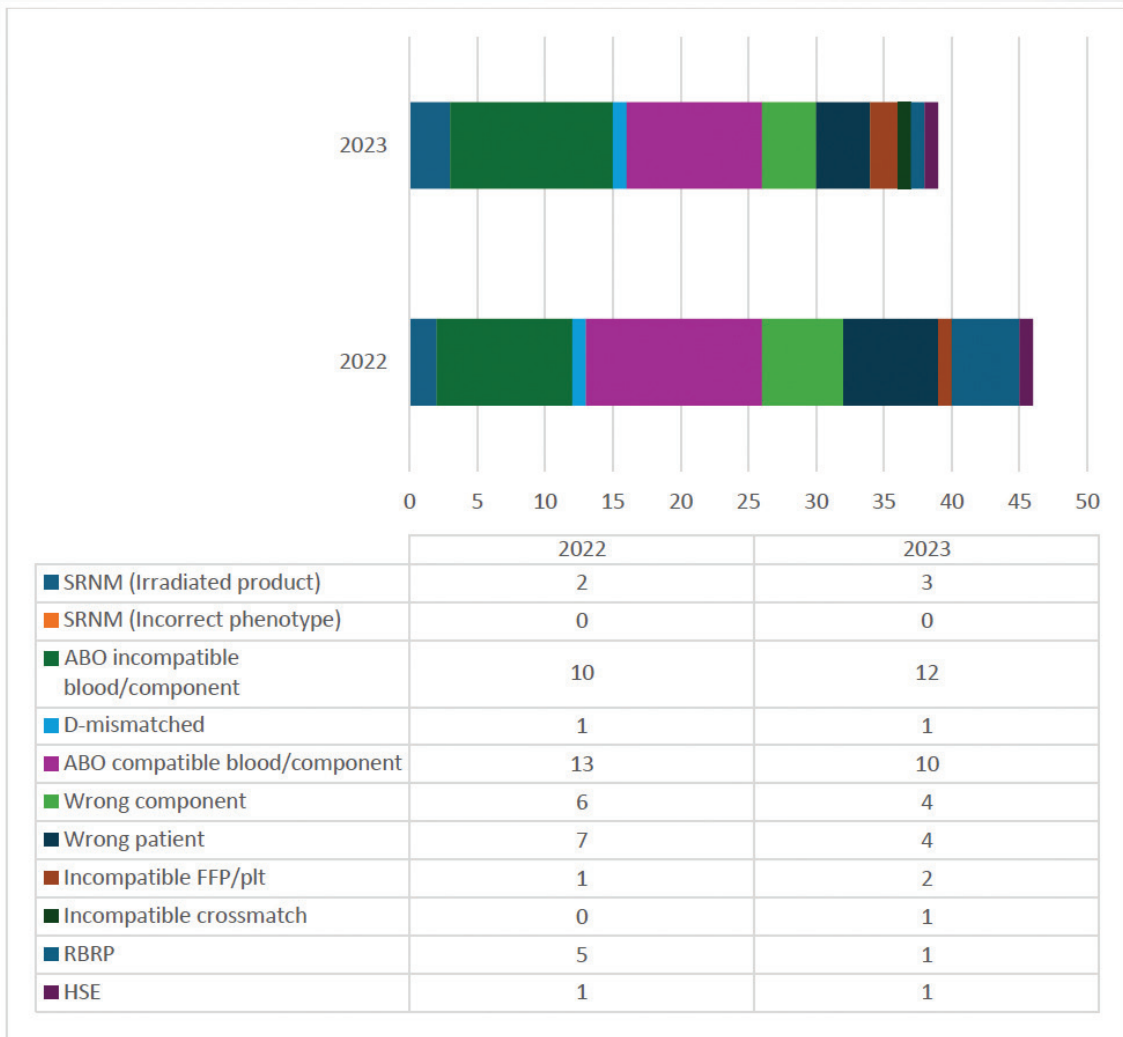


Figure 3.7.1a: Sub-categorisation of IBCT in 2022-2023

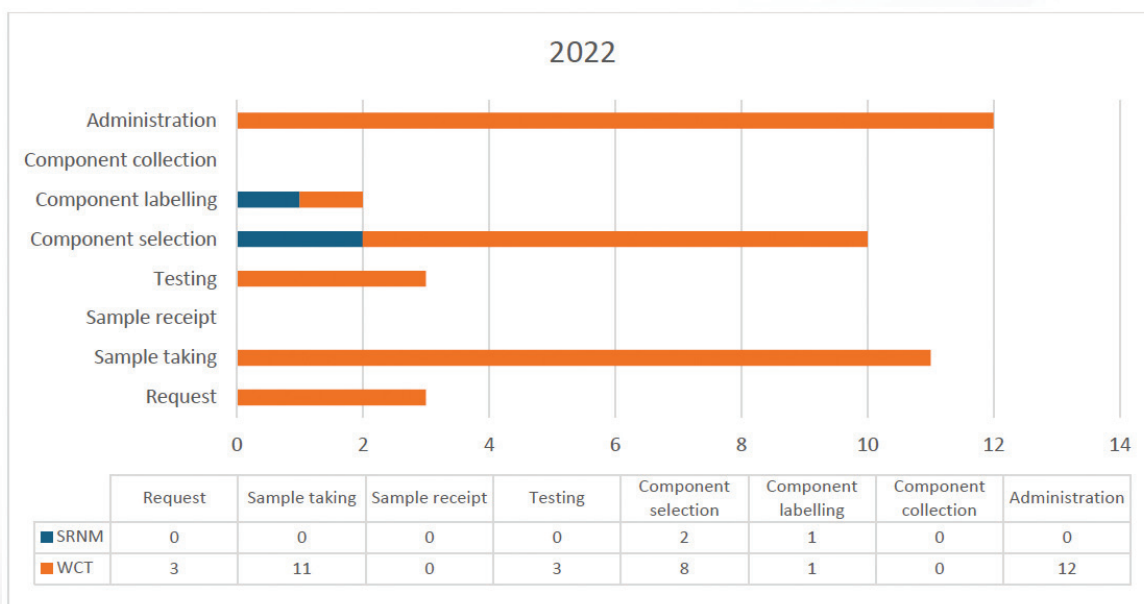


Figure 3.7.1b: Critical Control Point where Error Occurred on Type of IBCT (WCT and SRNM) in 2022

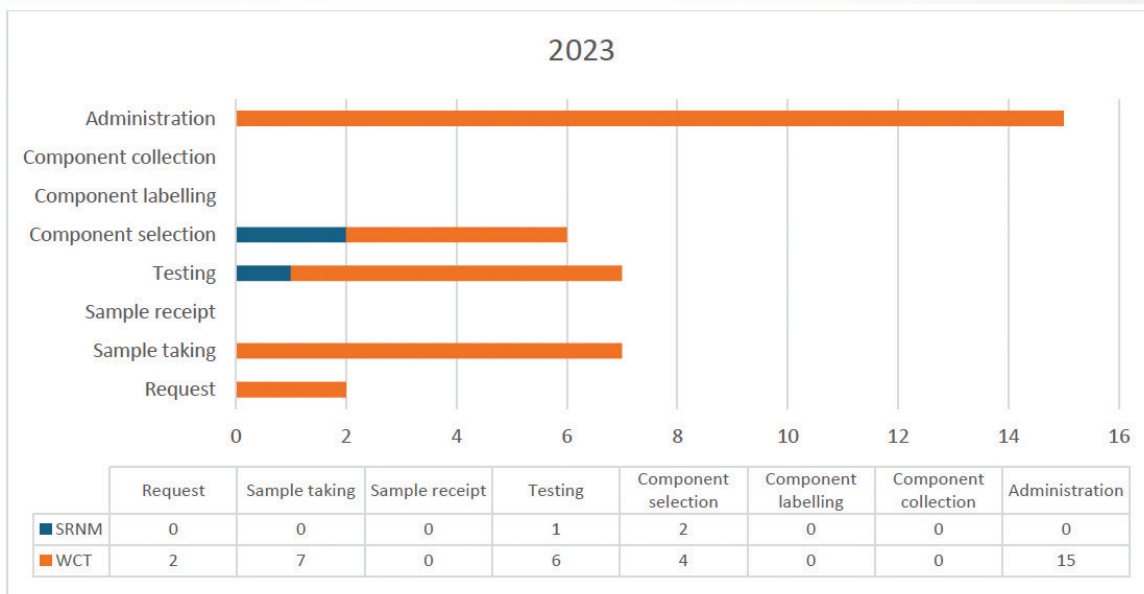


Figure 3.7.1c: Critical Control Point where Error Occurred on Type of IBCT (WCT and SRNM) in 2023

3.7.2 NEAR MISS – Figure 3.7.2a, 3.7.2b

3.7.2.1 The majority of near misses that might have likely resulted in WCT and SRNM in both years happened during sampling and labelling in the clinical setting. In both 2022 and 2023, 222 patients were transfused with the wrong components while 2 patients were transfused with blood in which specific requirements were not met. Since any ABO differences were detectable, the blood bank played a crucial role in preventing IBCT by checking the blood type from the sample with the patient’s historical record or by requesting a second sample if the prior record wasn’t accessible. As a result, it was determined how crucial it is for clinical and blood bank personnel to exercise utmost caution and abide by SOP in order to prevent errors at every stage of the transfusion process. There were also 23 near misses reported under RBRP, 1 case under ADU, 2 cases under HSE and 6 inconclusive reports in 2022 while there were only 4 cases of RBRP, 1 case of ADU and 1 incomplete report in 2023. All this cases will be elaborated in their respective chapters.

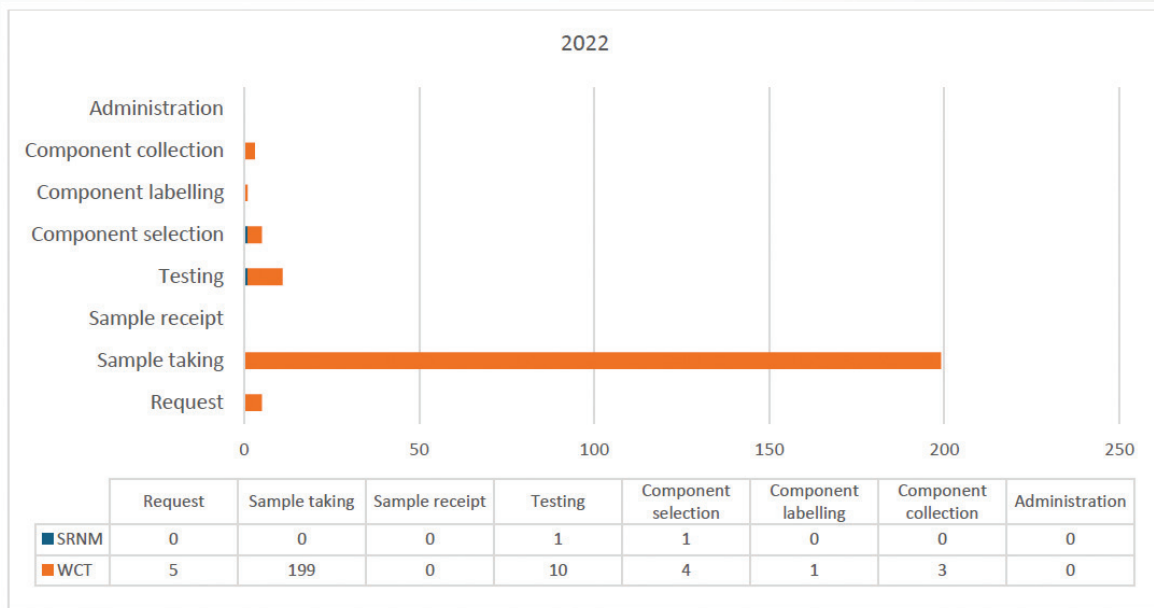


Figure 3.7.2a: Critical Control Point where Near Miss Occurred Leading to Probable WCT and Probable SRNM in 2022

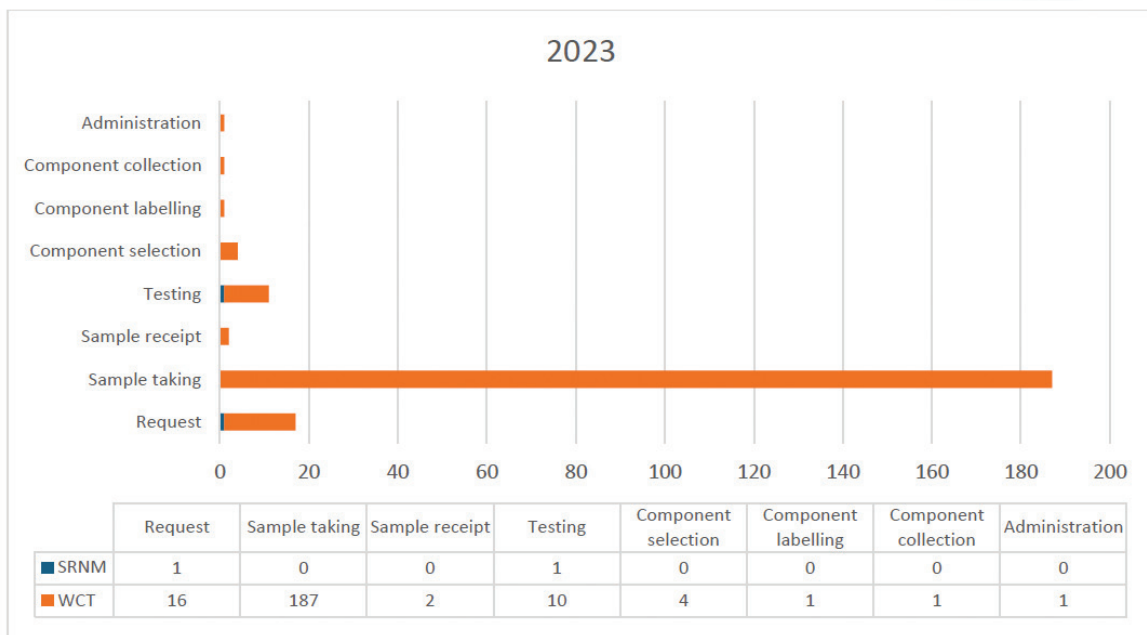


Figure 3.7.2b: Critical Control Point where Near Miss Occurred Leading to Probable WCT and Probable SRNM in 2023



3.8 IMPUTABILITY – Table 3.8.1, 3.8.2

3.8.1 After completing the investigation of an adverse transfusion event, the relationship between the event and the transfusion is assessed based on the levels of imputability shown in Table 3.8.1. This classification, adopted from the International Haemovigilance Network (IHN) and the Promoting Donor Care Imputability Assessment Tool, defines the strength of evidence linking the adverse event to the transfusion:

IMPUTABILITY	
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
Not assessable	Insufficient data to determine the relationship between the transfusion and the adverse event.

Table 3.8.1: Imputability

3.8.2 Among patients who received the wrong blood components, 98.7% recovered without any adverse effects. Only one case resulted in recovery with morbidity, where the patient developed acute kidney injury, requiring an extended hospital stay.

3.8.3 Two deaths were reported in 2022, but neither was related to transfusion. The deaths were attributed to the patients’ severe underlying clinical conditions.

In the first case, a 74-year-old, woman with heart disease and on warfarin therapy was admitted for upper gastrointestinal bleeding due to over-warfarinisation (INR 4.5). She required a transfusion of 1 unit of packed red blood cells (PRBCs). However, an error occurred when both blood samples (for grouping and crossmatching) were taken at the same time, without proper patient identification. As a result, the patient was transfused with group B Rh (D) positive PRBCs, while a later sample indicated she was group O Rh (D) positive. Despite developing symptoms like chills and abdominal pain during transfusion, she recovered. Unfortunately, the patient later died of cardiogenic shock due to complete heart block, unrelated to the transfusion error.



In the second case, a 34-year-old, male was admitted for meningoencephalitis with coagulopathy. He was scheduled to receive 4 units of fresh frozen plasma (FFP) to correct his condition but was mistakenly given 4 units of platelets instead. The error was missed during both the final check and by the MLT until documentation was completed. Although the patient did not suffer any adverse reactions from the incorrect transfusion, he later died due to sepsis and multiorgan failure, which were unrelated to the transfusion.

3.8.4 Imputability summary

- Confirmed/Certain: 82 cases (44 in 2022, 38 in 2023) recovered with no ill effects, 1 case in 2023 resulted in recovery with morbidity
- Likely/Probable: No cases.
- Possible: No cases.
- Excluded/Unlikely: 2 deaths in 2022 were deemed unrelated to transfusion.
- Not Assessable: No cases

	IMPUTABILITY										Total
	Confirmed/ Certain n=83		Likely/ Probable n=0		Possible n=0		Excluded/ Unlikely n=2		Not accessible n=0		
	2022	2023	2022	2023	2022	2023	2022	2023	2022	2023	
Recovered with no ill effect	44	38	0	0	0	0	0	0	0	0	82
Recovered with illness (morbidity)	0	1	0	0	0	0	0	0	0	0	1
Death	0	0	0	0	0	0	0	2	0	0	2
Outcome not available	0	0	0	0	0	0	0	0	0	0	0
Total	44	39	0	0	0	0	0	2	0	0	85

Table 3.8.2: Clinical Outcomes by Imputability for IBCT cases in 2022 - 2023



CHAPTER 4

RIGHT BLOOD RIGHT PATIENT (RBRP)



CHAPTER 4

RIGHT BLOOD RIGHT PATIENT (RBRP)

4.1 DEFINITION OF RBRP

4.1.1 RBRP refers to an incident where a patient was transfused correctly despite one or more serious errors that in other circumstances might have led to an incorrect blood component transfused (SHOT Report 2023). These can either be in clinical or laboratory setting which can occur at various stages of the transfusion process, including sample taking, request, prescription, sample receipt and registration, component selection, component labelling, as well as collection, administration and miscellaneous. Inaccuracy in patient identification data, prescription, labelling, no bedside check done, no identification band, incorrect data on either sample or form and entering the ID of another patient can contribute to this. In the clinical area, incorrect ID is usually related to first name, last name, date of birth, IC number or passport number.

4.2 INCIDENCE – Figure 4.2.1a, 4.2.1b, 4.2.1c, 4.2.3

4.2.1a RBRP: detected post-transfusion

In 2022, five RBRP were detected post-transfusion, decreasing to one case in 2023. This decline is attributed to the NHCC’s reclassification in October 2023, where cases involving the correct transfusion of blood were categorized as RBRP: detected post-transfusion, rather than as transfusion errors.

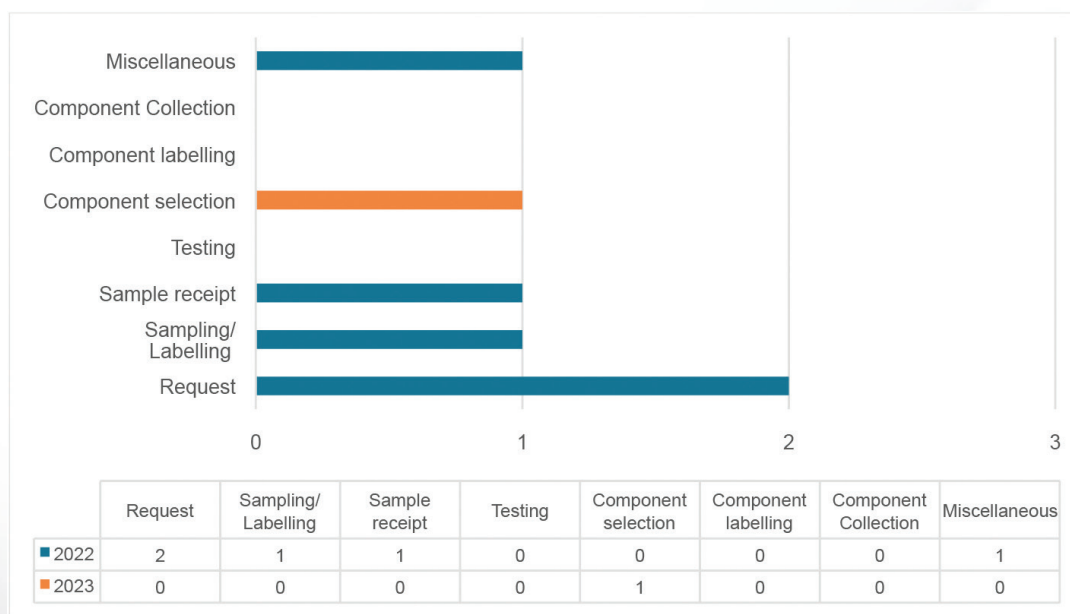


Figure 4.2.1a: RBRP: Detected Post-transfusion in 2022 - 2023



4.2.1b RBRP: detected pre-transfusion

Cases of RBRP that were detected before transfusion totalled 23 in 2022, dropping to four in 2023.

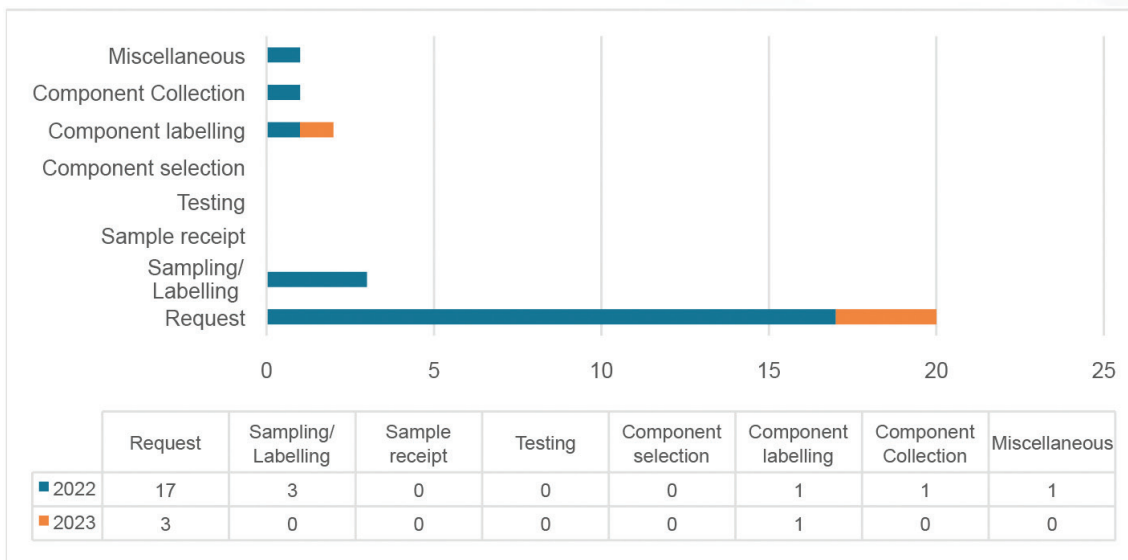


Figure 4.2.1b: RBRP: Detected Pre-transfusion in 2022 – 2023

4.2.1c RBRP: Incidents

No RBRP: Incidents were reported in 2022. In 2023, five RBRP- incidents were reported, primarily due to the new classification.

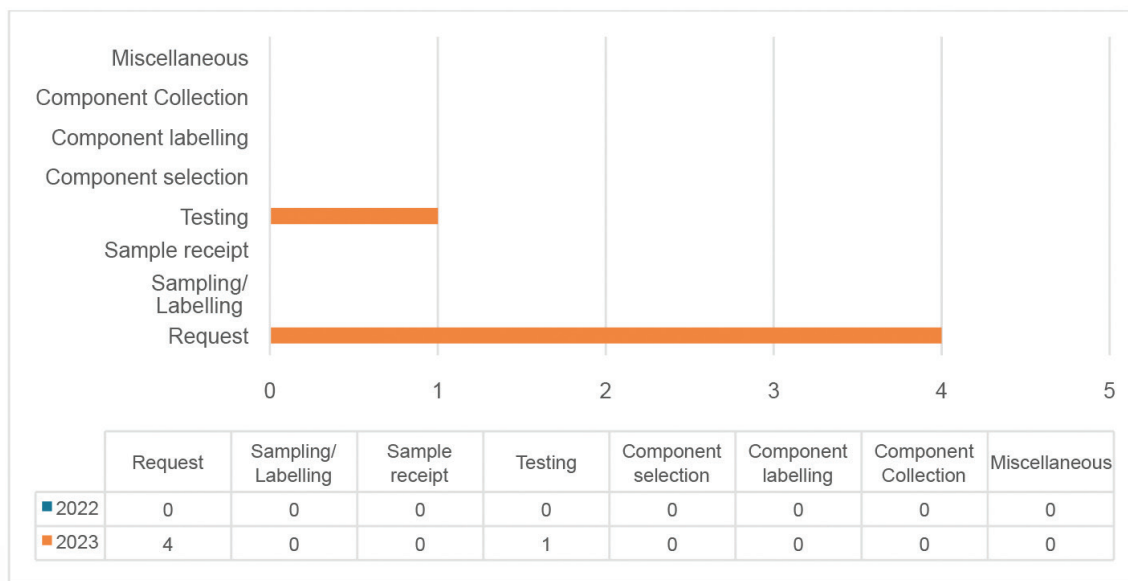


Figure 4.2.1c: RBRP: Incident in 2022 – 2023



4.2.2 Among the cases of RBRP: detected post-transfusion in both years, three errors occurred in the clinical setting, two in the blood bank, and one case resulted from a registration error during admission. Meanwhile from 2022-2023, RBRP: detected pre-transfusion showed the highest number of errors occurring during the request from the clinical area, followed by sampling or labelling error in the ward. In an incident of RBRP involving blood bank personnel at laboratory setting, NHCC received a case where two samples were sent for GXM and ABO & Rh blood group for a patient where AB Pos and AB Neg was transcribed respectively. The MLT did not realise the mistake during transcribing into the system. There were also 4 cases of RBRP where the patient’s name in the initial GXM request was mistakenly spelled by ward personnel, resulting in the blood bank supplying blood with the same misspelled name. Fortunately, for all the cases, the bloods supplied were meant for the intended patients.

4.2.3 SHOT report 2020 have suggested that collection checklist is crucial for preventing errors in blood component preparation and transfusion. Despite the relatively low frequency of RBRP-related cases, it is essential to capture and review these events to identify potential systemic issues and implement corrective actions to prevent patient harm. A comprehensive collection check can help detect errors before blood is transported to the patient, and by doing so, can potentially reduce the risk of adverse reactions as shown in Figure 5.2.3 which was adapted from SHOT report 2020.

Follow the collection PLEDGE

✓	P	P ick up and examine - is this the correct component type, is there any obvious damage or clots?
✓	L	L ong number (donation number) matches on bag and tag – check they match
✓	E	E xpiry date – inspect that component has not expired
✓	D	D ocumentation – forename, surname, DOB, unique number match on tag and collection paperwork
✓	G	G roup compatibility – are the groups of unit and patient compatible? If in doubt ask the laboratory for assistance
✓	E	E xit and deliver component to clinical area

Figure 4.2.3: The PLEDGE aide memoire



CHAPTER 5

HANDLING AND STORAGE ERRORS (HSE)



CHAPTER 5

HANDLING AND STORAGE ERRORS (HSE)

5.1 DEFINITION OF HSE

5.1.1 Handling and storage errors occur when a blood component, intended for a patient, becomes compromised due to errors in the transfusion process, making it potentially less safe for transfusion. These errors may arise from multiple factors, such as cold chain breaches, technical mishandling during administration, prolonged transfusion times, transfusion of damaged or expired components, among others.

5.2 INCIDENCE - [Figure 5.2](#)

5.2.1 Over the reporting period, two cases of HSE: detected post-transfusion were documented, with one case occurring each year. In 2022, two HSE: detected pre-transfusion cases were reported, while no such cases were recorded in 2023. Additionally, two HSE-Incident cases were documented in 2023, with none occurring in 2022.

5.2.2 Both HSE: detected post-transfusion cases involved the transfusion of expired blood components that had been selected and issued for patient use.

5.2.3 For the HSE: detected pre-transfusion cases, the first was attributed to a cold chain error, where packed red cells were left in an icebox on the ward counter for an extended period, resulting in a breach of cold chain integrity. The second case involved the attachment of the wrong form (cryoprecipitate) to packed red cells during patient transfer from a district hospital to a tertiary care centre.

5.2.4 The two HSE-Incident cases reported in 2023 were both due to over-puncturing of packed red cell units, which led to spillage and potential contamination.

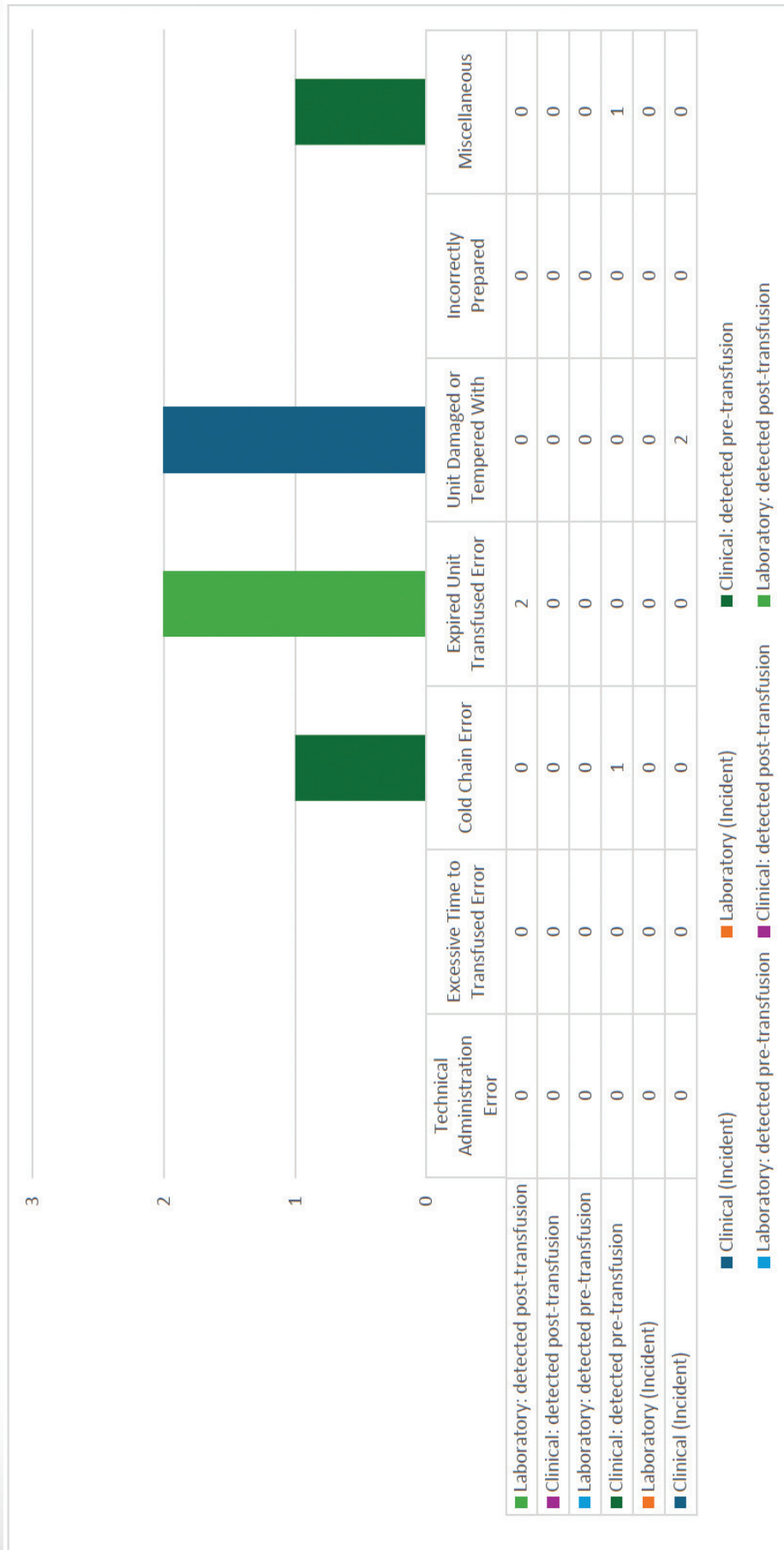


Figure 5.2: Handling and Storage Errors (HSE) in 2022- 2023





CHAPTER 6

AVOIDABLE, DELAYED, UNDER OR OVERTRANSFUSION (ADU)



CHAPTER 6

AVOIDABLE, DELAYED, UNDER OR OVERTRANSFUSION (ADU)

6.1 DEFINITION OF ADU

6.1.1 **Avoidable** transfusion is where the intended is carried out, and the blood/blood component itself is suitable for transfusion and compatible with the patient, but where the decision leading to the transfusion is flawed. **Delayed** transfusion is where a transfusion of a blood component was clinically indicated but was not undertaken or non-availability of blood components led to a significant delay. **Under or over transfusion** refers to instances where a patient receives a transfusion that is dose-inappropriate. This occurs when there is a failure in communication, incorrect decisions, or poor prescribing based on poor knowledge.

6.2 INCIDENCE - Figure 6.2

6.2.1 No cases of ADU: detected post-transfusion were reported in either 2022 or 2023. In 2022, there was one ADU: detected pre-transfusion case involving a probable avoidable transfusion. In 2023, one case of probable delayed transfusion was reported, where a doctor requested an emergency crossmatch for the wrong patient, causing a delay in the transfusion for a bleeding patient.

6.2.2 There was only one ADU-incident of undertransfusion reported in 2023. In this case, the haemodialysis unit had requested two units of packed red cells for a patient, but only one unit was transfused. The second unit remained unused in the icebox and was later returned to the blood bank.

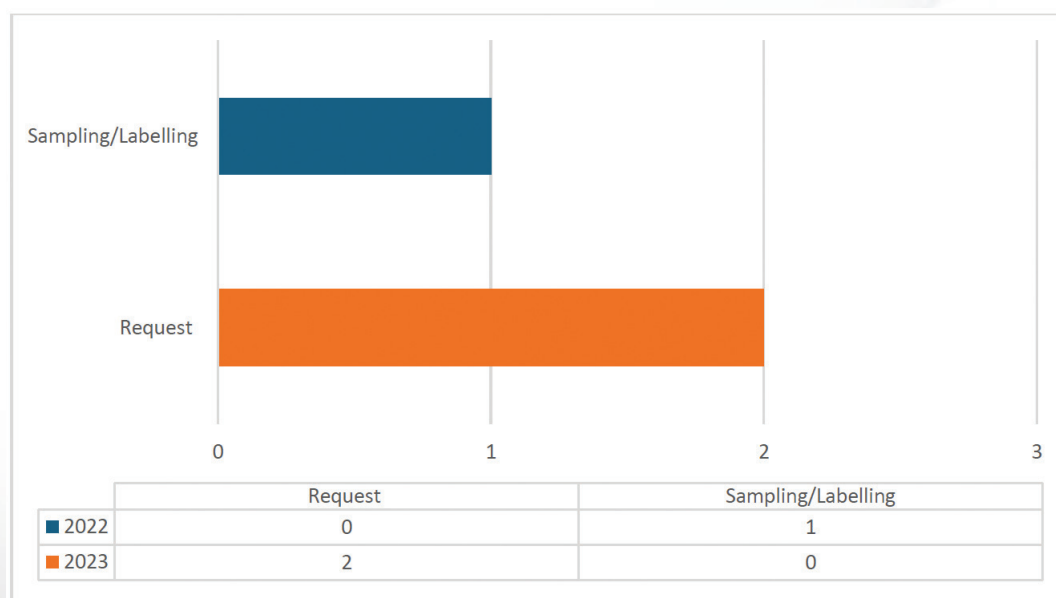


Figure 6.2: ADU Reports in 2022 - 2023



CHAPTER 7

INCIDENT



CHAPTER 7

INCIDENT

7.1 DEFINITION OF INCIDENT

An error that was detected and thorough investigations revealed that the cause of discrepancy was unrelated with the current step of the transfusion process is categorised as an incident. This could be due to several causes such as:

- i. Error in previous admission,
- ii. Error in other facilities,
 - a. Possible blood grouping error/ procedural error/ testing error in other hospital/ clinics,
 - b. Transcription error of patient's blood group in antenatal care (ANC) book or hospital record,
- iii. Patient using other person's identification (sharing same ID) during hospital admission,
- iv. Transcription error done by the hospital registration personnel

7.2 INCIDENCE - Figure 7.2

7.2.1 There were a total of 171 cases in 2022 and 124 cases reported in 2023.

7.2.2 In both 2022 and 2023, the highest number of recorded incidents was attributed to errors in previous admissions, with 70 cases and 52 cases of undetermined cause, respectively. Error in previous admissions that had undetermined cause were typically errors that occurred more than 10 years ago, where the pertinent records were already in the archive area.

7.2.3 Errors in other facilities represented the second highest number of reported cases in both 2022 and 2023. Specifically, possible transcription errors in antenatal books accounted for 27 cases in 2022 and 16 cases in 2023. This error was detected by the reporting hospital blood bank when the wrong blood group was used to request for blood. Additionally, errors in other facilities with undetermined causes reported in 2022 were 22 cases and 12 cases in 2023. The sub-category of undetermined cause was either the result of error in other hospitals or clinics, but insufficient information was available to make a more accurate determination.



7.2.4 In 2022, there were 32 reported cases of patients being admitted to the hospital using another person’s identification, or error during registration. This number decreased to 16 cases in 2023. One instance of a registration error occurred when a patient arrived with the pre-hospital care team, lacking family members, and a police officer handled the registration. However, the officer inadvertently used the identification of another casualty, who had passed away at the scene, assuming it belonged to the patient. Meanwhile, a common occurrence of shared identification occurred when a child’s admission was registered using the mother’s identification. Similar incidents occur among asylum seeker patients, where they share the same UNHCR identification.



Figure 7.2: Total Number of Incidents Reported in 2022 - 2023

7.3 CONTRIBUTING FACTORS

7.3.1 Individual factors contributing to incidents stated above include lack of concentration and communication where these behaviours can be the cause for grievous mistakes jeopardising patient’s safety. There is also the issue of training and experience where medical personnel struggle to handle emergency situations or sudden surge of multiple tasks simultaneously. Without proper training and experience, individuals may find it challenging to navigate complex scenarios effectively, increasing the likelihood of errors and compromising patient care.



- 7.3.2** Another contributing factor involves the management and organisational issues. In certain district hospitals, the ABO and Rh D tests were not conducted twice for GSH requests due to financial constraints. Additionally, certain hospitals' local Standard Operating Procedures (SOPs) do not require a second verification of blood grouping for GSH samples. Instead, second verification is only mandated for GXM requests or GSH requests converted to GXM requests. This could lead to undetectable errors of the wrong blood group recorded in the Laboratory Information System (LIS).
- 7.3.3** Limited knowledge can indeed contribute to incorrect transcription of blood groups, particularly when staff allocations do not align with their specialties. Furthermore, a lack of judgment regarding Patient Blood Management principles may result in failure to adhere to practices such as the single-unit policy. This policy aims to minimise blood product wastage and optimise patient care by ensuring that only the necessary amount of blood is transfused. Failure to implement such practices can compromise patient safety and lead to unnecessary wastage of blood products.
- 7.3.4** Team factors, such as insufficient staffing during specific hours, particularly after office hours, can exacerbate human error. Additionally, the lack of supervision by senior officers further compounds this issue, particularly when the workload is high. Inadequate staffing levels combined with limited oversight can increase the likelihood of errors occurring, highlighting the importance of adequate staffing and supervision to maintain patient safety and quality of care, especially during periods of increased workload.

7.4 RECOMMENDATIONS

- a. Adherence to SOPs is paramount in the blood transfusion process and should be followed by all personnel, including the doctor in charge, staff nurses, laboratory personnel, and registration staff.
- b. In the future, implementation of safety registration procedures, such as a thumbprint-based or radio-frequency identification (RFID) system, able to prevent incidents of patients sharing the same registration ID.
- c. Continuous medical education (CME) and training are essential to address the issue of lack of knowledge and compliance with SOPs.
- d. Periodic clinical audits and supervisions should be conducted to improve the quality and adherence to SOPs.
- e. Emphasize on the importance of presenting the correct identification during hospitals registration to avoid error and delay in receiving treatment.
- f. Patient Blood Management should be prioritised when transfusing patients in any clinical setting, ensuring the optimal use of blood products and promoting patient safety and care.

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CHAPTER 8

ADVERSE TRANSFUSION REACTION



CHAPTER 8

ADVERSE TRANSFUSION REACTION

8.1 DEFINITIONS OF ADVERSE TRANSFUSION REACTION (ATR)

Adverse transfusion reaction is an undesirable response or effect in a patient temporarily associated with the administration of blood or blood components.

8.2 OVERVIEW OF ADVERSE TRANSFUSION REACTION (ATR) REPORTS – Table 8.2

During 2022, there were 3752 ATR reports received compared to 4300 ATR reports received in 2023. Of the ATR reports received, these reports were further subcategorized into confirmed, incomplete or unrelated to ATR. 225 cases in 2022 and 303 cases in 2023 were reported as not related to transfusion. Hence, the total number of confirmed ATR cases were 3534 in 2022 and 3996 in 2023.

ATR REPORT	Number Of Report Received	
	2022 N=3752	2023 N=4300
Confirmed (analysed in the report)	3527	3997
Incomplete	0	0
Not Related to Transfusion (NTR)	225	303

Table 8.2: Total Number of Adverse Transfusion Reaction Reported

8.3 TYPES OF ADVERSE TRANSFUSION REACTION (ATR) REPORTED – Table 8.3

The number of confirmed adverse transfusion reaction reported increased from 3527 cases in 2022 to 3997 cases in 2023. Mild Allergic Reaction, FNHTR and Uncommon Complications of Transfusion (UCT) remained as the three most common types of ATR reported as consistent with previous Haemovigilance Reports.

No	Type of ATR	Number of cases	
		2022	2023
1	Acute Immune Haemolytic Transfusion Reaction	1	0
2	Delayed Immune Haemolytic Transfusion Reaction	2	2
3	Non Immune Haemolytic Transfusion Reaction	4	1
4	Febrile Non Haemolytic Transfusion Reaction (FNHTR)	1152	1149
5	Mild Allergic Reaction	1528	1927
6	Moderate Allergic Reaction	241	267
7	Severe Allergic Reaction	25	35
8	Transfusion Related Acute Lung Injury (TRALI)	6	4
9	Transfusion Associated Circulatory Overload (TACO)	93	127
10	Transfusion Associated Dyspnoea (TAD)	75	88
11	Transfusion associated Graft vs Host Disease (TA-GvHD)	0	0
12	Post Transfusion Purpura	0	0
13	Post Transfusion (Virus)	0	1
14	Post Transfusion (Bacteria)	0	0
15	Post Transfusion (Parasite)	0	0
16	Handling and Storage Area	0	0
17	Equipment related	0	0
18	Uncommon Complications of Transfusion (UCT)	471	450
19	Hypotensive Transfusion Reaction	11	13
20	Others	1	4
	Total Confirmed ATR	3611*	4068*
	Incomplete report	0	0
	Not Related to Transfusion (NTR)	225	301
	TOTAL	3836	4369

Table 8.3: Incidence of ATR based on Type of Reaction in 2022 & 2023

*Total confirmed ATR is greater than the number of reports received (excluding incomplete and NTR cases) because since year 2020, NHCC has begun accepting cases with two types of ATR.



8.4 ADVERSE TRANSFUSION REACTIONS REPORTS ACCORDING TO TYPES OF REACTION

8.4.1 FEBRILE, ALLERGIC, HYPOTENSIVE REACTIONS (FAHR) – Table 8.4.1.1, Figure 8.4.1.2, Figure 8.4.1.4

The reactions assessed are isolated febrile-type (not associated with other specific reaction categories), allergic and hypotensive reactions occurring up to 24 hours following a transfusion of blood or components, for which no other obvious cause is evident.

8.4.1.1 Definition:

Reactions	Definition	
Febrile type reaction	Mild	A temperature $\geq 38^{\circ}\text{C}$ and a rise between 1°C and 2°C from pre-transfusion values, but no other symptoms/signs
	Moderate	A rise in temperate of $\geq 2^{\circ}\text{C}$ or fever $\geq 39^{\circ}\text{C}$ and/or rigors, chills, other inflammatory symptoms/signs, such as myalgia, or nausea which precipitate stopping the transfusion
	Severe	A rise in temperate of $\geq 2^{\circ}\text{C}$ or fever $\geq 39^{\circ}\text{C}$ and/or rigors, chills, other inflammatory symptoms/signs, such as myalgia, or nausea which precipitate stopping the transfusion, prompt medical review, AND/OR directly results in, or prolongs hospital stay
Allergic type reaction	Mild	Transient flushing, urticaria or rash
	Moderate	Wheeze or angioedema with or without flushing/urticaria/rash but without respiratory compromise or hypotension
	Severe	Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention and/or, directly results in prolonged hospital stay, or anaphylaxis (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)
Reaction with both allergic and febrile features	Mild	Features of mild febrile and mild allergic reactions
	Moderate	Features of both allergic and febrile reactions at least one of which is in the moderate category
	Severe	Features of both allergic and febrile reactions at least one of which is in the severe category
Hypotensive Reaction	Moderate	Isolated fall in systolic blood pressure of ≥ 30 mmHg occurring during or within one hour of completing transfusion and a systolic blood pressure ≤ 80 mmHg in the absence of allergic or anaphylactic symptoms. No/minor intervention required
	Severe	Hypotension, as previously defined, leading to shock (eg: acidemia, impairment of vital organs function) without allergic or inflammatory symptoms. Urgent medical intervention required

Table 8.4.1.1: Definitions of FAHR (Adopted from SHOT Report 2022)



8.4.1.2 Mild allergic reaction was the most reported cases (3364, 54.43%) in both 2022 and 2023 among FAHR cases, followed by FNHTR (2193, 35.49%) and moderate allergic reaction (491, 7.94%). Total of 108 cases (1.75%) of mixed febrile and allergic reactions were reported for both 2022 and 2023. The least reportable in this category was transfusion associated hypotensive reaction (24, 0.39%).

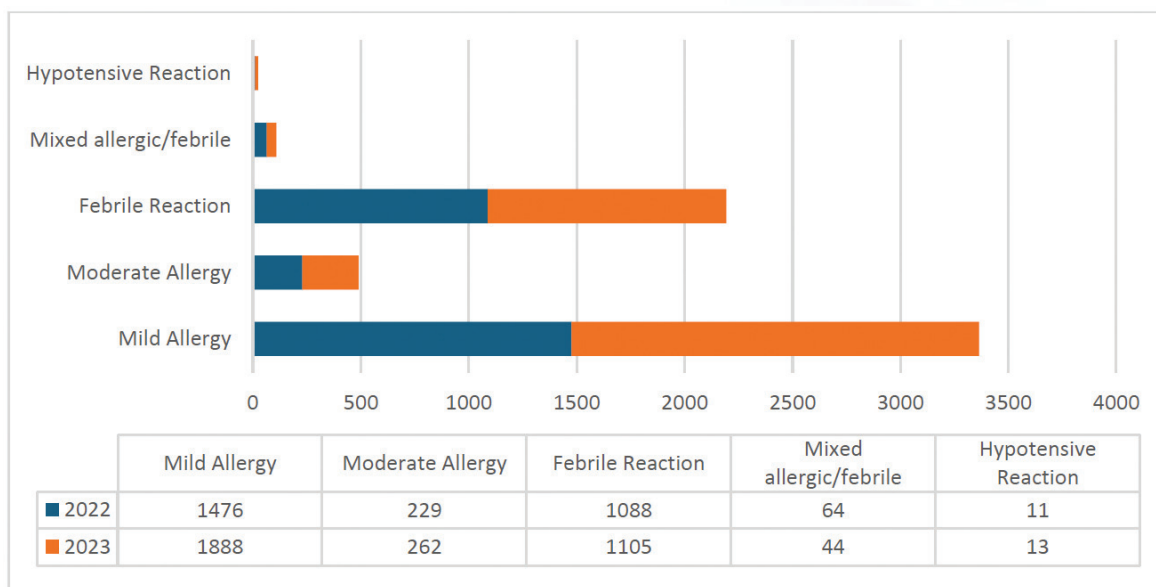


Figure 8.4.1.2: Number of Reported Cases of Febrile, Allergic, Mixed Allergic/ Febrile and Hypotensive Reactions in 2022 - 2023

8.4.1.3 There was an increase in number of moderate allergic reactions reported in both 2022 and 2023 compared to previous years.

8.4.1.4 Majority of ATR cases had reported patient recovery with no ill effects with less than 1% reported as recovered with ill effects and death. A total of 6 deaths reported but the cause of death were not related to transfusion.

	Recovered with no ill effects		Recovered with ill effects		Death	
	2022	2023	2022	2023	2022	2023
Febrile reaction	1088	1105	0	0	0	0
Allergic reaction	1702	2149	3	1	0	0
Mixed allergic/ febrile	61	41	0	0	3	3
Hypotensive reaction	11	13	0	0	0	0

Table 8.4.1.4: Outcome of Adverse Transfusion Reaction – FAHR in 2022 - 2023



8.4.1.5 FAHR should be managed accordingly based on patient's signs and symptoms. Febrile reactions should be treated with antipyretics whereas antihistamines should be prescribed in allergic reaction. In case of recurrent febrile reactions, it is recommended to give antipyretics 60 minutes as prophylaxis and pre-transfusion antihistamine can be prescribed in recurrent allergy reaction. Alternatively in serious reaction, communication with the transfusion specialist for the appropriate and specialised blood product for transfusion such as pooled platelet in platelet additives solution (PAS), solvent detergent treated plasma or washed platelet/red cell should be initiated.

8.4.2 PULMONARY COMPLICATIONS OF TRANSFUSION REACTION

TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI), TRANSFUSION-RELATED CIRCULATORY OVERLOAD (TACO), TRANSFUSION ASSOCIATED DYSPNOEA (TAD) AND SEVERE ALLERGIC REACTION - Table 8.4.2.1, Figure 8.4.2.2, Table 8.4.2.3, Table 8.4.2.4, Table 8.4.2.5, Table 8.4.2.6

8.4.2.1 Definition:

TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

Transfusion-related acute lung injury (TRALI) is defined as an acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within six hours of transfusion, in the absence of circulatory overload or other likely causes, or in the presence of human leucocyte antigen (HLA) or human neutrophil antigen (HNA) antibodies cognate with the recipient.

The updated TRALI definitions/classifications has been published widely. The changes include the use of the terminology of TRALI Type I (without an ARDS risk factor) and TRALI Type II (with an ARDS risk factor or with mild existing ARDS). Cases with an ARDS risk factor that meet ARDS diagnostic criteria and where respiratory deterioration over the 12 hours before transfusion implicates the risk factor as causative should be classified as ARDS. TRALI remains a clinical diagnosis and does not require detection of cognate white blood cell antibodies (*Vlarr et. al 2019*)



TRALI Type I - Patients who have no risk factors for ARDS and meet the following criteria:

- a. i. Acute onset
- ii. Hypoxemia (P/F \leq 300 or SpO₂ < 90% on room air)
- iii. Clear evidence of bilateral pulmonary edema on imaging (eg: chest radiograph, chest CT, or ultrasound)
- iv. No evidence of left atrial hypertension (LAH) or, if LAH is present, it is judged to not be the main contributor to the hypoxaemia
- b. Onset during or within six hours of transfusion
- c. No temporal relationship to an alternative risk factor for ARDS

TRALI Type II - Patients who have risk factors for ARDS (but who have not been diagnosed with ARDS) or who have existing mild ARDS (P/F of 200-300), but whose respiratory status deteriorates and is judged to be due to transfusion based on:

- a. Findings as described in categories a and b of TRALI Type I, and
- b. Stable respiratory status in the 12 hours before transfusion

An approximate mapping between the SHOT nomenclature and the redefinition are as table below:

Classification	Definition	Mapping to consensus redefinition
Highly likely	Cases with a convincing clinical picture and positive serology	TRALI type I + positive serology
Probable	Cases with positive serology but other coexisting morbidity which could independently cause acute lung injury of fluid overload	ARDS or 'TRALI/TACO cannot be distinguished' + positive serology
Antibody-negative TRALI	Cases with a convincing clinical picture where serology is not available or negative	TRALI type I + absent or negative serology
Unlikely – reclassify as TAD	Cases where the history and serology were not supportive of the diagnosis. These cases are transferred to TAD	TRALI type II or 'TRALI/TACO cannot be distinguished' + negative or absent serology

Table 8.4.2.1: SHOT Criteria for Assessment of TRALI Cases (Adopted from SHOT Report 2020)

TRANSFUSION - ASSOCIATED CIRCULATORY OVERLOAD (TACO)

Patients classified with TACO (surveillance diagnosis) should exhibit the following during or up to 24 hours after transfusion.

- At least one required criterion (i.e. A and/or B)
- With a total of at least 3 or more criteria (A to E)



* Required criteria (A and/or B)	
A	Acute or worsening respiratory compromise and/or
B	Evidence of acute or worsening pulmonary oedema based on: <ul style="list-style-type: none"> • clinical physical examination, and/or • radiographic chest imaging and/or other non-invasive 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.

TRANSFUSION ASSOCIATED DYSPNOEA (TAD)

Transfusion associated dyspnoea (TAD) is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria for transfusion-related acute lung injury (TRALI) or transfusion-associated circulatory overload (TACO) or allergic reaction. Respiratory distress in such cases should not be adequately explained by the patient's underlying condition.

SEVERE ALLERGIC REACTION

Severe allergic reaction is described as bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention and/or, directly results in prolonged hospital stay, or anaphylaxis (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).

8.4.2.2 Pulmonary complications related to transfusion include TRALI, TACO, TAD and severe allergic reaction. In 2022, 199 cases were related to pulmonary complications, while in 2023, this number increased to 254. TACO has become the most frequently reported case in both 2022 (93, 46.73%) and 2023 (127, 50%). The number of TACO cases reported in 2023 is the highest number of TACO cases reported since 2016. TRALI remained the least reported event for both years with 6 (3.02%) and 4 (1.57%) cases in each year respectively.

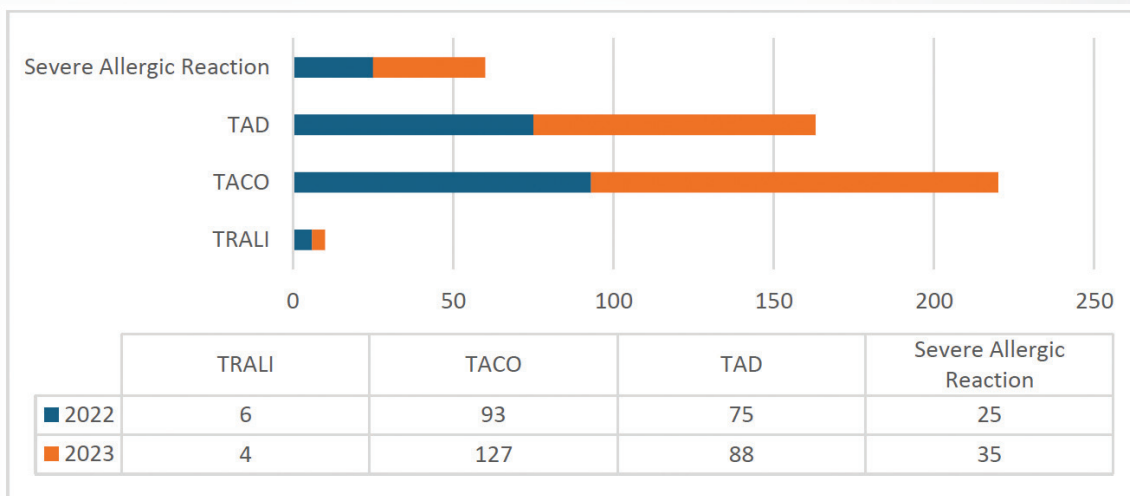


Figure 8.4.2.2: Total Number of Cases of Pulmonary Complications in 2022 - 2023

8.4.2.3 Four cases of TRALI were reported in 2022. From that, 1 case submitted a serology test and the result was negative. Serology result of 3 other cases were not available. However, all the cases had significant clinical pictures of TRALI. In 2023, one of six cases reported for TRALI showed negative result for serology HLA antibody test. Meanwhile the serology test for other 5 cases were unavailable but the cases had significant clinical picture of TRALI as well.

Category	TRALI Type I				TRALI Type II			
	Antibody-positive		Antibody-negative		Antibody-positive		Antibody-negative	
	2022	2023	2022	2023	2022	2023	2022	2023
Highly likely	-	-	-	-	-	-	-	-
Probable	-	-	-	-	-	-	-	-
Antibody-negative TRALI (serology negative)	-	-	1	-	-	-	-	1
Clinically suggestive of TRALI (serology result not available/ not sent)	-	-	3	-	-	-	-	5

Table 8.4.2.3: Summary of Reported TRALI Cases in 2022 and 2023

The rise in number of TACO cases may reflect either an actual number of TACO cases or improved reporting of TACO by healthcare providers. Nonetheless, clinicians are advised to widely apply the TACO pre-transfusion risk assessment as a way to reduce the risk of adverse transfusion reactions.



8.4.2.4 In 2022, 92.5% of pulmonary related ATR cases had reported patient recovery with no ill effects, 4.0% had recovered with ill effect and death reported in 3.5% of cases. There were 7 cases reported as deaths. Three deaths were related to underlying chronic diseases and two deaths were related to sepsis. One death was possibly due to transfusion related which due to fluid overload.

Meanwhile in 2023, 90.6% of pulmonary related ATR cases reported patient recovery with no ill effects and 6.3% had recovered with ill effects. There were eight (3.1%) cases reported as death whereby 3 cases were due to multi organ failures, 2 cases were due to progression of malignancy, 1 cases was due to cardiac condition and 1 case was due to underlying chronic diseases. One death was reported related to transfusion which was fluid overload.

	Recovered with no ill effects		Recovered with ill effects		Death	
	2022	2023	2022	2023	2022	2023
TRALI	3	2	2	2	1	0
TACO	85	110	3	10	5	7
TAD	73	87	1	0	1	1
Severe Allergic Reaction	23	31	2	4	0	0

Table 8.4.2.4: Outcome of Adverse Transfusion Reaction – Pulmonary Complications (2022 and 2023)



8.4.2.5 Careful assessment of patient prior to blood transfusion is crucial in preventing TACO-related transfusion reactions. Use of the TACO pre-transfusion risk assessment is strongly recommended to understand patient’s potential risk prior to any plan of blood transfusion. The risks and benefits of blood transfusion should be weighed carefully after risks are identified.

TACO CHECKLIST	PATIENT RISK ASSESSMENT	YES	NO
Cardio-vascular	Does the patient have any of the following: diagnosis of Heart Failure, Congestive Heart Failure, Severe Aortic Stenosis, and Moderate to Severe left Ventricular Dysfunction?		
	Is the patient on regular diuretic?		
	Does the patient have severe anaemia?		
Pulmonary	Is the patient known to have pulmonary oedema?		
	Does the patient have respiratory symptoms of undiagnosed cause?		
Circulatory	Is the patient fluid balance clinically significantly positive?		
	Is the patient receiving IV fluids? (or received them in the previous 24 hours)		
	Is there any peripheral oedema?		
	Does the patient have hypoalbuminemia?		
	Does the patient have significant renal impairment?		

If there is “YES” to any of the above risks proceed to the next table

IF RISKS IDENTIFIED	YES	NO
Review the need for transfusion (Do the benefits outweigh the risks?)		
Can the transfusion be safely deferred until the issue can be investigated, treated, or resolved?		

IF PROCEEDING WITH TRANSFUSION: ASSIGN ACTIONS	TICK
Body weight dosing for red cells	
Transfuse a single unit (red cells) and review symptoms	
Measure fluid balance	
Prescribe prophylactic diuretics (where appropriate/not contraindicated)	
Monitor the vital signs closely including oxygen saturation.	

Table 8.4.2.5: TACO Pre-transfusion Risk Assessment
(Adopted from SHOT Report 2023)



8.4.2.6 Understanding of pulmonary complications following blood transfusion will help in diagnosis of patients and eventually lead to optimal care of the patients.

	TRALI Type I	TRALI Type II	ARDS	TRALI/TACO	TACO	TAD
Hypoxaemia	Present	Present	Present	Present	May be present but not required	May be present but not required
Imaging evidence of pulmonary oedema	Documented	Documented	Documented	Documented	May be present but not required	May be present but not required
Onset within 6 hour	Yes	Yes	Yes	Yes	Yes	No
ARDS risk factors	None	Yes -with stable or improving respiratory function in prior 12 hours	Yes-with worsening respiratory function in prior 12 hours	None , or if present , with stable or improving respiratory function in prior 12 hours	Not applicable	Not applicable
LAH	None/mild	None/mild	None/mild	Present or not evaluable	Present	May be present but not required

Table 8.4.2.6: Comparison table to assist with pulmonary reaction classification (Adopted from SHOT Report 2022)



8.4.3 TRANSFUSION-ASSOCIATED GRAFT-VERSUS-HOST DISEASE (TA-GvHD)

Characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days after transfusion. The condition is due to engraftment and clonal expansion of viable donor lymphocytes in a susceptible host. There was no reported case for TA-GvHD in both years.

8.4.4 HAEMOLYTIC TRANSFUSION REACTION (HTR) – Figure 8.4.4.2, Table 8.4.4.3

8.4.4.1 Acute Haemolytic Transfusion Reactions (AHTR) are characterised by fever, a fall in haemoglobin (Hb), rise in bilirubin, lactate dehydrogenase (LDH) and a positive direct antiglobulin test (DAT) as well as presence of haemoglobinuria. Meanwhile, full blood picture can detect schistocytes and shift cells which are large polychromatic RBCs, suggestive of early release of reticulocytes into the circulation due to erythropoietin stimulation. These features generally present within 24 hours of transfusion.

Delayed Haemolytic Transfusion Reactions (DHTR), occur more than 24 hours following a transfusion and are associated with a fall in Hb or failure of increment, rise in (direct/indirect) bilirubin and LDH and an incompatible crossmatch not detectable pre transfusion.

Non Immune Haemolytic Transfusion Reaction can be due to thermal, osmotic, mechanical injury to red blood cells or other blood products.

8.4.4.2 One case of acute HTR was reported in 2022 and no case was reported in 2023. The cause of acute HTR was not mentioned. Meanwhile there were 3 cases of delayed HTR in 2022 and 2 cases of delayed HTR in 2023 in which all cases were due to presence of antibodies. In 2022 4 cases of non-immune HTR were reported and 2 cases were reported in 2023. All cases of non-immune HTR were due to mechanical and storage factors. Mechanical factors were due to unsuitable branula size, rapid blood infusion, hand pushing while transfusing and infusion pump problem. The storage factors were due to extended storage of red cell and also due to improper handling and storage of blood with multiple frequency of blood bag supply and return.

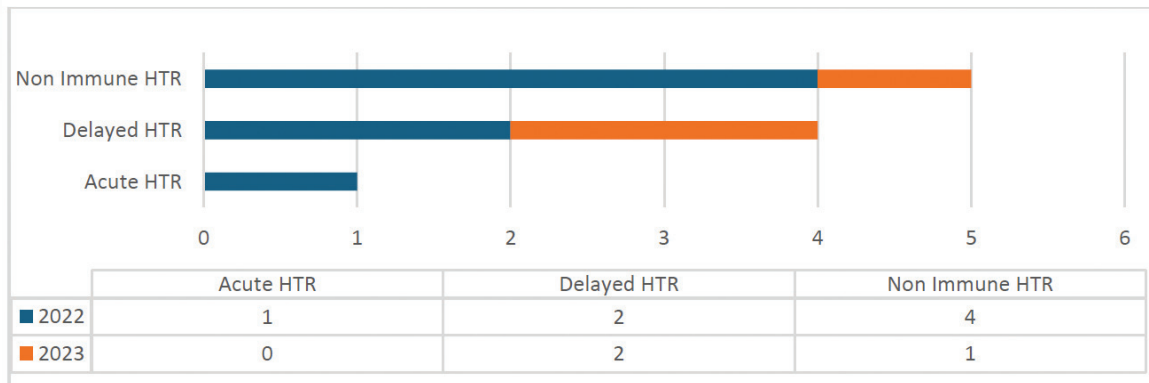


Figure 8.4.4.2: Number of Cases of Haemolytic Transfusion Reaction in 2022 - 2023

8.4.4.3 All HTR cases reported recovery with no illness. There was no mortality reported in both 2022 and 2023.

	Recovered with no ill effects		Recovered with ill effects		Death	
	2022	2023	2022	2023	2022	2023
Acute HTR	1	0	0	0	0	0
Delayed HTR	2	2	0	0	0	0
Non-immune HTR	4	1	0	0	0	0

Table 8.4.4.3: Outcome of Adverse Transfusion Reaction – HTR in 2022 - 2023

8.4.4.4 Patient with history of clinically significant antibody should be provided with matched phenotype and antibody-negative red cells to prevent the risk of immune HTR. Proper intravenous access and blood transfusion set can reduce risk of mechanical factor of non-immune HTR. Squeezing of blood while transfusing should be avoided as well. To prevent storage factor of non-immune HTR, blood products issuance and return need to be closely monitor.

8.4.5 UNCOMMON COMPLICATIONS OF TRANSFUSION (UCT) – Figure 8.4.5.2, 8.4.5.3

8.4.5.1 Pathological reaction or adverse effect in temporal association with transfusion which cannot be attributed to already defined side effects and with no risk factor other than transfusion, and do not fit under any of the other reportable categories, including cases of transfusion-associated hyperkalaemia. This type of transfusion reaction was previously named as unclassifiable complications of transfusion however it was changed to uncommon complications of transfusion in SHOT guidelines 2019.



8.4.5.2 Total number of UCT cases reported were 471 in 2022 and has dropped to 450 in 2023.

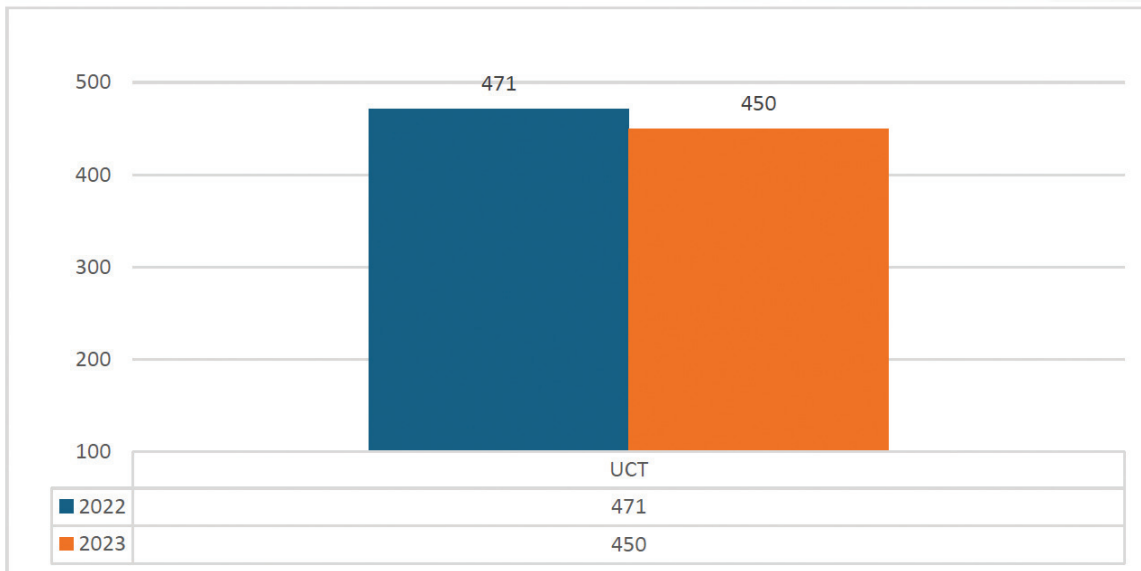


Figure 8.4.5.2: Number of cases of UCT in 2022 - 2023

8.4.5.3 Majority of cases reported recovery without illness. Three cases reported deaths but all were not related to transfusion. The cause of death include progression of malignancy and traumatic brain injury.

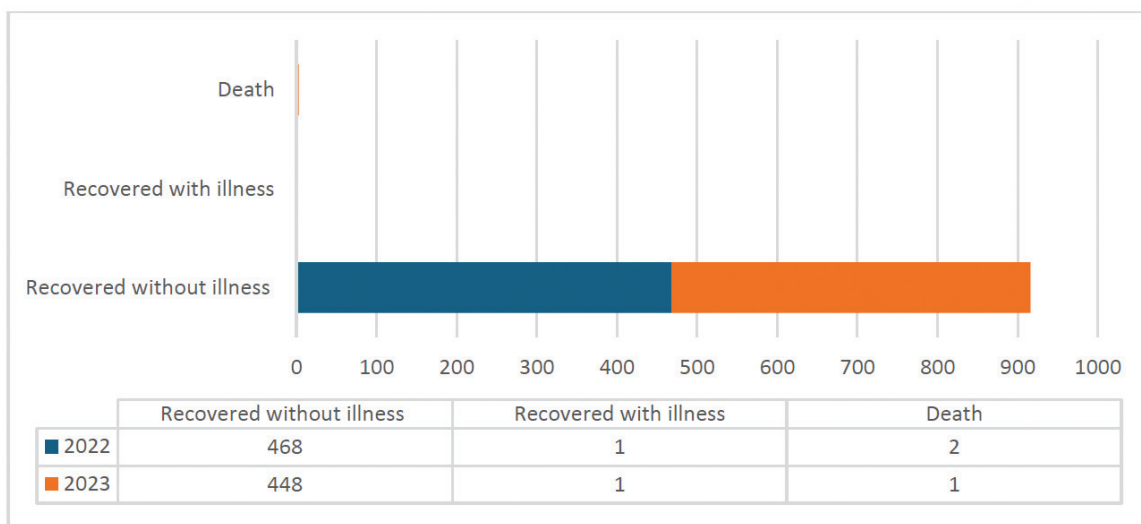


Figure 8.4.5.3: Outcome of Adverse Transfusion Reaction – UCT in 2022 - 2023

8.4.5.4 Close monitoring during transfusion is always important to identify any transfusion related symptoms and prompt management of patients.



8.4.6 TRANSFUSION-TRANSMITTED INFECTION (TTI)

8.4.6.1 A report was classified as a TTI if, investigation revealed:

The recipient(s) had evidence of infection post transfusion with blood components, and there was no evidence of infection prior to transfusion, and no evidence of an alternative source of infection and either:

- a. At least one component received by the infected recipient(s) was donated by a donor who had evidence of the same transmissible infection

or:

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

8.4.6.2 All donated blood in Malaysia are screened for Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) and Syphilis. However, parasitic infection screening is not routinely done. Nucleic acid testing (NAT) was only widely available throughout Malaysia in 2019. A case of TTI involving Hepatitis B infection was reported in 2023.

Case

A case of 42 years old gentleman with underlying leprosy. He was admitted to hospital in September 2015 for left leg cellulitis with infected neuropathic ulcer of the left foot. He underwent multiple surgeries and had received multiple blood transfusions during admission which were 1 unit whole blood (WB) , 5 units packed cells (PC) and 2 units fresh frozen plasma (FFP). During a look back and recall procedure for a Hepatitis B seroconverted donor, it was found out that the blood product (WB) donated in 2015 was transfused to the patient mentioned above. Patient was not traceable until October 2022. He was then screened for Hepatitis B and his HBsAg was reactive in October 2022. Patient denied any risk factors. No baseline Hepatitis B screening was done prior to this.

8.4.7 POST TRANSFUSION PURPURA (PTP)

8.4.7.1 Post-transfusion purpura is defined as thrombocytopenia arising 5-12 days following transfusion of cellular blood components (red cells or platelets) associated with the presence in the patient of antibodies directed against the human platelet antigen (HPA) systems.

8.4.7.2 There were no cases of PTP reported in 2022 and 2023.



8.5 TYPE OF BLOOD COMPONENT TRANSFUSED AND ATR COMPLICATION - Figure 8.5

The frequency of the blood components implicated in ATR were relatively corresponds to the total number of the blood components transfused. Packed red blood cells (PRBCs) which were the highest blood component transfused have the highest reported case of ATR while cryosupernatant (CSUP) were the least blood component transfused and have the lowest reported ATR event.

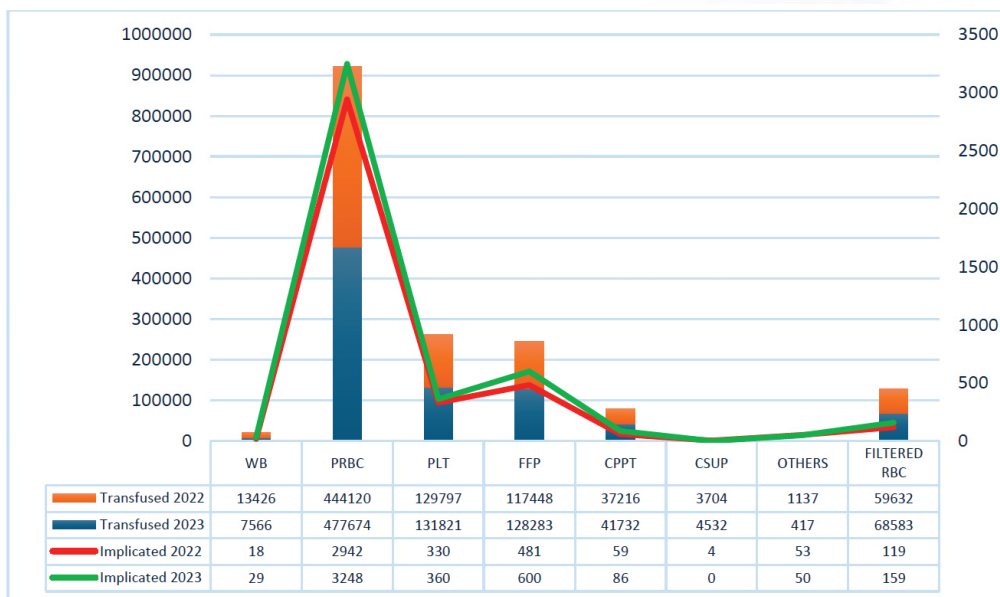


Figure 8.5: Total Number of Blood Component Transfused and Implicated with ATR in 2022 - 2023

8.6 INCIDENCE OF IMPLICATED BLOOD COMPONENTS IN 10,000 BLOOD COMPONENTS TRANSFUSED - Figure 8.6

The overall incidence of ATR in Malaysia was 51 per 10,000 blood components transfused. PRBC was the most implicated blood component with the ATR incidence of 67 per 10,000 PRBC transfused while cryosupernatant was the least with 5 per 10,000 transfused. Incidence of ATR associated with filtered RBC was 22 per 10,000 transfusion.

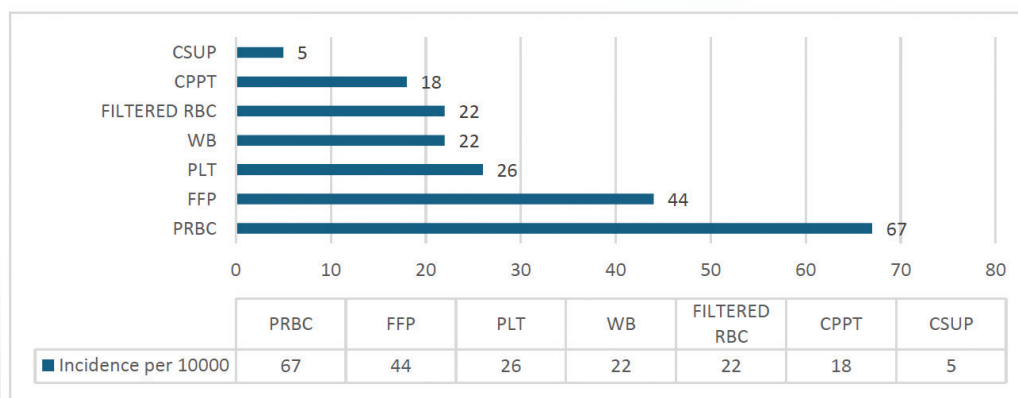


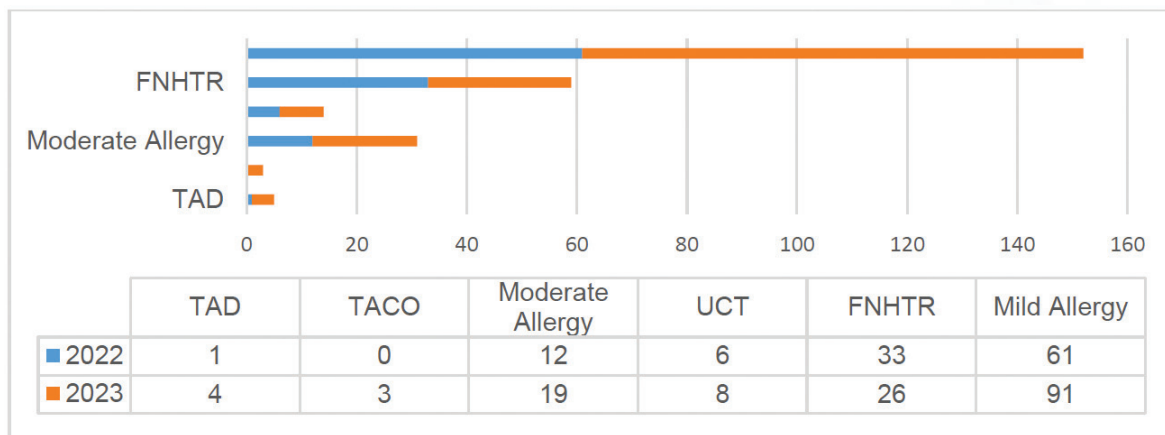
Figure 8.6: Incidence of ATR per 10,000 blood components transfused



8.7 TYPES OF ADVERSE EVENTS ASSOCIATED WITH LEUCOFILTERED RED BLOOD CELL (RBC) – Figure 8.7

8.7.1 Leucocyte filtration is used to remove leucocytes that are responsible for febrile non-haemolytic transfusion reactions (FNHTR), HLA and platelet alloimmunization and CMV transmission. In Malaysia, usage of filtered RBC is currently limited to thalassemia patients and patients who suffer a recurring episode of FNHTR. Report showed that 21% of patients who received filtered RBC experience FNHTR.

8.7.2 Leucofiltration can be performed by filtration prior to blood component storage (pre-storage leucofiltration) or during the transfusion (bedside filtration). Bedside filtration is least desirable due to variability in practice and absence of proficiency. The fourth generation filter able to remove 99.99% leukocyte. Pre-storage filtration within 48 hours of collection may reduce the residual leucocytes content < 1x 10⁶. Blood bank personnel must adhere to SOP during filtration process and quality check done for filtration to serve its purpose.



NTR= Not Transfusion Related

Figure 8.7: Types of ATR associated with Filtered Red Blood Cell in 2022 - 2023



CHAPTER 9

ADVERSE DONOR REACTION



CHAPTER 9

ADVERSE DONOR REACTION

9.1 DEFINITION OF ADVERSE DONOR REACTION (ADR)

9.1.1 Donor hemovigilance is the systematic monitoring of adverse reactions and incidents in the whole chain of blood donor care, with a view to improve quality and safety of blood donors.

9.1.2 Adverse donor reaction (ADR) is described as unintended response in a donor associated with the collection of blood or blood components which can happen acutely during the donation process or delayed after the donor has left the donation site.

9.2 OVERVIEW OF ADVERSE DONOR REACTION (ADR) REPORTS – **Figure 9.2**

9.2.1 The total number of blood donation collected by government hospitals recorded a dramatic increase in the year 2022 after a plummet in the year 2020 and 2021, due to the impact of COVID-19 pandemic on the blood transfusion services. A total of 737,108 blood collected in the year 2022 which showed an increment of 13.7% compared to the year 2021. This total number of blood donations saw another significant increase of 4.31% rising from 737,108 in the year 2022 to 768,872 for the year 2023.

9.2.2 As portrayed in the figure below, there was a steady increment of ADR reporting from the year 2016 until 2020, however the number has been plateauing from the year 2020 until 2023 which total reported cases of ADR were in the range of 2300 to 2500 cases per year. In the year 2022, there were 33 cases of ADR per 10,000 units blood collected compared to 30 cases in 2023.

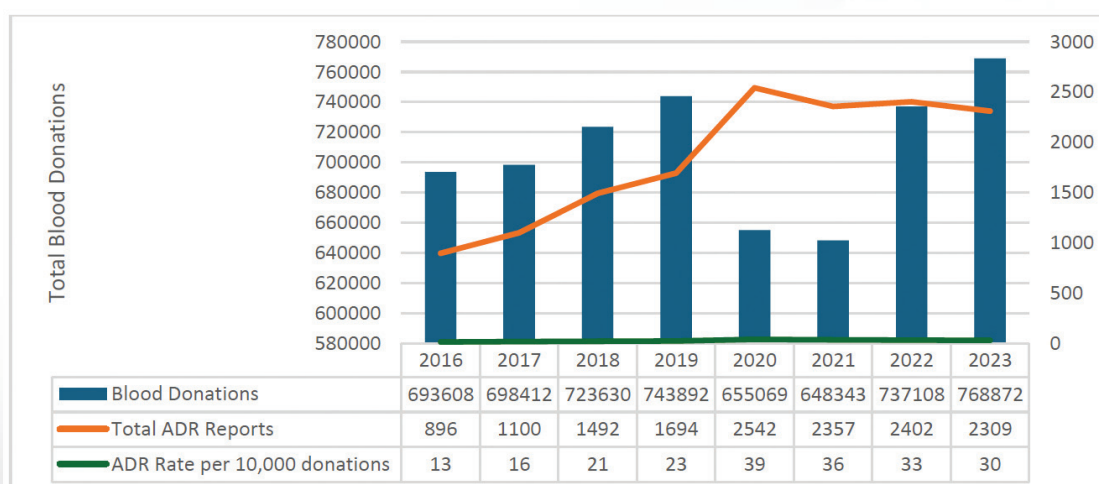


Figure 9.2: Rate of ADR per 10,000 blood collection from 2016 – 2023

9.3 TYPES OF ADVERSE DONOR REACTIONS (ADR) REPORTED – Table 9.3

Vasovagal reaction (VVR) remains the commonest ADR reported to NHCC every year in which there were 2315 cases for the year 2022 and 2241 cases in the year 2023. Second most-commonly reported ADR was hematoma whilst other ADRs generally recorded less than 10 cases each for both years 2022 and 2023.

No	Type of ATR	No of reported cases	
		2022	2023
1	Hematoma	67	57
2	Arterial puncture	2	2
3	Delayed bleeding	2	1
4	Nerve irritation	4	4
5	Nerve injury	2	1
6	Other arm pain	9	6
7	Thrombophlebitis	0	0
8	Cellulitis	0	0
9	Deep vein thrombosis (DVT)	0	0
10	Arteriovenous fistula	0	0
11	Compartment syndrome	0	0
12	Brachial artery pseudoaneurysm	0	0
13	Vasovagal reaction	2315	2241
14	Citrate reaction	5	2
15	Haemolysis	0	0
16	Air embolism	0	0
17	Local allergic reaction	1	1
18	Generalized (anaphylactic) reaction	0	0
19	Other serious complications related to blood donation	0	2
20	Others	3	3
	TOTAL	2410*	2317*

Table 9.3: Types of ADR in 2022 – 2023

* Total ADR is greater than the number of reports received as NHCC has begun accepting cases with double diagnoses.



9.3.1 VASOVAGAL REACTIONS (VVR) - Figure 9.3.1.2, 9.3.1.3, 9.3.1.4, 9.3.1.5, 9.3.1.6

9.3.1.1 Vasovagal reaction (VVR) is known to be the most common ADR that happened to donors during or after blood donation process has completed. Donors may experience either acute or delayed feeling of dizziness usually associated with nausea, sweating and general discomfort; and maybe associated with bradycardia and hypotensive episodes. In serious cases of VVR, donor may have episode of loss of consciousness or syncopal attack which put them at risk of serious injuries or unwanted accidents. Convulsions are another severe presentation of severe VVRs among donors.

9.3.1.2 In both years, the commonest reaction experienced by donors was immediate VVR followed by delayed VVR with 2272 cases and 2179 cases of immediate VVRs, respectively. In comparison to both years, incidence of delayed ADR reported to NHCC has reduced from 99 cases in the year 2022 to 77 cases in the year 2023. Incidence of ADR with injuries whether immediate or delayed were less than 1% each for both reported years.

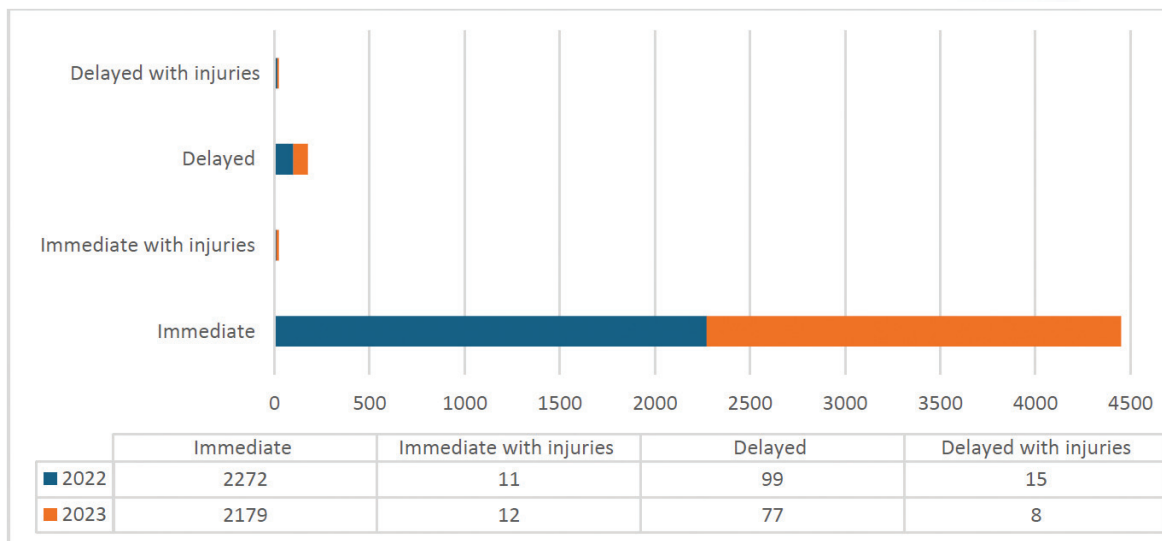


Figure 9.3.1.2: Category of VVR in 2022 – 2023



9.3.1.3 Annual Blood Report 2022 showed that 64% (471,697) of the blood donors in Malaysia are male and the remaining 36% (265,411) of the blood donors are female. The incidence of VVRs reported highest among female donors compared to the male donors.

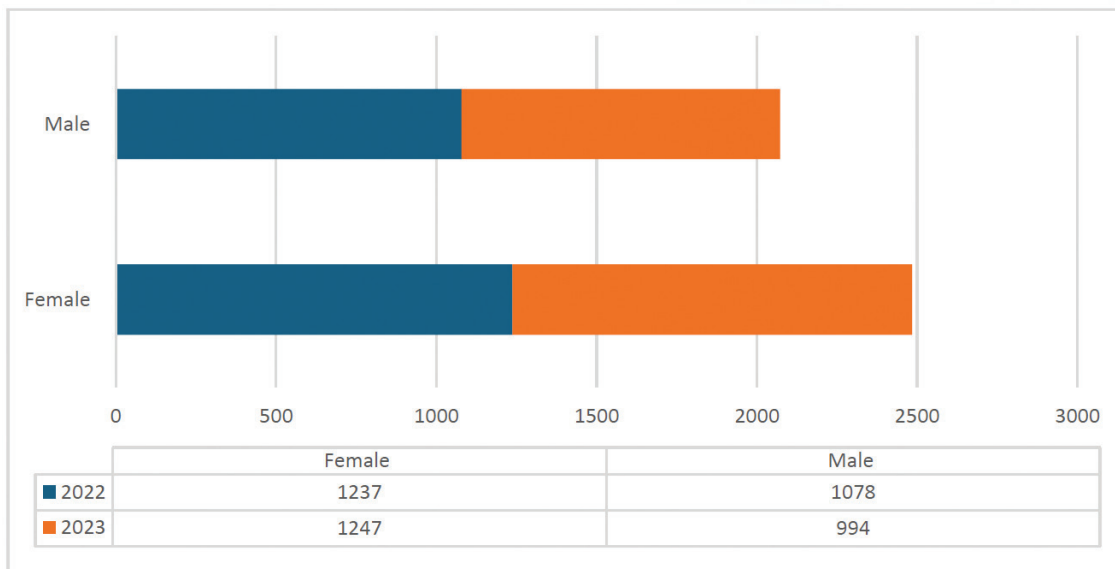


Figure 9.3.1.3: VVR Report based on Gender in 2022 – 2023

9.3.1.4 Similar to the reporting in the previous years, the incidence of VVR is highest among the younger donors of age 20 to 40 years old compared to donors age less than 20 years or older donors age above 41 years old. Most blood donors in Malaysia are also within the age range of 20 to 40 years old, thus it contributed to the higher VVR incidence among donors within this age range.

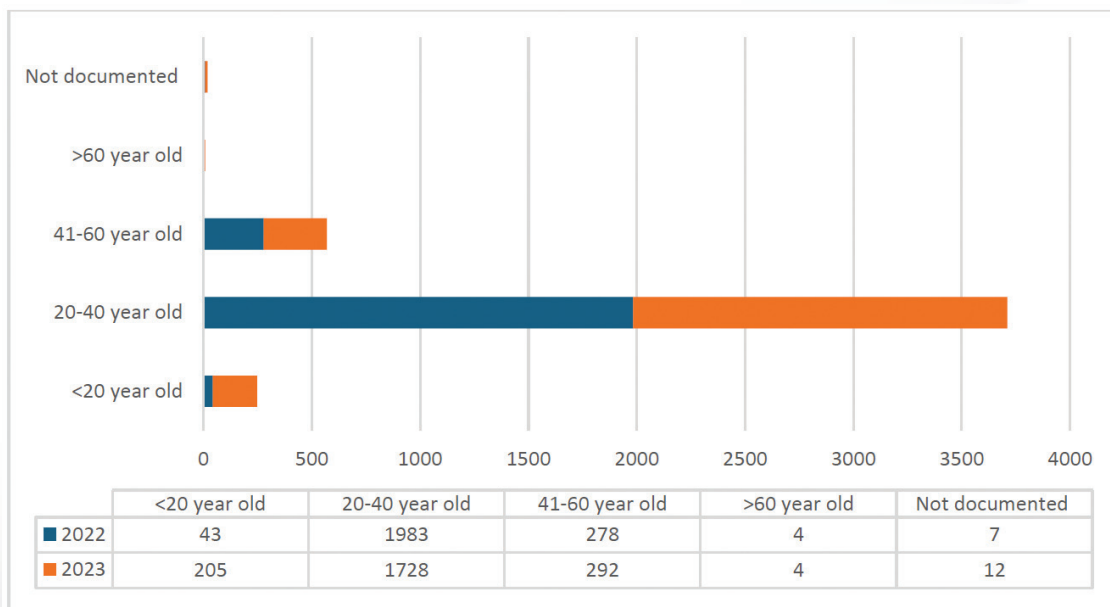


Figure 9.3.1.4: VVR Report based on Age in 2022 – 2023



9.3.1.5 Most VVR cases were reported in blood donors weigh more than 55kg which account to 72% and 67% of total VVR cases in the year 2022 and 2023, respectively. Unfortunately, few data with no documented weight still being reported as it was not a compulsory field for ADR reporting.

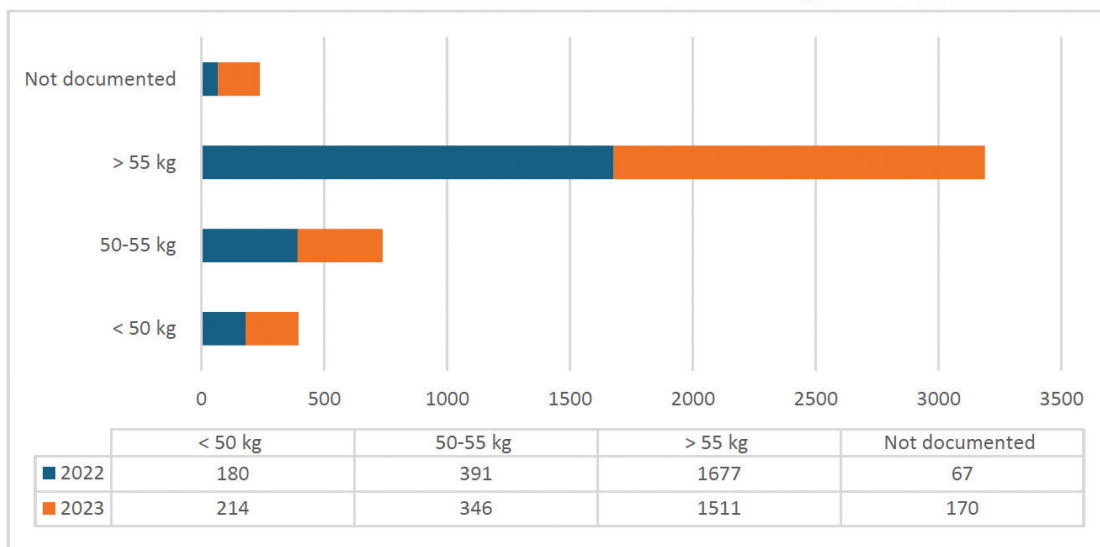


Figure 9.3.1.5: VVR Repost based on Weight in 2022 – 2023

9.3.1.6 Data from Annual Blood Report 2022 showed that the total number new donors were 175,348 while regular donors were 561,760. Data analysis showed that the incidence of VVR was nearly three times higher among new donors with 124 per 10,000 donations as compared to repeat donors of 42 per 10,000 donations.

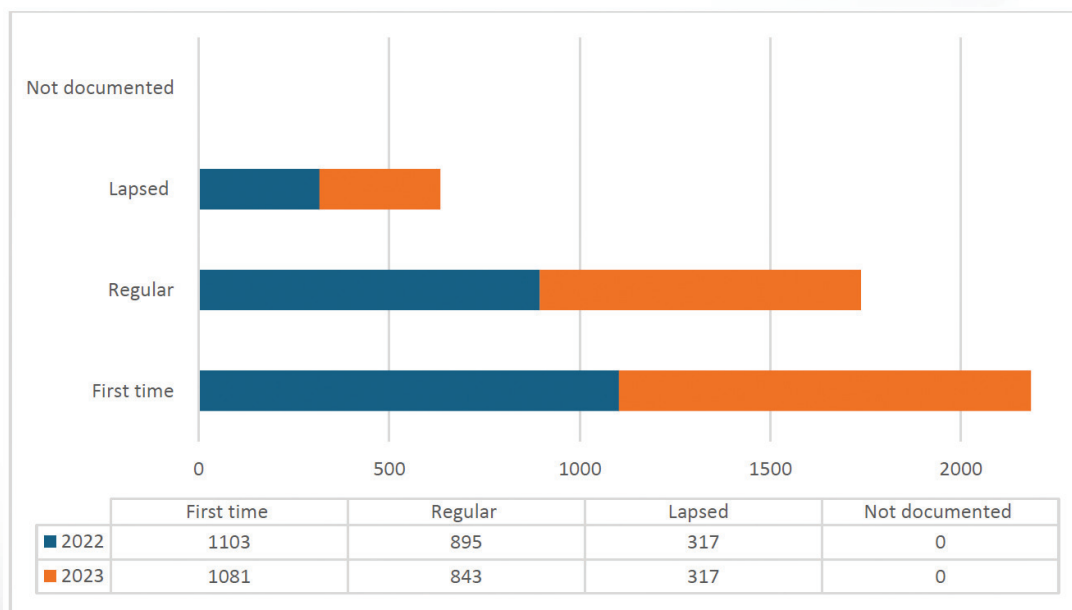


Figure 9.3.1.6: VVR Report based on Frequency of Donation in 2022 – 2023



9.3.1.7 Nine cases of VVR reported in 2022 for donor recovery with illness/morbidity. Five donors were reported to have immediate VVR with injury, in which they fainted and had a fall post donation which required further referral to the A&E. Three of the donors had laceration wounds over the face and head area requiring suturing, 1 donor had mild head swelling and another 1 donor complicated with left eye subconjunctival haemorrhage requiring no further intervention. All the donors were discharged home from A&E, none of them required hospital admission.

Another 2 cases of immediate VVR without any injury were reported in 2022, in which the donors complained of epigastric pain post donation and he was noted to be hypotensive as well. The donor was then referred to A&E for further assessment and then was discharged home with a diagnosis of ischemic pain post donation. The other case involved one regular donor who had a history of multiple episodes of delayed VVR post donation requiring prolonged monitoring at the donation site including the current VVR. Both donors were permanently deferred by the respective blood bank from future donations.

There was one reported case of immediate severe VVR with convulsion in 2022. The donor is a female regular donor about 5 times donation history. Donor weighed 55kg and donated 350mls of blood and the donation was uneventful. However, at the refreshment area, she had a syncopal attack and developed an episode of jerky movement of upper and lower limb, which lasted for more than 30 seconds. Otherwise, there was no drooling of saliva or urinary/bowel incontinence. It was noted that she was hypotensive and associated with reduced consciousness by the attending officer. She was then given intravenous fluid and referred to the A&E for further management. Donor was discharged later the same day after monitoring by the ED. She was permanently deferred from future donation as well.

For the year 2023, there were total of 8 cases of VVR for donor recovery with illness/morbidity. No mortality reported for both the year.



9.3.1.8 Recommendations:

- i. Re-strengthening the application of applied muscle tension (AMT) among donors particularly in the first-time donors as well as in donors who weigh less than 55kg. This involved repeated contraction of major muscle groups to increase blood pressure and to prevent the occurrence of VVR.
- ii. Adequate hydration prior to donation is also crucial in preventing VVR and hypotension among donors. Hence, blood donation centres are encouraged to supply some pre-hydration fluids for donors prior to donation if possible. Several studies have reported fewer complications when donors drink water or coffee before their donation. Other than that, intake of salty snacks is also one of the measures that can be taught to donors to sustain blood pressure during donation.
- iii. Minimise anxiety or fear of needles or even the sight of blood during donation by distraction techniques such as having a conversation with the donor or using an audio-visual diversion.
- iv. Observing the donor during and after donation, treating the donor if a complication occurs and making sure donor feels well before leaving the blood donation are crucial to prevent delayed VVRs. It should be a responsibility for all medical personnel involved in the donation process to be vigilant from the beginning until the end of the process. This procedure also can be enhanced by placing dedicated personnel at the refreshment area to monitor donors for any signs or symptoms of VVR. The medical personnel also must well train to manage complications that occur during or after blood donation sessions.
- v. Giving advice to the donor on secondary bleeding, driving, rest and return to work after donation are encouraged. Donor also can be reminded to contact the blood donation centre if symptoms reoccur.



9.3.2 HEMATOMA - Figure 9.3.2.2, 9.3.2.3a, 9.3.2.3b, 9.3.2.3c

9.3.2.1 Hematoma is defined as a localized collection of blood under the skin associated with swelling, with or without skin discoloration. It is caused by blood flowing out of damaged vessels and accumulating in the soft tissues. Severe cases of hematoma can lead to serious complications such as nerve irritation and injury and rarely compartment syndrome. In apheresis donation, hematoma can also be caused by infiltration of soft tissues by red cells during the return phase of the procedure. Common symptoms reported by donors are bruises, discoloration, swelling and local pain.

9.3.2.2 Hematoma was the second most frequently reported ADR in both 2022 and 2023. There was a slight decrease in the number of cases of hematoma reported in 2023 compared to 2022, with 57 and 67 cases respectively.

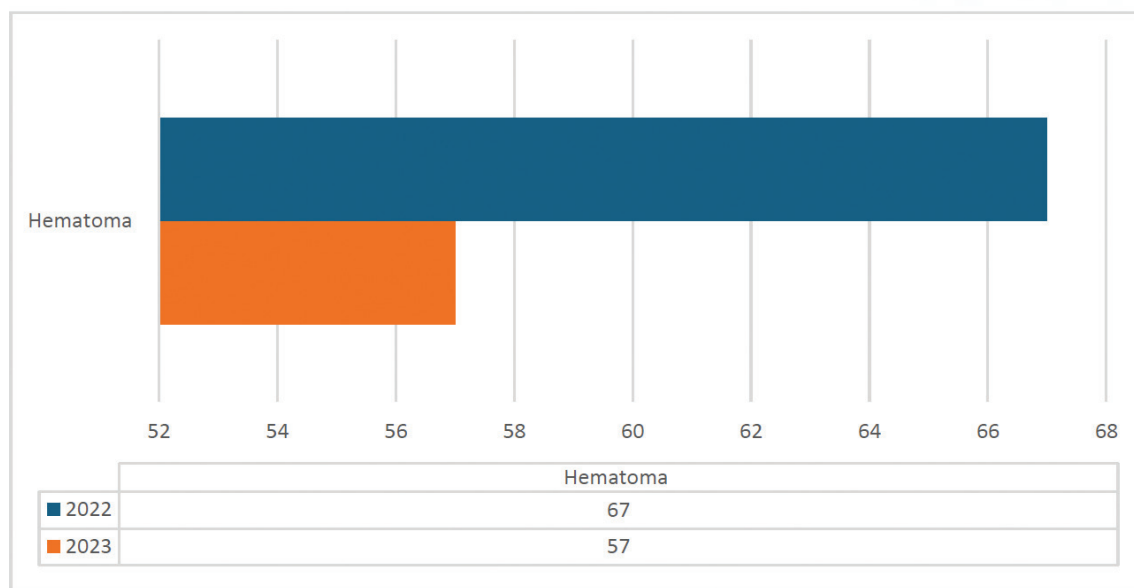


Figure 9.3.2.2: Total Number of Hematoma in 2022 – 2023



9.3.2.3 Data showed a higher incidence of hematoma, though statistically insignificant, in females, age group of 20-40 years and weigh more than 55 kg. However, since the data for age and weight are not compulsory for ADR reporting, there are some reports with no documented weight.

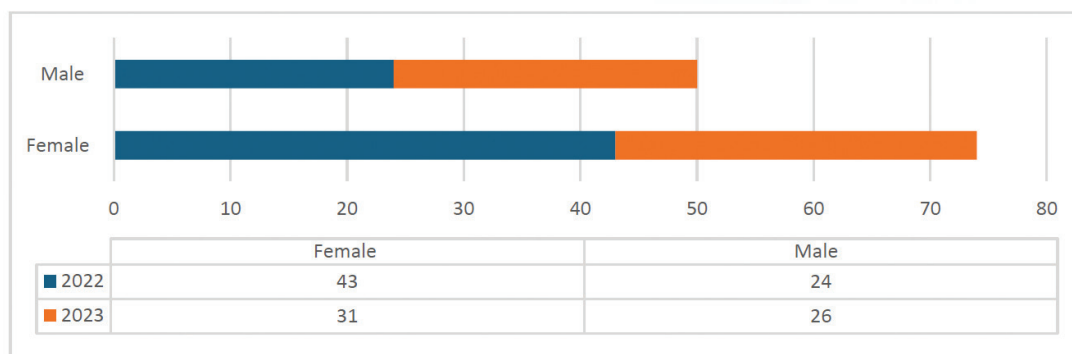


Figure 9.3.2.3a: Hematoma Report based on Gender in 2022 – 2023

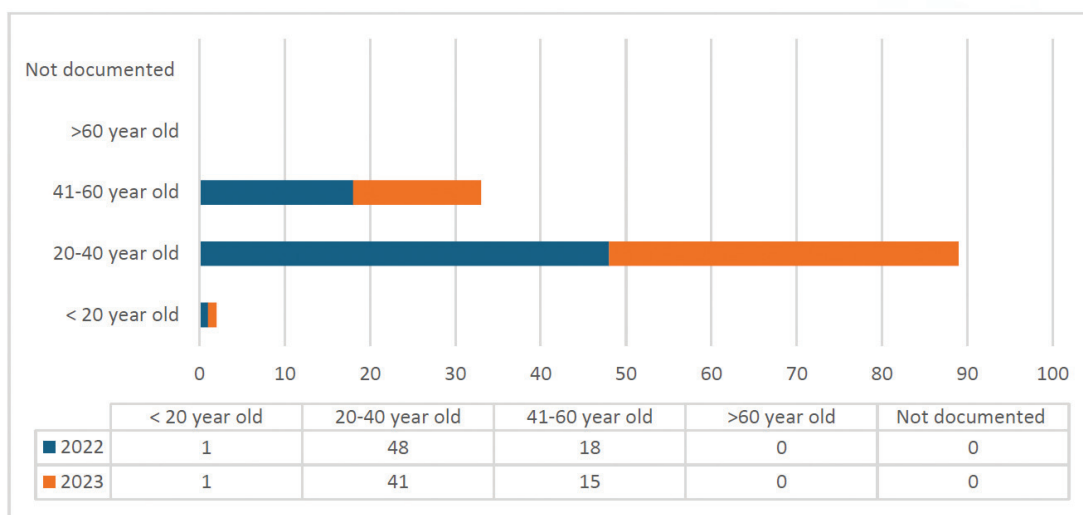


Figure 9.3.2.3b: Hematoma Report based on Age in 2022 – 2023

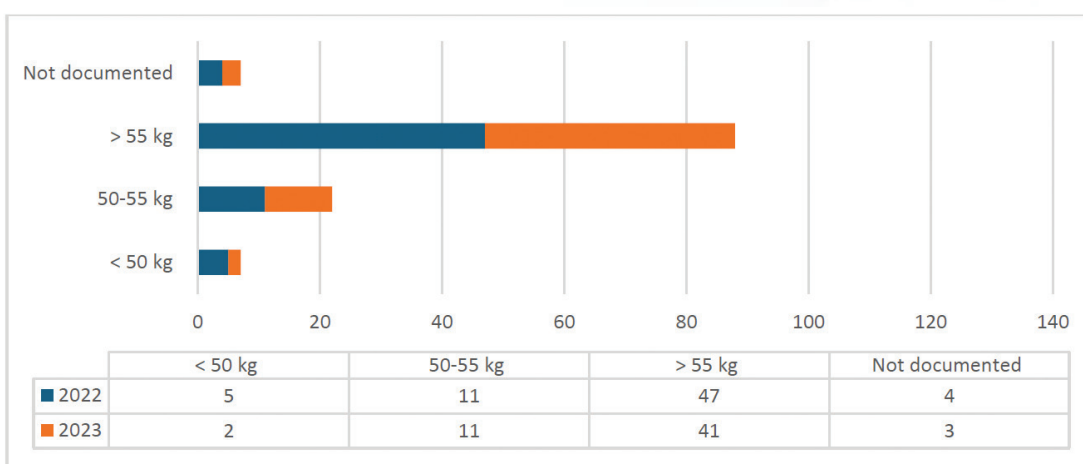


Figure 9.3.2.3c: Hematoma Report based on Weight in 2022 – 2023



9.3.2.4 All donors reported good recovery with no illness following hematoma.

- 9.3.2.5**
- i. Several strategies can be applied by the phlebotomist during venepuncture such as always move the needle forward in a slow ongoing movement. If the needle is not succeeded to be inserted in the first attempt, it is not advisable to do a second try by manipulating the needle in other direction, as this will increase the risk of injuries or occurrence of hematoma. It is advisable not to ask for help if the needle insertion was not a success as this will always include manipulation on a new direction.
 - ii. Avoid re-inserting the needle twice using the same puncture site and phlebotomist was encouraged to try the other arm if donor agrees.
 - iii. Frequent refresher training on the vein selections, needle insertion and puncturing technique, as well as the use of equipment such as tourniquet application are recommended among staffs/ phlebotomist.
 - iv. Continuous education to the donors on the post donation care including, application of pressure for 10 minutes on the venepuncture site, advices to avoid any heavy or strenuous activity on the donated arm for at least 24 hours.
 - v. Educational materials in regards to post donation care may be given to the donors before they leave the donation centre.



9.3.3 DELAYED BLEEDING - Figure 9.3.3.2

9.3.3.1 Delayed bleeding is defined as leakage of blood from the venepuncture site after the initial bleeding has stopped. Rebleeding may be caused by incorrect location or inadequate duration of pressure applied to the venepuncture site or premature removal of bandage post donation. The usage of the donated arm to lift heavy objects post donation also increase the risk of delayed bleeding. Certain medications such as blood thinners or anticoagulant may make the bleeding worsen.

9.3.3.2 There were a reduction in the number of reported cases for delayed bleeding for both years 2022 and 2023, with only 3 cases in total.

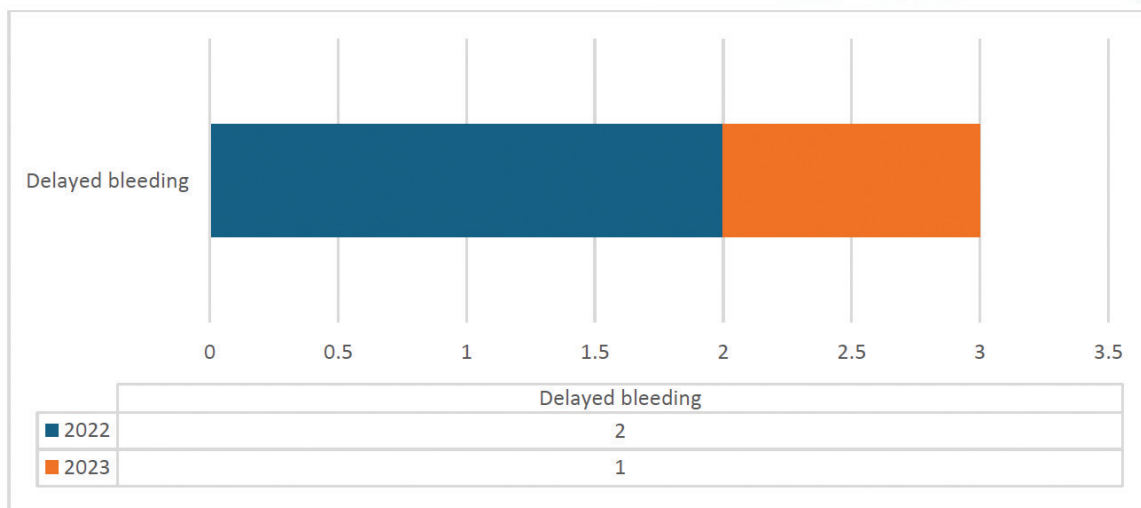


Figure 9.3.3.2: Total Number of Delayed Bleeding in 2022 – 2023

9.3.3.3 Most reported cases of delayed bleeding happened when donor had already left the donation site or at home. None of the donors had to be further referred to any clinic or hospital for further assessment.

9.3.3.4 All cases of delayed bleeding reported good recovery with no illness for both 2022 and 2023.

9.3.3.5 Recommendations:

Donor should be advised on the possibility of secondary bleeding following donation. Education of avoidance of physical and strenuous activities for the next 24 hours post donation is crucial to the donors, and this should be reminded on every occasion the donor donates. Application of firm pressure to the venepuncture site and if necessary, a pressure bandage if a hematoma is developing afterwards. Donors must immediately seek for medical attention for further management if the bleeding continuous and worsen. They also must notify the event to the blood bank immediately.



9.3.4 OTHER ARM PAIN - Figure 9.3.4.2

9.3.4.1 Pain in the arm may be the only presenting complain from donor. This criterion is chosen when all the diagnosis such hematoma, nerve injury or irritation has been ruled out. The pain may be associated with tissue injury.

9.3.4.2 Total of 15 cases reported in these two years with 9 cases in 2022 and 6 cases in 2023.

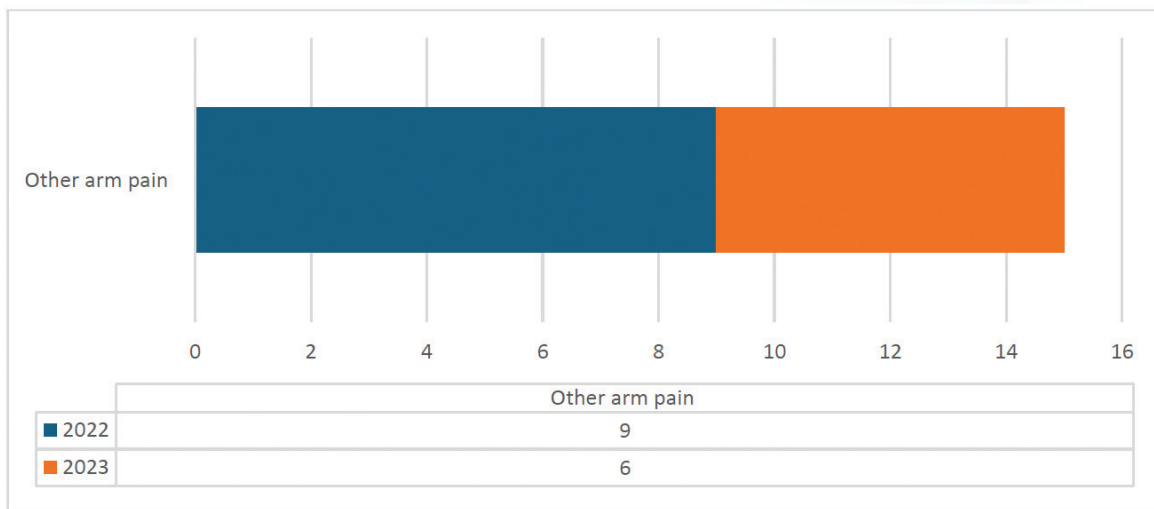


Figure 9.3.4.2: Total Number of Other Arm Pain in 2022 – 2023

9.3.4.3 Those cases of other arm pain were reported when there is nonspecific pain on the donation arm without any other symptoms of numbness, and no signs of arm swelling or hematoma.

9.3.4.4 All cases of other arm pain reported good recovery with no illness for both 2022 and 2023.

9.3.4.5 Recommendations:

- i. Education and training to the phlebotomist to ensure good phlebotomy technique which can minimize the incidence of arm pain.
- ii. Post donation education should be emphasized to blood donors e.g., avoid any heavy and strenuous activities and identification of possible post donation complications, and to inform blood donation for further notification and advise.



9.3.5 ARTERIAL PUNCTURE - Figure 9.3.5.2

9.3.5.1 Arterial puncture is defined as a puncture of brachial artery or one of its branches by the needle used to bleed donors. Few criteria to identify arterial puncture; they include a brighter red colour blood collected in the blood bag, pulsation observed at the needle and tubing, the blood bag fills up quickly (usually <4 minutes), and donors may complain weak localized pain on the elbow region. There is a risk of large hematoma following the rapid blood flow and this may lead to serious complication such as compartment syndrome.

9.3.5.2 There were total of 4 cases of arterial puncture reported for both 2022 and 2023.

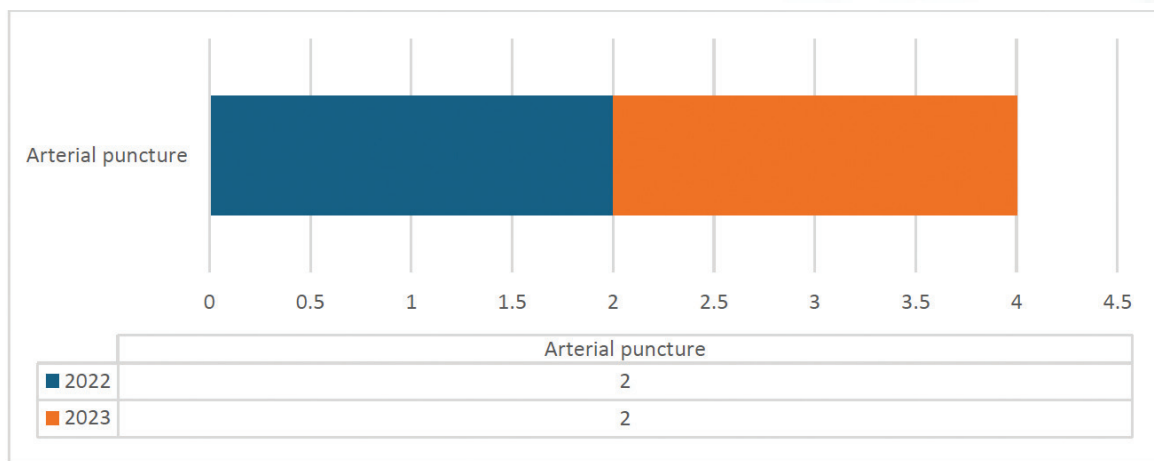


Figure 9.3.5.2: Total Number of Arterial Puncture in 2022 – 2023

9.3.5.3 Two cases of arterial puncture in the year 2022 were reported as mild, however, there were no further details reported. In the year 2023, both cases were also mild arterial punctures. It was reported that the phlebotomist in charge was able to recognize the signs of arterial puncture of bright red colour blood collected in the bag, pulsation at the blood bag, and the donation completed less than 4 minutes in one of the cases and thus immediately terminated the donations. Compressions were applied on the donated arms for up to 20 minutes, and one of the donors was given a compressor bandage afterwards by the staff in charge. They were given post donation advice and post donation care prior to discharge from the blood donation site. No hematoma reported for both donors. Follow up on donors on subsequent days also showed no active issue reported.

9.3.5.4 All donors reported good recovery with no illness following arterial puncture for both 2022 and 2023.



9.3.5.5 Recommendations:

- i. Frequent refresher training for the phlebotomist is mandatory in regards to the anatomy of arteries and veins. Phlebotomist should be able to immediately recognise the signs of arterial puncture and be able to manage it properly.
- ii. Donors who experienced arterial puncture should be advised on the possible complications and how to immediately detect them. Adequate explanation of what to expect can alleviate unnecessary concern. Serious cases of arterial puncture may be referred to A&E for further assessment and interventions.

9.3.6 CITRATE REACTION - Figure 9.3.6.2

9.3.6.1 During a plasmapheresis of platelet apheresis donation, citrate is added to stop the blood clotting as we collect it, and a small amount is returned to the donor with the red cells. Infusion of citrate anticoagulant during apheresis causes a fall in ionised calcium levels, leading to neuromuscular hyperactivity. Donor may experience a mild sensitivity to the citrate because of its effect on calcium and magnesium, which can include chills, tingling of the lips or tongue, or a metallic taste. Moderate symptoms are uncommon and include tingling of hands or feet, shivering and muscle twitching. If untreated, symptoms may progress to seizures, breathing difficulties or severe cardiac arrhythmias, including cardiac arrest.

9.3.6.2 There were 5 cases of citrate reaction reported in 2022 and 2 cases reported in 2023.

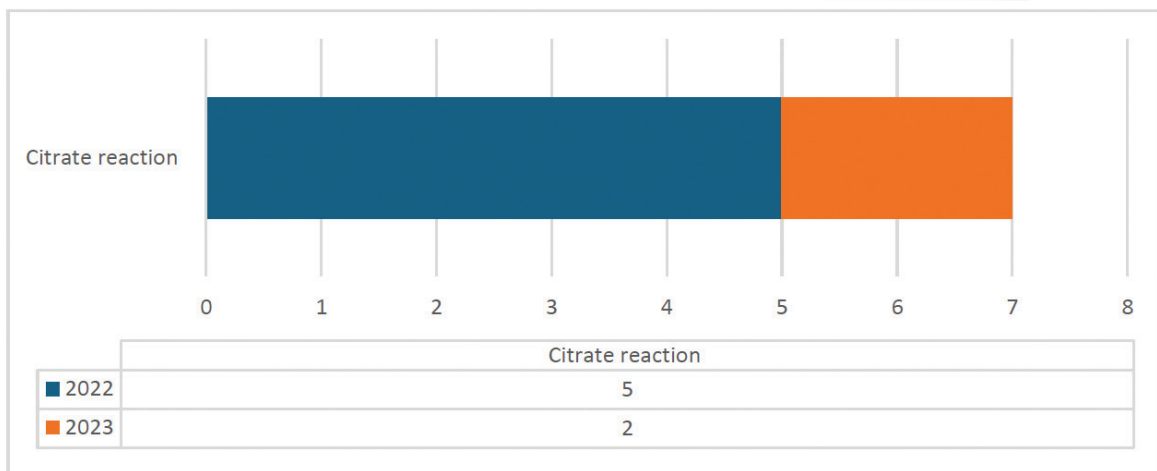


Figure 9.3.6.2: Total Number of Citrate Reaction in 2022 – 2023



9.3.6.3 The incidence of citrate toxicity is seen higher in male donors compared to female donors. However, most apheresis donors are male. Most donors with citrate toxicity ranging from age group 20-40 years old.

9.3.6.4 All cases of citrate toxicity reported good recovery for both 2022 and 2023.

9.3.6.5 Recommendations:

- i. Prophylactic oral calcium supplementation can be used to reduce the incidence of citrate-induced symptoms among regular apheresis donors. Supplementation of the return fluid with calcium gluconate also can be applied.
- ii. All staff should be well trained in the management of citrate toxicity.
- iii. Apheresis donors should be only allowed for maximum donation of a total volume of 15 litres in a period of 12 months or 24 times in a period of 12 months. Their calcium level also can be monitored regularly.

9.3.7 NERVE INJURY / IRRITATION - Figure 9.3.7.2

9.3.7.1 Nerve irritation can happen when the needle inserted accidentally hit the nearby nerve and may cause further nerve injury if it was directly hit on the nerve during needle insertion or withdrawal. Other than that, any swelling, inflammation, or hematoma post blood donation also can put a pressure on the nearby nerves causing feeling of discomfort or sharp electrical sensation in the distal arm or shoulder area. Usually, symptoms resolve within days but may persist for months as the nerve recovers.

9.3.7.2 Total of 3 cases of nerve injury were reported for both 2022 and 2023. Meanwhile, there were 4 cases of nerve irritation reported for each year of 2022 and 2023, sum up to total of 8 cases for both corresponding years.

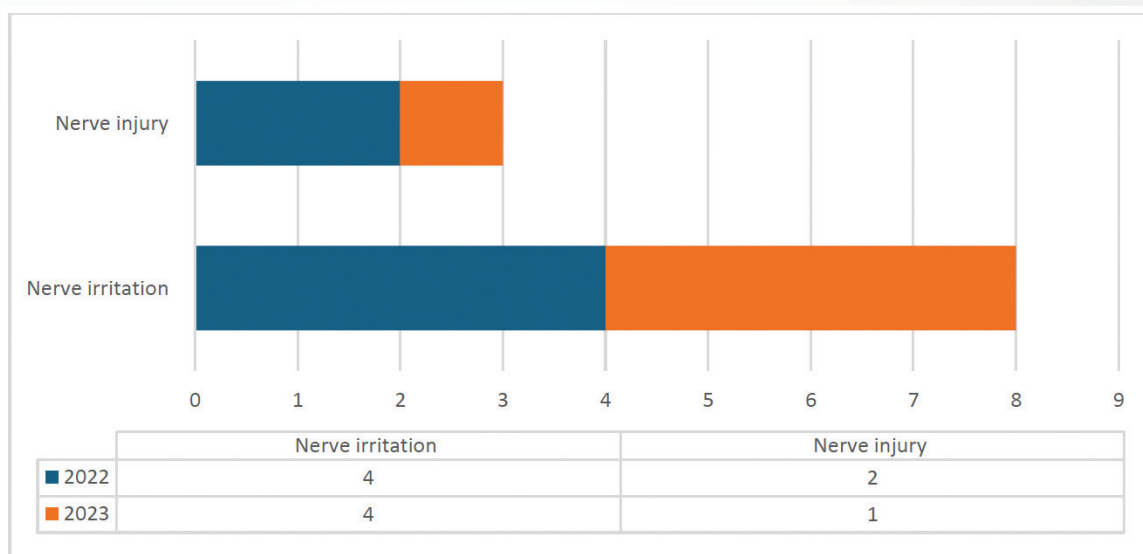


Figure 9.3.7.2: Total Number of Nerve Injury/ Nerve Irritation in 2022 – 2023

9.3.7.3 Most of the donors reported with the above ADR complained of numbness and electrical sensation distal to the donated arm. This could be due to the venepuncture procedure where the needle might have passed through or touched the nerves adjacent to the vein. There was no detailed report attached in the reporting.

9.3.7.4 There was one case of nerve irritation in 2022, that reported donor recovery with illness. The donor reported still having the numbness and electric sensation on the donated arm day 5 post donation. Otherwise, other cases reported as donors recovered with no ill effects.

9.3.7.5 Recommendations:

- i. Needle manipulation should be minimised or avoided to reduce the risk of nerve irritation/injury. Second attempt of venepuncture shall not be applied on the same arm, instead other arm should be used if donor agrees.
- ii. Continuous post donation education on identification of possible post donation complications and to seek medical attention for further treatment. Blood banks shall be informed regarding the incident.



9.3.8 LOCAL ALLERGIC REACTION - Figure 9.3.8.2

9.3.8.1 Allergic reaction on the skin due to the allergens or irritants used in solution for disinfection prior to venepuncture, may happen in certain donors. Contact with other medical appliances during blood donation such as latex gloves and adhesive bandage also can trigger local allergic reaction such as itchiness, redness, raised rash or hives at the venepuncture area. It may last from hours to days post donation.

9.3.8.2 Total of 2 cases reported for local allergic reaction for both years 2022 and 2023.

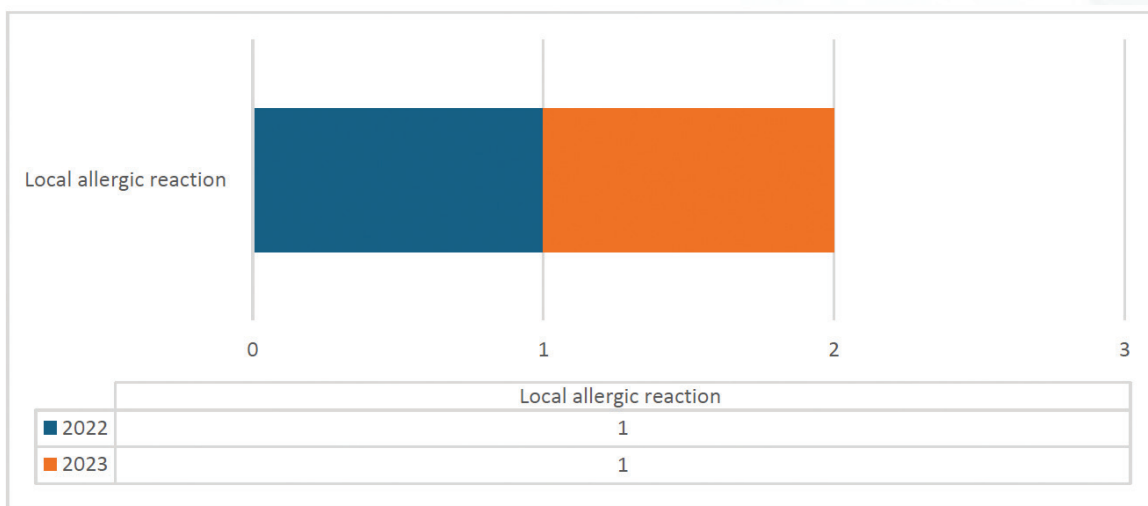


Figure 9.3.8.2: Total Number of Local Allergic Reaction in 2022 – 2023

9.3.8.3 All cases of local allergic was reported as mild allergic reaction. No detailed incident attached in ADR reporting.

9.3.8.4 All cases of local allergic reaction reported good recovery both in 2022 and 2023.

9.3.8.5 Recommendations:

Donor education on identification of possible post donation complications and to seek medical attention for further treatment. Blood banks shall be informed regarding the incident.



9.3.9 THROMBOPHLEBITIS/ CELLULITIS

9.3.9.1 Localised inflammation or infection over the venepuncture site or the surrounding area on the donated arm may happen following blood donation. The superficial vein inflammation is called thrombophlebitis whereas the inflammation to surrounding tissues is called cellulitis. Donors may present with warm skin, tenderness, redness and swelling at the venepuncture site.

9.3.9.2 There was no case of thrombophlebitis reported in 2022 and 2023.

9.3.10 DEEP VEIN THROMBOSIS (DVT)

9.3.10.1 Deep venous thrombosis (DVT) is defined as thrombosis developed in the deep vein on donor's donated arm. The superficial venous thrombosis may progress into deeper veins, but this rarely occurs. The usage of oral contraceptive pills in female donor also can predispose the donor to have DVT. They may have swelling and pain at the upper arm and be accompanied by symptoms of superficial vein inflammation.

9.3.10.2 No cases reported for this type of ADR for both 2022 and 2023.

9.3.11 ARTERIOVENOUS FISTULA

9.3.11.1 Arteriovenous fistula is a rare form of ADR related to the phlebotomy vein. It defined as an acquired connection between the vein and artery due to venepuncture lacerations. The channel is formed between the lacerated vein and artery post-venepuncture or during the healing process. Symptoms include pulsating mass with palpable thrill and it may associate with bruit. The affected arm usually feels warm while the distal part is cold from the presence of significant blood shunting. The distal veins also may be dilated and pulsating.

9.3.11.2 No reports received for case of arteriovenous fistula for both 2022 and 2023.



9.3.12 COMPARTMENT SYNDROME

9.3.12.1 Compartment syndrome is defined as increased in intra-compartment pressure leading to muscle and soft tissue necrosis. This is an emergency and must be referred to the A&E immediately. Compartment syndrome usually resulted from a large haematoma or inflammation in soft tissues leading to increased compartment pressure in the donated arms. Blockage of blood flow to the small blood vessels can lead to muscle and nerve tissue necrosis. Donors may have painful arms, paraesthesia, pallor, and later paralysis if not treated.

9.3.12.2 There was no case reported for compartment syndrome post donation for both 2022 and 2023.

9.3.13 BRACHIAL ARTERY PSEUDOANEURYSM

9.3.13.1 Pseudoaneurysm of brachial artery following blood donation is a very rare complication. It is a collection of blood outside an artery, contained by adventitia or the surrounding tissue alone. This is due to inadvertent complication from arterial puncture whereby blood may leak out from the artery and accumulate in the surrounding space. Donor may present with pulsatile swelling in the antecubital fossa and may be associated with pain and paraesthesia of hand.

9.3.13.2 No cases of brachial artery pseudoaneurysm reported for both 2022 and 2023.

9.3.14 HEMOLYSIS

9.3.14.1 Haemolysis in apheresis donor occur when there is a malfunctioning valves, kinks or obstruction of the tubing, incorrect installation of equipment, or other equipment failures affecting the extracorporeal circuit. Incompatible replacement fluids, such as dextrose D5W may be used in error. Donors may present with pink or red coloured plasma, blood in lines or filters may appear dark. The donor may also notice pink or red urine after collection.

9.3.14.2 No cases of haemolysis reported for both 2022 and 2023.



9.3.15 AIR EMBOLISM

9.3.15.1 Air embolism is the presence of air bubbles in a donor's circulation. Air may enter the lines due to the incomplete priming of lines, due a machine malfunction or defective collection kits or through incorrect manipulation by staff. Air in the donor's pulmonary circulation may occlude the pulmonary arteries in the lung and cause cardiopulmonary symptoms. Air may pass to the arterial circulation through an atrial septal defect and reduce blood flow to the brain. Donor will have a bubbling sound or feeling at the venepuncture site, or present with cough, dyspnoea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea, or vomiting.

9.3.15.2 There was no case reported of this ADR for both 2022 and 2023.

9.3.16 GENERALIZED (ANAPHYLACTIC) REACTION

9.3.16.1 In a severe allergic reaction known as anaphylactic reaction, it usually starts a few seconds or minutes after the procedure begins and can rapidly progress to cardiac arrest. Donors may present with sudden onset of severe hypotension, cough, bronchospasm from respiratory distress and wheezing, laryngospasm, angioedema, urticaria, rashes, shock, or loss of consciousness. This may be a fatal reaction.

9.3.16.2 No cases reported for this reaction for both 2022 and 2023.

9.3.17 OTHER SERIOUS COMPLICATIONS RELATED TO BLOOD DONATION-

Figure 9.3.17.2

9.3.17.1 Other serious complications include acute cardiac symptoms (other than myocardial infarct and cardiac arrest), myocardial infarct, transient ischaemic attack; and cerebrovascular accident.

9.3.17.2 There were 2 cases acute cardiac symptoms of myocardial infarction reported in the year 2023, whilst none for the year 2022.

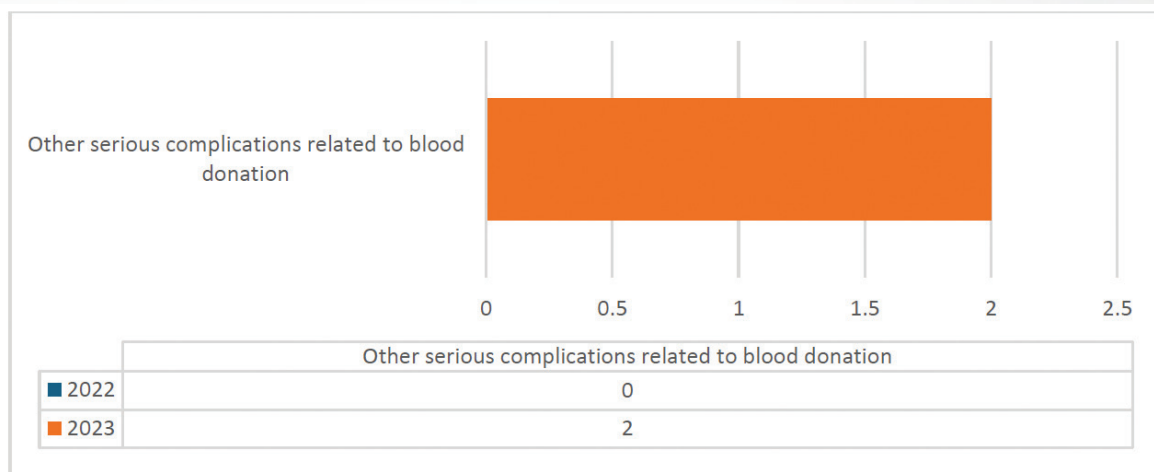


Figure 9.3.17.2: Total Number of Other Serious Complications Related to Blood Donation in 2022 – 2023

9.3.17.3 One ADR with severe myocardial infarction was reported in the year 2023, which happened to a regular, 38-year-old male apheresis donor during platelet apheresis donation. There was no detailed report on the sequence of event. However, donor had hypotensive episode and bradycardia at that time. He was given 1-pint normal saline and was immediately referred to A&E and diagnosed as acute inferior myocardial infarction (MI). He successfully underwent percutaneous coronary intervention (PCI) in the hospital and managed accordingly in the cardiac rehab. The blood bank officer visited donor on subsequent and reported donor was well post PCI and then was discharged few days later for recovery at home. He was subsequently permanently deferred by the respective blood bank from future donations.

Another reported case of severe ADR of myocardial infarction happened in a regular male donor age 49 years old post donation. Donor was able to complete 450mls of blood donation uneventfully. However, he later developed chest pain after already left the donation centre and immediately presented himself to A&E with complaint of chest pain, shortness of breath (SOB) and diaphoresis. Donor was diagnosed to have inferolateral myocardial infarction Killip I. His Hb level was 12.9 g/dL (post donation) and creatine kinase (CK) were 226, CKMB was 43 and lactate dehydrogenase (LDH) was 418. Donor was admitted to ward for further treatment and completed anticoagulant injection for 3 days prior to discharge home. Further history elicited from this donor in which he may not declared during counselling, was that he was already under investigation for heart block after his stress test done at a general practitioner (GP) was suggestive of ischemia. The donor was permanently deferred by the blood bank from future donation.



9.3.17.4 The 2 donors who experienced an acute cardiac symptom of myocardial infarctions during blood donation were otherwise well on discharge from hospital.

9.3.17.5 Recommendations:

- i. Serious cases of acute cardiac symptoms during or post blood donation are generally unpredictable and it can happen to any donors especially donors with higher cardiovascular risk factors. Vigilant and detailed counselling by the medical personnel may help to detect the possible risk factors among donors which can allow them to be deferred accordingly.
- ii. All medical personnels working in the blood bank particularly medical officers and staff nurses should be equipped with the basic knowledge on the acute management of any cardiac related event that happen during or post blood donation. Emergency trolley should always be available and in the vicinity of the bleeding room of the blood bank at all time.
- iii. Education to donors on the importance to disclose any crucial information about their health status during counselling can help prevent serious ADR from happening. Blood banks shall be informed regarding the incident.



9.3.18 OTHERS

9.3.18.1 Other ADRs that were reported to NHCC which did not fulfil the criteria of other ADRs listed will be labelled under Others.

9.3.18.2 There were 2 cases of panic attacks; and 1 case of non-specific palpitation reported in the year 2022. One of the cases of panic attack happened in one female donor as she complained of mild SOB, nausea, and feeling nervous and anxious post donation as she had previous history of ADRs. Other than she was noted to be slightly tachycardic, her other vital signs were normal. Another donor who was having panic attack during her donation resulted in the donation to be terminated immediately. Further questioning revealed that the donor was newly diagnosed to have anxiety disorder and panic disorder. Both donors recovered well and then were discharged home after reassurance and monitoring by the blood bank.

One donor was reported to have non-specific palpitation during her donation and this was a repeated event that already occurred to her in previous donation as well. Otherwise, she denied any chest pain, dizziness, or SOB. No documentation of episodes of tachycardia (her heart rate ranged from 82-92 bpm). Her donation however was terminated immediately. Donor denied any family history or cardiac events as well. She was permanently deferred by the respective blood bank and was referred to the nearest clinic for further assessment.

9.3.18.3 In the year 2023, two cases of hyperventilation syndrome secondary to anxiety during blood donation were reported. Donors were otherwise well afterwards. Another ADR that was reported under Others in the year 2023 involved a donor who complaint of mild petechiae developed over the donated arm around the tourniquet area. However, no itchiness, bruises or swelling noted. Vitals signs were all normal and donation completed uneventful. This petechiae may develop due to the tight compression of the tourniquet on the arm. Donor was advised on post donation care upon discharge.

9.3.18.4 All cases reported good recovery for both the year 2022 and 2023.

CHAPTER 10

SEROCONVERT DONOR



CHAPTER 10

SEROCONVERT DONOR

10.1 DEFINITION

- 10.1.1** A seroconvert donor is defined as a donor who is confirmed positive for a particular transfusion transmissible infection (TTI) in his current donation but was negative in the previous donation(s).
- 10.1.2** Seroconverted donors (SD) who were positive with transfusion transmitted infections (TTIs) such as human immunodeficiency virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) or Syphilis shall be counselled by the blood bank doctors and referred to the appropriate physician for further management according to the types of infection. These donors are barred from donating blood indefinitely.

10.2 LOOKBACK AND RECALL PROCEDURE

- 10.2.1** A look back and recall procedure is a retrospective analysis of a donor's donation history to ascertain whether the blood components from the previous donation(s) would require removal from blood bank inventory and/or notification to the transfusion recipients.
- 10.2.2** The unused blood components will be recalled, retested and discarded while ward/hospitals that were supplied with the blood components will be informed for recipient tracing and testing. Finally, the outcome of the look back investigations of seroconverted donors will be filled in the Seroconvert Donor Notification Form (Part 1 and Part 2) and reported to NHCC.
- 10.2.3** Look back investigations are important to be done on all implicated blood components, on recognition there may have been a risk of transmitting infection from a donor to a recipient and importantly to prevent, eliminate, or reduce the likelihood of harm and safeguard the patient's safety.



10.3 METHOD OF REPORTING

10.3.1 Reporting of seroconvert donor cases to NHCC is by submitting a Seroconvert Donor Notification Form, Part 1 and Part 2 (BTS/SC/1/2016). Part 1 consists of information such as donor details, infectious markers implicated and risk factors for acquiring the disease while Part 2 contains the outcome of the investigated blood components and recipient testing result.

10.3.2 In general Part 1 is submitted after the donor attends a post donation counselling (PDC) where a fresh sample was taken for confirmation testing and risk factors for acquiring the disease are elicited. Whereas, in a situation where donors did not turn up for their scheduled post donation counselling, Part 1 reports should be sent to NHCC for analysis after 1 year of seroconversion detection. Part 2 should be submitted after the outcome of the blood products has been fully investigated and risk of infection transmission has been concluded.

10.4 SEROCONVERT DONOR REPORTS – Figure 10.4.1, Table 10.4.3

10.4.1 The graph below shows the total number of seroconvert donor reports received from 2016 to 2023 (Part 1 and Part 2 combined). There has been an increase in SD reporting of more than 10 times when compared to previous years.

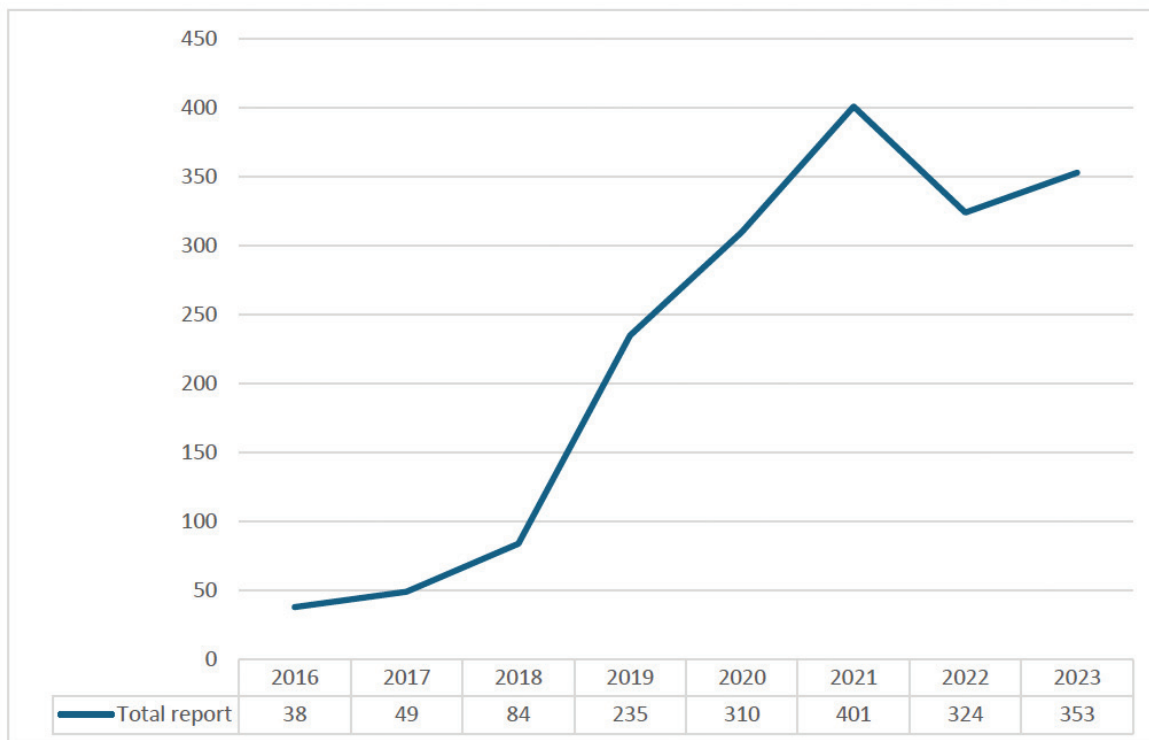


Figure 10.4.1: Total Number of Seroconvert Donor Reports Received from 2016 - 2023



10.4.2 The seroconvert donor report does not reflect the actual number of donor seroconversion in the reporting year due to Part 1 report is submitted after the donor has attended post donation counselling (PDC) while Part 2 is after the investigation on blood components completed and outcome concluded.

10.4.3 In 2022 there were 324 reports received and it increased to 353 in 2023. From the table below, 22 reports and 27 reports are from Part 1 without PDC in 2022 and 2023 respectively. For Part 1 reports with PDC, there were 193 reports in 2022 and 192 reports in 2023. Part 2 reports were found to be increasing in figure, from 109 in 2022 to 134 in 2023.

Year	Part 1 Post Donation Counselling (PDC)		Part	Total
	No	Yes		
2016	-	19	19	38
2017	-	46	3	49
2018	3	57	24	84
2019	13	132	90	235
2020	2	185	123	310
2021	21	221	159	401
2022	22	193	109	324
2023	27	192	134	353

Table 10.4.3: Total Number of Seroconvert Donor Reporting



10.5 PART 1 WITH POST DONATION COUNSELLING (PDC) REPORT – Table 10.5

The demographic characteristics of seroconvert donors retrieved from Part 1 with PDC are important to formulate control strategies and prevent TTI. Syphilis (159 reports in both years) accounts for the highest number of seroconversions reported followed by HIV (n=97), HBV (n=89) and the least are HCV (n=26) and co-infection (n=14) as shown in the table below.

Variables		2022 (N=193)					2023 (N=192)				
		HIV N= 52	HBV N= 40	HCV N= 16	Syphilis N= 82	Co-infection N= 3	HIV N= 45	HBV N= 49	HCV N= 10	Syphilis N= 77	Co-infection N= 11
Age	<20	1	1	0	0	1	1	0	0	0	0
	20 - 39	42	11	10	55	0	42	19	5	58	11
	40 - 60	9	28	6	27	2	2	28	4	19	0
	>60	0	0	0	0	0	0	2	1	0	0
	No data	0	0	0	0	0	0	0	0	0	0
Gender	Males	49	33	11	69	3	43	39	6	67	10
	Females	3	7	5	13	0	2	10	4	10	1
Number of previous donations	<5	30	28	14	58	3	26	31	7	45	7
	5 to 10	10	6	1	17	0	14	8	2	18	4
	>10	12	6	1	7	0	5	10	1	14	0
	No data	0	0	0	0	0	0	0	0	0	0
Risk Factors	High risk behaviours	33	4	4	38	3	26	7	0	42*	8
	Body piercing/ tattoo/ acupuncture/ cupping	5	5	3	3	0	3	11	2	4	0
	Hx of blood transfusion	0	0	0	0	0	0	0	0	0	0
	IV Drug Use	0	0	1	0	0	1*	0	1	0	0
	Deny risk factors	6	16	6	27	0	8	22	6	16	3
	Others	4	11	1	10	0	4	6	0	14	0
	No data	4	4	1	4	0	4	3	1	2	0

Table 10.5: Part 1 with PDC: Seroconvert Donor Demographic Characteristics according to Transfusion Transmissible Infection (TTI)

**Some donors have more than 1 risk factors*



10.6 HUMAN IMMUNODEFICIENCY VIRUS (HIV)

10.6.1 HIV

10.6.1.1 Human immunodeficiency virus (HIV) is one of the world’s leading infectious diseases, claiming more than 25 million lives over the last 30 years. HIV invades white blood cells, called T-lymphocytes, which have an important role to play in the body’s defences against infection and other diseases.

10.6.1.2 According to 2022 Global AIDS monitoring, until December 2021, there were estimated 81,942 people living with HIV (PLHIV) in Malaysia.

10.6.1.3 HIV can be transmitted via contact with bodily fluids, unprotected sex, sharing of injection drug equipment or vertical transmission from mother to child. HIV can also be transmitted by blood transfusion from an infected blood donor.

10.6.2 Total Number of HIV Seroconvert Donor – Figure 10.6.2

10.6.2.1 In 2022, a total of 91 reports of HIV Seroconvert Donor were sent to NHCC, of which 5 were Part 1 reports without PDC, 52 were from Part 1 reports with PDC, and the remaining 34 reports were Part 2. In 2023, there were 5 Part 1 reports without PDC, 45 reports of Part 1 with PDC, and 40 Part 2 reports received.

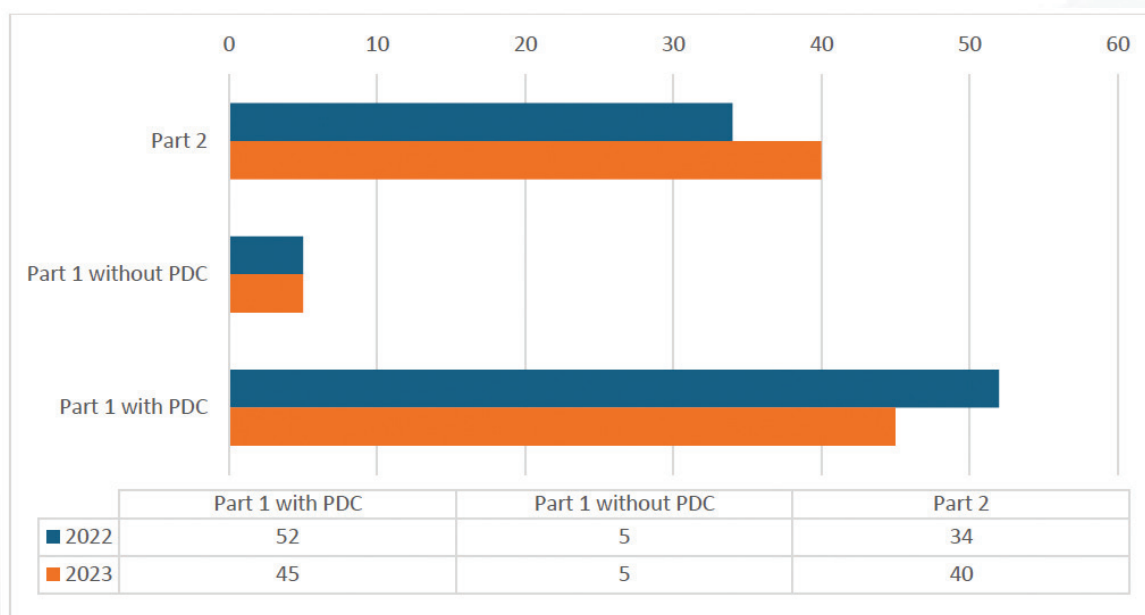


Figure 10.6.2: Total number of HIV Seroconvert Donors in 2022-2023



10.6.3 Characteristic of Seroconvert Donor for HIV

10.6.3.1 Age

In both 2022 and 2023, the majority of HIV infections occurred among 20-39 age group. In 2022, 42 out of 52 HIV-positive individuals were in this age group, while in 2023, 42 out of 45 cases fell into this category. There was a slight reduction in HIV cases in this age group from 2022 to 2023. No HIV seroconvert donors found in age group of more than 60 years old.

10.6.3.2 Gender

The majority of HIV cases were among males, with 49 out of 52 cases in 2022 and 43 out of 45 in 2023. This suggests a consistent trend of higher HIV prevalence among male donors.

10.6.3.3 Frequency of blood donation

The majority of HIV-positive seroconvert donors in both years had fewer than five previous donations. In 2022, 30 out of 52 had fewer than five donations, while in 2023, 26 out of 45 had fewer than five donations.

10.6.3.4 Risk factors

High-risk behaviours were the most common risk factor for HIV, reported by 33 out of 52 HIV-positive seroconvert donors in 2022 and 26 out of 45 in 2023. However, there was a slight increase in the number of donors who denied having any risk factors, from 6 in 2022 to 8 in 2023.



10.6.4 Summary of Seroconvert Donor for HIV - Figure 10.6.4

HIV infections were most prevalent among males aged 20-39, with a slight decrease in total cases from 2022 (52 cases) to 2023 (45 cases). The majority of these cases involved individuals with fewer than five previous donations, with high-risk behaviours were identified as the primary risk factor. There was also an increase in individuals denying any risk factors indicating potential underreporting or unrecognized risk.

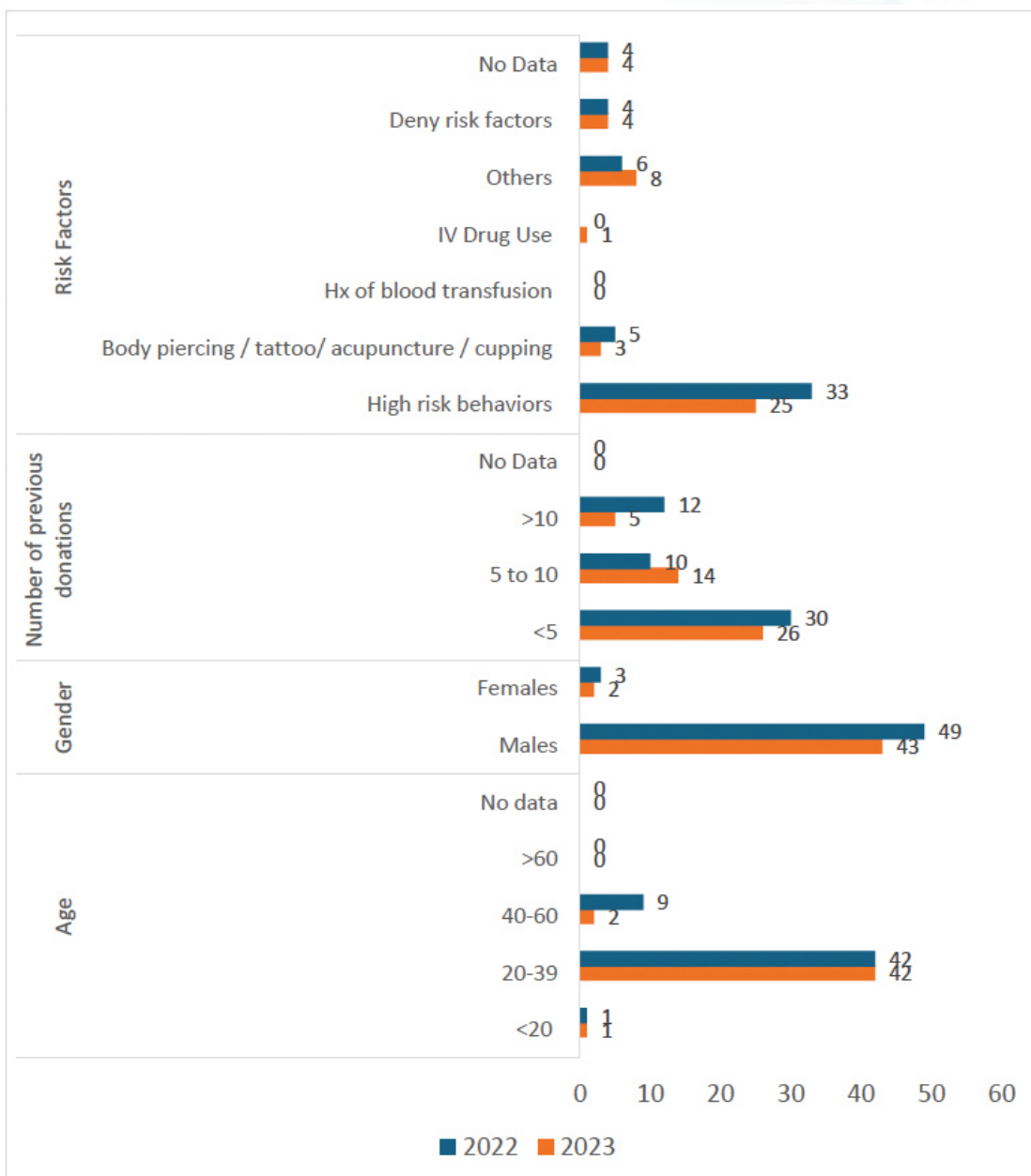


Figure 10.6.4: Demographic Distribution and Risk Factors for HIV Seroconvert Donors in Part 1 in 2022 – 2023



10.6.5 Outcome of Look Back and Recall (Part 2) Seroconvert Donor for HIV - Figure 10.6.5

10.6.5.1 As shown from figure 10.6.5, the total number of blood products investigated in the look back procedure was 97 for 2022 and 92 in 2023. From 97 blood products in 2022, 54 blood products were transfused to patients and 18 blood products have no data on their fate. 27 transfusions out of 54 transfused patients had passed away, remaining 22 patients were found to be non-reactive and 5 patients had no data of patients' outcomes. In 2023, out of 92 blood products, 71 were transfused. From 71 blood products transfused to recipients, 25 were non-reactive, 36 recipients have deceased and 10 recipients' outcome remain inconclusive up to date.

10.6.5.2 In both 2022 and 2023, no patients that were transfused were reported to have acquired an HIV infection after receiving blood.



Figure 10.6.5: Outcome of Blood Products and Recipient of Seroconvert Donors for HIV in 2022 – 2023



10.7 Hepatitis B Virus (HBV)

10.7.1 HBV

10.7.1.1 Hepatitis B is a global public health threat and the world's most common serious liver infection. In fact, Hepatitis B is known to be 100 times more infectious than HIV/AIDS virus. It also is the primary cause of liver cancer (or hepatocellular carcinoma), which is the second-leading cause of cancer deaths in the world.

10.7.1.2 Around the world, about one out of three people have been infected with the Hepatitis B virus. According to the figure shared by the Hepatitis B Foundation US, approximately 1.5 million people become newly infected each year, almost 300 million people are chronically infected; and an estimated 820,000 people die each year from Hepatitis B and its related complications such as liver cancer. The Ministry of Health (MoH), Malaysia has reported that about 5% of the Malaysian population is infected with HBV.

10.7.1.3 Mode of transmission of HBV includes transmission through sexual contact, vertical transmission from an infected mother to child at birth (mostly at endemic areas), exposure to infected bloods and body fluids, tattooing, body piercing, wet cupping - in which transmission occurred through reusing contaminated needles, syringes, or other contaminated equipment.

10.7.2 Total Number of Hepatitis B Seroconvert Donor – Figure 10.7.2

10.7.2.1 The total number of HBV seroconvert donors reported to NHCC is depicted in the graph below. A total of 5 Hepatitis B reports were received for Part 1 without PDC, 40 Part 1 with PDC and 21 Part 2 reports for the year 2022. In 2023, there is increment in all reports. 8 reports were from part 1 without PDC, 49 reports for Part 1 with PDC and 24 reports from Part 2.

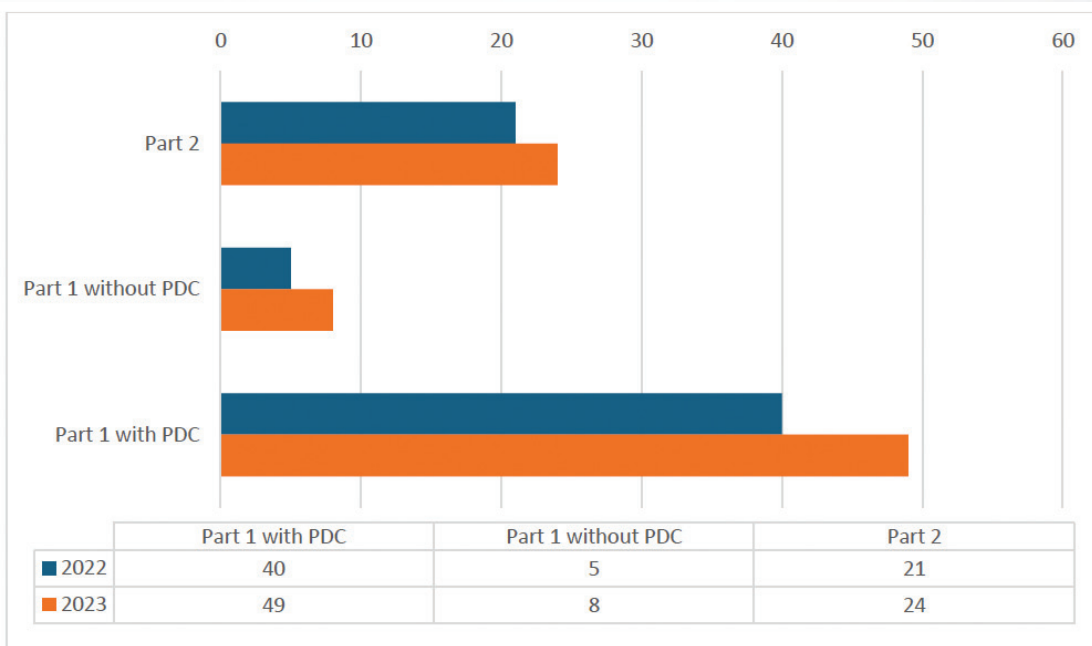


Figure 10.7.2: Total Number of Hepatitis B Seroconvert Donors in 2022-2023

10.7.3 Characteristic of Seroconvert Donor for Hepatitis B

10.7.3.1 Age

HBV infections were predominantly found in individuals aged 40-60. In 2022, 28 out of 40 cases were in this age group, and in 2023, this number remained steady at 28 out of 49. This consistency suggests a stable trend of HBV prevalence in this older age group.

10.7.3.2 Gender

Males also accounted for the majority of HBV cases. In 2022, 33 out of 40 cases were males, while in 2023, this number rose to 39 out of 49.

10.7.3.3 Frequency of blood donation

The data shows that HBV-positive donors typically had fewer than five previous donations. In 2022, 28 out of 40 had fewer than five donations, and in 2023, 31 out of 49 had fewer than five donations.

10.7.3.4 Risk factors

Many HBV-positive individuals reported high-risk behaviours, with a slight increase from 4 in 2022 to 7 in 2023. There was also a notable increase in individuals denying any risk factors, from 16 in 2022 to 22 in 2023.



10.7.4 Summary of Seroconvert Donor for Hepatitis B – Figure 10.7.4

HBV infections were most common in the 40-60 age group, with cases remaining stable at 28 in both 2022 and 2023. Males were predominantly affected, and most HBV-positive donors had fewer than five previous donations. High-risk behaviors were reported in a significant portion of cases, though there was an increase in individuals denying risk factors.

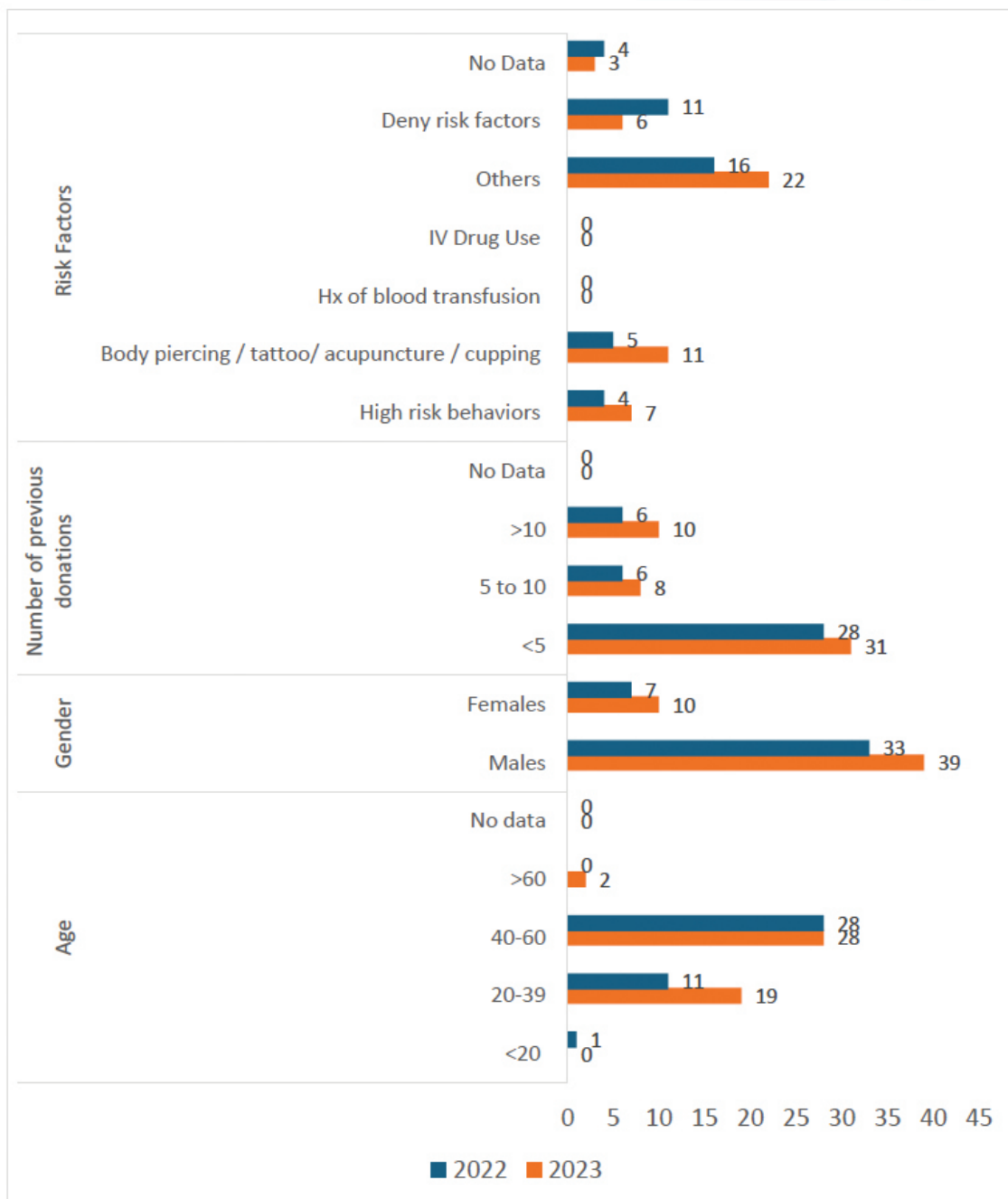


Figure 10.7.4: Demographic Distribution and Risk Factors for Hepatitis B Seroconvert Donors in Part 1 in 2022 – 2023



10.7.5 Outcome of Look Back and Recall (Part 2) Seroconvert Donor for Hepatitis B – Figure 10.7.5

10.7.5.1 A total of 49 blood products were investigated in 2022, of which 20 were transfused. Eleven recipients of the transfused blood tested negative for HBV, six of the recipients have since passed away, and three have no information on the recipient’s status. The remaining 29 blood products were not transfused where 11 units were discarded while 15 blood products have no information about their status and 3 products sent for CSL.

10.7.5.2 Of the 49 blood products that were investigated in 2023, 37 was transfused. Ten recipients were tested as non-reactive and 13 recipients deceased. One Hepatitis B transfusion transmitted infection (TTI) was reported, while the results of the other thirteen cases were not reported.

One case of TTI Hepatitis B reported involving one patient who was hospitalised in the year 2015, with the diagnosis of left leg cellulitis and neuropathic ulcer of the left foot. He was noted to have anaemia with Hb of 7.7g/dL and then was transfused with 1-unit packed cell during that admission. There was no infective screening available prior to the transfusion, however patient noted to be reactive for HbsAg upon lookback procedure from a seroconverted Hepatitis B donor. On further investigation, it was reported that the seroconverted donor had risk factor whilst the recipient denied any high-risk behaviour and had no known family history of Hepatitis B. This case was concluded as possible delayed case of adverse transfusion infection with TTI.

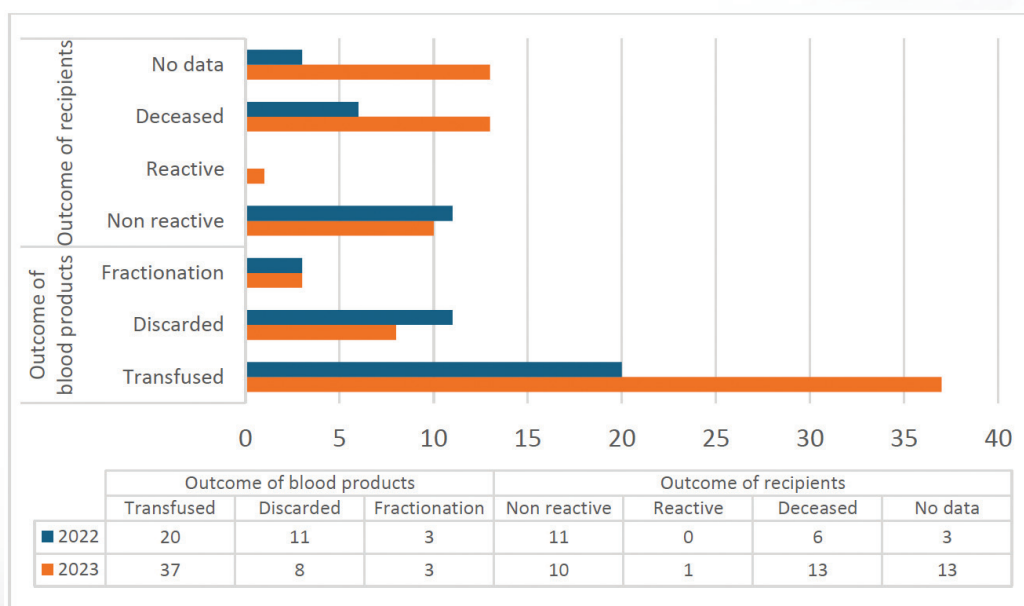


Figure 10.7.5: Outcome of Blood Products and Recipient of Seroconvert Donors for HBV in 2022 – 2023



10.8 Hepatitis C

10.8.1 HCV

10.8.1.1 Hepatitis C virus (HCV) infection is a major cause of chronic liver disease infection with worldwide approximation of 71 million people being infected by the hepatitis C virus (HCV). Hepatitis C is spread through contact with blood from an infected person. For some people, hepatitis C is a short-term illness, but for more than half of people who become infected with the hepatitis C virus, it becomes a long-term, chronic infection. (CPG Management of Hepatitis C in Malaysia)

10.8.1.2 In Malaysia, as of the end of 2019, it was estimated that more than 400 000 individuals have been chronically infected with hepatitis C, but only about 1% of them have been treated. Many of the estimated 380,000 people living with hepatitis C remain undiagnosed. (CPG Management of Hepatitis C in Malaysia)

10.8.1.3 Hepatitis C is spread through contact with infected blood. This can happen through sharing needles or syringes, or from unsafe medical procedures such as blood transfusions with unscreened blood products. Although less frequent, HCV can also be spread through sex with an HCV-infected person, sharing personal items contaminated with infectious blood, health-care procedures that involve invasive procedures, needle stick injuries in health-care settings, unregulated tattooing, and receipt of donated blood, blood products, and organs (CDC). Symptoms can include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine and jaundice.

10.8.2 Total Number of Hepatitis C Seroconvert Donor Report – Figure 10.8.2

The graph below shows the total number of HCV seroconvert donors reported to NHCC. In total, 22 HCV reports were received in 2022, with reductions of only 19 reports were received in 2023.

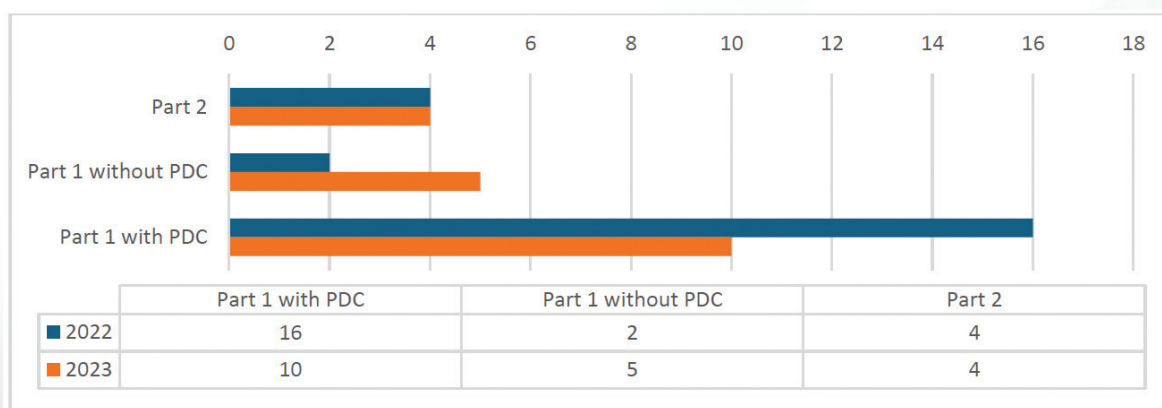


Figure 10.8.2: Total Number of Hepatitis C Seroconvert Donors in 2022-2023



10.8.3 Characteristic of Seroconvert Donor for Hepatitis C

10.8.3.1 Age

Most HCV cases were observed among 20-39 years old individuals, with 10 out of 16 cases in 2022 and 5 out of 10 in 2023. There was a noticeable reduction in HCV cases in this age group between the two years.

10.8.3.2 Gender

In 2022, the HCV-positive cases were relatively balanced between males and females, with 11 males and 5 females. In 2023, males accounted for 6 out of 10 cases, showing a slight decrease in female cases.

10.8.3.3 Frequency of blood donation

The majority of HCV-positive donors had fewer than five previous donations. In 2022, 14 out of 16 had fewer than five donations, while in 2023, 7 out of 10 had fewer than five donations.

10.8.3.4 Risk factors

In 2022, 4 out of 16 HCV-positive individuals reported high-risk behaviours, while no one reported it in 2023. There was also an increase in individuals denying any risk factors, from 6 in 2022 to 6 in 2023.

For hepatitis C seroconvert donors, most of them denied risk factors during PDC. In both years, 6 donors denied any risks. The remaining donors in 2022 had 4 donors with high-risk behaviours (multiple sex partners), 1 IV drug use, 3 with history of cupping, 1 other (partner with high-risk behaviour) and 1 report with no risk factor documented.

In 2023, there was no donor with high-risk behaviours. 2 donors did cupping and piercing, 6 donors denied any risk factors and 1 donor with IV drug use. The remaining 1 donor had denied having any risk factors for hepatitis C.



10.8.4 Summary of Seroconvert Donor for Hepatitis C – Figure 10.8.4

HCV cases primarily occurred among 20-39 years old individuals, with a notable decrease in total cases from 16 in 2022 to 10 in 2023. The majority of HCV-positive donors had fewer than five previous donations, and high-risk behaviours were reported less frequently in 2023, with more individuals denying risk factors.

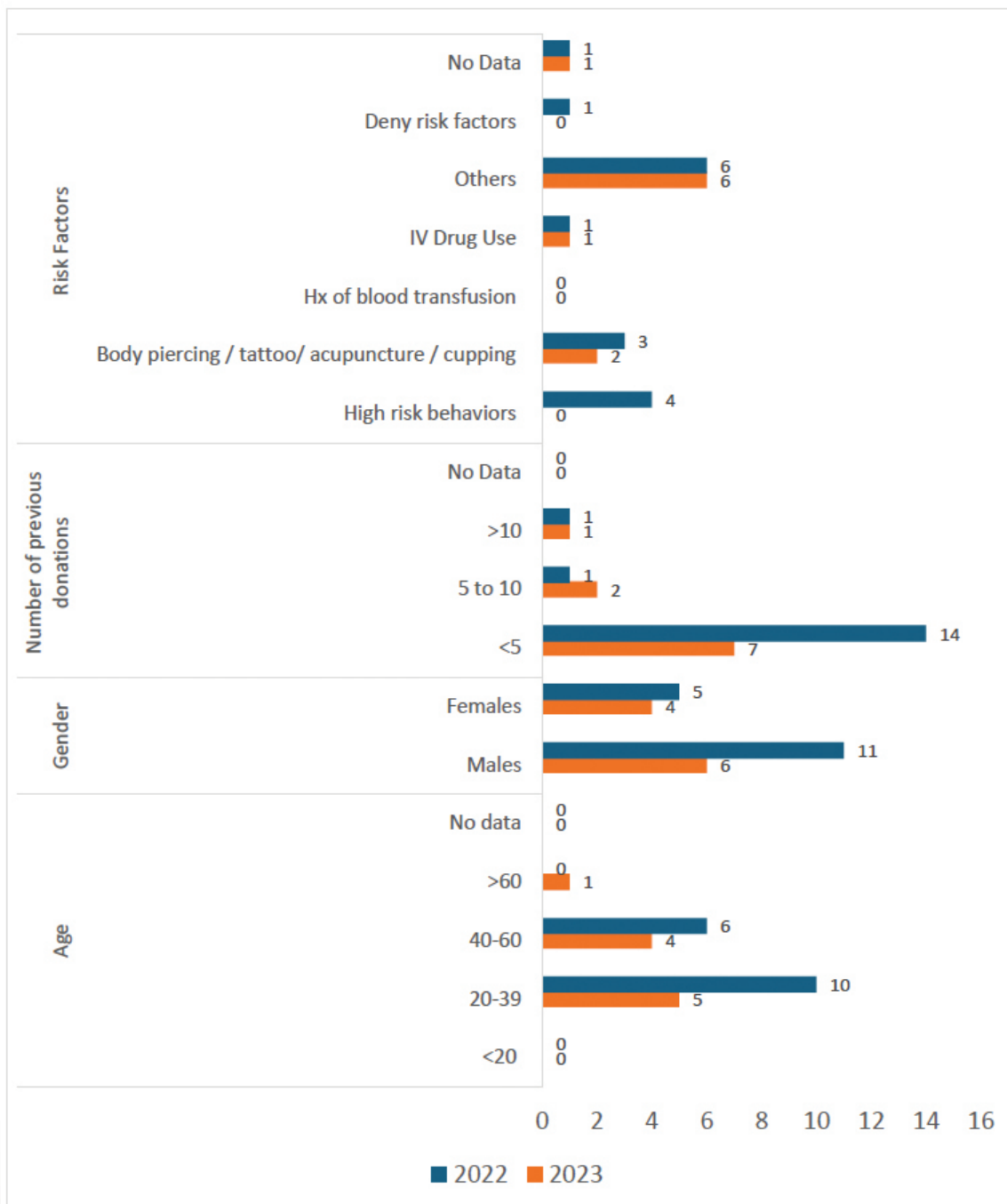


Figure 10.8.4: Demographic Distribution and Risk Factors for Hepatitis C Seroconvert Donors in Part 1 in 2022 - 2023



10.8.5 Outcome of Look Back and Recall (Part 2) Seroconvert Donor for Hepatitis C – Figure 10.8.5

A total of 5 blood products were investigated in 2022 and also 13 were investigated in 2023. Out of five products in 2022, 3 were transfused to patients, 1 was discarded and 1 product was not stated of its outcome. From 3 transfusions, 2 were found to be non-reactive for hepatitis C and 1 recipient passed away.

In 2023, from 13 products investigated, 11 were transfused, 1 was discarded and 1 product had no data of its outcome. From 11 transfusions, 3 recipients were non-reactive, 2 passed away and 6 had no outcome documented in their reports.

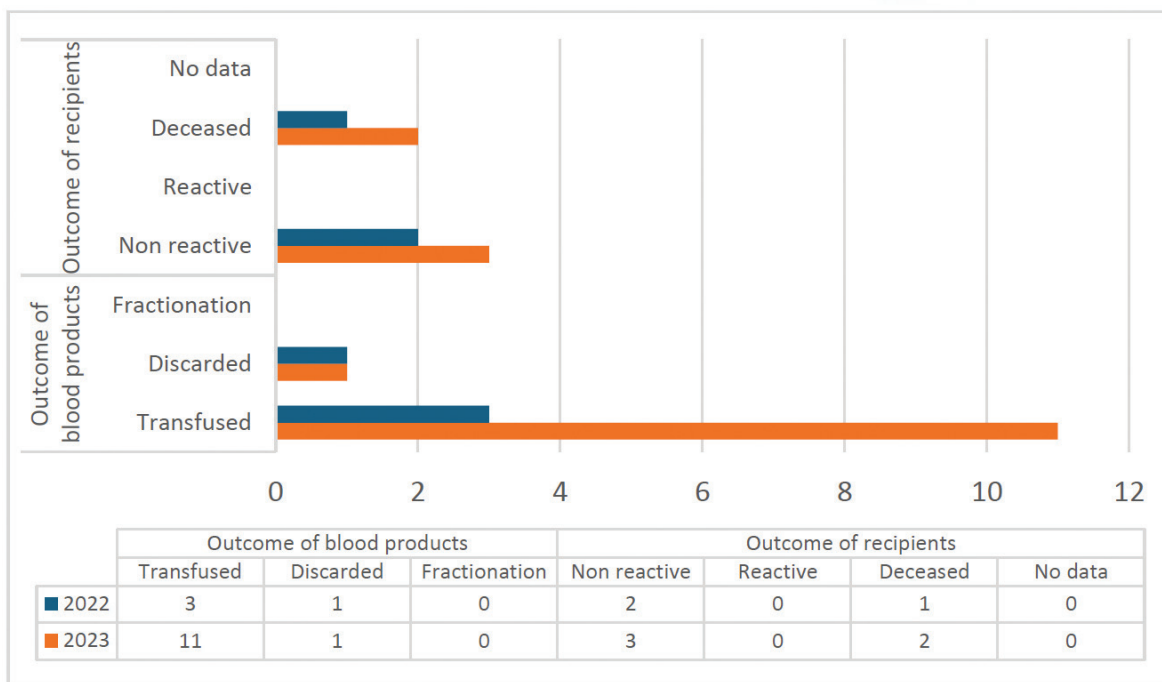


Figure 10.8.5: Outcome of Blood Products and Recipient of Seroconvert Donors for HCV in 2022 – 2023



10.9 Syphilis

10.9.1 Syphilis

10.9.1.1 Syphilis is a systemic disease caused by *Treponema pallidum*. Acquired infection is transmitted through direct person-to-person sexual contact with an individual with early or secondary syphilis. Incidence of syphilis is high in Malaysia especially among MSM population.

10.9.1.2 In 2022, approximately 4,669 syphilis cases were reported in Malaysia, while 1,211 cases of AIDS were reported in that year. Malaysia recorded an incident rate of around 3.71 per 100,000 population for AIDS in that year.

10.9.1.3 In a study from University Malaya Medical Centre (UMMC) revealed most of the patients with syphilis were also HIV positive and asymptomatic. Primary syphilis classically presents as a single painless ulcer or chancre at the site of infection but can also present with multiple, atypical, or painful lesions. Secondary syphilis manifestations can include skin rash, mucocutaneous lesions, and lymphadenopathy. Tertiary syphilis can present with cardiac involvement, gummatous lesions, tabes dorsalis, and general paresis.

10.9.2 Total Number of Syphilis Seroconvert Donors – Figure 10.9.2

The total number of Syphilis seroconvert donors reported to NHCC is the highest out of all other TTIs. 136 reports were received in 2022 which is quite similar to the figure in 2023 which is 143 reports.

60.3% comprised of reports for Part 1 with post donation counselling in 2022, and reduced to 53.8% in 2023. There were only 10 (7.4%) reports for 2022 and 9 (6.3%) reports in 2023 that were sent without post donation counselling. Moreover, for part 2, it was 44 (32.4%) in 2022 and 57 (39.9%) in 2023.

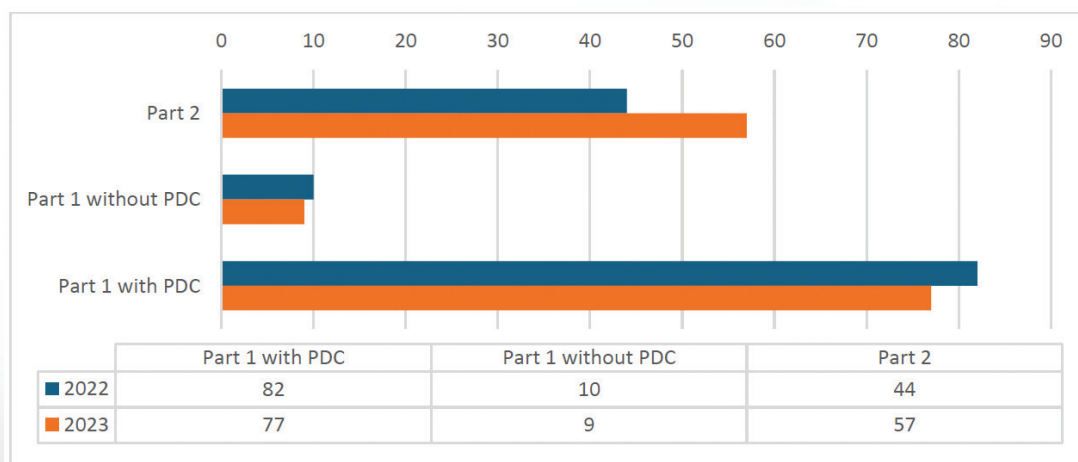


Figure 10.9.2: Total Number of Syphilis Seroconvert Donors in 2022-2023



10.9.3 Demographic characteristic of Part 1 Seroconvert Donor for Syphilis

10.9.3.1 Age

The 20-39 age group had the highest number of syphilis cases in both 2022 and 2023. In 2022, 55 out of 82 cases were in this age group, and in 2023, 58 out of 77 cases were in this age group. The numbers remained consistent, showing a stable trend.

10.9.3.2 Gender

Males also dominated the syphilis cases, with 69 out of 82 cases in 2022 and 67 out of 77 cases in 2023. The gender distribution shows a consistent higher prevalence of syphilis among males.

10.9.3.3 Frequency of blood donation

The majority of syphilis cases were among those with fewer than five previous donations. In 2022, 58 out of 82 syphilis-positive donors had fewer than five donations, while in 2023, 45 out of 77 had fewer than five donations.

10.9.3.4 Risk Factor

High-risk behaviors were the most commonly reported risk factor for syphilis in both years. In 2022, 38 out of 82 syphilis-positive individuals reported high-risk behaviors, and in 2023, this number slightly increased to 42 out of 77.



10.9.4 Summary of Seroconvert Donor for Syphilis – Figure 10.9.4

Syphilis infections were most common in the 20-39 age group, with a slight decrease in cases from 82 in 2022 to 77 in 2023. Males were disproportionately affected, and most syphilis-positive donors had fewer than five previous donations. High-risk behaviours were the primary risk factor, with a slight increase in reported cases from 2022 to 2023.

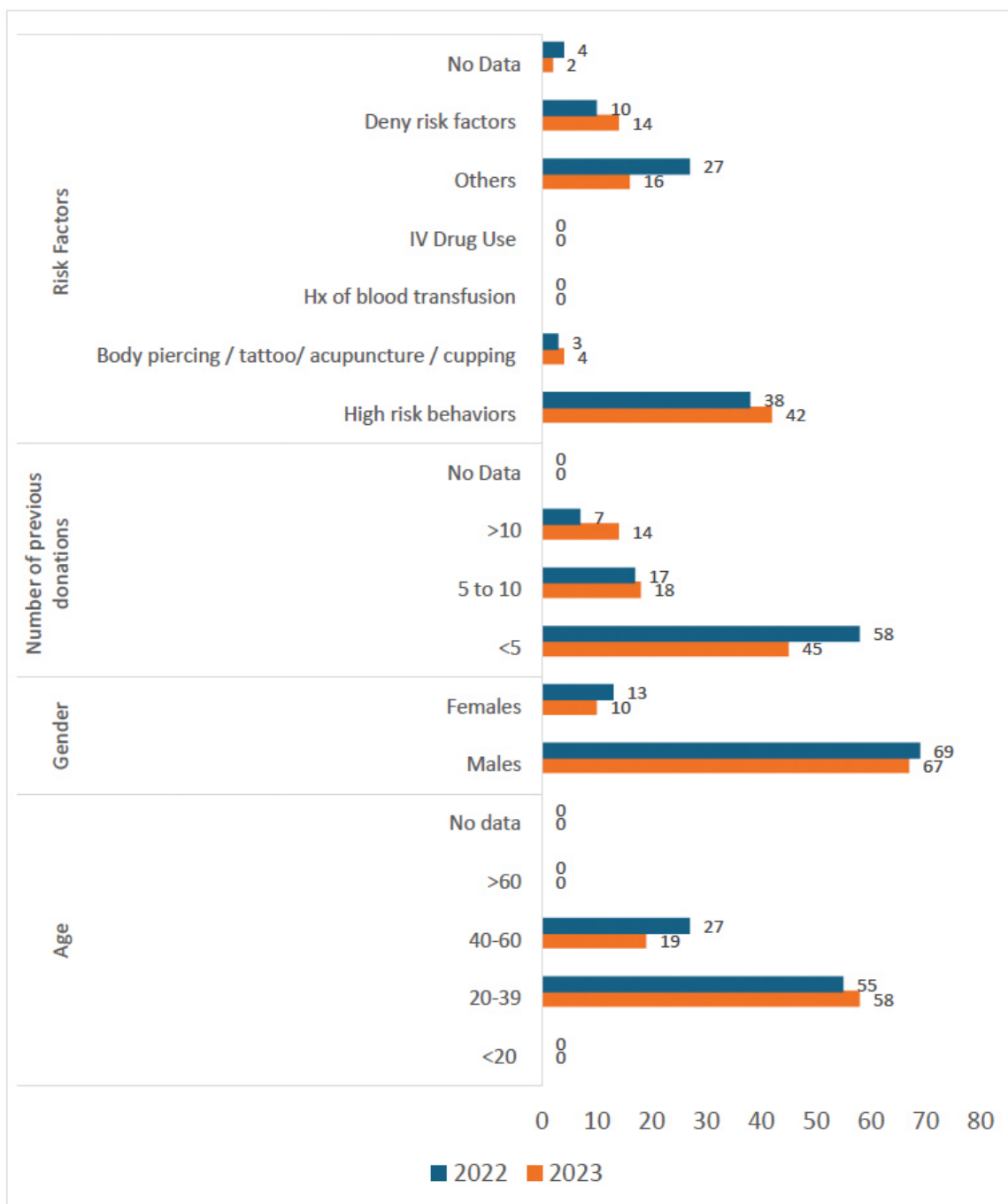


Figure 10.9.4: Demographic Distribution and Risk Factors for Syphilis Seroconvert Donors in Part 1 in 2022 – 2023



10.9.5 Outcome of look back and recall (Part 2) Seroconvert Donor for Syphilis – Figure 10.9.5

The look back and recall procedures for 137 blood products were investigated in 2022 (n=85) and 2023 (n=34). 48 blood products in 2022 and 104 blood products in 2023 that were kept below 20 degrees Celsius for more than 72 hours were not proceeded with look back and recall. This is due to *Treponema pallidum*'s inability to survive a prolonged period of cold storage (greater than 72 hours).

For the 85 blood products that were investigated in 2022, 34 blood products were transfused, 19 were discarded, 32 had no outcome documented in the Part 2 report. From 34 blood transfusions, 15 were non-reactive, 5 recipients had already deceased and 14 outcomes of recipients were not mentioned in Part 2 report.

In 2023, among 34 blood products that were investigated, 16 blood products were transfused to patients, 15 were discarded and data on 3 products' outcomes were not available. Out of 16 blood transfusions, 2 were non-reactive, 4 had passed away and 10 reports did not mention any outcome of patients.

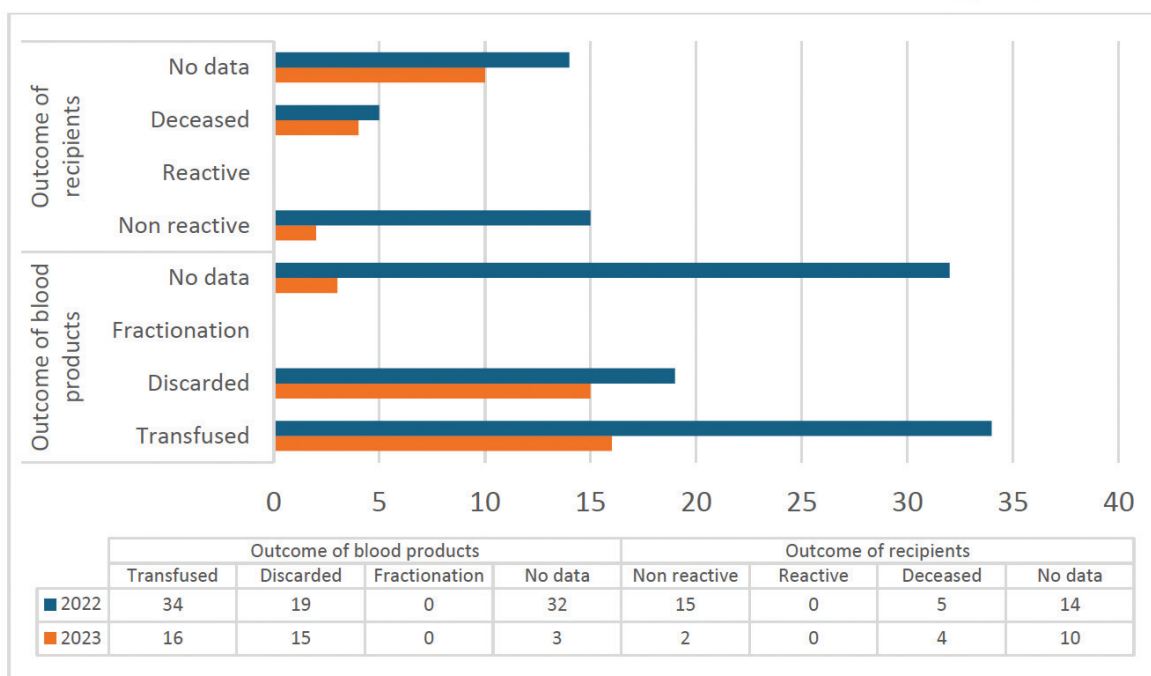


Figure 10.9.5: Outcome of Blood Products and Recipient of Seroconvert Donors for Syphilis in 2022 - 2023



10.10 Co-infection of TTIs

10.10.1 Co-infection of TTIs

10.10.1.1 Globally, nearly 6 million people are diagnosed with syphilis each year. Because syphilis can facilitate acquisition and transmission of HIV, the study of syphilis and HIV co-infections has been a focus of renewed interest, particularly among high-risk populations such as MSM.

10.10.1.2 In Malaysia, data are limited for both syphilis and syphilis-HIV co-infection among MSM. A study in 2018 recruited and enrolled 250 participants with MSM. Syphilis prevalence in the sample population was 19.2% and HIV prevalence was 17.6%. With co-infection of HIV and HCV, it is estimated that HCV affects 2-15% of people living with HIV worldwide and up to 90% of those are people who injects drug. In Malaysia, reported HIV/HCV co-infection was 15.1% (518 cases) of total HCV cases in 2019. One case of HIV and HCV co-infection reported from a donor who admitted to injection drug use (Global AIDS monitoring report, 2020)

10.10.1.3 Most of the new HIV infections in 2019 were due to sexual transmission. HBV and HIV are often diagnosed in the same patient because they share similar routes of transmission which is through sexual contact. This is the same case with HIV and Syphilis co-infection where the route of transmission is the same.

10.10.2 Total number of Co-infection TTI seroconvert donors – Figure 10.10.2

In 2022 and 2023, there is no seroconvert donors that did not attend post donation counselling. Thus, all reports received were from Part 1 with PDC and Part 2.

In 2022, 3 reports are from Part 1 with PDC (1 donor with HIV and syphilis, 1 donor with HIV and Hepatitis B and 1 donor with Hepatitis B and Hepatitis C). We also received 6 Part 2 reports in 2022.

For year 2023, there is an increment in part 1 with PDC reports (11 reports) and part 2 reports (9 reports). Out of 11 seroconvert donors from part 1 reports, there is one seroconvert donor with three infections (HIV, hepatitis B and syphilis), while the rest of them only has two infections.

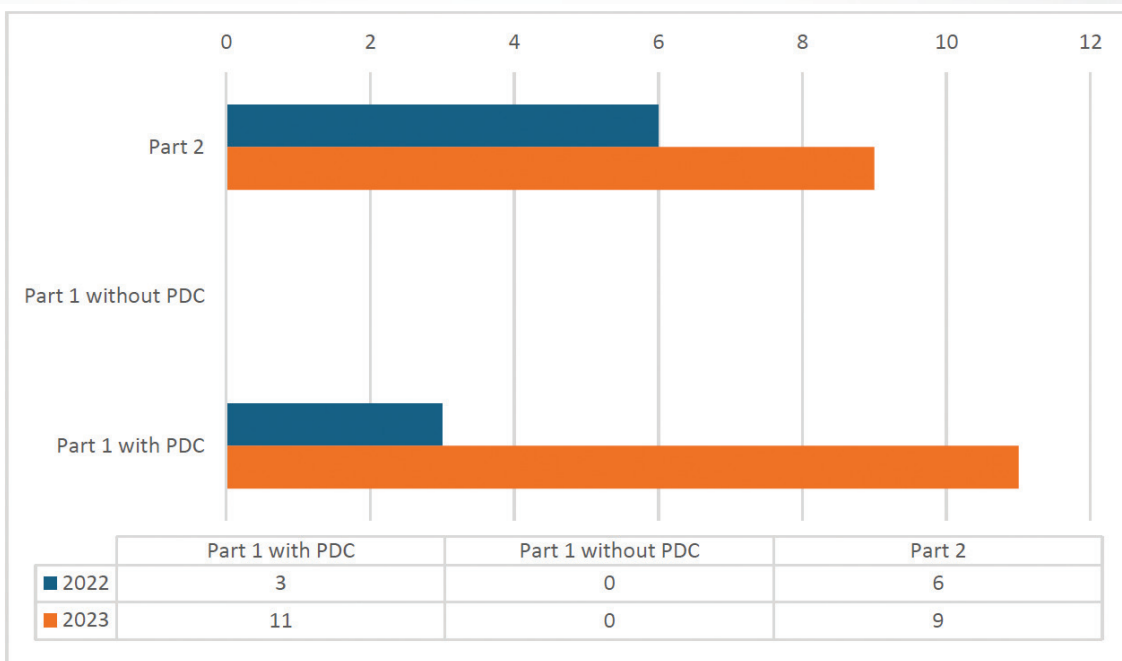


Figure 10.10.2: Total Number of Co-infections TTI Seroconvert Donors in 2022-2023

10.10.3 Demographic/Characteristic of Seroconvert Donors of Co-infection

10.10.3.1 Age

Co-infections were observed mainly in the 20-39 age group, with no cases among individuals older than 60. In 2023, 11 out of 11 cases were in this age group.

10.10.3.2 Gender

Co-infections were more prevalent in males in both years. In 2022, all 3 co-infection cases were in males, while in 2023, 10 out of 11 were males.

10.10.3.3 Frequency of blood donation

The data for co-infections shows that most cases were among donors with fewer than five previous donations. In 2022, all 3 co-infection cases had fewer than five donations, while in 2023, 7 out of 11 had fewer than five donations.

10.10.3.4 Risk Factor

High-risk behaviours were the most common risk factor for co-infections, reported by all 3 individuals in 2022 and 8 out of 11 in 2023.



10.10.4 Summary of Seroconvert Donor for Co-infection – Figure 10.10.4

Co-infections were relatively rare but showed an increase from 3 cases in 2022 to 11 in 2023, with all cases occurring in the 20-39 age group. The majority of co-infections were found in males with fewer than five previous donations, and high-risk behaviours were the most common risk factor, with a significant increase in 2023.

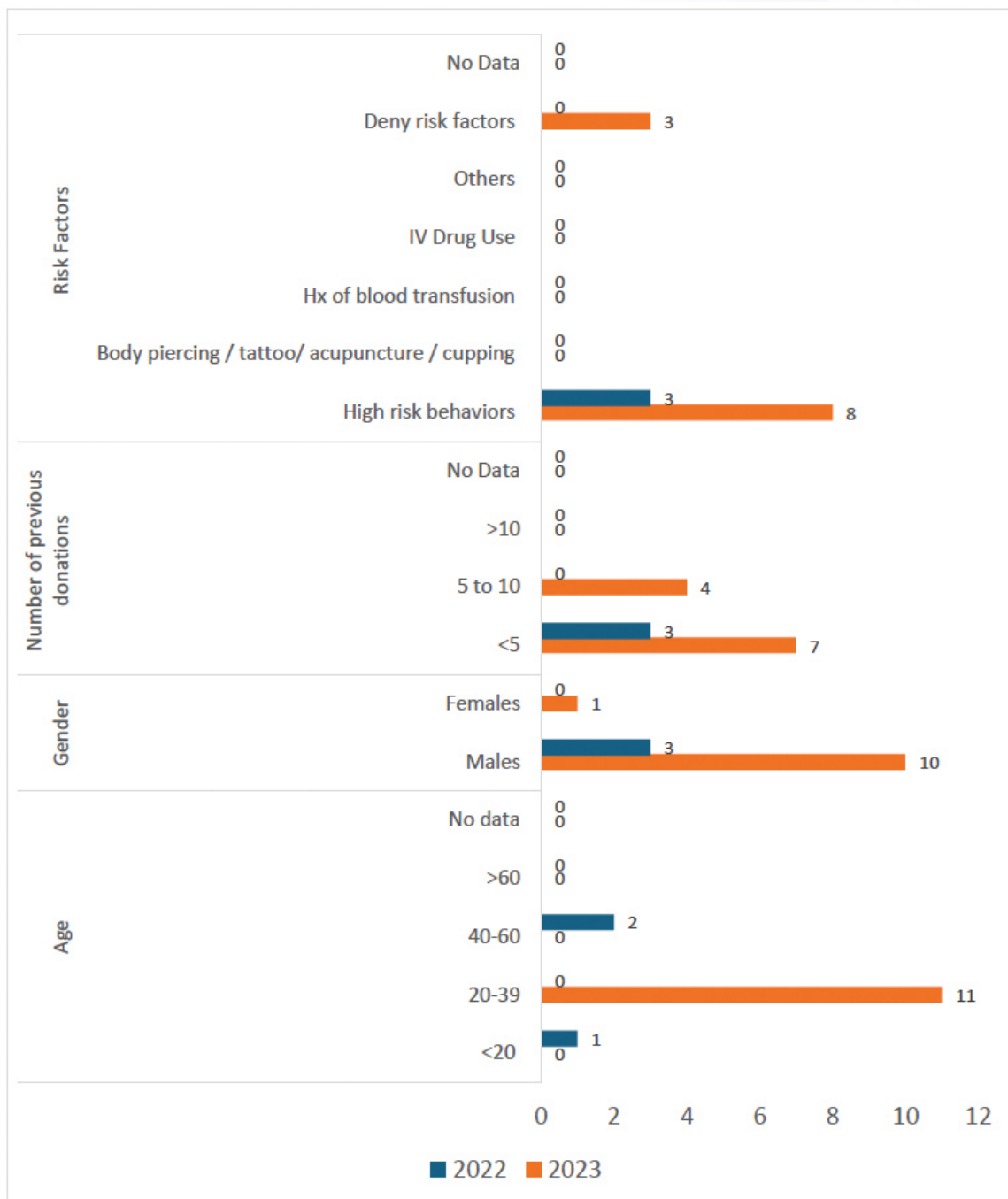


Figure 10.10.4: Demographic Distribution and Risk Factors for Co-infection Seroconvert Donors in Part 1 in 2022 - 2023



10.10.5 Outcome of Lookback and Recall for Co-infection Seroconvert Donors – Figure 10.10.5

A total of 14 blood products were investigated for co-infection in 2022. Out of 14, 4 blood products were transfused to patient. 7 blood products with no information of its outcome, 2 were supplied as CSL and 1 was discarded. Out of 4 blood products that were transfused, 3 patients had passed away and they could not find out the outcome of patients, while 1 patient that they traced tested negative for both HIV and syphilis.

In 2023, 15 out of the 24 blood products that were investigated in 2023 were transfused to patients. The results of 15 blood transfusion testing to recipients revealed that there was no recipients reactive for TTI, 5 recipients tested negative, 4 recipients had already passed away, and 6 reports had no information on recipients’ outcomes.

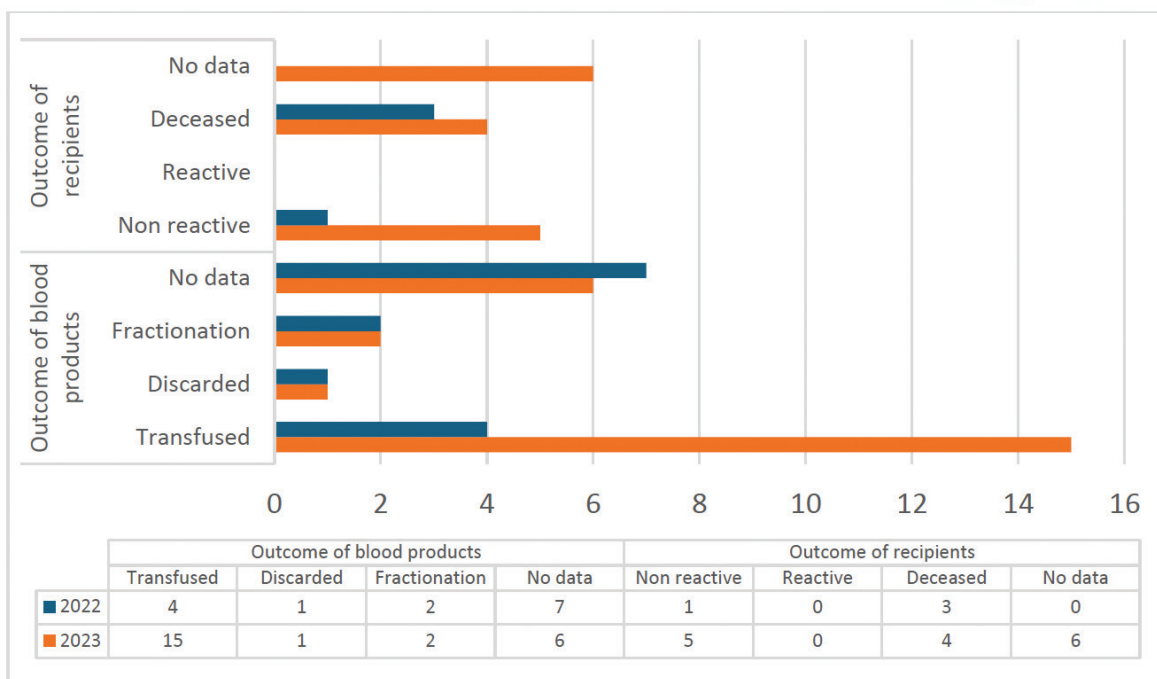


Figure 10.10.5: Outcome of Blood Products and Recipient of Seroconvert Donors for Co-infection in 2022 - 2023



10.11 Summary and Recommendations

The data from 2022 and 2023 shows varying trends in seroconversion for HIV, HBV, HCV, syphilis, and co-infections among blood donors.

- a. HIV: There was a slight decrease in HIV cases, with most infections among males aged 20-39 and primarily associated with high-risk behaviours
- b. HBV: HBV cases remained stable, with a higher prevalence in the 40-60 age group, predominantly among males.
- c. HCV: A decrease in HCV cases was noted, with a majority occurring in the 20-39 age group.
- d. Syphilis: A slight decrease in syphilis cases was observed, with infections primarily in the 20-39 age group.
- e. Co-infections: There was a notable increase in co-infections, particularly in males aged 20-39, linked to high-risk behaviours.

Blood banks should focus on refining donor screening processes, enhancing post-donation monitoring, and implementing targeted risk reduction strategies to minimize the risk of transfusion-transmitted infections. Continued collaboration with public health authorities and investment in research are also crucial in maintaining and improving the safety of the blood supply.



Variables		Seroconvert donor 2022		Seroconvert donor 2023		Seroconvert donor 2022-2023	
		Total (N= 193)	Percentage (%)	Total (N= 192)	Percentage (%)	Total (N= 385)	Percentage (%)
Age	<20	3	1.55	1	0.52	4	1.04
	20 - 39	118	61.14	135	70.31	253	65.71
	40 - 60	72	37.31	53	27.6	125	32.47
	>60	0	0	3	1.57	3	0.78
	No data	0	0	0	0	0	0
Gender	Males	165	85.49	165	85.9	330	85.71
	Females	28	14.51	27	14.1	55	14.29
No. of donations	<5	133	68.91	116	60.42	249	64.68
	5 to 10	34	17.62	46	23.96	80	20.78
	>10	26	13.47	30	15.62	56	14.54
	No data	0	0	0	0	0	0
Risk Factors	High risk behaviours	82	42.49	83	42.78	165	42.64
	Body piercing/ tattoo/ acupuncture/ cupping	16	8.29	20	10.31	36	9.3
	Hx of blood transfusion	0	0	0	0	0	0
	IV Drug Use	1	0.52	2	1.03	3	0.78
	Deny risk factors	55	28.49	55	28.35	110	28.42
	Others	26	13.47	24	12.37	50	12.92
	No data	13	6.74	10	5.16	23	5.94

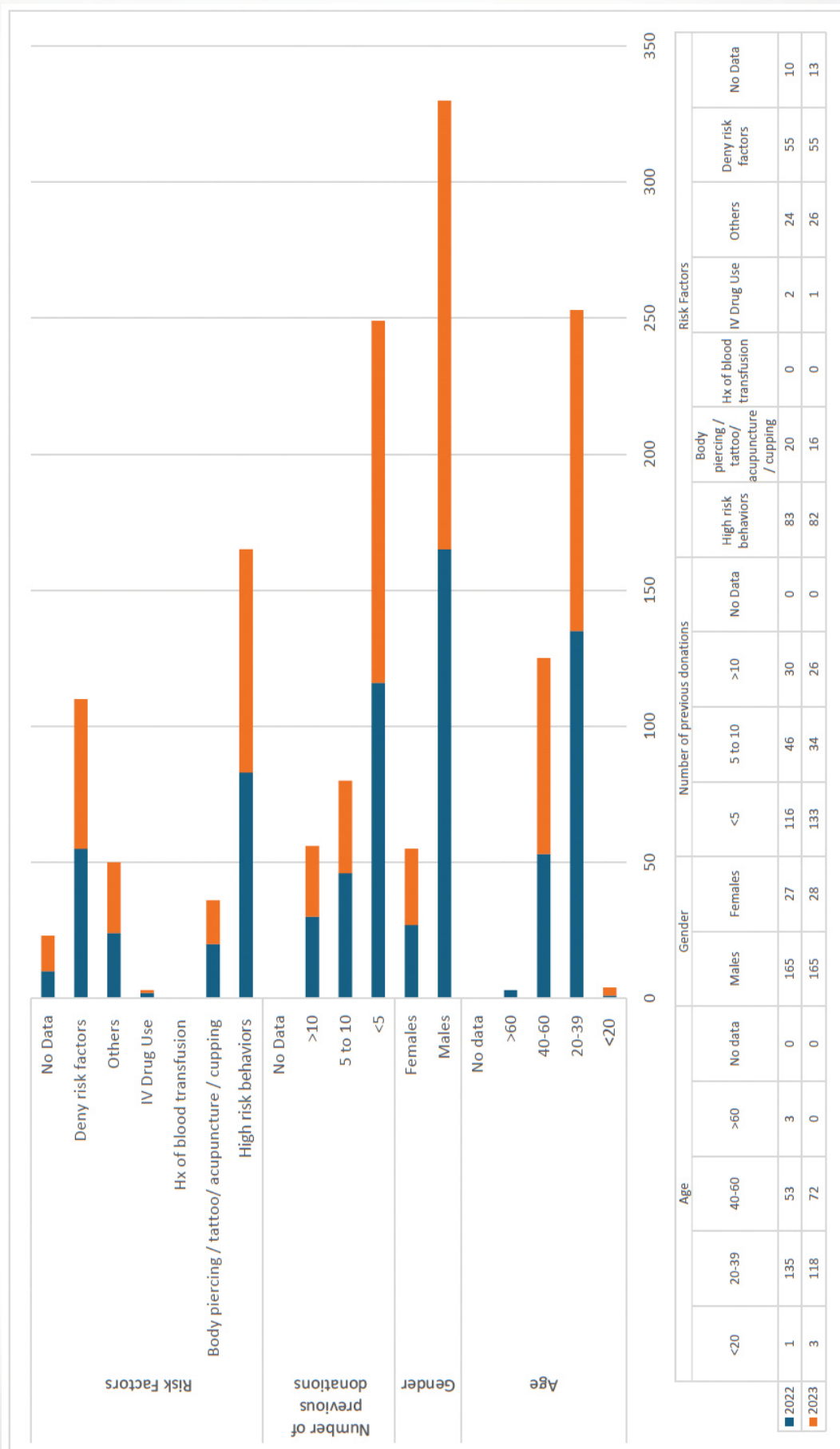


Figure 10.11 : Seroconvert Donor Summary 2022 and 2023



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**National Haemovigilance Coordinating Centre
Pusat Darah Negara**

Jalan Tun Razak

50400 Kuala Lumpur, Malaysia

No. Telefon: 03- 2613 2688

No. Faksimili: 03- 2698 0362

Emel: pdn.nhcc@moh.gov.my

www.pdn.gov.my