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NATIONAL HAEMOVIGILANCE COORDINATING CENTRE
PUSAT DARAH NEGARA

HAEMOVIGILANCE REPORT 2020-2021

NATIONAL TRANSFUSION MEDICINE SERVICE IN MALAYSIA

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Pusat Darah Negara
Ministry of Health Malaysia

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Haemovigilance Report
2020 – 2021
National Transfusion Medicine Service in Malaysia

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ACKNOWLEDGEMENT

The editorial group would like to express our special gratitude to all blood banks in Malaysia which have helped in providing data and information through participation in Haemovigilance Reporting Programme.

FOREWORD

Providing sufficient and secure blood is a crucial component of every blood transfusion service in the nation. The National Haemovigilance Coordinating Centre of Pusat Darah Negara nonetheless managed to compile the third Haemovigilance Report 2020–2021 for the National Transfusion Medicine Service in Malaysia despite the difficult circumstances brought on by the COVID–19 outbreak.

Globally, transfusion medicine is expanding. There is always a need to evaluate the risk to the blood supply and create a corresponding contingency plan. Haemovigilance's ultimate objective is to improve the transfusion chain's quality through corrective and preventive measures. Based on analysis of the incidents and events reported to NHCC, many findings and recommendations have been made. Hence, this has indirectly assisted a growing awareness of the extent and type of adverse events or reactions associated with transfusion practice in Malaysian hospitals.

The National Haemovigilance Coordinating Centre and all contributors deserve special thanks for their outstanding work and contributions that went into creating this report. To ensure the best possible care for patients and donors, I hope that this report is educational and serves as a valuable guide for all parties involved in the transfusion field.

YBRS. DR MOHD AZMAN YACOB
Director
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PREFACE

First and foremost, I would like to thank and congratulate all the contributors and the National Haemovigilance Coordinating Centre for successfully completing this report, especially during this difficult period with the COVID-19 outbreak. The Hemovigilance Report 2020-2021 serves as a document and resource for all medical professionals working in Ministry of Health (MOH) institutions around the nation to ensure that blood is not only available in sufficient amounts but is also safe. In each stage of the blood transfusion chain, this report seeks to identify undesirable events and take measures to prevent their occurrence or recurrence.

The number of reports received was encouraging over the years. The practice of reporting and learning from the analysis of the reports are amongst the widespread strategies used in all MOH hospitals in the country. Hence, this helped to reflect upon what is revealed about gaps and weaknesses of our healthcare system. Human factors played a major role in transfusion errors. The reports indirectly helped in increasing awareness and to be more vigilant in providing safe blood for transfusion.

I hope you will find this report useful in ensuring the best patient care. We are pleased to receive any suggestions and feedback that would enable us to improve and deliver a better-quality service.

DR AFIFAH BINTI HASSAN

Head of National Transfusion Medicine Service
Director
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EXECUTIVE SUMMARY

Haemovigilance, which includes monitoring, identifying, and monitoring into adverse events in the transfusion chain, is a component of the quality management systems of blood establishments. The objective of haemovigilance, according to the World Health Organization (WHO), is to "continuously improve the transfusion chain's quality through corrective and preventive actions to improve donor and patient safety, improve transfusion appropriateness, and reduce wastage."

Haemovigilance reporting is mandatory as stated in the National Transfusion Medicine Policy and mandated in the MSQH Malaysian Hospital Accreditation Standards, 6th Edition, for the accreditation of healthcare institutions. NHCC has observed inconsistencies in monthly reporting, despite improvements in hospitals reporting participation. Underreporting or an absence of cases to report may be the cause of this. To avoid underreporting, the NHCC requires that hospitals submit monthly reports using the standard letter for notifying adverse events (Laporan bulanan hemovigilan), even if there are no cases to report.

Haemovigilance is critical for data-driven changes in transfusion practise and is essential to the quality assurance procedures used across the transfusion chain. Haemovigilance enables the implementation of prevention strategies by facilitating the identification of risk factors for adverse reactions.

According to hemovigilance data, the top three reported adverse reactions associated with blood transfusions remain to be mild allergic reaction, febrile non haemolytic transfusion reaction (FNHTR), and uncommon complications of transfusion. Administering filtered blood could decrease the incidence of these undesirable events. Recent reports showed cases of transfusion-associated circulatory overload (TACO) have increased, and few cases have causes morbidity and mortality. The SHOT UK report has shared risk-reduction strategies that can be implemented with identification of at-risk patients to reduce the adverse event.

The incidence of transfusion error is similar to the previous year's data. Deficiency in positive patient identification during collection of samples has led to a significant number of near-miss incidents. However patient's historical record with the blood bank enabled the error to be discovered before blood transfusion took place. Yet, this shortcoming has resulted in transfusion errors when blood is administered to patients. To prevent errors, it is crucial to enforce appropriate patient identification procedure and emphasise the importance of taking blood from only one patient at a time.

In comparison to a clinical setting, a blood bank has a low near-miss rate. However, blood banks have high incidence of actual error during pretransfusion testing. It is crucial to handle one sample at a time to prevent the mixing of samples. Releasing of blood should only occur after secondary checks have been done to prevent errors. The most common contributing factors reported from the hospital and suggested steps to be performed by them to reduce the error have been outlined in this report. Through this, hospitals can strengthen their procedure by learning from other hospitals' errors.

The most frequent reported adverse donor event is a vasovagal reaction, followed by a hematoma, and these findings were consistent with earlier reports. The vasovagal adverse event could be reduced by improving post donation care and providing physiological and psychological support to donors throughout the donation process. Ongoing phlebotomy training is crucial to improve skill and lower the risk of haematoma.

Upon seroconversion of blood donors to a transfusion-transmitted infection, a lookback and recall procedure is initiated. According to data, Syphilis is the leading cause of reported seroconversions, followed by HIV and HBV, and the least common are HCV and co-infections.

Male donors between the ages of 20 and 39 and donation frequency of less than 5 times had a higher seroconversion risk. To encourage self-declaration of at-risk behaviour that could threaten blood safety, donor awareness and education are crucial.

NHCC hopes that this report will encourage preventative measures and quality procedure improvement, or serve as a foundation for new or improved regulations and recommendations. Therefore, to increase transfusion safety, all healthcare personnels participating in the transfusion chain should be made aware of this report.

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ABBREVIATIONS (A to Z)

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

CHAPTER

01

INTRODUCTION

1.1 NATIONAL HAEMOVIGILANCE COORDINATING CENTRE (NHCC)

1.1.1 The National Haemovigilance Coordinating Centre, which was established under the management of the National Blood Centre (NBC) in 2003 with the objectives of making blood transfusion safer, effective, and efficient, has developed a system in which all transfusion-related complications, both from the donor and the recipient, are reported and analysed, contributing to the advancement of transfusion safety in Malaysia over the past 17 years.

1.1.2 NHCC is responsible for the management of the scheme reviews and verifies reports received from hospitals. Where required, additional information is sought to accurately classify the type of adverse event, imputability, and severity of the case. NHCC has published 2 biennial reports previously for 2016 – 2017 and 2018 – 2019 and this third book which reporting all adverse events occurred starting from 1 January 2020 to 31 December 2021.

1.2 OBJECTIVES

1.2.1 NHCC alongside Patient Safety Council is committed to safeguards the transfusion of blood and blood products as stated in Goal 6 of The Malaysian Patient Safety Goals (MPSG). The key elements of a safe and high-quality transfusion programme are primarily to ensure the provision of universal access to safe, quality, and efficacious blood and blood products for transfusion. Therefore, these have become our vision and mission to present an evidence base report to promote advancement in Transfusion Medicine Service in Malaysia.

1.3 DEFINITION OF HAEMOVIGILANCE

1.3.1 Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence (WHO).

1.4 CHALLENGES IN BLOOD TRANSFUSION SURVEILLANCE DURING COVID-19 PANDEMIC

1.4.1 Although reporting to NHCC seem subsidiary amidst the COVID-19 pandemic, where the hospital blood bank experienced a blood collection shortage and contend to meet blood supply demand while the clinical side battling everyday giving the best care to patient, continuous reporting of adverse events while adapting to new normal must maintain to improve existing practices during the pandemic.

1.4.2 The extent of lockdowns, home quarantines, and the redeployment of health staff between departments, and even from one hospital to other healthcare facilities, has presented a challenge to the NHCC team in terms of tracking and following up on incomplete reports. Thanks to the dedication and cooperation of all participating hospitals, NHCC successfully collected and compiled the 2020-2021 haemovigilance report.

1.5 REPORTING PROCESS AND LIMITATION IN DATA ANALYSIS

1.5.1 The report consists of adverse event related to blood transfusion process right from blood collection to post transfusion. The report submission deadline, which had been set for March 31st of the following year, was changed to June 30th because of the pandemic.

1.5.2 Reports received were reviewed and either marked as verified or pending if they contained insufficient information. The corresponding reporter need to resubmit the details required within the given report submission period. A verified report is a report which provides sufficient details for NHCC to proceed with data analysis. In 2020, total number of cases analysed were 7338 while in 2021 were 6639.

1.6 REPORTING STEPS OF AN ADVERSE EVENT TO NHCC

1.6.1 Table below shows 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 is reporting?

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

02

PARTICIPATION OF HAEMOVIGILANCE REPORTING

2.1 OVERVIEW OF HAEMOVIGILANCE REPORTING – Figure 2.1

2.1.1 Haemovigilance reporting in Malaysia continue to increase yearly with slight reduction of reports received in 2019 due to the unprecedented COVID-19 pandemic in December 2019 which later affected the total report received before closing date on 31st March 2020. Therefore in 2020, NHCC extended the dateline to 30th June and this measure recorded a substantial increase in total number of reporting.

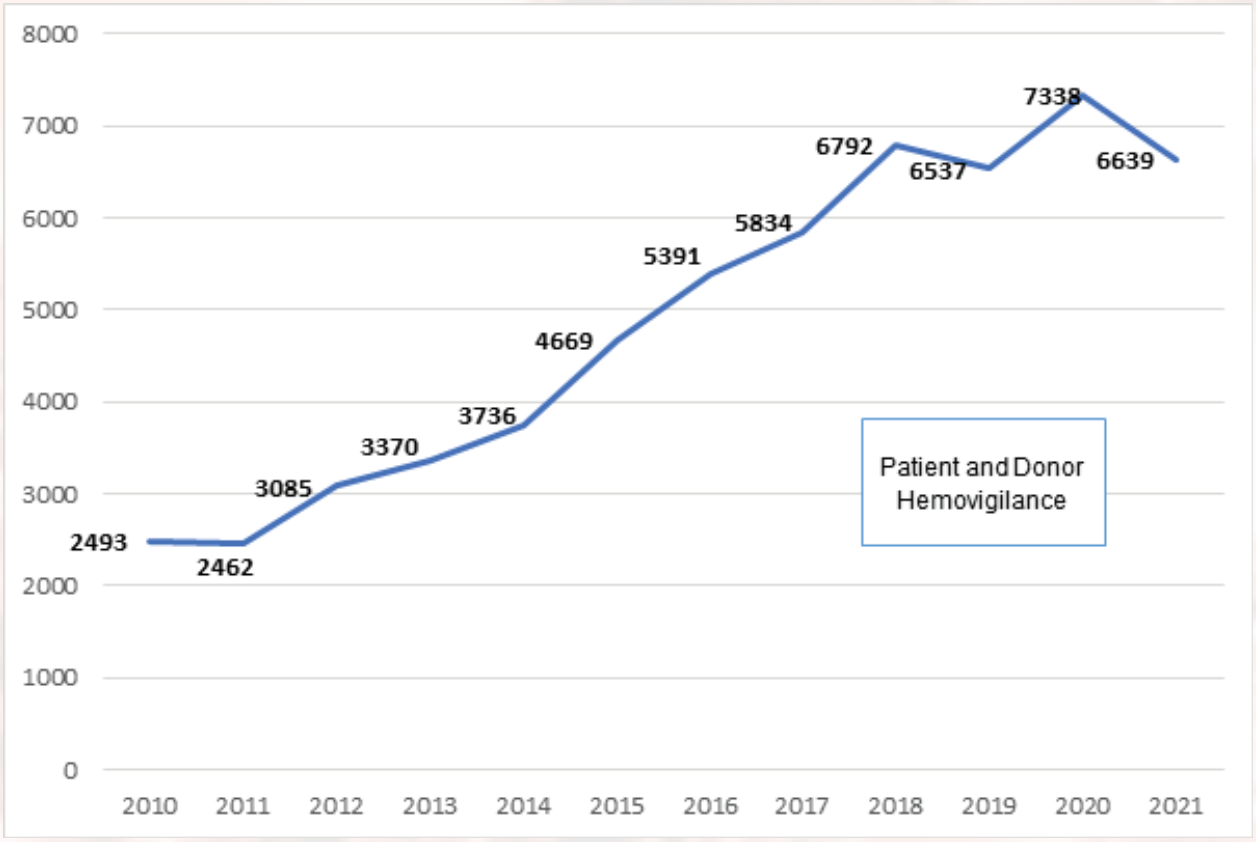
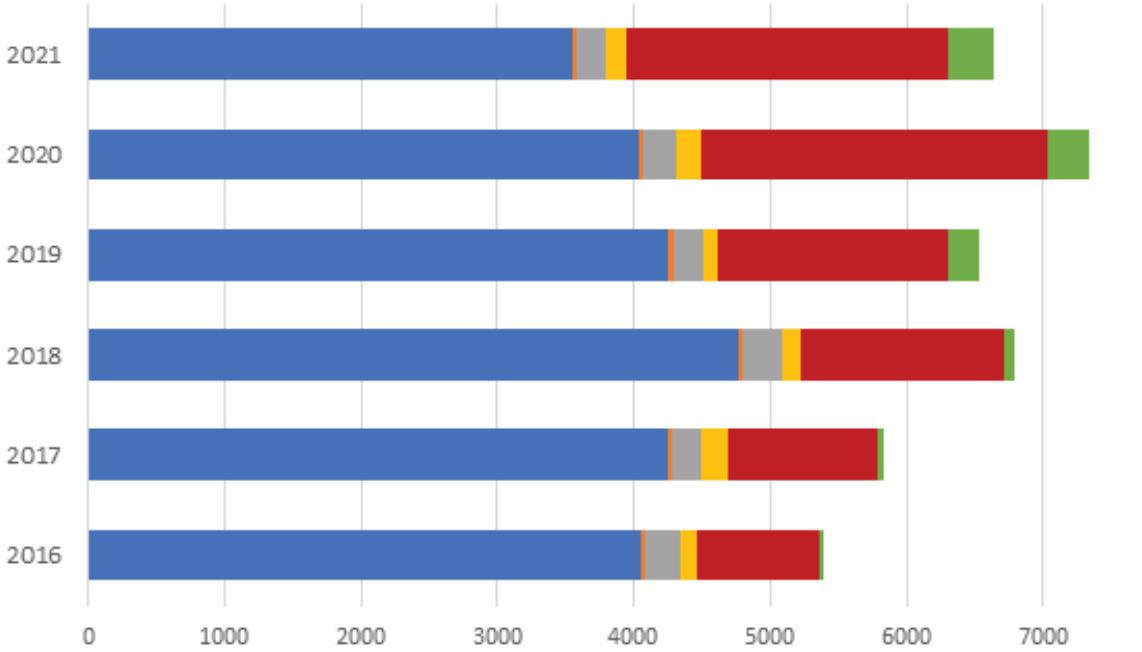


Figure 2.1: Total Number of Haemovigilance Reports Received from 2020 – 2021

2.2 TYPE OF ADVERSE EVENTS – Figure 2.2

2.2.1 Patient haemovigilance reports in 2020 and 2021 comprised of 61% (4498) and 59% (3944) respectively from the total report submitted to NHCC. These reports are Adverse Transfusion Reaction (ATR), Incorrect Blood Component Transfused (IBCT), Near Miss (NM) and Incident. More than 99% of adverse events were attributed to ATR while IBCT showed the least reported event of less than 1% for the past years.

2.2.2 Donor haemovigilance reports submitted to NHCC are Adverse Donor Reaction (ADR) and Seroconvert Donor (SD) which comprised of 39% (2840) from the total report in 2020 and of 41% (2695) in 2021. More than 94% of the report attributed to ADR.



	2016	2017	2018	2019	2020	2021
ATR	4049	4245	4766	4247	4042	3549
IBCT	38	35	34	52	30	33
NM	260	219	288	211	245	218
INCIDENTS	110	186	128	98	181	144
ADR	896	1100	1492	1694	2530	2357
SD	38	49	84	235	310	338

Figure 2.2: Total number of Adverse Transfusion Reaction (ATR), Incorrect Blood Component transfused (IBCT), Near Misses (NM), Incident, Adverse Donor Reaction (ADR) and Seroconvert Donor (SD) reported to NHCC from 2016 – 2021

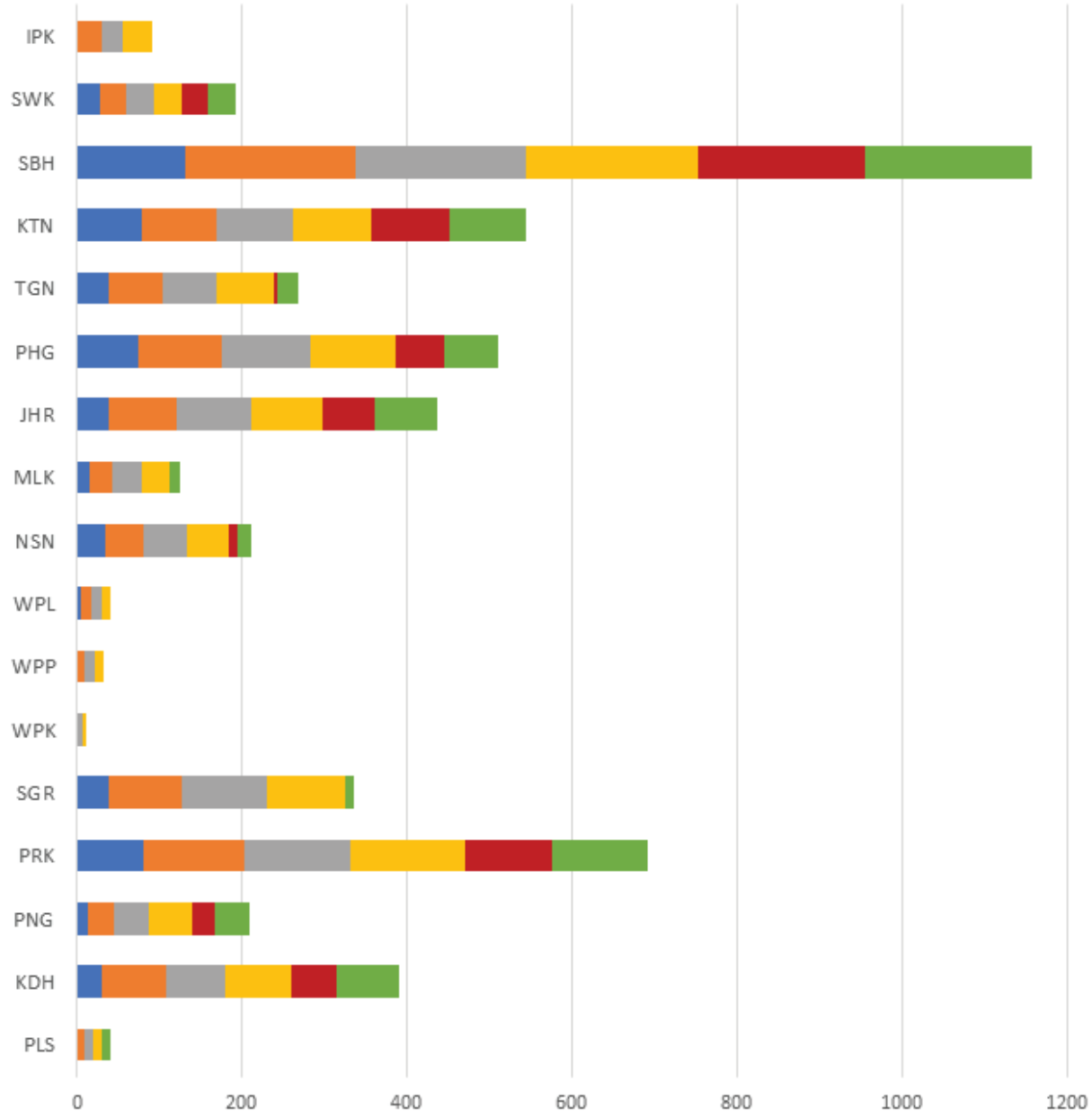
2.3 REPORTED NO CASES OF ADVERSE EVENT (AE) – Figure 2.3.1, 2.3.2a, 2.3.2b

2.3.1 In occasion of no cases for any type of adverse event occurred in the hospital for the particular reporting month, NHCC will count and categorize those reports as Reported No Cases of Adverse Event. This is to differentiate between no case to report and non-participation in reporting. Therefore, IBCT was frequently reported as no cases occurred in many hospitals for each month in 2020 and 2021.

	ATR	IBCT	NM	INCIDENT	ADR	SD
No Case of AE in 2020	608	1121	1043	1090	656	776
No Case of AE in 2021	519	1120	1022	1043	607	780

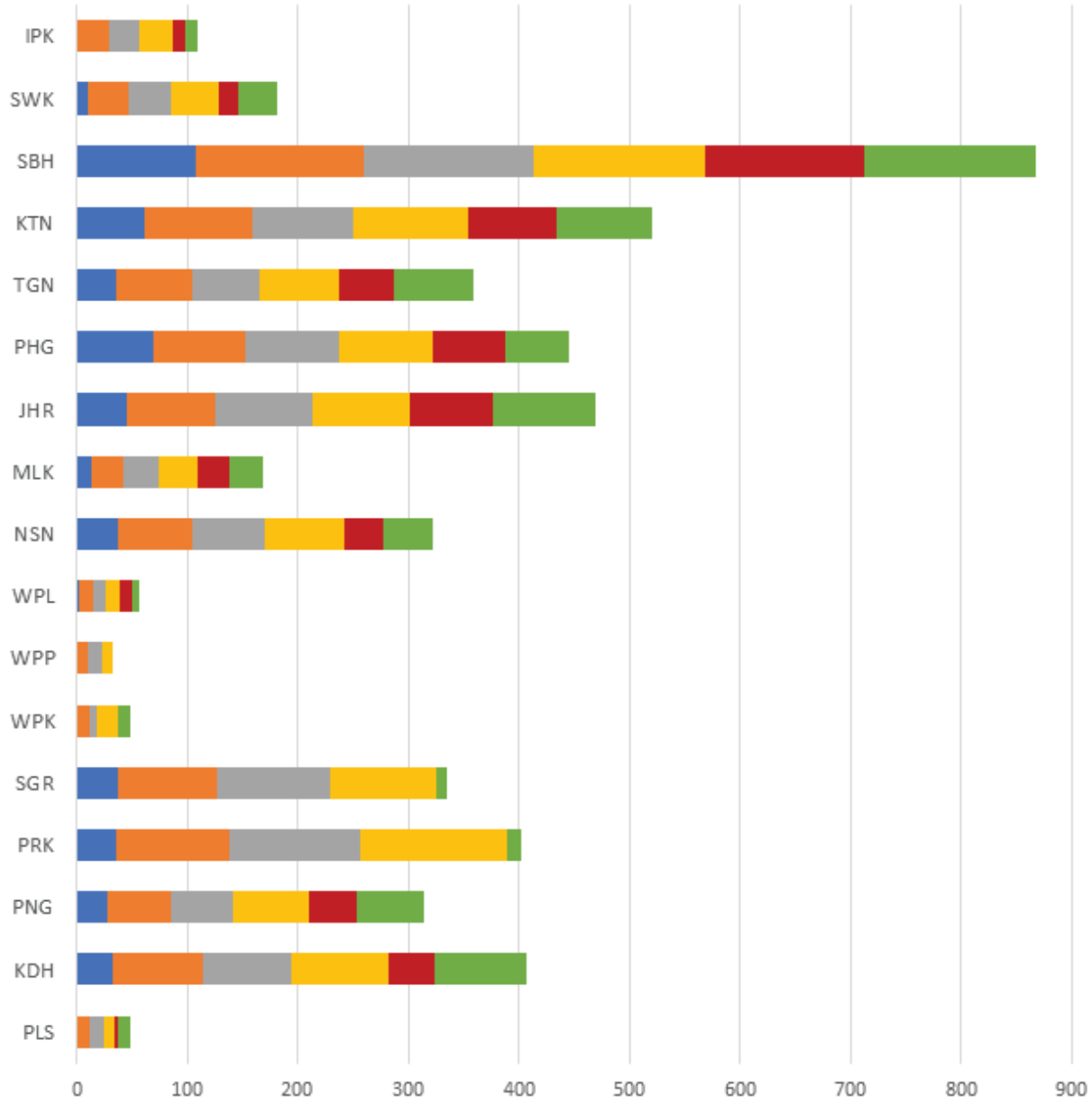
Figure 2.3.1: Total Number of Reported No Case of Adverse Event (ATR, IBCT, NM and Incident, ADR and SD) in 2020 and 2021

2.3.2 Total number of reported No Case of Adverse Event were highly dependent to total number of hospitals in each state and their participation of reporting as shown in Figure 2.3.2. For example, Sabah and Sarawak have 22 hospitals in their state. Only one hospital in Sarawak compared to 14 out of 22 hospitals in Sabah reported No Case of Adverse Event throughout the 12 months in 2020. Thus, the total number of No Case of Adverse Event reported in Sarawak was significantly lower than Sabah. However, this data could not capture an incomplete participation or no participation at all.



	PLS	KDH	PNG	PRK	SGR	WPK	WPP	WPL	NSN	MLK	JHR	PHG	TGN	KTN	SBH	SWK	IPK
ATR	0	31	13	80	38	0	0	6	34	15	39	75	39	78	131	28	1
NM	10	78	33	123	89	2	10	12	48	28	83	100	66	91	208	33	29
INC	10	71	42	129	103	5	11	12	51	35	89	109	64	94	206	33	26
IBCT	10	81	53	139	95	5	12	12	51	34	87	102	70	94	208	33	35
ADR	1	53	27	106	0	0	0	0	10	1	64	60	5	94	202	33	0
SD	10	77	42	114	10	0	0	0	17	12	76	65	24	94	202	33	0

Figure 2.3.2a: Total Number of Reported No Case in Adverse Event (ATR, IBCT, NM, and Incident, ADR and SD) by States in 2020



	PLS	KDH	PNG	PRK	SGR	WPK	WPP	WPL	NSN	MLK	JHR	PHG	TGN	KTN	SBH	SWK	IPK
ATR	0	32	28	36	38	0	0	3	38	13	45	69	36	62	108	11	0
NM	12	83	57	103	89	12	11	12	66	29	81	84	68	97	152	36	30
INC	12	79	57	118	103	7	12	12	67	32	87	85	62	91	154	39	26
IBCT	11	88	69	132	95	18	10	12	71	36	89	85	71	105	154	43	31
ADR	2	42	43	1	0	0	0	12	35	29	74	65	50	80	145	17	12
SD	11	83	61	12	10	11	0	6	46	30	94	58	72	85	155	35	11

Figure 2.3.2b: Total Number of Reported No Case in Adverse Event (ATR, IBCT, NM, and Incident, ADR and SD) by States in 2021

2.4 PARTICIPATION TO HAEMOVIGILANCE REPORTING

2.4.1 Haemovigilance reporting is participated by the blood banks from government hospitals, private hospitals, university hospital, military hospital and institutions. Hospital must send the summary of monthly adverse event to NHCC using the Haemovigilance Monthly Report (Appendix 1). This assists NHCC to monitor participation and improve data accuracy.

2.4.2 Depending on the report provided to NHCC for the reporting year, hospitals are categorized into three participation groups. No report received (NRR) refers to hospitals that didn't submit any reports throughout the entire year. Hospitals that submitted their reports in full for the whole reporting year are categorised as complete, while those that only sent their reports for one or more months of the reporting year are categorised as incomplete.

2.4.3 Participation in 2021 was slightly less than 2020 with 12% reduced in "complete participation" while "incomplete participation" and NRR increased to 18% and 23% respectively. The NHCC commends Melaka and Terengganu for their dedication to reporting for two years in a row.

2.4.4 NHCC would like to disclose the participation information in the table below as an encouragement to all hospitals to start reporting if never did and to maintain reporting in order to improve the quality of blood transfusion service in Malaysia. This information could help blood banks to understand their own level of 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	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
1	Perlis	Hospital Tuanku Fauziah Kangar	State Hospital		*		*		*		

KEDAH (KDH)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
11	Pulau Pinang	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	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	Minor 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		*	*				*	

WILAYAH PERSEKUTUAN (WPK)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
43	Wilayah Perse-kutuan	Hospital Kuala Lumpur	State Hospital	*			*			*	
43a		Hospital Tuanku Azizah	Major Specialist	*			*			*	
44		Hospital Putrajaya	Major Specialist		*	*			*		
45		Hospital Labuan	Minor Specialist		*	*			*		

NEGERI SEMBILAN (NSN)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
46	Negeri Sembilan	Hospital Tuanku Jaafar, Seremban	State Hospital	*			*		*		
47		Hospital Tuanku Ampuan Najihah, Kuala Pilah	Major Specialist		*	*			*		
48		Hospital Tampin	Minor Specialist		*	*			*		
49		Hospital Port Dickson	Minor Specialist		*	*			*		
50		Hospital Jelebu	Non Specialist		*	*				*	
51		Hospital Jempol	Non Specialist		*	*			*		

MELAKA (MLK)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
52	Melaka	Hospital Melaka	State Hospital	*		*			*		
53		Hospital Alor Gajah	Non Specialist		*	*			*		
54		Hospital Jasin	Non Specialist		*	*			*		

JOHOR (JHR)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
55	Johor	Hospital Sultanah Aminah, Johor Bahru	State Hospital	*			*		*		
56		Hospital Sultan Ismail, Johor Bahru	Major Specialist		*	*			*		
57		Hospital Pakar Sultanah Fatimah,Muar	Major Specialist		*	*				*	
58		Hospital Sultanah Nora Ismail, Batu Pahat	Major Specialist	*			*			*	
59		Hospital Segamat	Major Specialist		*		*			*	
60		Hospital Enche' Besar Hajah Khalsom, Kluang	Minor Specialist		*		*		*		
61		Hospital Kota Tinggi	Minor Specialist		*		*			*	
62		Hospital Pontian	Non Specialist		*		*				*
63		Hospital Mersing	Non Specialist		*	*			*		
64		Hospital Tangkak	Non Specialist		*	*			*		
65		Hospital Maharaja Tun Ibrahim, Kulai	Non Specialist		*		*		*		

PAHANG (PHG)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
66	Pahang	Hospital Tengku Ampuan Afzan, Kuantan	State Hospital	*			*			*	
67		Hospital Sultan Haji Ahmad Shah, Temerloh	Major Specialist	*			*			*	
68		Hospital Pekan	Minor Specialist		*	*				*	
69		Hospital Kuala Lipis	Minor Specialist		*	*			*		
70		Hospital Bentong	Minor Specialist		*	*				*	
71		Hospital Raub	Non Specialist		*	*				*	
72		Hospital Jerantut	Non Specialist		*	*			*		
73		Hospital Jengka	Non Specialist		*		*			*	
74		Hospital Muadzam Shah	Non Specialist		*	*			*		
75		Hospital Sultanah Kalsom Cameron Highland	Non Specialist		*	*				*	
76		Hospital Rompin	Non Specialist		*	*				*	

TERENGGANU (TRG)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
77	Terengganu	Hospital Sultanah Nur Zahirah, Kuala Terengganu	State Hospital	*		*			*		
78		Hospital Kemaman	Major Specialist		*	*			*		
79		Hospital Dungun	Minor Specialist		*	*			*		
80		Hospital Besut	Non Specialist		*	*			*		
81		Hospital Hulu Terengganu	Non Specialist		*	*			*		
82		Hospital Setiu	Non Specialist		*	*			*		

KELANTAN (KTN)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
83	Kelantan	Hospital Raja Perempuan Zainab II, Kota Bahru	State Hospital	*			*		*		
84		Hospital Kuala Krai	Major Specialist		*		*			*	
85		Hospital Tanah Merah	Major Specialist		*	*			*		
86		Hospital Gua Musang	Minor Specialist		*	*			*		
87		Hospital Machang	Non Specialist		*	*				*	
88		Hospital Tumpat	Non Specialist		*	*			*		
89		Hospital Pasir Mas	Non Specialist		*	*			*		
90		Hospital Tengku Anis, Pasir Puteh	Non Specialist		*	*				*	
91		Hospital Jeli	Non Specialist		*	*			*		

SABAH (SBH)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
92	Sabah	Hospital Queen Elizabeth I, Kota Kinabalu	State Hospital		*		*		*		
93		Hospital Queen Elizabeth II, Kota Kinabalu	Major Specialist	*			*			*	
94		Hospital Duchess of Kent, Sandakan	Major Specialist	*			*		*		
95		Hospital Tawau	Major Specialist	*			*			*	
96		Hospital Beaufort	Minor Specialist		*	*			*		
97		Hospital Keningau	Minor Specialist		*	*			*		
98		Hospital Lahad Datu	Minor Specialist		*	*					*
99		Hospital Kota Marudu	Minor Specialist		*	*					*
100		Hospital Kota Belud	Non Specialist		*	*				*	
101		Hospital Kudat	Non Specialist		*			*			*
102		Hospital Papar	Non Specialist		*	*					*
103		Hospital Ranau	Non Specialist		*	*			*		

104		Hospital Semporna	Non Specialist		*	*				*	
105		Hospital Tambunan	Non Specialist		*	*					*
106		Hospital Tenom	Non Specialist		*	*			*		
107		Hospital Sipitang	Non Specialist		*	*				*	
108		Hospital Beluran	Non Specialist		*			*		*	
109		Hospital Kinabatangan	Non Specialist		*	*				*	
110		Hospital Kuala Penyu	Non Specialist		*			*			*
111		Hospital Kunak	Non Specialist		*	*				*	
112		Hospital Pitas	Non Specialist		*	*				*	
113		Hospital Tuaran	Non Specialist		*		*			*	

SARAWAK (SWK)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
114	Sarawak	Hospital Umum Sarawak	State Hospital	*			*			*	
115		Pusat Jantung Sarawak	Major Specialist		*			*			*
116		Hospital Sibu	Major Specialist	*			*			*	
117		Hospital Miri	Major Specialist	*			*			*	
118		Hospital Bintulu	Major Specialist		*			*			*
119		Hospital Sri Aman	Minor Specialist		*		*			*	
120		Hospital Limbang	Minor Specialist		*			*			*
121		Hospital Sarikei	Minor Specialist		*			*			*
122		Hospital Kapit	Minor Specialist		*			*			*
123		Hospital Mukah	Minor Specialist		*		*				*
124		Hospital Serian	Non Specialist		*			*			*
125		Hospital Lundu	Non Specialist		*			*			*
126		Hospital Saratok	Non Specialist		*			*			*
127		Hospital Kanowit	Non Specialist		*			*			*

128		Hospital Marudi	Non Specialist		*			*			*
129		Hospital Lawas	Non Specialist		*			*			*
130		Hospital Bau	Non Specialist		*			*			*
131		Hospital Simunjan	Non Specialist		*			*			*
132		Hospital Betong	Non Specialist		*			*			*
133		Hospital Daro	Non Specialist		*			*			*
134		Hospital Rajah Charles Brooke Memorial	Non Specialist		*			*			*
135		Hospital Dalat	Non Specialist		*	*				*	

INSTITUT PERUBATAN KHAS (IPK)

No	States	Hospital	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
136	Institut Perubatan Khas	Hospital Wanita dan Kanak-kanak, Likas	Special Medical Institution		*		*		*		
137		Institut Kanser Negara	Special Medical Institution		*	*			*		
138		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	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
1	Perlis	Hospital Tuanku Fauziah, Kangar	State Hospital		*	*			*		

KEDAH (KDH)

No	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
11	Pulau Pinang	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	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	Non Specialist		*			*	*		

		Batu Gajah									
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	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
30	Selangor	Hospital Tengku Ampuan Rahimah, Klang	State Hospital	*		*			*		

WILAYAH PERSEKUTUAN (WPK)

No	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
31	Wilayah Perseku-tuan	Pusat Darah Negara	Special Medical Institution	*		*			*		
32		Hospital Labuan	Minor Specialist		*			*	*		

NEGERI SEMBILAN (NSN)

No	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
37	Melaka	Hospital Melaka	State Hospital	*		*			*		

JOHOR (JHR)

No	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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			*			*	*		
61		Hospital Besut	Non Specialist		*			*	*		
62		Hospital Hulu Terengganu	Non Specialist		*			*	*		

KELANTAN (KTN)

No	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
63	Kelantan	Hospital Raja Perempuan Zainab II, Kota Bahru	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	States	Hospital	Collection Center	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	States	Hospital	Collection Center	Mode of Reporting		Report submission 2020			Report submission 2021		
				BBISv2	Form	Complete	Incomplete	NRR	Complete	Incomplete	NRR
93	Sarawak	Hospital Umum Sarawak	State Hospital	*		*				*	
94		Pusat Jantung Sarawak	Major Specialist		*			*			*
95		Hospital Sibu	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	States	Collection Center	Hospital Category	Mode of Reporting		Report submission 2020			Report submission 2021		
				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	2020				2021			
STATE	ATR	IBCT	NM	Incident	ATR	IBCT	NM	Incident
PLS	139	0	0	0	120	1	0	0
KDH	327	2	17	14	320	6	19	6
PNG	361	4	56	19	317	1	26	20
PRK	346	1	13	14	345	1	14	10
SGR	509	1	42	40	444	2	41	22
WPK	284	2	16	18	272	3	11	12
NSN	229	1	0	3	150	0	10	2
MLK	242	1	9	1	149	0	9	6
JHR	385	5	17	11	368	8	19	8
PHG	170	2	3	22	97	0	3	5
TGN	186	2	8	7	159	1	9	11
KTN	104	0	10	9	108	1	12	16
SBH	271	4	7	13	240	2	3	16
SWK	206	2	11	10	179	3	10	10
IPK	116	0	0	0	90	0	0	0
MOD	14	0	0	0	4	1	0	0
UNI	60	3	36	0	112	2	30	0
PVT	93	0	0	0	75	1	2	0
Total	4042	30	245	181	3549	33	218	144

Table 2.5.1: No of Patient Haemovigilance Reports Submitted by States in 2020 – 2021

2.5.2 The rate of adverse event per 10,000 blood components issued in Malaysia decreased from 77 in 2020 to 70 in 2021 corresponding to lesser number of total blood component issued in 2021.

YEAR	2020			2021		
STATE	Total Component Issued	No. of Adverse Event	Rate/10000 component Issued	Total Component Issued	No. of Adverse Event	Rate/10000 component Issued
PLS	8647	139	161	8180	121	148
KDH	44981	360	80	45420	351	77
PNG	37461	440	118	34224	364	106
PRK	43961	374	85	47455	370	78
SGR	88927	592	67	75744	512	68
WPK	34861	320	92	37544	299	80
NSN	30635	233	76	27765	162	58
MLK	18464	253	137	17649	166	94
JHR	61025	418	68	59311	403	68
PHG	25372	197	78	26340	105	40
TGN	21122	203	96	20368	180	88
KTN	28295	123	43	23544	137	42
SBH	62532	295	47	60386	261	43
SWK	33233	229	69	34601	210	61
Total	539516	4176	77	518531	3641	70

Table 2.5.2: Rate of Adverse event per 10,000 blood components issued by states in 2020 – 2021

**1. This data only includes government hospital blood banks*
**2. Total patient adverse event in 2020 was 4498. Another 322 cases were from non MOH hospitals (Private, Institution, University)*
**3. Total patient adverse event in 2021 was 3944. Another 303 cases were from non MOH hospitals (Private, Institution, University)*

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	2020		2021	
STATE	ADR	Seroconvert (Part 1 + Part 2)	ADR	Seroconvert (Part 1 + Part 2)
PLS	33	2	42	1
KDH	113	20	123	34
PNG	492	18	313	24
PRK	332	42	398	61
SGR	64	6	28	0
WPK	758	140	823	138
NSN	21	0	29	2
MLK	30	5	17	14
JHR	324	49	242	24
PHG	47	10	35	13
TGN	81	0	66	1
KTN	18	2	32	12
SBH	69	0	83	3
SWK	148	16	126	11
Total	2530	310	2537	338

Table 2.5.3: No. of Donor Haemovigilance Reports Submitted by States in 2020 – 2021

2.5.4 The rate of adverse donor reaction per 10,000 blood collection in Malaysia slightly decreased from 39 in 2020 to 36 in 2021.

YEAR	2020			2021		
STATE	Total Blood Collection	No. of ADR	Rate/10000 Blood Collection	Total Blood Collection	No. of ADR	Rate/10000 Blood Collection
PLS	8738	33	38	8633	42	49
KDH	43403	113	26	45333	123	27
PNG	42325	492	116	40183	313	78
PRK	53231	332	62	56550	398	70
SGR	29591	64	22	26212	28	11
WPK	171106	758	44	174871	823	47
WPL	1262	0	0	1525	0	0
NSN	23434	21	9	21078	29	14
MLK	27907	30	11	28108	17	6
JHR	70751	324	46	68677	242	35
PHG	27306	47	17	26850	35	13
TGN	19429	81	42	19956	66	33
KTN	22095	18	8	20600	32	16
SBH	68741	69	10	64565	83	13
SWK	45750	148	33	45202	126	28
Total	655069	2530	39	648343	2357	36

Table 2.5.4: Rate of Adverse Donor Reaction per 10,000 Blood Collection by States in 2020 – 2021

**1. This data only includes government hospital blood banks*

CHAPTER

03

TRANSFUSION ERROR

3.1 DEFINITION OF ERRORS

3.1.1 According to the Malaysian 4th 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 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. In this report, near miss and actual errors are analysed together since it is crucial to recognise a near miss as a warning event that requires action to avoid the actual error from occurring.

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

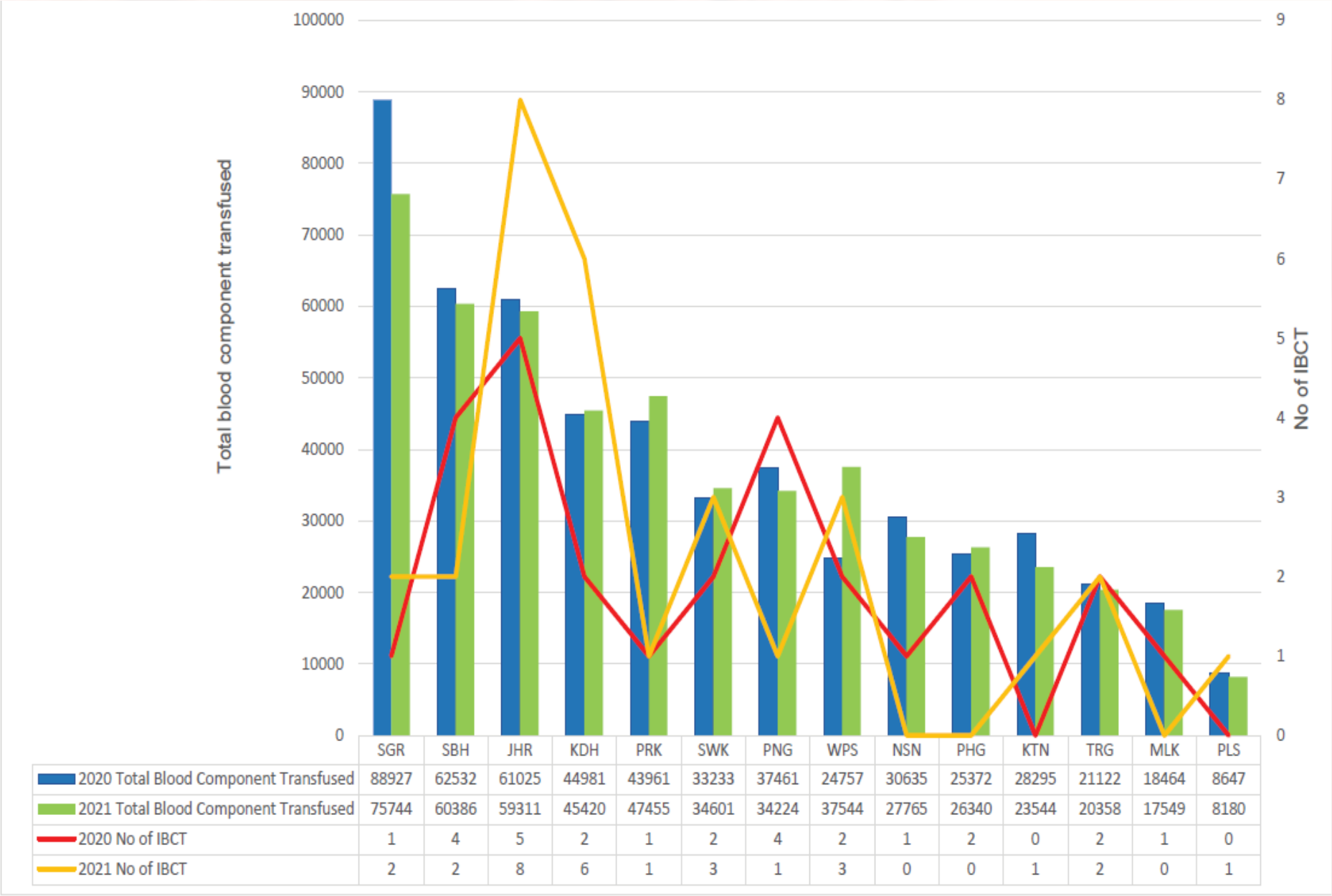
The total number of blood components transfused for hospital blood banks under MOH for 2020 and 2021 were 529,412 and 518,421 respectively. The incidence of IBCT in relation to the number of blood components transfused was less than 1 in 10,000 blood components transfused for both years. Meanwhile, the incidence of NM in relation to the number of blood components transfused was 5 in 10,000 in 2020 and 4 in 10,000 in 2021.

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

3.2.1.1 Selangor, Sabah, and Johor were three states that have transfused more than 50,000 blood components. Selangor reported the highest incidence of near miss in both years. However, Johor recorded the most IBCT cases, with 5 cases in 2020 and an increase to 8 cases in 2021.

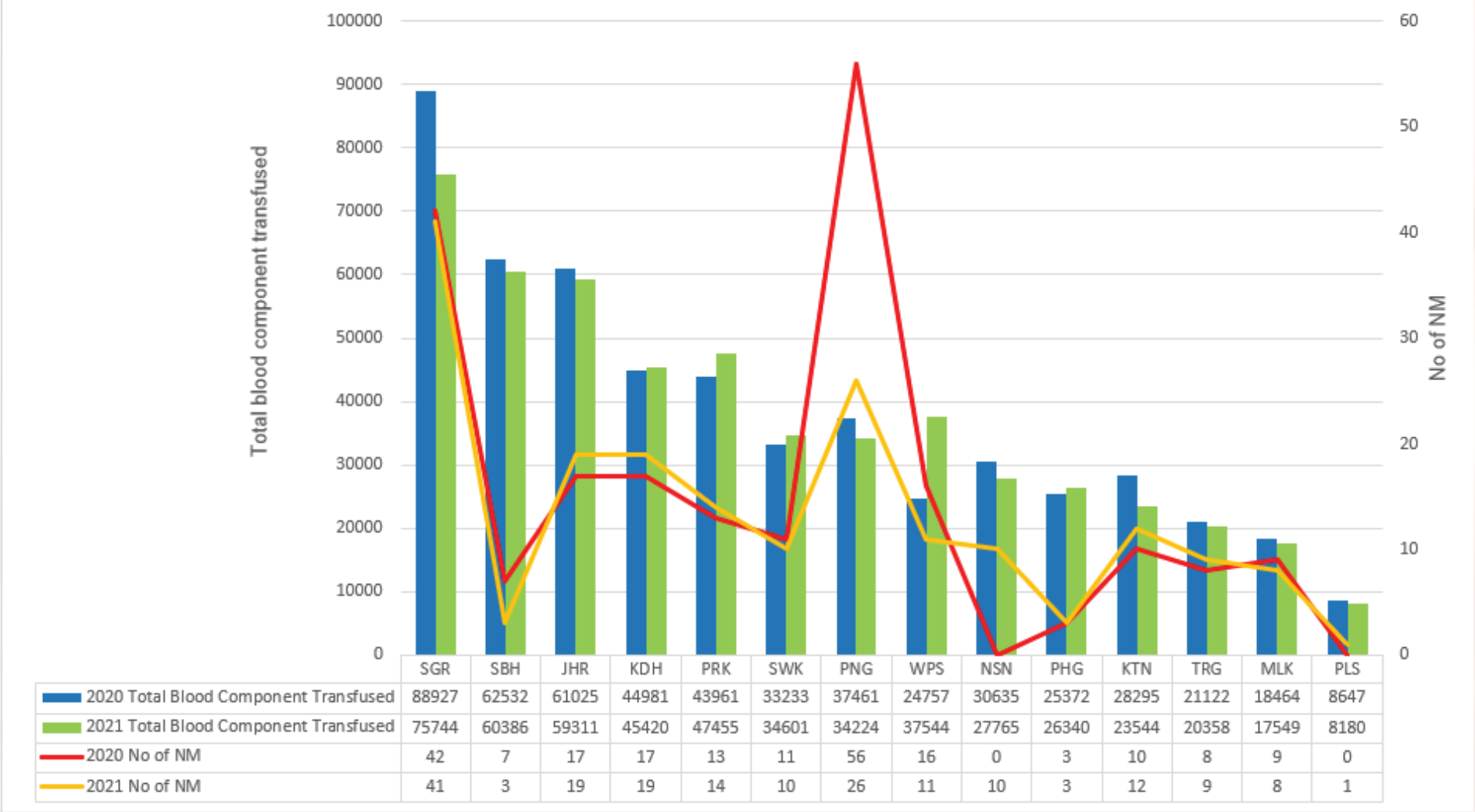
3.2.1.2 In Kedah, Perak, Sarawak, Penang, Wilayah Persekutuan, Pahang, Kelantan, Negeri Sembilan, and Terengganu, between 20,000 and 50,000 blood components were transfused. Penang recorded the most number of near-misses (56 cases) and IBCT cases in 2020 (4 cases). In 2021, Penang still had the most near-misses, but the number had significantly decreased to 26 cases, while Kedah had the most IBCT cases (6 cases).

3.2.1.3 Melaka and Perlis were the 2 states with the least number of blood components transfused less than 20,000. They reported 1 case of IBCT throughout 2020 to 2021.



	SGR	SBH	JHR	KDH	PRK	SWK	PNG	WPS	NSN	PHG	KTN	TRG	MLK	PLS
2020 Total Blood Component Transfused	88927	62532	61025	44981	43961	33233	37461	24757	30635	25372	28295	21122	18464	8647
2021 Total Blood Component Transfused	75744	60386	59311	45420	47455	34601	34224	37544	27765	26340	23544	20358	17549	8180
2020 No of IBCT	1	4	5	2	1	2	4	2	1	2	0	2	1	0
2021 No of IBCT	2	2	8	6	1	3	1	3	0	0	1	2	0	1

Figure 3.2.1a: Incidence of IBCT and Number of Blood Components Transfused by State, 2020 and 2021



	SGR	SBH	JHR	KDH	PRK	SWK	PNG	WPS	NSN	PHG	KTN	TRG	MLK	PLS
2020 Total Blood Component Transfused	88927	62532	61025	44981	43961	33233	37461	24757	30635	25372	28295	21122	18464	8647
2021 Total Blood Component Transfused	75744	60386	59311	45420	47455	34601	34224	37544	27765	26340	23544	20358	17549	8180
2020 No of NM	42	7	17	17	13	11	56	16	0	3	10	8	9	0
2021 No of NM	41	3	19	19	14	10	26	11	10	3	12	9	8	1

Figure 3.2.1b: Incidence of Near Misses and Number of Blood Components Transfused by State, 2020 and 2021

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. The total number of near misses was 245 in 2020 and 222 in 2021 while IBCT was 30 and 33 respectively was analysed and discussed according to the CCP.

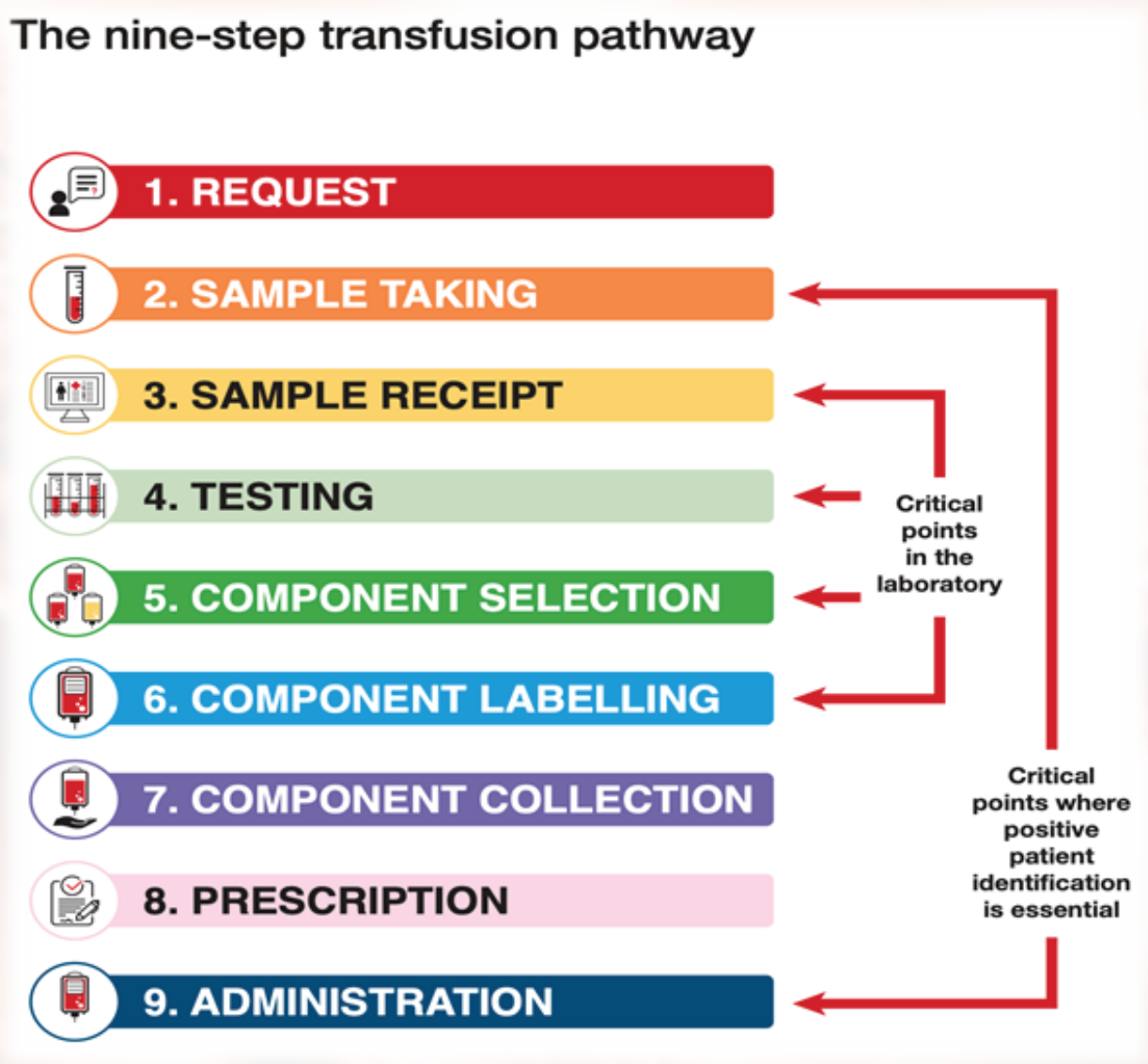


Figure 3.3: Critical Control Point in the Transfusion Process

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 of nine steps in the transfusion process, after deciding to transfuse, is the request for a blood transfusion. The type of blood component needed for the transfusion as well as the patient core identifiers must be included in the request for the selection and release of components.

3.3.3.1.2 In 2020, there were a total of 74 errors related to this important step which decreased to 34 in 2021. Thirty two NM and 2 IBCT were reported in 2021, compared to 71 NM and 3 IBCT in 2020. For 2020 and 2021, respectively, errors involving incorrect patient information accounted for 97.3% (n=72) and 94.1% (n=32) of the errors under this step. This was either because the patient's name was misspelt, the ID number was copied incorrectly, or the blood group was incorrectly entered on the GSH form, which resulted in the discrepancy. On the other hand, due to a lack of knowledge and awareness of specific requirements, 1.4% (n=1) reported incorrect blood component requests in 2020 and 5.9% (n=2) in 2021. There was also a case at the general OT in 2020 where the doctor wrongly ordered blood products for a patient but fortunately noticed the discrepancy upon checking the blood products and patient identification prior to administration of the product.

STEP 1: REQUEST ERRORS	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=71	N=3	N=32	N=2
1a) Request (incorrect transcription/ patient information)	70	2	31	1
1b) Lack of knowledge and awareness of specific requirements	0	1	1	1
1c) Others, to specify	1	0	0	0

Table 3.3.3.1: Request Error in 2020 – 2021

3.3.3.1.3 Contributing factors:

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

a) A team factor, in which written communication was an issue, other than a staff member who engaged in risky behaviour like assuming and failing to seek clarification.
b) Ineffective communication between clinical and laboratory settings
c) Incomplete clinical information on request forms
d) A lack of knowledge and awareness of the specific requirements of blood transfusion

3.3.3.1.4 Recommendations:

a) Supervision and monitoring from superiors are necessary to ensure that housemen in training do not take short shortcuts able to ask for assistance when necessary.
b) Ongoing training and education in medicine (CME) to address the issue of knowledge gaps and SOP observance
c) Regular clinical audits to enhance the standard of care and compliance with SOP

3.3.3.2 SAMPLE TAKING– Table 3.3.3.2

3.3.3.2.1 During the collection of a blood sample for pre-transfusion testing and during the administration of blood to the patient, it is crucial to successfully identify the patient. One patient and one trained, competent, and authorised staff member are required to 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 Patient 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 is the minimal requirements for sample tube information. The person who took the sample must promptly label the sample tubes at the patient's bedside.

3.3.3.2.3 Sampling and labelling errors have the potential to cause enormous harm and can be further classified as Wrong Blood in Tube (WBIT), in which the sample may have been taken from the incorrect patient and labelled for the intended recipient, or Wrong Name on Tube (WNOT), in which the sample has been taken for the intended recipient but has been labelled with the information of another patient. In blood banks, these errors were primarily found during pre-transfusion testing processes. The root cause of the ABO discrepancy will be investigated if there is a disagreement between the patient's blood group in the current sampling and the patient's previous record in the blood bank information system.

3.3.3.2.4 NHCC received 147 NM events and 4 IBCT occurred in 2020 and 159 NM events and 7 IBCT in 2021. Almost half of the error was due to failure to conduct a positive patient identification during the blood taking. On the other hand, 29.8% (n=45) in 2020 and 22.9% (n=38) in 2021 were due to multiple personnel involved during sample taking *("gotong-royong")*. Another striking fact predisposed to error is when the personnel pre-label the sample elsewhere and/or not doing the procedure continuously which accounted for 22.5% (n=34) reports in 2020 and 31.3 % (n=52) reports in 2021. Despite the fact that sample and labelling errors most frequently occurred at the clinical site, IBCT only results from these errors if the patient has no prior transfusion record with the blood bank.

STEP 2: SAMPLE / LABELLING ERRORS	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=147	N=4	N=159	N=7
2a) Positive patient identification was not performed	69	3	72	4
2b) More than one person involved in blood taking (Sample not labelled by the person taking the blood)	45	0	35	3
2c) Pre-labelled sample /form. Sample was not labelled at the bedside	33	1	52	0

Table 3.3.3.2: Sampling/Labelling Error in 2020 – 2021

3 3.3.2.5 Contributing factors:

The following were some of the frequent causes of this error that were noted in the RCA report:

a) Work/Environmental Factor: Insufficient staff, a severe workload, a busy and noisy environment, and insufficient break.
b) Personal staff factor: insufficient knowledge, experience, or skill, as well as exhaustion or stress. One instance involved a houseman who had just been posted and was still in the tagging phase, lacking understanding about transfusion errors and experience handling blood supplies. Some were also not clear about their roles and responsibilities which lead to breaching of SOP.
c) Team factor: Insufficient oversight or monitoring

3.3.3.2.6 Recommendations:

a) In many of the instances reported to NHCC, staffing issues were identified as the primary cause. All areas involved in transfusion require the adequate staffing numbers. At all times, adequate staffing, training, and monitoring are necessary.
b) Non-compliance with SOP is the other issue in situations where there is a sample error. To address this, we suggest that housemen receive training on blood-taking protocol and transfusion safety early in their postings.
c) Periodically performing clinical audits to enhance quality and SOP adherence is recommended.
d) Strengthen the Hospital Transfusion Committee's involvement (HTC). In matters relating to blood transfusion activities, HTC is to act as a liaison between the clinical and blood bank. It also provides solutions, feedback, education, and best practises in relation to issues that have been identified, with the goal of ensuring that transfusion practise is in line with national standards.

3.3.3.3 SAMPLE RECEIPT– Table 3.3.3.3

3.3.3.3.1 For the right investigation to be carried out for the right patient on the right sample at the right time, proper sample receipt and registration at the blood bank are crucial. The data on the request form and the sample's label must match. The failure to recognise the patient's transfusion history at this step will result in an error.

3.3.3.3.2 There were 4 cases of near miss in 2020 and 1 in 2021 involving blood bank personnel who accidentally switched a patient's sample during labelling with the laboratory barcode number at the blood bank receiving counter or demographic data entry error on the name and ID number. Unfortunately, there were 2 IBCT in 2021 of which 1 case resulted in this type of error as the patient had no prior transfusion record with the blood bank. The other IBCT case in 2021 was a patient who was given the wrong phenotype blood as the historical information of the patient was not heeded and missed. As of 2020, there was no IBCT involving this step.

STEPS 3: SAMPLE RECEIPTS & REGISTRATION ERROR	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=4	N=0	N=1	N=2
Incorrect sample receipt and registration at blood bank/ patient's previous history not being checked or entered/ error during relabelled of patient's sample / switching patient's blood samples, etc.	4	0	1	2

Table 3.3.3.3: Receipt and Registration Error in 2020 – 2021

3.3.3.3.3 Contributing factors:

Among the contributing factors described in the RCA report relating to this error were mainly:

a) Work/ Environmental factor: Inadequate staff, heavy workload, cluttered, noisy, and busy surroundings, inadequate break
b) Individual staff factor: Fatigue/stress
c) Team factor: Lack of supervision/ monitoring

3.3.3.3.4 Recommendations:

a) Lack of staff and the high workload was the main issue reported which led to fatigability and error. Thus, it is crucial that the blood bank management analyse and fill in an adequate number of posts required to perform the task or arrange and structure the shift to accommodate a high workload during a certain time.
b) It is also very important for superiors to perform a periodic check and remind staff to always adhere to SOP despite a heavy workload as it could greatly reduce the risk of such errors recurring in the near future.
c) Patient historical data must always be checked to detect discrepancies in the current sample and verified with patient demographic data.

3.3.3.4 TESTING – Table 3.3.3.4

3.3.3.4.1 In accordance with local and national guidelines, the proper pre-transfusion testing technique is necessary to guarantee the safe provision of blood components for transfusion. This is vital in order to get an accurate result for interpretation of a patient's blood group, antibody screening, and antibody identification test. The process should not be interrupted until the blood bank personnel has finally transcribed the findings in the blood bank information system.

Under the nine steps of the transfusion process, this error was classified as procedural, interpretation, transcription, and technical causes. Under procedural error, it can be due to:

i. wrong procedure performed,
ii. procedure or steps performed incorrectly or omitted,
iii. clinically significant antibody not excluded/identified,
iv. antibody identification not performed following positive antibody screen and
v. blood components issued to the patient before a second person verified the blood grouping

Interpretation error occurs when the entire procedure was done correctly but the result of either ABO grouping, Rh D typing, antibody identification and others were interpreted wrongly. On the other hand, transcription errors occur when the pre-transfusion testing was performed correctly but transcribed wrongly in the GXM form or blood bank information system. Currently, technical error represents an error in information technology (IT) either due to inappropriate use of electronic crossmatch or IT system failure.

3.3.3.4.2 In 2020, the total number of NM reported was 13 with 69.2% (n=9) for transcription error, 15.4% (n=2) for procedural errors, 7.7 % (n=1) for interpretation, and 7.7% (n=1) was a technical error. In 2021, there were 18 NM reports involving blood banks with 1 (5.6%) procedural error, 2 (11.1%) errors in interpretation, 14 (77.7%) errors during transcription and 1 (5.6%) in technical.

The pre-transfusion testing error was the most common cause of the error that led to IBCT although the incidence of a near miss for this type of error was low compared to sampling/ labelling error as depicted in table 3.3.3.2. Procedural error was the main cause of IBCT for both years under testing with 6 cases (60%) in 2020 and 5 (71.4%) in 2021. Furthermore, there were a total of 4 reports on interpretation error for 2020 and 3 in 2021 of which 3 (30%) were IBCT occurring in 2020 and 1 (14.3%) in 2021. There was 1 transcription error that led to IBCT in 2021 but none were due to this in 2020. On the other hand, although there was no technical error reported to cause IBCT in 2021 but there was one in 2020.

STEPS 4: TESTING ERROR	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=13	N=10	N=18	N=7
4a) Procedural error (e.g.: Pre-transfusion testing procedure or steps performed incorrectly or omitted, etc.).	2	6	1	5
4b) Interpretation error (e.g.: wrong interpretation of blood group/Rh/ antibody/barcode)	1	3	2	1
4c) Transcription error (e.g.: wrong transcription of blood group/Rh/ antibody/barcode)	9	0	14	1
4d) Technical error (e.g.: BBISV2 error/ inappropriate use of electronic issues, etc.)	1	1	1	0

Table 3.3.3.4: Testing Error in 2020 – 2021

3.3.3.4.3 Contributing factors:

a) This was mainly because blood bank personnel either performed a test on multiple samples at one time and inadvertently switched samples or wrongly read another patient's results.
b) Failing to detect weak reactions in forward grouping resulted in a wrong grouping.
c) In some instances, verification was only done after the blood was released or transfused.
d) There was no second verifier to confirm the blood grouping.
e) Inappropriate step in data overriding when the system detected a discrepancy.
f) Lack of staff and high workload were also reported which led to a shortcut in performing the procedure.

3.3.3.4.4 Recommendations:

a) Since the protocol is not standardized for all the hospitals, it is highly recommended for the hospitals that have yet to update their protocol to revise the SOP on ABO and Rh grouping by adding in the SOP of having a second verification step such as preparing a new red cell suspension for blood group verification or verification of blood grouping by a different individual.
b) There were cases involving the BBIS in which users were able to override the warning alert of incompatible blood transfusion. Security measures must be in place to protect data integrity. In these cases, it is suggested for the staff to log in a ticket in helpdesk BBIS to change business rules so that the BBIS will be able to block incompatible transfusion and disable override except for certain special cases such as changes of blood group following the bone marrow transplant.
c) Automation in blood grouping and antibody screening in blood banks with high workloads should be considered as this could reduce manual errors and increase the quality of work.

d) NHCC urges blood banks to recognize the unavailability of a patient's historical blood bank record as the weakest link and introduce strategies such as two independent sample processes for ABO blood grouping in the event where the patient has no historical blood bank record and sharing of patient transfusion data between hospital blood banks.

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 NMs were reported in 7 cases in 2020 and 2 cases in 2021. The majority of the cases for both years were caused on by blood bank personnel selecting the incorrect blood component, blood group, or even blood meant for another patient.

3.3.3.5.3 A total of 9 cases of IBCTs were reported for these two years with 4 cases in 2020 and 5 cases in 2021. In 2020 there were 2 cases involving wrong blood groups of which 1 was ABO compatible while the other was ABO incompatible whereas another 2 cases were due to incorrect phenotype. While in 2021 there were 2 cases involving wrong components issued, 1 case involving ABO compatible blood while the other case was due to incorrect phenotype. Unfortunately, there was an expired blood component issued to a patient in 2021.

STEPS 5: COMPONENT SELECTION ERROR	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=7	N=4	N=2	N=5
5a) Wrong blood group/ Component / Specific requirement requested not selected / wrong blood issued to patient/ unscreened blood	7	4	2	4
5b) Expired blood component issued	0	0	0	1

Table 3.3.3.5: Component Selection Error in 2020 – 2021

3.3.3.5.4 Contributing factors

Among the factors contributing to the error were

a) Staff factor whereby the blood bank personnel involved had a lapse of concentration which led to the error.
b) There is also a lack of knowledge among the staff on the selection of non-red cell components for transfusion.
c) Technology factor was also an issue whereby in one of the cases, the blood banking system in the hospital was not yet up and running which made it inaccessible for the staff in the wards to trace the blood request and availability.
d) The system was well established but there were limitations in which the system did prompt the incompatibility of selected blood groups but did not stop the staff from releasing the incompatible unit as the staff's login level can override the order.
e) Substandard inventory management causes expired blood release for usage.

3.3.3.5.5 Recommendations

a) To reduce the incidence of errors caused by lack of knowledge among staff, retraining and yearly competency tests are recommended.
b) Blood banks that are short-staffed to be prioritized in their request for more blood bank personnel to ensure a safe working environment as it is evident that working with a limited number of staff can lead to a stressful working environment and be followed by errors being done at the blood bank.
c) As for hospitals without blood banking systems, upgrading the current system is crucial.
d) While upgrading is being done, hospitals without blood banking information systems should immediately come up with systematic strategies and ways to tackle possible errors that could happen in the ward as well at the blood bank.
e) Efficient management of the blood stock inventory with the concept of first expiry, first out (FEFO) is important to adhere to prevent expired blood from being transfused.

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 4 reports received involving this step in 2020 of which 3 NM and 1 IBCT and 1 NM in 2021. The 3 cases of NM were due to the failure of blood bank personnel to label the blood components with the correct patient identifiers. One of the cases in 2020 was the blood bank personnel performed GXM on 2 samples at once and after completing the test, he printed an adhesive label for both patients and mistakenly switched the label between them. Fortunately, the ward personnel detected the error prior to transfusion and immediately informed the blood bank for verification.

On the other hand, there was a case of IBCT in 2020 whereby the blood bank received a request for crossmatching (GXM) by paediatric day-care for a patient with Thalassemia Major. The blood group of patients was O Rh Positive, R1R1 with positive antibody screening, and a new antibody was detected (anti-E). Hence an investigation was done to find the cause of anti-E as phenotype blood was selected for each transfusion. Three units of the packed red cells were transfused previously and one of them was found to be R1R2 phenotype that led to alloimmunisation. Blood bank personnel who selected the blood bag for crossmatching did not verify the phenotype that was labelled on the blood bag.

STEPS 6: COMPONENT LABELLING, AVAILABILITY AND HANDLING AND STORAGE	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=3	N=1	N=1	N=0
6a) Failure to label the blood component with the correct patient identifiers.	2	1	0	0
6b) Failure to handle and store blood components in the correct way as defined in the guidelines	0	0	1	0
6c) Others, please specify	1	0	0	0

Table 3.3.3.6: Component Labelling, Availability and Handling & Storage Errors in 2020 – 2021

3.3.3.6.3 Contributing factors

a) Blood bank personnel involved had performed tests on multiple samples at one time and inadvertently switched labels on the blood bags.
b) Lack of staff and high workload leads to a shortcut in performing the procedure
c) Technology factor was also an issue whereby, in this case, the correct donor phenotype was in the system but couldn't automatically be printed on screened blood bag sticker as it was only in the archive data system and not entered in BBIS twice.
d) Although the system was well established, there were limitations in BBISV2 where phenotype will only be printed automatically on screened sticker if it has been entered in the BBISV2 module of immunohematology under donor testing twice.

3.3.3.6.4 Recommendations:

a) Lack of staff and the high workload was the main issue reported which led to fatigue and error. Thus, it is crucial that the blood bank management analyse and fill in an adequate number of posts required to perform the task or arrange and structure the shift to accommodate a high workload during a certain time.
b) It is also very important for superiors to perform a periodic check and remind staff to always adhere to SOP despite a heavy workload as it could greatly reduce the risk of such errors recurring in the near future.
c) Patient historical data must always be checked to detect discrepancies in the current sample and verified with patient demographic data.
d) To reduce the incidence of errors caused by lack of knowledge among staff, retraining and yearly competency tests are recommended.

3.3.3.7 COMPONENT COLLECTION – Table 3.3.3.7

3.3.3.7.1 When the proper procedures are followed, the correct component will be collected, fulfilling the clinical request and the requirements listed on the collection slip. The laboratory personnel must check that all components fulfill the criteria of the clinical request and the collection slip before directly delivering them to clinical personnel.

3.3.3.7.2 There were no cases of near miss reported for this type of error in 2020 but there were 3 in 2021. However, there was one IBCT reported in 2020 and none in 2021. One of the 3 cases of NM was due to the failure of the ward personnel to check the blood bag details of the component to be collected against the details on the laboratory-generated label attached to the blood bag from the OT fridge. The other two cases involved the ward personnel asking her colleague to help collect the blood bag, but the colleague collected the wrong blood bag that was not meant for the patient. Fortunately, the ward personnel in charge of the administration of the blood detected the errors prior to transfusion for the three cases.

In 2020, the IBCT case was due to failure to check the blood against the patient's full identity and details of the component to be collected against the details of the laboratory–generated label attached to the blood bags in the ICU. The ward personnel did not comply with the SOP and this occurred in the medical department. This blood has been issued out from the blood bank and stored in the clinical area blood fridge before transfusion.

STEPS 7: COMPONENT COLLECTION ERROR	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=0	N=1	N=3	N= 0
7a) Blood component not collected or received by trained, competent and authorised members of staff.	0	0	0	0
7b) Failure to check the patient's core identifiers and details of the component to be collected against the details on the laboratory-generated label attached to the blood bag	0	1	3	0

Table 3.3.3.7: Component Collection Error in 2020 – 2021

3.3.3.7.3 Contributing factors:

a) Failure to comply with protocol by keeping unused blood in the clinical area blood fridge when they were supposed to return them immediately to the blood bank.
b) Non-compliance to SOP by ward personnel whereby the ward personnel did not cross-check the patient's information against the details on the laboratory laboratory-generated label attached to the blood bag.

3.3.3.7.4 Recommendations:

a) Continuous training and CME should be done to educate and remind staff regarding the importance of following the SOP and have understood that the blood should be transfused within 30 minutes after being issued from the blood bank to ensure safe transfusion to patients.
b) The hospital ward refrigerator is for short-term storage of issued blood from the blood bank to maintain the blood cold chain if the transfusion cannot be commenced within 30 minutes. The refrigerator must maintain a temperature of between 2-6 Celsius and equip with an appropriate alarm system where the ward staff knows the step to be taken if the alarm is activated. This refrigerator might be shared between many departments, thus a clear SOP on the management of blood fridge must be in place to safeguard the contents of the refrigerator.
c) Positive patient identification must be done at every stage of the transfusion process which is to check on patient identifiers such as the first name, last name, date of birth, and unique identification number on the blood bag and the patient as well to ensure there is no discrepancy between both.

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 should be completed and checked prior to the final administration step. Blood component authorisation must include the patient's core identifiers, the component to be transfused, the date of transfusion, the volume number of units, the rate of transfusion, and any other clinical requirements or instructions required and must be signed by the authoriser.

3.3.3.8.2. No cases of NM were documented for either year. In 2020, there was a case reported where the rate of transfusion was too slow. Blood transfusion started at 4.15 pm but was still ongoing at 10.45 pm. This was noticed and terminated by the surgeon who was doing her night ward round. The patient was a psychiatric disorder patient who was admitted for sepsis secondary to an infected wound post-incision and drainage. Fortunately, there were no cases of IBCT reported in 2021.

STEP 8: PRESCRIPTION ERROR	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=0	N=1	N=0	N=0
Blood transfusion not authorised by an appropriately trained staff/failure to document specific clinical requirements (e.g.: component to be transfused /volume or number of units required/rate of transfusion /requirement for blood warmer/other clinical instructions required, etc.)	0	1	0	0

Table 3.3.3.8: Prescription Error in 2020– 2021

3.3.3.8.3 Contributing factors:

There were multiple factors that could have contributed to the error.

a) Poor communication and a sense of accountability among staff contributed to the wrong blood product prescribed as well as a lack of adherence to SOP.
b) Work/environmental factors contributed to a transfusion of more than 4 hours as the heavy workload may have led the staff to be preoccupied with ward work thus leading to a lack of monitoring during a blood transfusion.
c) The patient factor whereby the patient with underlying psychiatric disorder was not cooperative and restless. There were multiple attempts to pull out the cannula that caused a distraction to staff.

3.3.3.8.4 Recommendations:

a) It is important to have courses to educate and create awareness among staff on the rate of blood transfusion and the importance of following the SOP to prevent bacterial contamination.
b) It is highly advisable for patients with certain medical condition s or aggressive patients to be managed by experienced or more than one staff for closer monitoring during a blood transfusion.
c) Ensure all the junior staff/doctors have undergone safe transfusion training prior to being put in charge of patients whom we anticipate would have issues during a blood transfusion.

3.3.3.9 Administration – Table 3.3.3.9

3.3.3.9.1 The final opportunity to prevent patients from getting the wrong component or not getting what they need attributable to errors made earlier in the transfusion process is during administration. It is crucial that qualified, authorised, registered, and controlled healthcare staff carries out the final administration check. It is essential to perform this last bedside check prior to the administration of blood. The component blood group must be appropriate for the patient, and the donation barcode number, blood group, and expiration date on the component pack label must match those on the laboratory-generated label attached to the component. Additionally, any specific clinical requirements have been met, such as leukodepletion or irradiation before transfusion.

3.3.3.9.2 There have not been any documented near misses over the previous two years. However, 2 IBCT cases and 10 IBCT cases were reported in 2020 and 2021, respectively. A total of 9 IBCT cases were caused by not performing a pre-transfusion check or positive patient identification at the bedside for both years.

3.3.3.9.3 On the other hand, there were 2 cases in 2021 in which there was a failure to check the details of the components against the details on the laboratory-generated label attached to the blood bag. Unfortunately, in 2021 one report was put under others as unable to conclude the actual cause that led to the error as the root cause analysis was not sent.

In 2020, there was a failure of the ward personnel to confirm the identity of the patient and details on the blood form prior to transfusion. Unfortunately, identification of the baby was only done by bed number without knowing the baby's identification. Meanwhile in 2021, one of the cases where the final administration check was not done at the bedside where the ward personnel checked the second packed cell and passed it to another ward personnel in charge of blood transfusion. However, the personnel in charge placed the intended packed cell in the cool box which had another packed cell that belonged to another patient. She went to collect a new infusion tubing and accidentally attached the wrong blood bag to it. The other two cases were also due to failure to check the patient's details and the component collected against the label attached to the blood bag. Unfortunately, in 2021, a report received from one of a major specialist hospital was incomplete and unable to conclude where the error in administration occurred.

STEPS 9: ADMINISTRATION ERROR	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=0	N=2	N=0	N=10
9a) Final administration check not done at bedside	0	2	0	7
9b) 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	0	0	0	2
9c) Others (requirement not met)	0	0	0	1

Table 3.3.3.9: Administration Error in 2020– 2021

3.3.3.9.4 Contributing factors:

These are among the contributing factors that were identified:

a) Individual/staff factors for instance lack of knowledge, non-compliance to SOP and unsafe behaviour like assuming and not asking for clarification if in doubt
b) Team factors like ineffective leadership, responsibility, lack of supervision as well as lack of communication between fellow colleagues in clinical and at the blood bank.
c) Positive patient identification was not done at the bedside which also contributed to the error.
d) Having the first and the second verifier verify the blood at the bedside as well as prior to transfusion was not done in some cases

3.3.3.9.5 Recommendations:

a) Every step of the transfusion process must involve positive patient identification (PPI), which entails verifying the accuracy of the patient identifiers on the blood bag and the recipient, including the patient's name, last name, date of birth, and unique identification number before the transfusion of blood. PPI with a two-step verification must be done by two different staff membersat the bedside before the administration of blood.
b) The patient's details of components collected must be verified and tallied against the details on the laboratory-generated label attached to the blood bag.
c) Prior to being off-tagged in the department, housemenmust complete the necessary training in safe transfusion.

3.3.3.10 Miscellaneous – Table 3.3.3.10

3.3.3.10.1 The primary error will be categorised as miscellaneous if it wasn't related to any of the nine steps in the transfusion process, including the inconclusive root cause, such as cases where there wasn't enough information to complete the investigation, for example, the patients were already deceased or discharged home when the error was discovered.

3.3.3.10.2 There were 4 cases of IBCT in 2020 and none in 2021 involving this step. Two cases were due to transcription errors at the registration counter in A&E prior to the patient's admission. The first case was merely due to registration that was done at the counter without the patient's IC but instead used the patient's Orthopaedic appointment card and the error was noted by the referral hospital. The other error was a case that was referred from a Klinik Kesihatan and registration was done based on the referral letter. In both cases, SOP was not followed as the situation at A&E was very busy.

3.3.3.10.3 NHCC also received 2 inconclusive reports in 2020. In 2020, there was a case where a patient was admitted and treated for severe acute respiratory infection (SARI) with symptomatic anaemia. The cause of the error from the ward cannot be determined as blood samples that belonged to a COVID-19/SARI patient were required to be discarded immediately after being processed. Therefore, the discrepancy could not be investigated. The other case occurred in a state hospital where the cause of the error could not be determined as the error occurred in the previous admission.

On the other hand, a major specialist hospital reported a near-miss in 2021, but the report did not include a root cause analysis (RCA).

MISCELLANEOUS	NM 2020	IBCT 2020	NM 2021	IBCT 2021
	N=0	N=4	N=1	N=0
10a) Error not associated with the nine steps	0	2	0	0
10b) Inconclusive	0	2	1	0

Table 3.3.3.10: Miscellaneous in 2020 – 2021

3.3.3.10.4 Contributing factors:

a) Hospital registration error as a result of using other than an identification card or legit document to register patient admission.
b) Precautionary measure on handling a blood sample for pre-transfusion testing from a Covid-19 patient.

3.3.3.10.5 Recommendations:

a) Hospital registration is an important process by which a patient's name and identity are enrolled into the records of the hospital. This is also the first step to generating a medical record of the patient in which all medical details of the patient are documented. Thus, hospitals must have a well-defined and documented policy and procedure for carrying out the registration of patients as shortcuts in the process or unclear procedures can cause registration errors and delay in treatment.

b) Develop infection prevention and control guidance that is more stringent in handling the pre-transfusion sample. This is to protect blood bank staff from exposure to potentially infectious agents. Some blood banks forgo the pre-transfusion testing and supply the universal group pack cell and plasma for transfusion. This decision should be discussed where the benefit should outweigh the risk to both patients and staff.

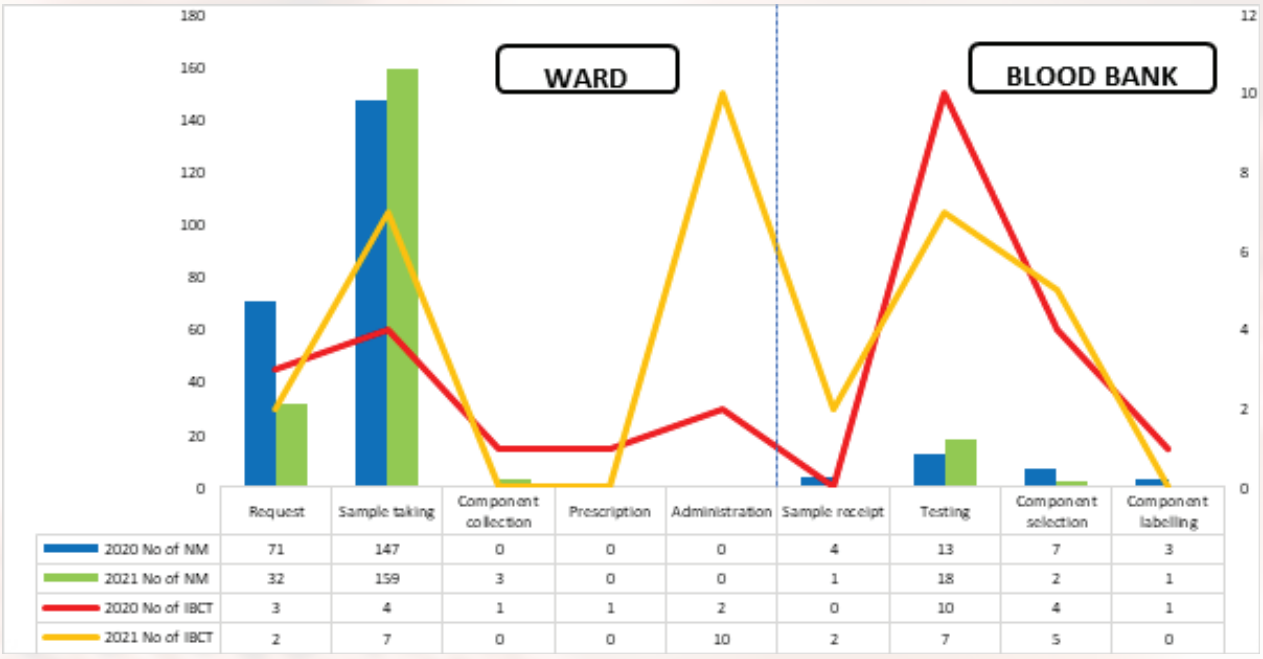
3.4 CCP WHERE ERROR OCCURRED – Figure 3.4

3.4.1 In 2020, there were 275 transfusion errors (TE) reported, of which 245 were near misses and 30 were IBCT. Four of the 30 IBCT cases reported in 2020 classified under the miscellaneous category. The number of transfusion error cases decreased to 250 in 2021, with 217 cases of near-miss and 33 cases of IBCT. One of the 217 near-miss cases was reported as inconclusive.

3.4.2 The total number of reports received in the clinical area were 218 in 2020 and 194 in 2021, as shown in figure 3.4. In addition, IBCT was a cause in 11 and 19 cases in each of the two years. With 147 reports in 2020 and 159 in 2021, sampling/labelling appears to be the most common. The ABO discrepancy will typically be investigated to identify the underlying cause when the patient's blood type in the current sampling and the patient's previous record in the blood bank information system mismatch. Due to the blood bank information system's accessibility to patients' prior medical data, ward errors in 2020 and 2021 were able to be prevented from becoming actual errors in 95.2% and 91.1%, respectively.

3.4.3 While in the blood bank, there were 27 cases of near miss and 15 IBCT in 2020 and 22 near miss and 14 IBCT in 2021. Pre-transfusion testing errors accounted for the majority of errors in this case, with 13 cases (48.1%) in 2020 and 18 (81.8%) in 2021. Component selection follows, with 7(25.9%) and 2(9.1%) in 2020 and 2021, respectively. However, during the checking before the blood was administered to patients, 64.2% of blood bank errors in 2020 and 61.1% in 2021 were successfully identified before becoming actual errors.

3.4.4 On the other hand, in 2020 there were four IBCT cases that were classified as miscellaneous and were excluded from figure 3.4, of which two were miscellaneous because the primary error was not related to the nine steps of the transfusion process and the other two were inconclusive because there was not enough evidence to conclude the error. Similarly, there was another incident of a near-miss in 2021 that was excluded from figure 3.4 because the information was not conclusive.



	Request	Sample taking	Component collection	Prescription	Administration	Sample receipt	Testing	Component selection	Component labelling
2020 No of NM	71	147	0	0	0	4	13	7	3
2021 No of NM	32	159	3	0	0	1	18	2	1
2020 No of IBCT	3	4	1	1	2	0	10	4	1
2021 No of IBCT	2	7	0	0	10	2	7	5	0

Figure 3.4: Critical Control Point in the Transfusion Process where IBCT/NMOccurred in 2020-2021

3.5 Location of Error - Figure 3.5.1, 3.5.2

3.5.1 Location of the error was where the error had occurred. This could be either in the wards or anywhere in the clinical setting or at the blood bank. Locations of error in the ward or clinical setting are divided into 5 main locations according to the nature of the workplace.

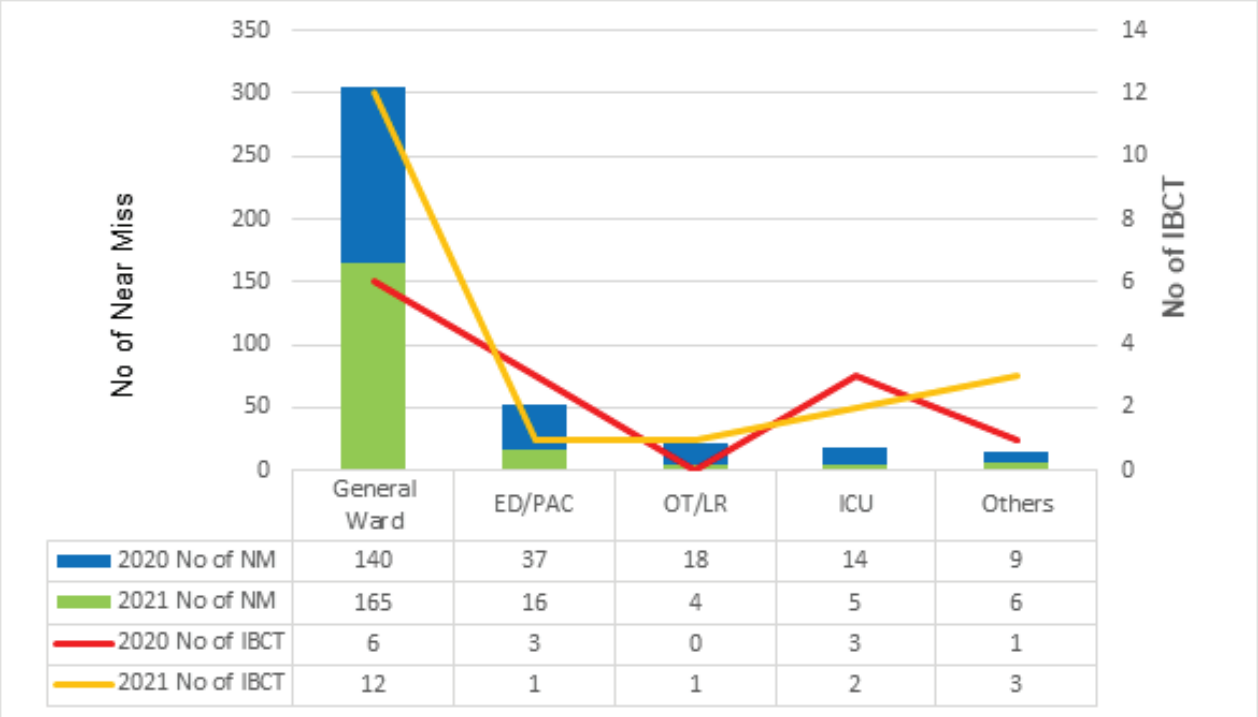
3.5.2 Clinical Area

3.5.2.1 There were 231 errors in 2020 and 215 in 2021 in which the most common location was in the General Ward. An error occurred in Emergency Department (ED) and Obstetrics' Patient Admission Centre (PAC) were summed up together in view of both settings having rapid and high turnovers of patients with almost every patient warranted for Group, Screen and Hold (GSH) test to standby. There were 37 cases and 16 cases of near misses in ED/PAC in 2020 and 2021 respectively with 3 cases and 1 case of IBCT in that order.

3.5.2.2 There was 18 NM in 2020 and 4 in 2021 that occurred in Operation Theatres (OT)/ and Labour Rooms (LR). ABO discrepancy between the patient's historical record and the current sample was successfully detected by the blood bank personnel. However, in 2021, there was a case of Triple Vessel Disease for an Emergency CABG where the patient was pushed into OT but the previous patient's blood box was left in OT with packed cells. During the surgery, the Anaesthesiologists warmed up one unit of the packed cell without doing a proper positive patient identification and blood was transfused. After the surgery when the patient was transferred to ICU, the staff there noticed the error as the transfusion was still in progress with a different patient's name.

3.5.2.3 Although Intensive Care Units (ICU) including Paediatrics and Neonatal ICU were self-contained areas of a hospital with specially trained staff and fully equipped to attend to patients with life-threatening conditions, errors still can occur. Both 2020 and 2021 logged 14 and 5 NM respectively, and in 2020 there were 3 IBCTs that occurred due to unverified component collection and final administration check which was not performed next to the patient. In 2021, there were 2 cases of IBCT which were also due to the final administration check which was not performed and the other was because of sampling error in which positive patient identification was not performed.

3.5.2.4 Other locations such as the Day care center reported 9 and 6 NM in 2020 and 2021 respectively. There were also 1 and 3 IBCT cases each in 2020 and 2021 due to a final administration check which was not done at the bedside.



	General Ward	ED/PAC	OT/LR	ICU	Others
2020 No of NM	140	37	18	14	9
2021 No of NM	165	16	4	5	6
2020 No of IBCT	6	3	0	3	1
2021 No of IBCT	12	1	1	2	3

Figure 3.5.1: Location of Error in Ward

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 In the blood bank, there were 38 reported cases of transfusion error in 2020 and 39 cases in 2021. In 2020 and 2021, the clinical site reported higher IBCT cases, at 13 and 19, respectively, than the blood bank site, which had 11 and 14 cases, respectively.

3.5.3.3 There were 11 cases of IBCT in 2020 and 9 in 2021 over at the CTD. Out of these in 2020, 6 were due to procedural errors, 3 interpretation errors, one labelling error and one technical due to an IT error. Meanwhile in 2021, 5 procedural errors, 1 interpretation error, 1 transcription error and 2 over at receipt and registration contributed to the error over there. On the other hand, in 2021 at the inventory, there were 5 cases due to component selection errors of which one was due to expired blood issued.

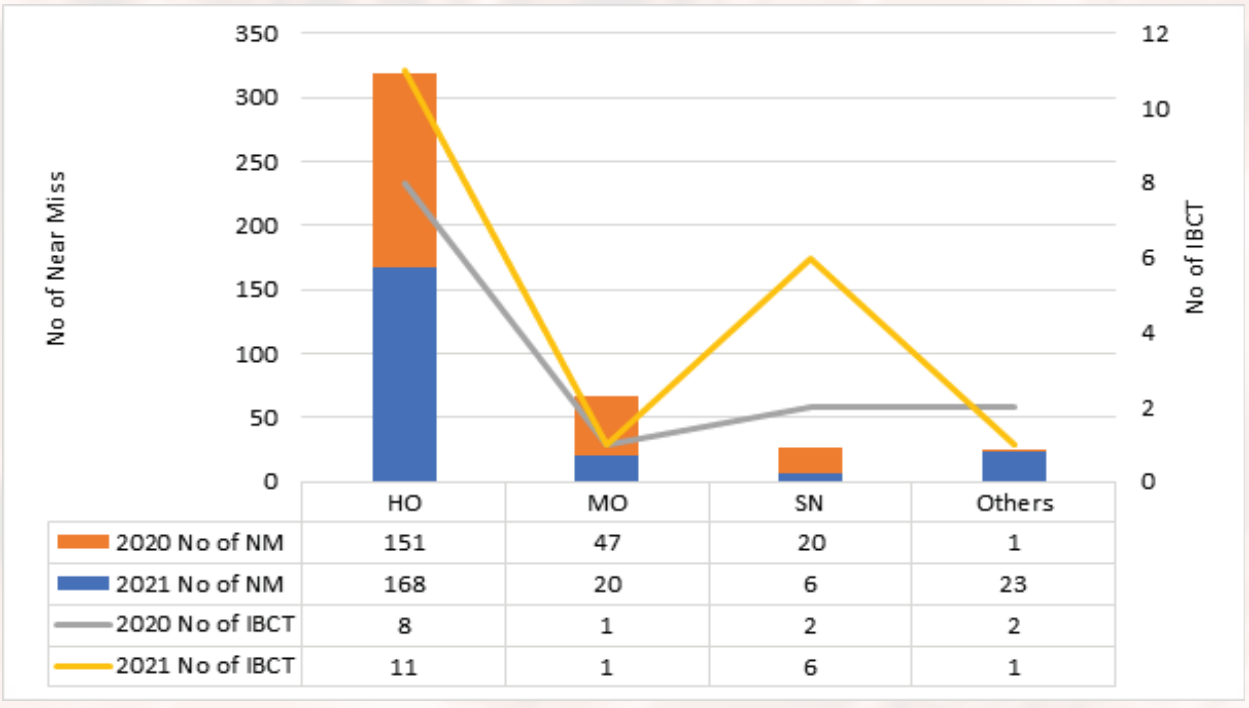
	CTD/IH	Inventory
2020 No of NM	20	7
2021 No of NM	21	4
2020 No of IBCT	11	0
2021 No of IBCT	9	5

Figure 3.5.2: Error in Blood Bank

3.6 CATEGORY OF STAFF INVOLVED - Figure 3.6.1

3.6.1 Clinical Error

The majority of the hospital staff who involved in NM and IBCT for both years were house officers (HO). This could be due to HOs are still in training and are primarily in charge of taking blood in the ward. There were many cases where it was claimed that staff did not follow standard operating procedures because of their high workloads and exhaustion. Other categories of personnel who contributed to the error are depicted in Figure 3.6.



	HO	MO	SN	Others
2020 No of NM	151	47	20	1
2021 No of NM	168	20	6	23
2020 No of IBCT	8	1	2	2
2021 No of IBCT	11	1	6	1

Figure 3.6.1: Category of Staff Involved in Near Miss

3.7 OUTCOME OF IBCT AND PROBABLE OUTCOME OF NM

To classify and analyse the results of transfusion errors, the NHCC has once again adopted the SHOT Annual Report 2018.

3.7.1 WRONG COMPONENT TRANSFUSED (WCT) AND SPECIFIC REQUIREMENT NOT MET (SRNM)

A wrong component transfused to recipients could be a transfusion of blood component with an incorrect blood group, which may be incompatible or compatible with the patient, D-mismatched or it could be an entirely different blood component other than prescribed. On the other hand, if a patient is transfused with the correct blood component but not fulfilling its specific indication (e.g.: filtered, phenotype) the outcome falls into SRNM. The outcome of IBCT can be divided into Wrong Component Transfused (WCT) and Specific Requirement Not Met (SRNM) while NM could have the same probable outcome.

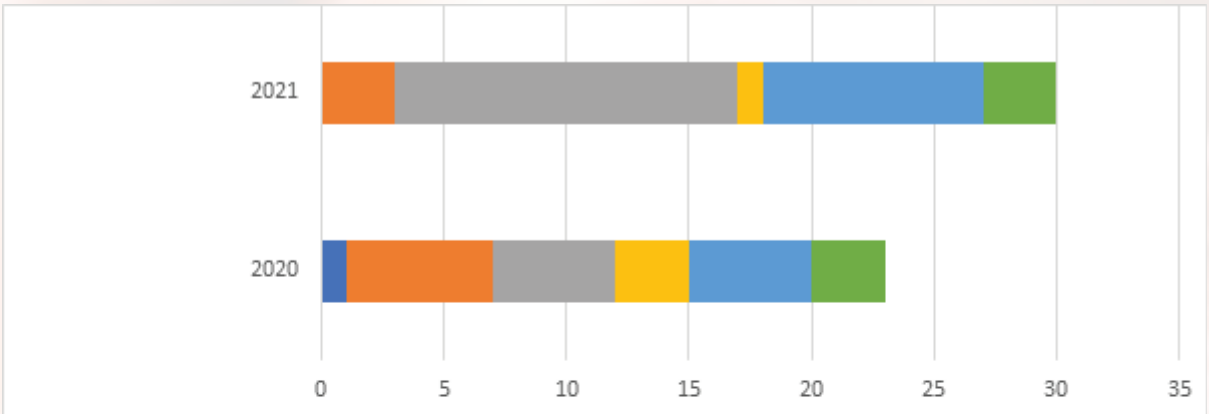
3.7.1.1 IBCT – Figure 3.7.1.1a, 3.7.1.1b, 3.7.1.1c

3.7.1.1.1 In 2020, out of 30 IBCT cases reported 16 patients were transfused with the wrong blood group/components and 7 patients were transfused with blood in which specific requirements were not met. Despite 16 of them being transfused with the wrong blood group /components, only one patient showed evidence of a haemolytic transfusion reaction.

3.7.1.1.2 On the other hand, 14 patients had incompatible blood transfusions out of the 27 WCT cases and 3 SRNM cases reported in 2021. Seven of the patients showed signs and symptoms of a haemolytic transfusion reaction, and 13 of them experienced mild to moderate allergic reactions.

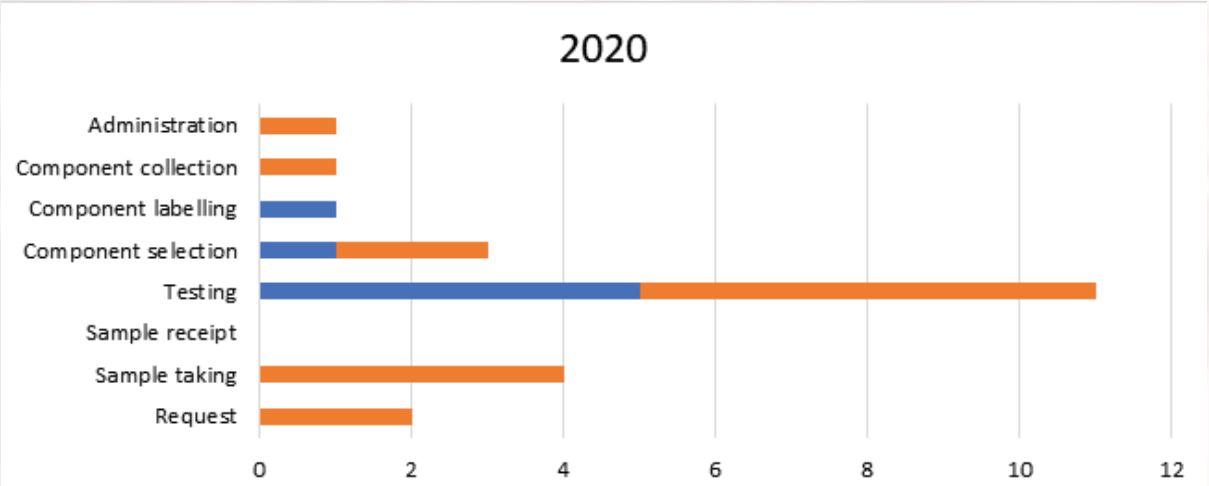
3.7.1.1.3 The commonest error that led to WCT and SRNM in 2020 occurred in the blood bank during pre-transfusion testing. This occurred when blood bank personnel deviated from the SOP resulting in incorrect blood being transfused to patients and patients with no prior record with the blood bank. However, in 2021 errors in the clinical area predominated in the number of errors that occurred which were due to sample taking and administration. Among the common contributing factors that led to errors in the clinical area was the work/environmental factor which shows heavy workload with inadequate breaks as well as cluttered, noisy and busy surroundings. Individual or staff factors too contributed like lack of knowledge, skill, fatigue, and stress. Team factors like lack of supervision/monitoring by supervisors too contributed to this. Besides that, no prior transfusion record with the blood bank too led to a higher risk for an IBCT to occur in sampling/labelling error if staffs were not vigilant.

3.7.1.1.4 Staffing challenges were the main contributor to many events that were reported to NHCC. Inadequate staffing, lack of training, and poor supervision were associated with an increased risk of errors that led to patient safety at risk. Hence, staffing levels must be appropriate in all areas. NHCC also urges all blood banks to recognize the unavailability of patients' historical records for blood transfusion records and strategies like two independent personnel for ABO blood grouping or sampling/labelling is essential.



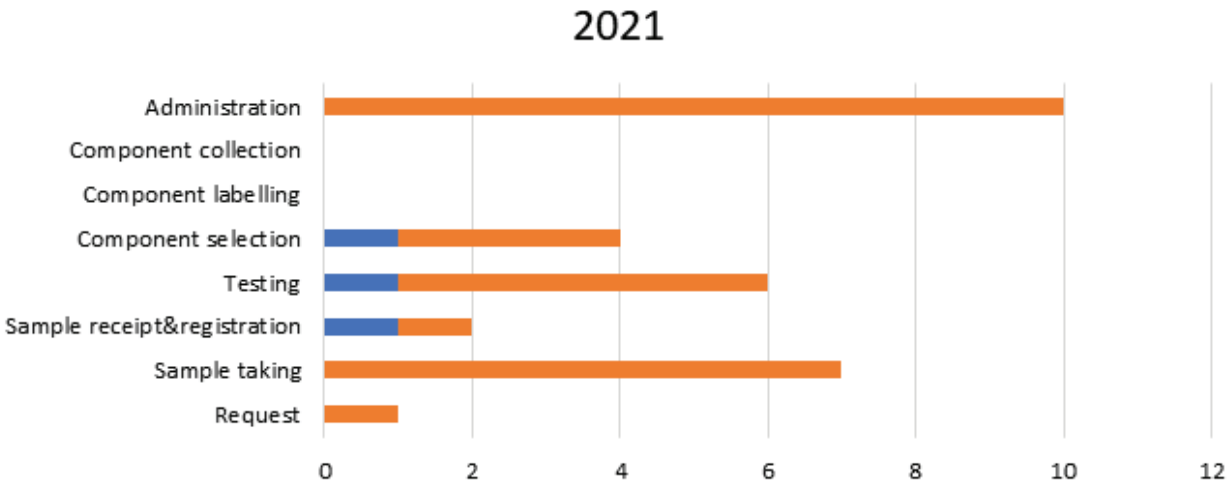
	2020	2021
SRNM (Irradiated blood)	1	0
Incorrect phenotype	6	3
ABO incompatible blood/component	5	14
D-mismatched	3	1
ABO compatible blood/component	5	9
Wrong component	3	3

Figure 3.7.1.1a: Sub-categorisation of WCT and SRNM in 2020-2021



	Request	Sample taking	Sample receipt	Testing	Component selection	Component labelling	Component collection	Administration
SRNM	0	0	0	5	1	1	0	0
WCT	2	4	0	6	2	0	1	1

Figure 3.7.1.1b: Critical Control Point where Error Occurred Leading to WCT and SRNM in 2020

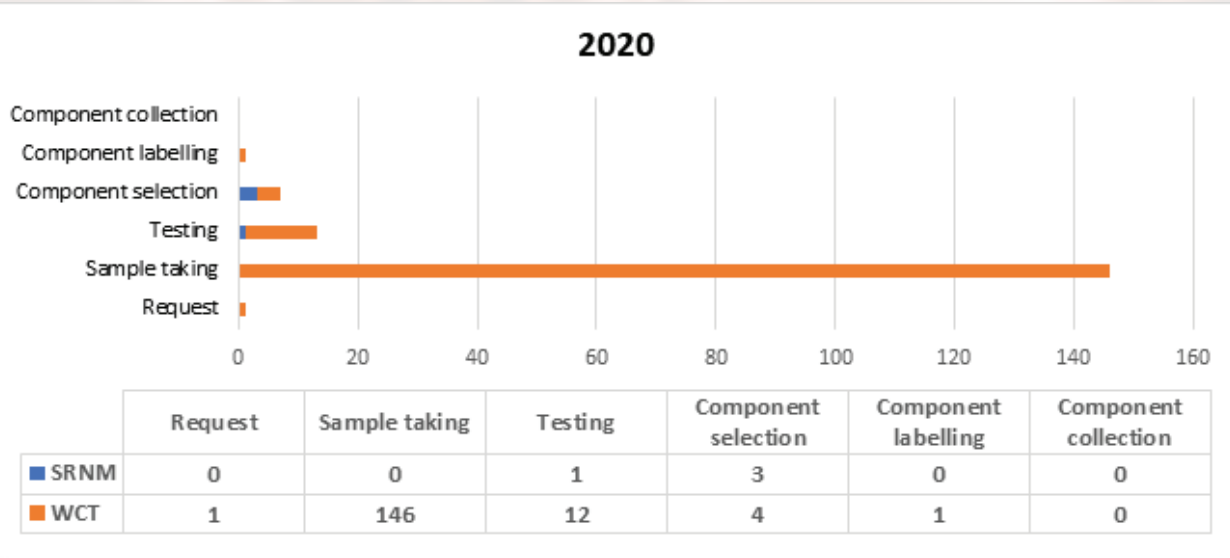


	Request	Sample taking	Sample receipt&registration	Testing	Component selection	Component labelling	Component collection	Administration
SRNM	0	0	1	1	1	0	0	0
WCT	1	7	1	5	3	0	0	10

Figure 3.7.1.1c: Critical Control Point where Error Occurred Leading to WCT and SRNM in 2021

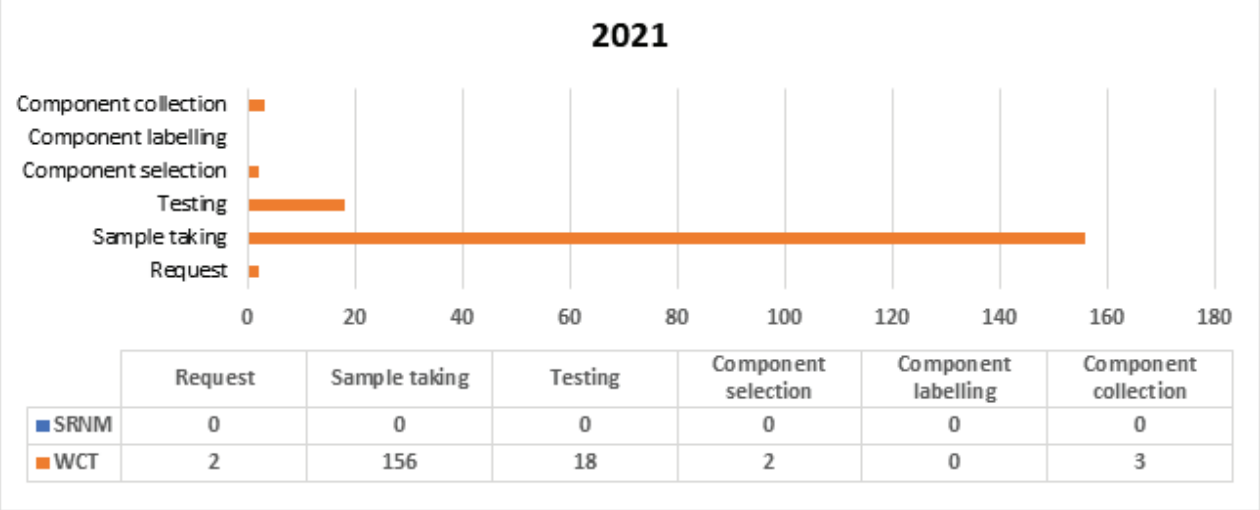
3.7.1.2 NEAR MISS – Figure 3.7.1.2a, 3.7.1.2b

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 area. 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.



	Request	Sample taking	Testing	Component selection	Component labelling	Component collection
SRNM	0	0	1	3	0	0
WCT	1	146	12	4	1	0

Figure 3.7.1.2a: Critical Control Point Where Error Occurred Leading to probable WCT and probable SRNM in 2020



	Request	Sample taking	Testing	Component selection	Component labelling	Component collection
SRNM	0	0	0	0	0	0
WCT	2	156	18	2	0	3

Figure 3.7.1.2b: Critical Control Point Where Error Occurred Leading to probable WCT and probable SRNM in 2021

3.7.2 HANDLING AND STORAGE ERROR (HSE)

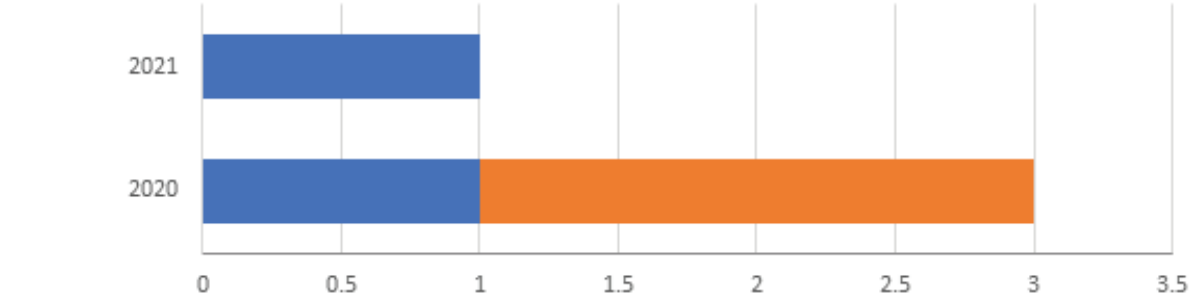
3.7.2.1 Handling and storage error are defined when the patient was transfused with a blood component intended for the patient, but in which during the transfusion process, the handling, and storage may have rendered the component less safe for transfusion (SHOT UK 2018). There could be several causes, for instance, errors that occur in the cold chain, technical administration errors, excessive time to transfuse, transfusion of damaged components and even an expired unit transfused.

3.7.2.2 There was a case of near miss in 2021 but none in 2020. Meanwhile, there was one IBCT in 2020 and 2 in 2021. As for the IBCT in 2020, it was due to a packed cell, which was transfused for more than 4 hours to a patient. For the IBCT in 2021, an expired blood component was issued because of wrongly keyed in the collection date as the received date in the system by the blood bank personnel. The other case was a matched phenotype packed cell but incompatible blood was issued to the patient and fortunately patient recovered with no ill effects

3.7.3 RIGHT BLOOD RIGHT PATIENT (RBRP) – Figure 3.7.3a, 3.7.3b

3.7.3.1 A patient was transfused correctly despite one or more serious errors that in other circumstances might have led to an incorrect blood component transfused. This can occur either in clinical or laboratory settings. Error in patient identification data, prescription errors, labelling errors, 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, and IC or passport number. Nevertheless, over in the laboratory area, this was also mainly because of demographic data entry errors.

3.7.3.2 In 2020, there were 2 cases classified under miscellaneous and 1 case of request error. The cases under miscellaneous were due to incorrect transcription of patient's identification at the registration counter in A&E while request error was due to clerical error during filling up the request form. However, in 2021 there was one request error which was also a result of a clerical error during filling up the request form.



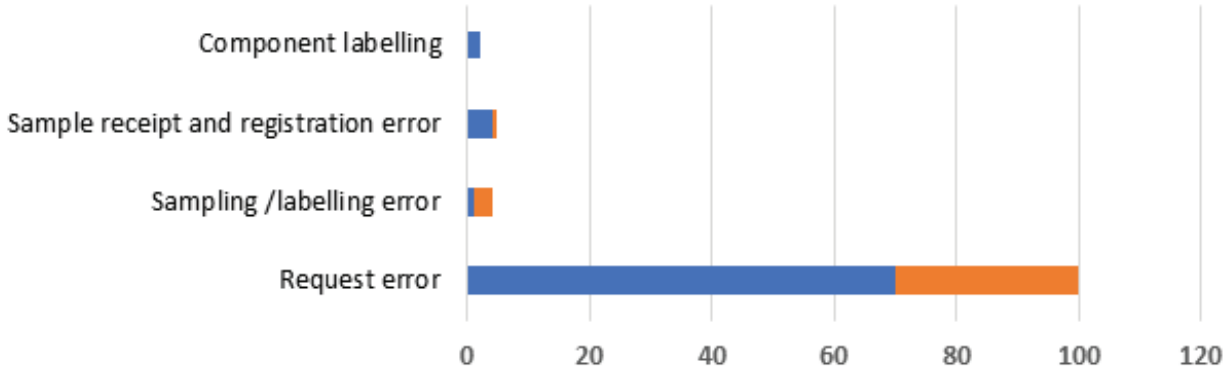
	2020	2021
Request error	1	1
Miscellaneous	2	0

Figure 3.7.3a: RBRP in 2020 – 2021

3.7.3.3 Near miss that could lead to probable RBRP is shown in figure 3.7.3b. Data from 2020–2021 showed the highest number of cases occurred during the sampling/labelling step which could have led to RBRP. On the other hand, for the last two years request errors amounted to 102 cases which were mainly due to incorrect patient information. Most of the time, the blood bank personnel would detect discrepancies between patient identification data written on the request form and the patient's historical data. Nevertheless, a lack of knowledge and awareness of specific requirements too contributed to this outcome.

Twenty cases of NM in 2021 were during pre-transfusion testing due to transcription errors of the barcode manually which did not tally with the generated label on the blood bag. This was only discovered during the final administration of checking at the bedside. In 2020 and 2021, there were 2 and an error respectively during component labelling in which blood bank personnel performed GXM on two patients at one time. However, the blood bank personnel mistakenly pasted the result that belonged to the patient to the other.

In 2020, another 4 cases were due to sample receipt and registration error where errors were due to incorrect sample receipt and registration at the blood bank in which there was a switching of patient's samples as well as previous history was not being checked. Meanwhile, in 2021 there was one error involving this step.



	Request error	Sampling /labelling error	Sample receipt and registration error	Component labelling
2020	70	1	4	2
2021	30	3	1	0

Figure 3.7.3b: Probable RBRP in 2020 – 2021

3.7.4 AVOIDABLE/ DELAYED/ UNDERTRANSFUSED (ADU) – Figure 3.7.4

3.7.4.1 According to SHOT UK 2018, ADU category of outcome 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. This occurs when there is a failure in communication, incorrect decisions, or poor prescribing based on poor knowledge.

3.7.4.2 NHCC received 1 case of IBCT that was avoidable in 2020 but fortunately none in 2021.

3.7.4.3 In 2020, there was a case where the patient was not planned for platelet transfusion but was transfused with platelet. There were too many HOs involved for a patient and there was a failure of the staff nurse to check the blood against the patient's full identity.

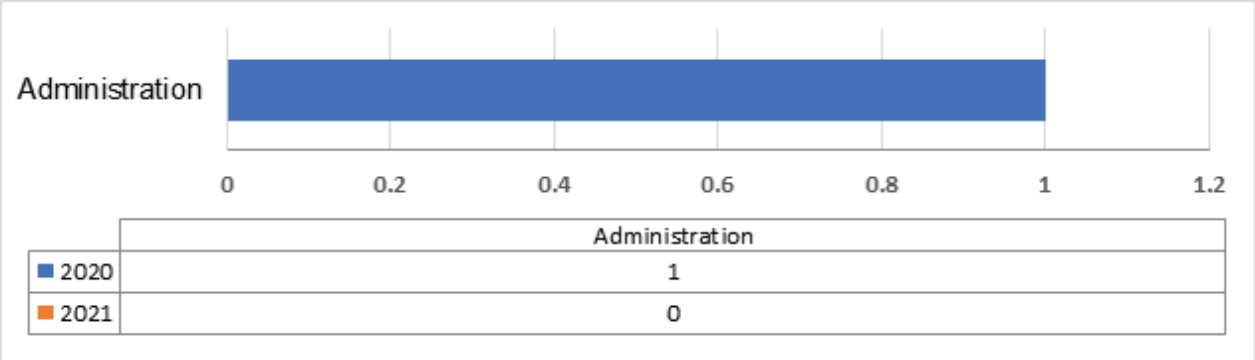


Figure 3.7.4: Avoidable Transfusion in 2020 – 2021

3.8 IMPUTABILITY – Table 3.8.1, 3.8.2

3.8.1 Once the investigation of the adverse transfusion event is completed, the assessment of the strength of the relationship to the transfusion of the adverse transfusion event is performed based on the definition shown in table 3.8.1. [Adopted from IHN July 2011 and Promoting Donor care-Imputability Assessment Tool-170720-1408-4248]

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	When there is insufficient data for imputability assessment

Table 3.8.1: Imputability

3.8.2 Nearly 89% (n=49) of the patients that were confirmed transfused with the wrong blood components have recovered with no ill effects and the remaining were reported with recovery but required extended length of stay.

3.8.3 Meanwhile there was a death reported in 2020 and two in 2021. These deaths were reported as unlikely related to transfusion. The cause of death was due to the severity of the patients underlying clinical condition.

3.8.4 Aside from this, there were 3 cases in 2020 and 2 cases in 2021 where the imputability was not assessable in which the outcome was not stated. Although considerable time and expenses were invested in instituting procedures and policies, human errors continue to occur at a seemingly irreducibly small rate in transfusion practices, sometimes with catastrophic results. The completion of reporting is vital to analyse the report.

	IMPUTABILITY										
	Confirmed/ Certain n=55		Likely/ Probable n=0		Possible n=0		Excluded/ Unlikely n=3		Not accessible n=5		Total
	2020	2021	2020	2021	2020	2021	2020	2021	2020	2021	
Recovered with no ill effect	22 2	7	0	0	0	0	0	0	0	0	49
Recovered with illness (morbidity)	4	2	0	0	0	0	0	0	0	0	6
Death	0	0	0	0	0	0	1	2	0	0	3
Outcome not available	0	0	0	0	0	0	0	0	3 2	5	
Total	26 2	9	0	0	0	0	1	2	3 2	6	3

Table 3.8.2: IBCT Clinical Outcome Severity by Imputability in 2020 – 2021

CHAPTER

04

INCIDENT

4.1 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

4.2 INCIDENCE- Figure 4.2

4.2.1 There were a total of 181 cases in 2020 and 144 cases reported in 2021 (including 2 incomplete reports).

4.2.2 Error in previous admission recorded the highest number of incidences for both 2020 and 2021 with 62 cases of blood bank error, and 44 cases of undetermined cause respectively. One example of blood bank error, involved blood bank interpretation error in the previous admission. The reporting hospital's investigation found that the blood bank personnel misinterpreted the blood group after reading forward and reverse grouping, which led to incorrect transcription of the blood group in the GSH form and LIS system. Another example is the transcription error of a rare phenotypic by blood bank personnel as a result of the lack of knowledge which resulted in the wrong phenotype being recorded in the system. While error in previous admission that had undetermined cause were typically errors that occurred more than 10 years ago and for which the pertinent records were already in the archive area.

4.2.3 Error in other facilities was the second highest number of cases in both 2020 and 2021 whereby possible procedural error by labarotory personnels in Klinik Kesihatan reported 44 cases, while error in other facilities of undetermined cause reported 24 cases. Whereas, there were 32 cases reported in 2020 and decrease to 12 in 2021 under the sub-category of transcription error in ANC book. This error was detected by the reporting hospital blood bank when the wrong blood group was used to request for blood. There was also an incident in which a different patient's blood result was attached and documented in the ANC book, resulting in discrepancy of blood group between current GSH and the blood group written in the request form. Undetermined cause events were either the result of a blood bank error or a sampling or labelling error in the ward since there was not enough information available to make a more accurate determination.

4.2.4 There were 25 reported cases in 2020 and increased to 37 in 2021 in which patient admitted to hospital by using other person's identification. There was a case reported whereby a patient was admitted to a hospital using someone else's identification card found. Further history revealed that the patient was born in Malaysia to foreign parents and claimed has been applying for citizenship since 2012. Patient allegedly misused the lost ID card as the registration ID during admission. Another case example involving sharing same ID was reported involving a foreign patient. Blood bank noted that there was a blood group discrepancy with the previous record of admission. Otherwise, patient denied any history of hospital admission. Further investigation revealed that the employer kept his passport together with other foreign workers' passports. Hence, there was a possibility of his employer using his passport for his colleague's hospital admission in which the diagnosis on the GSH tallied with his colleague's admission diagnosis.

	WBG written on ANC Book (10C)	WBG on formal result from lab @ KK (10D)	Cause can't be determined (10B)	Share same ID/ Registration error (10A)	Blood bank error (10F)	Cause can't be determined (10E)	Ward error (10G)
2020	32	44	8	25	62	10	0
2021	12	11	24	37	10	44	4

Figure 4.2: Total Number of Incidents Reported in 2020– 2021

4.3 CONTRIBUTING FACTORS

4.3.1 The contributing factor involved in the case of blood grouping error in KK, were due to wrong techniques (tile method) or reagent used for ABO blood grouping.

4.3.2 Another contributing factor involved is the management and organisational factors. In certain district hospitals, ABO and Rh D test were not done twice for GSH request due to financial constraint. In local SOP of certain hospitals, second verification of blood grouping is not required for GSH sample. Second verification is only done for GXM request or GSH converted to GXM request. This could lead to undetectable error of wrong blood group record in LIS system due to misinterpretation of blood group result by blood bank personnel.

4.3.3 Technology factor involving old LIS system also contributed to the undetectable wrong blood grouping interpretation error by the blood bank personnel. In one reported case received by NHCC, the previous LIS system (Delphyn version 7.4.5) cannot automatically detect wrong blood group interpretation when the forward and reverse blood grouping results were entered in the system. Instead, it saved the records according to the entry keyed-in by the blood bank personnel. In this setting, the system should be able to be a safeguard and able to give a warn or a flag if the wrong blood grouping was keyed-in.

4.3.4 Team factors such as of lack of staffing during certain hours (i.e. after office hours) was also an important factor that contributed to the human error especially when the workload was high.

4.3.5 Limited knowledge on rare phenotype may lead to wrong blood group transcription.

4.4 RECOMMENDATIONS

a) Adherence to standard operating procedure (SOP) is crucial in the blood transfusion process and this should be applied by all personnel including the doctor in charge, staff nurses, laboratory personnel and also the registration staff.

b) In future, all hospitals shall implement safety registration procedures, for example, using a thumbprint-based system to avoid incidents of sharing the same registration ID by patients.

c) Continuous medical education (CME) and training in order to address the issue of lack of knowledge and compliance to SOP.

d) Periodic clinical audits to improve the quality and adherence to SOP.

CHAPTER

05

ADVERSE TRANSFUSION REACTION

5.1 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.

5.2 OVERVIEW OF ADVERSE TRANSFUSION REACTION (ATR) REPORTS – Table 5.2

The total number of ATR report received in 2020 was 4042 and 3549 in 2021. NHCC had further sub-categorized these reports into confirmed, incomplete or unrelated to ATR. In 2020, there were 6 cases with incomplete data and the numbers has increased to 8 in 2021. There were 202 cases in 2020 and 235 cases in 2021 initially reported as ATR, however they were withdrawn and recategorised as Not Related to Transfusion (NTR), leaving a complete report for analysis of 3834 in 2020 and 3306 in 2021.

ATR REPORT	Number Of Report Received	
	2020 N=4042	2021 N=3549
Confirmed (analysed in the report)	3834*	3306*
Incomplete	6	8
Not Related to Transfusion (NTR)	202	235

Table 5.2: Total Number of Adverse Transfusion Reaction Reported

5.3 TYPES OF ADVERSE TRANSFUSION REACTION (ATR) REPORTED – Table 5.3

The number of confirmed adverse transfusion reaction reported has reduced from 3834 in 2020 to 3306 in 2021. Mild Allergic Reaction, FNHTR and Uncommon Complications of Transfusion (UCT) were the three most common type of ATR. This remains similar to previous Haemovigilance Reports.

No	Type of ATR	Number of cases	
		2020	2021
1.	Acute Immune Haemolytic Transfusion Reaction	0	0
2.	Delayed Immune Haemolytic Transfusion Reaction	3	2
3.	Non Immune Haemolytic Transfusion Reaction	2	1
4.	Febrile Non Haemolytic Transfusion Reaction (FNHTR)	1304	1081
5.	Mild Allergic Reaction	1881	1576
6.	Moderate Allergic Reaction	143	174
7.	Severe Allergic Reaction	10	26
8.	Transfusion Related Acute Lung Injury (TRALI)	3	4
9.	Transfusion Associated Circulatory Overload (TACO)	50	66
10.	Transfusion Associated Dyspnoea (TAD)	73	58
11.	Transfusion associated Graft vs Host Disease (TA-GvHD)	0	0
12.	Post Transfusion Purpura	1	0
13.	Post Transfusion (Virus)	1	0
14.	Post Transfusion (Bacteria)	0	0
15.	Post Transfusion (Parasite)	1	0
16.	Handling and Storage Area	0	0
17.	Equipment related	0	0
18.	Uncommon Complications of Transfusion (UCT)	434	382
19.	Hypotensive Transfusion Reaction	2	10
20.	Others	0	2
	Total Confirmed ATR	**3908***	**3382***
	Incomplete report	6	8
	Not Related to Transfusion (NTR)	202	235
	TOTAL	**4116**	**3625**

Table 5.3: Incidence of ATR based on Type of Reaction in 2020 & 2021

**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.*

5.4 ADVERSE TRANSFUSION REACTIONS REPORTS ACCORDING TO TYPES OF REACTION

5.4.1 FEBRILE, ALLERGIC, HYPOTENSIVE REACTIONS (FAHR) – Table 5.4.1.1, Figure 5.4.1.2, Figure 5.4.1.4

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.

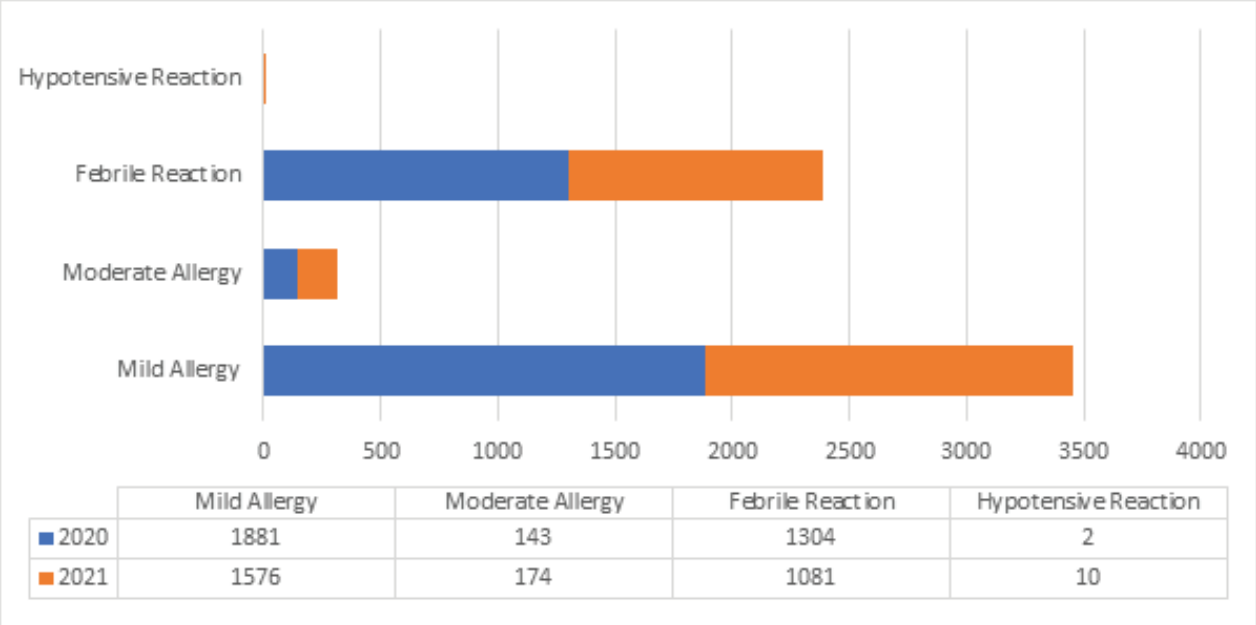
5.4.1.1 Definition:

Reactions	Definition	
Febrile type reaction	Mild	A temperature ≥38℃ and a rise between 1℃ and 2℃ from pre-transfusion values, but no other symptoms/signs
	Moderate	A rise in temperature of ≥2℃ or fever ≥39℃ and/or rigors, chills, other inflammatory symptoms/signs, such as myalgia, or nausea which precipitate stopping the transfusion
	Severe	A rise in temperature of ≥2℃ or fever ≥39℃ 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)
	Mild	Features of mild febrile and mild allergic reactions

Reaction with both allergic and febrile features	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: acidaemia, impairment of vital organs function) without allergic or inflammatory symptoms. Urgent medical intervention required

Table 5.4.1.1: Definitions of FAHR *(Adopted from SHOT Report 2021)*

5.4.1.2 Mild allergic reaction was the highest reported cases (3457, 56%) in both years among FAHR cases, followed by FNHTR (2385, 38.6%) and moderate allergic reaction (317, 5.1%). The least reportable in this category was transfusion associated hypotensive reaction (12, 0.3%).



	Mild Allergy	Moderate Allergy	Febrile Reaction	Hypotensive Reaction
2020	1881	143	1304	2
2021	1576	174	1081	10

Figure 5.4.1.2: Number of Reported Cases of Allergic, Febrile, and Hypotensive Reactions

5.4.1.3 Due to recent update in the SHOT definition on reaction with both allergic and febrile features, hospital blood banks are urged to follow this changes as NHCC will count these type of reaction on its own category in the subsequent haemovigilance report.

5.4.1.4 Majority of ATR cases had reported patient recovery with no ill effects and less than 1% reported as recovered with ill effects and death. There was a total of 12 deaths reported but the cause of death were reported as not related to transfusion.

	Recovered with no ill effects		Recovered with ill effects		Death	
	2020	2021	2020	2021	2020	2021
Febrile reaction	1294	1080	2	1	8	0
Allergic reaction	2019	1745	1	2	4	3
Hypotensive reaction	2	10	0	0	0	0

Figure 5.4.1.4: Outcome of Adverse Transfusion Reaction

5.4.1.5 The treatment suggested for febrile reactions is antipyretics whereas allergic reaction should be treated with antihistamine (steroid should not be used routinely) and in case of anaphylaxis, adrenaline is essential. The recommended prevention of recurrent febrile reaction is to give antipyretics 60 minutes before anticipated time of reaction. Pre-transfusion antihistamine can be given 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.

5.4.2 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 5.4.2.1, Figure 5.4.2.2, Table 5.4.2.3, Table 5.4.2.4, Table 5.4.2.5, Table 5.4.2.6

5.4.2.1 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 term “possible TRALI” has been dropped. 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) is proposed. 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 ≤ 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 5.4.2.1 SHOT Criteria for Assessment of TRALI Cases *(Adopted from SHOT Report 2020)*

TRANSFUSION-RELATED 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: • clinical physical examination, and/or • radiographic chest imaging and/or other noninvasive assessment of cardiac function
Additional criteria	
C	Evidence for cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema
D	Evidence of fluid overload including any of the following: a positive fluid balance; clinical improvement following diuresis
E	Supportive result of a relevant biomarker, e.g. an increase of B-type natriuretic peptide levels (BNP) or N-terminal-pro brain natriuretic peptide) NT-pro BNP to greater than 1.5 times the pre-transfusion value.

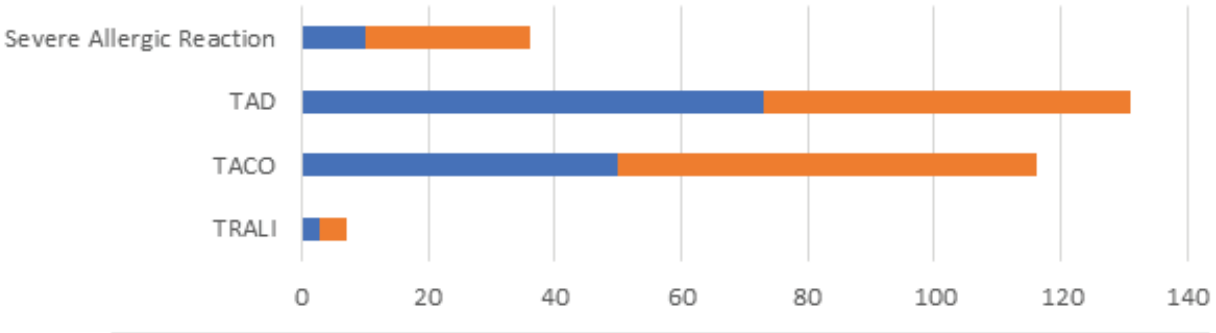
TRANSFUSION ASSOCIATED DYSPNOEA (TAD)

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).

5.4.2.2 There were a total of 136 cases in 2020 and 154 cases in 2021 related to pulmonary complications. The adverse event included are TRALI, TACO, TAD and severe allergic reaction. TAD showed the highest number of reported case in 2020 (73, 53.7%) while TACO was the highest reported case in 2021 (66, 42.9%). TRALI was the least reported event for both years with 3 (2.2%) and 4 (2.6%) cases in each year respectively.



	TRALI	TACO	TAD	Severe Allergic Reaction
2020	3	50	73	10
2021	4	66	58	26

Figure 5.4.2.2: Total Number of Cases of Pulmonary Complications

5.4.2.3 In 2020 all three reported TRALI cases showed significant clinical pictures but only 1 case submitted a complete serology HLA antibody test, of which the result was negative. The serology test for the two other cases were unavailable as the reporting hospitals did not manage to send both patients' blood sample for testing. Meanwhile in 2021, 4 cases of TRALI was reported but only one case submitted a complete serology HLA antibody test, of which the result was negative. For the 3 other cases no serology test was sent by reporting hospital but all the cases had significant clinical picture of TRALI.

Category	TRALI Type I				TRALI Type II			
	Antibody-positive		Antibody-negative		Antibody-positive		Antibody-negative	
	2020	2021	2020	2021	2020	2021	2020	2021
Highly likely	-	-	-	-	-	-	-	-
Probable	-	-	-	-	-	-	-	-
Antibody-negative TRALI (serology negative)	-	-	1	-	-	-	-	1
Clinically suggestive of TRALI (no serology sent)	-	-	2	1	-	-	-	2

Table 5.4.2.3 Summary of Reported TRALI Cases in 2020 and 2021

Then, in light of the previously mentioned increase in TACO cases in 2021, clinicians are urged to implement the TACO pre-transfusion checklist to reduce the risk of adverse transfusion reactions.

5.4.2.4 In 2020, 89.7% of pulmonary related ATR cases had reported patient recovery with no ill effects, 7.4% had recovered with ill effect and death reported in 2.9% of cases. There were 4 cases reported as deaths but all were not related to transfusion. One death was related to gastrointestinal bleeding, while the other three were related to sepsis.

Meanwhile in 2021, 87% of pulmonary related ATR cases reported patient recovery with no ill effects and 8.4% had recovered with ill effects. There were seven (4.5%) cases related to death where five cases were sepsis-related, one was related to malignancy and another was due to acute coronary syndrome.

	Recovered with no ill effects		Recovered with ill effects		Death	
	2020	2021	2020	2021	2020	2021
TRALI	0	2	2	1	1	1
TACO	41	54	7	8	2	4
TAD	72	56	1	0	0	2
Severe Allergic Reaction	9	22	0	4	1	0

Table 5.4.2.4: Outcome of Adverse Transfusion Reaction (2020 and 2021)

5.4.2.5 Patients must be informed about risks of transfusion as a part of their consent discussion. Clinicians must assess risks, initiate mitigating measures where possible, and manage complications as thorough investigations can help to identify areas for improvement. Use of the TACO pre-transfusion checklist is recommended for preventing TACO-related transfusion reactions.

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 RISK 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	
Monitor the vital signs closely including oxygen saturation.	

Table 5.4.2.5: TACO Checklist (Adopted from SHOT Report 2020)

5.4.2.6 Categorisation of pulmonary complications following transfusion remains a complex area. Knowing the differences in clinical presentations will definitely help to identify ATR earlier. For instance,, TAD is an exclusion diagnosis that does not fit TRALI, TACO or severe allergic reaction criteria, either because clinical features do not meet criteria or because there was insufficient information to classify.

	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	Yes
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 5.4.2.6: Comparison table to assist with pulmonary reaction classification
(Adopted from SHOT Report 2021)

5.4.3 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.

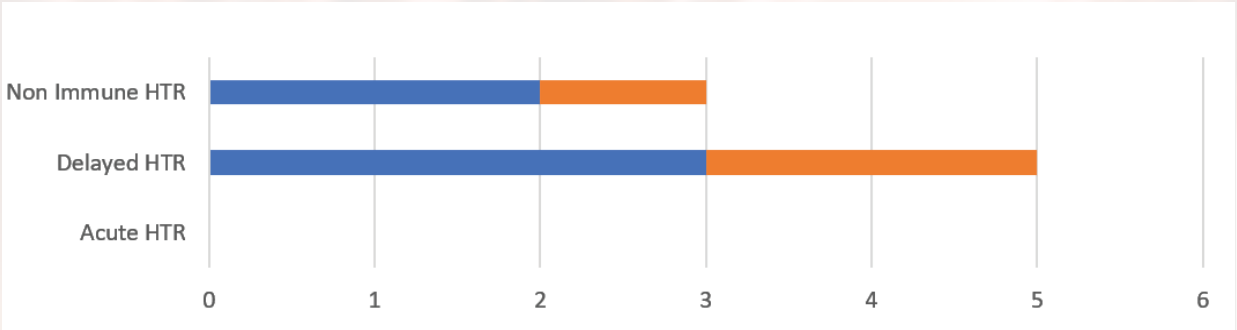
5.4.4 HAEMOLYTIC TRANSFUSION REACTION (HTR) -Figure 5.4.4.2, Table 5.4.4.3

5.4.4.1 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.

5.4.4.2 There were no reported cases of acute HTR in 2020 and 2021. In 2020, there were 3 cases of DHTR and 2 cases of Non Immune HTR while in 2021 there were 2 cases of DHTR and 1 cases of Non Immune HTR. In 2020 out of 3 DHTR reports, 2 of them were due to presence of antibody and 1 was due to possible unmatched phenotype. Both of non-immune HTR were due to mechanical and storage factors. Mechanical factor was due to unsuitable branula size and manual process of syringing out the red cells during transfusion. In addition, in both cases, the red cells were not stored at correct place and temperature prior transfusion. Meanwhile in 2021 both DHTR cases occurred due to presence of antibodies. One case of a non-immune hemolytic transfusion reaction in a patient taking the iron chelating medication defarasirox was documented, however the reason of the haemolysis was unknown.



	Acute HTR	Delayed HTR	Non Immune HTR
2020	0	3	2
2021	0	2	1

Figure 5.4.4.2: Number of Cases of Haemolytic Transfusion Reaction

5.4.4.3 All HTR cases recovered with no illness except for 1 non immune HTR whereby the patient suffered from jaundice. There was no mortality reported in both 2020 and 2021.

	Recovered with no ill effects		Recovered with ill effects		Death	
	2020	2021	2020	2021	2020	2021
Acute HTR	0	0	0	0	0	0
Delayed HTR	3	2	0	0	0	0
Non-immune HTR	1	1	1	0	0	0

Table 5.4.4.3: Outcome of Adverse Transfusion Reaction

5.4.4.4 To prevent an immune HTR, patients must be given correct blood products as well as matched phenotype and antibody-negative red cells when clinically significant antibodies are detected. For non-immune HTR, suitable intravenous access and blood administration set must be available for transfusion. Temperature of blood products should be closely monitored as well as kept at suitable place to ensure safe transfusion. The usage of 3-way connectors or syringe pumps should be avoided.

5.4.5 UNCOMMON COMPLICATIONS OF TRANSFUSION (UCT) - Figure 5.4.5.2, 5.4.5.3

5.4.5.1 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.

5.4.5.2 Total number of UCT cases reported were 434 in 2020 and has dropped to 382 in 2021.

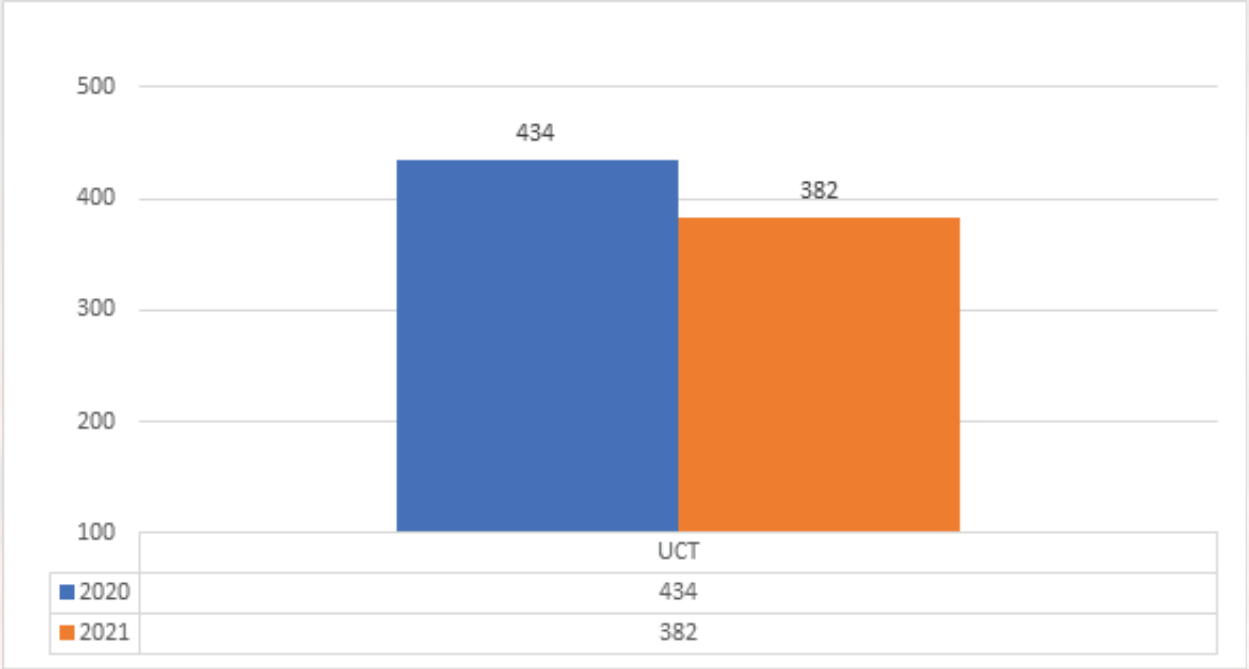
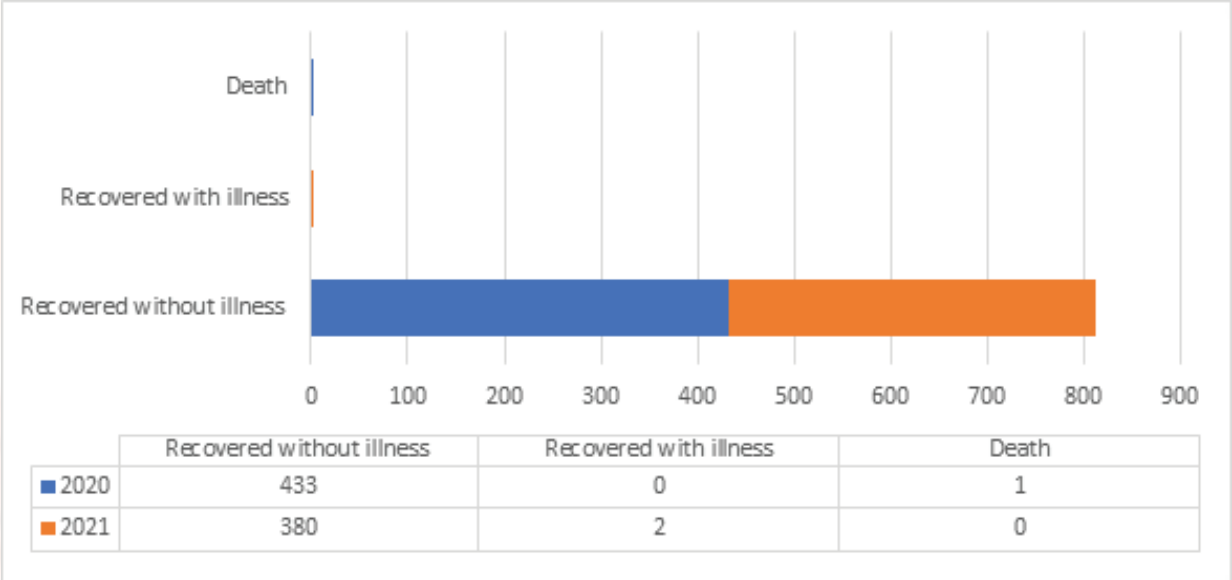


Figure 5.4.5.2: Number of cases of UCT

5.4.5.3 Majority of the patients recovered without illness. However, there was one reported death in UCT but it was not related to transfusion. The cause of death was acute coronary syndrome. Other than that, two patients were reported to have recovered with ill effects in 2021 none in 2020.



	Recovered without illness	Recovered with illness	Death
2020	433	0	1
2021	380	2	0

Figure 5.4.5.3: Outcome of Adverse Transfusion Reaction

5.4.5.4 Blood transfusion should only be done after weighing the risks and benefits. Close monitoring during transfusion is vital to detect early signs and symptoms of transfusion reactions to prevent worsening of patient's condition. Preventive measure should be taken prior to future transfusions to avoid recurrence.

5.4.6 TRANSFUSION-TRANSMITTED INFECTION (TTI)

5.4.6.1 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

5.4.6.2 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. There were two reported cases of TTI in 2020 involving HIV and parasitic infection of Plasmodium Malariae. These patients with TTI recovered with illness and being treated accordingly. There were no cases of TTI reported in 2021.

Case I
This is a case of a 51 years old gentleman with underlying hypertension, diabetes and history of TB spine. He received 1 unit of packed cell transfusion in October 2014 and was started on anti-TB treatment for spinal TB based on MRI findings. A month later in November 2014, he presented to another hospital with a complaint of bilateral lower limb weakness, urinary & bowel incontinence and fever. Infective screening was taken at the time. Two weeks later in December 2014, the patient underwent a spinal operation. Subsequently, he was referred to a district hospital for continuation of care. His infective screening taken back in November 2014 was reviewed and noted to be positive for HIV infection. Confirmatory investigations also showed similar findings. Prior to transfusion, there was no baseline virology test on the patient.

The blood donor was contacted, fresh bleed done in June 2020 revealed positive for HIV and syphilis. The donor had a risk factor of high risk behaviour prior to past donation until present. Donation serological screening in 2014 showed negative for HIV, Hepatitis B, Hepatitis C and Syphilis. The lookback on the other blood components from the same donation revealed that the fresh frozen plasma was transfused but the patient had passed away due to underlying medical illness while the platelet expired and discarded.

This case was only reported to blood bank in year 2020 as the patient defaulted his follow up from 2015 to 2019. There was a discussion for HIV RNA sequencing/genotyping test with Institute of Medical Research (IMR), but it is not advisable in view of HIV virus is easily mutated due to many factors such as upon consuming medication or having multiple sexual partners. For this case, the possibility of acquiring infection during window period donation could not be excluded.

Case II
Patient A is a 61 year old Sabahan male with no known medical illness who was admitted for moderate traumatic brain injury with polytrauma in February 2020. He was transfused with 1 unit of packed cell. Post transfusion noted patient had persistent fever. Upon further investigation, BFMP noted Plasmodium Malariae infection.PCR was done
to confirm the diagnosis.

The blood donor was contacted, look back and recall was done. The donor tested positive for Plasmodium Malariae. The donor donated once in November 2019 and once more in February 2020. The blood product from November 2019 donation was transfused to patient B. However, patient B tested negative for Plasmodium Malariae. The blood products from February 2020 donation were transfused to Patient A and Patient C. However, upon tracing, patient C had passed away due to severe sepsis secondary to small bowel obstruction with bowel ischaemia. Patient A was treated for Malaria and required a prolonged hospital stay.

BFMP is not a routine screening done for donated blood in Malaysia. That could be the possible cause of missing the infection if the donor did not have any presenting complaints upon counselling. The gold standard diagnostic tool for Malaria is PCR however in view of the cost it is not routinely done compared to BFMP.

5.4.7 POST TRANSFUSION PURPURA (PTP)

5.4.7.1 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.

5.4.7.2 There was one case of PTP reported in 2020 and no case reported in 2021.

Case I
32 years old malay male with underlying severe pulmonary hypertension, hypogonadism and Beta Thallasaemia Major on regular monthly transfusion, presented with myalgia, arthralgia and multiple bruises with purpuric lesions mainly over bilateral lower limbs 10 hours post transfusion. It was not associated with itchiness or swelling. Pre transfusion blood investigation showed Hb of 8.5, Platelet 201, WBC 5.71 and post transfusion blood investigation showed Hb 11, Platelet 122, and

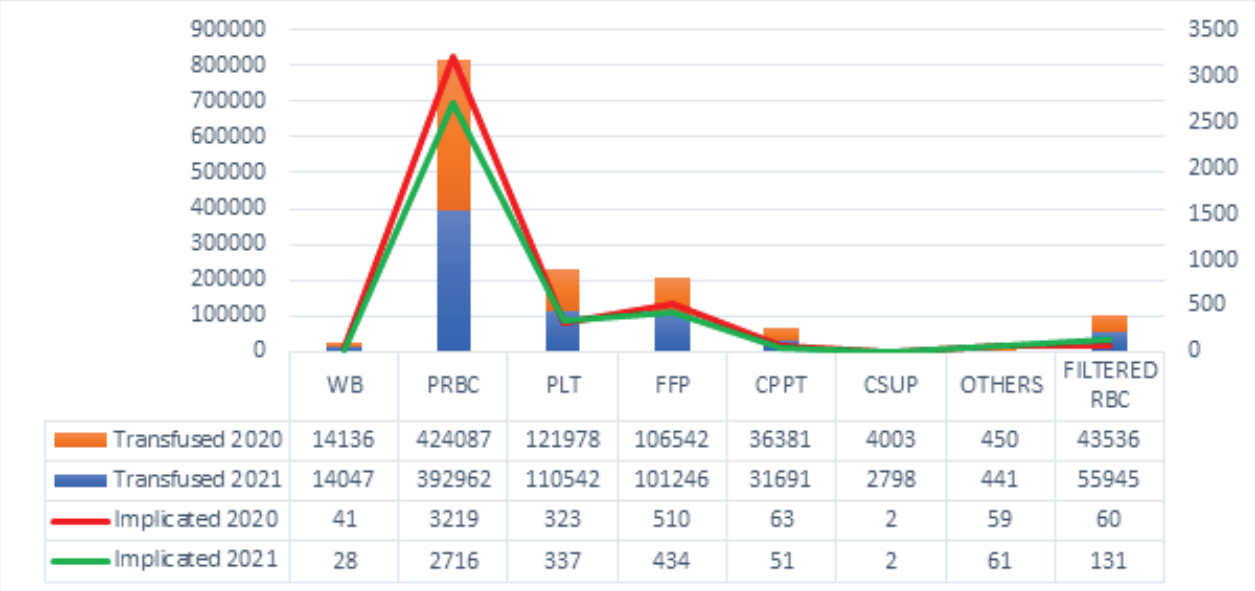
WBC 4. A reduction in the platelet count was observed. Other causes of thrombocytopaenia were ruled out. The patient was given IVIg for 3 days followed by tapering dose of steroids. Patient's condition improved and he recovered without illness. However, further testing to detect HPA antibodies was not done.

5.4.8 EMERGING DISEASES

In the early year of 2020, the world had been badly hit by COVID-19 global pandemic. The world of medicine had undergone many changes since then. Blood banks were also affected tremendously in matters of donor selection criteria, blood collections and balancing the need to supply whilst ensuring donor and patient safety. The National Blood Centre had come up with many measures to ensure blood safety such as Confidential Unit Exclusion (CUE) card distribution to donors by allowing donors to indicate confidentially if they think that their blood is not safe for transfusion, which includes any COVID-19 contact or confirmed cases. In the event of any CUE, the implicated blood products will be quarantined until further notice and discarded if indicated. However if the blood products have been transfused, clinicians will be notified for further action. To date, there has not been any reported case of transfusion transmitted SARS-CoV-2 to NHCC.

5.5 TYPE OF BLOOD COMPONENT TRANSFUSED AND ATR COMPLICATION – Figure 5.5

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.

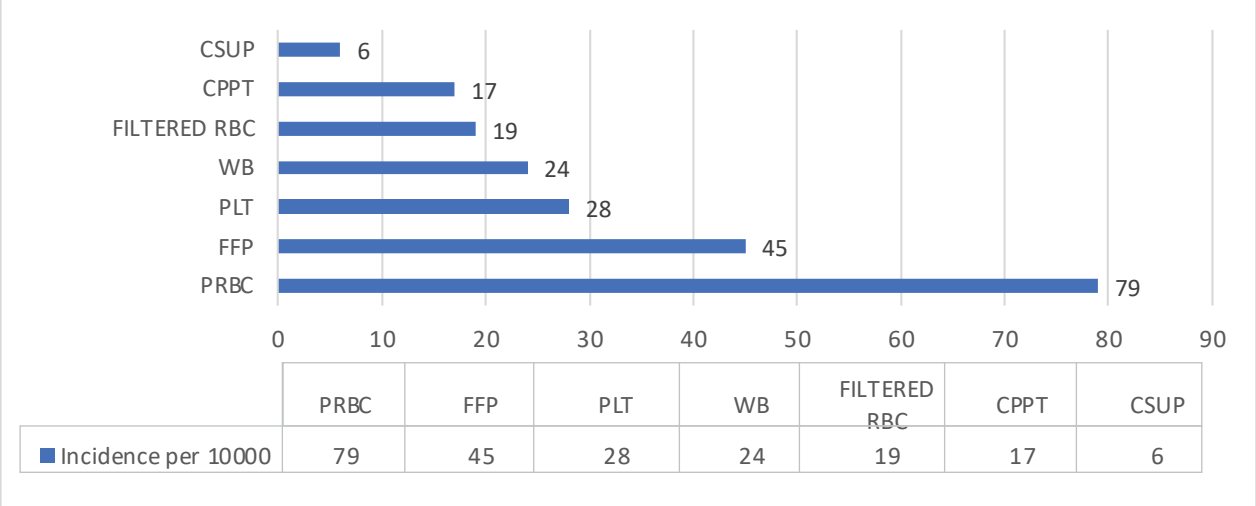


	WB	PRBC	PLT	FFP	CPPT	CSUP	OTHERS	FILTERED RBC
Transfused 2020	14136	424087	121978	106542	36381	4003	450	43536
Transfused 2021	14047	392962	110542	101246	31691	2798	441	55945
Implicated 2020	41	3219	323	510	63	2	59	60
Implicated 2021	28	2716	337	434	51	2	61	131

Figure 5.5: Total Number of Blood Component Transfused and Implicated with ATR

5.6 INCIDENCE OF IMPLICATED BLOOD COMPONENTS IN 10,000 BLOOD COMPONENTS TRANSFUSED- Figure 5.6

The overall incidence of ATR in Malaysia was 55 per 10,000 blood components transfused. PRBC was the most implicated blood component with the ATR incidence of 73 per 10,000 PRBC transfused while cryosupernatant was the least with 6 per 10,000 transfused. Incidence of ATR associated with filtered RBC was 19 per 10,000 transfusion.



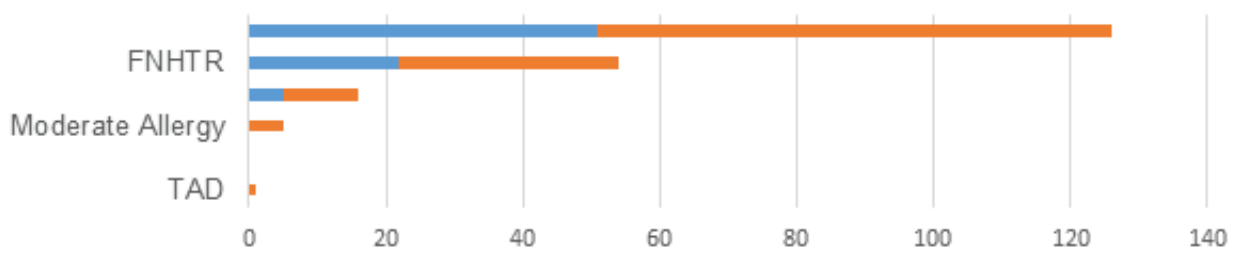
	PRBC	FFP	PLT	WB	FILTERED RBC	CPPT	CSUP
Incidence per 10000	79	45	28	24	19	17	6

Figure 5.6: Incidence of ATR per 10,000 blood components transfused

5.7 TYPES OF ADVERSE EVENTS ASSOCIATED WITH LEUCOFILTERED RED BLOOD CELL (RBC) - Figure 5.7

5.7.1 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. However, report showed that 29% of patients who received filtered RBC experience FNHTR.

5.7.2 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 10^6. Blood bank personnel must adhere to SOP during filtration process and quality check done for filtration to serve its purpose.



	TAD	TACO	Moderate Allergy	UCT	FNHTR	Mild Allergy
2020	0	0	0	5	22	51
2021	1	0	5	11	32	75

NTR= Not Transfusion Related

Figure 5.7: Types of ATR associated with Filtered Red Blood Cell

CHAPTER

06

ADVERSE DONOR REACTION

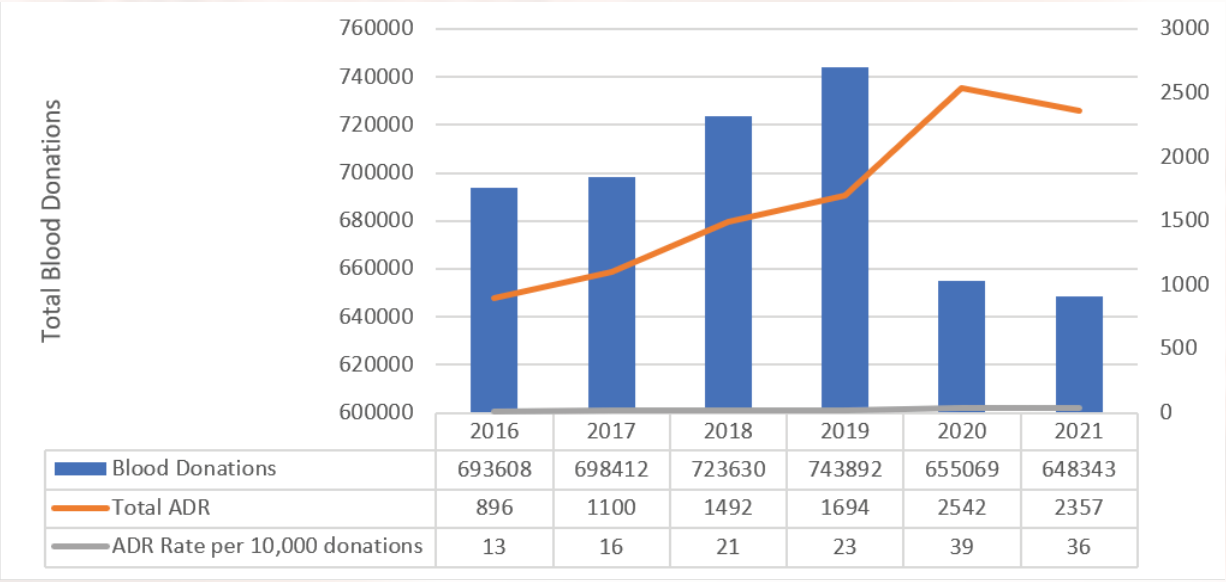
6.1 DEFINITION

6.1.1 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.

6.2 OVERVIEW OF ADVERSE DONOR REACTION (ADR) REPORTING – Figure 6.2

6.2.1 The total number of blood donations collected by government hospitals has increased over time. But the COVID-19 pandemic has had an unprecedented effect on blood supply and demand, resulting in a nearly 12% decline in blood collection in 2020 compared to 2019, and an additional 1% drop in 2021 compared to 2020.

6.2.2 Despite this, the blood bank collection centre improved its awareness of the need to report ADR in 2020, when the NHCC saw an increase in ADR reporting compared to previous years. However, this number then fell once more in the following year, 2021. As a result, in 2020 there were 39 cases of ADR per 10,000 units of blood collected, over doubling the previous year's rate of 23 cases per 10,000 units of blood collected. However, in 2021, this number decreased once more. As a result, the incidence of ADR increased from 23 per 10,000 blood donations in 2019, to 39 per 10,000 blood donations in 2020 before receding to 36 per 10,000 blood donations in 2021.



	2016	2017	2018	2019	2020	2021
Blood Donations	693608	698412	723630	743892	655069	648343
Total ADR	896	1100	1492	1694	2542	2357
ADR Rate per 10,000 donations	13	16	21	23	39	36

Figure 6.2: Rate of ADR per 10,000 blood collection from 2016 – 2021

6.3 TYPES OF ADVERSE DONOR REACTIONS (ADR) – Table 6.3

The trend of ADR was similar for both 2020 and 2021 where the incidence of vasovagal reaction (VVR) was the highest followed by haematoma. Other types of reactions reported included arterial puncture, delayed bleeding, nerve irritation, nerve injury, other arm pain, thrombophlebitis, cellulitis, citrate reaction, local allergic reaction and other serious complications related to blood donation.

No	Types of ADR	No of reported cases	
		2020	2021
1.	Hematoma	121	65
2.	Arterial puncture	3	2
3.	Delayed bleeding	7	2
4.	Nerve irritation	1	3
5.	Nerve injury	0	1
6.	Other arm pain	6	3
7.	Thrombophlebitis	1	0
8.	Cellulitis	0	1
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	2397	2276
14.	Citrate reaction	4	2
15.	Haemolysis	0	0
16.	Air embolism	0	0
17.	Local allergic reaction	1	0
18.	Generalized (anaphylactic) reaction	0	0
19.	Other serious complications related to blood donation	1	2
	Total	**2542**	**2357**

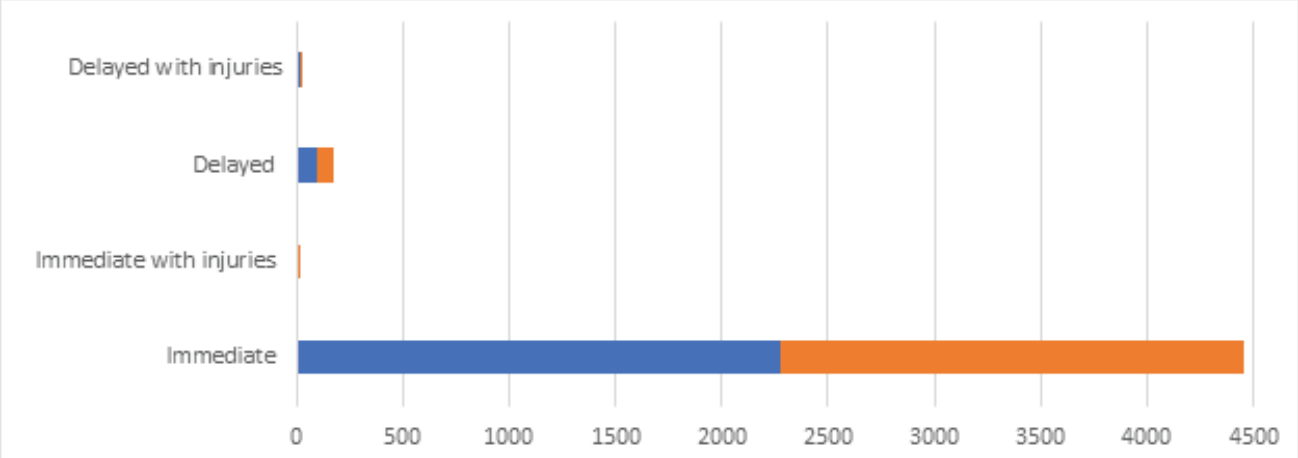
Table 6.3: Types of ADR in 2020 – 2021

6.3.1 VASOVAGAL REACTIONS (VVR) – Figure 6.3.1.2, 6.3.1.3, 6.3.1.4, 6.3.1.5, 6.3.1.6

6.3.1.1 Vasovagal reaction (VVR) is described as a general feeling of discomfort and weakness with anxiety, dizziness and nausea which may progress to loss of consciousness (faint). It is the most common acute complication related to blood donation. The mechanism can be from both physiologic and psychological factors. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors and the volume of blood removed, relative to the donor's total blood volume. Reactions can occur before phlebotomy (rare), during phlebotomy, or immediately after phlebotomy when the donor stands up abruptly, in the refreshment area, or later when the donor has left the donation area. Reactions accompanied by loss of consciousness (LOC) carry a risk of injury, particularly if they occur once the donor has left the collection site (delayed vasovagal reactions). It can be further classified based on severity (mild, moderate and severe) or also relating to whether VVR occurs with injury (fall, accidents) or without.

Mild VVR is a vasovagal reaction prior to or shortly after start of donation due to anxiety, fear, pain and manipulation at venepuncture site. The heart rate is usually low, and recovery is spontaneous or after certain measures. In addition to mild VVR, protracted hypotension, impaired consciousness, delayed responsiveness, recovery delayed (>30minutes); and improvement after medical treatment (sympathomimetic, IV infusion of crystalloids) is classified as Moderate VVR. In this situation, collection of blood is often impossible or prematurely discontinued. Whereas severe VVR is a VVR prior to or shortly after start of donation with shock, sometimes with loss of consciousness (LOC) accompanied by rigidity or tremor of extremities, pale to cyanotic, incontinence of urine and/or convulsions.

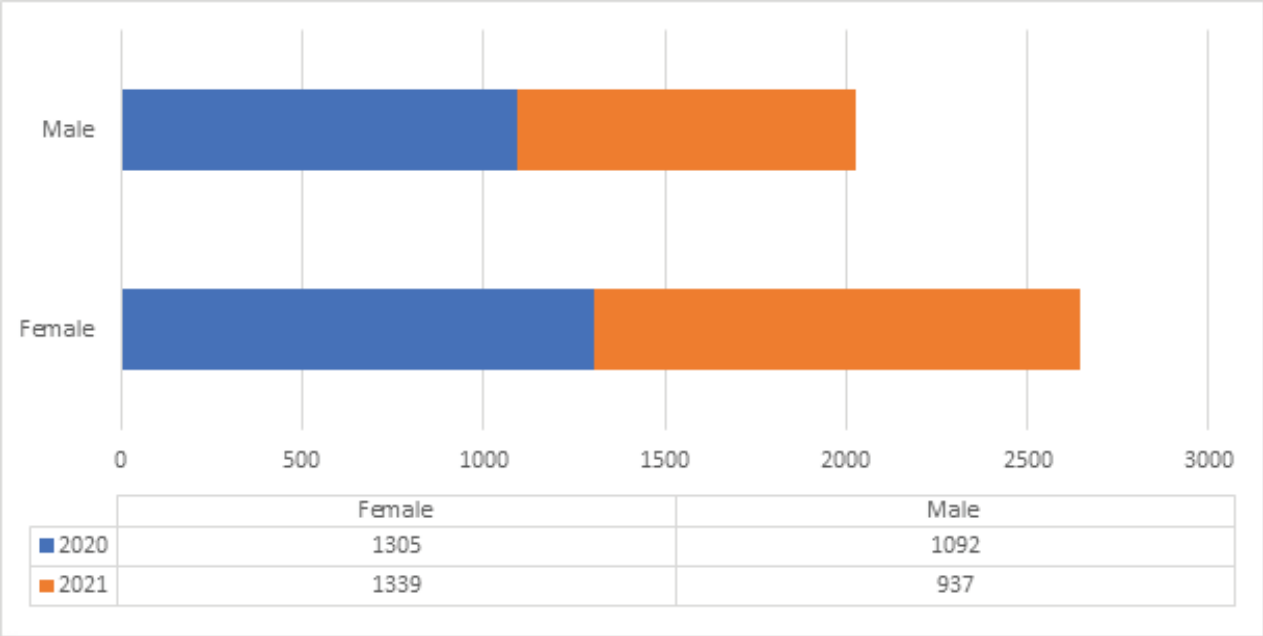
6.3.1.2 In both years, the commonest reaction experienced by donors was immediate VVR followed by delayed VVR. Incidence of ADR with injuries whether immediate or delayed were less than 1% each.



	Immediate	Immediate with injuries	Delayed	Delayed with injuries
2020	2272	11	99	15
2021	2179	12	77	8

Figure 6.3.1.2: Category of VVR in 2020 – 2021

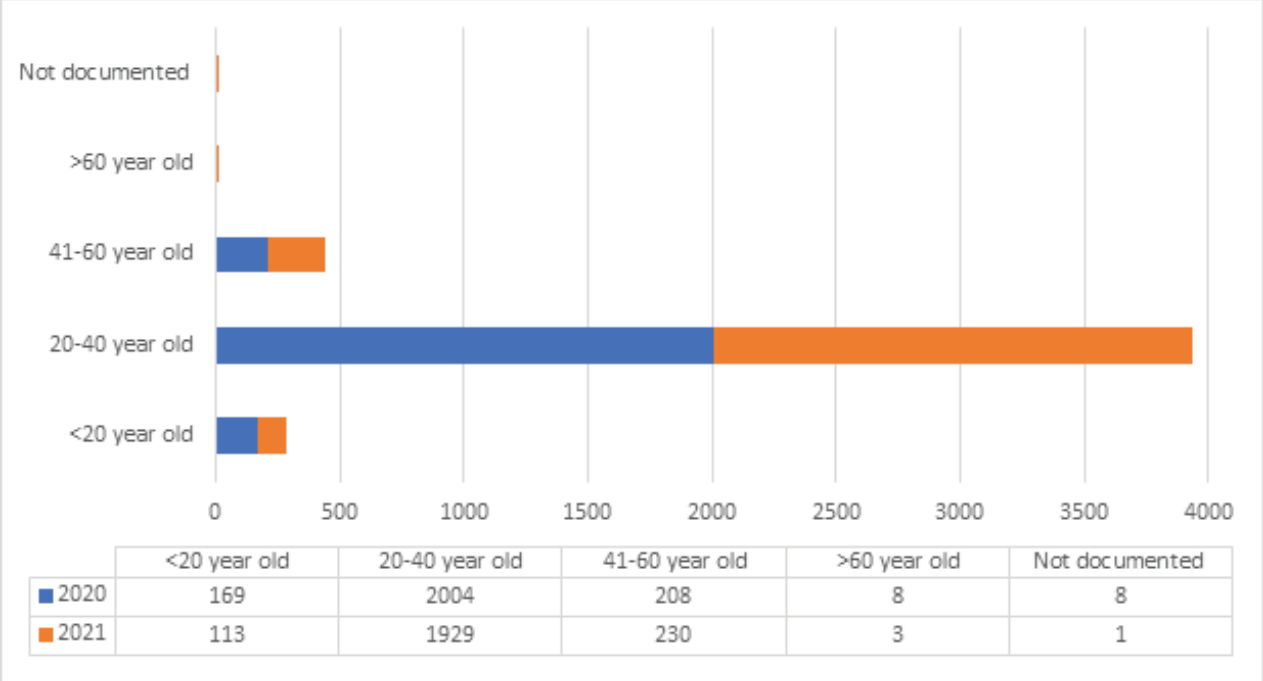
6.3.1.3 Annual Blood Report 2020 and 2021 showed that nearly two-third of the donors in MOH, Malaysia were males who contributed 64% (389,249) of the total donors in year 2020 with females 36% (218,808); and 63% (411,693) of donors were males in year 2021 with the remaining 37% (236,650) were females. Therefore, the incidence of VVR was two times higher in female donors with incidence of approximately 60 per 10,000 female donors as compared to 28 per 10,000 in male donors.



	Female	Male
2020	1305	1092
2021	1339	937

Figure 6.3.1.3: VVR Report based on Gender in 2020 – 2021

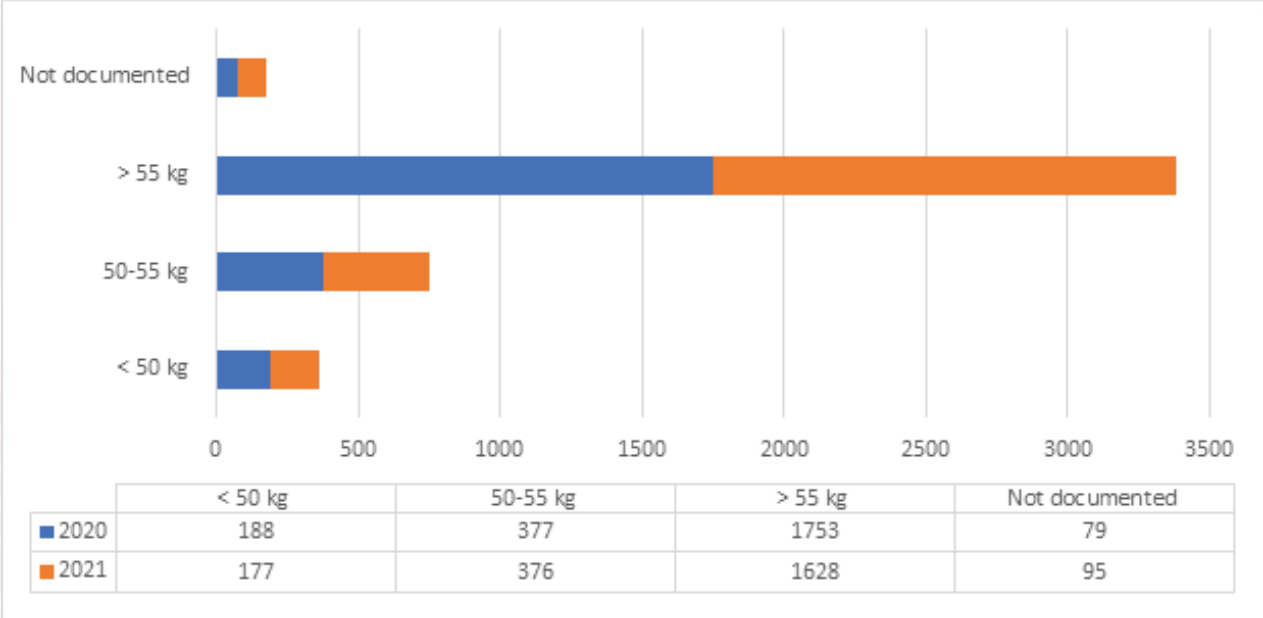
6.3.1.4 Younger donors were likely to experience VVR compared to older donors whereby donors in the age group of 20-40 years showed highest risk in developing VVR.



	<20 year old	20-40 year old	41-60 year old	>60 year old	Not documented
2020	169	2004	208	8	8
2021	113	1929	230	3	1

Figure 6.3.1.4: VVR Report based on Age in 2020 – 2021

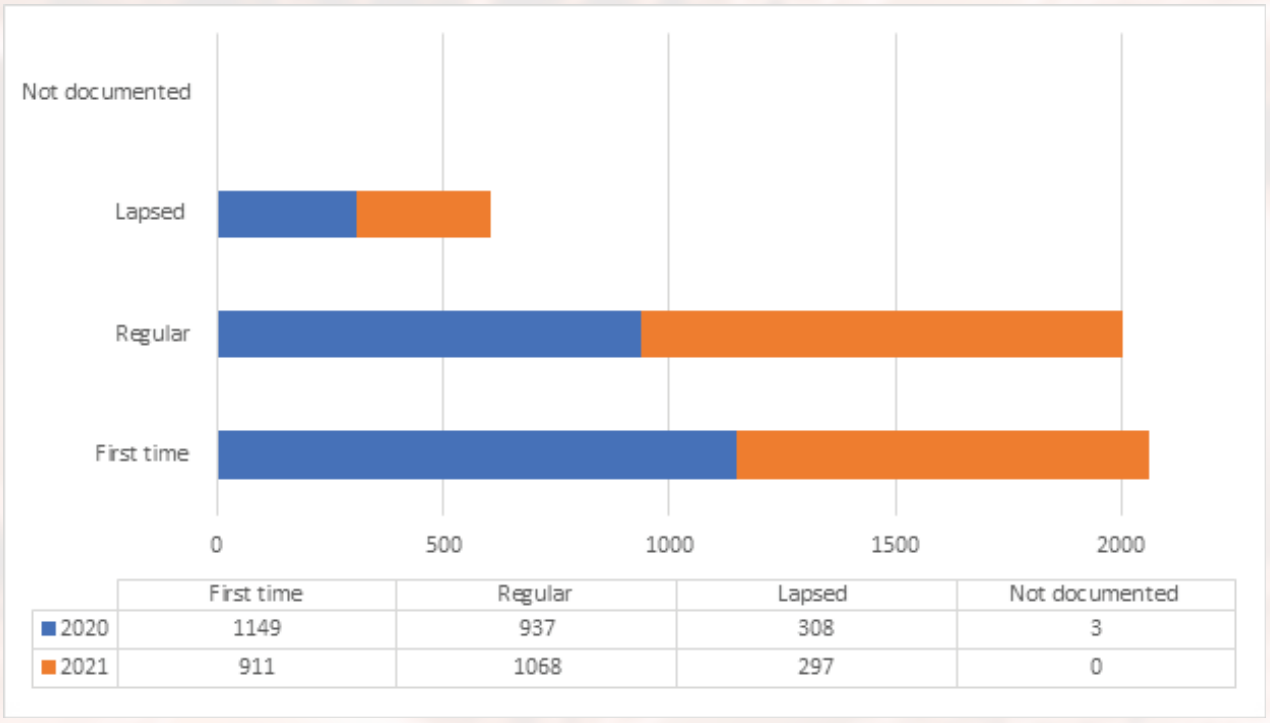
6.3.1.5 Most VVR cases were reported in blood donors that weigh more than 55kg. However, the incidence of ADR related to body weight could not be calculated as this data was not available. Furthermore, there were few data with no documented age or weight as it was not a compulsory field for ADR reporting.



	< 50 kg	50-55 kg	> 55 kg	Not documented
2020	188	377	1753	79
2021	177	376	1628	95

Figure 6.3.1.5: VVR Report based on Weight in 2020 – 2021

6.3.1.6 Data from Annual Blood Report 2020 showed that the total number new donors were 159,404 while repeat donors (regular and lapsed) were 495,665. Meanwhile, there were 136,870 new donors and 511,473 repeat donors (regular and lapsed) in year 2021. Data analysis showed that the incidence of VVR was nearly three times higher among new donors with 70 per 10,000 donations as compared to repeat donors of 26 per 10,000 donations.



	First time	Regular	Lapsed	Not documented
2020	1149	937	308	3
2021	911	1068	297	0

Figure 6.3.1.6: VVR Report based on Frequency of Donation in 2020 – 2021

6.3.1.7 All VVR cases had reported donor recovery with no ill effects for both 2020 and 2021. None of the donors ended up with morbidity or mortality.

6.3.1.8 Recommendations:

i. Physiological support: Strategies should be deployed to minimise vasovagal reaction such as preventing hypotension. Many studies have shown the benefit of increasing hydration 30 minutes prior to donation or eating a salty snack could help to sustain blood pressure during donation. Furthermore, donors could be taught and encouraged to do applied muscle tension (AMT) exercises which involve repeated contraction of major muscle groups to increase blood pressure and prevent the occurrence of VVR.

ii. Psychological support: 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.

iii. Donors should be made resting at least 15 minutes after donation for recovery before being allowed to leave for refreshment. Therefore sufficient waiting chairs to avoid prolonged standing while waiting for donation, sufficient donation couches to allow resting and avoid rushing, ample donation space especially in hot environments and ability to prevent crowding at donation sites can maximise donor care and reduce the occurrence of adverse reaction.

6.3.2 HEMATOMA – Figure 6.3.2.2, 6.3.2.3a, 6.3.2.3b, 6.3.2.3c

6.3.2.1 Hematoma is an accumulation of blood in the tissues outside the vessels. It is caused by blood flowing out of damaged vessels and accumulating in the soft tissues. Blood accumulating in deeper tissues may cause pressure on the surrounding tissue and adjacent structures resulting in 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. Affected donors may present with bruises, discoloration, swelling and local pain.

6.3.2.2 Hematoma was the second most frequently reported ADR in both 2020 and 2021. There was a decrease in the number of cases of hematoma reported in 2021 compared to 2020, with 65 and 121 cases respectively.

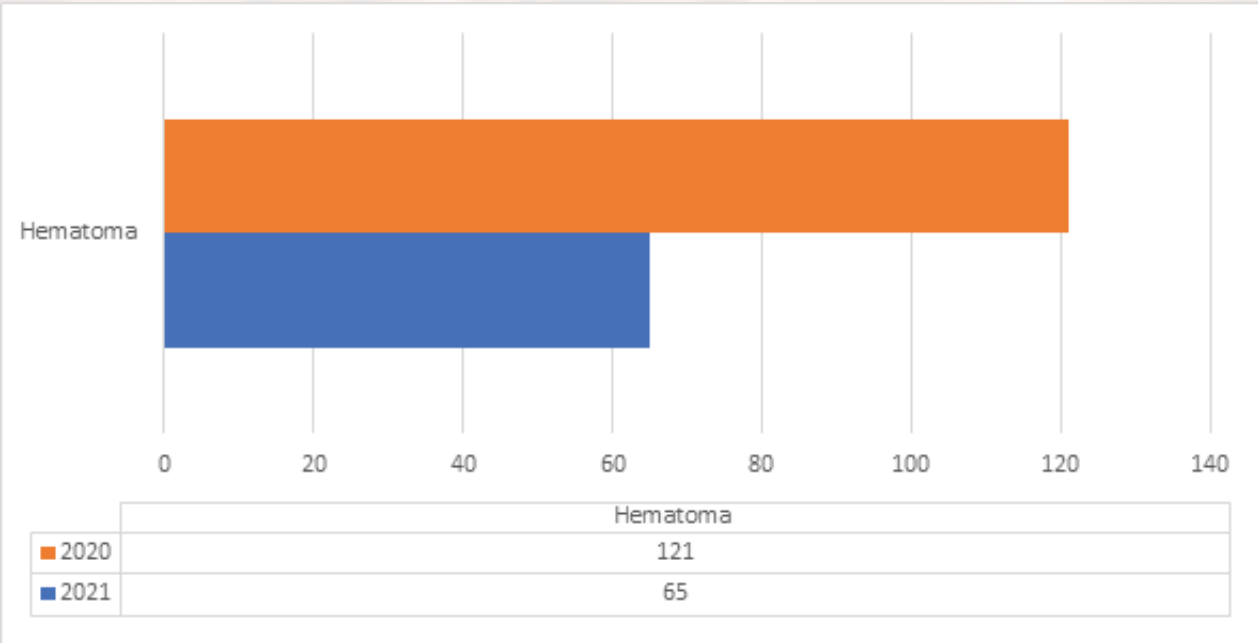
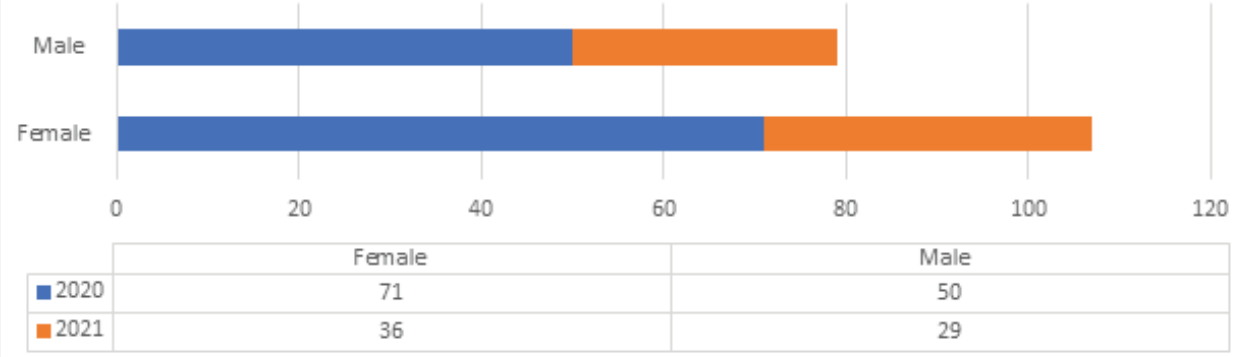


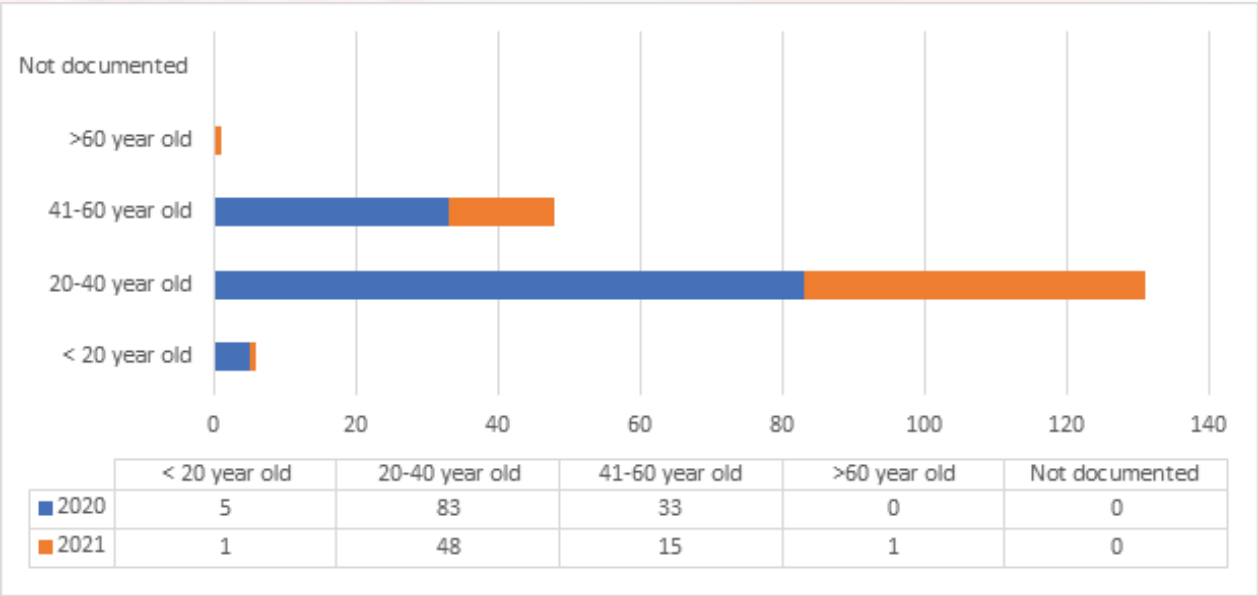
Figure 6.3.2.2: Total Number of Hematoma in 2020 – 2021

6.3.2.3 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 were not compulsory for ADR reporting, there were some reports with no documented age and weight.



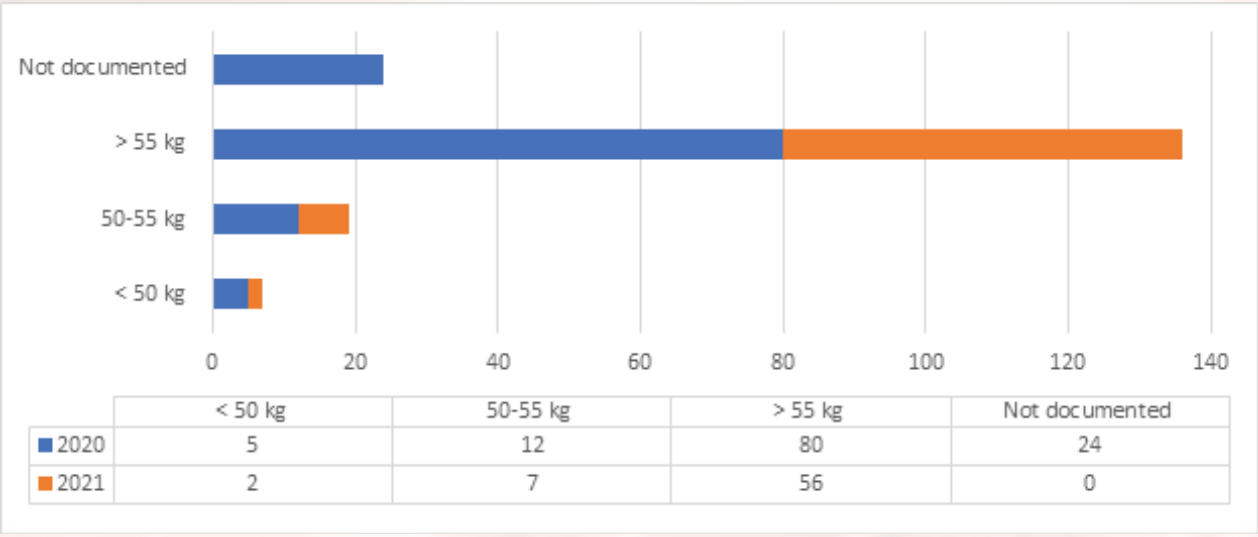
	Female	Male
2020	71	50
2021	36	29

Figure 6.3.2.3a: Hematoma Report based on Gender in 2020 – 2021



	< 20 year old	20-40 year old	41-60 year old	>60 year old	Not documented
2020	5	83	33	0	0
2021	1	48	15	1	0

Figure 6.3.2.3b: Hematoma Report based on Age in 2020 – 2021



	< 50 kg	50-55 kg	> 55 kg	Not documented
2020	5	12	80	24
2021	2	7	56	0

Figure 6.3.2.3c: Hematoma Report based on Weight in 2020– 2021

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

6.3.2.5 Recommendations:

i. Continuous training of the phlebotomist in vein selections (anatomical skills), puncturing procedure and tourniquet pressure application.
ii. 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.
iii. Educational materials in regards to post donation care may be given to the donors before they leave the donation centre.

6.3.3 DELAYED BLEEDING – Figure 6.3.3.2

6.3.3.1 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. After donation, the donor might strain the donation arm or lift heavy objects thus increasing the risk of delayed bleeding. Other causes might be due to underlying medical illness or medication the donor is on such as anticoagulants. Re-bleeding from the venepuncture site can be seen after the initial bandage has been removed or leaking from the bandage.

6.3.3.2 There were 7 cases of delayed bleeding reported in 2020, and 2 cases reported in 2021.

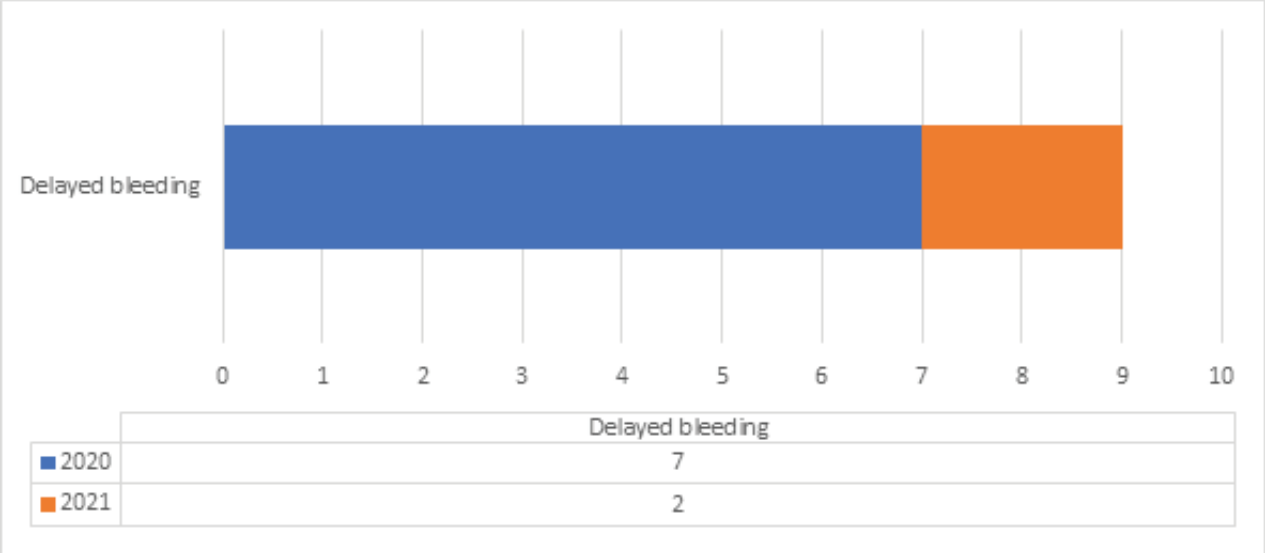


Figure 6.3.3.2: Total Number of Delayed Bleeding in 2020– 2021

6.3.3.3 Most reported cases of delayed bleeding happened when donor had already left the donation site or at home. However, some donors admitted that they did some form of physical activity or strenuous exercise on their donated arm before noticing the rebleeding. None of the donors had to be further referred to any clinic or hospital for further assessment.

6.3.3.4 All cases of delayed bleeding reported good recovery with no illness for both 2020 and 2021.

6.3.3.5 Recommendations:

Donor education following donation should be prioritised. This entails instructing them to apply firm pressure if it occurs and to seek medical assistance for further management, as well as refraining from any heavy or vigorous activity on the donation arm for at least 24 hours. For document requirements, they must also notify the blood donation facility.

6.3.4 OTHER ARM PAIN – Figure 6.3.4.2

6.3.4.1 Pain in the arm may be the only presenting complaint 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.

6.3.4.2 Total of 9 cases reported in these two years with 6 cases in 2020 and 3 cases in 2021.

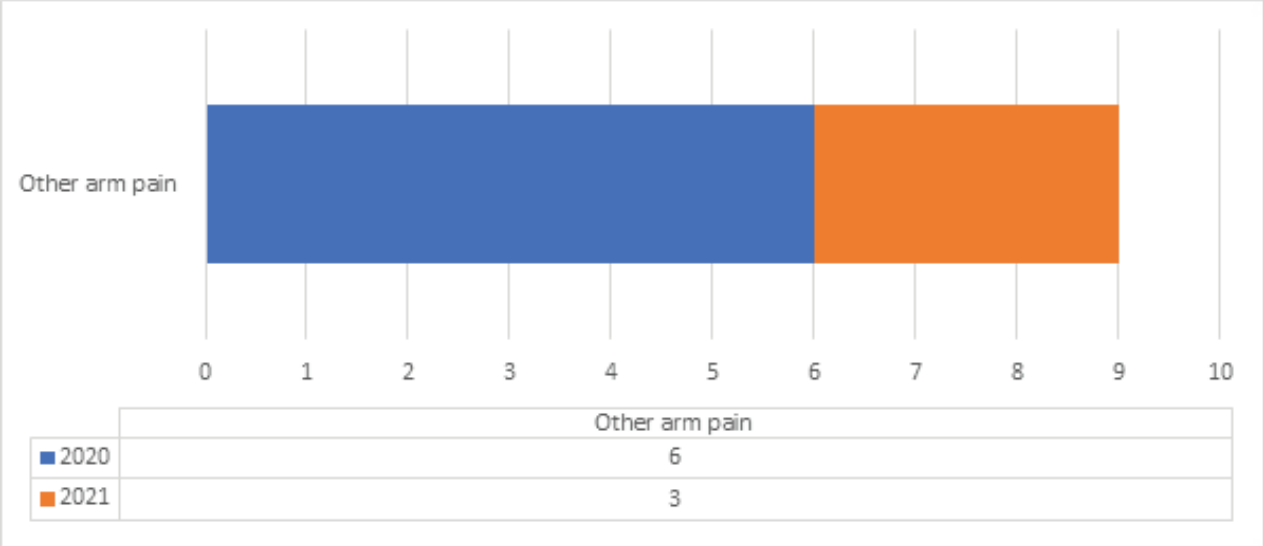


Figure 6.3.4.2: Total Number of Other Arm Pain in 2020 – 2021

6.3.4.3 A few reported cases of other arm pain happened when donor complained of nonspecific pain on the donation arm without any other symptoms of numbness, and no signs of arm swelling or hematoma noted. Reassurance was given with advice to seek further medical treatment if pain not resolved. None of these donors were reported to be referred to clinical institution.

6.3.4.4 All cases of other arm pain reported good recovery with no illness for both 2019 and 2020.

6.3.4.5 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.

6.3.5 ARTERIAL PUNCTURE – Figure 6.3.5.2

6.3.5.1 Arterial puncture is defined as a puncture of brachial artery or one of its branches by the needle used to bleed donors. There is a risk of large hematoma following the rapid blood flow which may lead to compartment syndrome. The blood collected is usually brighter red in colour. The needle and tubing may be seen pulsate and the blood bag fills up quickly (usually <4 minutes). There may be weak pain localized in the elbow region.

6.3.5.2 There was 3 cases of arterial puncture reported in 2020 and 2 cases reported in 2021.

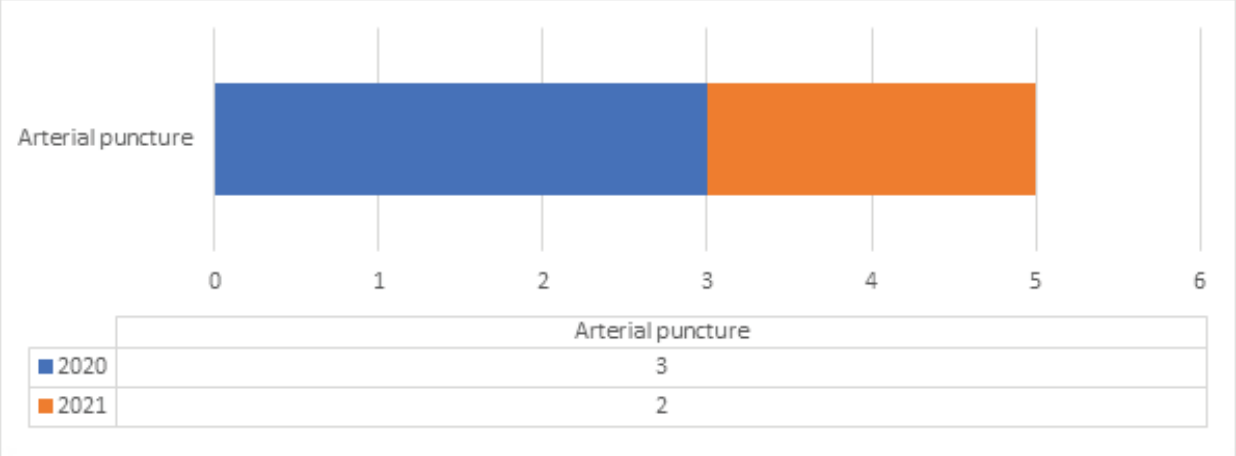


Figure 6.3.5.2: Total Number of Arterial Puncture in 2020 – 2021

6.3.5.3 One case reported in 2020 as moderate arterial puncture involving one male donor who reported increase swelling over the medial aspect of his left brachial and biceps region post donation. However, the bleeding time was less than 5 minutes and there was no documentation on the colour of the blood. He was referred to Emergency Department for further assessment. There was no neurovascular complication and no worsening pain and donor was then discharged home with advice to monitor his biceps circumference. Follow up on donor noted that his swelling has reduced and no further symptoms reported.

6.3.5.4 All donors reported good recovery with no illness following arterial puncture for both 2020 and 2021.

6.3.5.5 Recommendations:

i. Continuous education and training of the phlebotomist in arteries and veins anatomy. Phlebotomist should be able to immediately recognise the signs of arterial puncture and the proper measures to be done once it happens.
ii. Donors who experienced arterial puncture during blood donation may be referred to A&E for further assessment and interventions. They also should be educated on the do's and don'ts post arterial puncture and they should be properly followed up for any worsening symptoms.

6.3.6 CITRATE REACTION – Figure 6.3.6.2

6.3.6.1 Infusion of citrate anticoagulant during apheresis causes a fall in ionised calcium levels, leading to neuromuscular hyperactivity. If untreated, symptoms may progress to tetany and severe cardiac arrhythmias, including cardiac arrest. Operator error with mix up saline and citrate bags may occur with some apheresis equipment and lead to rapid citrate infusion. Donor may present with numbness or tingling of lips, feelings of vibrations, numbness or tingling in the fingers, metallic taste, chills, and shivering, light-headedness, feeling of tightness, muscle twitching, rapid or slow pulse or shortness of breath. Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalised muscle contractions, shock, irregular pulse and cardiac arrest.

6.3.6.2 There was 4 cases of citrate reaction reported in 2020 and 2 cases reported in 2021.

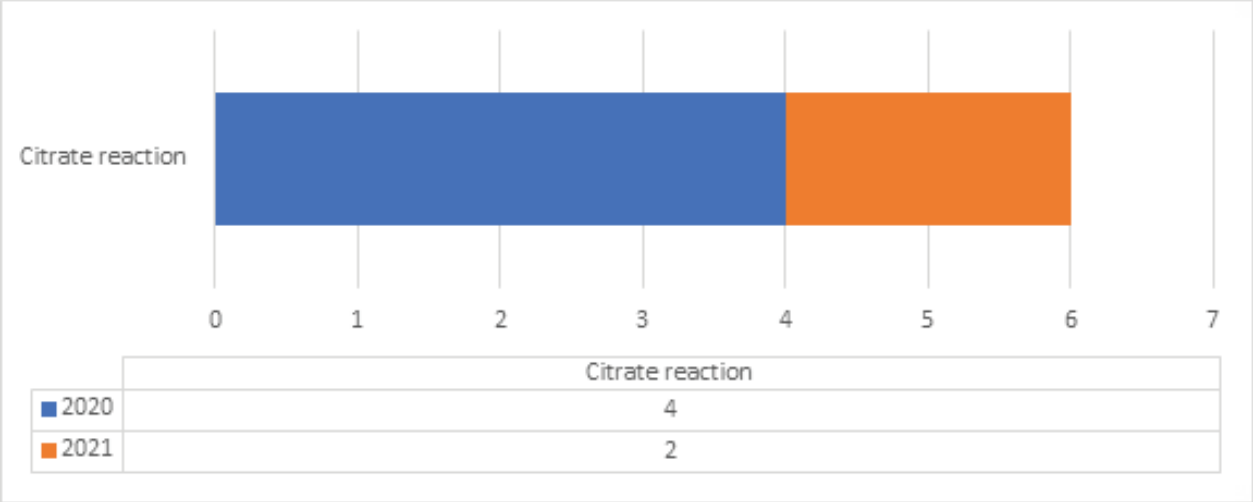


Figure 6.3.6.2: Total Number of Citrate Reaction in 2020 – 2021

6.3.6.3 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 20-39 years old.

6.3.6.4 All cases of citrate toxicity reported good recovery for both 2019 and 2020.

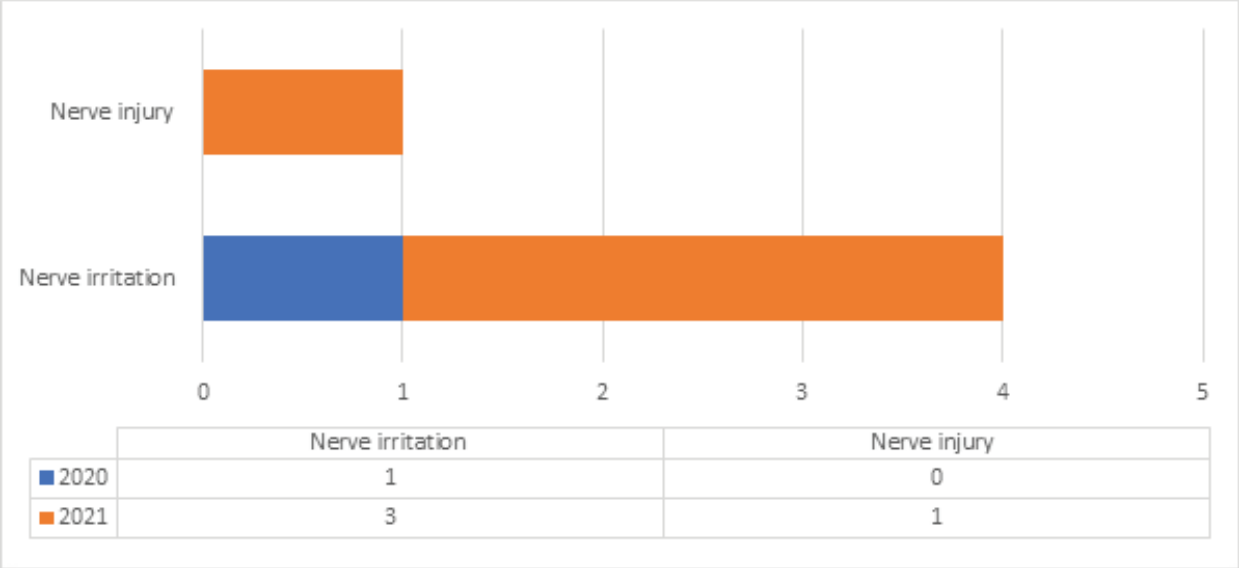
6.3.6.5 Recommendations:

i. Monitoring of ionized serum calcium in regular apheresis donors.
ii. Prophylactic oral calcium supplementation or a continuous infusion of intravenous can be used to reduce the incidence of citrate-induced symptoms among regular apheresis donors.
iii. All staff should be well trained in the management of citrate toxicity.
iv. 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.

6.3.7 NERVE INJURY/IRRITATION – Figure 6.3.7.2

6.3.7.1 At insertion or withdrawal of needle, a nerve might be hit directly causing injury to the nerve. Meanwhile, swellings from the surrounding tissues caused by hematoma or inflammation of soft tissues may also cause pressure on the nerve. Donor may experience radiating or electrical sharp pain moving away from the venepuncture site or tingling and burning sensation in the hand, wrist or shoulder area. Symptoms may appear immediately following needle insertion or withdrawal, or if it is related to hematoma, pain may be felt later when the hematoma has increased certain size. Certain positions or arm motions may have worsened symptoms and rarely donor complains of arm weakness. Usually, symptoms resolve within days but may persist for months as the nerve recovers.

6.3.7.2 One case of nerve injury was reported in 2021. Meanwhile, there was one case of nerve irritation reported in 2020 and 3 cases in 2021.



	Nerve irritation	Nerve injury
2020	1	0
2021	3	1

Figure 6.3.7.2: Total Number of Nerve Injury/ Nerve Irritation in 2020 – 2021

6.3.7.3 All cases of nerve irritation/ injury were reported as mild reaction. No detailed incident attached in ADR reporting.

6.3.7.4 All cases of nerve injury and nerve irritation reported good recovery with no illness for both 2019 and 2020.

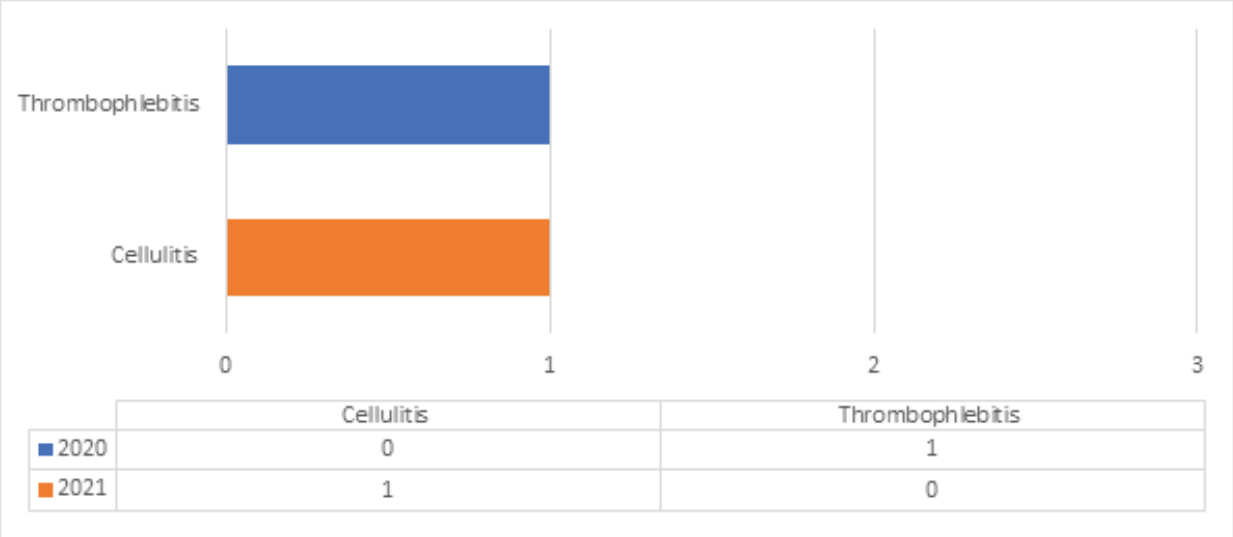
6.3.7.5 Recommendations:

i. Phlebotomist should minimise needle adjustment or multiple needle punctures attempt as these increase the risk of nerve injury/nerve irritation.
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.

6.3.8 THROMBOPHLEBITIS/ CELLULITIS- Figure 6.3.8.2

6.3.8.1 Inflammation along the course of the vein may progress to localised infection a few days after 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.

6.3.8.2 There was 1 case of thrombophlebitis reported in 2020 while 1 case of cellulitis reported in 2021.



	Cellulitis	Thrombophlebitis
2020	0	1
2021	1	0

Figure 6.3.8.2: Total Number of Thrombophlebitis/ Cellulitis in 2020 – 2021.

6.3.8.3 One thrombophlebitis case reported post donation in which the donor was given reassurance and was supplied with oral Paracetamol for analgesia and Papase tablet to reduce swelling. No worsening symptoms reported.

6.3.8.4 Both cases reported good recovery with no ill effects.

6.3.8.5 Recommendations:

i. Proper swabbing procedure shall be applied when cleaning donor's arm during bleeding, to reduce the risk of infection or contamination in that area.
ii. The importance of post donation wound care should be emphasised to avoid entry of microorganism that can cause thrombophlebitis or cellulitis.

6.3.9 LOCAL ALLERGIC REACTION – Figure 6.3.9.2

6.3.9.1 Any red or irritated skin at the venepuncture site caused by allergens or irritants in solutions used to disinfect arms such as iodine or chlorhexidine. It could also be caused by adhesive bandage or latex from the gloves used. Donor may have itchiness and redness or raised rash or hives at the venepuncture area and may expand to cover a larger area of the arm. It may last from hours to days post donation.

6.3.9.2 Only 1 case reported for local allergic reaction for both 2020 and no case reported in 2021.

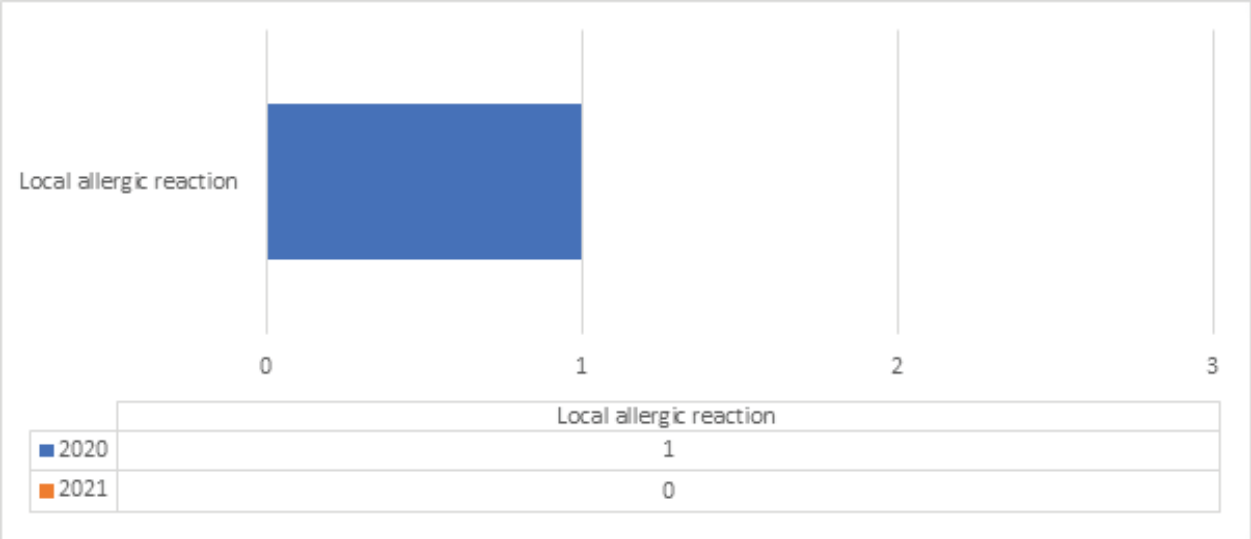


Figure 6.3.9.2: Total Number of Local Allergic Reaction in 2020 – 2021

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

6.3.9.4 All cases of local allergic reaction reported good recovery both in 2019 and 2020.

6.3.9.5 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.

6.3.10 DEEP VEIN THROMBOSIS

6.3.10.1 Deep venous thrombosis is defined as thrombosis in deep vein on donor's phlebotomy arm. The superficial venous thrombosis may progress into deeper veins, but this rarely occurs. Other risk factors such as the use of oral contraceptives may present in these donors. They may have swelling and pain at the upper arm and also be accompanied by symptoms of superficial vein inflammation.

6.3.10.2 No cases reported for this type of ADR for both 2019 and 2020.

6.3.11 ARTERIOVENOUS FISTULA

6.3.11.1 Arteriovenous fistula is 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. Donors may present with pulsating mass with palpable thrill and associated bruit. The affected arm feels warm while the distal part is cold from the presence of significant blood shunting. The distal veins may be dilated and pulsating.

6.3.11.2 No reports received for case of arteriovenous fistula for both 2020 and 2021

6.3.12 COMPARTMENT SYNDROME

6.3.12.1 Compartment syndrome is an increased in intra-compartment pressure leading to muscle and soft tissue necrosis. This results from large haematoma or inflammation in soft tissues leading to increased compartment pressure in the donating arm. Blood may accumulate in the frontal deep areas of the forearm thus closing small blood vessels and lead to muscle and nerve tissue necrosis. Donors may have painful arms, paraesthesia, pallor and later paralysis if not treated.

6.3.12.2 There was no case reported for compartment syndrome post donation for both 2020 and 2021.

6.3.13 BRACHIAL ARTERY PSEUDOANEURYSM

6.3.13.1 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.

6.3.13.2 No cases of brachial artery pseudoaneurysm reported for both 2020 and 2021.

6.3.14 HEMOLYSIS

6.3.14.1 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.

6.3.14.2 No cases of haemolysis reported for both 2020 and 2021.

6.3.15 AIR EMBOLISM

6.3.15.1 Air embolism is the presence of air bubbles in a donor's circulation. Air may enter into the lines due to the incomplete priming of lines, as a result of 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.

6.3.15.2 There was no case reported of this ADR for both 2020 and 2021.

6.3.16 GENERALIZED (ANAPHYLACTIC) REACTION

6.3.16.1 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.

6.3.16.2 No cases reported for this reaction for both 2020 and 2021.

6.3.17 OTHER SERIOUS COMPLICATIONS RELATED TO BLOOD DONATION

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

6.3.17.2 There was 1 case of cardiac symptoms reported both in 2020 and 2021.

6.3.17.3 One ADR with an acute cardiac symptom resulted in the donation being stopped when the donor complained of chest pain while bleeding. All of his vital signs were in the normal range. Donor was transported to the ED by ambulance, and the results of the ECG revealed no abnormalities. Cardiac markers did not point to any recent cardiac events. His post-donation repeated haemoglobin level was 15.6 g/dL. Another case of symptomatic premature ventricular contraction was recorded, in which the donor briefly lost consciousness and experienced a fitting before it subsided. Donor was brought to the emergency department, and the ECG revealed sinus bradycardia, sinus arrhythmia, and premature ventricular contraction.

6.3.17.4 The 2 donors who experienced an acute cardiac symptom during blood donation were otherwise well afterward.

CHAPTER

07

SEROCONVERT DONORS

7.1 DEFINITION

7.1.1 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).

7.1.2 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.

7.2 LOOKBACK RECALL PROCEDURE

7.2.1 A look back and recall procedure is a retrospective analysis of donor's donation history to ascertain whether the blood components from the previous donation(s) that would require removal from blood bank inventory and/or notification to the transfusion recipients.

7.2.2 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 donor will be filled in the Seroconvert Donor Notification Form (Part 1 and Part 2) and reported to NHCC.

7.2.3 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 safety.

7.3 METHOD OF REPORTING

7.3.1 Reporting of seroconvert donor cases to NHCC are 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 contain the outcome of the investigated blood components and recipient testing result.

7.3.2 In general Part 1 is submitted after the donor attend a post donation counselling (PDC) where fresh sample was taken for confirmation testing and risk factors for acquiring the disease is elicited. Whereas, in a situation where donor 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.

7.4 SEROCONVERT DONOR REPORTS- Figure 7.4.1

7.4.1 The graph below shows the total number of seroconvert donor reports received from 2016 to 2021 (Part 1 and Part 2 combined). There has been an increase in SD reporting of more than 10 times when compared to previous years.

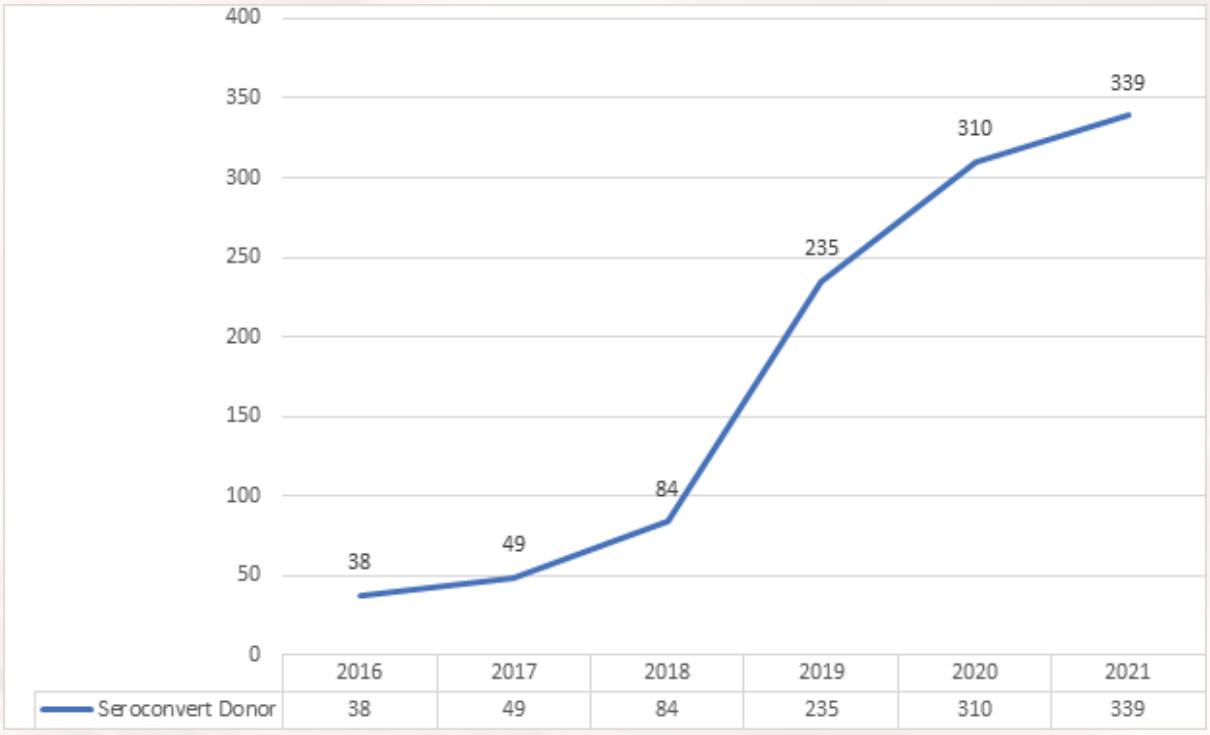


Figure 7.4.1: Total Number of Seroconvert Donor Reports Received

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

7.4.3 In 2020 there were 310 reports received and it has increased to 401 in 2021. From these, 187 reports were for part 1 and 123 reports were for part 2 in 2020. Whereas in 2021 242 reports were for part 1 and 159 reports for part 2. Reports that were sent prior to post donation counselling were lacking information on donor risk factor for acquiring the infection.

Year	Part 1 Post Donation Counselling (PDC)		Part 2	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**

Table 7.4.3: Total Number of Seroconvert Donor Reporting

7.5 PART 1 WITH POST DONATION COUNSELLING (PDC) REPORT – Table 7.5

The demographic characteristics of seroconvert donors retrieved from Part 1 with PDC are crucial to formulate control strategies and preventing TTI. Syphilis accounts for the highest number of seroconversions reported followed by HIV, HBV and the least are HCV and co-infection as shown in the table below.

Variables		2020 (N=185)					2021 (N=221)				
		HIV (N=55)	Hep B (N=28)	Hep C (N=10)	Syphilis (N=81)	Co-infections (N=11)	HIV (N=62)	Hep B (N=31)	Hep C (N=13)	Syphilis (N=105)	Co-infections (N=10)
Age	<20	0	0	0	0	0	2	0	8	1	0
	20 - 39	51	9	5	57	9	53	14	4	72	9
	40 - 60	4	18	4	23	2	7	17	1	30	1
	>60	0	1	1	1	0	0	0	0	2	0
	No data	0	0	0	0	0	0	0	0	0	0
Gender	Males	54	24	9	64	11	58	27	10	95	10
	Females	1	4	1	17	0	4	4	3	10	0
Number of previous donations	<5	37	14	9	51	7	39	21	12	71	8
	5 to 10	9	8	1	19	2	15	7	1	23	1
	>10	9	6	0	11	2	7	3	0	10	1
	No data	0	0	0	0	0	1	0	0	1	0
Risk Factors	High risk behaviors	33	9	3	37	8	41	5	5	49	7
	Body piercing / tattoo/ acupuncture / cupping	4	5	3	5	0	2	2	0	6	0
	Hx of blood transfusion	0	1	0	0	0	1	0	0	0	0
	IV Drug Use	0	0	0	0	1	0	1	1	0	0
	Others	6	0	0	14	0	5	2	2	14	0
	Deny risk factors	12	13	4	25	2	13	15	5	33	3
	No data	0	0	0	0	0	0	6	0	3	0

Table 7.5: Part 1 with PDC: Seroconvert Donor Demographic Characteristics according to Transfusion Transmissible Infection (TTI)

7.6 HUMAN IMMUNODEFICIENCY VIRUS (HIV)

7.6.1 HIV

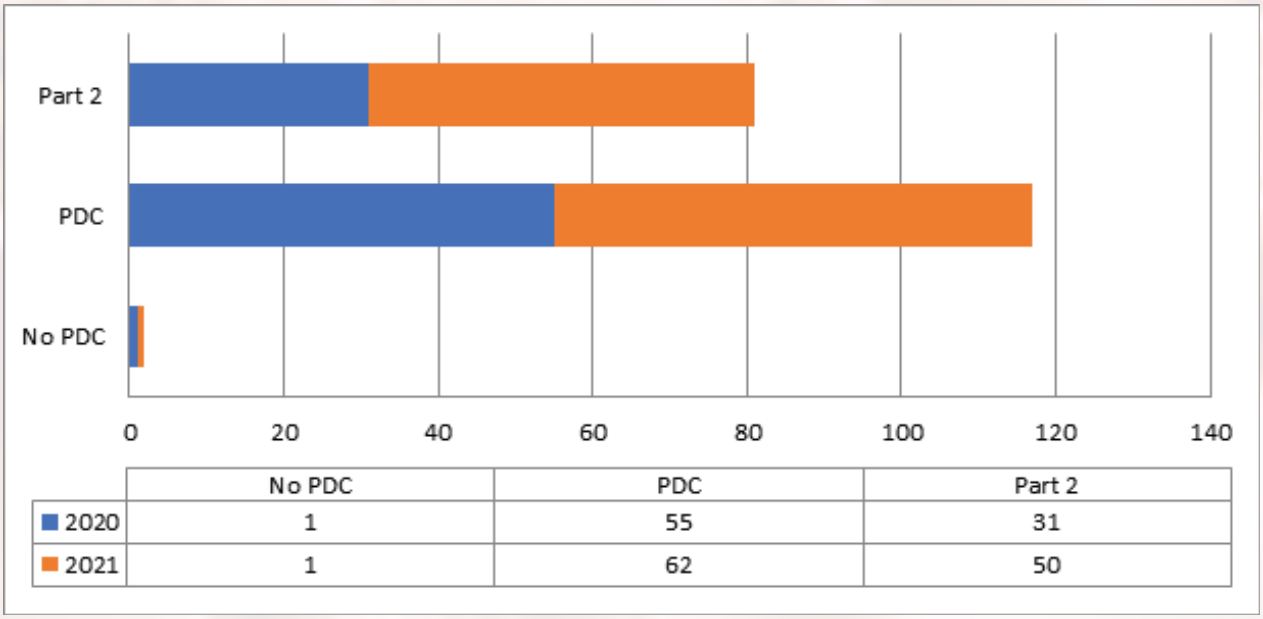
7.6.1.1 HIV is a human immunodeficiency virus, in which it attacks the immune system rendering it more vulnerable to other infections and diseases. It is spread by contact with bodily fluids, unprotected sex, sharing of injection drug equipment or vertical transmission from mother to child. HIV in long term can lead to fatal condition, AIDS (acquired immunodeficiency syndrome).

7.6.1.2 In Malaysia, the first HIV case was discovered in 1986. Since that period, HIV has emerged as one of the nation's most serious health and development issues. Around 87,000 persons with HIV are estimated to be living in Malaysia as of 2019. Incidence rates decreased by 70% from 28.5 cases per 100,000 people in 2002 to 8.5 incidences per 100,000 people in 2020 in Malaysia according to Global AIDS Monitoring 2020.

7.6.1.3 Blood-borne infections like HIV are typically contracted through sexual contact, contact with infected blood, or perinatal transfer. High viral loads, specific sexual behaviours, the presence of ulcerative STDs, lack of circumcision, and a few other host and genetic variables are all risk factors for HIV transmission.

7.6.2 Total Number of HIV Seroconvert Donor – Figure 7.6.2

7.6.2.1 In 2020, a total of 87 cases of HIV Seroconvert Donor were reported to NHCC, of which 55 were Part 1 reports with PDC, one was Part 1 report without PDC, and the remaining 31 were Part 2 reports. In 2021, there were 62 were report of Part 1 with PDC, one was Part 1 report without PDC, and there were 50 Part 2 cases reported.



	No PDC	PDC	Part 2
2020	1	55	31
2021	1	62	50

Figure 7.6.2: Total number of HIV Seroconvert Donors in year 2020-2021

7.6.3 Characteristic of Seroconvert Donor for HIV

7.6.3.1 Age

According to Figure 7.6.4, the majority of HIV seroconvert donors come from the age group between 20-39 years old (92.7% in 2020 and 85.5% in 2021), whereas the remaining 7.3% in 2020 and 11.3% in 2021 were between ages 40-60 years old. Another 3.2% of seroconvert HIV donors in 2021 are from age group less than 20 years old.

7.6.3.2 Gender

Males predominate (98%), compared to female in 2020. There is one female seroconvert donor who has given blood more than ten times before, makes up the 2%. She denied having any of the risk factors. In 2021, 93.6% of HIV seroconvert donors are males and 6.4% are females.

7.6.3.3 Frequency of blood donation

In 2020, 67% (n=37) donors had donation counts less than five, while 16% (n=9) donors had donated between 5-10 times, and more than 10 times respectively. For 2021, 62.9% of donors had previous donation less than 5 times, 24.2% donated 5-10 times, 11.3% donated more than 10 times and 1.61% (n=1) report did not had any data on the donor's previous donations.

7.6.3.4 Risk factors

According to Figure 7.6.4, in 2020, 60% of HIV seroconvert donors (n=33) acknowledged engaging in high-risk behaviours, 22% (n=12) denied having any risk factors, and 11% (n=6) stated other risk factors. Thirty-three donors had high-risk behaviour, of which 19 were men who have sex with men (MSM), three had a history of having sex with prostitutes, ten had multiple sexual partners, and one had no further information given.

In 2021, 66.13% (n=41) donors were reported to have high risk behaviour, 3.23% (n=2) had history of acupuncture and cupping, 1.61% (n=1) case had history of blood transfusion and also admitted of MSM, 20.97% (n=13) denied any risk factors and 8.06% (n= 5) were others. These 5 other risk factors comprise of 1 donor with history of orthopaedic surgery, 3 history of premarital sexual contact with 1 partner but they were unsure of partner's status and one case of history with sexual assault.

7.6.4 Summary of Seroconvert Donor for HIV - Figure 7.6.4

In conclusion, the highest number of HIV seroconverted donors in both years were primarily male and belonged to the 20 to 39 age range. The majority of HIV seroconvert donors have histories of high-risk behaviours and have donated blood no more than five times before.

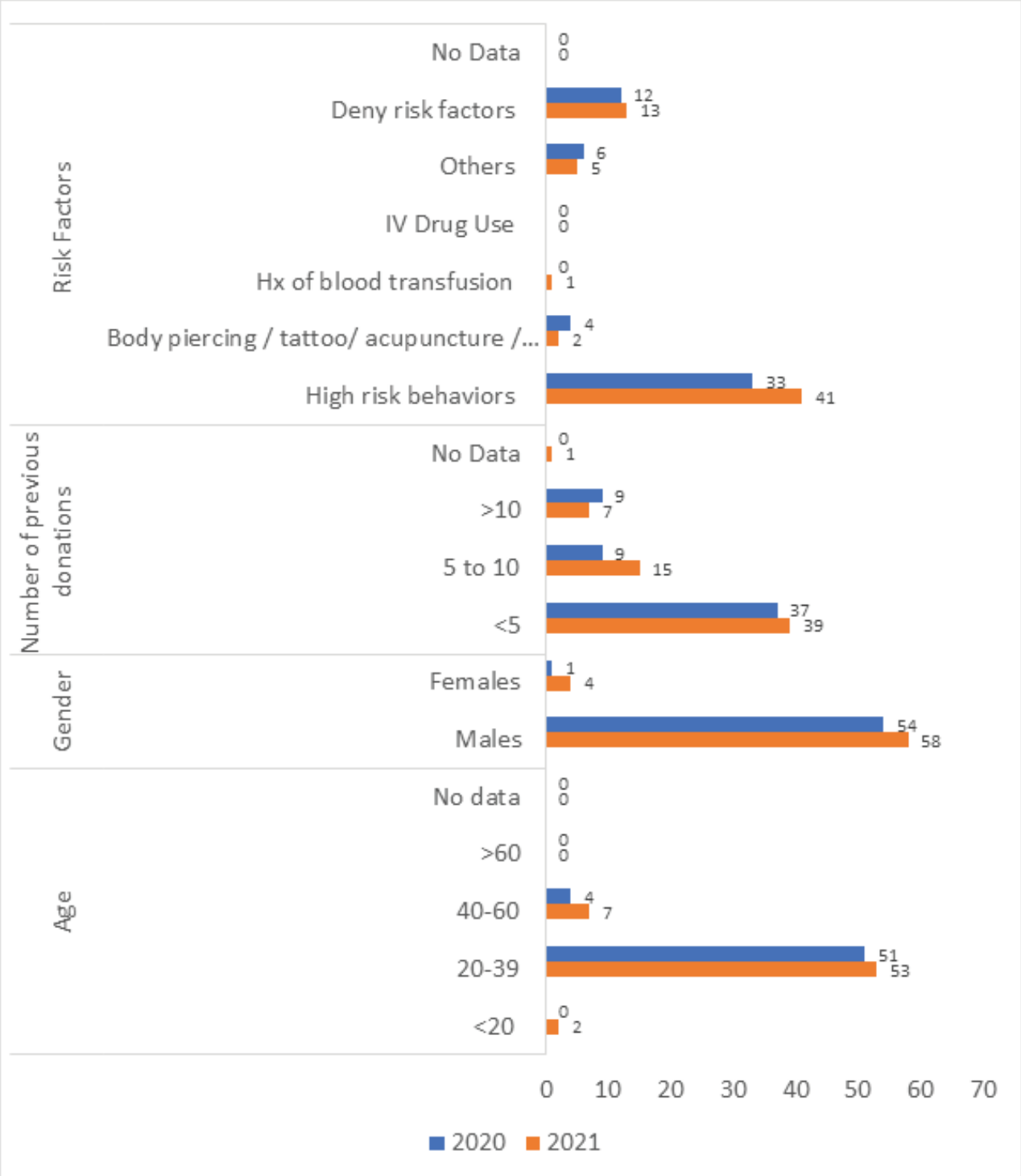
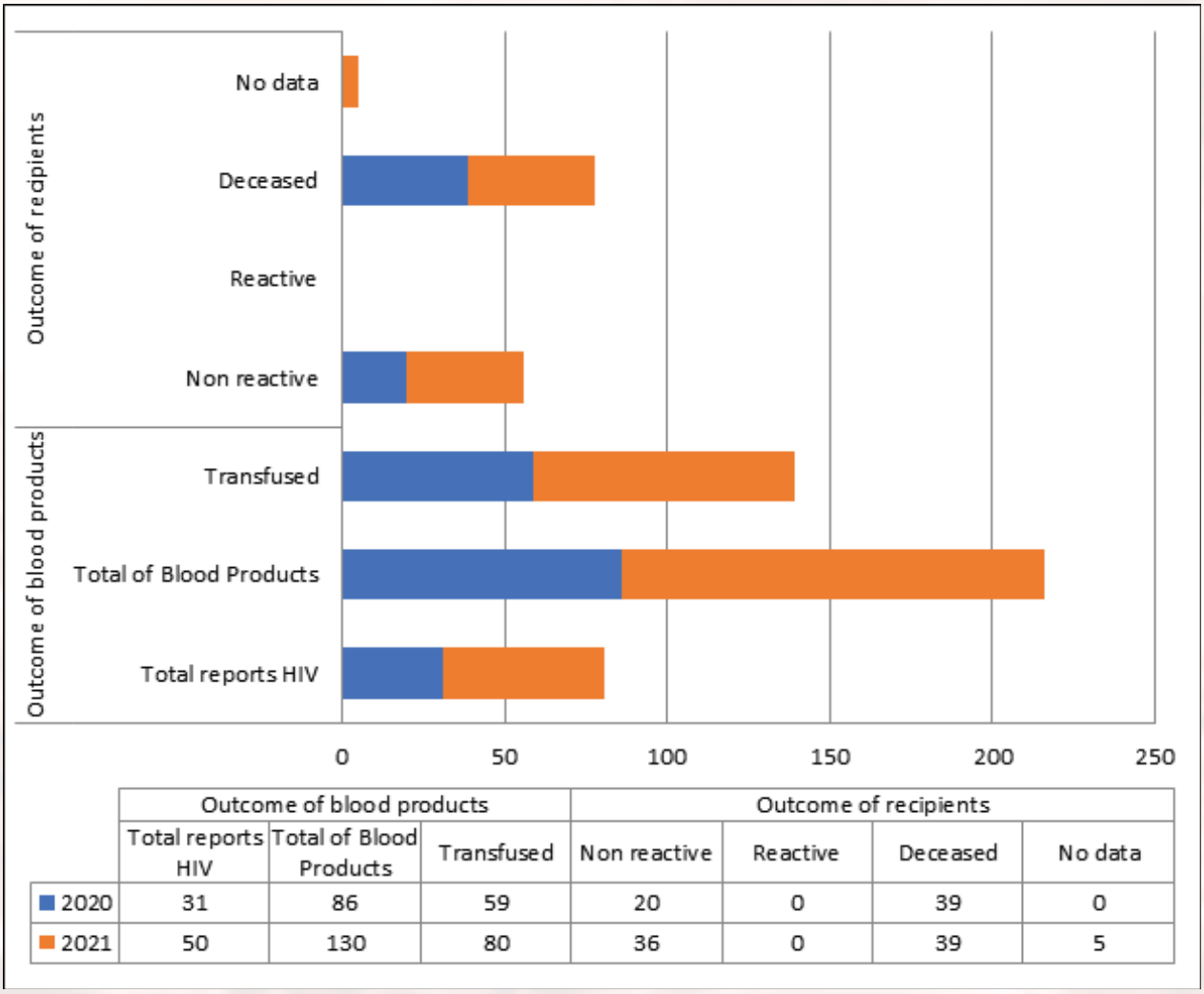


Figure 7.6.4: Demographic Distribution and Risk Factors for HIV Seroconvert Donors in Part 1

7.6.5 Outcome of Look Back and Recall (Part 2) Seroconvert Donor for HIV - Figure 7.6.5

7.6.5.1 As shown from table 7.6.5, the total number of blood products investigated in look back procedure was 86 for 2020 and 130 in 2021. From 86 blood products in 2020, 59 blood products were transfused to patients. 39 out of 50 transfusion patients had passed away; remaining 20 patients were found to be non-reactive. In 2021, out of 130 blood products, 80 were transfused. From 80 blood products transfused to recipients, 36 were non-reactive, 39 recipients have deceased and 5 recipients were not concluded on the outcome.

7.6.5.2 In both reporting years, no patients were reported to have acquired an HIV infection after receiving blood.



	Outcome of blood products			Outcome of recipients			
	Total reports HIV	Total of Blood Products	Transfused	Non reactive	Reactive	Deceased	No data
2020	31	86	59	20	0	39	0
2021	50	130	80	36	0	39	5

Figure 7.6.5: Outcome of Blood Products and Recipient of Seroconvert Donor for HIV

7.7 HEPATITIS B VIRUS (HBV)

7.7.1 HBV

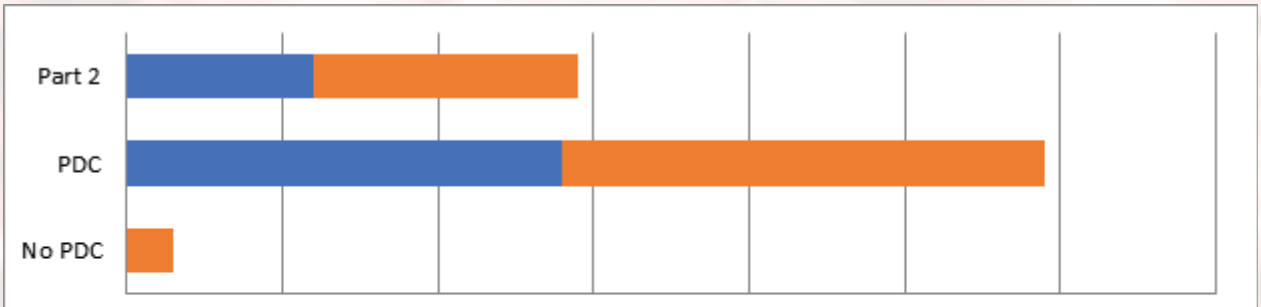
7.7.1.1 Hepatitis B is a potentially life threatening liver infection caused by the hepatitis B virus (HBV). Hepatitis B can cause chronic liver infection and puts patients at high risk for liver cirrhosis and liver carcinoma (WHO).

7.7.1.2 Seroprevalence for the hepatitis B virus (HBV) surface antigen (HBsAg) in the general population of Malaysia is 1.5-9.8%. An estimated 1 million people are chronically infected with hepatitis B in Malaysia. Approximately 75% of all viral hepatitis cases are due to hepatitis B infection, with a male-to-female ratio of 2:1. Chronic hepatitis B (CHB) accounts for more than 80% of the hepatocellular carcinoma (HCC) cases seen in Malaysia, and HCC is the 3rd most common malignant neoplasm and among the 10 leading causes of death.

7.7.1.3 HBV can be transmitted through sexual contact and through a spread from infected mother to child at birth mostly at endemic areas. Other less likely transmissions are through needle stick injuries, tattooing, piercing, exposure to infected blood and body fluids, through reusing contaminated needles, syringes, or other contaminated equipment. The HBV can remain alive outside the body for at least 7 days, potentially infecting a person who is not protected by the vaccine.

7.7.2 Total Number of Hepatitis B Seroconvert Donor – Figure 7.7.2

7.7.2.1 The total number of HBV seroconvert donors reported to the NHCC is depicted in the graph below. A total of 40 Hepatitis B reports were received for the year 2020 and 51 reports in 2021.



	No PDC	PDC	Part 2
2020	0	28	12
2021	3	31	17

Figure 7.7.2: Total Number of Hepatitis B Seroconvert Donors in 2020-2021

7.7.3 Characteristic of Seroconvert Donor for Hepatitis B

7.7.3.1 Age

Most hepatitis B seroconvert donors in both years were between the ages of 40 and 60. In 2020, there were 64.29 %, while in 2021, there were 54.8%. The age range of 20 to 39 years old makes up the second common group, with 9 (32.14%) cases in 2020 and 14 (45.20%) cases in 2021. In 2020, there was just 1 case of hepatitis B among those older than 60. In both years, no seroconvert donors under the age of 20 were reported.

7.7.3.2 Gender

Males made up the majority of the HBV seroconvert donors in both years, with 24 cases in 2020 and 27 cases in 2021, compared to females, who had 4 cases in each year.

7.7.3.3 Previous number of blood donation

In both years, the majority of hepatitis B seroconvert donors came from donors with a history of less than five blood donations, followed by five to ten donations, and the least was from donors with a history of more than ten donations.

7.7.3.4 Risk factors

For the risk factors elicited from first visits in 2020, it was found that 9 (32.14%) of them had high risk behaviours, 5 (17.86%) had history of cupping and acupuncture, 1 case (3.57%) had history of previous blood transfusion, no donors with IV drug use and most donors with Hepatitis B denied any risk factors during their first visit which comprises of 13 cases (46.43%).

Meanwhile in year 2021, 16.67% (n=5) had high risk behaviours, 6.45% (n=2) had history of body cupping, 3.23% (n=1) had history of using IV drugs, 48.39% (n=15) denied any risk factors, 19.36% (n=6) had no data on their risk factors and 6.45% (n=2) cases were categorized as others. These other risk factors are 2 seroconvert donors with family history of hepatitis B.

7.7.4 Summary of Seroconvert Donor for Hepatitis B – Figure 7.7.4

According to the data, 64.3% of seroconvert donors are from the age group of 40-60 years old, and a higher male percentage (85.7%). Most hepatitis B seroconvert donors had less than 5 previous blood donations. Nearly half of them (46%) denied having any risk factors.

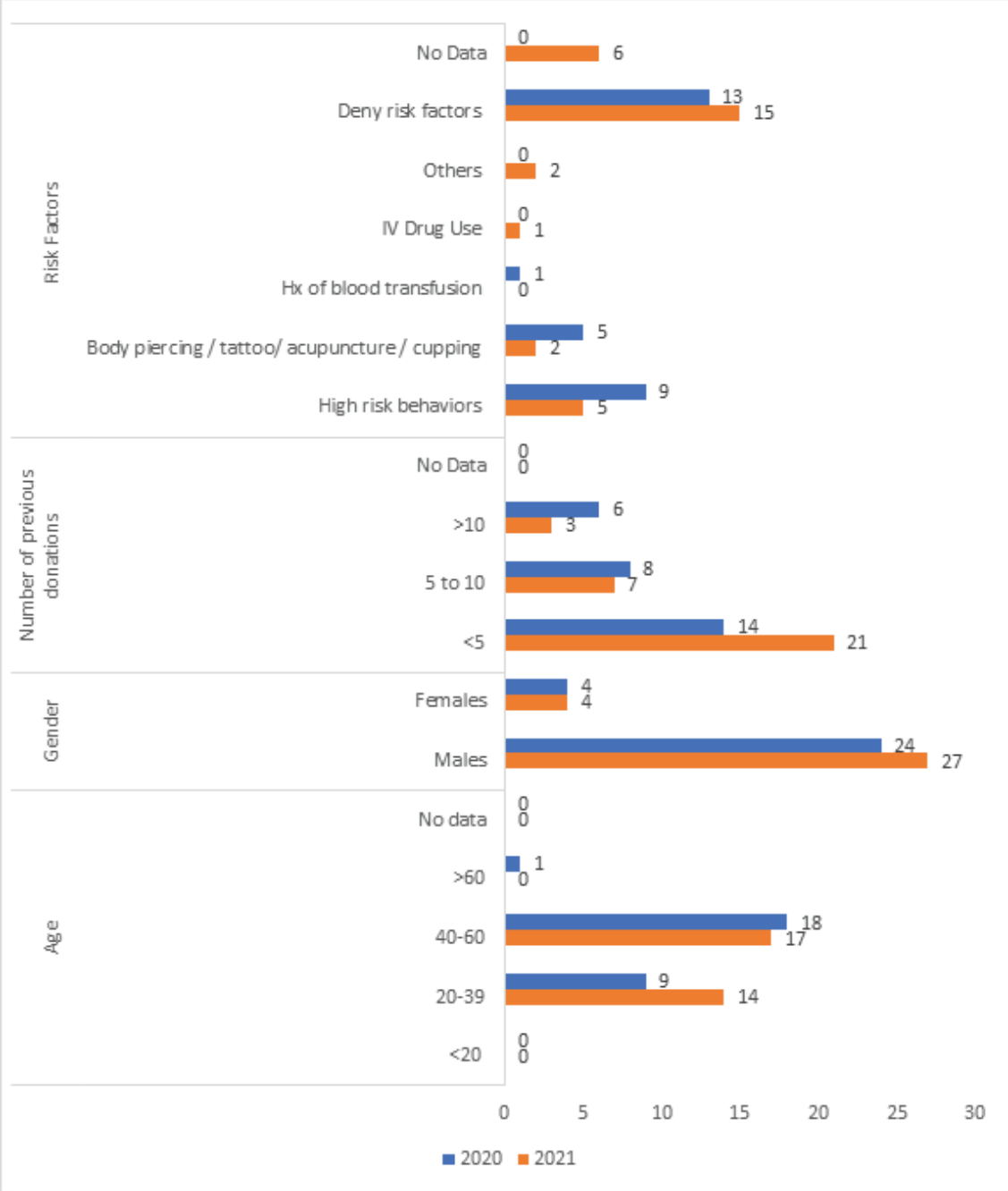
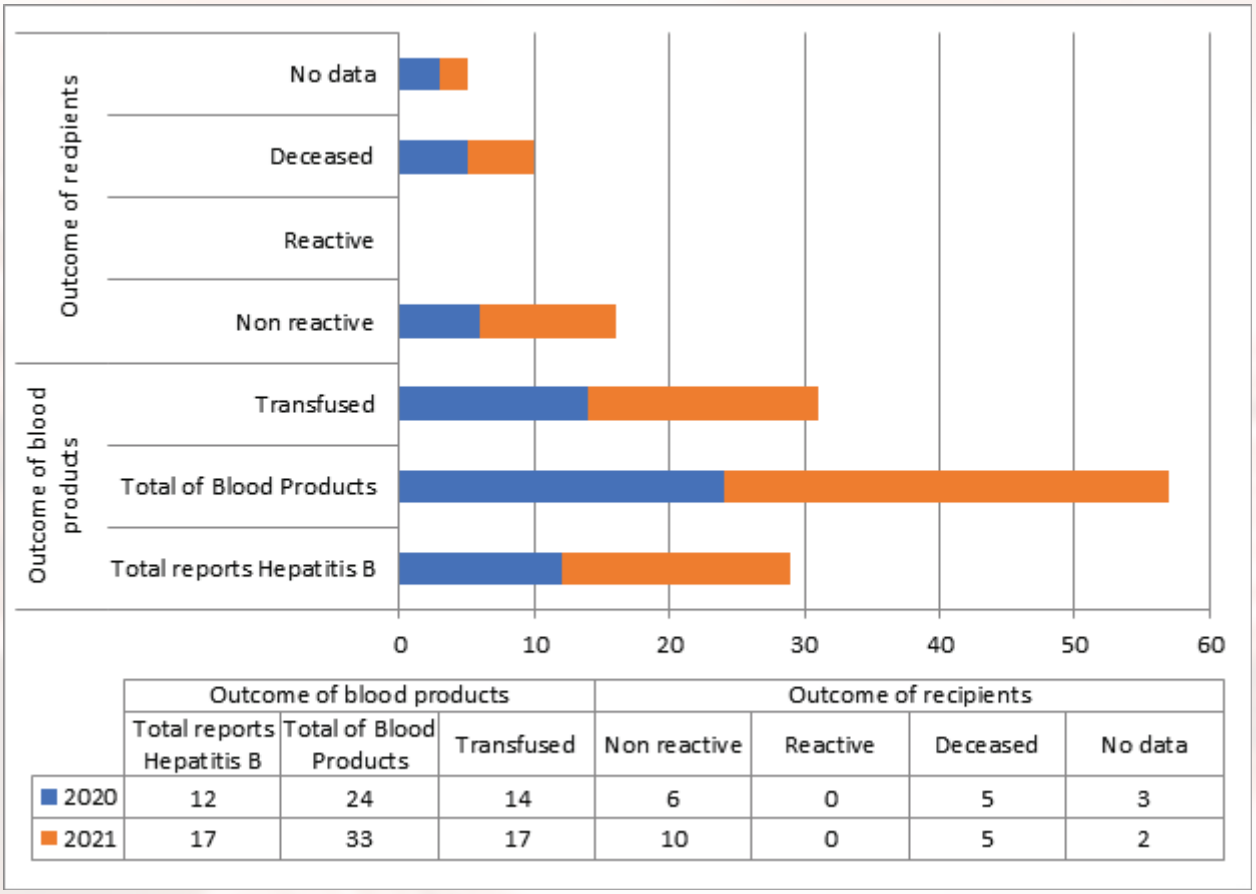


Figure 7.7.4: Demographic Distribution and Risk Factors for Hepatitis B Seroconverted Donors in Part 1

7.7.5 Outcome of Look Back and Recall (Part 2) Seroconvert Donor for Hepatitis B – Figure 7.7.5

7.7.5.1 A total of 24 blood products were investigated in 2020, of which 14 were transfused. Six recipients of the transfused blood tested negative for HBV, five of the recipients have since passed away, and three have no information on the recipient's status. The remaining 10 blood products were not transfused where 6 units were discarded while4 blood products have no information about their status.

7.7.5.2 Of the 33 blood products that were investigated in 2021, 17 were transfused. All 10 recipients out of 17 recipients being non-reactive. Five recipients deceased, while the results of the other two were not reported.



	Outcome of blood products			Outcome of recipients			
	Total reports Hepatitis B	Total of Blood Products	Transfused	Non reactive	Reactive	Deceased	No data
2020	12	24	14	6	0	5	3
2021	17	33	17	10	0	5	2

Figure 7.7.5: Outcome of Blood Products and Recipient of Seroconvert Donor for HBV

7.8 HEPATITIS C (HCV)

7.8.1 HCV

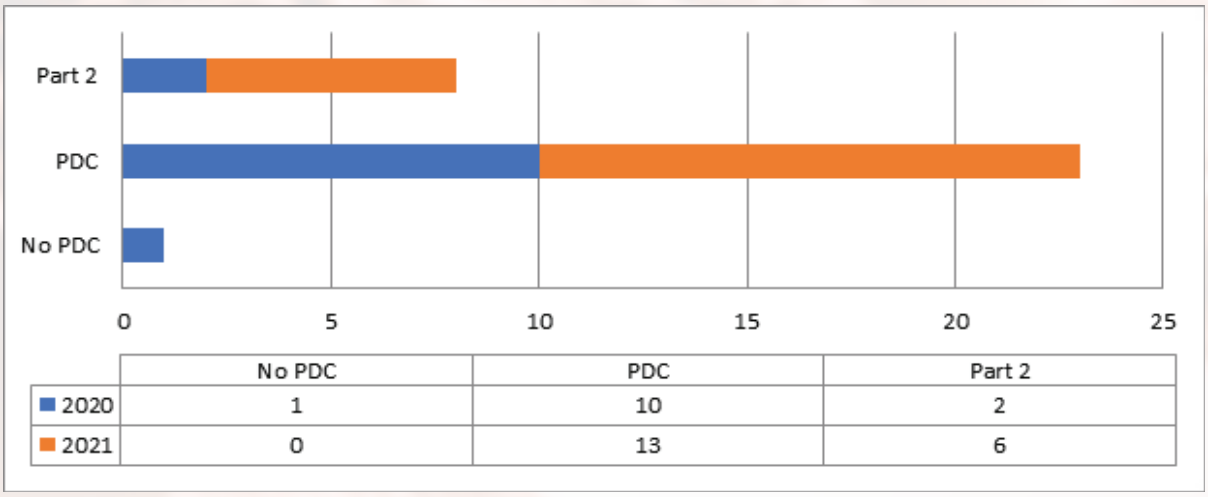
7.8.1.1 Hepatitis C is a liver infection caused by the hepatitis C virus (HCV). Hepatitis C is spread through contact with blood from an infected person. For some people, hepatitis C is a short-term illness, but for more than half of people who become infected with the hepatitis C virus, it becomes a long-term, chronic infection. (CDC)

7.8.1.2 With an estimated 32 million people, Malaysia has an estimated 1.5% prevalence of HCV, which equates to nearly around 330,000 infected adults. Between 2003 and 2017, the MOH had received a notification of 23,112 confirmed hepatitis C cases. The notification rate increased to 11.0 per 100,000 in 2016 before slightly declining to 9.54 per 100,000 in 2017. Similar in males and females, slightly more than 50% of the patients were aged between 26 and 45 years.

7.8.1.3 HCV is transmitted primarily through parenteral exposures to infectious blood or body fluids that contain blood. Possible exposures include injection-drug use and birth to an HCV-infected mother. 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)

7.8.2 Total Number of Hepatitis C Seroconvert Donor Report - Figure 7.8.2

The graph below shows the total number of HCV seroconvert donors reported to the NHCC. In total, 13 HCV reports were received in 2020, while 19 reports were received in 2021.



	No PDC	PDC	Part 2
2020	1	10	2
2021	0	13	6

Figure 7.8.2 - Total Number of Hepatitis C Seroconvert Donor in 2020-2021

7.8.3 Characteristic of Seroconvert Donor for Hepatitis C

7.8.3.1 Age

In 2020, there were 50% (n = 5) of cases from the 20-39 age range, 40% (n = 4) from the 40-60 age group, and one donor who was over 60.While in 2021, there were 61.5% (n=8) of cases in the under-20 age group, 4 cases in the 20–39 age group, and 1 case in the 40–60 age group.

7.8.3.2 Gender

The majority of seroconvert donors for Hepatitis C in both reporting years were men with 90% in 2020 and 76.9% in 2021.

7.8.3.3 Previous number of blood donation

Approximately 90% of seroconvert donors have donated blood no more than five times and the remaining 10% have donated blood 5-10 times.

7.8.3.4 Risk factors

In year 2020, 30% of Hepatitis C seroconvert donors in 2020 engaged in high-risk behaviours, most notably having a history of multiple sexual partners. Another 30% had history of cupping and the remaining 40% denied any risk factor.

In 2021, 6 donors denied having any risk factors, whereas 5 donors had a history of high-risk behaviours, 1 donor had a history of IV drug use, and 1 donor had a family member with hepatitis C.

7.8.4 Summary of Seroconvert Donor for Hepatitis C - Figure 7.8.4

The age group of those under 40 years old makes up the majority of seroconverted donors for hepatitis C. Male donors dominated female donors, and most of them had donated blood no more than five times in the past. Nearly 40% of donors reported engaging in high risk behaviours.

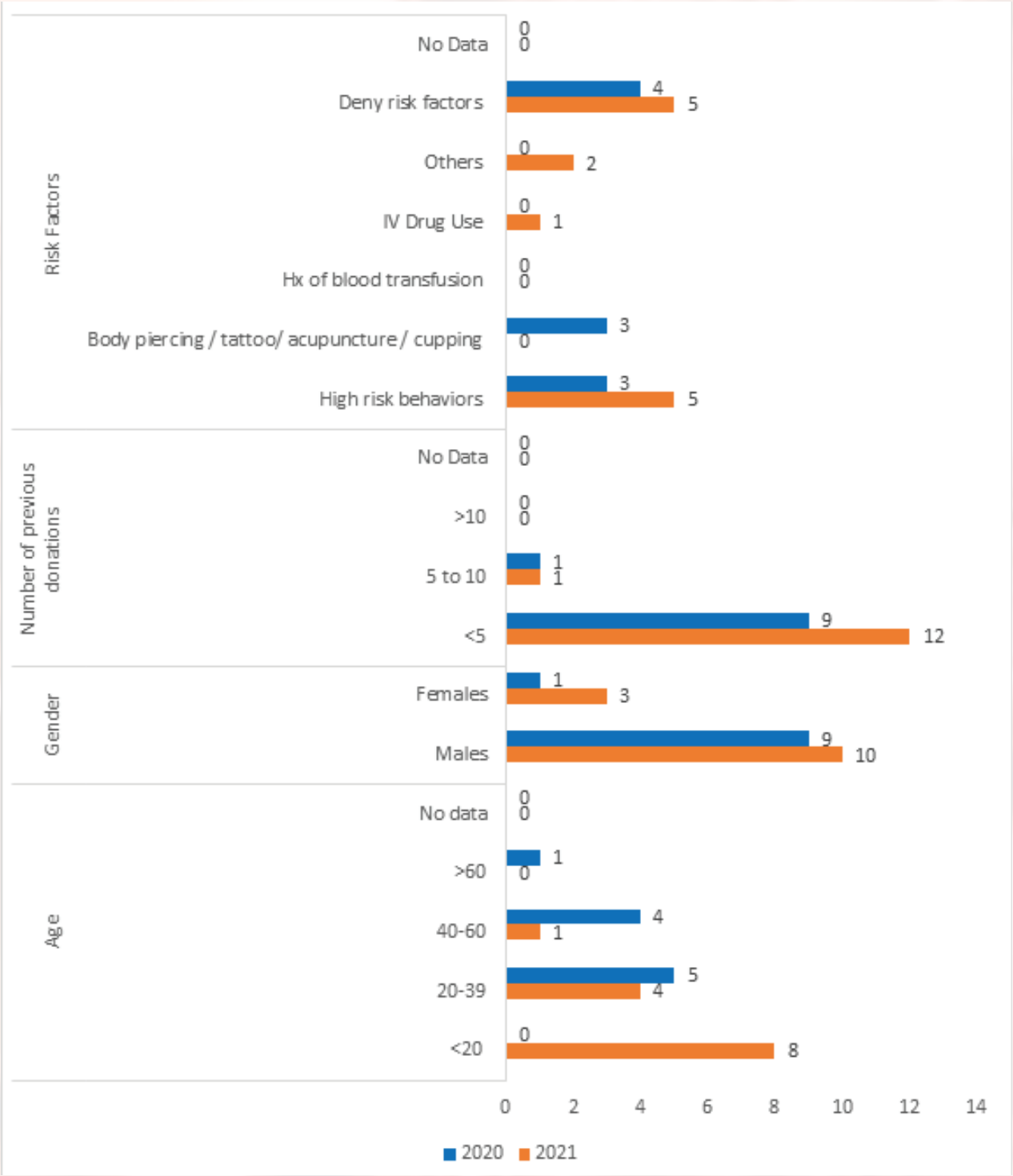
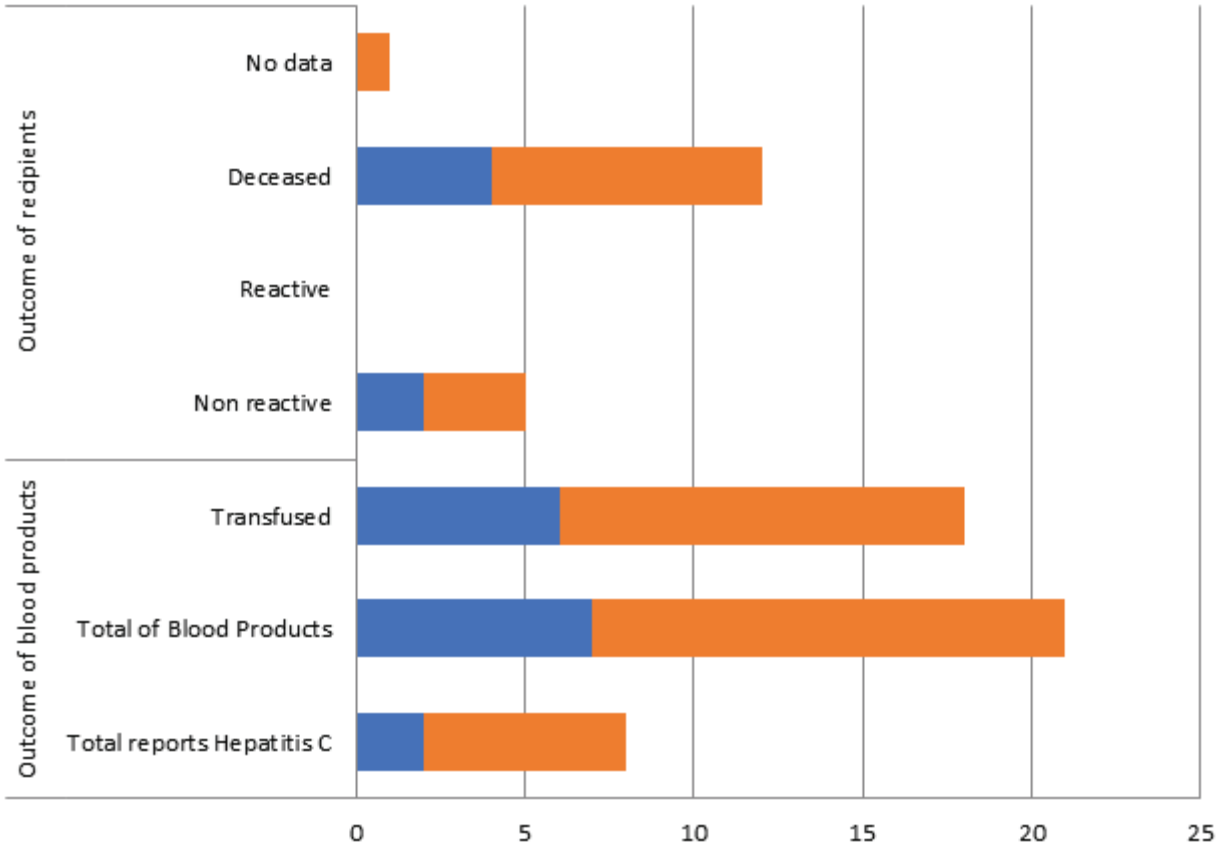


Figure 7.8.4: Demographic Distribution and Risk Factors for Hepatitis C Seroconvert Donors in Part 1

7.8.5 Outcome of look back and recall (Part 2) Seroconvert Donor for Hepatitis C- Figure 7.8.5

A total of 21 blood products were investigated, of which 18 were transfused and the other 9 were either discarded or expired. One report lacked any information on the recipient outcome, and twelve of the recipients were already deceased. Five recipients had HCV tests that came back negative.



	Outcome of blood products			Outcome of recipients			
	Total reports Hepatitis C	Total of Blood Products	Transfused	Non reactive	Reactive	Deceased	No data
2020	2	7	6	2	0	4	0
2021	6	14	12	3	0	8	1

Figure 7.8.5: Outcome of Blood Products and Recipient of Seroconvert Donor for HCV

7.9 SYPHILIS

7.9.1 Syphilis

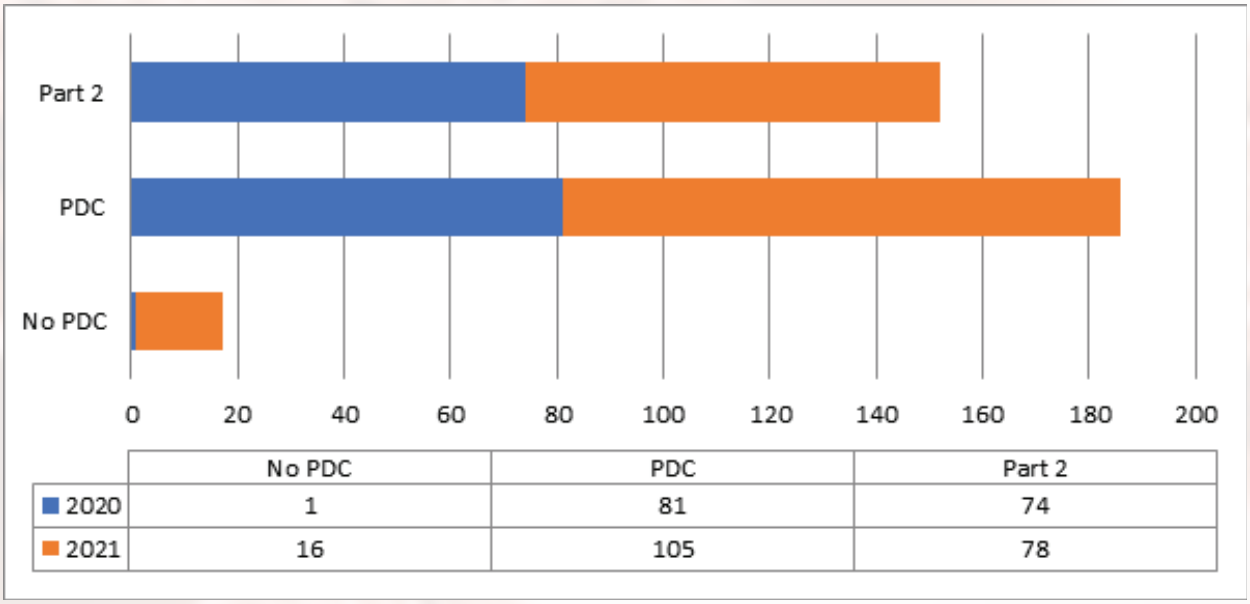
7.9.1.1 Syphilis is a common sexually transmitted infection caused by bacterium Treponema pallidum. Acquired infection is transmitted through direct person-to-person sexual contact with an individual with early or secondary syphilis.

7.9.1.2 Syphilis incidence rates in Malaysia climbed from 5.7 per 100,000 people in 2012 to 8.0 per 100,000 people in 2017, according to the STI surveillance systems that were in place at the time. There were over 3.5 thousand syphilis cases reported in 2020.

7.9.1.3 Clinical presentation is often asymptomatic. Untreated syphilis facilitates HIV transmission and causes considerable morbidity, such as cardiovascular and neurological disease, as well as a congenital syndrome in the newborn.

7.9.2 Total Number of Syphilis Seroconvert Donors – Figure 7.9.2

The total number of Syphilis seroconvert donors reported to the NHCC is the highest and depicted in the graph below. 199 reports were received in 2021 compared to 156 reports overall in 2020. A total of 81 cases for part 1 with post donation counselling was reported in 2020, and 105 cases were reported in 2021. In 2020, there was only one part 1 case without a PDC, while in 2021, there were 16 cases. In total, 74 cases of part 2 were recorded in 2020, while 78 cases of part 2 were reported in 2021.



	No PDC	PDC	Part 2
2020	1	81	74
2021	16	105	78

Figure 7.9.2: Total Number of Syphilis Seroconvert Donor in 2020-2021

7.9.3 Demographic characteristic of Part 1 Seroconvert Donor for Syphilis

7.9.3.1 Age

The majority of reported seroconversions in both years were for syphilis. About 70% of the donors were in the 20-39 age range, followed by nearly 30% of those in the 40-60 age range.

7.9.3.2 Gender

In both of the reporting years, men made up approximately 80% of seroconvert donors for syphilis, increasing to 90.5% in 2021.

7.9.3.3 Previous number of blood donation

The majority of donors who seroconvert for syphilis gave blood less than five times, followed by donors who gave blood five to ten times, and the least number of donors gave blood more than ten times.

7.9.3.4 Risk Factor

Nearly 50% of the donors admitted engaging in high-risk behaviour, while around 30% of them denied having any risk factors. The 37 donors with high risk behaviours were further analysed, and 16 donors admitted to having multiple sexual partners, 12 donors claimed to having had sex with prostitutes in the past, and the remaining 9 donors admitted to being MSM.

The risk factor "Others" was assigned to a total of 14 donors. Premarital sex contact with stable partners was admitted by 11 donors. All but one donor, who confirmed that his sexual partner has syphilis infection, were uncertain about their partners' syphilis infection status. The remaining 3 seroconvert donors disclosed that they could become infected as their partner had another sexual relationship.

7.9.4 Summary of Seroconvert Donor for Syphilis – Figure 7.9.4

Seven male donors between the ages of 20 and 39 who donated less than five times and acknowledged to engaging in high-risk behaviour made up the majority of donors who seroconverted for syphilis.

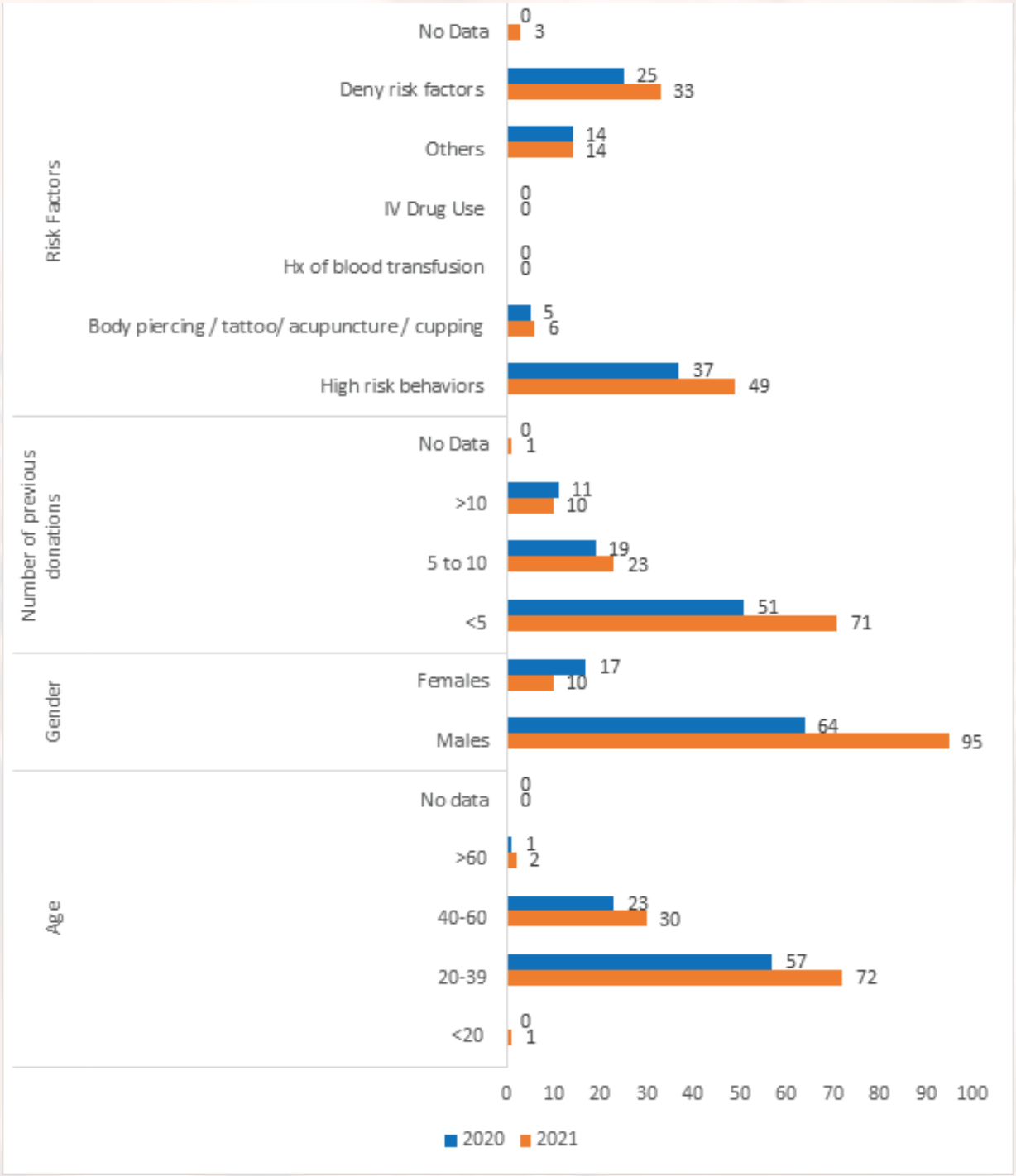
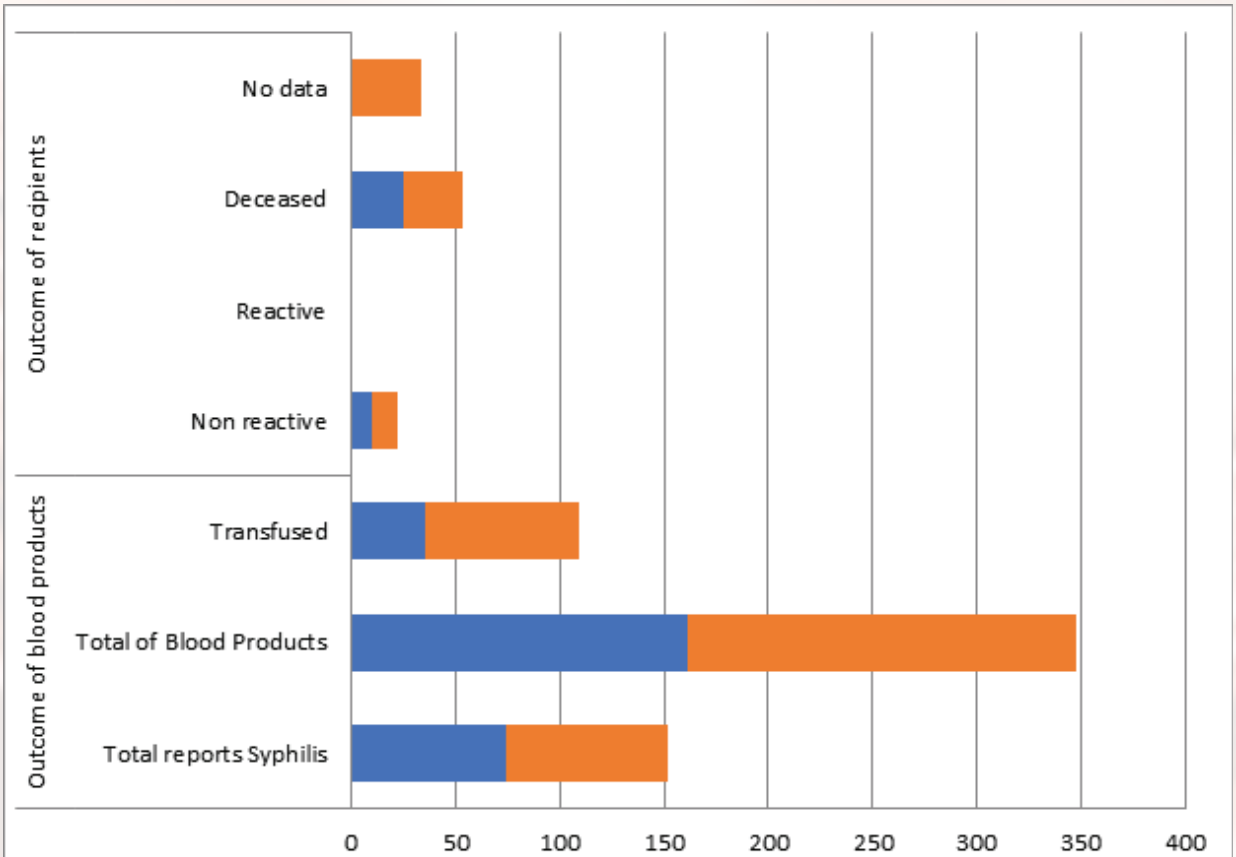


Figure 7.9.4 Demographic Distribution and Risk Factors for Syphilis Seroconvert Donors in Part 1

7.9.5 Outcome of look back and recall (Part 2) Seroconvert Donor for Syphilis- Figure 7.9.5

The look back and recall procedures for 348 blood products were investigated into. 161 blood products that were kept below 20 degrees Celsius for more than 72 hours were not given recipient notification. This is due to Treponema pallidum's inability to survive a prolonged period of cold storage (greater than 72 hours).

Recipient notification was performed out for 109 blood products that were supplied out for transfusion. 22 were reported to be Syphilis non-reactive, and 53 had already passed away. The other 34 recipients were classified as non-complete reports since no results were recorded for them.



	Outcome of blood products			Outcome of recipients			
	Total reports Syphilis	Total of Blood Products	Transfused	Non reactive	Reactive	Deceased	No data
2020	74	161	35	10	0	25	0
2021	78	187	74	12	0	28	34

Figure 7.9.5: Outcome of Blood products and Recipient of Seroconvert Donor for Syphilis

7.10 CO-INFECTION OF TTIs

7.10.1 Co-infection of TTIs

7.10.1.1 As stated above, people who are infected with HIV are around 87,000 in 2019. Some of them were infected with other infection such as Hepatitis B, Hepatitis C and Syphilis and were labeled as co-infection. (Puoti M et al, 2002)

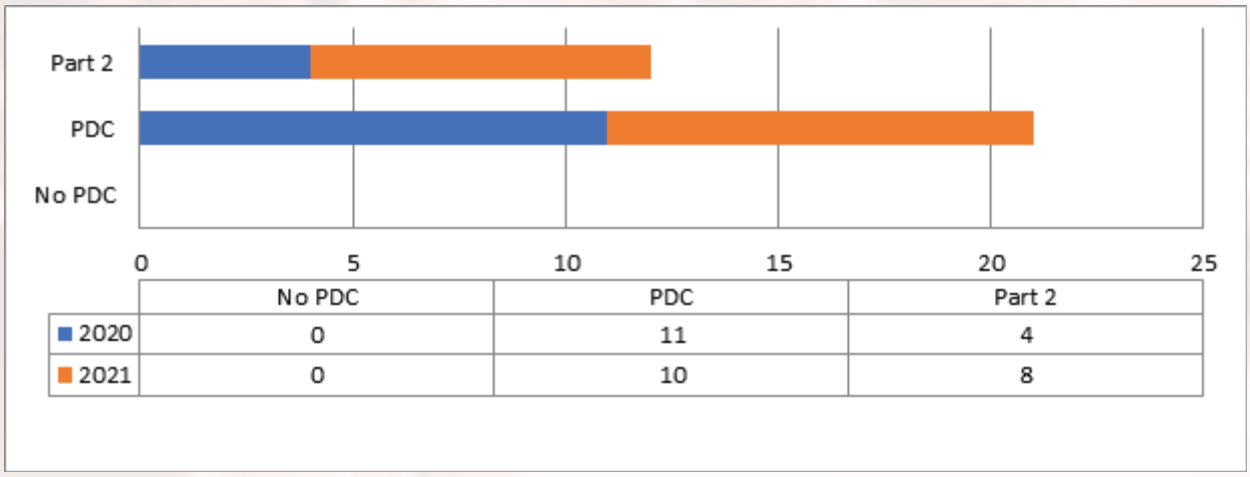
7.10.1.2 With co-infection of HIV and HCV, it is estimated that HCV affects 2-15% of people living with HIV worldwide and up to 90% of those are people who injects drug. In Malaysia, reported HIV/HCV co-infection was 15.1% (518 cases) of total HCV cases in 2019. One case of HIV and HCV co-infection reported from a donor who admitted to injection drug use (Global AIDS monitoring report, 2020)

7.10.1.3 More than 80% of 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.

7.10.2 Total number of Co-infection TTI seroconvert donors – Figure 7.10.2

In 2020, 11 reports of Part 1 with PDC were received for co-infection. From 11 cases of co-infection reported to NHCC,5 cases were co-infection of HIV/Syphilis, four cases of HIV/HBV, one case of HIV/HCV, and one case of HCV/Syphilis.

In 2021, there were 10 reports of Part 1 with PDC for co-infection. The infection comprises of 6 cases of HIV/Syphilis co-infection, 1 HCV/HBV cases, 1 HCV/Syphilis and 2 reports that did not mention the co-infection diseases. No reports were received without first visit for both years. As for Part 2, there were 4 reports in 2020 and 8 reports received in 2021.



	No PDC	PDC	Part 2
2020	0	11	4
2021	0	10	8

Figure 7.10.2: Total Number of Co-infection TTI Seroconvert Donors in 2020-2021

7.10.3 Demographic/Characteristic of Seroconvert Donors of Co-infection

7.10.3.1 Age

Nine of the eleven co-infected donors that were reported for the year 2020 belonged to the younger age group. They are in the 20-39 years old age range, with 81.82% in 2020 and 90% in 2021.

7.10.3.2 Gender

All eleven donors were male.

7.10.3.3 Previous number of blood donation

With 7 reported cases in 2020 and 8 cases in 2021, the majority of donors have donation counts of less than five times. Two donors had five to ten donations in 2020; one admitted to being homosexual, and the other had engaged in prostitution. The two donors who had more than 10 donations denied having any risk factors. Whereas in 2021, one donor had a history of donating blood 5–10 times, and another donor had a history of donating blood more than 10 times.

7.10.3.4 Risk Factor

Eight of the donors from the eleven cases in 2020 admitted to engaging in high-risk behaviours, including four who identified as homosexual, two who had several sexual partners, one who admitted to prostitution, and one who claimed to be bisexual. In contrast, three donors in 2021 denied having any risk factors, while the remaining seven seroconvert donors reported a history of engaging in high-risk behaviours.

7.10.4 Summary of Seroconvert Donor for Co-infection – Figure 7.10.4

Donors who seroconverted for co-infection were male donors in the younger age group (20-39 years old), with donation frequency of less than five times, and engaging in high risk behaviours.

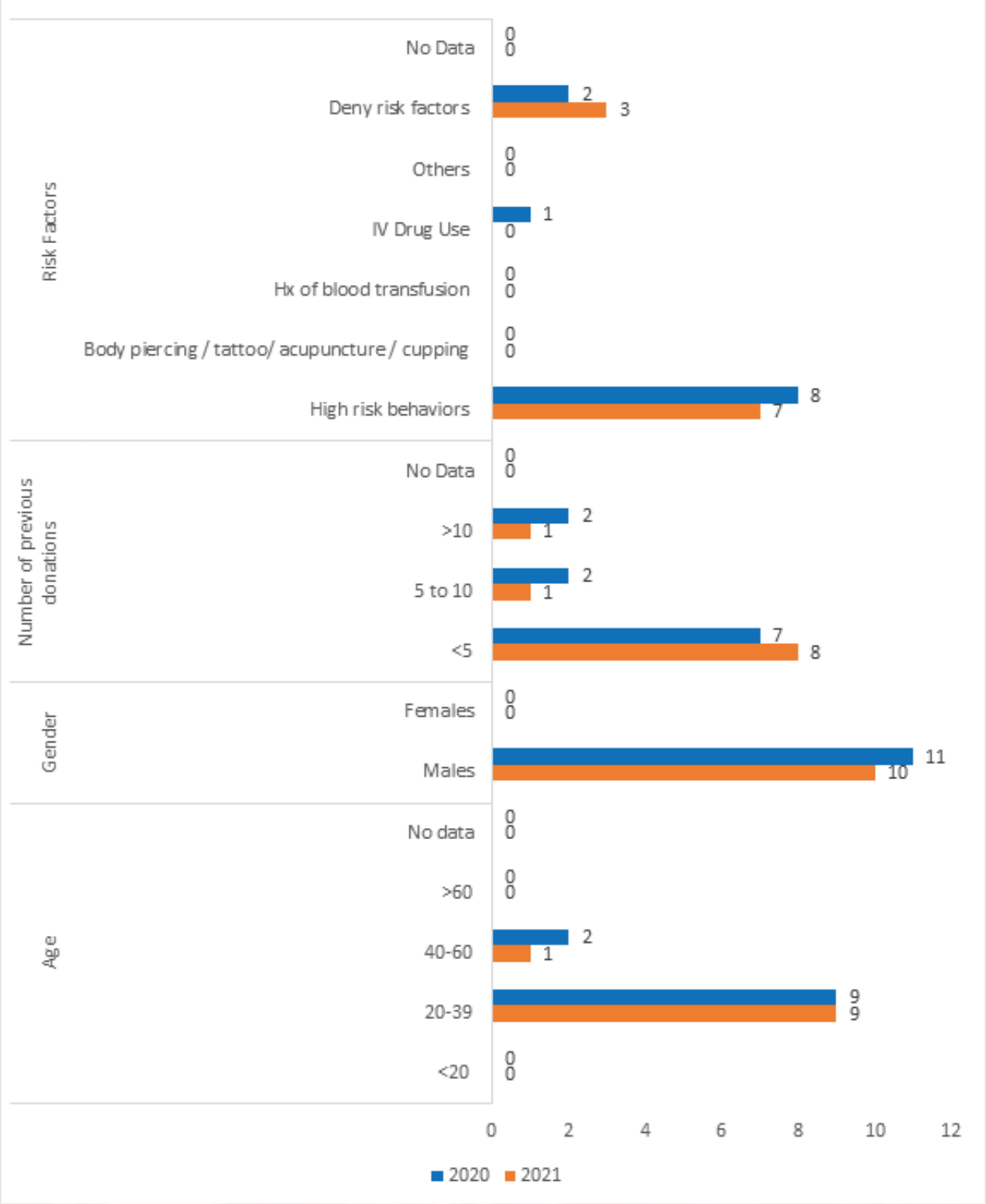
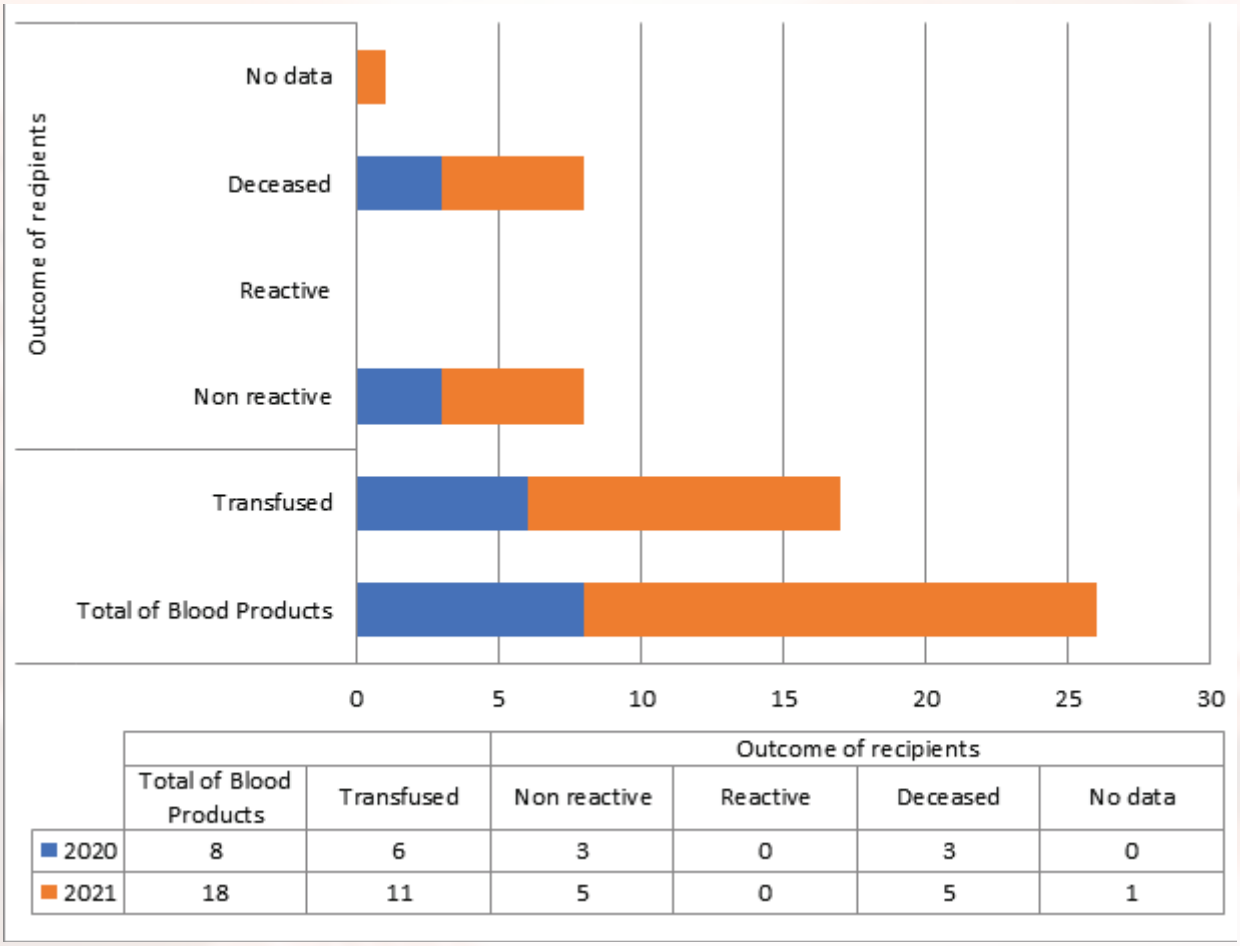


Figure 7.10.4 : Demographic Distribution and Risk Factors for Co-infection Seroconvert Donors in Part 1

7.10.5 Outcome of Lookback and Recall for Co-infection Seroconvert Donors - Figure 7.10.5

A total of 8 blood products were investigated into in 2020. Six of eight blood products were given to patients as transfusions. Three of the six patients who received the blood products were found to be non-reactive, three of them died, and there was no reactive case among the recipients, according to the report.

In 2021, eleven of the 18 blood products that were investigated in 2021 were transfused to patients. The results of 11 blood transfusion look-back procedures revealed that 5 patients tested negative, 5 patients had already passed away, and 1 report had no information on patient outcomes.



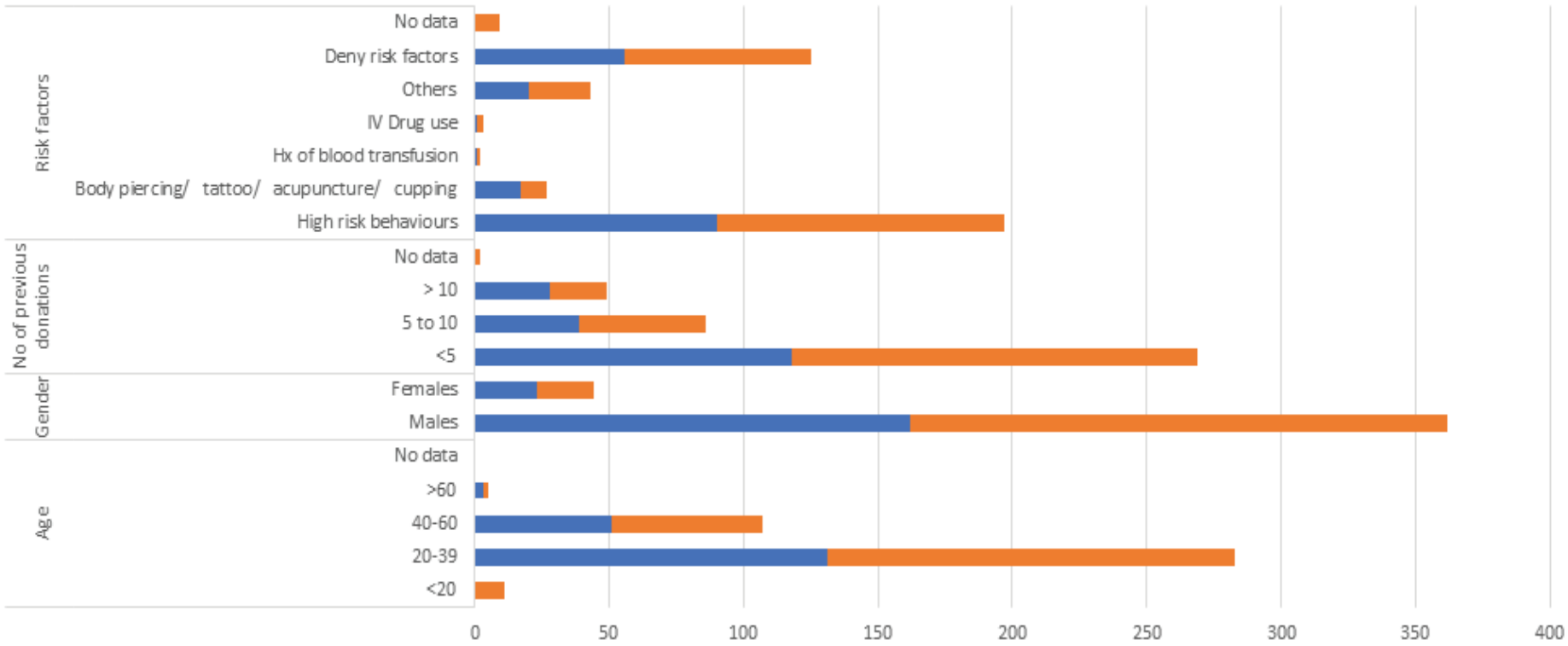
			Outcome of recipients			
	Total of Blood Products	Transfused	Non reactive	Reactive	Deceased	No data
2020	8	6	3	0	3	0
2021	18	11	5	0	5	1

Figure 7.10.5 : Outcome of Blood Products and Recipient of Seroconvert Donor for Co-infection

7.11 Summary and Recommendations

The results for all four infections are described below. It is evident in both years that donors between the ages of 20 and 39 have the highest percentage of seroconverts (69.70%), while donors older than 60 have the lowest percentage (1.23%). Comparing male and female donors during the past two years, the percentage of male donors is greater at 89.16%. The second largest number (30.79%) denied having any risk factors during initial visits, while the highest percentage (48.52%) had a history of high-risk behaviours. This demonstrates the need to enhance the efficacy of our counselling sessions and to improve donor education.

Variables		Total all TTI in 2020		Total all TTI in 2021		Total all TTI in 2020 and 2021	
		Total (N= 185)	Percentage	Total (N= 221)	Percentage (%)	Total (N= 406)	Percentage (%)
Age	<20	0	0.00%	11	4.98%	11	2.71%
	20 - 39	**131**	**70.81%**	**152**	**68.78%**	**283**	**69.70%**
	40 - 60	51	27.57%	56	25.34%	107	26.35%
	>60	3	1.62%	2	0.90%	5	1.23%
	No data	0	0.00%	0	0.00%	0	0.00%
Gender	**Males**	**162**	**87.57%**	**200**	**90.50%**	**362**	**89.16%**
	Females	23	12.43%	21	9.50%	44	10.84%
Number of previous donations	**<5**	**118**	**63.78%**	**151**	**68.33%**	**269**	**66.26%**
	5 to 10	39	21.08%	47	21.27%	86	21.18%
	>10	28	15.14%	21	9.50%	49	12.07%
	No data	0	0.00%	2	0.90%	2	0.49%
Risk Factors	**High risk behaviors**	**90**	**48.65%**	**107**	**48.42%**	**197**	**48.52%**
	Body piercing/ tattoo/ acupuncture/ cupping	17	9.19%	10	4.52%	27	6.65%
	History of blood transfusion	1	0.54%	1	0.45%	2	0.49%
	IV Drug Use	1	0.54%	2	0.90%	3	0.74%
	Others	20	10.81%	23	10.41%	43	10.59%
	Deny risk factors	56	30.27%	69	31.22%	125	30.79%
	No data	0	0.00%	9	4.07%	9	2.22%



	Age					Gender		No of previous donations				Risk factors						
	<20	20-39	40-60	>60	No data	Males	Females	<5	5 to 10	> 10	No data	High risk behaviours	Body piercing/ tattoo/ acupuncture/ cupping	Hx of blood transfusion	IV Drug use	Others	Deny risk factors	No data
2020	0	131	51	3	0	162	23	118	39	28	0	90	17	1	1	20	56	0
2021	11	152	56	2	0	200	21	151	47	21	2	107	10	1	2	23	69	9

Figure 7.11: Seroconvert Donor Summary 2020 and 2021

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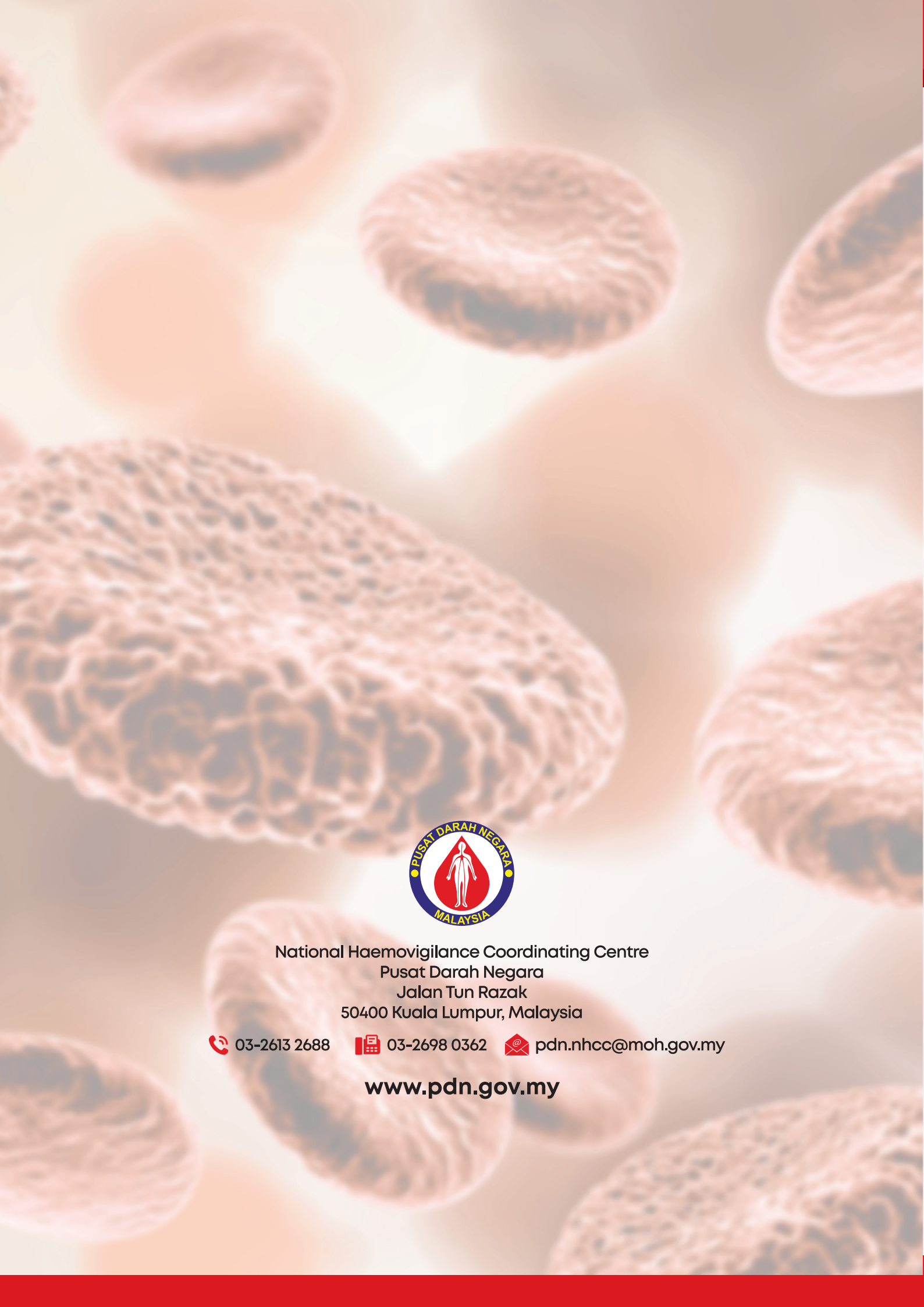

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