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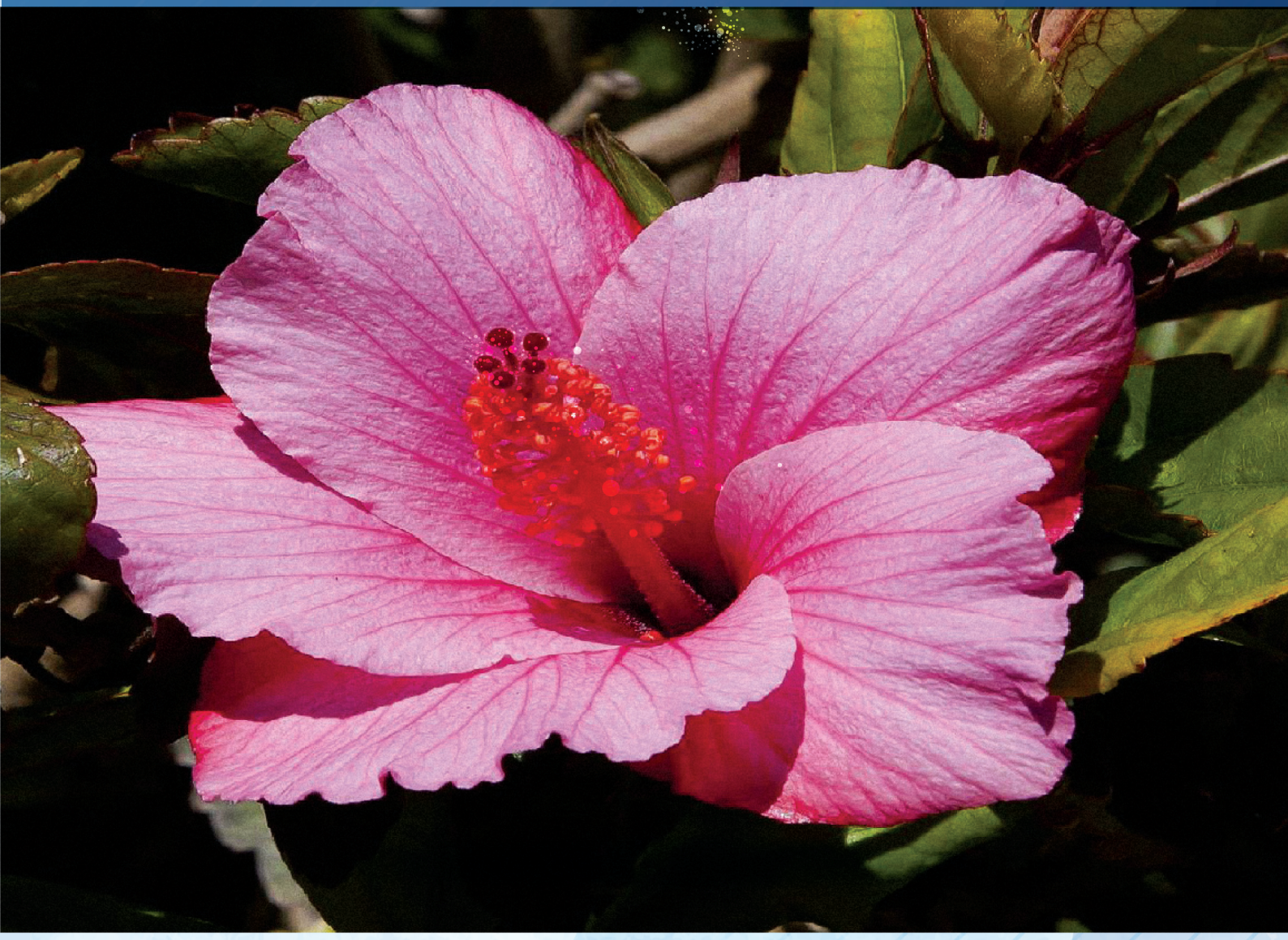
NATIONAL HAEMOVIGILANCE COORDINATING CENTRE,
PUSAT DARAH NEGARA

HAEMOVIGILANCE REPORT 2018-2019

NATIONAL TRANSFUSION MEDICINE SERVICE IN MALAYSIA



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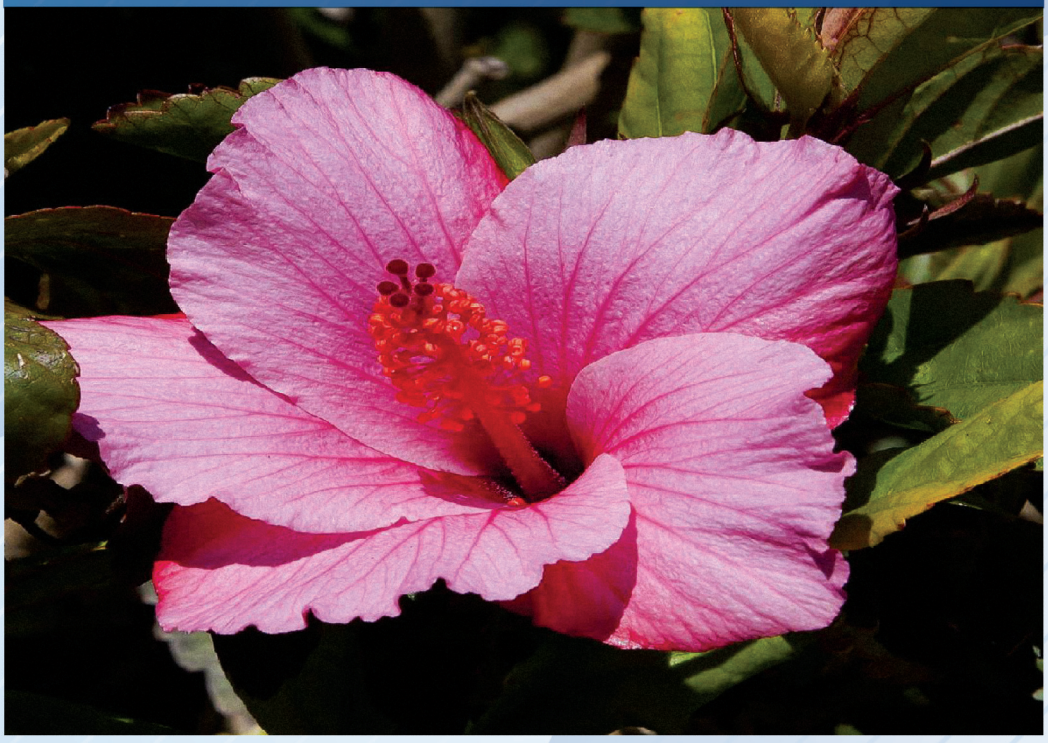

Pusat Darah Negara
Ministry of Health Malaysia

Second Edition
October 2020

Haemovigilance Report
2018 – 2019
National Transfusion Medicine Service in Malaysia

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Special gratitude to:

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Haemovigilance Reporting Programme
and
Dr Mawaddah bt Ghazali
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FOREWORD

HAEMOVIGILANCE REPORT
2018-2019
NATIONAL TRANSFUSION MEDICINE SERVICE IN MALAYSIA

Dato' Dr Norhizan bin Ismail
Director
Medical Development Division
Ministry of Health Malaysia

Publication of the second biannual Haemovigilance report 2018-2019 for Malaysia confirms the ongoing success of the scheme. I would like to convey my heartiest congratulations to the Director of Pusat Darah Negara and acknowledge all hospitals who have submitted the Haemovigilance reports without fail during this challenging time with the outbreak of COVID-19.

In these two years, numerous findings and recommendations have been issued, based on analysis of the events and incidents reported to NHCC. This has assisted a growing awareness of the extent and type of adverse events or reactions associated with transfusion practice in Malaysian hospitals and the measures available to address these. The utmost goal of haemovigilance is to achieve quality improvement of the transfusion chain and ultimately help improve donor and patient safety as well as improve transfusion appropriateness.

Special acknowledgement is conveyed to the Haemovigilance Working Group for their perseverance to produce this report. I hope those involved in the care of donors and patients will find the report informative and look forward to your ongoing support of the programme.

PREFACE

HAEMOVIGILANCE REPORT
2018-2019
NATIONAL TRANSFUSION MEDICINE SERVICE IN MALAYSIA

Dr Noryati Abu Amin
Head of National Transfusion Medicine Service
Director
Pusat Darah Negara

Providing safe and sufficient blood is an integral part in every Blood Transfusion Service. Relentless challenges were faced in publishing the second Hemovigilance Report 2018-2019 especially during this challenging time with the outbreak of COVID-19. The report published is a reference for all doctors, nurses and various health care providers of hospitals in the country to supply safe, adequate and appropriate blood of good quality, its component and products to all in need in accordance to the core function of blood transfusion service.

The numbers of reports received were encouraging over the years, yet participation from private hospital was not remarkable as noted in the previous annual report. The aim of this report is to not only identify critical areas in transfusion process but also monitor the implementation of corrective and preventive actions. Human factors play a major role in medical mistakes. These reports helps us increase awareness and be more vigilant in providing safe blood for transfusion.

I would like to thank all the contributors and the Haemovigilance working group for their excellent efforts, diligence, and inputs as well as to the Ministry of health Malaysia for their continuous support. I hope this report will be handy guide to all stakeholders in the transfusion chain in ensuring patent safety.

EXECUTIVE SUMMARY

National Haemovigilance Coordinating Centre analyse the adverse event in the transfusion chain and addresses the opportunities to learn and improve the current work process for the betterment of the Transfusion Medicine Service in Malaysia.

This biannual report is the second edition produce by Pusat Darah Negara (PDN) following voluntary reporting of all blood banks in Malaysia using the official haemovigilance form that can be downloaded from the PDN website (www.pdn.gov.my). In September 2019, mark another milestone where Haemovigilance and Seroconvert modules have successfully operated in Blood Bank Information System version 2 (BBISv2). Twenty-two selected blood banks are now able to utilize this modules to report the adverse event online.

The participations of reporting towards patient haemovigilance are far better than blood donor. This could be due to selective reporting or lack of awareness and willingness to report an adverse event. Improving importance and consistency in reporting despite its positive or negative impacts, specifically those arising from the shortcoming of the work process should be encouraged.

The haemovigilance programme in Malaysia is focusing on blood donor and patient safety. Thus the reporting forms are design to monitor the adverse event in blood donors, adverse outcome of transfusion to the recipients and risk of transfusion transmissible infection from the seroconvert donor.

This report is structured in a similar manner to previous ones and the findings are discussed in each chapter. Thus this executive summary describes few pertinent points with particular attention to the following:

3.1 Adverse Donor Reaction (ADR):

The frequency of ADR is nearly two times higher in whole blood donation compared to apheresis donation. Majority of these donors sustain a mild vasovagal reaction (VVR) that was transient and self-limiting. Severe reaction is uncommon and mostly due to severe VVR with fitting episodes. The occurrence of ADR is higher in new and female blood donor. Around 1 of every 5 repeat donors could experience ADR in subsequent donation. Implementing measures aim to prevent hypotension or psychological support on fear of needle as well as good post donation care can reduce the occurrence of VVR and subsequently increase the probability of donor return.

3.2 Seroconvert Donor (SD):

Since 2019, more than 90% of blood donation in Malaysia have been screened with nucleic acid testing (NAT) as a routine screening. However, despite various efforts to ensure blood safety, blood transfusion still carry risk of transfusion transmissible infection (TTI). Thus a lookback and recall procedure is done to safeguard the recipient.

The donor demographic profiles for each type of TTI were generated from data of 20% participated blood collection centre in SD reporting. While incidence of hepatitis B is the highest type of infection in new donor, syphilis seroconversion was the highest among repeat donor. In general male donor, frequency of donation of less than 5 times and age ranging from 20-29 years old were found to have higher risk of seroconversion. Previously intravenous drug usage was the commonest risk factor for HIV infection among seroconvert donor. However, we now have observed high risk sexual activity especially men sex with men (MSM) as the common route of infection.

The recipients suspected of receiving blood during the window period from the seroconverted donors are traced in the lookback and recall procedure. Fortunately none has acquired TTI during these reporting years.

3.3 Adverse Transfusion Reaction (ATR)

Packed Red Blood Cell (PRBC) was the most common type of blood component transfused. The three commonest types of adverse transfusion reactions are mild allergy, febrile non-haemolytic transfusion reaction (FNHTR) and unclassifiable complication of transfusion. Since leukocyte depleted PRBC usage is only limited to thalassemia patient, the risk of the common ATR is inevitable. Thus effort must be taken to expand the usage to other transfusion dependent group of patient and eventually to all patients.

Interestingly, NHCC observed risk of ATR in patient receiving leukocyte depleted PRBC. This could be due to leukodepletion procedure was done to selected phenotype blood post storage. Since NHCC has no information on the timing of leukodepletion post collection to associate with the occurrence of adverse event, additional data provided by the reporting hospital would help in analysing this event in the future.

3.4 Transfusion Error (TE):

Ward error was the highest especially during sample taking and labeling due to patient positive identification was not done appropriately. However, due to availability of patient's historical record in blood bank, this discrepancy was detected before error occurred. However blood bank pre-transfusion testing error contributed to the highest cases of incorrect blood component transfused (IBCT). Thus pre-transfusion testing done independently on the second fresh sample in patient

with no historical record that need transfusion may minimise the incidence of IBCT when currently automated techniques for blood grouping and crossmatching could be deemed costly.

Approximately half of the patient that transfused with the wrong blood component had recovered with no ill effect. However 1 in 4 sustained morbidity and required prolonged hospitalisation and unfortunately there was one death was reported as probably related to transfusion.

Finally, NHCC hopes the finding of this report could affect changes in the work process to enhance donor and patient safety as the expression goes, if we focus on problems, we will have more problems but if we focus on possibilities, we will have more opportunities to become better.

Dr Idaleswati Nor Mohamed
Transfusion Medicine Specialist
Head of Division
National Surveillance and Assessment
Pusat Darah Negara

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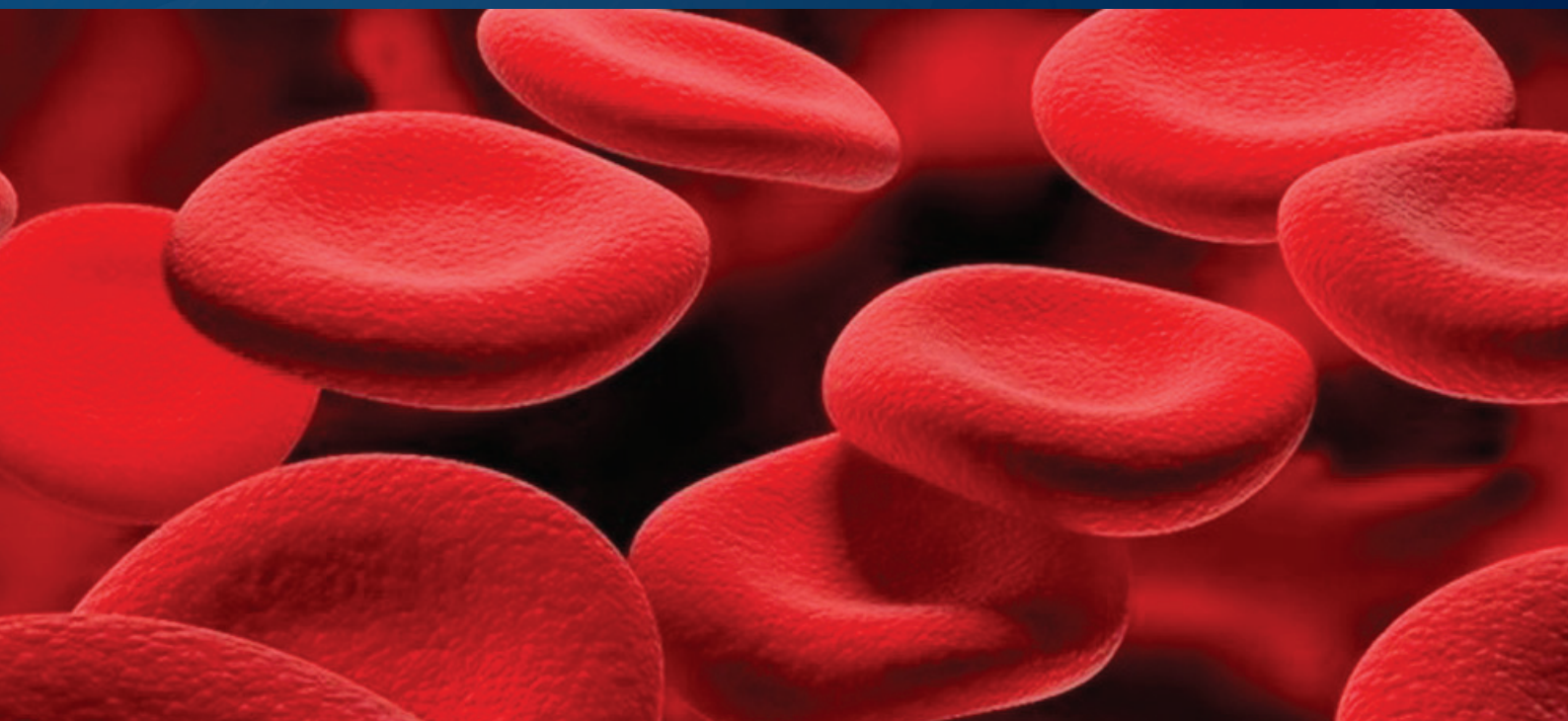
Abbreviations (A to Z)

ADR	Adverse Donor Reaction
ADU	Avoidable/ Delayed/ Undertransfused
AMT	Applied Muscle Tension
ANC	Antenatal Care
ATR	Adverse Transfusion Reaction
BBIS	Blood Bank Information System
CCP	Critical Control Point
CDC	Centers for Disease Control and Prevention
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
HO	House Officer
HSE	Handling and Storage Error
HTC	Hospital Transfusion Team
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
NHCC	National Haemovigilance Coordinating Centre
NHSBT	National Health Service Blood and Transplant
NM	Near Miss
NRR	No Report Receives
NSN	Negeri Sembilan
OT	Operation Theatre
PAC	Patient Admission Centre
PBM	Patient Blood Management
PC	Packed Cell
PHG	Pahang
PLS	Perlis
PLT	Platelet
PNG	Pulau Pinang
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
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
WPS	Wilayah Persekutuan

CHAPTER 1

INTRODUCTION



1.1 NATIONAL HAEMOVIGILANCE COORDINATING CENTRE (NHCC)

The transfusion of blood product is one of the core components for healthcare service delivery to patients and it is also understood that blood transfusion is not without risk. Since 2003, National Haemovigilance Coordinating Centre (NHCC) under the administration of National Blood Centre has created a system in which all complications of transfusions both from recipient and donor were reported and critically analysed, leading on the progression of transfusion safety in Malaysia over the last 17 years.

NHCC is responsible for the overall management of the reporting procedures and report verifications of transfusion event received at the Haemovigilance office. At times, additional information is sought from the medical personnel involved in the events to get more complete information to classify the type of adverse event, imputability, and severity of the event. The first Hemovigilance Report was published in 2019 consisting of 2016-2017 analysis has become an eye-opener to more hospitals with blood banks to participate in reporting and sharing information on transfusion events. This is the second published Haemovigilance Report for National Transfusion Medicine Service in Malaysia. This report is particularly compiled from transfusion events that occurred from January 2018 to December 2019.

1.2 OBJECTIVES

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, their safety and appropriate use to ensure blood donor and patient safety. These have become our vision and mission to present an evidence based report that can be applied to improve transfusion medicine service in Malaysia. NHCC is also working closely together with Patient Safety Counsel and committed in ensuring the safety of transfusion of blood and blood products as stated in Goal 6 of The Malaysian Patient Safety Goals (MPSG).

1.3 DEFINITION OF HAEMOVIGILANCE

Haemovigilance is a surveillance programme set to monitor adverse events, near misses, and errors related to the transfusion chain that comprises identification, investigation, and reporting of the incidents. The reports were then analysed to improve the understanding of the causes and clinical outcomes of these events to prevent their occurrence and recurrence.

1.4 HAEMOVIGILANCE REPORTING

Each undesirable event shall be reported to NHCC by the hospital blood bank using gazetted forms, which include:

1. Reporting Form for Transfusion Related Adverse Events (BTS/HV/3/2016)
2. Reporting Form for Adverse Donor Reaction (BTS/DV/2/2016) and
3. Seroconvert Donor Notification Form, Part 1 And 2 (BTS/SC/1/2016)
4. Monthly Haemovigilance Report – cover letter

For more than a decade NHCC has received hard copies of these reporting forms through postal mail, fax or by hand. Few hospitals still send in a summary of the adverse events via email. Reports on these adverse events then reviewed, tabulated, and analysed by the NHCC team comprising of medical officers and transfusion medicine specialist.

The Blood Bank Information System (BBIS) has been around since 2005 and limited usage within PDN. In 2016, KKM has approved an upgrade project of the BBIS to version 2. The system has been expanded to be used by 22 blood banks with shared cloud based data storage and more modules have been established including Haemovigilance and Seroconvert.

The Blood Bank Information System version 2 (BBISv2) Haemovigilance Module was officially released in September 2019. We have then started to receive reports via BBISv2 system from several hospitals included in the upgrade. All transfusion-related events reports now can be submitted using system online which means reduce paperwork and turn-around-time (TAT). The system also offers more secure and efficient record keeping and data sharing without compromising confidentiality.

While it can capture and analyse the data for learning and pattern recognition with the least workload on reporting side, we certainly hope it will encourage and improve compliancy from all designated hospitals in sharing adverse events reporting so that we would be able to analyse the adverse transfusion events and improve the service quality in the future. In view of BBISv2 Haemovigilance Module is a new system, NHCC greatly encouraged 100% participation from hospitals with BBISv2 from 2020 onwards to ensure it runs and serves its function as desired. Below are 22 hospitals involved in BBISv2.

State	No	Hospital
Kedah	1.	Hospital Sultanah Bahiyah, Alor Setar
Pulau Pinang	2.	Hospital Pulau Pinang
	3.	Hospital Seberang Jaya
Perak	4.	Hospital Raja Permaisuri Bainun, Ipoh
	5.	Hospital Taiping
	6.	Hospital Manjung

State	No	Hospital
Wilayah Persekutuan	7.	Pusat Darah Negara
Selangor	8.	Hospital Tengku Ampuan Rahimah, Klang
Negeri Sembilan	9.	Hospital Tuanku Jaafar, Seremban
Melaka	10.	Hospital Melaka
Johor	11. 12.	Hospital Sultanah Aminah, Johor Bahru Hospital Sultanah Nora Ismail, Batu Pahat
Pahang	13. 14.	Hospital Tengku Ampuan Afzan, Kuantan Hospital Sultan Haji Ahmad Shah, Temerloh
Terengganu	15.	Hospital Sultanah Nur Zahirah, Kuala Terengganu
Kelantan	16.	Hospital Raja Perempuan Zainab II, Kota Bharu
Sabah	17. 18. 19.	Hospital Queen Elizabeth II, Kota Kinabalu Hospital Sandakan Hospital Tawau
Sarawak	20. 21. 22.	Hospital Umum Sarawak, Kuching Hospital Miri Hospital Sibu

1.5 LIMITATION

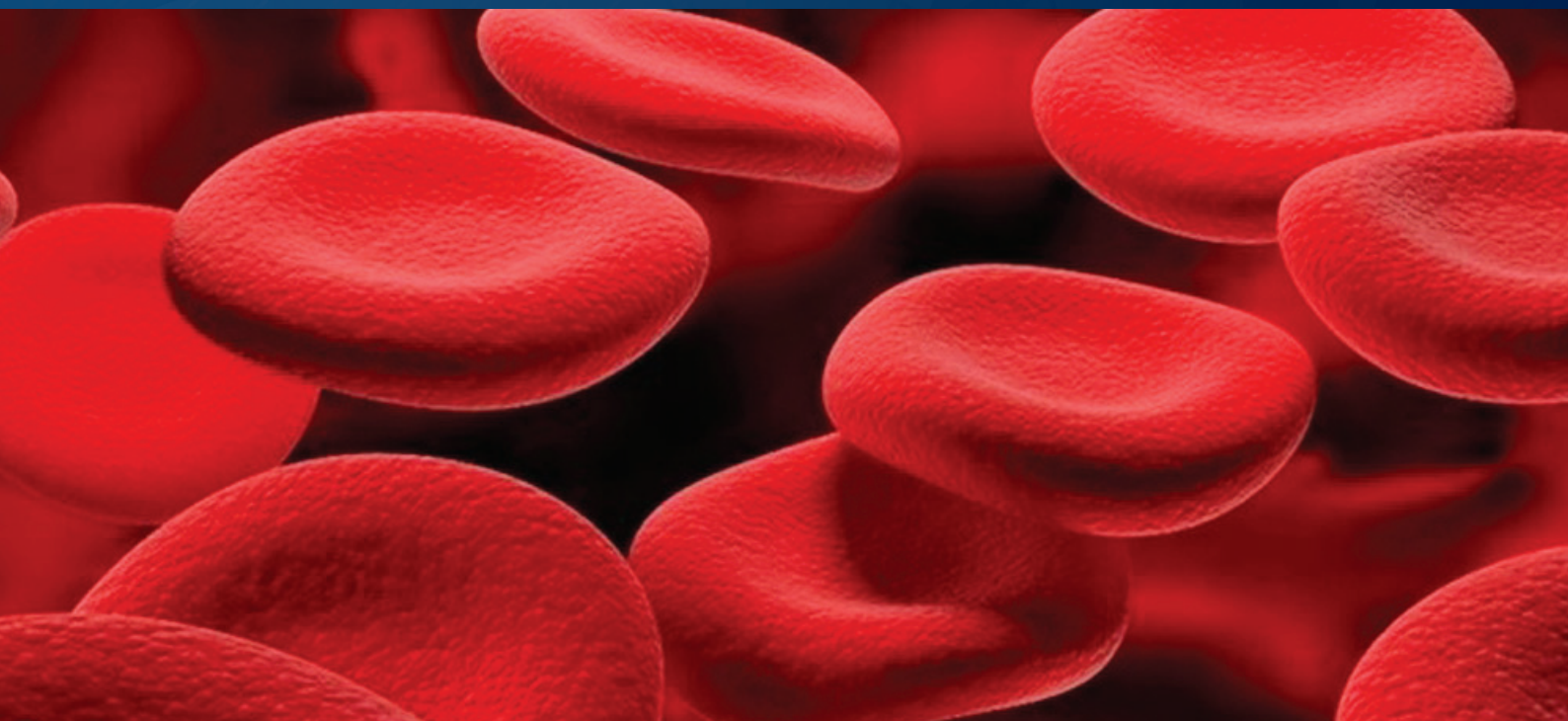
NHCC observe an improvement in terms of compliance for using the latest haemovigilance reporting forms and a reduction of incomplete data. This improve the validity of the data analyse as an accurate data collection and analysis was the key to haemovigilance objectives.

Another concern that were discussed in the previous Haemovigilance Report was underreporting due to passive data collection system and non-standardised methods of reports submission which resulted in failure to reach NHCC office. NHCC team has introduced the cover letter for monthly haemovigilance reporting since middle of 2019 and this cover letter can be downloaded from the PDN website. A periodic follow-up with hospital blood banks were also been undertaken.

The haemovigilance and seroconvert modules in BBISv2 are new and hospital blood banks personnel might need time to be competent and adapt to the changes. Thus BBISv2 training of Hemovigilance and Seroconvert Module have been done to respective representatives of 22 hospitals in March 2019 as a part of collaboration between NHCC and BBISv2 upper management to train and ensure user's competency.

CHAPTER 2

PARTICIPATION OF PATIENT HAEMOVIGILANCE REPORTING



2.1 OVERVIEW OF PATIENT HAEMOVIGILANCE REPORTING – Figure 2.1

"What gets measured gets improved". Therefore, haemovigilance reporting aims to enhance transfusion safety in Malaysia. All reports will be analysed and used as an evidence-based recommendations to improve the quality of the blood transfusion chains, primarily focusing on patient safety and safe transfusion practice. Since the start of haemovigilance reporting programme in 2004, the number of reports received have shown a steadily increase in trend. However, there was a reduction of reports received in 2019. This could be due to the change of final date of report accepted by NHCC from end of June to end of March on following year, starting from March 2020. This is to assist NHCC to produce the biannual report before the end of the following year.

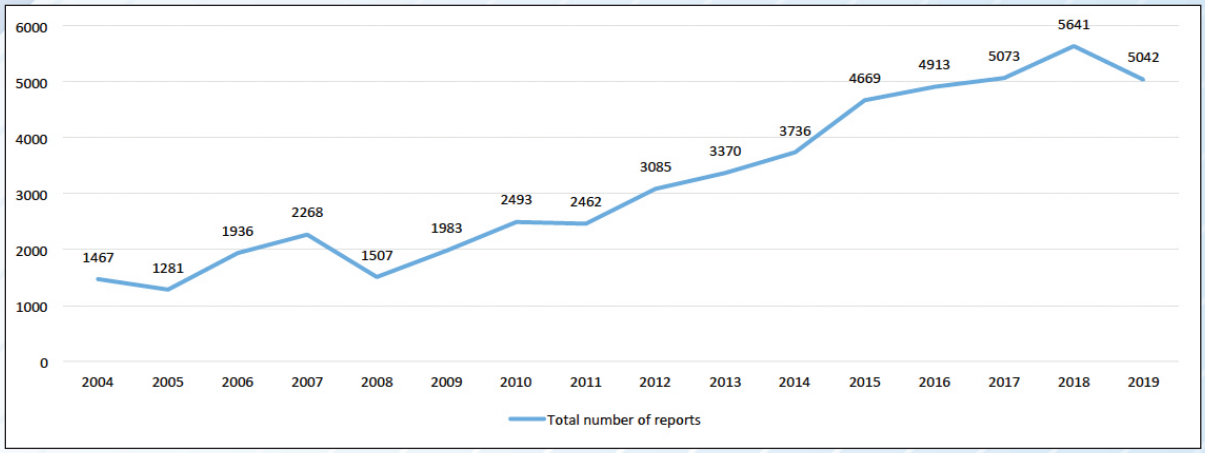
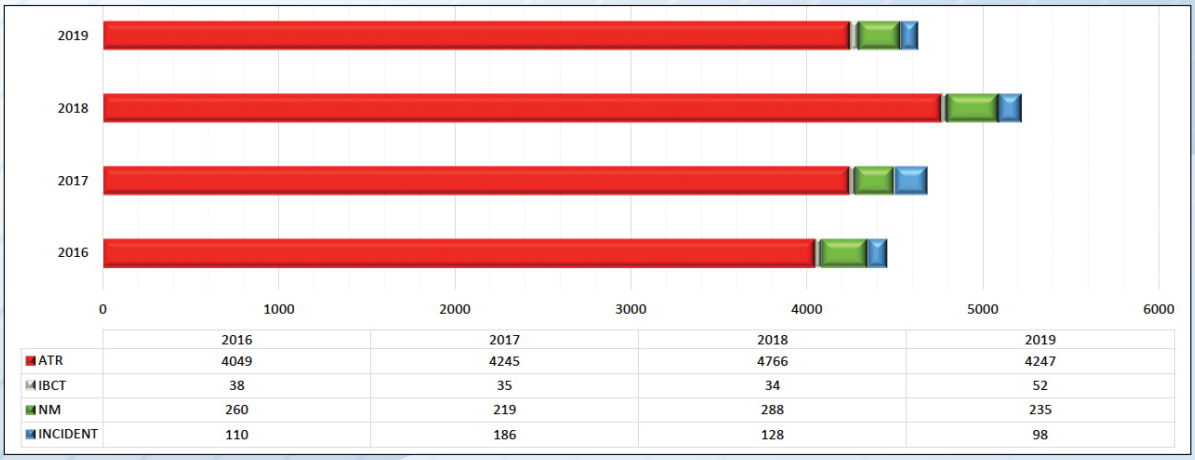


Figure 2.1: Total Number of Haemovigilance Reports Received

2.2 TYPE OF ADVERSE EVENTS – Figure 2.2

Patient haemovigilance report submitted to NHCC are adverse transfusion reaction (ATR), incorrect blood component transfused (IBCT), near miss (NM) and incident. More than 90% of adverse events were attributed to ATR while IBCT showed the least reported event of less than 1% for two consecutive years.

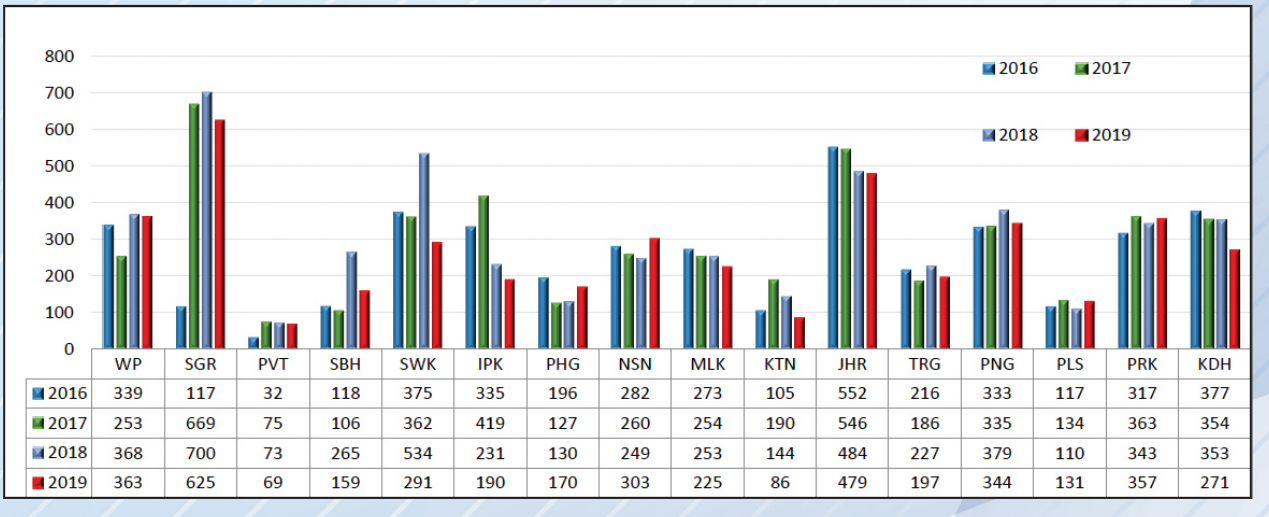


	2016	2017	2018	2019
ATR	4049	4245	4766	4247
IBCT	38	35	34	52
NM	260	219	288	235
INCIDENT	110	186	128	98

Figure 2.2: Total Number of Adverse Transfusion Reaction (ATR), Incorrect Blood Component transfused (IBCT), Near Misses (NM) and Incident Reported

2.3 ADVERSE TRANSFUSION REACTION (ATR) REPORTED BY STATES – Figure 2.3

Approximately 90% of reported ATR in 2018 and 2019 were reported by government hospital blood banks. In general, there were 4 states which showed an increase in number of reports submitted in 2019 compared to 2018. These states are Pahang, Negeri Sembilan, Perlis and Perak. Selangor has the highest number of reports submitted in 2019, which consist of 13.84% (625) while Kelantan reported the least with 1.90% (86). In 2019, 11 states showed a decline in the number of reports compared to 2018. Sarawak reported the most significant decline of 46% of ATR compared to the previous year. However, it is difficult to distinguish whether this is due to underreporting or a true decrease of the incidence of ATR.

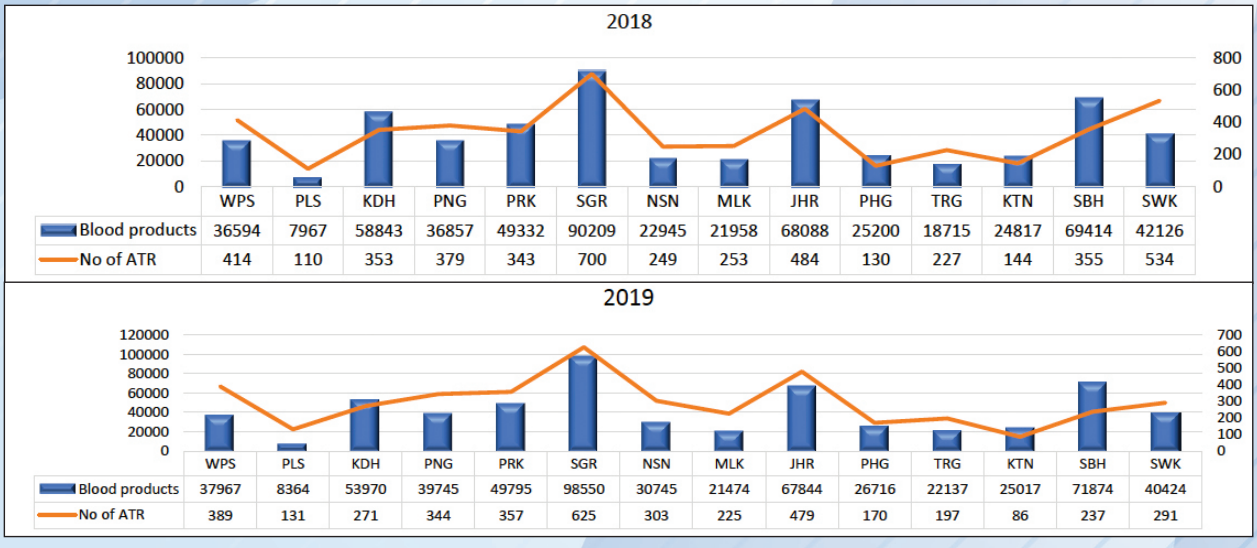


	WP	SGR	PVT	SBH	SWK	IPK	PHG	NSN	MLK	KTN	JHR	TRG	PNG	PLS	PRK	KDH
2016	339	117	32	118	375	335	196	282	273	105	552	216	333	117	317	377
2017	253	669	75	106	362	419	127	260	254	190	546	186	335	134	363	354
2018	368	700	73	265	534	231	130	249	253	144	484	227	379	110	343	353
2019	363	625	69	159	291	190	170	303	225	86	479	197	344	131	357	271

Figure 2.3: Numbers of ATR Reports Received by States

2.4 ATR REPORTED BY STATES IN RELATION TO BLOOD COMPONENT TRANSFUSED – Figure 2.4

NHCC received 75.2 ATR reports per 10,000 blood components transfused for 2018-2019. In general, the usage of blood components increased in 2019 compared to 2018.



	WPS	PLS	KDH	PNG	PRK	SGR	NSN	MLK	JHR	PHG	TRG	KTN	SBH	SWK
Blood products	36594	7967	58843	36857	49332	90209	22945	21958	68088	25200	18715	24817	69414	42126
No of ATR	414	110	353	379	343	700	249	253	484	130	227	144	355	534

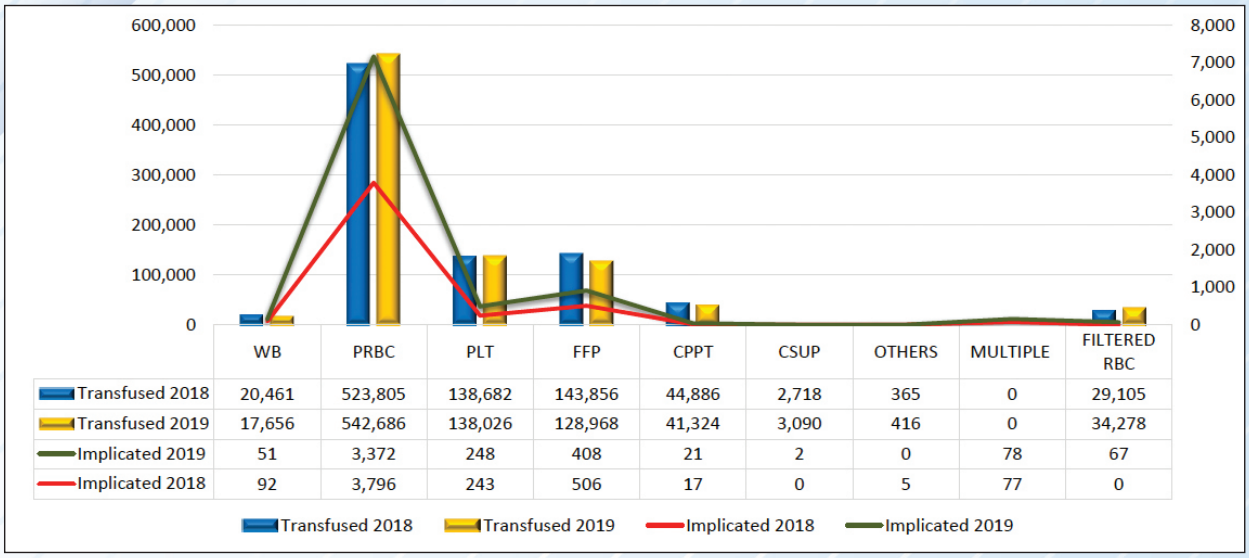
	WPS	PLS	KDH	PNG	PRK	SGR	NSN	MLK	JHR	PHG	TRG	KTN	SBH	SWK
Blood products	37967	8364	53970	39745	49795	98550	30745	21474	67844	26716	22137	25017	71874	40424
No of ATR	389	131	271	344	357	625	303	225	479	170	197	86	237	291

**1. This data only includes government hospital blood banks 2. WPS: WPS and Institut Kanser Negara 3. Sabah: Sabah and Hospital Wanita dan Kanak-Kanak, Likas*

Figure 2.4: Number of Blood Products Utilized and Number of Reported ATR

2.5 TYPE OF BLOOD COMPONENT TRANSFUSED AND ATR COMPLICATION – Figure 2.5

The frequency of the blood components implicated in ATR were relatively corresponds to the total number blood component 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. Since 2019, NHCC has separated the data analysis of ATR on filtered RBCs from PRBC. Therefore in 2019 there were 67 reported cases of ATR in patients transfused with filtered RBC.



	WB	PRBC	PLT	FFP	CPPT	CSUP	OTHERS	MULTIPLE	FILTERED RBC
Transfused 2018	20,461	523,805	138,682	143,856	44,886	2,718	365	0	29,105
Transfused 2019	17,656	542,686	138,026	128,968	41,324	3,090	416	0	34,278
Implicated 2019	51	3,372	248	408	21	2	0	78	67
Implicated 2018	92	3,796	243	506	17	0	5	77	0

Figure 2.5: Total Number of Blood Component Transfused and Implicated with ATR

2.6 INCIDENCE OF IMPLICATED BLOOD COMPONENTS IN 10,000 BLOOD COMPONENTS TRANSFUSED – Figure 2.6

The overall incidence of ATR in Malaysia was 50 per 10,000 blood components transfused. PRBC was the most implicated blood component with the ATR incidence of 67 per 10,000 PRBC transfused while cryosupernatant was the least with 3 incidences per 10,000 transfused. In 2019, filtered RBC showed the incidence of 20 per 10,000 filtered RBC transfused. FFP has almost 2 times higher incidence causing ATR compared to platelet.

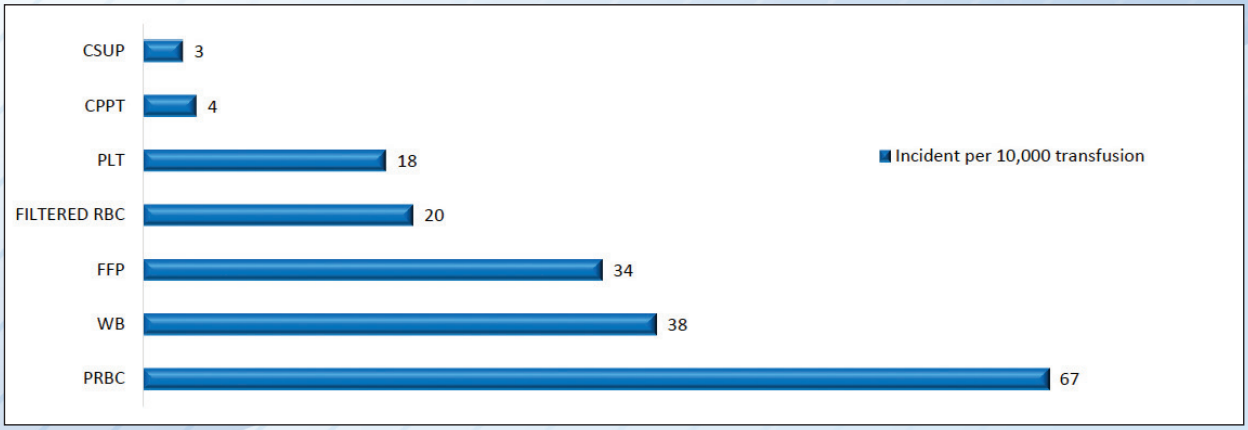
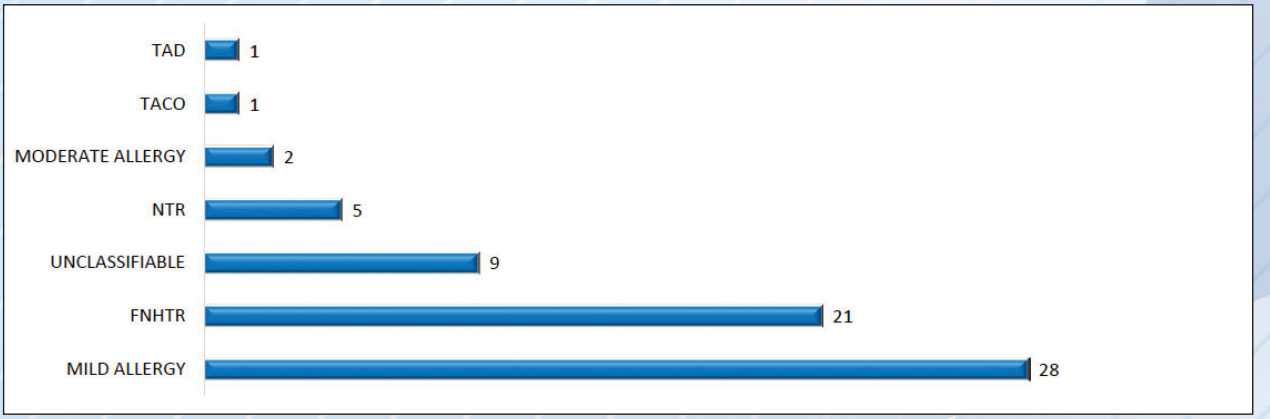


Figure 2.6: Incidence of ATR per 10,000 Blood Components Transfused

2.7 PERCENTAGE OF TYPES OF ADVERSE EVENTS ASSOCIATED WITH FILTERED RED BLOOD CELL (RBC) – Figure 2.7

Leukocyte 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 mainly for thalassemia patients. The pre-storage filtration within 48 hours of collection which remove the leukocytes content to < 1x 106 should be practiced. However, our report showed that mild allergic reaction and febrile non haemolytic transfusion reaction which accounts for 42% and 31% respectively were the most common reported ATR associated with filtered RBC transfusion. Thus, the mechanism of filtration should be reevaluated to make sure that it adheres to the quality requirement needed for the filtration process.



NTR= Not Transfusion Related

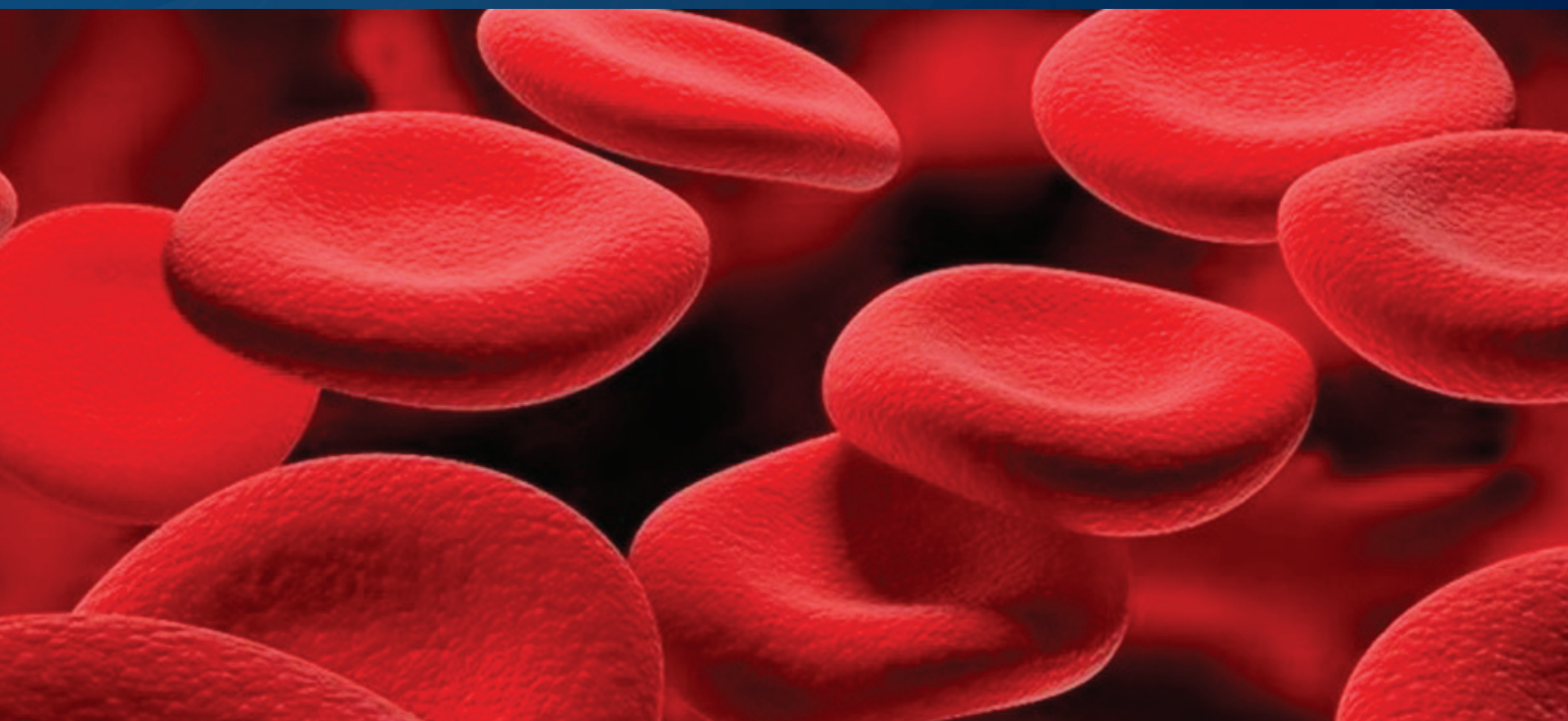
Figure 2.7: Types of ATR associated with Filtered Red Blood Cell

HAEMOVIGILANCE REPORT 2018-2019

NATIONAL TRANSFUSION MEDICINE SERVICE IN MALAYSIA

CHAPTER 3

ERROR REPORTS



3.1 DEFINITION OF ERRORS

According to World Health Organisation (WHO) Conceptual Framework for the International Classification for Patient Safety (ICPS), error is defined as an unintentional deviation from standard operating procedures or practice guidelines that may or may not cause harm to patients.

In Malaysia haemovigilance setting, errors are categorized as incorrect blood component transfused (IBCT) and near misses (NM). Malaysia 4th edition Transfusion Practice Guideline stated that an IBCT arises where a patient is transfused with blood/blood components that does not meet the appropriate requirements or which is intended for another patient, whereas a near miss event refers to an error which 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.

It is important to recognise a near miss as an alarming event that needs action to prevent actual error from happening. Hence, in this report near miss is analysed together with the actual errors.

3.2 INCIDENCE OF ERRORS REPORTED BY HOSPITAL BLOOD BANKS UNDER MINISTRY OF HEALTH

Total number of blood component transfused for hospital blood banks under MOH for 2018 and 2019 were 573,065 and 594,622 respectively. The incidence of IBCT in relation to the number of blood component transfused were less than 0.01% for both years. Meanwhile, the incidence of NM in relation to the number of blood component transfused were 0.04% in 2018 and 0.03% in 2019.

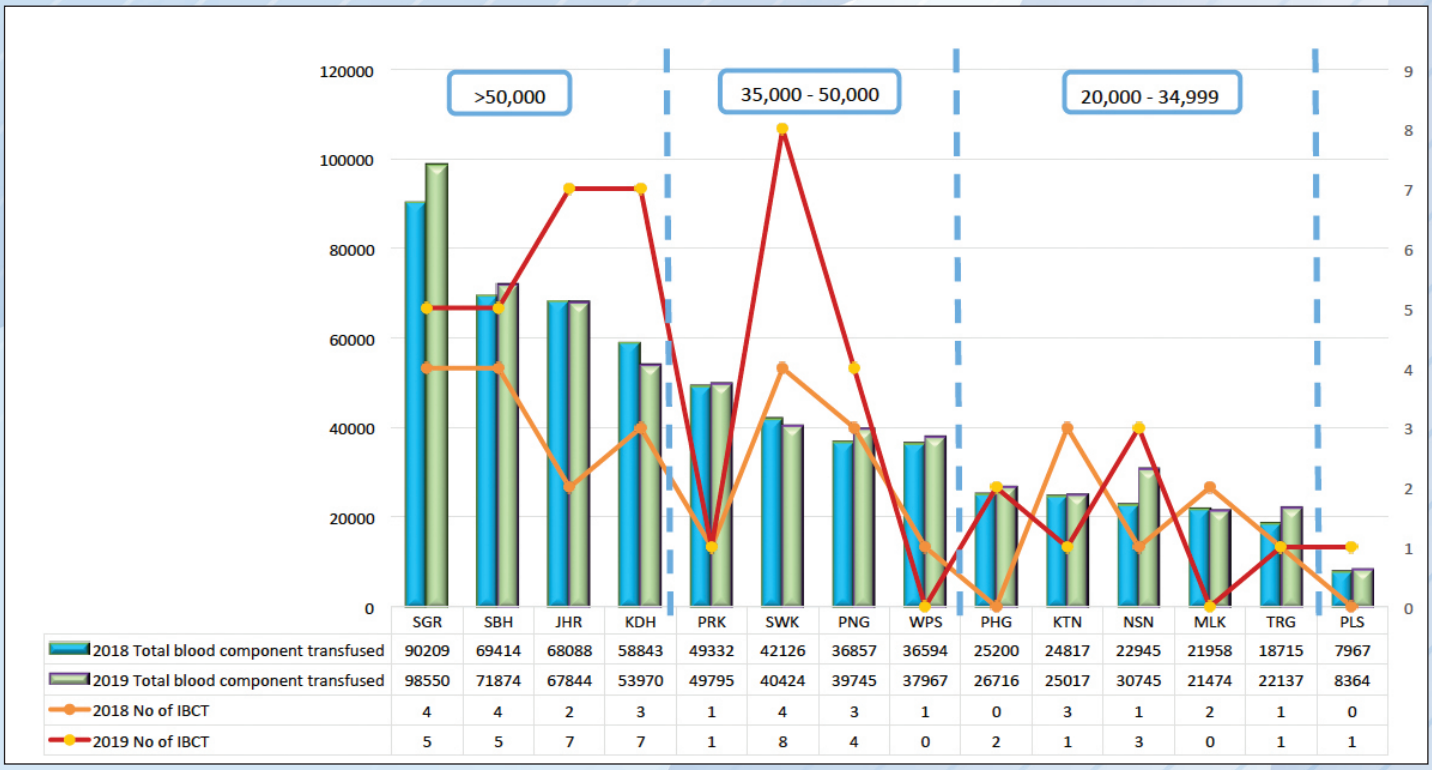
3.2.1 INCIDENCE OF IBCT REPORTED BY HOSPITAL BLOOD BANKS UNDER MINISTRY OF HEALTH – Figure 3.2.1

There were four states with more than 50,000 blood component transfused. These states include Selangor, Sabah, Johor and Kedah. In 2018, Selangor and Sabah reported 4 IBCT each while Johor and Kedah only 2 and 3 IBCT respectively. However, in 2019, both Johor and Kedah showed increment on IBCT with 7 cases each while Selangor and Sabah reported 4 cases each.

There were four states with number of blood component transfused between 50,000 to less than 35,000. These states were Perak, Sarawak, Pulau Pinang and Wilayah Persekutuan including WPS Labuan. For this category, Sarawak showed the highest number on IBCTs both in 2018 and 2019 with 4 and 8 cases respectively followed by Pulau Pinang with 3 and 4 cases respectively. Perak reported 1 IBCT each year while WPS Labuan had 1 IBCT in 2018.

There were five states with number of blood component transfused between 35,000 to less than 15,000. These states include Pahang, Kelantan, Negeri Sembilan, Melaka and Terengganu. IBCT reported in both years from Kelantan with 3 cases in 2018 and 1 case in 2019, likewise for Negeri Sembilan with 1 case in 2018 and 3 cases in 2019. Melaka reported 2 cases in 2018 and none in 2019, whereas Pahang had no IBCT in 2018 but 2 cases in 2019. Other than that, Terengganu reported only 1 case in each year.

Perlis is the only state with the least number of blood component transfused of less than 15,000. However, there was still an IBCT reported in 2019 from this state.



	SGR	SBH	JHR	KDH	PRK	SWK	PNG	WPS	PHG	KTN	NSN	MLK	TRG	PLS
2018 Total blood component transfused	90209	69414	68088	58843	49332	42126	36857	36594	25200	24817	22945	21958	18715	7967
2019 Total blood component transfused	98550	71874	67844	53970	49795	40424	39745	37967	26716	25017	30745	21474	22137	8364
2018 No of IBCT	4	4	2	3	1	4	3	1	0	3	1	2	1	0
2019 No of IBCT	5	5	7	7	1	8	4	0	2	1	3	0	1	1

Figure 3.2.1: Incidence of IBCT and Number of Blood Component Transfused by State, 2018 and 2019

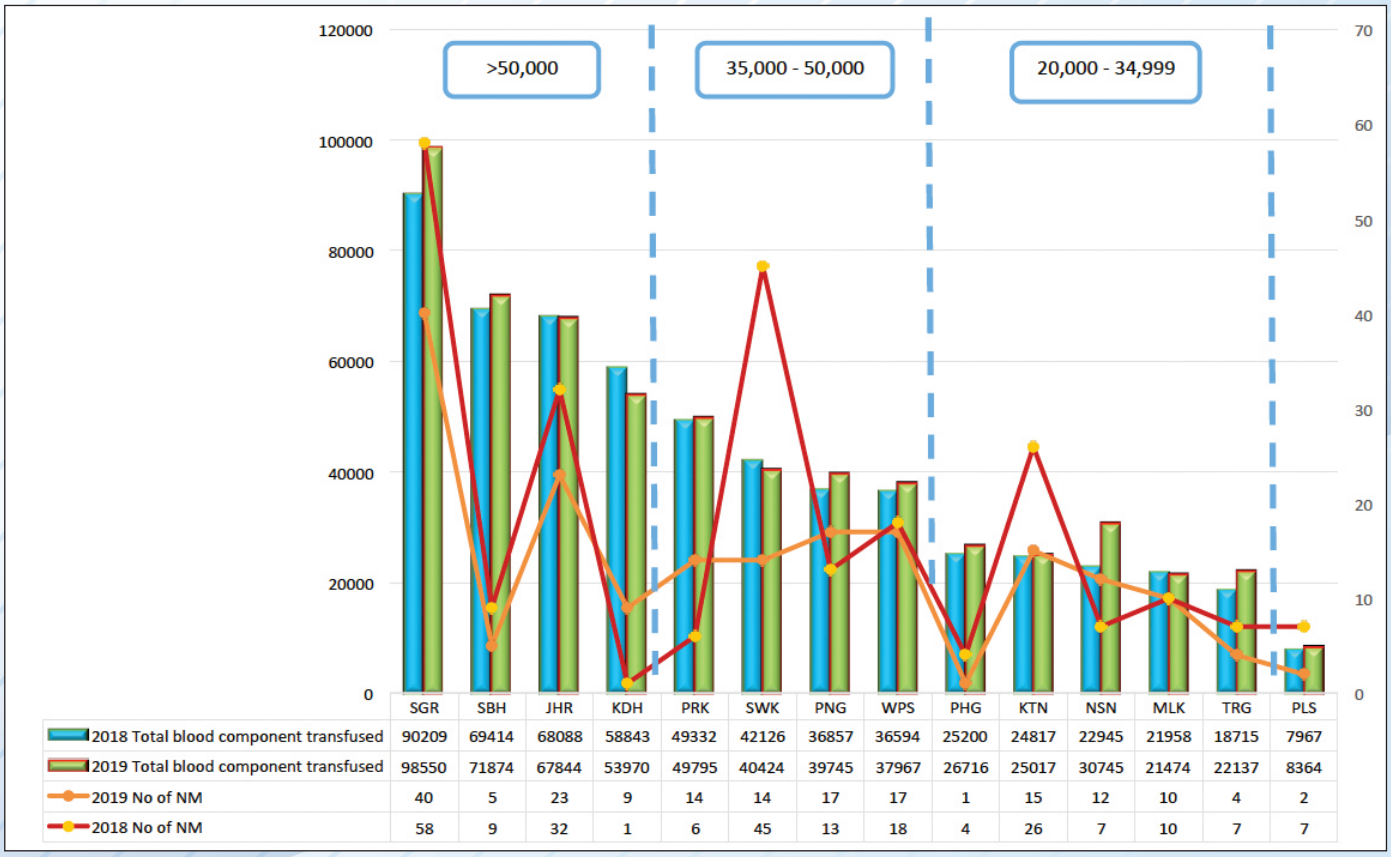
3.2.2 INCIDENCE OF NM REPORTED BY HOSPITAL BLOOD BANKS UNDER MINISTRY OF HEALTH – Figure 3.2.2

For category with more than 50,000 blood component transfused, Selangor has the highest number of NM reported of 58 cases in 2018 and 40 cases in 2019, followed by Johor with 32 cases and 23 cases respectively. Sabah reported 9 NM in 2018 and 5 NM in 2019 while Kedah reported only 1 case in 2018. All states showed reduction on NM event in 2019 except for Kedah which increased to 9 cases.

The four states with number of blood component transfused between 50,000 to less than 35,000 showed Sarawak had the most NM reported in 2018 with 45 cases followed by WPS with 18 cases, Pulau Pinang of 13 cases and Perak had the least report on NM of 6 cases. However, in 2019, both WPS and Sarawak had decrement in number of NM reported with 17 and 13 cases respectively while NM in Penang and Perak had increased to 17 and 14 cases respectively.

Next in line for discussion are the states with number of blood component transfused between 35,000 to less than 15,000. These states include Pahang, Kelantan, Negeri Sembilan, Melaka and Terengganu. NM event in Pahang, Kelantan and Terengganu showed reduction in number of cases in 2019 compared to the previous year. In 2018, Pahang initially had 4 NM but went down to only 1 case in 2019, Kelantan had 26 NM dropped to 15 cases while Terengganu had 7 NM decreased to 4 cases in 2019. Melaka kept at 10 NM for both years while Negeri Sembilan almost doubled the case from 7 in 2018 to 12 in 2019.

Finally for Perlis who only had less than 15,000 blood components transfused, there were 7 NM reported in 2018 and 2 NM reported in 2019.

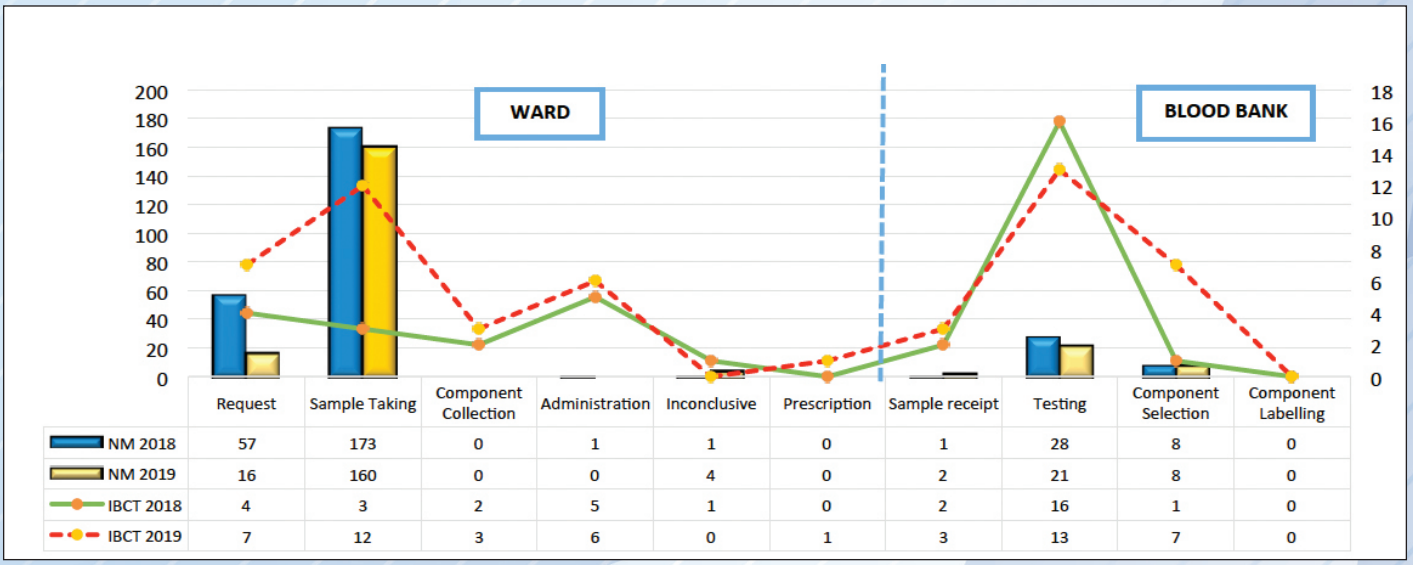


	SGR	SBH	JHR	KDH	PRK	SWK	PNG	WPS	PHG	KTN	NSN	MLK	TRG	PLS
2018 Total blood component transfused	90209	69414	68088	58843	49332	42126	36857	36594	25200	24817	22945	21958	18715	7967
2019 Total blood component transfused	98550	71874	67844	53970	49795	40424	39745	37967	26716	25017	30745	21474	22137	8364
2019 No of NM	40	5	23	9	14	14	17	17	1	15	12	10	4	2
2018 No of NM	58	9	32	1	6	45	13	18	4	26	7	10	7	7

Figure 3.2.2: Incidence of NM and Number of Blood Component Transfused by State, 2018 and 2019

3.3 INCIDENCE OF ERROR – Figure 3.3

NHCC received a total of 269 cases of NM and 34 cases of IBCT in 2018 where 247 of events occurred in the ward and another 56 events occurred in the blood bank. In 2019, NHCC received a total of 211 cases of NM and 52 cases of IBCT where 208 of events occurred in the ward and another 55 events occurred in the blood bank. Error during sample taking which led to either wrong blood in tube or wrong name on tube were found to have the highest level of occurrence in the ward with 71.3% in 2018 and 82.7% in 2019. While in blood bank, error during pre-transfusion testing was most commonly occurred with 78.6% in 2018 and 61.8% reports in 2019. The detail of the error in the transfusion process was shown in figure 3.3. NHCC also received 2 inconclusive reports in 2018 and 6 inconclusive reports in 2019. In these cases, further investigations were halt as patients deceased or discharged home. However, these inconclusive cases were most likely an error during sample taking as depicted in the report.



	Request	Sample Taking	Component Collection	Administration	Inconclusive	Prescription	Sample receipt	Testing	Component Selection	Component Labelling
NM 2018	57	173	0	1	1	0	1	28	8	0
NM 2019	16	160	0	0	4	0	2	21	8	0
IBCT 2018	4	3	2	5	1	0	2	16	1	0
IBCT 2019	7	12	3	6	0	1	3	13	7	0

Figure 3.3: Critical Control Point in the Transfusion Process Where IBCT/ NM Occurred in 2018 – 2019

3.4 WARD AND BLOOD BANK ERROR – Figure 3.4a and 3.4b

There were 303 cases of transfusion error (TE) reported in 2018 and reduce to 263 in 2019. In 2018 there were 93.9% of errors originated from ward and 86.5% in 2019 were able to be detected by the blood bank due to availability of patient's historical record in the blood bank information system, while 66.1% of blood banks errors in 2018 and 56.4% in 2019 managed to be detected before administration of the blood to the patients.

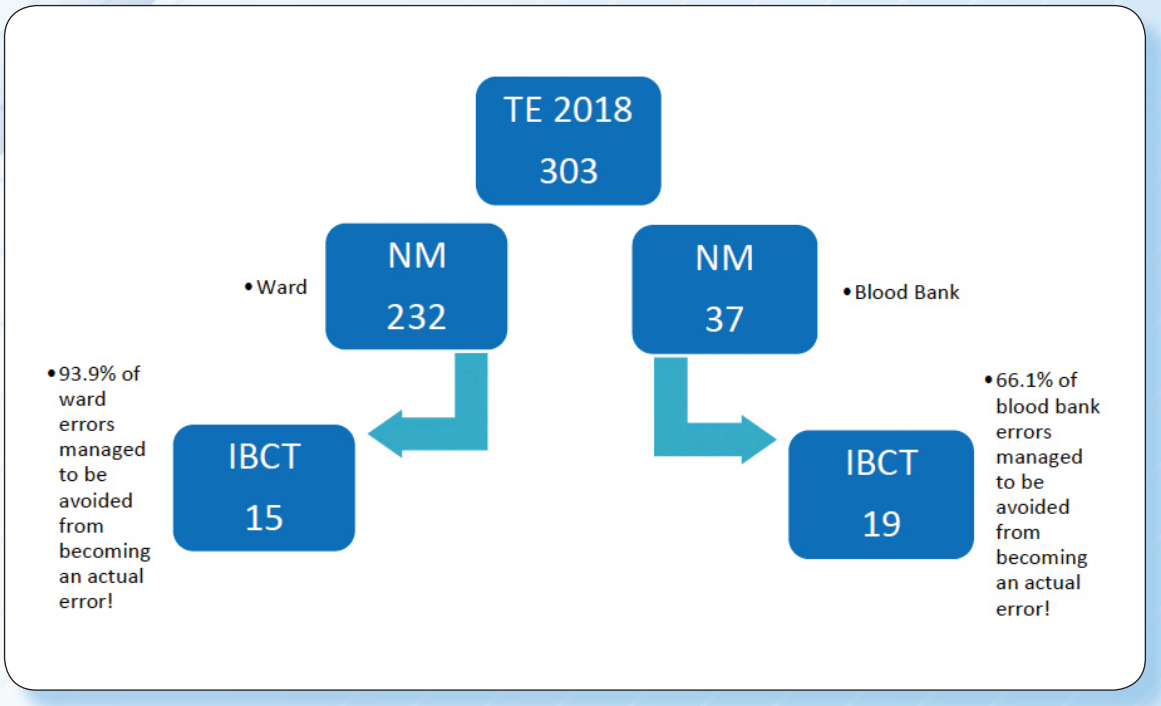


Figure 3.4a: Ward and Blood Bank Error 2018

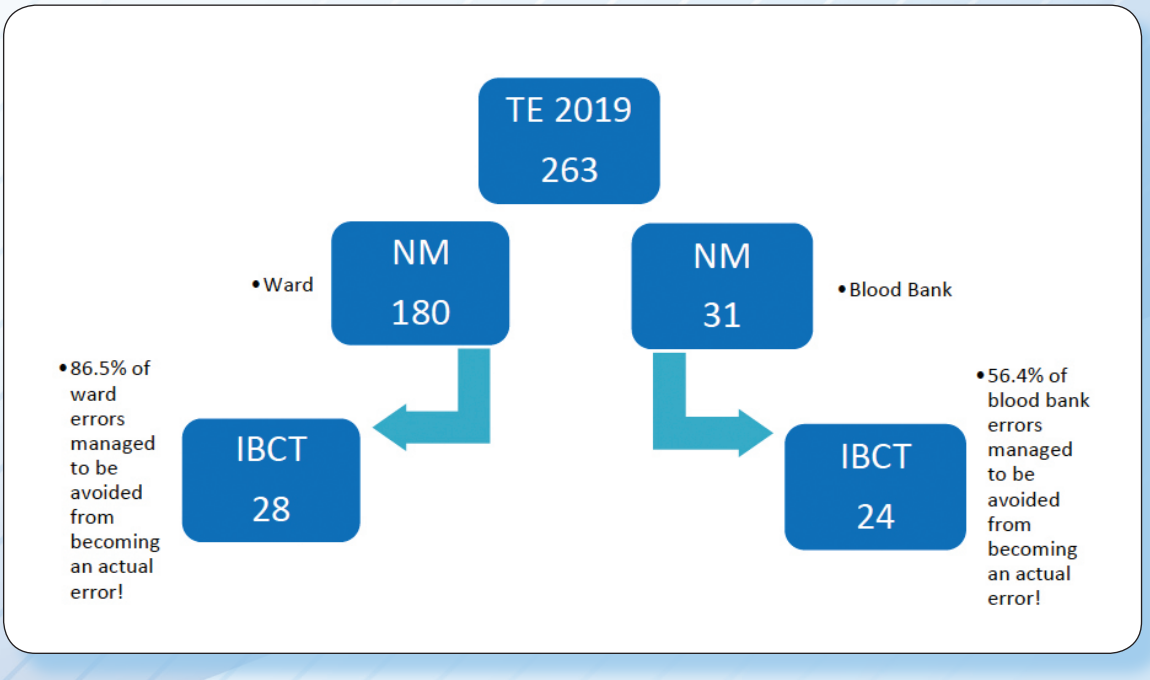


Figure 3.4b: Ward and Blood Bank Error 2019

3.5 CRITICAL CONTROL POINT (CCP) – Figure 3.5

According to National Health Service Blood and Transplant (NHSBT UK), critical control point is a step in a process which, if it went wrong would lead to an adverse or undesired event. It is critical to ensure all the critical steps in the transfusion process do not go wrong in order to prevent an adverse event.

This edition of NHCC 2018 – 2019 biannual report has adopted SHOT report which highlighted the nine critical steps where errors can occur anywhere in the transfusion chain. This report provides an opportunity to identify the system weaknesses, to address and to improve pre-existing Standard operating procedure.

All the errors that occurred during the process of blood transfusion starting from sample request until the administration of blood component to the patient were categorized and analysed. SOP during these steps can be over sighted and lead to NM or IBCT.

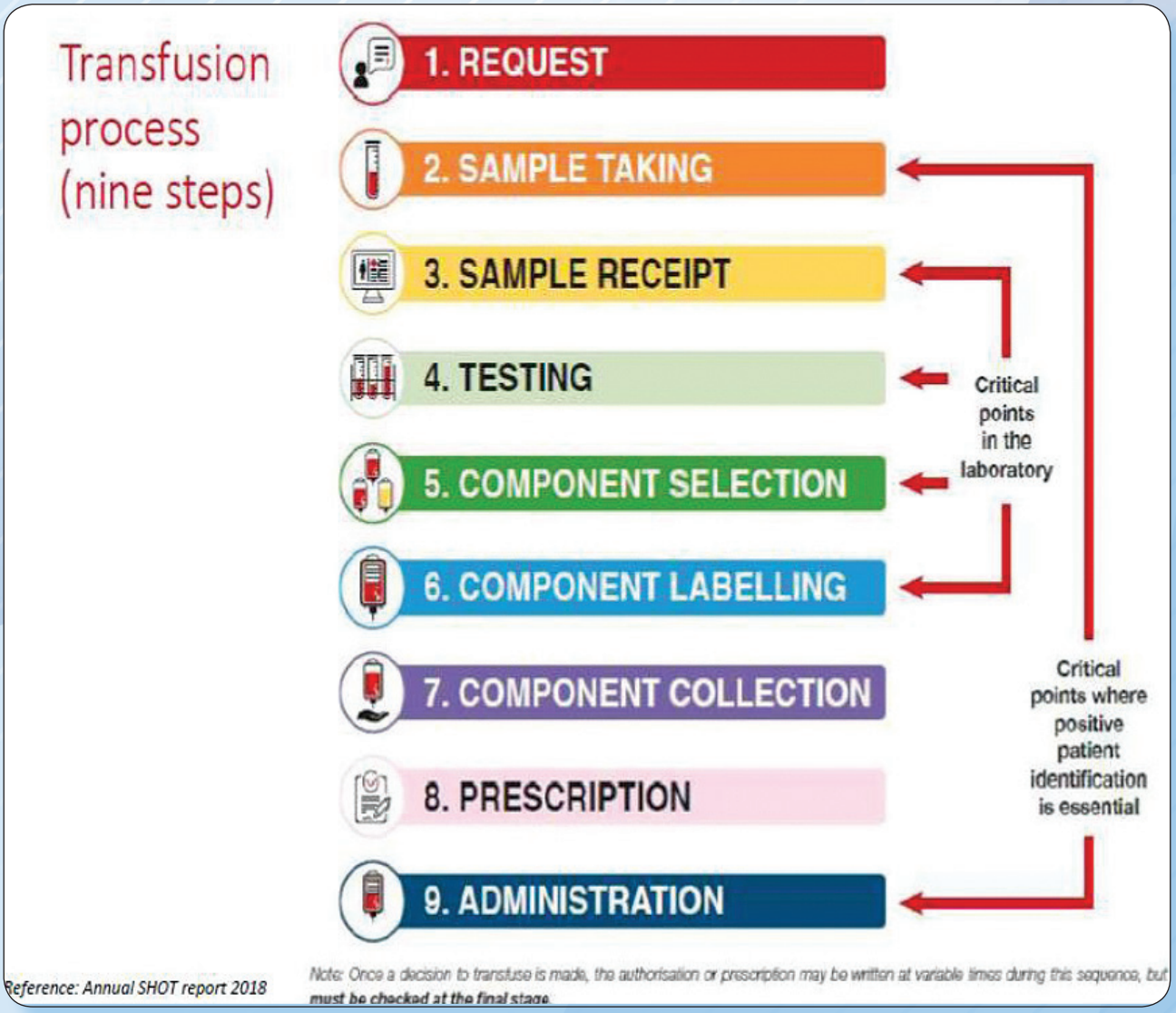


Figure 3.5: Critical Control Point in Transfusion Process

3.5.1 REQUEST – Table 3.5.1

Request for blood transfusion is the first critical control point in the nine steps of the transfusion process following the decision to transfuse. The request for the selection and release of components mandatorily must include patient core identifiers and type of blood component required for transfusion.

NHCC received a total of 61 errors in 2018 and reduced to 23 in 2019 related to this critical step. Out of these, 57 NM and 4 IBCT were reported in 2018 where 90.2% of the errors involved incorrect patient information. This was either due to patient's name was wrongly spelt, wrong ID number was copied or wrong blood group was written in the GSH form causing discrepancy. On the other hand, 9.8% reported wrong blood component request due to lack of knowledge and awareness of specific requirements which the error only can be detected after issuing of blood product.

In 2019, there were 16 NM and 7 IBCT reports received with 82.6% were due to incorrect patient information while 7.4% were due to lack of knowledge and awareness of specific requirements. The chances of near miss during request to be an actual error markedly increased from 7.0% in 2018 to 43.8% in 2019. From the root cause analysis (RCA) report, main contributing factors that lead to IBCT were team factor in which written communication was an issue other than individual staff factor who practiced unsafe behaviour such as assuming and not asking clarification. Monitoring and supervision from superiors are essential to make sure houseman in training does not take shortcuts and is able to seek help when in doubt.

STEPS 1 : REQUEST ERRORS	NM 2018	IBCT 2018	NM 2019	IBCT 2019
	57	4	16	7
1a) Request (incorrect transcription/ patient information)	52	3	15	4
1b) Lack of knowledge and awareness of specific requirements	5	1	1	3

Table 3.5.1: Request Error

3.5.2 SAMPLING/LABELLING – Table 3.5.2

Taking a blood sample for pre-transfusion testing is one of two critical positive patient identification steps in the transfusion process besides during the administration of blood. Collection of the blood sample from the patient and subsequent completion of details on the sample must be performed as one continuous, uninterrupted procedure, involving one patient and one trained, competent and authorised member of staff.

The minimum sample tube information requirements are patient core identifiers (name, ID number, and hospital registration number), date and time sample taken and identification of member of staff taking the sample. Sample tubes must be immediately labelled at the patient's bedside by the individual who took the sample.

Sampling/labelling error has potential for catastrophic harm and may be further categorised as Wrong Blood in Tube (WBIT) of which the sample may have been taken

from the wrong patient and labelled as the intended recipient, or Wrong Name on Tube (WNOT) when the sample taken from the intended recipient and labelled with another patient's information. These errors were mostly detected in blood bank during pre-transfusion testing procedure. The difference of the patient's blood group in current sampling with patient's historical record in blood bank information system will elicit an investigation to determine the root cause of the ABO discrepancy.

NHCC received 173 NM events and 3 IBCT in 2018 and 160 NM events and 12 IBCT in 2019. Almost half of the errors here related to this step were due to failure to conduct a positive patient identification during the blood taking. On the other hand, 27.3% in 2018 and 19.8% in 2019 were due to multiple personnel involved during sample taking ("gotong-royong"). Another significant fact that predisposes to error is when the personnel pre-labelled the sample elsewhere and/or not doing the procedure continuously which accounted 25% reports in 2018 and 30.8% reports in 2019.

Other infrequent cause of WBIT was due to wrong patient blood group as the patient's sample was withdrawn from the same vein that was used to transfuse safe O (Group O RhD Positive). Although sampling/labelling error was the most common error done at the clinical site, this error can lead to IBCT if the patient has no prior transfusion record with the blood bank.

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

- Work/ Environmental factor:
  Cluttered, noisy and busy surrounding, heavy workload, inadequate break
- Individual staff factor:
  Lack of knowledge/ experience/ skill, fatigue/stress
- Team factor:
  Lack of supervision/ monitoring

Staffing challenges are noted as main contributor in many events reported to NHCC. Staffing levels must be appropriate in all areas involved in transfusion. Inadequate staffing, lack of training and poor supervision is associated with an increased risk of errors and putting patient safety at risk.

STEPS 2 : SAMPLE / LABELLING ERRORS	NM 2018	IBCT 2018	NM 2019	IBCT 2019
	173	3	160	12
2a) Positive patient identification was not performed	83	0	76	6
2b) More than one person involved in blood sampling/labelling (Sample not labelled by person taking the blood)	45	3	32	2
2c) Pre-labelled sample /form. Sample not labelled at bedside	44	0	50	3
2d) Others, to specify: Wrong sampling technique	1	0	2	1

Table 3.5.2: Sampling/Labelling Error

3.5.3 RECEIPT AND REGISTRATION – Table 3.5.3

Correct sample receipt and registration at the blood bank is essential to ensure that the right investigation performed for the right patient on the right sample at the right time. Information on the request form and the label of the sample must tally. Error which happens during this step is totally dependent on the patient's transfusion history to be detected.

There was 1 case of near miss in 2018 and 2 in 2019 involving MLT who accidentally switch patient's sample during labelling with the laboratory barcode number at the blood bank receiving counter. Unfortunately, there were 2 IBCT each in 2018 and in 2019 resulted by this type of error as those patients have no prior transfusion record with the blood bank. The other IBCT case in 2019 was a Thalassemia patient who was given a wrong phenotype blood as the historical information of the patient was not heeded and missed.

STEPS 3 : SAMPLE RECEIPTS & REGISTRATION ERROR	NM 2018	IBCT 2018	NM 2019	IBCT 2019
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.	1	2	2	3

Table 3.5.3: Receipt and Registration Error

3.5.4 TESTING – Table 3.5.4

Correct pre-transfusion testing procedure is required to ensure the safe provision of blood components for transfusion and should be in full compliance with local and national guidelines. This is vital in order to get an accurate result for interpretation of patient's blood group, antibody screening and antibody identification test. The process should not be interrupted until the MLT has finally transcribed the findings in the blood bank information system.

Previously blood bank error was classified as technical, transcription and issuing error. However, 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:

- wrong procedure performed,
- procedure or steps performed incorrectly or omitted,
- clinically significant antibody not excluded/identified,
- antibody identification not performed following positive antibody screen and
- blood components issued to patient before a second MLT verified the blood grouping

Interpretation error occurs when the entire procedure was done correctly but the result of either ABO grouping, RhD 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 an inappropriate use of electronic crossmatch or IT system failure.

In 2018 there were 28 NM reports of blood bank errors in which 28.6% of procedural error, 14.3% of errors on interpretation, 57.1% of errors during transcription and none on technical. In 2019, the total number of NM reported were 21 with 28.6% of errors on interpretation, 61.9% on transcription error and 9.5% was technical error where 2 ABO discrepancies reported due to error during data migration to blood bank information system version 2 (BBISv2).

Pre-transfusion testing error was the most common cause of error that lead to IBCT although the incidence of near miss for this type of error was low compared to sampling/labelling error as shown in figure 3.3. Procedural error was the main cause of IBCT for both years under testing with 9 cases in 2018 and 5 in 2019. This was mainly because MLT either performed test on multiple samples at one time and inadvertently switched samples or wrongly read another patient's results. In some instances, regrouping was only done after the blood has been released and, in some case, there was no second verifier to confirm the blood grouping. Furthermore, there were a total of 7 reports on interpretation error for two years in blood banks with 2 occurred in 2018 and 5 in 2019. There were 5 transcription errors in 2018 compared to 3 in 2019 and no technical error reported for both years that lead to IBCT.

STEPS 4 : TESTING ERROR	NM 2018	IBCT 2018	NM 2019	IBCT 2019
	28	16	21	13
4a) Procedural error (e.g.: Pre-transfusion testing procedure or steps performed incorrectly or omitted, etc.).	8	9	0	5
4b) Interpretation error (e.g.: wrong interpretation of blood group/Rh/ antibody/barcode)	4	2	6	5
4c) Transcription error (e.g.: wrong transcription of blood group/Rh/ antibody/barcode)	16	5	13	3
4d) Technical error (e.g.: BBISV2 error/ inappropriate use of electronic issues, etc.)	0	0	2	0

Table 3.5.4: Testing Error

3.5.5 COMPONENT SELECTION – Table 3.5.5

This step ensures that the correct components together with the specific requirements were selected to comply with the patien's requirements and the clinical request. There were 8 NM reported in each 2018 and 2019 involving component selection. For both years, 7 of the MLTs had chosen the wrong blood group or component or even issued blood meant for another patient whereas there was one case in both years where MLT had issued an expired blood product to the patients. Thus, efficient management of the blood stock inventory with concept of first expiry, first out (FEFO) is important to adhere to prevent expired blood from being transfused.

Total of 8 cases of IBCTs were reported for these two years with 1 case in 2018 and 7 cases in 2019. In 2018, it was due to wrong blood component issued (platelet instead of FFP). In 2019, 3 cases were due to wrong component selected, 3 wrong blood groups (2 ABO compatible and 1 ABO incompatible) and 1 case of incorrect phenotype.

STEPS 5 : COMPONENT SELECTION ERROR	NM 2018	IBCT 2018	NM 2019	IBCT 2019
	8	1	8	7
5a) Wrong blood group/ Component / Specific requirement requested not selected / wrong blood issued to patient/ unscreened blood	7	1	7	7
5b) Expired blood component issued	1	0	1	0

Table 3.5.5: Component Selection Error

3.5.6 COMPONENT LABELLING, AVAILABILITY AND HANDLING AND STORAGE

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. Fortunately, there were no cases of near miss nor IBCT reported involving this step for the past two years.

3.5.7 COMPONENT COLLECTION – Table 3.5.7

Correct procedure will ensure that the correct component is collected and that it fulfills the clinical request and meets the details on the collection slip. Laboratory staffs are responsible for directly handing over components to a nurse/porter at the centre and they need to ensure that all components meet the requirements of the clinical request and the collection slip.

While there was no case of near miss reported for this type of error in 2018 – 2019, a total of 5 cases of IBCT occurred. Both errors in 2018 were due to failure to check patient's core identifiers and details of the blood component against the details on the laboratory-generated label attached to the blood bag. One of the cases happened due to the staff nurse wrongly took blood belonged to another patient instead of safe O for the intended patient as both were group O in ED. For the second case, the MO wrongly took blood belonged to another patient to be transfused to the intended patient as both were group O positive in OT. There was 1 case in 2019, where the MO failed to check the blood against 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.

STEPS 7 : COMPONENT COLLECTION ERROR	NM 2018	IBCT 2018	NM 2019	IBCT 2019
	0	2	0	3
7a) Blood component not collected or received by trained, competent and authorised members of staff.	0	0	0	2
7b) Failure to check 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	2	0	1

Table 3.5.7: Component Collection Error

3.5.8 PRESCRIPTION – Table 3.5.8

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, date of transfusion, the volume number of units, the rate of transfusion, any other clinical requirements or instructions required and must be signed by the authoriser.

There was one reported case for the entire two years involving IBCT. This was a case in 2019 where 4 units of FFP were prescribed instead of 4 units of platelet that were intended to transfuse. Neither the doctor nor the staff nurse notices the error prior to transfusion.

STEP 8 : PRESCRIPTION ERROR	NM 2018	IBCT 2018	NM 2019	IBCT 2019
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	0	0	1

Table 3.5.8: Prescription Error

3.5.9 ADMINISTRATION – Table 3.5.9

Administration is the final opportunity to prevent patients receiving the incorrect component or missing their specific requirements due to errors earlier in the transfusion process. It is essential that the final administration check is conducted by trained, competent and authorised, registered regulated health care personnel. This final administration check must be performed next to the patient. The donation barcode number, blood group and expiry date on the component pack label must match the laboratory-generated label attached to the component and the component blood group must be appropriate for the patient. Furthermore, any additional clinical requirements have been met e.g. irradiated or leukodepleted before transfusion.

There was one isolated case of NM in 2018 where the administration of the wrong blood just started and the transfusion promptly stopped right before the blood entered the patient's vein. Meanwhile, a sum of 11 IBCT cases reported with 5 in 2018 and 6 in 2019. In 2018, there was a case where requirements were not met in which volume of cryosupernatant transfused was not according to the prescription while the other was miscommunication between MLT and HO resulted in requirement for the blood component to be transfused was not met. There was a total of 8 IBCT of administration error resulted in patient positive identification was not done as the pre-transfusion administration was not done at the bedside while 1 case was due to wrong blood transfused as the patient's core identifiers was not checked with the blood component labels.

STEPS 9 : ADMINISTRATION ERROR	NM 2018	IBCT 2018	NM 2019	IBCT 2019
	1	5	0	6
9a) Final administration check not done at bedside must be performed next to the patient)	0	3	0	5
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	1	1	0	0
9c) Others (requirement not met)	0	1	0	1

Table 3.5.9: Administration Error

3.5.10 MISCELLANEOUS – Table 3.5.10

In the occasion where primary error was not associated with the nine steps of the transfusion process, the event would be categorized as miscellaneous.

There was one case of NM in 2018 categorised as miscellaneous. This was a case where the MLT noted discrepancy between patient's historical record which was O RhD positive and current blood group which is B RhD positive. Upon investigation the discrepancy derived was a result of the patient had undergone a bone marrow transplant in 2017 in another hospital. Thus, the discrepancy was not due to any error in the work process.

MISCELLANEOUS	NM 2018	IBCT 2018	NM 2019	IBCT 2019
	1	0	0	0
10a) Miscellaneous	1	0	0	0

Table 3.5.10: Miscellaneous

3.6 INCIDENT – Table 3.6

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

- error was done by other facilities,
- transcription error of patient's blood group in antenatal care (ANC) book or hospital record,
- transcription error done by the hospital registration personnel,
- patient used other person's identification (sharing same ID) during hospital admission,
- Previous error, however the cause of error could not be determined.

Total numbers of reported incidents related to transfusion process were 147 cases in 2018 and decrease to 121 cases in 2019. Under the category of possible wrong blood grouping in Klinik Kesihatan (KK), a subcategory of wrong blood group stated in ANC book is where a wrong blood group was transcribed by Klinik Kesihatan Ibu dan Anak (KKIA) personnel in ANC book.

This error was detected by the reporting hospital blood bank when the wrong blood group was used to request for blood. Other subcategory was a procedural error done by the MLT in KK laboratory. Investigation done by the reporting hospital revealed that the cause of blood grouping error in KK was due to wrong techniques (tile method) or reagent used for ABO blood grouping. Details of type of incident reported are shown in the table below.

INCIDENT	2018	2019
	147	121
a) Possible wrong blood grouping in KK: i) Wrong blood group stated in ANC book	58	27
a) Possible wrong blood grouping in KK: ii) Procedural error by MLT	19	24
b) Previous error	54	52
c) Registration error / share ID	16	18

Table 3.6: Total number of Incident Reported

3.7 LOCATION OF ERROR – Figure 3.7

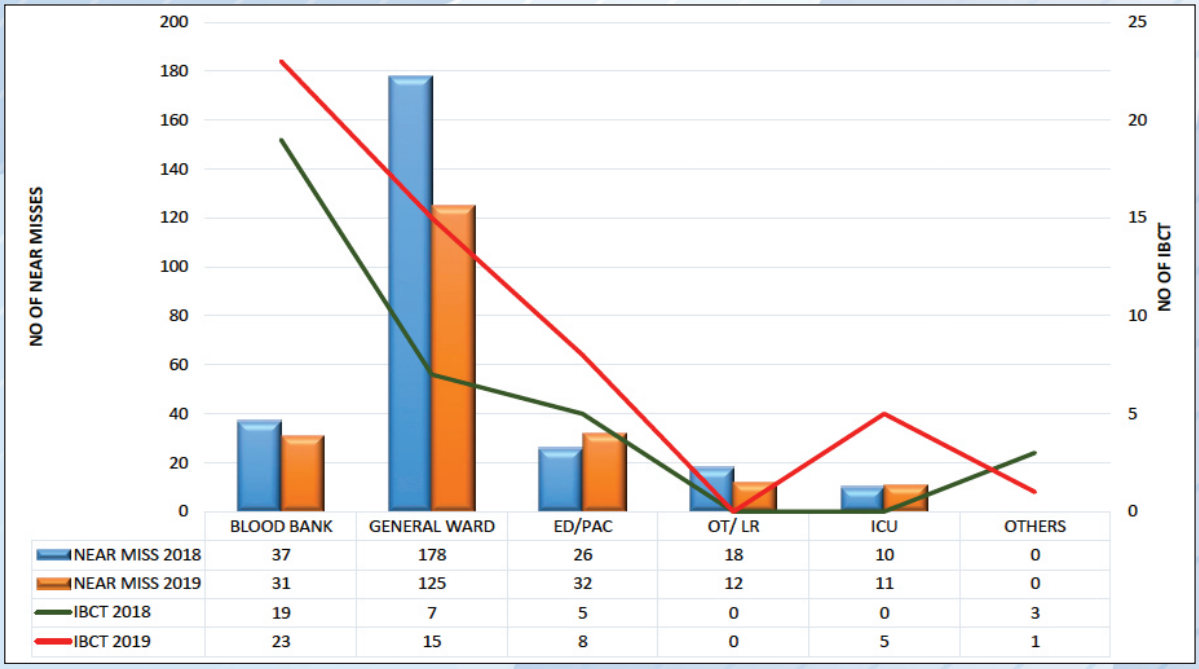
In the blood bank, there were 56 cases in 2018 and 54 cases in 2019. Blood bank errors were the main contributor for IBCT in 2018. However, in 2019, the clinical site reported higher number of IBCT of 29 compared to blood bank of 23 cases.

Locations of error in the ward/clinical setting were divided into 5 main locations according to the nature of the workplace. Most common location was in General Ward with total of 185 errors in 2018 and 140 errors in 2019. Error occurred in Emergency Room (ER) and Obstetrics' Patient Admission Centre (PAC) were summed up together in view of both settings has rapid and high turnovers of patient with almost every patient are warranted for Group, Screen and Hold (GSH) test to standby. There were 26 cases and 32 cases of near misses in ER/PAC in 2018 and 2019 respectively with 5 cases and 8 cases of IBCT in that order.

There were 18 NM in 2018 and 12 in 2019 that occurred in Operation Theatres (OT) and Labour Rooms (LR) and fortunately no IBCT cases reported for the both years. ABO discrepancy between patient's historical record and current sample was successfully detected by the blood bank MLTs.

Although Intensive Care Units (ICU) including Paediatrics and Neonatal ICUs were self-contained areas in a hospital with specially trained staffs and fully equipped to attend patients with life threatening conditions, errors still could occur. Both 2018 and 2019 had logged 10 and 11 NM respectively, and in 2019 there were 5 IBCT that occurred due to unverified component collection and final administration check which was not performed next to the patient.

Other locations such as Haemodialysis Centres and Day-care Centres had not reported any NM events, although there were 3 IBCT cases and 1 IBCT case reported in 2018 and 2019 respectively due to final administration check which was not done at bedside.

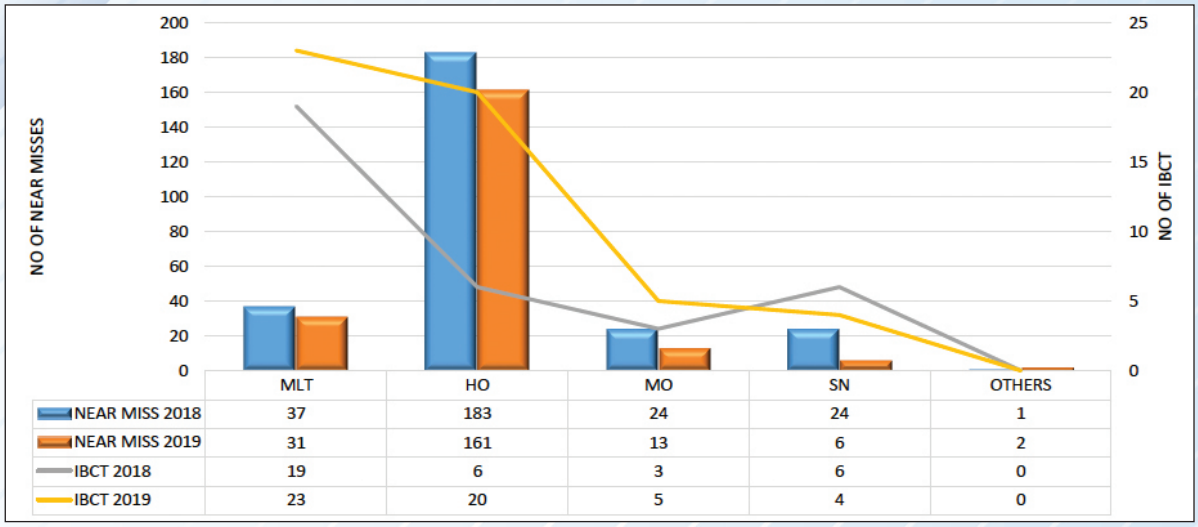


	BLOOD BANK	GENERAL WARD	ED/PAC	OT/ LR	ICU	OTHERS
NEAR MISS 2018	37	178	26	18	10	0
NEAR MISS 2019	31	125	32	12	11	0
IBCT 2018	19	7	5	0	0	3
IBCT 2019	23	15	8	0	5	1

Figure 3.7: Location of Error

3.8 CATEGORY OF STAFF INVOLVED IN ERROR – Figure 3.8

Majority of hospital personnel involved in NM and IBCT for both years were house officers (HO). This was expectable as HOs are still in training and mostly in charge of blood taking in the ward. Many cases claimed that they failed to follow standard operating procedure (SOP) because of high workload and exhaustion. On the contrary, majority IBCT cases are caused by MLT in blood bank with 19 cases in 2018 and 23 case in 2019. Other category of personnel involved in error can be seen in figure 3.8.



	MLT	HO	MO	SN	OTHERS
NEAR MISS 2018	37	183	24	24	1
NEAR MISS 2019	31	161	13	6	2
IBCT 2018	19	6	3	6	0
IBCT 2019	23	20	5	4	0

*** Other personnel in 2018 – medical students from university hospital ** Other personnel in 2019 – IT error*

Figure 3.8: Category of Staff Involved in Error

3.9 OUTCOME OF IBCT AND PROBABLE OUTCOME OF NEAR MISS

NHCC has again adapted SHOT Annual Report 2018 to categorize and analyse the outcome of IBCT and probable outcome of NM.

3.9.1 WRONG COMPONENT TRANSFUSED (WCT) AND SPECIFIC REQUIREMENT NOT MET (SRNM) – Figure 3.9.1a, 3.9.1b and 3.9.1c

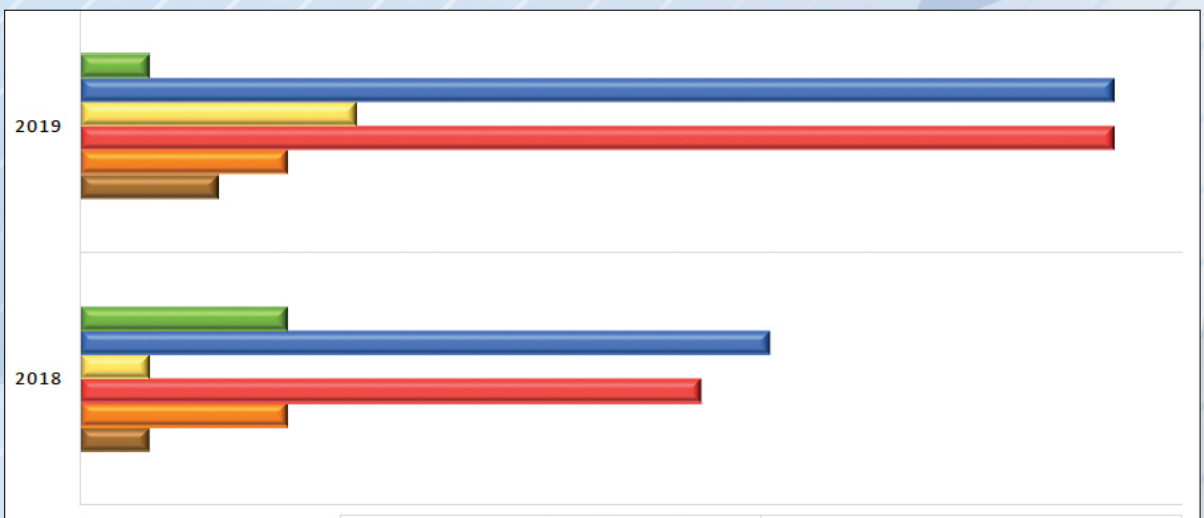
The outcome of IBCT can be divided to Wrong Component Transfused (WCT) and Specific Requirement Not Met (SRNM). A wrong component transfused to recipients could be transfusion of blood component with incorrect blood group, which may be incompatible or compatible to the patient, D-mismatched or it could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

Out of 34 IBCT cases reported in 2018, 23 patients were transfused with wrong blood group/ component and 4 patients were transfused with blood in which specific requirement not met. Thirteen of them were transfused with incompatible blood where 10 patients had developed either allergic or febrile reaction and another 2 patients showed evidence of haemolytic transfusion reaction.

In 2019 there were 35 cases of WCT and 5 SRNM reported, where 22 patients were transfused with incompatible blood. Nonetheless, only 11 of them had mild to moderate allergic reaction and one patient showed evidence of haemolytic transfusion reaction.

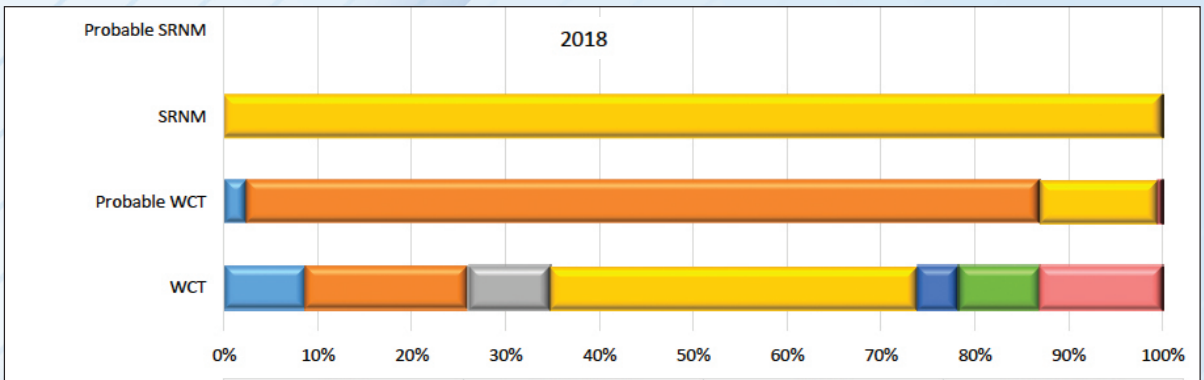
The commonest error that led to WCT and SRNM in both years occurred in blood bank. This potentially occurred if blood bank personnel deviate from the SOP especially during sample testing, an incorrect blood will be transfused to patients as ward personnel fully depend on blood bank to determine the blood group of patients. Thus NHCC urge blood bank to recognize the unavailability of patient's historical blood bank record as the weakest link and introduce strategies such as two independent sample process for ABO blood grouping in the event where patient has no historical blood bank record and sharing of patient transfusion data between hospital blood bank.

Data for both years showed that all near misses led to WCT and none cause SRNM. The main cause of this probable outcome was due to sampling/labelling error in ward which was because there was no positive patient identification performed, pre-labelled samples and more than one person involved in sample taking. In this case, blood bank played an important role to prevent IBCT from occurring by verifying the blood group from the sample with patient's historical record or by requesting second sample if previous record was not available thus any ABO discrepancies were detectable. This concluded on how critical it is for clinical and blood bank staffs to be extremely vigilant and follow SOP to prevent error in each step of the transfusion process.



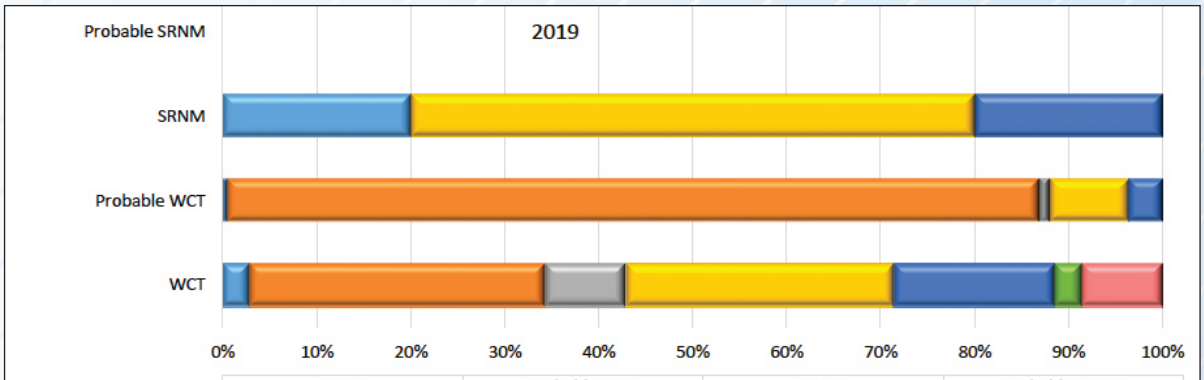
	2018	2019
Wrong component	3	1
ABO compatible blood/component	10	15
D-mismatched	1	4
ABO incompatible blood/component	9	15
Incorrect phenotyped	3	3
SRNM (Irradiated blood)	1	2

Figure 3.9.1a: Errors Resulting in WCT and SRNM



	WCT	Probable WCT	SRNM	Probable SRNM
Request	2	5	0	0
Sample taking	4	174	0	0
Sample receipt	2	0	0	0
Testing	9	26	4	0
Component selection	1	0	0	0
Component collection	2	0	0	0
Administration	3	1	0	0

Figure 3.9.1b: Critical Control Point Where Error Occurred Leading to WCT and SRNM in 2018



	WCT	Probable WCT	SRNM	Probable SRNM
Request	1	1	1	0
Sample taking	11	164	0	0
Sample receipt	3	2	0	0
Testing	10	16	3	0
Component selection	6	7	1	0
Component collection	1	0	0	0
Administration	3	0	0	0

Figure 3.9.1c: Critical Control Point Where Error Occurred Leading to WCT and SRNM in 2019

3.9.2 HANDLING AND STORAGE ERROR (HSE)

Handling and storage error is defined as when the patient is 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 cold chain, technical administration error, excessive time to transfuse, transfusion of damaged component and even when an expired unit is transfused.

There was a case of near miss in both years that could have led to HSE and none for IBCT. In both cases, expired blood component was issued as a result of wrongly keyed in collection date as received date in the system by the blood bank MLT. These errors were detected in ward during the final administration check at bedside.

3.9.3 RIGHT BLOOD RIGHT PATIENT (RBRP) – Figure 3.9.3a and 3.9.3b

A patient could still be transfused correctly with correct blood despite one or more serious missing steps of transfusion. This can occur either in clinical or in laboratory setting. Errors in patient identification data, prescription errors, labelling errors, no bedside check done, no identification band, incorrect data on either sample or form and entering ID of another patient could contribute to this. In clinical area, incorrect ID is usually related with the first name, last name, date of birth, IC or passport number. Nevertheless, in the laboratory area the error was mainly because of demographic data entry.

There were 3 RBRP reported in 2018 and 6 in 2019 despite error not detected at CCP. All RBRP cases in 2018 occurred in the laboratory, in which 2 were due to transcription errors where discrepancies were noted between blood request form and blood bag. The other error occurred due to initially reactive NAT blood that was supposed to be discarded but was issued and transfused. Fortunately, the repeated NAT test done on this blood unit was non-reactive. However, in 2019, there were 6 cases from the clinical area in which 5 were due to clerical error during filling up the request form and the other error from component collection. This happened when there was a 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.

Probable RBRP in near miss that could lead to IBCT are shown in figure 3.9.3b. Data 2018 – 2019 showed 67 cases of error during request that could have led to RBRP. Most of the time, MLTs in the blood bank would notice discrepancies between patient identification data written on the request form and patient's historical data.

Ten cases of NM during pre-transfusion testing were always due to transcription error of barcode manually which did not tally with generated label on blood bag. This was only discovered during the final administration of checking at bedside.

In 2018, there were 3 cases of procedural error during testing in blood bank resulting in RBRP whereas 1 case was due to wrong solution fluid used for red cell washing while another 2 were due to blood was issued before a second MLT verified the patient's blood group.

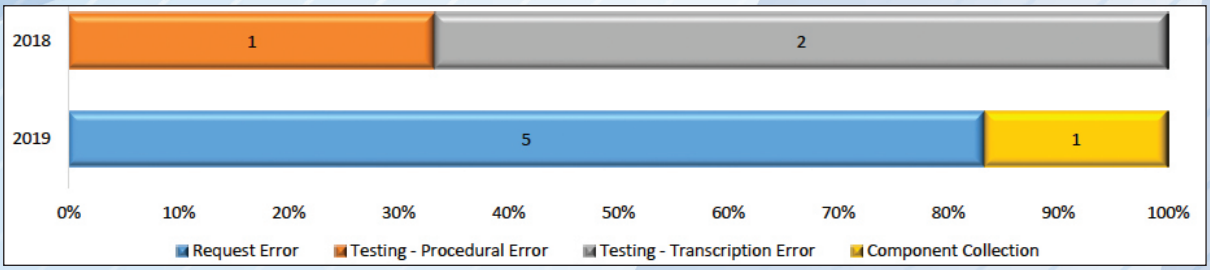


Figure 3.9.3a: RBRP

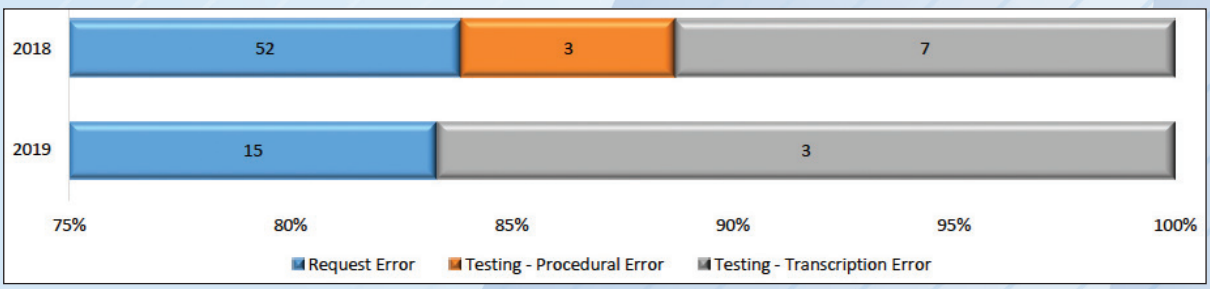


Figure 3.9.3b: Probable RBRP

3.9.4 AVOIDABLE/ DELAYED/ UNDERTRANSFUSED (ADU) – Figure 3.9.4

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 failure in communication, incorrect decisions, or poor prescribing and based on poor knowledge.

NHCC received 10 cases of IBCT that were avoidable in which 4 in 2018 and 6 in 2019 with 2 probable delayed transfusion due to IT error in blood bank.

In 2018, two avoidable cases were due to request error, as due to lack of knowledge as the doctor request FFP instead of platelet as he thought FFP contained Platelets and the other was failure of communication between MO and specialist in which MO wrongly heard the issued code for the blood component resulting in the wrong component transfused. While 2 cases of administration errors caused ADU were; inadequate volume of cryosupernatant was transfuse and wasn't according to prescription while the other case was where blood for the intended case was already transfused to another patient but when SN discovered the error she stopped the transfusion but instead of returning the blood bag to blood bank, the same bag of blood was transfused to the intended patient.

In 2019, out of the 6 cases, 3 were due to error in administration. There was miscommunication between MLT and HO when administration of blood was ongoing as two patients were admitted in A&E red zone with similar name. When HO was asked to halt transfusion, he assumed the order was meant for the other patient. Another one was a case where HO did not do any positive patient identification prior to transfusion of blood and no second verifier resulting in patient was transfused with FFP belonged to another patient. The third was where blood was transfused to a patient who did not require transfusion.

The other 3 cases were due to sample taking error, where blood was drawn at the same site of the drip set, prescription error where blood transfusion was not authorised by a trained staff to meet clinical requirements and finally, PPK collected uncrossmatched phenotype blood from other hospital and went straight to ward without the blood being crossmatching in his blood bank laboratory.

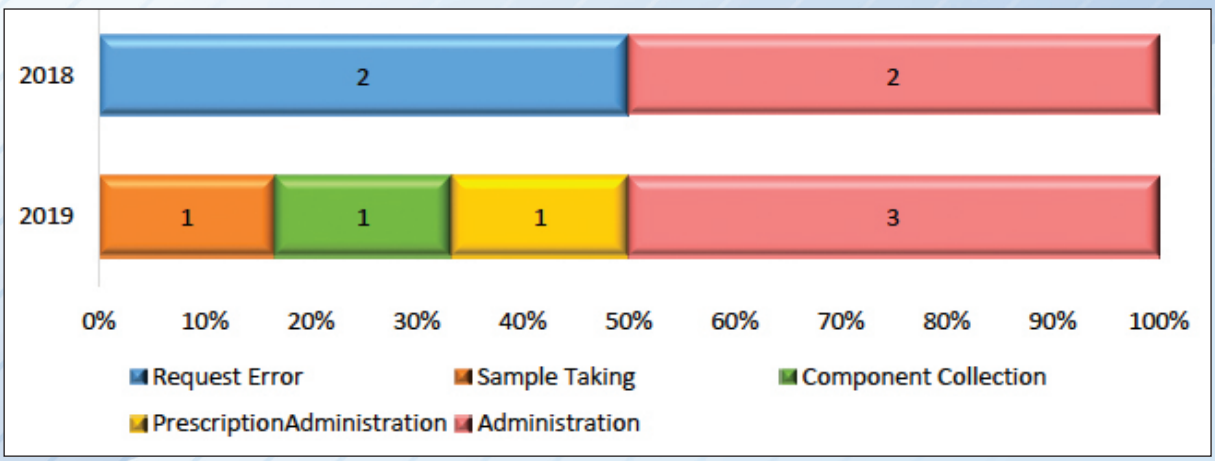
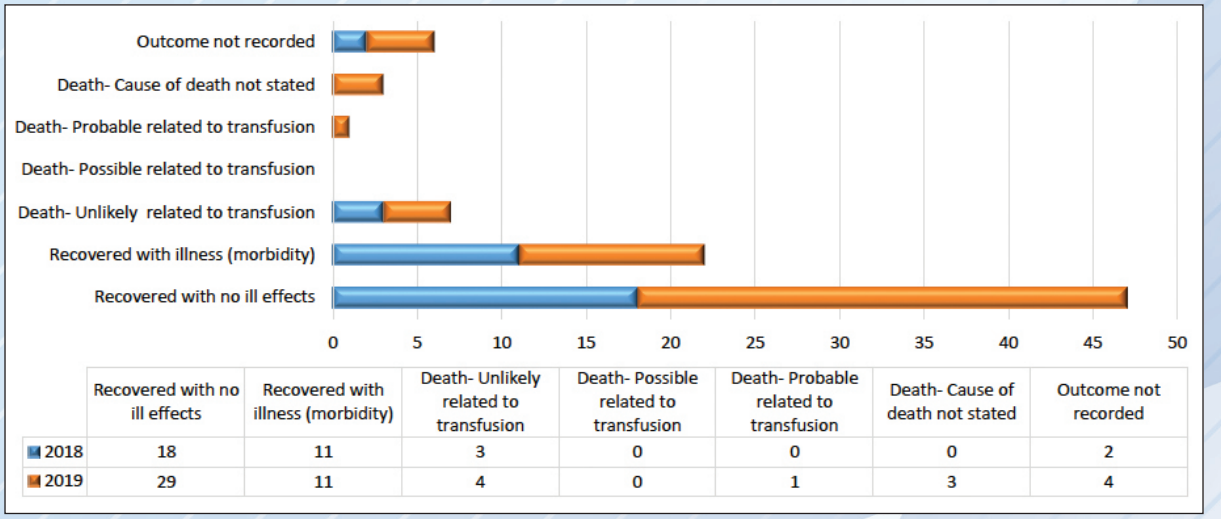


Figure 3.9.4: Avoidable Transfusion

3.10 IMPUTABILITY – Figure 3.10

As shown in figure 3.10, half of the patients with IBCT had recovered with no ill effects of which 52.9% in 2018 and 55.8% in 2019. A total of 22 cases in both years were reported with recovery but required extended length of stay. This was 32.4% in 2018 and 21.1 % in 2019. Meanwhile there were 3 deaths reported in 2018 and 8 in 2019. Out of these figures, 7 deaths were reported as unlikely related to transfusion. The cause of death was due to severity of patients underlying condition. One case was reported as probably related to transfusion and another 3 cause of death were not stated precisely. Unfortunately, there were 2 reports (5.9%) received in 2018 and 4 (7.7%) in 2019 which did not state the patient outcome.



	Recovered with no ill effects	Recovered with illness (morbidity)	Death- Unlikely related to transfusion	Death- Possible related to transfusion	Death- Probable related to transfusion	Death- Cause of death not stated	Outcome not recorded
2018	18	11	3	0	0	0	2
2019	29	11	4	0	1	3	4

Figure 3.10: Imputability

3.11 RECOMMENDATIONS

1. Identifying root cause of error is pivotal and executing necessary corrective and preventive actions within the stipulated time is essential. Reporting all NM, incident and IBCT is important. Each hospital should have a proactive hospital transfusion committee (HTC) with members from all clinical departments, nursing and blood bank to monitor this and eventually help minimize the future occurrence of same event.

2. Human error is inevitable but can be minimised with courses and training. Deviation from SOP should be tackled with education and constant reminder amongst colleague. All personnel involved in blood transfusion process should be on continuous assessment and supervision and also trained to be aware of their roles in transfusion safety at all times.

3. Testing errors: Testing multiple samples at one time predispose to error as lab personnel might mixed the samples and wrongly read the other patient's results. The frequent contributing factors were high workload which resorted the personnel to multitasked and do "shortcuts" in the work process. Proper staffing in the laboratory both at hospital's blood bank or KK need to be considered seriously, ideally proportionate with the census of workload.

4. The importance of taking heed of information given by clinical area should not be neglected. Robust procedures needs to be applied within the laboratories if patients are transferred in from another hospitals. This is to ensure that any transfusion history or specific requirements are passed on to the other end. Transfusion practitioners and clinician should ensure that knowledge of blood group compatibility is included and emphasised in training and competency assessments.

5. Counterchecking of the blood bag issued and request form should be done vigilantly by lab and ward personnel using a checklist at the blood bank counter prior to any release of blood or blood products to prevent component collection error.

6. Requirement for two independent samples for ABO blood grouping in patient who has no historical record with blood bank will help to prevent ward and blood bank error.

7. Sharing of patient transfusion database between hospital blood bank information systems to build patient's historical blood bank record to prevent ABO incompatible transfusion and adhere to patient's transfusion requirement in order to enhance patient safety.

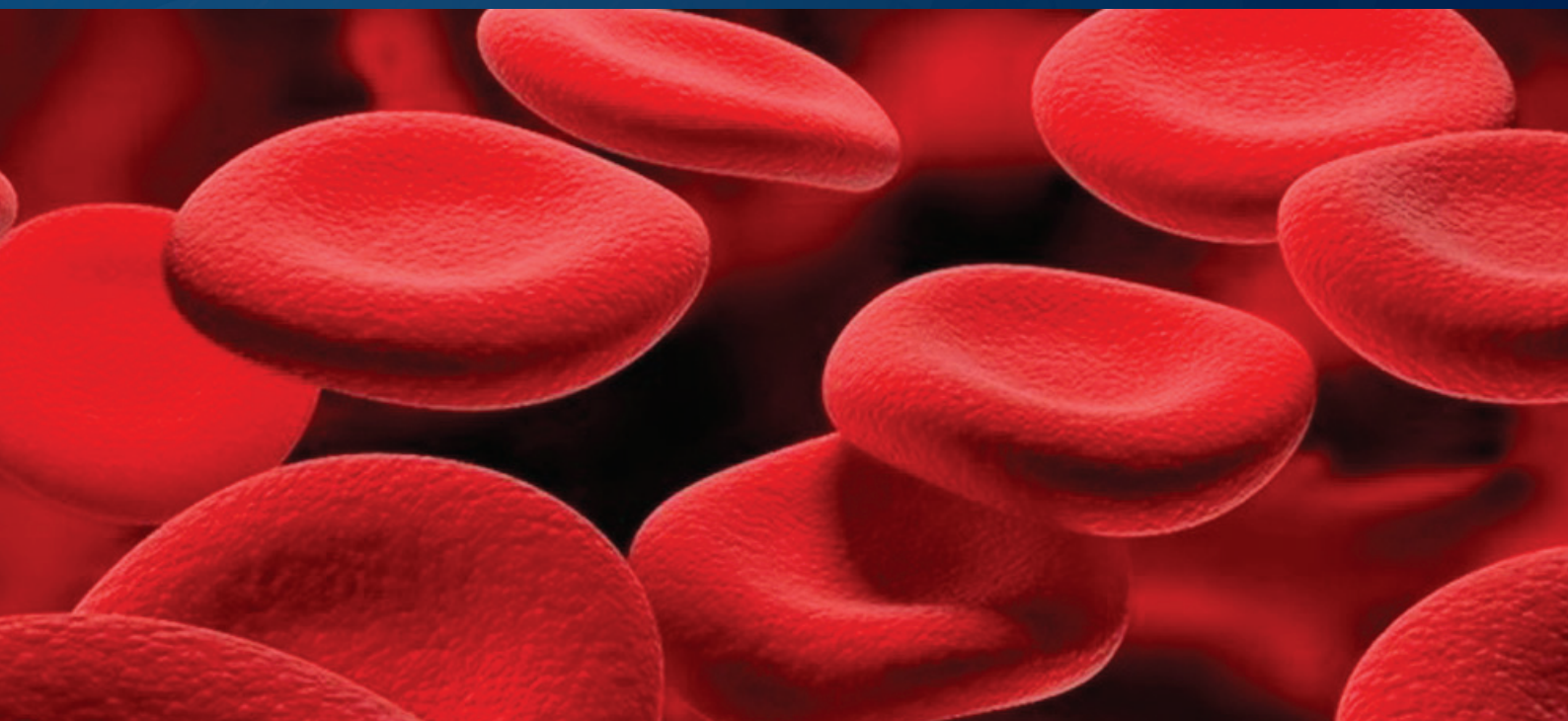
8. There shall be a quality management system in all blood banks with regular internal and external audits in quality and transfusion should be performed to ensure all process and procedures are in accordance with the national guidelines and standards.

9. The full support from the Hospital/State Transfusion Committee to ensure safe and appropriate transfusion practices within the hospitals in each state may ease the implementation of corrective and preventive actions.

10. Implementation of patient blood management (PBM) should be educated and become a common practice among clinician to reduce the use of blood products. This eventually will help to reduce the need of transfusion and eventually risk of transfusion error.

CHAPTER 4

TYPES OF ADVERSE TRANSFUSION REACTION



4.1 ADVERSE TRANSFUSION REACTION (ATR) REPORTS – Table 4.1

The total number of ATR report received in 2018 was 5140 and 4516 in 2019. NHCC had further sub-categorized these reports into confirmed ATR cases, incomplete ATR report, unrelated to ATR and no adverse event. In 2018, there were 5 out of 4766 cases with incomplete data and the number increased to 48 cases out of 4247 in 2019. The increment of incomplete cases in 2019 were likely due to shorter duration in report closure compared to previous year.

On the other hand, 235 cases in 2018 and 214 cases in 2019 were reported as not related to transfusion. These reactions were caused by underlying illness, complications or procedures unrelated to transfusion. Meanwhile, there were 374 cases in 2018 and 269 cases in 2019 were reported as no adverse events. Thus, the total numbers of confirmed ATR analyzed in 2018 were 4526 (88.05%) cases and 3984 cases in 2019 (88.22%).

ATR REPORT		Number of Reports Received	
		2018	2019
Adverse Transfusion Reactions	ATR cases (analysed in the report)	4526	3985
	Incomplete ATR report	5	48
	Unrelated to ATR	235	214
	SUB TOTAL	**4766**	**4247**
No Adverse Event		374	269
Total Number of Reports Received		**5140**	**4516**

**Incomplete report received where insufficient/incomplete data sent and unable to conclude for analysis*

Table 4.1: Total Number of Adverse Transfusion Reaction Reported

4.2 TYPE OF ADVERSE TRANSFUSION (ATR) REPORTED – Table 4.2

The number of confirmed adverse transfusion reaction reported has increased to 4526 cases in 2018 and then dropped to 3985 cases in 2019. This decrement likely due to changes applied to due date for 2019 report submission and the transitional period of 22 hospitals with BBISv2 system from manual to online system reporting as discussed in earlier chapter.

The trend of types of adverse transfusion reactions was similar to previous years. Mild allergic reaction remained as the commonest event for both 2018 and 2019 followed by febrile non-haemolytic transfusion reaction (FNHTR) for both years. Unclassifiable complication of transfusion reported as the third common cause of ATR with 10.52% in 2018 and 11.45% in 2019. Moderate allergic reaction and transfusion associated dyspnoea (TAD) accounted for 1-2% incidence each year. While the incidence of transfusion related acute lung injury (TRALI) was infrequent, no case is reported for delayed haemolytic transfusion reaction (DHTR), non-immune haemolytic transfusion reaction and transfusion transmittable infection (TTI).

No.	Type of ATR	2019		2019	
		No of cases	%	No of cases	%
1.	FNHTR	1573	34.75	1482	37.20
2.	Mild Allergic	2206	48.74	1798	45.13
3.	Unclassifiable Complication of Transfusion	476	10.52	456	11.45
4.	Moderate Allergic Reaction	83	1.83	106	2.66
5.	TAD	127	2.81	100	2.51
6.	TACO	38	0.84	30	0.75
7.	Hypotension Transfusion Reaction	12	0.27	6	0.15
8.	Anaphylaxis	8	0.18	6	0.15
9.	Inconclusive	0	0	0	0
10.	TRALI	3	0.07	1	0.03
11.	DHTR	0	0	0	0
12.	Non-immune HTR	0	0	0	0
13.	HIV	0	0	0	0
14.	Hepatitis B	0	0	0	0
15.	Hepatitis C	0	0	0	0
16.	Malaria	0	0	0	0
	TOTAL	**4526**		**3985**	

Table 4.2: Incidence of ATR based on type of reaction in 2018 and 2019

4.3 ADVERSE TRANSFUSION REACTIONS REPORTS ACCORDING TO TYPE OF REACTION – Figure 4.3.1, 4.3.2 and 4.3.3

4.3.1 FEBRILE NON-HAEMOLYTIC TRANSFUSION REACTION, ALLERGIC REACTION AND HYPOTENSIVE REACTION

Reactions	Definition
Febrile type reaction	Fever and/or chills/rigors which may be accompanied by headache and nausea occurring during or within four hours following transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition. Fever in this context is defined as temperature ≥38^{0}C oral or equivalent and a change of ≥1^{0}C from pre-transfusion value.
Allergic type reaction	Mucocutaneous signs and symptoms during or within 4 hours of transfusion: morbilliform rash with pruritus, urticaria, localised angioedema, oedema of lips, tongue and uvula, periorbital pruritus, erythema and oedema, conjunctival oedema.
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 result in or prolong hospital stay, or anaphylaxis (severe, life-threatening, generalized or systemic hypersensitivity reaction with rapidly developing airway and/or breathing and/or circulation problems, usually associated with skin and mucosal changes).
Reaction with both allergic and febrile features	Features of febrile and mild allergic reactions
Hypotensive reaction	Decrease in systolic and/or diastolic blood pressure of >30 mmHg occurring during or within one hour of completing transfusion.

SHOT UK 2018

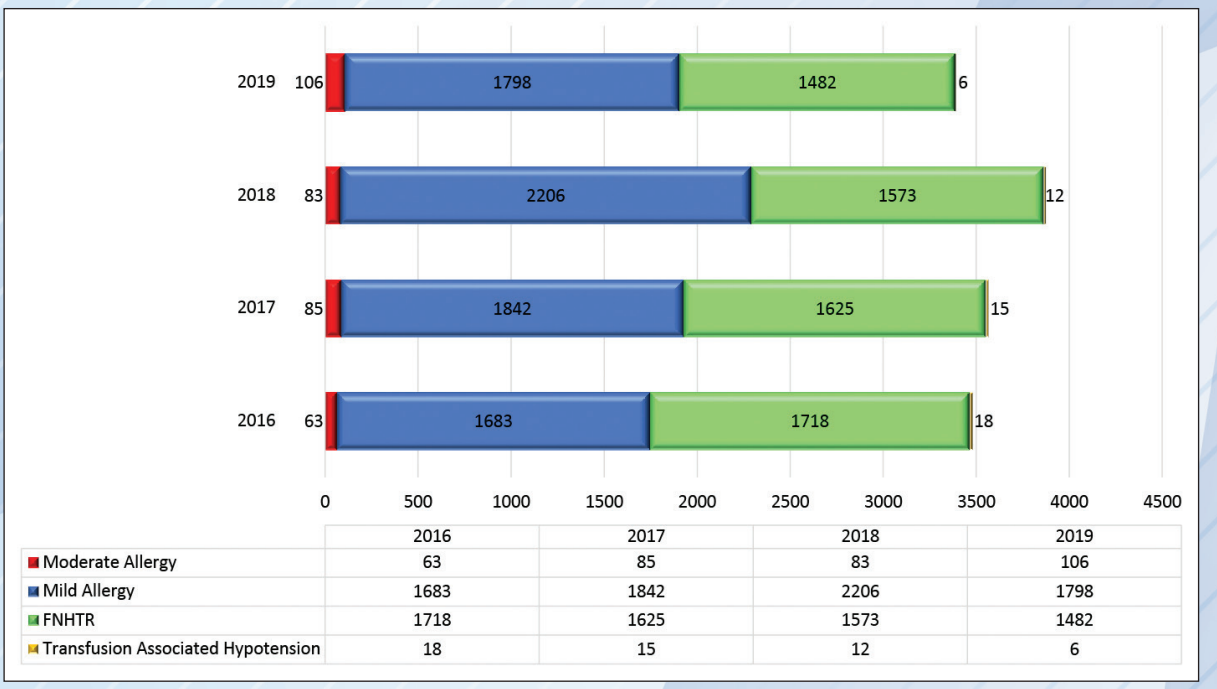
The reactions which were discussed under this category were febrile non haemolytic transfusion reactions, allergic reactions and hypotensive transfusion reaction that occurred up to 24 hours post transfusion event. These reactions classification are displayed in the following table which were originally sourced from the International Society for Blood Transfusion/International Haemovigilance Network (ISBT/IHN) definitions and adopted from SHOT 2018.

Although there was a reduction in the number of reported cases of allergic reactions in 2019 compared to 2018, mild allergic reaction remained the commonest type of ATR reported in both years. The data analysis showed that the incidence of mild allergic reaction was 48.7% while moderate allergic reactions was 1.8% and this is relatively similar in 2019 with 45.1% and 2.7% respectively. Nevertheless, no morbidity or mortality was attributed by allergic reactions for both years.

FNHTR was the second most frequent reported case in both 2018 and 2019 which accounted for 34.75% (1573 cases) and 37.2% (1482 cases) respectively. All recipients reported good outcome with no morbidity or mortality. Pre-medication with antipyretics or use of filtered blood are recommended as preventive measures to reduce risk of recurrent reactions. Due to data limitation, NHCC was unable to analyse the association of these reactions with type of blood component. Hopefully for year onwards NHCC would be able to display the relation after several improvement steps have been taken in data collection starting in year 2020 with the assistance of BBISv2. NHCC is keen to provide better data analysis to enhance the quality of transfusion service

Starting from 2020, case of reaction with both febrile and allergic features that fulfil the criteria outlined in SHOT 2019 will be included as one category in the data analysis by NHCC. Therefore, all hospitals are encouraged to identify related cases and report accordingly.

Meanwhile, there were 12 cases (0.27%) of hypotensive transfusion reaction reported in 2018 and 6 cases (0.15%) in 2019. Fewer cases reported compared to previous years as well. Good recovery reported following this type of adverse event. Termination of transfusion is recommended with fluid replacement if indicated.



	2016	2017	2018	2019
Moderate Allergy	63	85	83	106
Mild Allergy	1683	1842	2206	1798
FNHTR	1718	1625	1573	1482
Transfusion Associated Hypotension	18	15	12	6

Figure 4.3.1: Total Number of FNHTR, Mild allergic, Moderate allergic and Transfusion Associated Hypotension

4.3.2 UNCLASSIFIABLE COMPLICATIONS OF TRANSFUSION

Reactions	Definition
Unclassifiable complications of transfusion	Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined transfusion event and with no risk factor other than the transfusion, and no other explanation.

SHOT UK 2019

Total number of cases reported in 2018 and 2019 were 476 cases (10.52%) and 456 cases (11.45%) respectively. These numbers included reclassified cases by NHCC team from diagnosis of FNHTR as reported temperature rise less than 1^{0}C, the presence of chills and rigors only or event which cannot fit into already defined transfusion event. Neither morbidity nor mortality to recipients was reported in both years. Understanding the definition of each adverse event is essential for an accurate diagnosis.

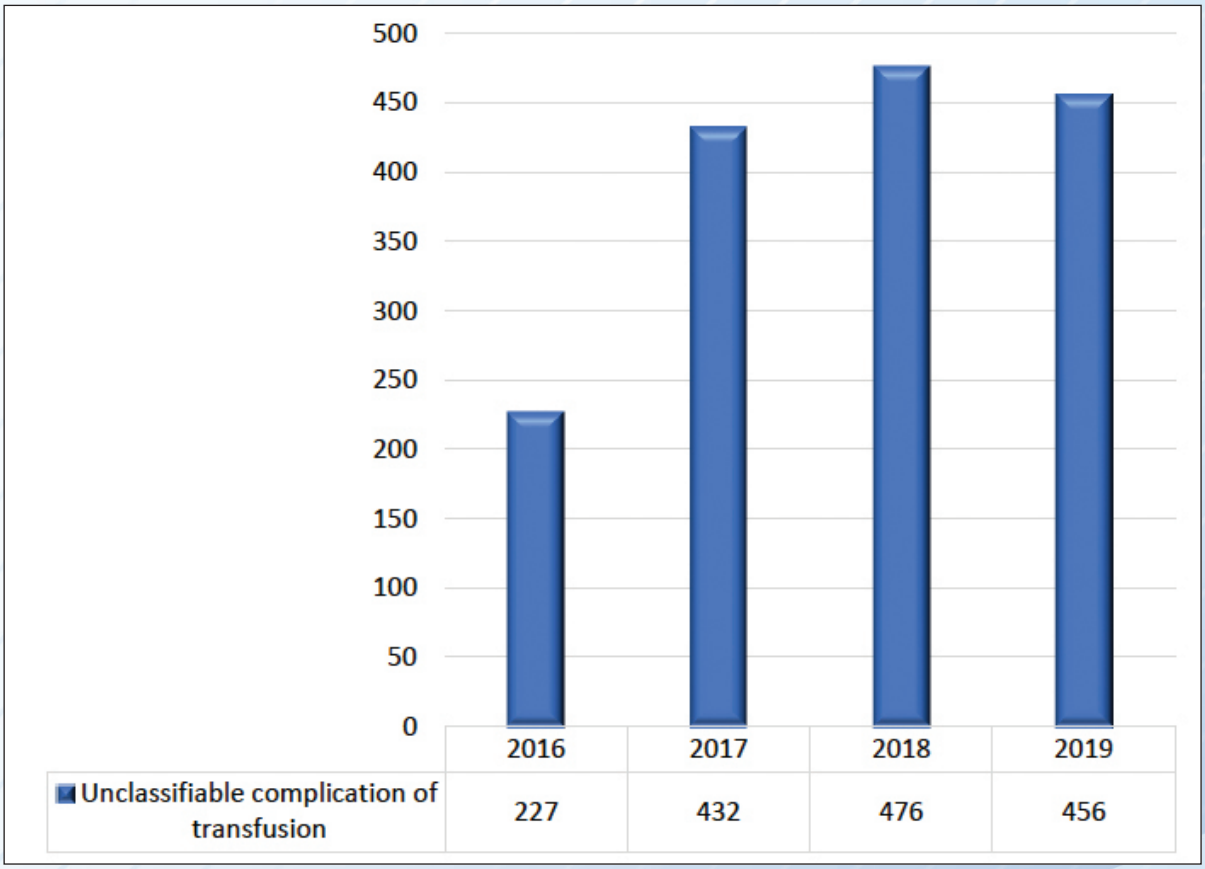


Figure 4.3.2: Total Number of Reported Unclassifiable Complication of Transfusion

4.3.3 PULMONARY COMPLICATIONS

Reactions	Definition
Transfusion-Related Acute Lung Injury (TRALI)	Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within 6 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.
Transfusion-Associated Circulatory Overload (TACO)	Inability of the circulatory system to handle an increased blood volume. The patient will present with acute pulmonary oedema when cardiac output cannot be maintained. Other symptoms include cyanosis, orthopnoea, hypertension, headache, tachycardia, chest tightness, and cough. Symptoms usually set in near the end of the transfusion.
Severe Allergy	Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention AND/OR, directly result in or prolong hospital stay, or anaphylaxis (severe, life-threatening, generalized or systemic hypersensitivity reaction with rapidly developing airway and/or breathing and/or circulation problems, usually associated with skin and mucosal changes)
Transfusion Associated Dyspnoea (TAD)	Respiratory distress within 24 hours of transfusion that does not meet the criteria for TRALI, TACO or allergic reaction and it is not explained by the patient's underlying condition

SHOT UK 2016 & 2018

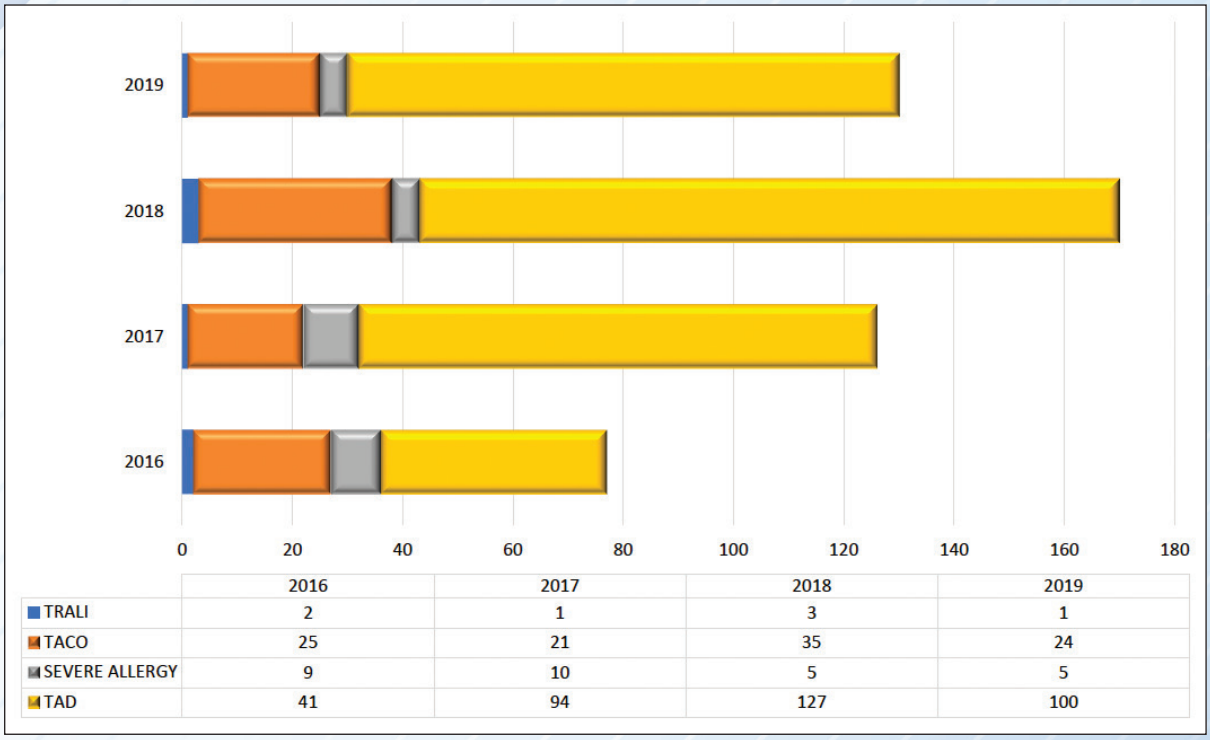
There were a total of 3.75% (170 cases) in 2018 and 3.26% (130 cases) in 2019 related to pulmonary complications. These cases included TRALI, TACO, severe anaphylaxis reaction and TAD.

TAD was the most type of pulmonary complication reported with 2.8% (127 cases) in 2018 and 2.51% (100 cases) in 2019. Usually the symptoms were transient and subsided with the dismissal of the transfusion.

TACO was the second commonest with 0.77% (35 cases) in 2018 and 0.6% (24 cases) in 2019. All cases of TACO showed improvement after the use of diuretic. Thirty cases showed evidence of overload picture in the x-ray and 2 cases showed significant reduction in ejection fraction. Transfusion of PRBC, FFP and platelet were avoidable in 16 cases. Reducing inappropriate transfusion by following the principles outline in patient blood management would avoid such adverse event. Massive transfusion was seen in 13 cases. Most patients implicated with TACO has underlying medical illness such as heart failure and kidney disease. Thus, the key of preventing TACO is by identifying the at-risk group such as an extreme of age, having pre-existing heart and/or (potentially) renal disease, acute myocardial infarction, and patients receiving FFP. In this identified group of patients, the use of diuretic, slow transfusion rates, small volume (split bag) and appropriately monitor the patient are paramount to prevent the adverse event.

There were 5 cases each on both years reported to suffer severe allergic reaction towards blood transfusion. The patient's IgA level was checked as IgA deficient patient with anti-IgA antibody need a long-term transfusion plan to avoid anaphylaxis during transfusion. Severe anaphylaxis can be prevented with appropriate pre-medication and transfusion of washed blood component.

TRALI was the least reported event with 0.07% (3 cases) in 2018 and 0.03% (1 case) in 2019. There was one reported case of Antibody negative TRALI. The case was a 6 years old child diagnosed with acute crises secondary to congenital TTP and on antibiotic for secondary bacterial infection. The child had multiple histories of blood transfusions. The child developed shortness of breath and cough 1-hour post transfusion of 2 pints of cryosupernatant. Furthermore, the patient desaturated to 94% SPO2 under room air, tachypneic and increase temperature to 37.8^{0}C. On auscultation the lungs revealed bilateral crepitation. The child was put on nasal prong oxygen and antibiotics were changed to cefepim, bactrim and azithromycin. No significant improvement seen with IV furosemide. Chest imaging revealed bilateral patchy infiltrates compared to normal x-ray before transfusion. The child fully recovered 24 hours later.

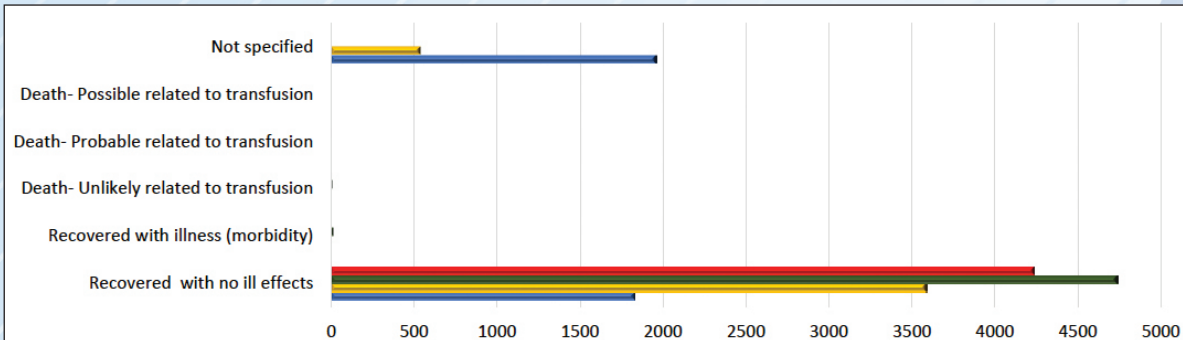


	2016	2017	2018	2019
TRALI	2	1	3	1
TACO	25	21	35	24
SEVERE ALLERGY	9	10	5	5
TAD	41	94	127	100

Figure 4.3.3: Total number of Pulmonary Complications

4.4 OUTCOME OF ADVERSE TRANSFUSION REACTIONS – Figure 4.4

Majority of ATR cases had reported patient recovery with no ill effects which were 4736 in 2018 and 4236 in 2019 and less than 1% in both years reported as recovered with ill effects or morbidity. Meanwhile, there were 11 cases (0.24%) in 2018 and 7 cases (0.18%) in 2019 reported with death but not related to transfusion. There was one case reported as death with possible related to transfusion which was a case of TACO.



	Recovered with no ill effects	Recovered with illness (morbidity)	Death- Unlikely related to transfusion	Death- Probable related to transfusion	Death- Possible related to transfusion	Not specified
2019	4236	4	7	0	0	0
2018	4736	18	11	1	0	0
2017	3588	1	1	0	0	541
2016	1831	7	2	0	0	1955

Figure 4.4: Outcome of Adverse Transfusion Reaction

4.5 RECOMMENDATIONS

1. It is prudent for the clinical and blood bank personnel to recognise ATR and take necessary steps to minimise the recurrence. The correct diagnosis of ATR requires knowledge and continuous reporting of adverse events helps to mend the practice appropriately.

2. Blood bank medical doctor to review, investigate and manage recipients in term of transfusion requirement in cases of moderate to severe ATR and reports to be verified by specialists to ensure correct diagnosis and management.

3. Implementing standardised reporting on all transfusion related adverse events including the procedure for further investigations of transfusion reactions, use of new format form for reporting (BTS/ HV/3/2016) and monthly reporting as outline in the Transfusion Practice Guidelines 2016. Compliancy to report submission using BBISv2 system also shall be encouraged.

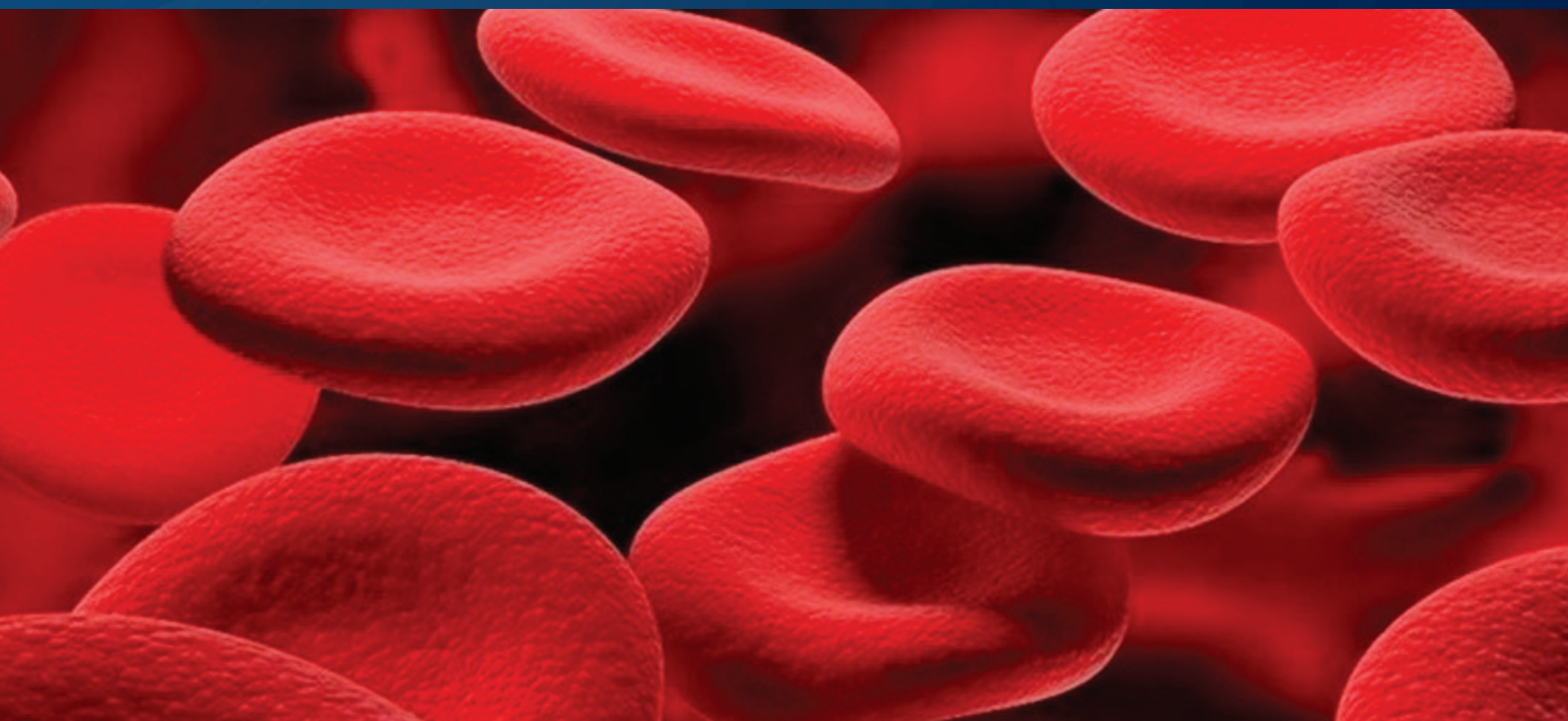
4. Expand the usage of leukodepeleted blood to the other group of transfusion dependent patient other than thalassemia to reduce the incidence of ADR.

5. To monitor the scheduling of leukodepleted where guidelines instructed that it should be done within 48 hours after donation.

6. The reduction in the number of participating hospitals may compromised the fundamental role of haemovigilance in enhancing patient safety by sharing learning, innovations, solutions and best practices to prevent occurrence or recurrence of undesirable events. Thus, awareness and understanding in the rationale of voluntary haemovigilance reporting for better hospital participation is necessary.

CHAPTER 5

DONOR HAEMOVIGILANCE – ADVERSE DONOR REACTION



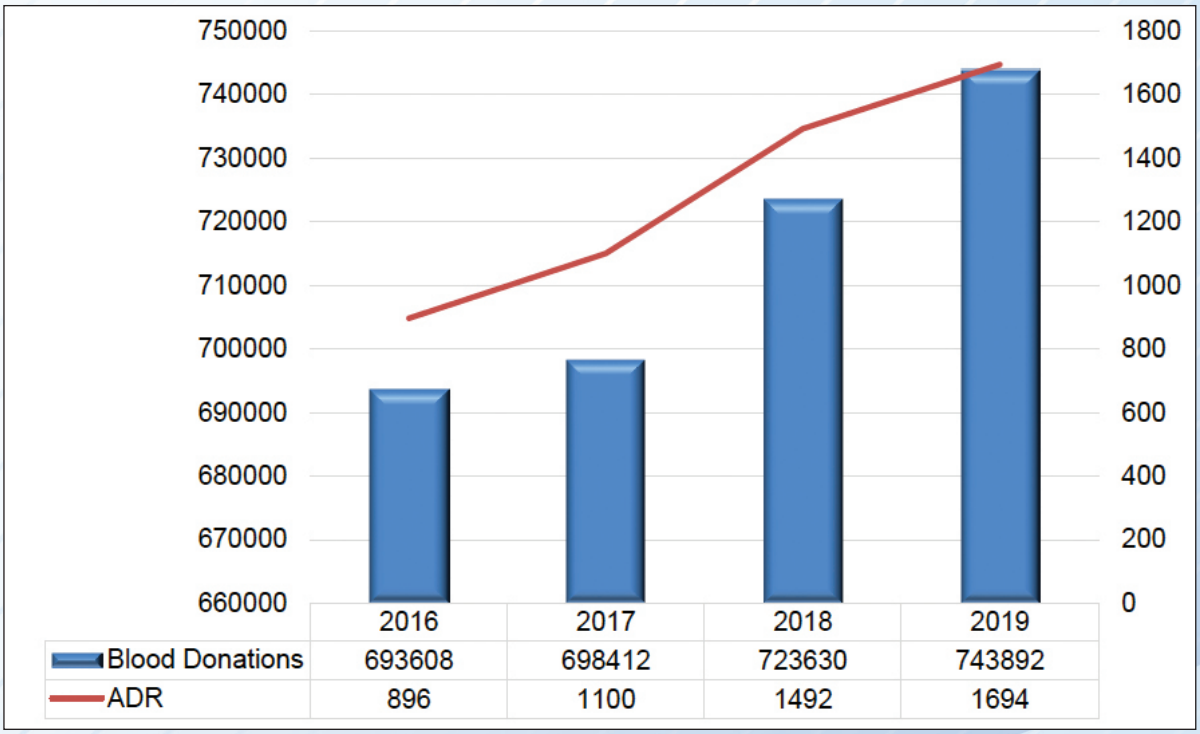
5.1 DEFINITION

Donor haemovigilance is the systematic monitoring of adverse reactions and incidents in the whole chain of blood donor care, with a view to improving quality and safety for blood donors (SHOT 2019).

5.2 OVERVIEW OF ADVERSE DONOR REACTION (ADR) REPORTING – Figure 5.2

Blood donation is generally a safe process and unfortunately adverse reaction during the donation process may still occur. Thus, reporting of donor adverse event enables the blood donation services to monitor and form action to increase donor safety. An uneventful blood donation experience may encourage more donors to repeat donation and eventually increase the regular donor pools and give confidence to new blood donors.

There are 153 government hospitals in Malaysia and 73.9% (113) of these hospitals carried out a blood collection activity. The total number of bloods collected by the government hospitals had increase each year and NHCC has seen an increasing Adverse Donor Reaction (ADR) reporting as shown in the Figure 5.2 below.

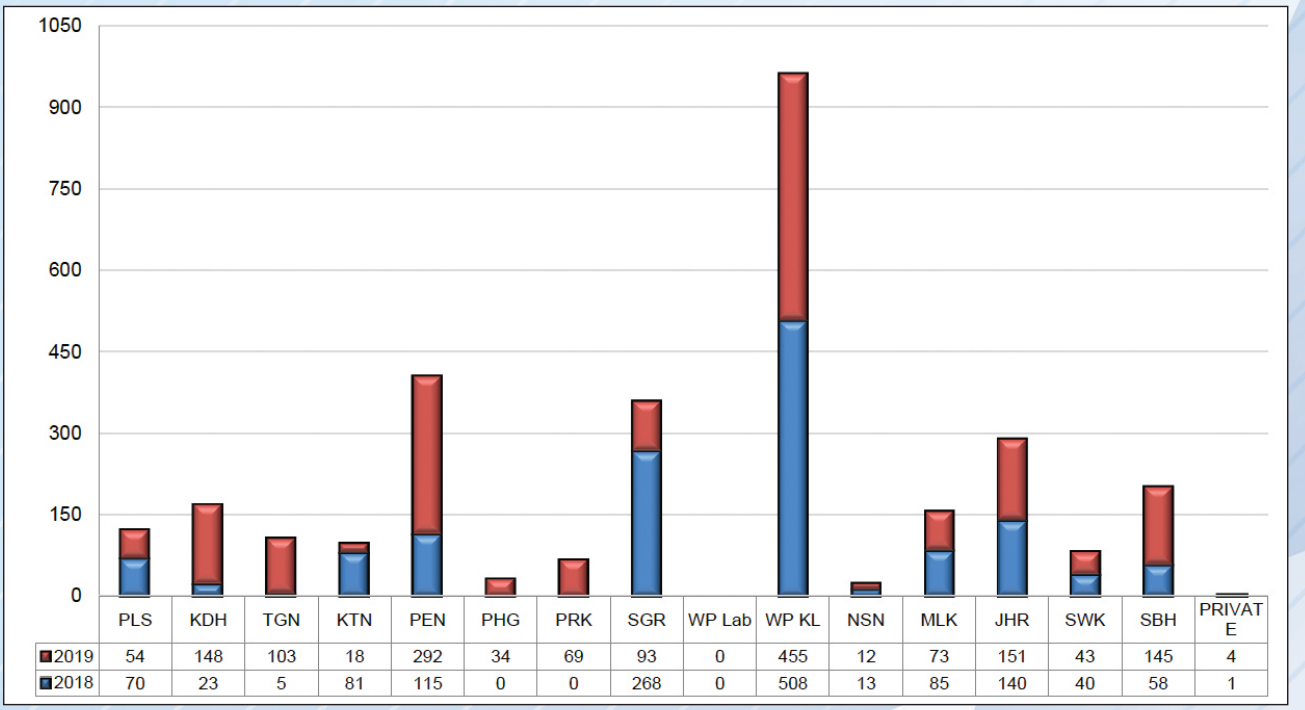


	2016	2017	2018	2019
Blood Donations	693608	698412	723630	743892
ADR	896	1100	1492	1694

Figure 5.2: Number of Blood Donations and ADR reporting from 2016 – 2019

5.3 PARTICIPATION OF ADR REPORTING – Figure 5.3, Table 5.3a and 5.3b

Approximately one-third on the blood collection centers participated in reporting for adverse donor reactions of which 38 in 2018 and 45 in 2019. The total number of reports received for both years are shown below.



	PLS	KDH	TGN	KTN	PEN	PHG	PRK	SGR	WP Lab	WP KL	NSN	MLK	JHR	SWK	SBH	PRIVATE
2019	54	148	103	18	292	34	69	93	0	455	12	73	151	43	145	4
2018	70	23	5	81	115	0	0	268	0	508	13	85	140	40	58	1

Figure 5.3: Total Number of ADR Reported by State in Malaysia

Following table showed the number of ADR reports received from each blood collection centers in Malaysia. Inconsistent reporting causes the incident of ADR to be zero for the entire year for few blood collection centers, in which they did not report ADR cases to NHCC for certain months in that year. Blood collection centers that did not send any ADR report were labelled as No Report Received (NRR). Thus, both of these data are excluded from the analysis. With the disclosure of these statistics, NHCC hopes to encourage more blood collection centers to participate in NHCC reporting.

States	Hospitals	2018			2019		
		Total ADR	Total blood collection	Percentage of ADR	Total ADR	Total blood collection	Percentage of ADR
Perlis							
State	Hospital Tuanku Fauziah	70	9145	0.77	54	8963	0.60
Kedah							
State	Hospital Sultanah Bahiyah	0	23109	0	8	8963	0.03
Major	Hospital Sultan Abdul Halim, Sg Petani	28	11597	0.24	81	12280	0.66
Major	Hospital Kulim	0	8251	0	9	9056	0.10
Minor	Hospital Langkawi	23	3180	0.73	48	3229	1.49
Non Specialist	Hospital Baling	NRR	796	-	NRR	994	-
Non Specialist	Hospital Jitra	0	741	0	2	1072	0.19
Non Specialist	Hospital Kuala Nerang	NRR	544	-	NRR	436	-
Non Specialist	Hospital Sik	NRR	1109	-	NRR	889	-
Non Specialist	Hospital Yan	NRR	529	-	NRR	693	-
Terengganu							
State	Hospital Sultanah Nur Zahirah	0	16486	0	88	16366	0.54
Major	Hospital Kemaman	5	3278	0.15	15	3692	0.41
Minor	Hospital Dungun	NRR	730	-	NRR	695	-
Non Specialist	Hospital Besut	NRR	652	-	NRR	660	-
Non Specialist	Hospital Hulu Terengganu	NRR	230	-	NRR	201	-

States	Hospitals	2018			2019		
		Total ADR	Total blood collection	Percentage of ADR	Total ADR	Total blood collection	Percentage of ADR
Kelantan							
State	Hospital Raja Perempuan Zainab II	81	14807	0.55	18	11714	0.15
Major	Hospital Kuala Krai	NRR	1766	-	NRR	4050	-
Major	Hospital Tanah Merah	NRR	1506	-	NRR	1868	-
Minor	Hospital Gua Musang	NRR	585	-	NRR	233	-
Non Specialist	Hospital Jeli	NRR	446	-	NRR	76	-
Non Specialist	Hospital Machang	NRR	1696	-	NRR	2436	-
Non Specialist	Hospital Pasir Mas	NRR	1224	-	NRR	2122	-
Non Specialist	Hospital Tengku Anis, Pasir Puteh	NRR	1303	-	NRR	1171	-
Non Specialist	Hospital Tumpat	NRR	634	-	NRR	725	-
Pulau Pinang							
State	Hospital Pulau Pinang	36	28168	0.14	178	26873	0.66
Major	Hospital Seberang Jaya	115	15515	0.74	108	17176	0.63
Minor	Hospital Bukit Mertajam	0	1346	0	4	1545	0.26
Minor	Hospital Kepala Batas	0	2166	0	2	2427	0.08
Non Specialist	Hospital Sungai Bakap	NRR	709	-	0	821	0

States	Hospitals	2018			2019		
		Total ADR	Total blood collection	Percentage of ADR	Total ADR	Total blood collection	Percentage of ADR
Pahang							
State	Hospital Tengku Ampuan Afzan	NRR	15002	-	21	15600	0.13
Major	Hospital Sultan Haji Ahmad Shah, Temerloh	0	6833	0	5	6235	0.08
Minor	Hospital Bentong	0	1609	0	2	1438	0.14
Minor	Hospital Kuala Lipis	0	1169	0	1	1527	0.07
Minor	Hospital Pekan	0	1533	0	5	2153	0.23
Non Specialist	Hospital Hajjah Kalsom, Cameron Highlands	NRR	356	-	NRR	356	-
Non Specialist	Hospital Jengka	NRR	350	-	NRR	292	-
Non Specialist	Hospital Jerantut	NRR	497	-	NRR	489	-
Non Specialist	Hospital Raub	NRR	626	-	0	602	0
Perak							
State	Hospital Raja Permaisuri Bainun	NRR	29364	-	6	28627	0.02
Major	Hospital Taiping	0	10648	0	32	10139	0.32
Major	Hospital Teluk Intan	0	7132	0	2	8199	0.02
Minor	Hospital Kuala Kangsar	NRR	603	-	NRR	592	-
Minor	Hospital Slim River	NRR	2567	-	0	2901	0

States	Hospitals	2018			2019		
		Total ADR	Total blood collection	Percentage of ADR	Total ADR	Total blood collection	Percentage of ADR
Minor	Hospital Seri Manjung	0	6534	0	29	5729	0.51
Minor	Hospital Gerik	NRR	230	-	NRR	241	-
Non Specialist	Hospital Batu Gajah	NRR	344	-	NRR	340	-
Non Specialist	Hospital Changkat Melintang	NRR	208	-	NRR	146	-
Non Specialist	Hospital Kampar	NRR	138	-	NRR	228	-
Non Specialist	Hospital Parit Buntar	NRR	809	-	NRR	887	-
Non Specialist	Hospital Selama	NRR	323	-	NRR	389	-
Non Specialist	Hospital Sungai Siput	NRR	324	-	NRR	358	-
Non Specialist	Hospital Tapah	NRR	519	-	NRR	710	-
Selangor							
State	Hospital Tengku Ampuan Rahimah	268	27709	0.97	93	28388	0.33
WPS Labuan							
State	Hospital Labuan	NRR	2315	-	0	2563	0
WPS Kuala Lumpur							
State	Pusat Darah Negara	508	191552	0.27	455	199721	0.23

States	Hospitals	2018			2019		
		Total ADR	Total blood collection	Percentage of ADR	Total ADR	Total blood collection	Percentage of ADR
Negeri Sembilan							
State	Hospital Tuanku Ja'afar, Seremban	28	17291	0.16	8	18542	0.04
Major	Hospital Tuanku Ampuan Najihah Kuala Pilah	4	4505	0.09	2	4960	0.04
Minor	Hospital Port Dickson	1	2068	0.05	2	1852	0.11
Minor	Hospital Tampin	1	1562	0.06	0	1562	0
Non Specialist	Hospital Jelebu	NRR	102	0	NRR	158	-
Melaka							
State	Hospital Melaka	85	30531	0.28	73	30523	0.24
Johor							
State	Hospital Sultanah Aminah	56	26988	0.21	104	31639	0.33
Major	Hospital Sultan Ismail	46	11872	0.39	33	13027	0.25
Major	Hospital Pakar Sultanah Fatimah, Muar	25	9657	0.26	11	9439	0.12
Major	Hospital Segamat	12	4681	0.26	0	5104	0
Major	Hospital Sultanah Nora Ismail, Batu Pahat	NRR	10168	-	NRR	10945	-
Minor	Hospital Enche Besar Hajah Khalsom, Kluang	1	5834	0.02	3	6182	0.05

States	Hospitals	2018			2019		
		Total ADR	Total blood collection	Percentage of ADR	Total ADR	Total blood collection	Percentage of ADR
Minor	Hospital Kota Tinggi	NRR	2340	-	NRR	259	-
Non Specialist	Hospital Mersing	NRR	1315	-	NRR	127	-
Non Specialist	Hospital Pontian	NRR	1571	-	NRR	253	-
Non Specialist	Hospital Tangkak	NRR	20	-	NRR	0	-
Non Specialist	Hospital Temenggong Seri Maharaja Tun Ibrahim, Kulai	NRR	1872	-	NRR	368	-
Sarawak							
State	Hospital Umum Kuching	0	21222	-	9	21079	0.04
Major	Hospital Bintulu	NRR	4309	-	NRR	4501	-
Major	Hospital Limbang	NRR	803	-	NRR	1016	-
Major	Hospital Miri	9	8040	0.11	14	8734	0.16
Major	Hospital Sibu	31	8155	0.38	20	7693	0.26
Non Specialist	Hospital Sarikei	NRR	1735	-	NRR	1989	-
Non Specialist	Hospital Bau	NRR	272	-	NRR	238	-
Non Specialist	Hospital Betong	NRR	418	-	NRR	508	-
Non Specialist	Hospital Daro	NRR	229	-	NRR	252	-
Non Specialist	Hospital Kanowit	NRR	183	-	NRR	183	-
Non Specialist	Hospital Kapit	NRR	814	-	NRR	841	-
Non Specialist	Hospital Lawas	NRR	748	-	NRR	728	-
Non Specialist	Hospital Lundu	NRR	434	-	NRR	385	-

States	Hospitals	2018			2019		
		Total ADR	Total blood collection	Percentage of ADR	Total ADR	Total blood collection	Percentage of ADR
Non Specialist	Hospital Marudi	NRR	207	-	NRR	138	-
Non Specialist	Hospital Mukah	NRR	652	-	0	740	0
Non Specialist	Hospital Saratok	NRR	756	-	NRR	698	-
Non Specialist	Hospital Serian	NRR	1432	-	NRR	1304	-
Non Specialist	Hospital Simunjan	NRR	121	-	NRR	115	-
Non Specialist	Hospital Sri Aman	NRR	323	-	NRR	400	-
Sabah							
State	Hospital Queen Elizabeth I	NRR	5759	-	NRR	4242	-
Major	Hospital Queen Elizabeth II	53	24447	0.22	145	26084	0.56
Major	Hospital Duchess of Kent, Sandakan	5	9204	0.05	0	9873	0
Major	Hospital Tawau	NRR	8110	-	NRR	7762	-
Minor	Hospital Beaufort	NRR	1881	-	NRR	2232	-
Minor	Hospital Keningau	NRR	3163	-	NRR	3745	-
Minor	Hospital Lahad Datu	NRR	4880	-	NRR	0	-
Minor	Hospital Kota Marudu	NRR	1754	-	NRR	1968	-
Non Specialist	Hospital Beluran	NRR	339	-	NRR	464	-
Non Specialist	Hospital Kinabatangan	NRR	871	-	NRR	1126	-
Non Specialist	Hospital Kota Belud	NRR	1532	-	NRR	1498	-

States	Hospitals	2018			2019		
		Total ADR	Total blood collection	Percentage of ADR	Total ADR	Total blood collection	Percentage of ADR
Non Specialist	Hospital Kuala Penyu	NRR	589	-	NRR	589	-
Non Specialist	Hospital Kudat	NRR	1157	-	NRR	1292	-
Non Specialist	Hospital Kunak	NRR	903	-	NRR	844	-
Non Specialist	Hospital Likas	NRR	6566	-	NRR	7604	-
Non Specialist	Hospital Papar	NRR	621	-	NRR	654	-
Non Specialist	Hospital Pitas	NRR	1290	-	NRR	944	-
Non Specialist	Hospital Ranau	NRR	1280	-	NRR	1413	-
Non Specialist	Hospital Semporna	NRR	989	-	NRR	920	-
Non Specialist	Hospital Sipitang	NRR	516	-	NRR	612	-
Non Specialist	Hospital Tambunan	NRR	608	-	NRR	795	-
Non Specialist	Hospital Tenom	NRR	1000	-	NRR	1302	-
Non Specialist	Hospital Tuaran	NRR	1399	-	NRR	1565	-
TOTAL	**Malaysia**	**1491**	**723630**		**1690**	**743892**	
Private Hospital	Loh Guan Lye, Penang	1	1201	0.08	4	1249	0.32

Table 5.3a: Blood Collection Centres in Malaysia Participated in the ADR Reporting

Apheresis donation facility is only available in state hospital except for Negeri Sembilan. Below are the details of number of Apheresis – ADR report received.

States	Hospitals	2018			2019		
		Total ADR	Total Aphresis Collection	% Of ADR	Total ADR	Total Aphresis Collection	% Of ADR
Perlis	Hospital Tuanku Fauziah	0	5	0	0	2	0
Kedah	Hospital Sultan Abdul Halim, Sg Petani	0	3	0	0	120	0
Terengganu	Hospital Sultanah Nur Zahirah	0	15	0	0	13	0
Kelantan	Hospital Raja Perempuan Zainab II	0	0	0	0	7	0
Pulau Pinang	Hospital Pulau Pinang	0	349	1	1	282	3.9
Pahang	Hospital Tengku Ampuan Afzan	NRR	20	-	1	10	10.0
Perak	Hospital Raja Permaisuri Bainun	NRR	1147	0	0	1621	0
Selangor	Hospital Tengku Ampuan Rahimah	0	68	0	0	44	0
Wilayah Persekutuan Kuala Lumpur	Pusat Darah Negara	13	5861	0.2	19	6532	0.3
Melaka	Hospital Melaka	0	111	0	0	108	0
Sarawak	Hospital Umum Kuching	0	108	0	0	146	0
Sabah	Hospital Queen Elizabeth II	0	303	0	1	671	0.2
	TOTAL	**13**	**8178**	**0.2**	**22**	**9710**	**0.2**

Table 5.3b: ADR reports for apheresis donation

5.4 INCIDENCE OF ADR BY TYPES OF DONATION – Table 5.4

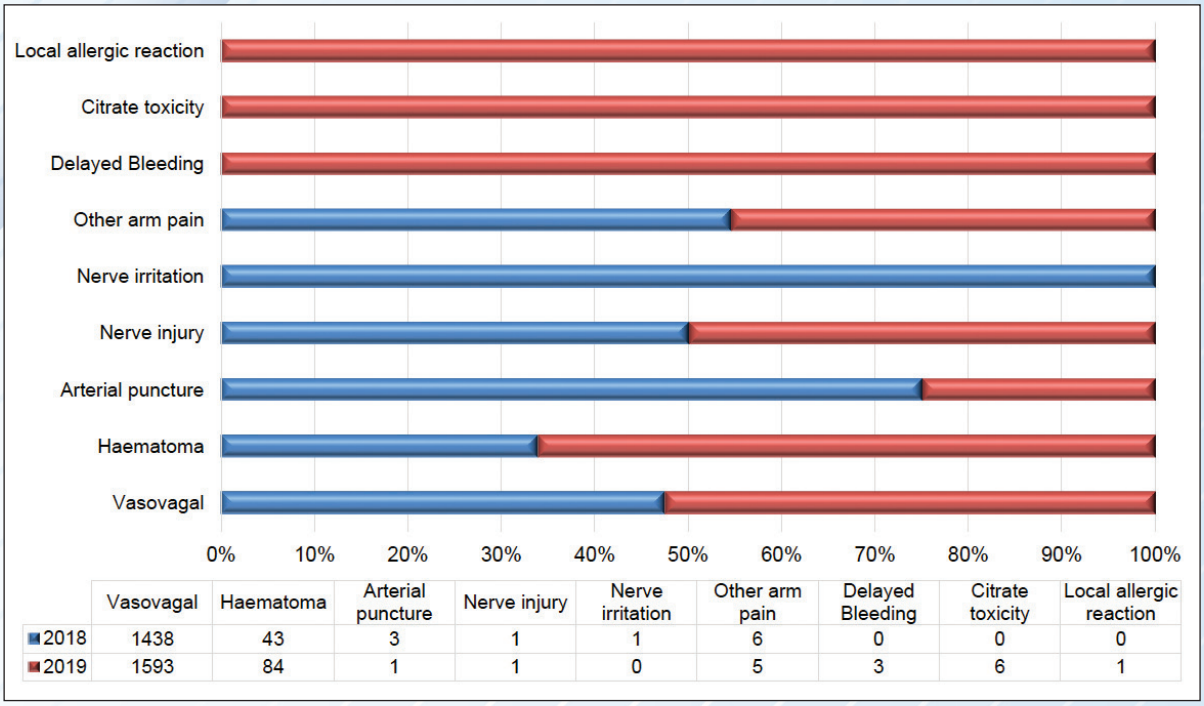
In 2018, there were a total of 1491 ADR reported out of 467,776 donations from 23 government blood collection centers while in 2019, there were 1690 ADR reported out of 491,480 donations from 36 government blood collection centers. Hence, the incidence of ADR is 33 in 10,000 for whole blood donations, and 20 in 10,000 apheresis donations.

Year	Total Whole Blood Donation	ADR-Whole Blood	Total Apheresis Donation	ADR-Apheresis
2018	459,598	1,478	8,178	13
2018	481,770	1,668	9,710	22
TOTAL	**941,368**	**3,146**	**17,888**	**35**
Incidence	33 in 10,000 Whole Blood Donations		20 in 10,000 Apheresis Donations	

Table 5.4: Total ADR and Incidence of ADR by Type of Donation

5.5 ADR BY TYPES OF REACTION AND ITS SEVERITY – Figure 5.5a and 5.5b

The incidence of vasovagal reaction was the highest in both reporting years and the second commonest ADR was haematoma. Other types of reactions are rare. There were 6 reported cases of citrate toxicity in 2019 compared to none in 2018.



	Vasovagal	Haematoma	Arterial puncture	Nerve injury	Nerve irritation	Other arm pain	Delayed Bleeding	Citrate toxicity	Local allergic reaction
2018	1438	43	3	1	1	6	0	0	0
2019	1593	84	1	1	0	5	3	6	1

Figure 5.5a: Types of ADR

Citrate toxicity reaction occurred during apheresis blood donation when an infusion of citrate anticoagulant causes a fall in ionized calcium levels, leading to neuromuscular hyperactivity. Apheresis donor may present with numbness and tingling of lips, feeling of vibrations, numbness and tingling of fingers, metallic taste, chills and shivering, light headedness, feeling of tightness, muscle twitching, rapid or slow pulse, shortness of breath - in which if left untreated may lead to tetany and severe cardiac arrhythmias and worst is cardiac arrest.

One of the reported cases of citrate toxicity occurred in apheresis donor, who complained of numbness and tingling over the lips, hands and feet after completing 2 cycles of platelet apheresis donation. He was alert and conscious with stable vital signs. He was encouraged to increase fluid intake and given 2 tablets of Calcium Lactate 500mg stat. His symptoms resolved after 15 minutes. He was then allowed home with daily calcium supplement for a week. His blood results (renal profile, liver function test, serum calcium, magnesium and phosphate) were all within normal range. In the event where symptoms persist and/or increasing in severity, donor should be immediately referred to the nearest hospital for further management.

Most ADR cases are mild reaction and resolve after rest at the donation site while severe reaction was mostly due to severe vasovagal reactions that presented with fitting episodes.

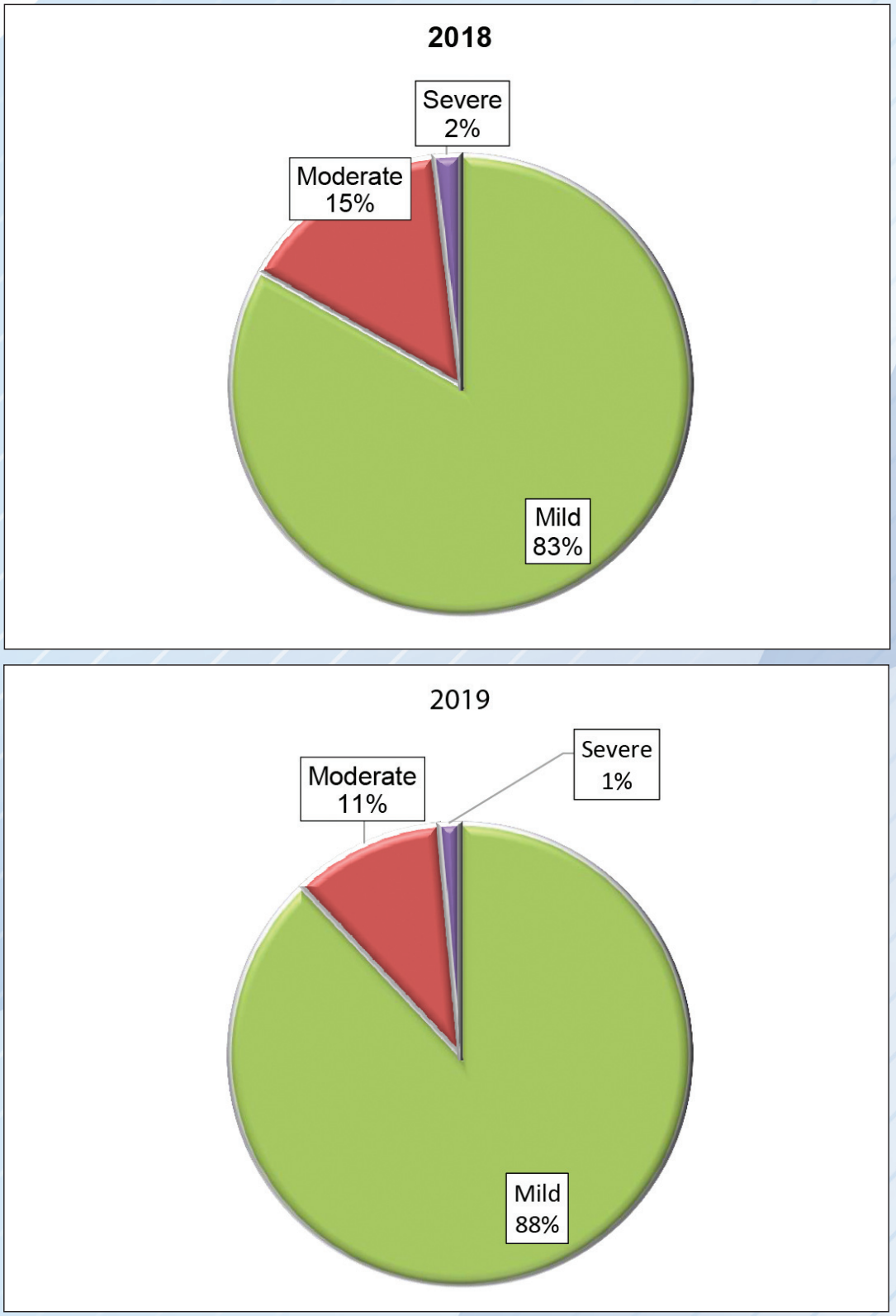


Figure 5.5b: Severity of Reported ADR Cases

5.6 ADR BY DEMOGRAPHIC – GENDER, AGE AND WEIGHT – Figure 5.6a, 5.6b and 5.6c

The incidence of ADR is higher in female donors in view of approximately only one-third of the blood donors is of the female gender.

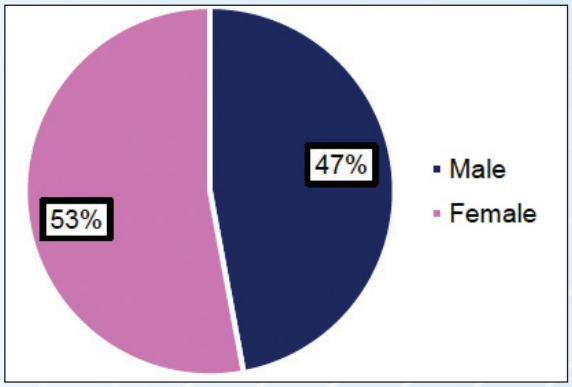


Figure 5.6a: ADR Report Based on Gender

Most donors that experience ADR are from 20-39 years old age group. No ADR reported on donor above 60 years old.

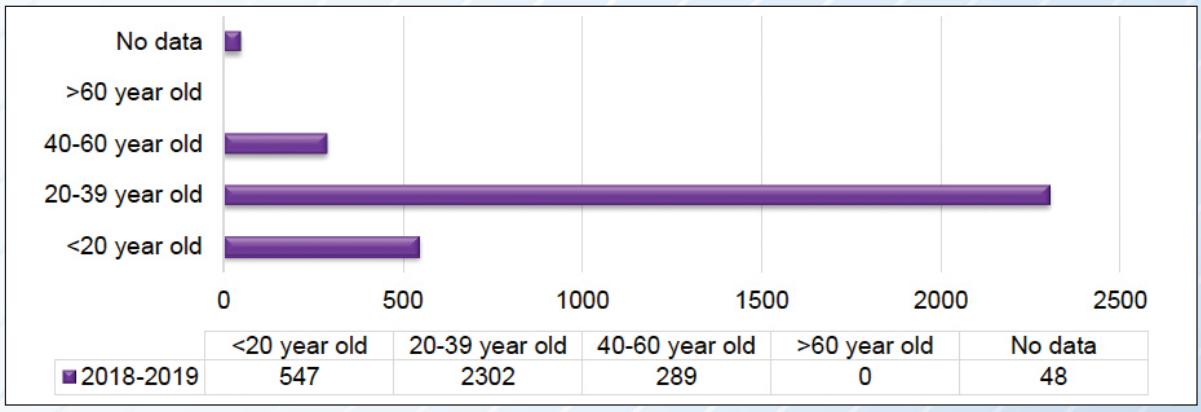


Figure 5.6b: ADR Report Based on Age

Most of the Malaysian blood donors have weight of more than 50kg and they are able to donate more than 350mls of blood. Thus our data demonstrated that the incidence of ADR are higher in these weight range.

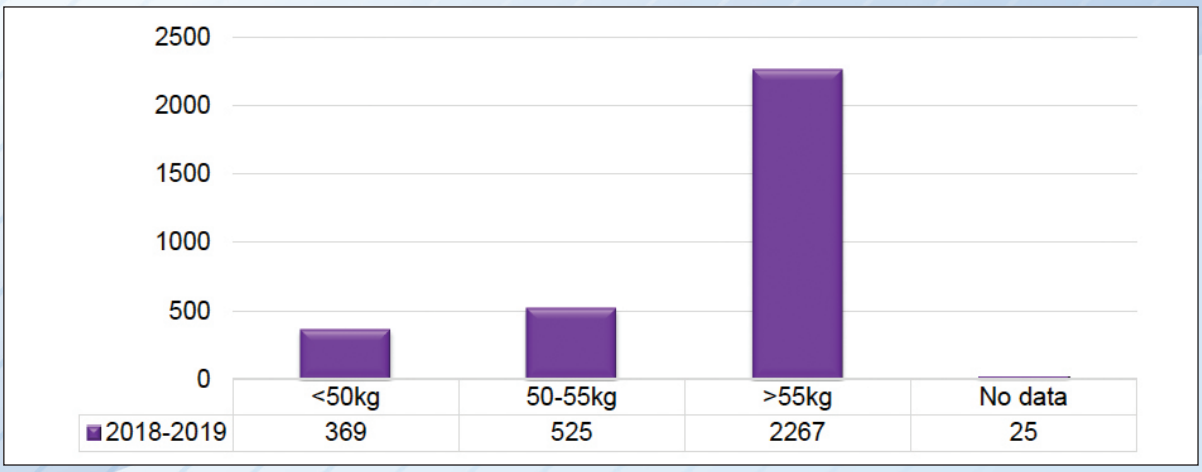


Figure 5.6c: ADR Report based on Weight

5.7 ADR ACCORDING TO FREQUENCY OF DONATION – Figure 5.7

Our data showed the incidence of ADR are higher in new donor as Malaysian blood donor populations consist of one-third new donors.

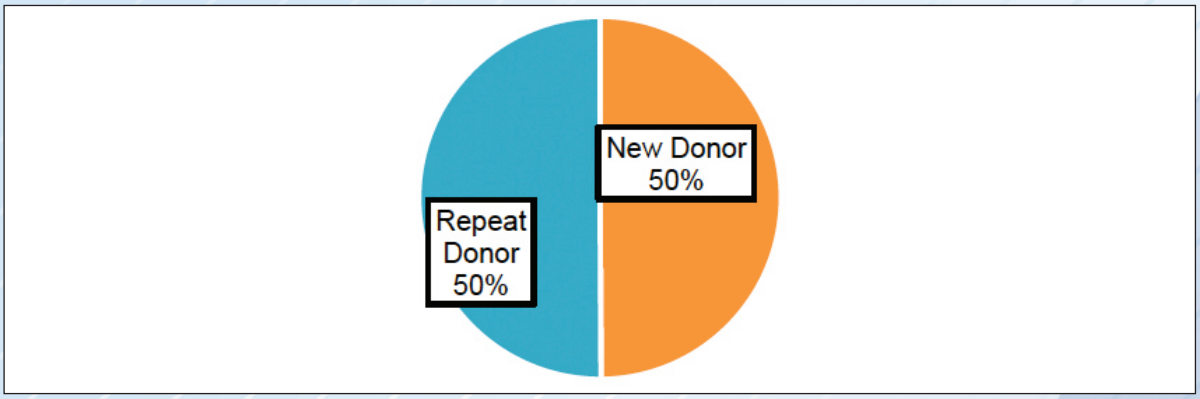


Figure 5.7: ADR Reports Based on Frequency of Donation

5.8 REPEAT DONORS WITH HISTORY OF PREVIOUS ADR – Figure 5.8

Our data showed that 279 (15%) out of 1566 repeat donors with ADR, had experienced ADR in their previous donation(s). Thus, these donors need to be identified during pre-donation counseling where advises such as application of applied muscle tension (AMT) to improve blood flow, adequate fluid intake pre and post donations, taking meals at least 4 hours prior to donation, and adequate sleep prior to donation - can be given to donors so as to reduce the risk of complications related to blood donation. Furthermore, these donors can be prearranged for an extra time to rest post donation.

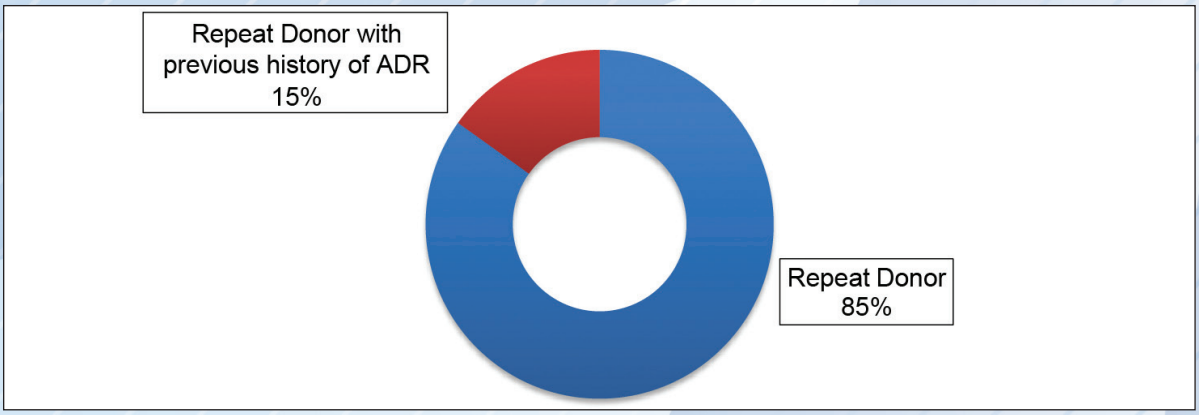


Figure 5.8: Percentage of Repeat Donors with History of Previous ADR

5.9 TERMINATION OF BLOOD DONATION – Table 5.9

Nearly 50% of the ADR happen during blood donation and resulted in termination of the procedure to safeguard the donor.

YEAR	DONATION TERMINATED	PERCENTAGE
2018	699	46.9%
2018	769	45.4%

Table 5.9 Percentage of Termination of Blood Donation

5.10 RECOMMENDATIONS

1. Adverse Donor Reaction (ADR) reporting is crucial in any blood procurement procedure in order to improve the safety of blood collection and to desirably reduce the risks of ADR to a minimum in safeguarding the donors and retention of regular donors.

2. Higher incidence of ADR is seen in first time donor and female donor. Thus preventive measure should be taken to minimise the adverse event in these groups of donor.

3. Donor education brochure with information on the do and don't as well as the donation work process will ease their first time experience.

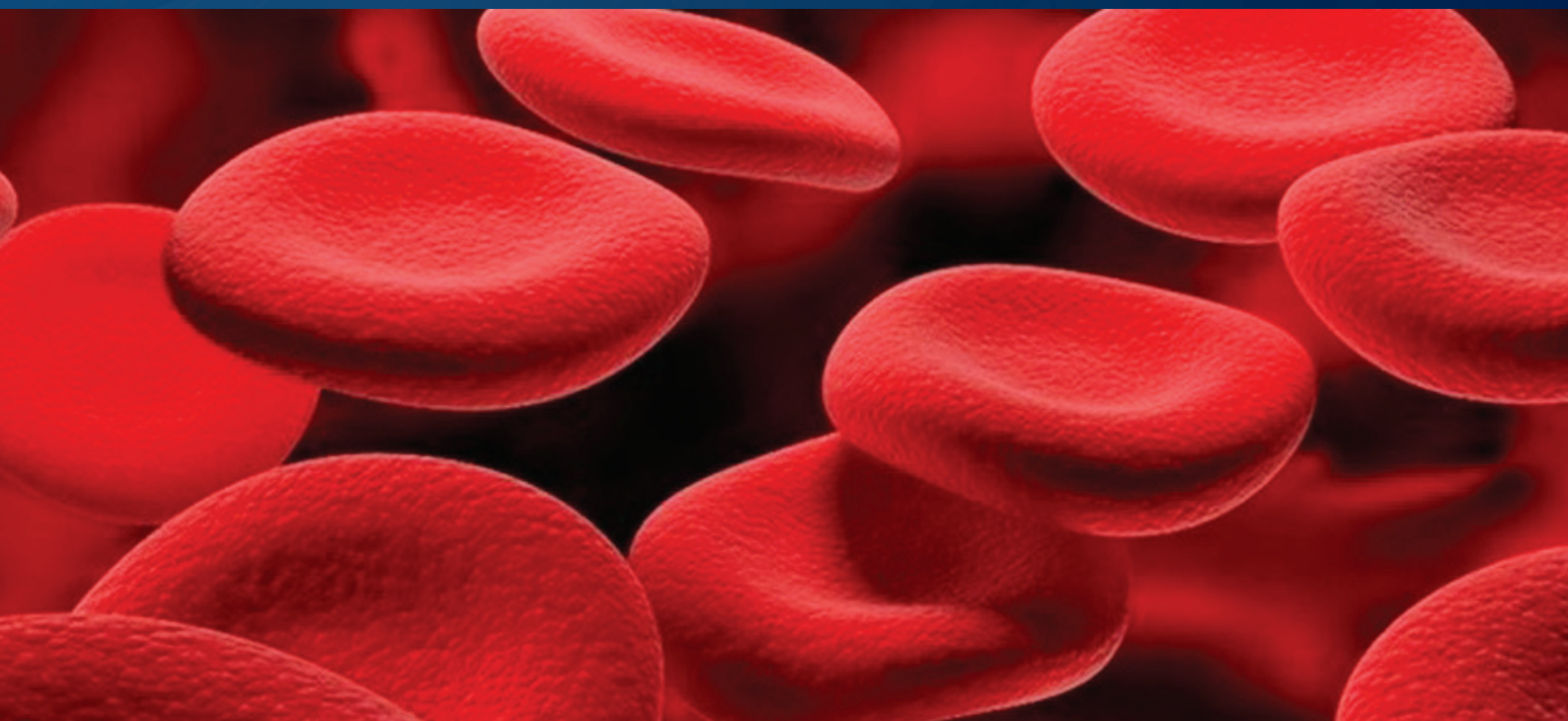
4. Physiological support:
   - Strategies should be deployed to minimise vasovagal reaction such as preventing hypotension. Many studies have shown the benefit of increase hydration 30 minutes prior to donation or eating a salty snack could help to sustain blood pressure during donation. Furthermore donor could be taught and encourage to do an applied muscle tension exercises which involves repeated contraction of major muscle group to increase blood pressure and prevent the occurrence of VVR.

5. Psychological support:
   - Minimise anxiety or fear of needle 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.

6. Donor should be made resting at least 10 minutes after donation for recovery before 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 site can maximise donor care and reduce the chance of adverse reaction.

CHAPTER 6

SEROCONVERT DONOR



6.1 DEFINITION

A seroconvert donor is defined as a donor who is confirmed positive for a particular transmitted infection (TTI) in his current donation but was negative in the previous donation(s).

Seroconverted donors who were positive with transfusion transmitted infections (TTIs) such as human immunodeficiency virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) or Syphilis shall be counseled 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.

6.2 A LOOK BACK AND RECALL PROCEDURE

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.

This procedure is conducted for the last negative donation and donations in the six months period prior to the last negative donation. The unused blood components will be recalled and hospitals that were supplied with the blood components will be informed. 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.

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 eventually increase the patient safety.

6.3 METHOD OF REPORTING

A Seroconvert Donor Notification Form, Part 1 and Part 2 (BTS/SC/1/2016) shall be reported to NHCC. Part 1 consists of donor details, infectious markers implicated and risk factors for acquiring the disease while Part 2 contains the outcome of the investigated blood components.

6.4 PARTICIPATION IN SEROCONVERT DONOR REPORTING – Figure 6.4 and Table 6.4

NHCC observed that more blood collection centres are now participating in seroconvert donor reporting even though the number is still low compared to other reported adverse event. A total of 19 from 113 blood collection centres in Malaysia submitted seroconvert donor reporting in 2019 compared to only 9 centres in 2018. The deficient of reporting limits NHCC ability to analyze the data adequately. This data is important to improve the blood procurement procedure by understanding the donor profiles and enhance the quality and safety of blood transfusion process as a whole.

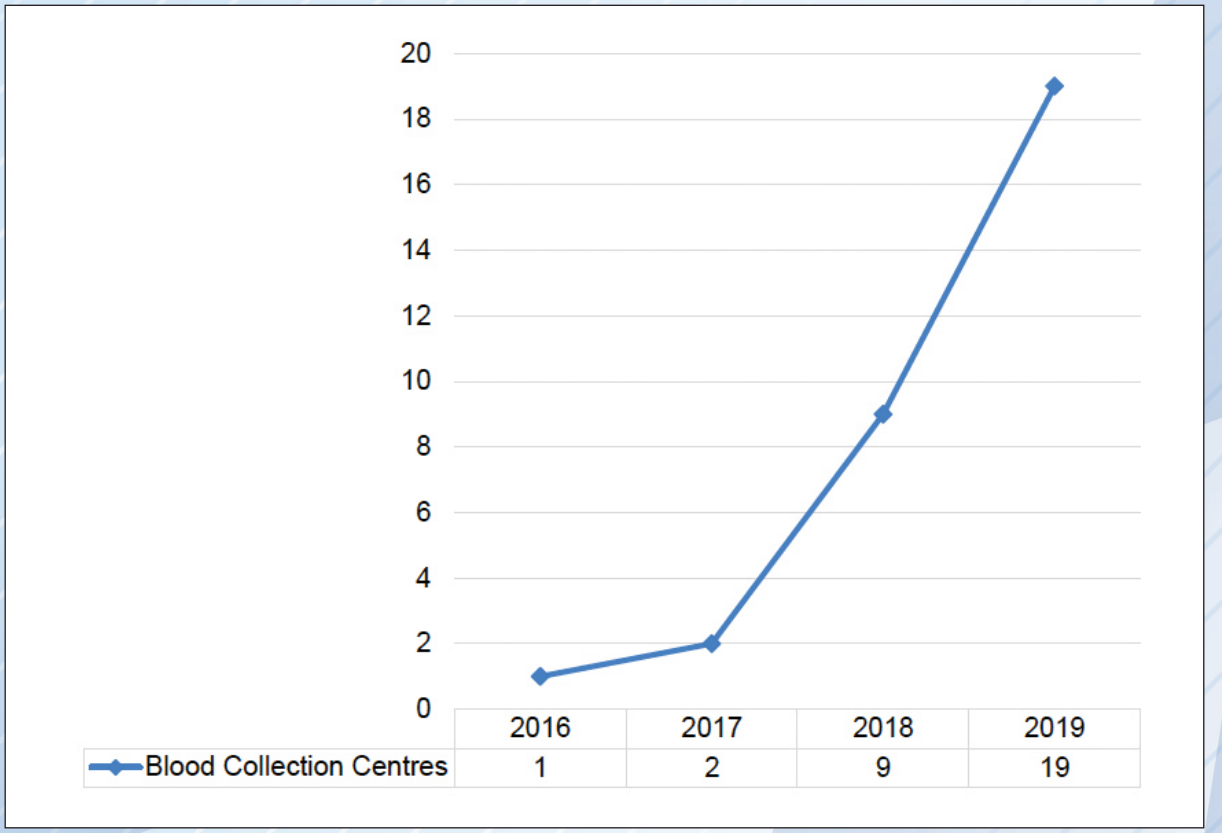


Figure 6.4: Total Number of Blood Bank Participated in Seroconvert Donor Reporting

Table below shows the blood collection centres in Malaysia which participated in the seroconvert donor reporting for the year 2018 and 2019. No Report received (NRR) are blood collection centres that did not submit any report while Not Applicable (NA) indicate that no blood collecting activity done by the respective hospitals.

NHCC would like to emphasis the disclosure of these data as an encouragement to all blood banks to start reporting if never did and/or to maintain reporting in order to improve the quality of blood transfusion service in Malaysia. This data could help blood bank to understand their performance in compliancy to reporting in comparison to other blood bank with similar capacity. All hospitals listed in the tables were arranged according to the state hospital, major/minor or non-specialist hospitals.

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Perlis							
State	Hospital Tuanku Fauziah	0	1	0	1	0	0
Kedah							
State	Hospital Sultanah Bahiyah	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Sultan Abdul Halim, Sg Petani	1	0	0	0	6	1
Major	Hospital Kulim	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Baling	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Jitra	0	0	0	0	0	0
Non Specialist	Hospital Kuala Nerang	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Langkawi	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Sik	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Yan	NRR	NRR	NRR	NRR	NRR	NRR
Terengganu							
State	Hospital Sultanah Nur Zahirah	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Kemaman	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Besut	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Dungun	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Hulu Terengganu	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Setiu	NA	NA	NA	NA	NA	NA

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Kelantan							
State	Hospital Raja Perempuan Zainab II	NRR	NRR	NRR	11	31	13
Major	Hospital Kuala Krai	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Tanah Merah	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Gua Musang	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Jeli	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Machang	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Tengku Anis	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Tumpat	NRR	NRR	NRR	NRR	NRR	NRR
Pulau Pinang							
State	Hospital Pulau Pinang	NRR	NRR	NRR	0	2	1
Major	Hospital Seberang Jaya	2	7	3	0	7	4
Minor	Hospital Bukit Mertajam	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Kepala Batas	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Sungai Bakap	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Balik Pulau	NA	NA	NA	NA	NA	NA

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Pahang							
State	Hospital Tengku Ampuan Afzan	NRR	NRR	NRR	0	2	1
Major	Hospital Sultan Haji Ahmad Shah, Temerloh	NRR	NRR	NRR	0	4	3
Minor	Hospital Kuala Lipis	0	0	0	0	1	0
Minor	Hospital Pekan	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Bentong	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Cameron Highlands	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Jengka	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Muadzam Shah	NA	NA	NA	NA	NA	NA
Non Specialist	Hospital Raub	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Rompin	NA	NA	NA	NA	NA	NA
	Hospital Bahagia Ulu Kinta	NA	NA	NA	NA	NA	NA
Perak							
State	Hospital Raja Permaisuri Bainun	NRR	NRR	NRR	0	1	1
Major	Hospital Taiping	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Teluk Intan	NRR	NRR	NRR	NRR	NRR	NRR

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Minor	Hospital Kuala Kangsar	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Seri Manjung	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Slim River	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Gerik	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Batu Gajah	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Kampar	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Parit Buntar	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Selama	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Sungai Siput	NRR	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Tapah	NRR	NRR	NRR	NRR	NRR	NRR
Selangor							
State	Hospital Tengku Ampuan Rahimah	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Ampang	NA	NA	NA	NA	NA	NA
Major	Hospital Kajang	NA	NA	NA	NA	NA	NA
Major	Hospital Serdang	NA	NA	NA	NA	NA	NA
Major	Hospital Shah Alam	NA	NA	NA	NA	NA	NA
Major	Hospital Sungai Buloh	NA	NA	NA	NA	NA	NA
Minor	Hospital Banting	NRR	NRR	NRR	NRR	NRR	NRR

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Non Specialist	Hospital Kuala Kubu Bharu	NA	NA	NA	NA	NA	NA
Non Specialist	Hospital Orang Asli	NA	NRR	NRR	NRR	NRR	NRR
Non Specialist	Hospital Tanjung Karang	NA	NA	NA	NA	NA	NA
Non Specialist	Hospital Tengku Ampuan Jemaah	NA	NA	NA	NA	NA	NA
WPS Kuala Lumpur							
	Pusat Darah Negara	0	43	16	0	32	34
Minor	Hospital Rehabilitasi Cheras	NA	NA	NA	NA	NA	NA
WPS Labuan							
State	Hospital Labuan	NRR	NRR	NRR	NRR	NRR	NRR
WPS Putrajaya							
Minor	Institut Kanser Negara	NA	NA	NA	NA	NA	NA
Minor	Hospital Putrajaya	NA	NA	NA	NA	NA	NA
Negeri Sembilan							
State	Hospital Tuanku Ja'afar, Seremban	NRR	NRR	NRR	0	7	0
Major	Hospital Tuanku Ampuan Najihah Kuala Pilah	NRR	NRR	NRR	NRR	NRR	NRR

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Minor	Hospital Port Dickson	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Tampin	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Jelebu	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Jempol	NA	NA	NA	NA	NA	NA
Melaka							
State	Hospital Melaka	NRR	NRR	NRR	0	1	0
Non specialist	Hospital Alor Gajah	NA	NA	NA	NA	NA	NA
Non specialist	Hospital Jasin	NRR	NRR	NRR	NRR	NRR	NRR
Johor							
State	Hospital Sultanah Aminah	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Sultan Ismail	0	1	1	1	1	1
Major	Hospital Pakar Sultanah Fatimah, Muar	NRR	NRR	NRR	0	3	0
Major	Hospital Sultanah Nora Ismail	NA	NA	NA	NA	NA	NA
Major	Hospital Segamat	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Kluang	0	1	1	0	2	1
Minor	Hospital Kota Tinggi	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Sarikei	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Mersing	NRR	NRR	NRR	NRR	NRR	NRR

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Non specialist	Hospital Permai	NA	NA	NA	NA	NA	NA
Non specialist	Hospital Pontian	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Tangkak	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Temenggong Seri Maharaja Tun Ibrahim	NRR	NRR	NRR	NRR	NRR	NRR
Sarawak							
State	Hospital Umum Kuching	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Miri	0	4	3	0	7	5
Major	Hospital Sibu	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Bintulu	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Sri Aman	NA	NA	NA	NA	NA	NA
Non specialist	Hospital Marudi	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Rajah Charles Brooke Memorial	NA	NA	NA	NA	NA	NA
Non specialist	Hospital Saratok	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Sentosa	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Serian	NRR	NRR	NRR	NA	NA	NA
Non specialist	Hospital Simunjan	NRR	NRR	NRR	NRR	NRR	NRR

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Sabah							
State	Hospital Queen Elizabeth I	NA	NA	NA	NA	NA	NA
Major	Hospital Queen Elizabeth II	NRR	NRR	NRR	0	23	23
Major	Hospital Duchess of Kent	NRR	NRR	NRR	NRR	NRR	NRR
Major	Hospital Tawau	NRR	NRR	NRR	NRR	NRR	NRR
State	Hospital Beaufort	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Keningau	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Lahad Datu	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Kota Marudu	NRR	NRR	NRR	NRR	NRR	NRR
Minor	Hospital Wanita dan Kanak-Kanak Sabah, Likas	NRR	NA	NA	NA	NA	NA
Non specialist	Hospital Beluran	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Kinabatangan	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Kota Belud	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Kuala Penyu	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Kudat	NRR	NRR	NRR	NA	NA	NA
Non specialist	Hospital Kunak	NRR	NRR	NRR	NRR	NRR	NRR

States	Hospitals	2018			2019		
		Part 1 without first visit	Part 1 with first visit	Part 2	Part 1 without first visit	Part 1 with first visit	Part 2
Non specialist	Hospital Likas	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Mesra Bukit Padang	NA	NA	NA	NA	NA	NA
Non specialist	Hospital Papar	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Pitas	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Semporna	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Sipitang	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Tambunan	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Tenom	NRR	NRR	NRR	NRR	NRR	NRR
Non specialist	Hospital Tuaran	NRR	NRR	NRR	NRR	NRR	NRR
Private Hospital							
	Loh Guan Lye, Penang	NRR	NRR	NRR	NRR	NRR	NRR
University Hospital							
	Hospital Universiti Sains Malaysia	NRR	NRR	NRR	0	2	2

*NRR = No Report Received
*NA = Not applicable (i.e Not a Blood Collection Centres)

Table 6.4: Blood Collection Centres in Malaysia Participated in the Seroconvert Donor Reporting

6.5 SEROCONVERT DONOR REPORTS – Table 6.5

The total number of reports received in 2018 was 84 and increase to 235 in 2019. From these, 60 for part 1 and 24 reports for part 2 in 2018, and 145 and 90 reports in 2019 respectively. These figures show nearly 2.5 times increment of reporting for Part 1 and 4 times increment of reporting for Part 2. However, reports that were sent without first counselling visit was deficient with information on donor risk factor for acquiring the disease. Therefore, total of 16 reports were excluded in the analysis of risk factor. There was also 1 incomplete report for Part 1 as contain no detail of the donor's specific TTI; hence this was also being excluded.

However, these data do not reflect the actual number of seroconvert donor cases in the reporting year due to Part 1 reporting is to be sent after the donor has come to counselling clinic while Part 2 is after completion of the look back and recall procedure.

Table below showed the total number of seroconvert donor reports submitted to NHCC from 2016 to 2019 for Part 1 and Part 2.

Year	PART 1		Part 2	Total
	No First Counselling Visit	With First Counselling Visit		
2016	-	19	19	38
2017	-	46	3	49
2018	3	57	24	84
2019	13	*132	90	235

*1 out of 132 cases has no specific TTI mentioned in the Part 1 report.

Table 6.5: Total Number of Seroconvert Donor Reporting

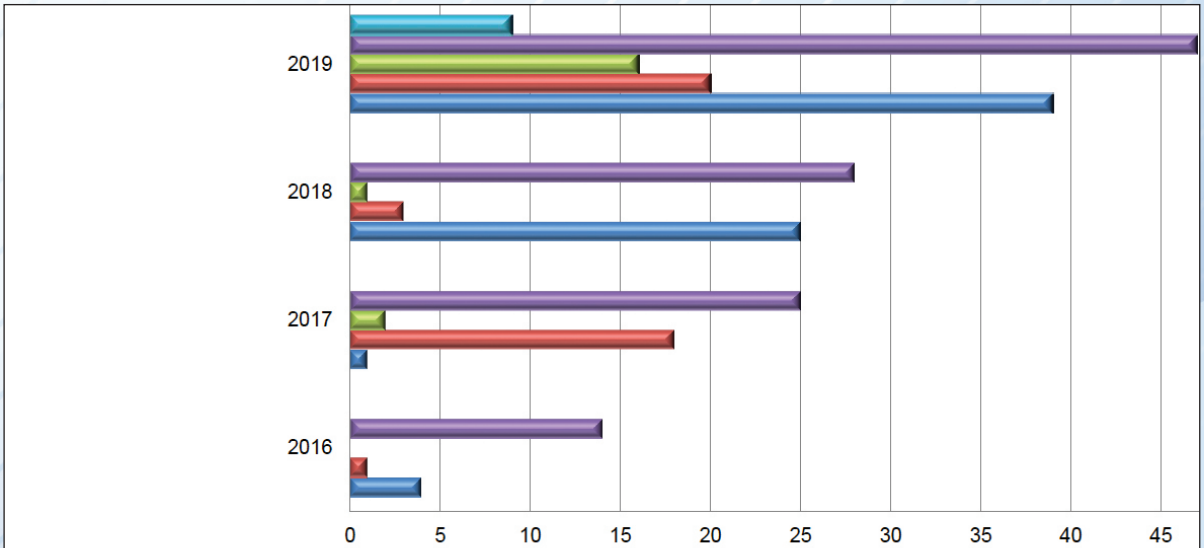
6.6 TRANSFUSION TRANSMITTED INFECTIONS (TTIs) – Figure 6.6 and Table 6.6

Multiple precautionary actions and measures had been implemented in the blood banking services including promoting voluntary non-remunerated donors, retention of repeat donors, self-deferral measures, strict donor selection and advanced laboratory screening for viral markers for TTIs, in order to obtain a safer donor and reduce risk of infection to the patient via blood transfusion. In 2019, more than 90% of blood donations in Malaysia were screened using Nucleic Acid Amplification Technique (NAT). NAT screening able to reduce the window period of the infection by detecting the presence of antigen at the early stage of infection thus make the blood much safer.

According to WHO recommendations, screening of all blood donations should be mandatory for 4 types of TTIs including HIV, Hepatitis B, Hepatitis C and Syphilis, to ensure the transfusion is as safe as possible and to reduce the risk of transmission to very low levels. Application of NAT screening as mentioned helps to increase detection rate of TTIs during their immunological window period - a time between infection and viral seropositivity detected by screening test, on top of our regular serological screening (antigen-antibody) test for HIV, HBV, HCV and Syphilis.

In addition, the integration of blood bank data through BBIS version 2 systems across 22 state/ major hospitals nationwide since 2019 would further increase blood safety. We anticipated that by sharing the donor's database, more donors might be detected as seroconverted and led to initiation of a look back procedure. By having the sharing system, the traceability of blood and blood products from donors to recipients and vice versa (bi-directional tracking) will be significantly improved.

The demographic characteristic of TTI among blood donors is crucial to formulating control strategies and preventing TTI. This will be explained in each section of the infection. From the report received, Syphilis accounts for the highest seroconversion cases followed by HIV, HBV and the least are HCV as shown in the graph below.



	2016	2017	2018	2019
HIV & SYPHILIS COINFECTION	0	0	0	9
SYPHILIS	14	25	28	47
HEPATITIS C	0	2	1	16
HEPATITIS B	1	18	3	20
HIV	4	1	25	39

Figure 6.6: Total number of seroconvert donor report based on TTIs

Table below shows the distribution of demographic data of the seroconvert donors based on TTI. Some of the data was incomplete or missing, hence they were not included in the analysis.

Variables	2018 (N = 57)				2019 (N = 132)				
	HIV (N=25)	Hep B (N=3)	Hep C (N=1)	Syphilis (N=28)	HIV (N=39)	Hep B (N=20)	Hep C (N=16)	Syphilis (N=47)	HIV & Syphilis coinfection (N=9)
Age (years)									
• <20	-	-	-	-	-	-	-	-	-
• 20 to 39	21	1	1	19	33-	9	8	30	8
• 40 to 60	4	2	-	9	5	10	7	13	1
• >60	-	-	-	-	-	1	-	1	-
• No data	-	-	-	-	1	-	1	3	-
Gender									
• Males	24	2	1	24	37	16	13	42	9
• Females	1	1	-	4	2	4	3	5	-
Number of previous donations									
• <5	15	1	-	18	23	11	11	23	8
• to 10	7	1	-	5	9	1	2	11	1
• >10	2	1	1	4	4	6	1	7	-
• No data	1	-		1	3	2	2	6	-
Risk factors									
• High risk behaviours	19	-	-	9	20	2	2	27	7
• Body piercing/tattoo/ acupuncture/cupping	1	-	-	1	2	-	3	2	1
• Hx of blood transfusions	1	-	-	-	2	-	-	1	-
• IV Drug Use	1	-	-	-	-	-	2	-	-
• Deny risk factors	2	2	1	15	10	11	1	12	-
• Others	2	1	-	3	-	7	2	2	-
• No data	-	-	-	-	5	-	6	3	1

Table 6.6: Demographic distribution of seroconvert donors based on TTIs

6.6.1 HIV – Figure 6.6.1a and 6.6.1b

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).

Figure 6.6.1a showed the demographic distribution of HIV seroconversion reported to NHCC based on different age, gender, number of previous donations and their risk factors. It was observed that most HIV seroconvert donors were in the age group of 20 to 39 years old, which account for more than 85% of the cases for both years. This could be due to most blood donations made by this age group in Malaysia. Male donors were more predominantly to acquire HIV compared to their counterpart. This could be due to higher involvement rate in high risk behaviors/activities which may expose them to HIV infection. Donors with history of less than 5 times blood donation are the group with highest HIV seroconversion rate.

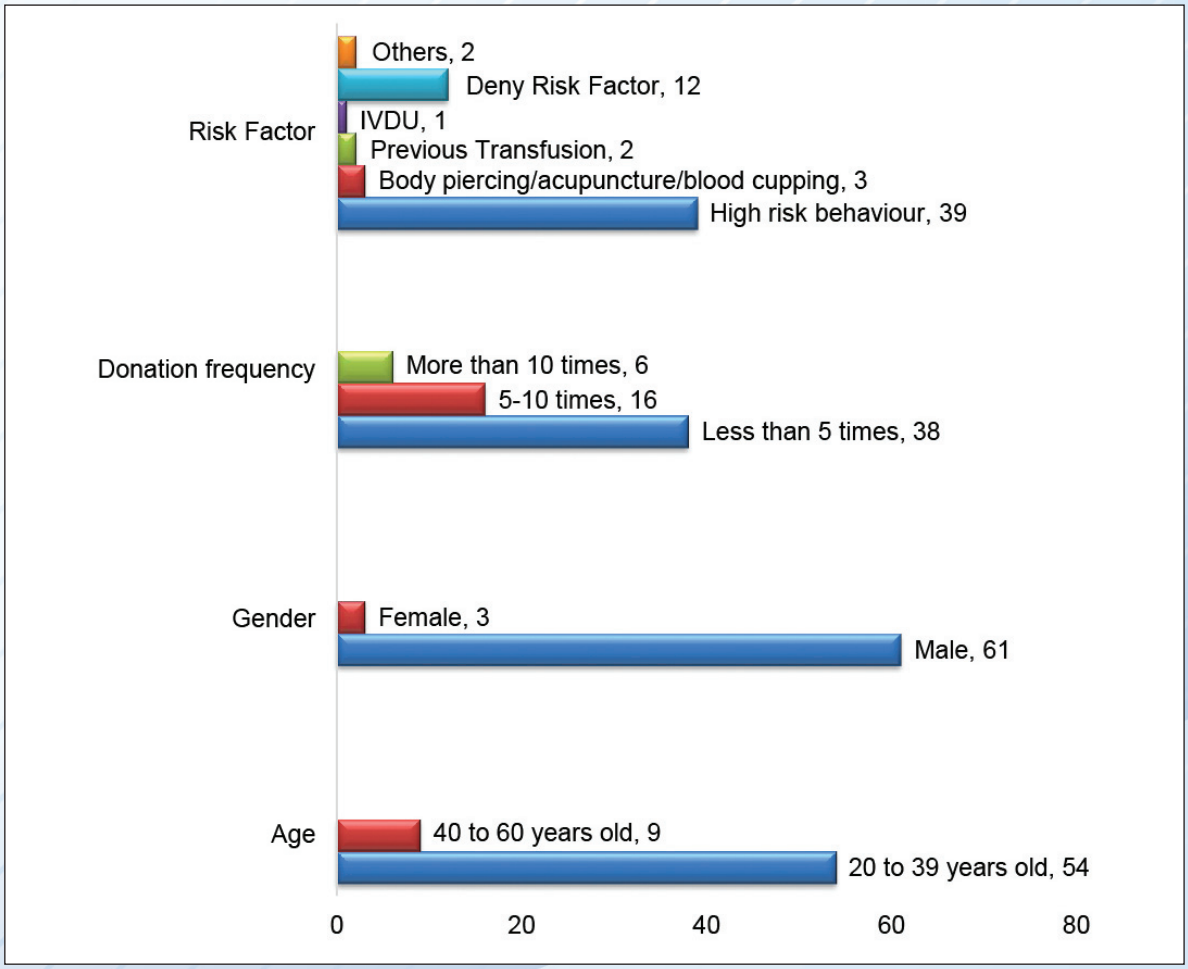


Figure 6.6.1a: Demographic distribution of HIV seroconversion for both 2018 and 2019

High risk sexual behavior remains the main risk factor for donors to acquire HIV with total of 39 cases for both years. Pie chart below (Figure 6.6.1b) shows the distribution of their high-risk behaviors in detail. Men who have sex with men (MSM) and multiple sexual partners (MSP) account for the majority of high-risk behavior for HIV infection amongst donors, with 17 and 18 cases respectively. One donor admitted to have a bisexual risk behavior and the other 3 were engaging with sex workers. There was one donor who husband has pass away due to HIV and the other has history of sexual intercourse with girlfriend. Both of these cases were categorized as others.

There was one donor admitted to have history of intravenous drug used (IVDU) in the past while 3 donors gave history of either body piercing/acupuncture/blood cupping.

Twelve HIV seroconvert donors had denied any risk factor while 2 donors had history of blood transfusions in the past. One of these donors had received transfusions more than 20 years ago while the other no date of transfusion was mentioned in the report. In both of the cases, the outcome of the look back and recall were inconclusive as the transfusion record were no longer available.

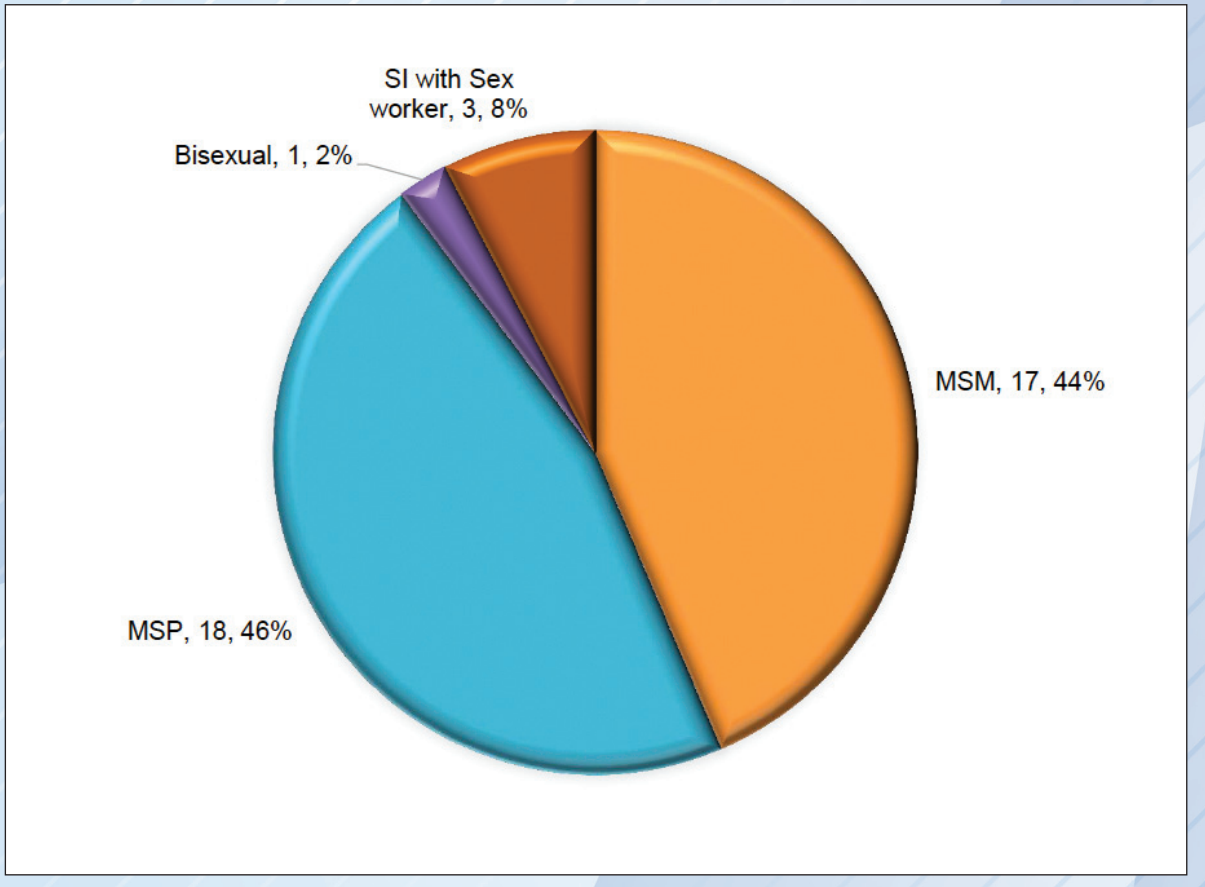


Figure 6.6.1b: Distribution of risk factors for high risk behaviors in HIV seroconvert donors for both 2018 and 2019

6.6.2 HIV WITH SYPHILIS COINFECTION – Figure 6.6.2

HIV and syphilis co-infection are indeed dangerous combinations. Study shows it is associated with sexual practice particularly among the MSM population and those with HIV infection. In fact, syphilis infection significantly increases susceptibility to HIV infection. And HIV itself can alter the clinical course of syphilis, increase the likelihood of relapse and confound the diagnosis of neurosyphilis. Individuals infected with these infections can have severe complications later in life.

There were nine cases of seroconverted donors reported to have co-infection of HIV with Syphilis in 2019, as compared to no cases from 2016-2018. All of them were of male gender and 87% of them had high risk behaviours as their risk factor. Furthermore, repeat donors with history of less than 5 donations in the past and of considerably young age group of 20 to 39 years old were predominant.

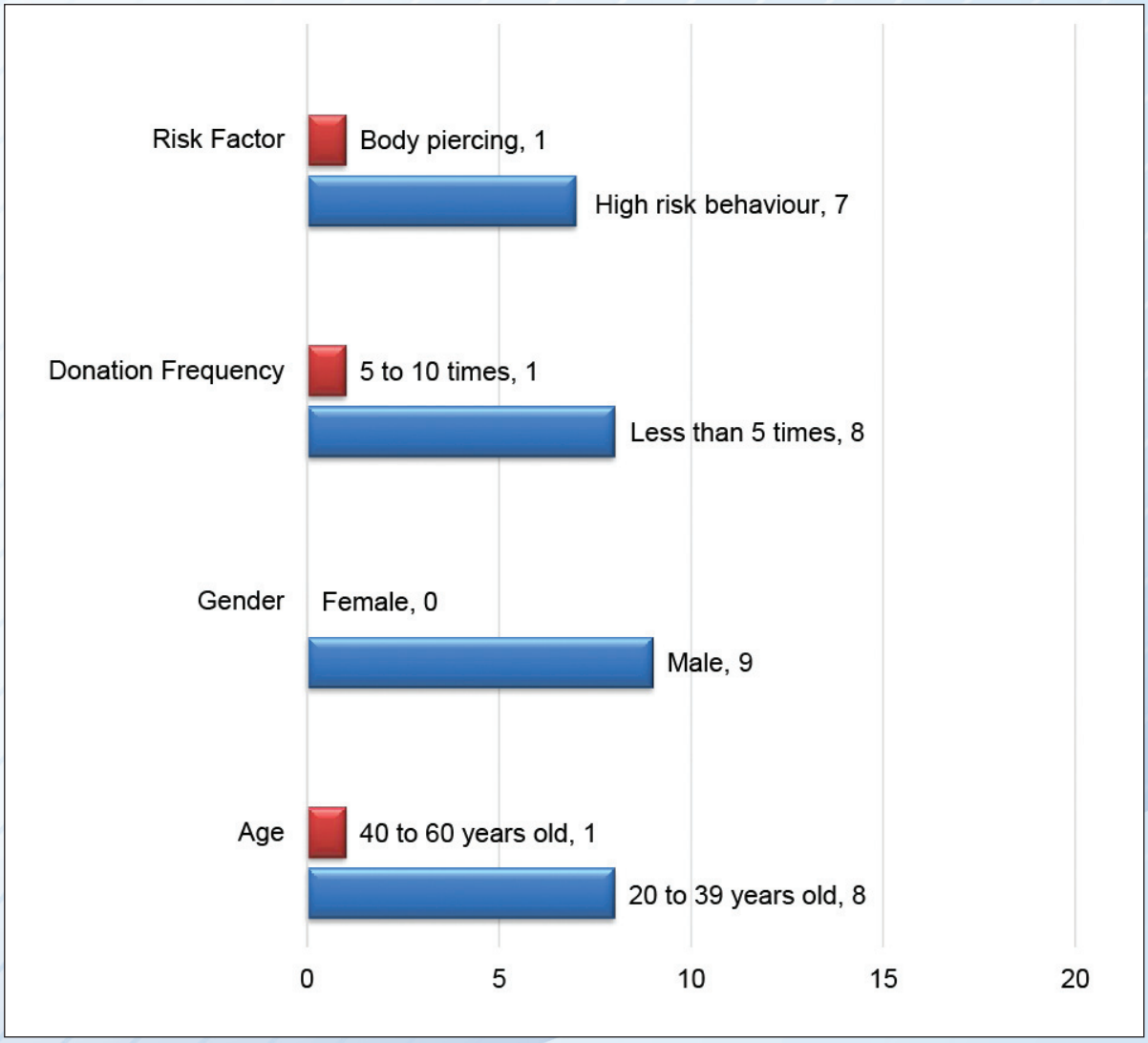


Figure 6.6.2: Demographic distribution of HIV with Syphilis co-infection seroconversion for both 2018 and 2019

6.6.3 HEPATITIS B – Figure 6.6.3

Hepatitis B is one of the most common diseases transmitted hematogenously, sexually and also through contact with blood or other body fluids. A person can be acutely infected with it, or it can present as chronic infection in an individual in which they have high risk of developing liver cirrhosis and hepatocellular carcinoma later in life.

The incidence of Hepatitis B seroconversion mostly among male donors with a slightly older age group ranging between 40 to 60 years of age. Quite a number of these donors had donated more than 10 times donation in the past. However, donors with history of less than 5 times donation still accounts for the highest seroconversion rate for Hepatitis B. In regards to their risk factors, only 2 of the donors admitted of having high risk behavior whilst majority of them denied any risk factors when further investigated. The details of the data are shown in the table below.

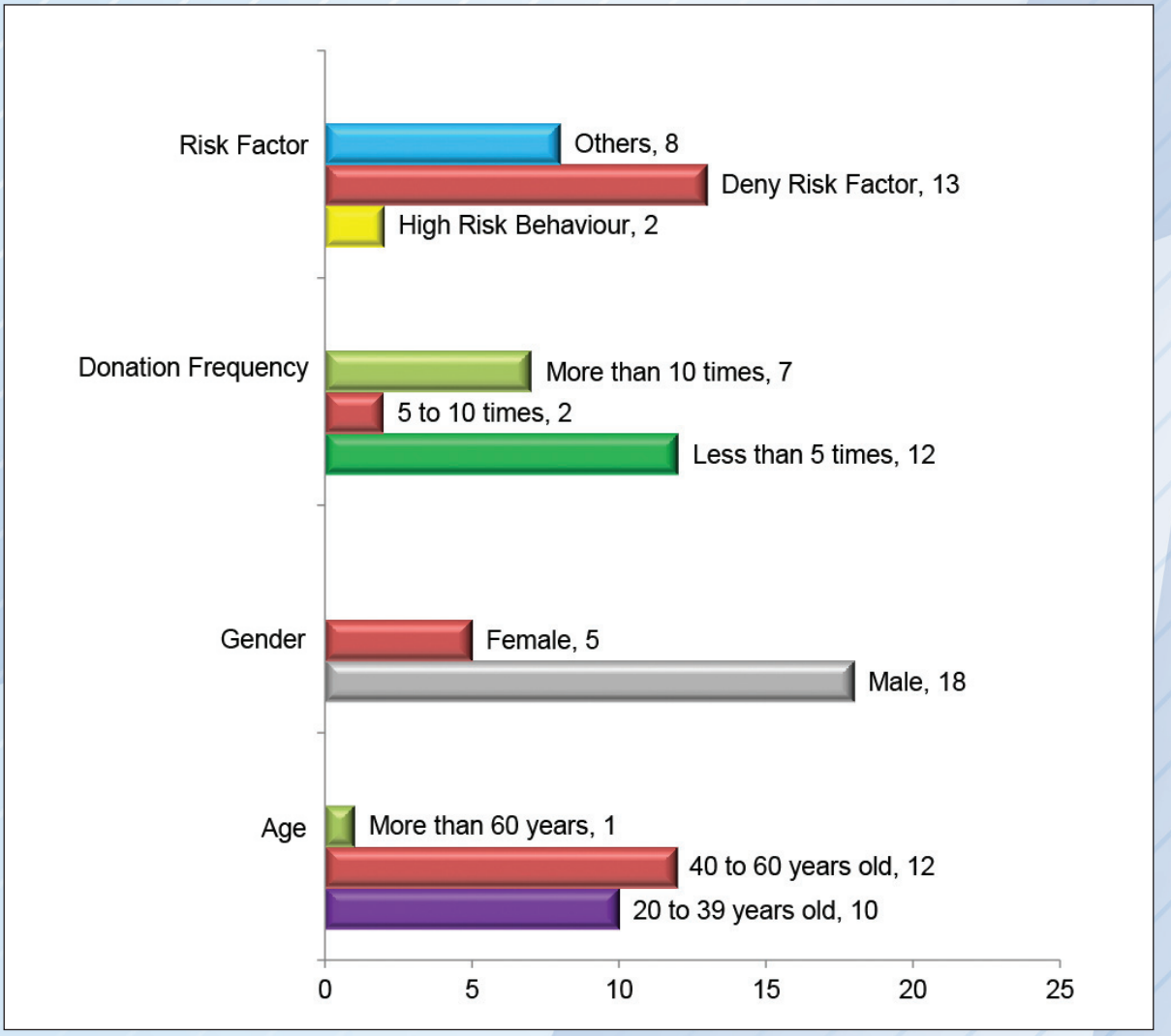


Figure 6.6.3: Demographic distribution of Hepatitis B seroconversion for both 2018 and 2019

6.6.4 HEPATITIS C – Figure 6.6.4

Hepatitis C virus infection is another common chronic blood borne infection with high rate of development of liver cirrhosis and subsequently liver cancer. The most common modes of transmission are through injection drug use, unsafe injection practices, sexual practices that lead to exposure of blood, and transfusion of unsafe blood and blood products. Hepatitis C infection can cause serious mortality and morbidity and thus is one of the major global health problems.

The reported cases for hepatitis C has increase from 1 case in 2018 to 16 cases in 2019. Most of the HCV seroconverted donors were found amongst the male gender with the main age range of 20 to 39 years of age. This was followed by the age group of 40 to 60 years old with 7 cases. Hepatitis C was predominantly detected in the repeat donors with less than 5 times donation history which accounts for 73% of the cases. Variety of risk factors was found in these seroconverted Hepatitis C donors. History of cupping and tattoo accounts for the highest number of risk factor. This was followed by high risk behaviors including multiple sexual partners, history of IV drug use and others (i.e. exposure to sharp injury when working as garbage collector).

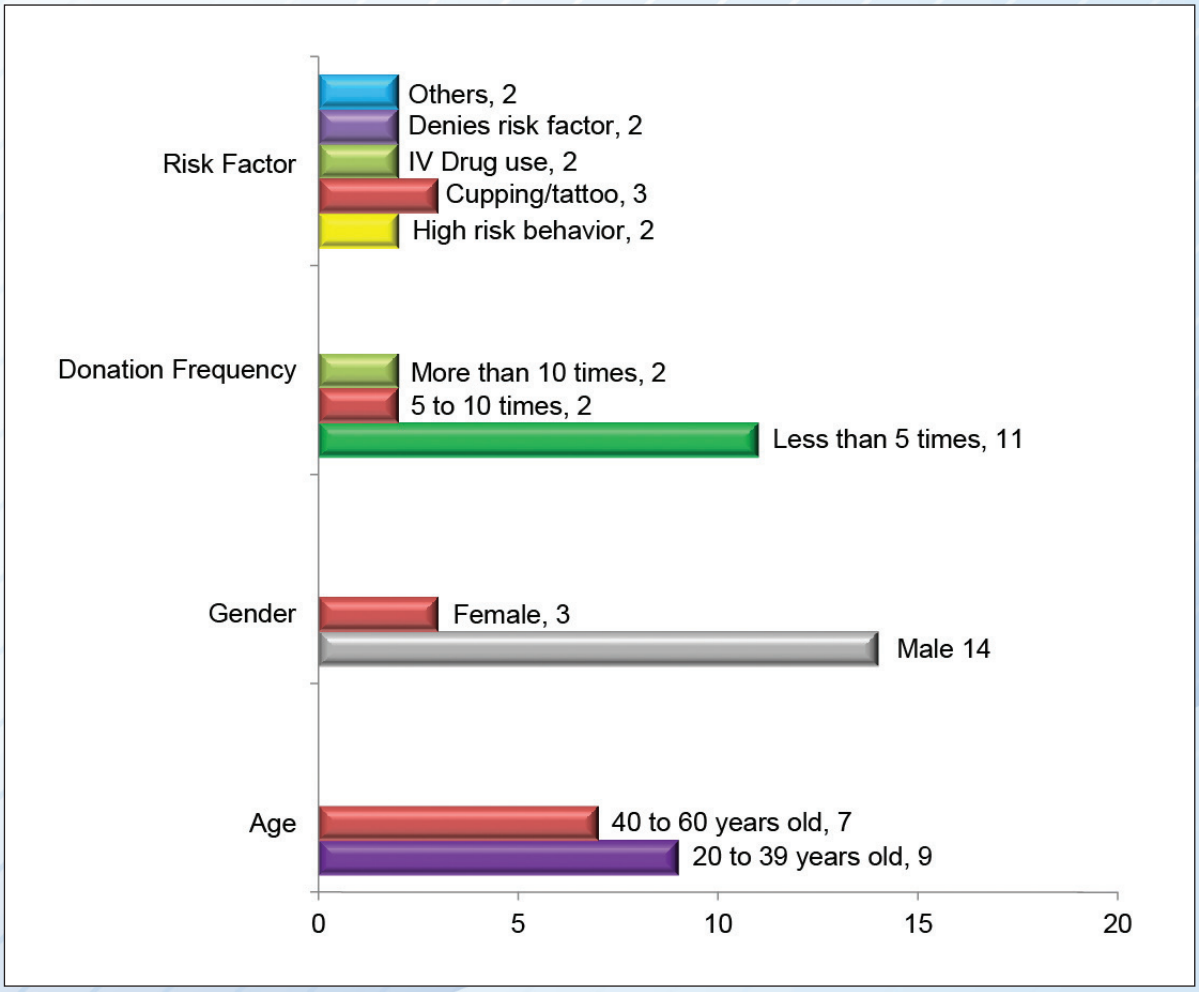


Figure 6.6.4: Demographic distribution of Hepatitis C seroconversion for both 2018 and 2019

6.6.5 SYPHILIS – Figure 6.6.5

Syphilis is a disease caused by bacteria *Treponema pallidum*. It is a systemic disease which predominantly spread by direct contact with a syphilitic sore (known as chancre) and sexual contact, although other modes of transmission including blood transfusion and vertical transmission have been reported. According to Centers for Disease Control and Prevention (CDC), the majority of primary and secondary syphilis occurred among gay, bisexual and MSM group. Some people may have latent syphilis in which they are asymptomatic and may spread the infection to others without knowing it.

Based on figure 6.6.5, Syphilis accounts for the highest and increasing seroconversion rate among other infections. There were 47 seroconversion syphilis cases in 2019, an increment of ~1.7 folds from 28 cases in 2018. Majority of them were in the age group of 20 to 39 years old (75%) and 89% of the donors were male. It was observed that they were among repeat donors with less than 5 times donations in the past. Fifty percent of these syphilis seroconvert donors had high risk behavior including having multiple sexual partners and MSM, which is usually the main mode of transmission for syphilis. However, 27 out of 72 donors denied any risk factors.

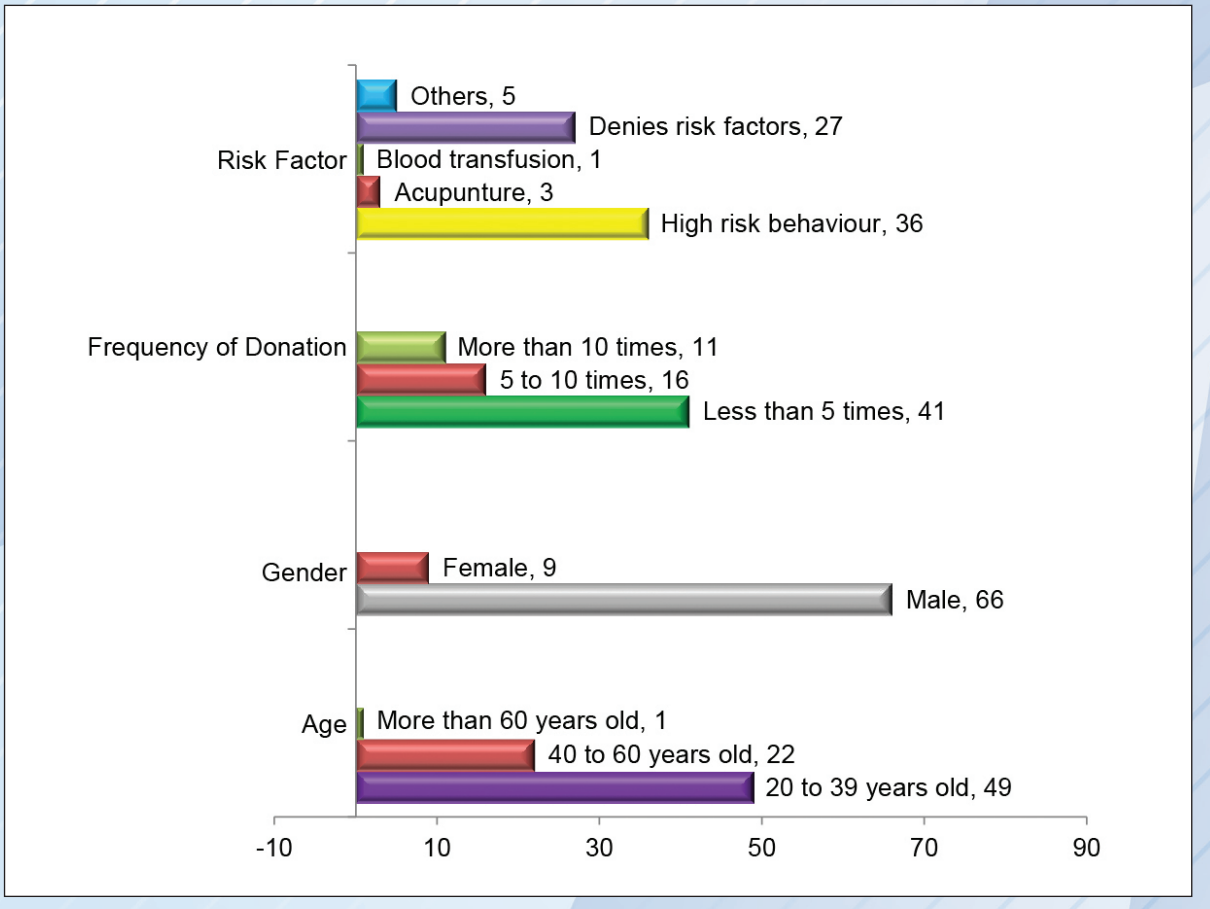


Figure 6.6.5: Demographic distribution of Syphilis seroconversion for both 2018 and 2019

6.7 OUTCOME OF THE LOOK BACK AND RECALL PROCEDURE – Table 6.7

Following seroconversion of repeat donors, look back investigations were done on all blood components from those donations - on recognition of a risk of transmitting infection from a donor to a recipient during window period.

This involves identification of all blood components prepared from those donation, documentation of the fate of blood components, notification of hospital transfusion laboratories in receipt of involved blood components and details on any identified recipients including whether they were tested reactive/non-reactive for that particular TTIs.

Table below shows total number of blood products from seroconverted donors and their outcomes, including recipient infection status. This will be further discussed below according to each TTIs.

A total of 74 recipients had no data on their infection status for both 2018 and 2019. This could be due to incomplete investigation done by the respective reporting hospitals, before it was being submitted to NHCC. Most reports were submitted to NHCC whilst the investigations were still ongoing.

TTIs	2018						
	Outcome of Blood Products			Outcome of Recipients			
	Total of blood products	Transfused	Stored at < 6'C for more than 72 hours	Non-reactive (NR)	Reactive (R)	Patient deceased	No data
HIV	27	17	N/a	3	-	7	7
Hepatitis B	-	-	-	-	-	-	-
Hepatitis C	2	2	N/a	-	-	2	-
Syphilis	39	8	16	1	-	5	2
HIV & Syphilis Coinfection	-	-	-	-	-	-	-
TTIs	**2019**						
	Outcome of Blood Products			Outcome of Recipients			
	Total of blood products	Transfused	Stored at < 6'C for more than 72 hours	Non-reactive (NR)	Reactive (R)	Patient deceased	No data
HIV	71	55	N/a	24	-	11	20
Hepatitis B	26	16	N/a	3	-	2	11
Hepatitis C	6	5	N/a	-	-	4	1
Syphilis	108	46	33	8	-	7	29
HIV & Syphilis Coinfection	16	10	-	2	1	3	4

Table 6.7: Data on the Outcome of Blood Products for Each TTIs and Its Recipients

6.7.1 HIV – Figure 6.7.1

Based on the graph below, there were total of 98 blood products were look back from a HIV seroconvert donor for both 2018 and 2019. Seventy-two of the blood products were transfused to patients. Out of the 72 transfused products, 27 patients were tested non-reactive for HIV whilst 18 of the recipients already deceased, in which no further investigation was done by the reporting hospitals. Twenty-seven reports submitted were incomplete.

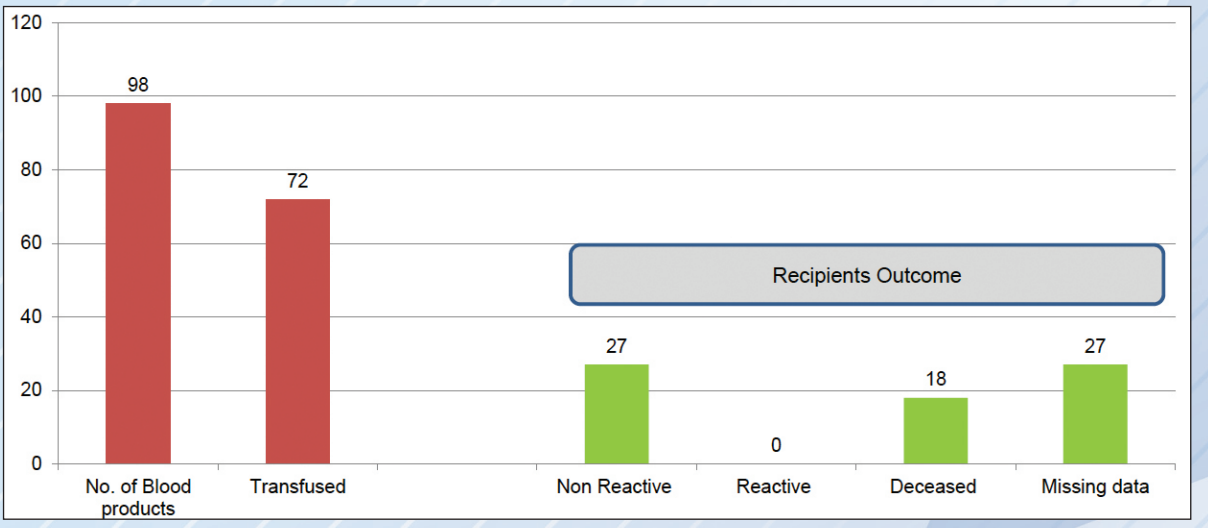


Figure 6.7.1: Outcome of Blood Products of HIV Seroconvert Donor and Its Recipient for 2018 – 2019

6.7.2 HIV WITH SYPHILIS CO-INFECTION – Figure 6.7.2

The graph below showed a total of 16 blood products were issued and 10 of them were transfused to patients. Out of the 10 recipients, two recipients were non-reactive while one recipient was tested reactive for syphilis only after a look back procedure was done. However, another recipient of the blood products from that particular donor was tested negative for HIV and syphilis, while another recipient had deceased. Hence, seroconvert committee of the hospital conclude that the case was unlikely due to blood transfusion. Recipient's risk factor could have contributed to syphilis infection.

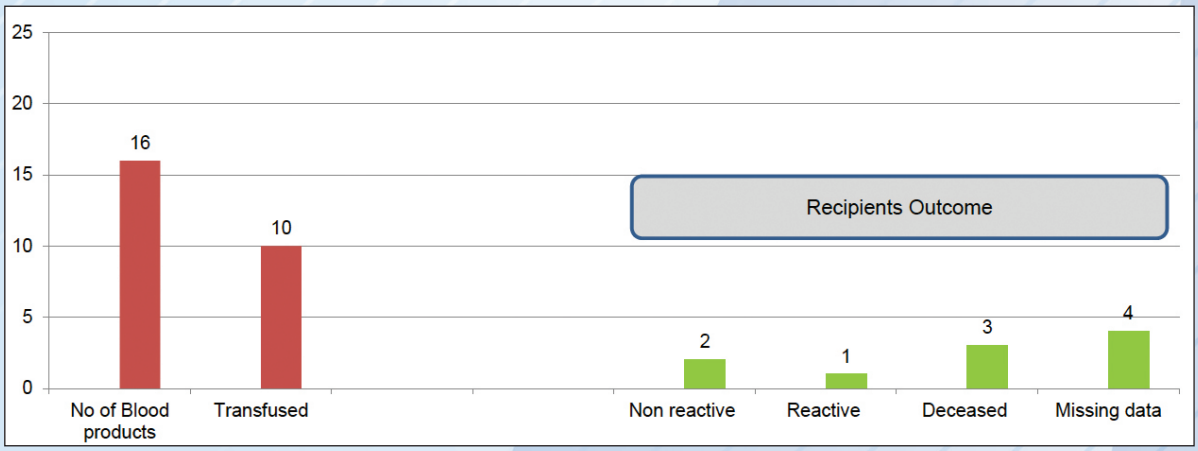


Figure 6.7.2: Outcome of Blood Products of HIV-Syphilis Coinfection Seroconvert Donor and Its Recipient for 2018 – 2019

6.7.3 HEPATITIS B – Figure 6.7.3

There was a total of 26 blood products were look back and recall in 2019 and none reported in 2018. Out of these figure, 16 blood products were transfused to patients. Three recipients were screened non-reactive whilst 2 recipients had deceased. There was a total of 11 incomplete reports received.

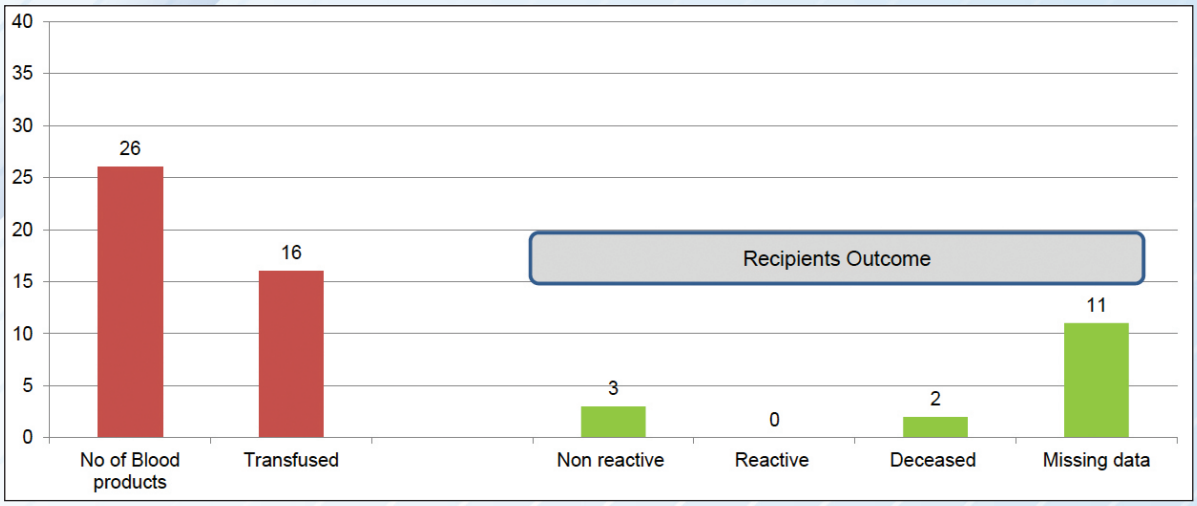


Figure 6.7.3: Outcome of Blood Products of Hepatitis B Seroconvert Donor and Its Recipient for 2018 – 2019

6.7.4 HEPATITIS C – Figure 6.7.4

Hepatitis C had the least reported outcomes of the blood products and its recipients, compared to other infections. Of 8 blood products from seroconvert donors, 7 products were successfully transfused to patients. From those 7 patients who received the transfusion, 6 were already deceased upon the look back procedure was carried out, whilst 1 recipient had unknown infection status in which the case was still under investigation by the respective hospital.

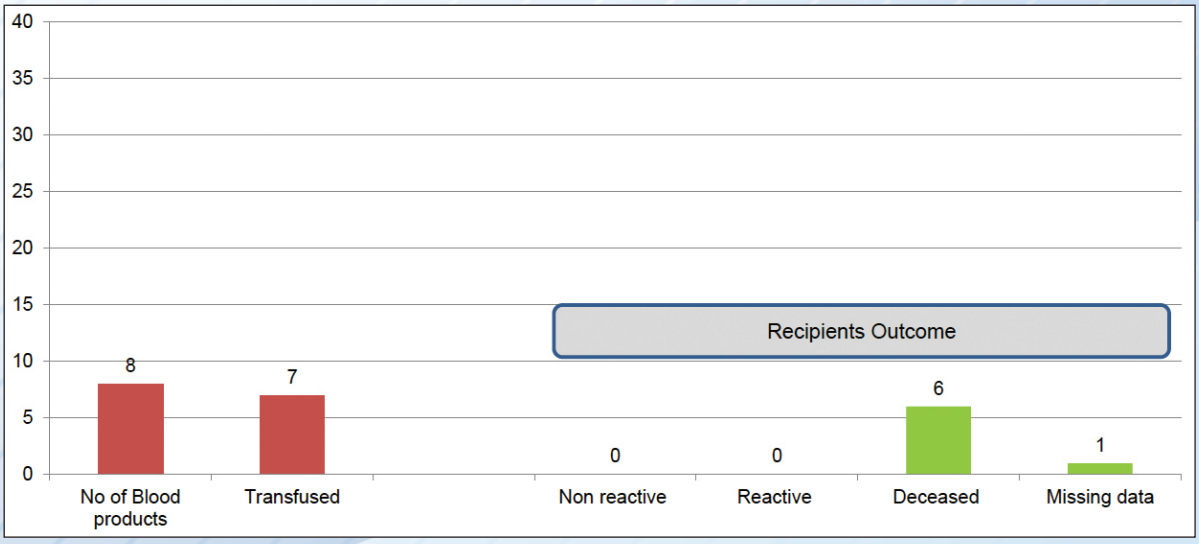


Figure 6.7.4: Outcome of Blood Products of Hepatitis C Seroconvert Donor and Its Recipient for 2018 – 2019

6.7.5 SYPHILIS – Figure 6.7.5

Syphilis has the highest seroconversion rate and has the highest look back and recall done by the respective hospitals. However, many published researches concluded the survival time of *Treponema pallidum* in banked donor blood lies between 72 - 120 hours and furthermore their survival time could also depend on the number of treponemes initially present in the donor blood. Thus, a look back and recall was not performed for blood product transfused at least after 3 days of storage in cold temperature.

A total of 147 blood products were look back and recall and 54 blood products were transfused. Forty-nine blood products were stored in fridge either 2-6-degree Celsius or stored at -30 degree Celsius for more than 72 hours. Out of 54 recipients who received the blood products, 9 recipients were tested non-reactive whilst 12 recipients already passed away. There were still quite a lot of recipients with unknown infection status in regards to Syphilis, due to incomplete reports submitted to NHCC.

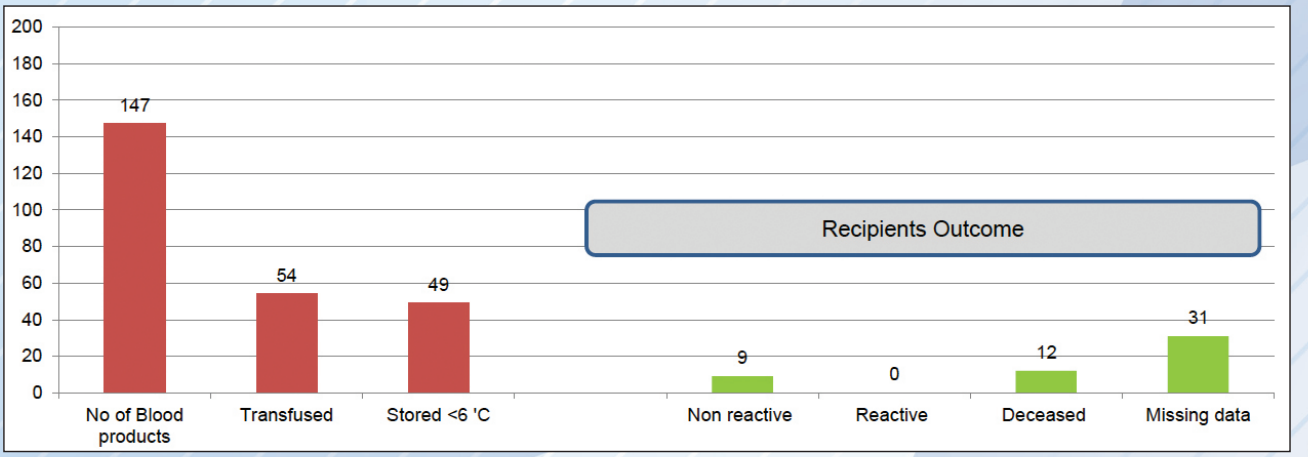


Figure 6.7.5: Outcome of Blood Products of Syphilis Seroconvert Donor and Its Recipient for 2018 – 2019

6.8 RECOMMENDATIONS

1. Educational program for donors to increase their knowledge and their level of awareness regarding TTI risk before blood donation, high risk behaviors and lifestyle that might contribute to the seropositivity of the donors, and the importance of safe sex practices.

2. Regular blood donors should be informed regarding the free Hepatitis B vaccine services provided by the blood collection center.

3. Promotion of transparency and honesty among repeated donors during counseling, self-deferral measures, and reassurance of information confidentiality should be emphasized and enhanced during blood procurement procedure.

4. Medical personnel involved in the blood procurement procedure shall be more vigilance in certain group of repeated donors, to ensure strict selection of safe donor being practiced.

5. To enforce NHCC submission of seroconvert donor reporting as per transfusion guidelines.

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