NATIONAL HAEMOVIGILANCE COORDINATING CENTRE,
PUSAT DARAH NEGARA

HAEMOVIGILANCE REPORT 2016-2017

NATIONAL TRANSFUSION MEDICINE SERVICE IN MALAYSIA

www.pdn.gov.my

NATIONAL HAEMOVIGILANCE COORDINATING CENTRE,
PUSAT DARAH NEGARA

HAEMOVIGILANCE REPORT 2016-2017

NATIONAL TRANSFUSION MEDICINE SERVICE IN MALAYSIA

Pusat Darah Negara
Ministry of Health Malaysia

January 2019

Haemovigilance Report
2016 – 2017
National Transfusion Medicine Service in Malaysia

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

Foreword

First and foremost, I wish to acknowledge all hospitals who have submitted the haemovigilance reports and I also would like to convey my heartiest congratulations to the Director of Pusat Darah Negara and the Haemovigilance Working Group for their perseverance to produce the first Haemovigilance Report 2016-2017 for National Transfusion Medicine Service in Malaysia.

The ultimate goal of haemovigilance is to achieve a quality improvement of the transfusion chain through corrective and preventive actions. With this it will improve donor and patient safety, improve transfusion appropriateness, and reduce wastage in the transfusion service. Thus I am pleased to see the effort to analyse and turn the data on patient and donor into information and information into insight, to be used in formulating corrective and preventive measures.

I hope this report will be a useful guide to all stakeholder in the transfusion chain in ensuring the best patient and donor care.

Dato' Dr Haji Bahari bin Dato' Tok Muda Hj. Che Awang Ngah
Director
Medical Development Division
Ministry of Health Malaysia

Preface

The Haemovigilance Report 2016-2017 is a reference for all doctors, nurses and various health care providers of hospitals in the country not only to provide adequate but safe blood. The aim of this report is to identify and to prevent occurrence or recurrence of undesirable events and is crucial in order to improve safety, efficacy and efficiency in every step of blood transfusion chain.

The number of reports received over the two years although were encouraging but we hope for more participation from other institutions, private and district hospitals in the future. These reports will help to create more awareness and to be more vigilant in order to provide safe blood in transfusion service. The input from reports received from various hospitals in this annual report will benefit doctors to identify and manage adverse transfusion events.

Special acknowledgement to all contributors, Haemovigilance Working Group for the excellent effort, cooperation and inputs as well as to the Medical Development Division, Ministry of Health Malaysia for their continuous support. I hope this report will be a useful guide to all our customers in ensuring best patient care.

Dr Noryati Abu Amin
Director
Pusat Darah Negara
Kuala Lumpur

Editorial Group for Haemovigilance Report

Advisor	:	**Dr Noryati Abu Amin** Senior Consultant Transfusion Medicine Director
Chairperson	:	**Dr Idaleswati bt Nor Mohamed** Transfusion Medicine Specialist Head of Division, National Surveillance and Assessment
Members	:	**Dr Thayani a/p Sivamsabu** Senior Medical Officer Head of Section, NHCC
		Dr Nurul Farhana bt Iberahim Medical Officer Head of Unit, Patient Haemovigilance, NHCC
		Dr Nur Izzati bt Izhar Medical Officer Head of Unit, Donor Haemovigilance, NHCC
		Dr Noor Azeeha bt Enunar Medical Officer
		Dr Nurdiana bt Basharuddin Medical Officer
		Dr Sudarcini a/p Arumugam Medical Officer
		Dr Farahin bt Amat Tamiyes Medical Officer
		Pn Shahratulhashima bt Rashid Medical Laboratory Technologist

Executive Summary

Introduction

The National Haemovigilance Programme in Malaysia is coordinated by the National Haemovigilance Coordinating Centre (NHCC), Pusat Darah Negara. Haemovigilance is an important tool to improve the effective and appropriate management of blood and blood products, and to ensure the safety of patient and blood donor. This is the first published haemovigilance report for National Transfusion Medicine Service in Malaysia since it was initiated in 2003. This report particularly is compiled from data gathered between January 2016 until December 2017. There are two major components that are covered in hemovigilance which are patient hemovigilance and donor hemovigilance.

Haemovigilance reporting and hospital participation

Transfusion related adverse events, adverse donor reaction and seroconvert donor must be reported to NHCC. The voluntary reporting by the hospital and passive data collection by NHCC showed a reduction in the number of the participating hospital from 135 in 2016 to 102 hospitals in 2017. However, the number of reports received has increased from 4913 to 5073 respectively.

Patient Haemovigilance:

Adverse Transfusion Reaction (ATR)

The incidence of ATR reported was 1 in 100 patients. Red blood cell was the most common blood component transfused (60%) and implicated in 75% of the ATR. The most often reported ATR for both years were febrile non haemolytic transfusion reaction (FNHTR) and mild allergic transfusion reaction which comprised about 40% each. The third most common cause was an unclassifiable complication of transfusion. Evaluation on cost-effectiveness of routine use of leukoreduced blood component is recommended to reduce the risk of ATR.

The incidence of moderate allergic reaction, transfusion associated dyspnoea (TAD) and transfusion associated fluid overload (TACO) were less than 2%. The incidence of transfusion related acute lung injury (TRALI), delayed haemolytic transfusion reaction (DHTR) and non-immune haemolytic transfusion reaction was infrequent.

There was one reported case of HIV-transfusion transmitted infection during this period. This transfusion dependent patient contracted HIV from a regular donor whose blood was tested negative for a serological screening test to detect antibodies/antigens on Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Syphilis.

Majority of patients with ATR had recovered with no ill effects while less than 0.2% reported as recovered but with morbidity. There was no reported death related to transfusion. However, almost half of the reports received in 2016 did not state the patient's outcome of ATR and reduce to 13% in 2017.

Near Miss

The total number of near miss reported was 260 in 2016 and reduced to 219 in 2017. Majority of hospital personnel involved in near miss were house officers (80%). Approximately 85% of near miss reported was due to ward error caused by failure to correctly identify the patients. Blood bank error contributed to 10% of the case and almost half of these was due to a technical error during blood testing. About 5% of near miss cases, the cause of error could not be determined.

Incorrect Blood Component Transfused (IBCT)

While near miss lead to no harm to a patient, the incorrect blood component transfused (IBCT) can contribute to severe morbidity and even mortality. Total number of IBCT reported were 38 in 2016 and reduced to 35 in 2017. Thus, the incidence of IBCT was about 1 per 10,000 recipients. Blood bank error showed a rise from 19 to 20 cases while ward error showed a reduction from 19 to 15 cases in 2016 and 2017 respectively.

Blood issued meant for another patient was the commonest cause of error in the blood bank. Active checking by two person during issuing of blood could prevent this error.

Technical error during blood testing was the second most common cause of the error. Continuous training to MLT as well as monitoring of adherence to a standard operating procedure (SOP) is crucial. On the other hand, there were 5 cases of a transcription error in 2016 and no case reported in 2017.

IBCT in the ward was due to a pre-transfusion error during blood sampling and/or labeling and failure of the patient's identification at bedside resulted in wrong blood being transfused to the patient. These errors were due to patient misidentification

despite manual positive patient identification have been advocated. There are technologies which can improve patient identification, for example, utilizing biometric identification to identify patient accurately. However further study is needed to prove the interoperability across multiple clinical systems and the cost-effectiveness of usage.

An adequate number of personnel and resources are essential in preventing errors in ward or blood bank with a higher number of workload.

Approximately 60% of patients with IBCT had recovered with no ill effects. Eight cases reported with recovery but required an extended length of stay. Although nine deaths were recorded for both years, 7 were not related to transfusion while 2 were probably related to transfusion.

Other incidents related to the transfusion process

These were cases of a patient's actual blood group in the current admission was discrepant with the patient's historical record in the blood bank, and further investigation has rule out near miss incidence. There were 110 cases in 2016 and increase to 186 cases reported in 2017. Thus patient historical record should always be checked to confirm the patient's blood grouping. However historical record should not be considered valid until repeat testing with a fresh sample for confirmation is done.

Donor Haemovigilance:

Adverse Donor Reaction (ADR)

Although the requirement to report ADR was stated in the Transfusion Practice Guidelines for Clinical and Laboratory Personnel, the number of blood collection centers reported was less than 7% in 2016 and increase to 14% in 2017.

ADR happen mostly in whole blood donor (>95%) and the most common reaction was a vasovagal reaction (VVR) followed by haematoma. Other causes of ADR include vein collapse, compartment syndrome, nerve irritation, and nerve injury.

Most ADR that occurred were mild reactions (85%) while the incidence of a severe reaction was approximately 1%. Among the severe reaction reported were compartment syndrome and severe vasovagal reaction with loss of consciousness and fitting.

Seroconvert Donor (SD)

There were clearly underreporting of SD cases as only 1 centre in 2016 and 2 centres reported in 2017. In 2016, there were 19 SD cases reported and increased to 46 in 2017. None of the recipients were positive with the implicated infection in both years.

Seroconversion was found to be higher in male, whole blood donors with age ranging from 20-29 years old and donated less than 5 times. More than half of these donors were seroconversion for syphilis.

Conclusion

Haemovigilance programme is essential to identify critical areas for action and monitor the implementation of corrective actions. Increasing awareness of haemovigilance among health personnel and training on reporting transfusion reactions would likely improve spontaneous reporting and help to strengthen the blood transfusion system. Ultimately the success of haemovigilance system requires coordination and collaboration among all stakeholders involves in the transfusion chain.

Table of Contents

Figures

Tables

Abbreviations (A to Z)

1.	ATR	Adverse Transfusion Reaction	21.	PC	Packed Cell
2.	ADR	Adverse Donor Reaction	22.	PHG	Pahang
3.	CPPT	Cryoprecipitate	23.	PLS	Perlis
4.	CSUP	Cryosupernatant	24.	PLT	Platelet
5.	DHTR	Delayed Haemolytic Transfusion Reaction	25.	PNG	Pulau Pinang
6.	FFP	Fresh Frozen Plasma	26.	PRK	Perak
7.	FNHTR	Febrile Non Haemolytic Transfusion Reaction	27.	SBH	Sabah
8.	HBV	Hepatitis B Virus	28.	SD	Seroconvert Donors
9.	HCV	Hepatitis C Virus	29.	SGR	Selangor
10.	HIV	Human Immunodeficiency Virus	30.	SWK	Sarawak
11.	IBCT	Incorrect Blood Component Transfused	31.	TACO	Transfusion Associated Circulatory Overload
12.	IPK	Institut Perubatan Khas	32.	TAD	Transfusion Associated Dyspnoea
13.	JHR	Johor	33.	TRALI	Transfusion Related Acute Lung Injury
14.	KDH	Kedah	34.	TRG	Terengganu
15.	KTN	Kelantan	35.	TTI	Transfusion Transmittable Infection
16.	MLK	Melaka	36.	UNI	Universiti
17.	MOH	Ministry Of Health	37.	VVR	Vasovagal reaction
18.	NHCC	National Haemovigilance Coordinating Centre	38.	WB	Whole Blood
19.	NM	Near Miss	39.	WP	Wilayah Persekutuan
20.	NSN	Negeri Sembilan			

Chapter 1

Introduction

1.0 Introduction

"Let the eye of vigilance never be closed"

1.1 NATIONAL HAEMOVIGILANCE COORDINATING CENTRE

National Haemovigilance Coordinating Centre (NHCC) is currently a section under National Surveillance and Assessment Division, Pusat Darah Negara which is responsible for the National Haemovigilance Programme in Malaysia since it was initiated in 2003. Haemovigilance reporting by health service is voluntary. NHCC receives reports from blood banks from all over Malaysia in accordance to Transfusion Practice Guidelines for Clinical and Laboratory Personnel (4th edition 2016) produced by Pusat Darah Negara.

1.2 OBJECTIVES OF HAEMOVIGILANCE PROGRAM IN NATIONAL TRANSFUSION MEDICINE SERVICE, MALAYSIA

Haemovigilance is a surveillance programme includes identification, investigation, reporting, analysis and monitoring of adverse events, near misses and errors related to blood transfusions. The main objective of haemovigilance system is to identify and to prevent occurrence or recurrence of undesirable events. This is achieved by a systematic approach in detection of new risks and quality defects by collecting and analysing the data reported. This is crucial in order to improve safety, efficacy and efficiency of blood transfusion as recommended by the World Health Organisation (*A Guide to establishing a national haemovigilance system WHO 2016*).

1.3 DEFINITION OF HAEMOVIGILANCE

- **The International Haemovigilance Network definition :**

  'A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence'.

  https://ihn-org.com/about/haemovigilance

- **World Health Organization**

  Haemovigilance is required to identify and prevent occurrence or recurrence of transfusion related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient. The system should include monitoring, identification, reporting, investigation and analysis of adverse events near-misses and reactions related to transfusion and manufacturing.

  https://www.who.int/bloodsafety/bts_haemovigilance/en/

1.4 PARTICIPATION IN NHCC REPORTING

In 2016, 135 hospitals across the country have submitted their haemovigilance reports to NHCC. Eight of these hospitals are private hospitals, 2 university hospitals under the Ministry of Higher Education, 1 military hospital under the Ministry of Defense and 1 institute under the Ministry of Finance. This number of participating hospitals has increased from 125 reporting hospitals in 2015. However, in 2017 the number of participating hospitals reduces to 102. Of 102, 3 are university hospitals, 3 institutes and 9 are private hospitals.

In 2016, there was no report received from 38 government hospitals, private hospitals and institution for the whole year. This number has increased to 55 hospitals with no participation in 2017. Of these 55 hospitals, 19 are from Sabah (with total of 22 government hospitals in the state). In other words, only 4 hospitals in Sabah have submitted their reports. On the other hand, as compared to 2016, there is 100% reporting compliance by the private hospitals in 2017.

1.5 HAEMOVIGILANCE REPORTING

Any adverse events and errors related to blood donors and recipients throughout the transfusion chain are reported by the attending doctor to the respective hospital blood bank. The hospital blood bank is responsible to review and verify the reports before sending to NHCC and present the summary of reports during their respective Hospital and State Transfusion Committee Meeting.

Revised reporting forms have been distributed to all participating hospitals in 2016. These include:

- Reporting form for transfusion related adverse Events (BTS/HV/3/2016),
- Reporting form for adverse donor reaction (BTS/DV/2/2016) and
- Seroconvert donor notification form, Part 1 and 2 (BTS/SC/1/2016).

NHCC received the hard copies of these reporting forms mostly through postal mail. However, few hospitals submitted using the outdated reporting forms while others only sent the summary of the transfusion adverse event. Data on these adverse events were reviewed and analysed by NHCC team comprising of medical officers and transfusion medicine specialist. When required, additional information is retrieved from the corresponding hospital blood bank.

Hospital reported to NHCC for 2017 are listed below:

Perlis (PLS)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Tuanku Fauziah Kangar	●				●		

Kedah (KDH)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Sultanah Bahiyah Alor Setar	●				●		
2.	Sultan Abd Halim, Sg Petani		●			●		
3.	Kulim		●				●	
4.	Langkawi			●		●		
5.	Baling				●			✕
6.	Yan				●	●		
7.	Jitra				●	●		
8.	Sik				●	●		
9.	Kuala Nerang				●		●	

Pulau Pinang (PNG)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Pulau Pinang	●				●		
2.	Seberang Jaya		●			●		
3.	Bukit Mertajam			●		●		
4.	Kepala Batas			●		●		
5.	Sg Bakap				●	●		
6.	Balik Pulau				●			✕

Melaka (MLK)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Melaka	●				●		
2.	Alor Gajah				●	●		
3.	Jasin				●	●		

Perak (PRK)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Raja Permaisuri Bainun, Ipoh	●				●		
2.	Taiping		●			●		
3.	Teluk Intan		●			●		
4.	Kuala Kangsar			●				✕
5.	Slim River			●		●		
6.	Seri Manjung			●		●		
7.	Gerik			●		●		
8.	Parit Buntar				●			✕
9.	Batu Gajah				●	●		
10.	Kampar				●			✕
11.	Tapah				●			✕
12.	Selama				●	●		
13.	Changkat Melintang				●			✕
14.	Sungai Siput				●	●		

Selangor (SGR)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Tengku Ampuan Rahimah, Klang	●				●		
2.	Kajang		●			●		
3.	Ampang		●			●		
4.	Selayang		●			●		
5.	Sungai Buloh		●			●		
6.	Serdang		●			●		
7.	Shah Alam		●			●		
8.	Banting			●		●		
9.	Kuala Kubu Baru				●			✕
10.	Tg Karang				●	●		
11.	Tengku Ampuan Jemaah, Sabak Bernam				●	●		
12.	Orang Asli. Gombak				●			✕

Wilayah Persekutuan (WP)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Kuala Lumpur	●				●		
2.	Putrajaya		●					✕
3.	Labuan			●		●		

Negeri Sembilan (NSN)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Tuanku Jaafar, Seremban	●					●	
2.	Tuanku Ampuan Najihah, Kuala Pilah		●				●	
3.	Port Dickson			●			●	
4.	Tampin			●			●	
5.	Jelebu				●		●	
6.	Jempol				●	●		

Johor (JHR)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Sultanah Aminah, Johor Bahru	●				●		
2.	Sultan Ismail, Johor Bahru		●			●		
3.	Sultanah Fatimah, Muar		●			●		
4.	Sultanah Nora Ismail, Batu Pahat		●				●	
5.	Segamat		●				●	
6.	Enche' Besar Hajah Khalsom, Kluang			●		●		
7.	Kota Tinggi			●			●	
8.	Pontian				●	●		
9.	Mersing				●	●		
10.	Tangkak				●	●		
11.	Maharaja Tun Ibrahim, Kulai				●		●	

Pahang (PHG)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Tengku Ampuan Afzan, Kuantan	●						✕
2.	Sultan Haji Ahmad Shah, Temerloh		●			●		
3.	Pekan			●			●	
4.	Bentong			●		●		
5.	Kuala Lipis			●				✕
6.	Raub				●		●	
7.	Jerantut				●		●	
8.	Jengka				●			✕
9.	Muadzam Shah				●		●	
10.	Sultanah Hajjah Kalsom, Cameron Highland				●			✕
11.	Rompin				●			✕

Terengganu (TRG)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Sultanah Nur Zahirah, Kuala Terengganu	●				●		
2.	Kemaman		●					✕
3.	Dungun			●		●		
4.	Besut				●	●		
5.	Hulu Terengganu				●			✕
6.	Setiu				●			✕

Kelantan (KTN)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Raja Perempuan Zainab II, Kota Bahru	●				●		
2.	Kuala Krai		●				●	
3.	Tanah Merah		●					✕
4.	Gua Musang			●				✕
5.	Machang				●		●	
6.	Tumpat				●			✕
7.	Pasir Mas				●			✕
8.	Tengku Anis, Pasir Puteh				●	●		
9.	Jeli				●	●		

Sabah (SBH)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Queen Elizabeth I	●				●		
2.	Queen Elizabeth II		●			●		
3.	Dutchess of Kent, Sandakan		●					✕
4.	Tawau		●			●		
5.	Beaufort			●				✕
6.	Keningau			●				✕
7.	Lahad Datu			●				✕
8.	Kota Marudu			●				✕
9.	Beluran				●			✕
10.	Kota Belud				●			✕
11.	Kudat				●			✕
12.	Papar				●			✕
13.	Ranau				●			✕
14.	Semporna				●			✕
15.	Tambunan				●			✕
16.	Tenom				●			✕
17.	Sipitang				●			✕
18.	Kinabatangan				●			✕
19.	Kuala Penyu				●			✕
20.	Kunak				●			✕
21.	Pitas				●			✕
22.	Tuaran				●	●		

Sarawak (SWK)

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Umum Sarawak	●				●		
2.	Pusat Jantung Sarawak		●			●		
3.	Sibu		●			●		
4.	Miri		●			●		
5.	Bintulu		●					✕
6.	Sri Aman			●		●		
7.	Limbang			●				✕
8.	Sarikei			●				✕
9.	Kapit			●		●		
10.	Mukah			●		●		
11.	Serian				●	●		
12.	Lundu				●	●		
13.	Saratok				●	●		
14.	Kanowit				●	●		
15.	Marudi				●			✕
16.	Lawas				●	●		
17.	Bau				●			✕
18.	Simunjan				●			✕
19.	Betong				●	●		
20.	Daro				●			✕
21.	Rajah Charles Brooke memorial				●			✕
22.	Dalat				●			✕

University Hospital

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Pusat Perubatan HUKM					●		
2.	Pusat Perubatan UM					●		
3.	CTC UiTM					●		

Institut Perubatan Khas

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Hospital Rehabilitasi, Cheras							X
2.	Institut Perubatan Respiratori, KL					●		
3.	Hospital Bahagia, Ulu Kinta							X
4.	Hospital Permai, Tampoi							X
5.	Pusat Kawalan Kusta Negara, Selangor							X
6.	Hospital Mesra Bukit Padang, Sabah							X
7.	Hospital Sentosa, Sarawak							X
8.	Hospital Wanita dan Kanak-Kanak, Likas							X
9.	Institut Jantung Negara						●	
10.	Institut Kanser Negara						●	

Other Hospital

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	Tunku Mizan						●	

Private

No.	Hospital	Hospital Category				Reported with		Unreported
		State	Major	Minor	Non-Specialist	New form	Old form	
1.	KPJ Damai, Sabah					●		
2.	Island Hospital					●		
3.	Tropikal Medical Centre					●		
4.	Sri Kota Specialist					●		
5.	Pusat Rawatan Putra					●		
6.	Sunway Medical					●		
7.	KPJ Sabah					●		
8.	Pantai Ampang					●		
9.	Loh Guan Lye					●		

1.6 LIMITATION

The passive data collection system by NHCC and voluntary reporting requirement by the hospital blood banks predispose to underreporting of adverse event. Outdated reporting forms that were still in used by few hospitals contributed to incomplete data, whereas reporting using the summary of transfusion adverse events limit NHCC ability to analyse the given data.

There were also various ways used by hospital blood banks to send reports to NHCC such as, postal mail, e-mail, fax or porter during transportation of blood. Furthermore, few hospitals address the postal mail to individual name or Pusat Darah Negara in general which could results in failure to reach NHCC.

These factors may contribute to the number of actual errors or adverse events become underreporting and limit the capacity of NHCC from analysing the data with satisfactory validity.

Chapter 2

Patient Haemovigilance

2.0 Overview of Adverse Transfusion Reaction

"How quickly and responsibly we react to adversity is far more important than the adversity itself"

2.1 OVERVIEW OF PATIENT HAEMOVIGILANCE REPORTING – Figure 2.1

Since the beginning of the haemovigilance reporting programme in 2004, the number of reports received in 2017 have increased tremendously to 245.81%. The number of reports received showed a modest increment of 160 (3.26%) in 2017 compared to 2016 with a total number of reports of 5073 and 4913 respectively.This increment implies positive response to voluntary reporting system by the Ministry of Health hospitals, private hospitals and institutions. Haemovigilance reporting is a tool to improve transfusion practice. Thus; these reports contribute to evidence based recommendations aimed at improving quality of the blood transfusion chain, primarily focusing on patient safety and safe transfusion practice.

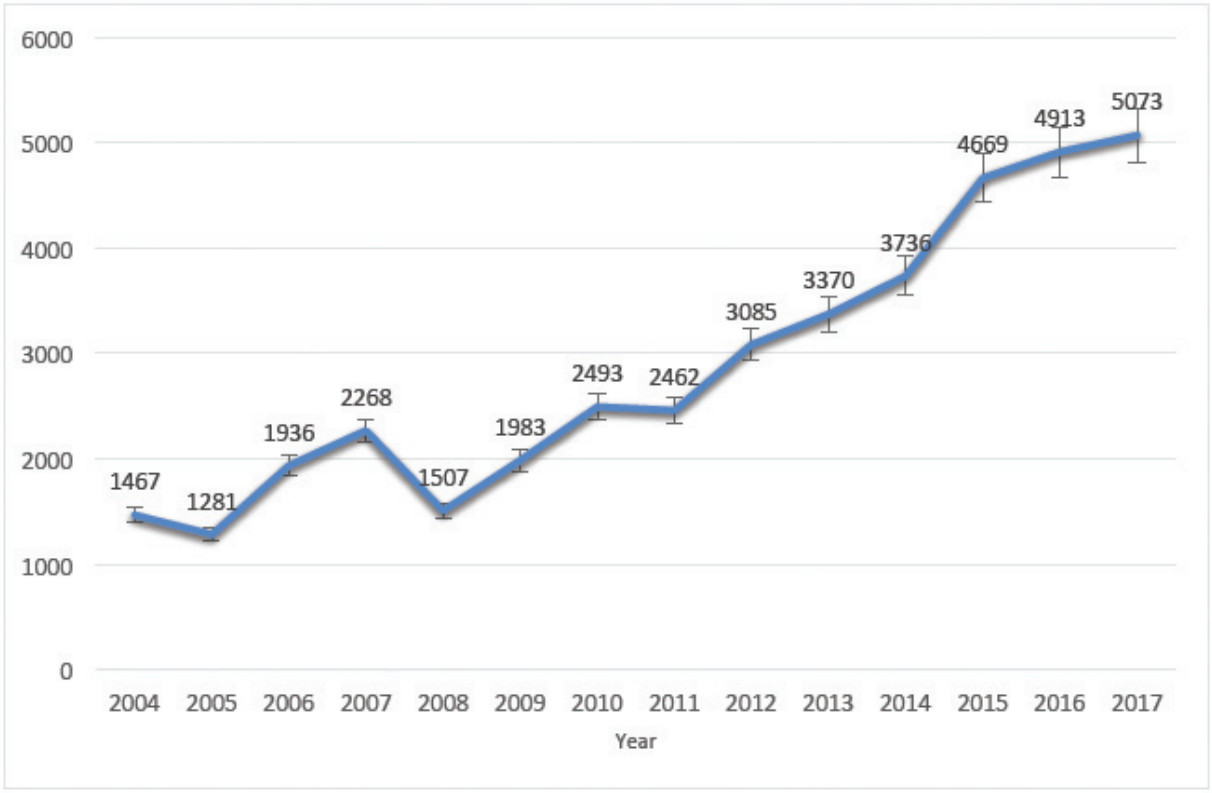


Figure 2.1: Number of Haemovigilance Reports Received Between 2004 And 2017

2.2 TYPE OF ADVERSE EVENTS – Table 2.2

Reports received by NHCC were adverse transfusion reaction (ATR), incorrect blood component transfused (IBCT), near miss and incident. More than 80% of adverse events were attributed to ATR while IBCT showed the least reported event of less than 1% for two consecutive years. NHCC promotes hospital blood banks to notify monthly even if there is no adverse transfusion event in order to minimise underreporting. This is classified as no adverse event.

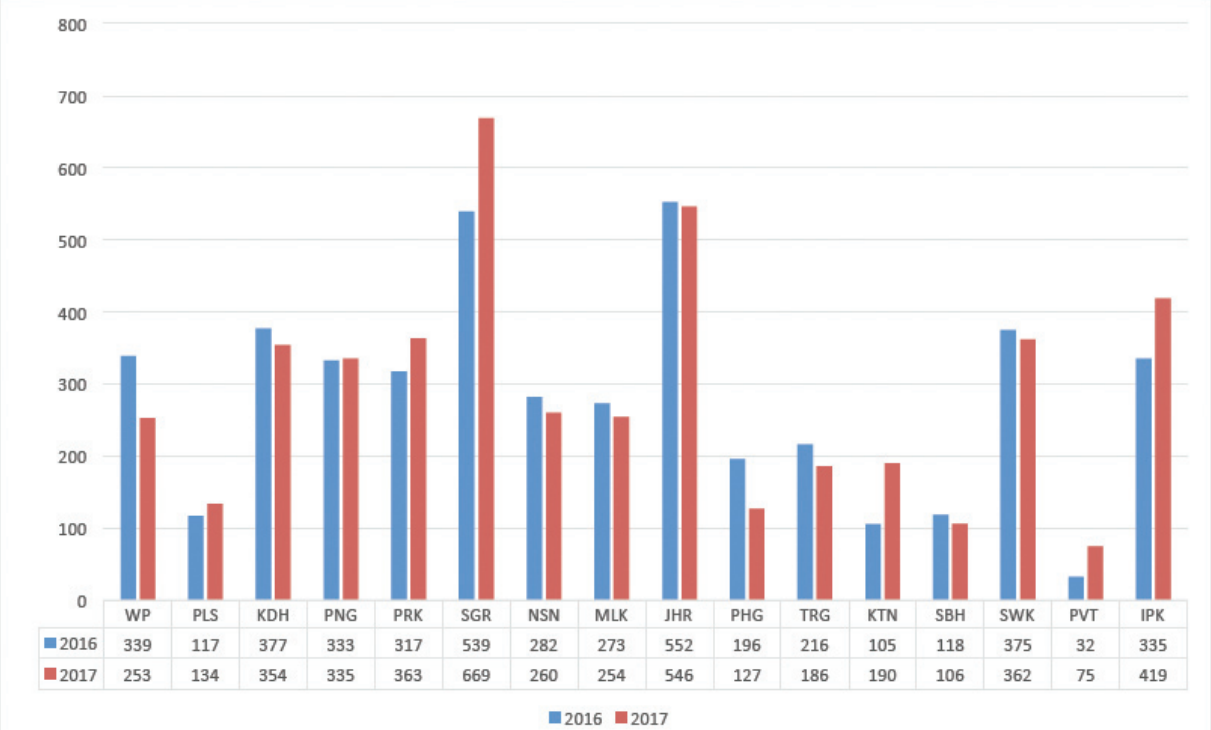
No.	Types Of Adverse Events	Number Of Reports Received	
		2016	2017
1.	Adverse Transfusion Reactions	4049	4245
2.	No Adverse Events	456	388
3.	Incorrect Blood Component Transfusion	38	35
4.	Near Misses	260	219
5.	Incidents	110	186
No.	**Total Number Of Reports Received**	**4913**	**5073**

Table 2.2: Types of Adverse Events

2.3 ADVERSE TRANSFUSION REACTION REPORTED BY STATES – Figure 2.3 and Table 2.3

Hospital blood banks under Ministry of Health (MOH) contribute 91.70% (4505) of ATR reports in 2016 and 91.3% (4633) in 2017. In general, there were 5 states which showed an increase in number of reports submitted in 2017 compared to 2016. These states include Perak, Kelantan, Perlis, Selangor and Penang. Institutions and private hospitals also showed a rise in the number of reports received. Selangor has the highest number of reports submitted in 2017, which consist of 14.4% (669) while Sabah reported the least with 2.3% (106). There was also a remarkable increase of reports received from the private hospitals (134.4%) and Kelantan (81.0%) in 2017.

In 2017, there were 9 states that showed a decline in the number of reports compared to 2016 which include Wilayah Persekutuan, Sabah, Kedah, Melaka, Sarawak, Johor, Pahang, Terengganu and Negeri Sembilan. Pahang reported the most significant decline of more than 35% 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.



**Reports do not include Incorrect Blood Component Transfused, Near Miss and Incidents.*

Figure 2.3: Numbers of Reports Received by States from 2016 to 2017

No.	STATES	2016	2017	Differences	Percentage (%)
1.	Wilayah Persekutuan	339	253	-86	-25.4
2.	Perlis	117	134	+17	+14.5
3.	Kedah	377	354	-23	-6.1
4.	Penang	33	335	+2	+0.6
5.	Perak	317	363	+46	+14.5
6.	Selangor	539	669	+130	+24.1
7.	Negeri Sembilan	282	260	-22	-7.8
8.	Melaka	273	254	-19	-7.0
9.	Johor	552	546	-6	-1.1
10.	Pahang	195	127	-68	-34.9
11.	Terengganu	216	186	-30	-13.9
12.	Kelantan	105	190	+85	+81.0
13.	Sabah	118	106	-12	-10.2
14.	Sarawak	375	362	-13	-3.5
15.	Private	32	75	+43	+134.4
16.	Institution	335	419	+84	+25.1
	Total	**4505**	**4633**		

Table 2.3: Adverse transfusion reaction reports submitted to NHCC in 2016 and 2017

2.4 INCIDENCE OF ADVERSE TRANSFUSION REACTION

According to Annual Report: Blood Transfusion Services 2016 and 2017 released by the Health Informatics Centre, Planning Division, Ministry of Health, the number of blood recipients were 362,530 and 343,959 respectively. Therefore, the incidence of ATR were 1.1% in 2016 and 1.2% in 2017.

2.4.1 INCIDENCE OF ADVERSE TRANSFUSION REACTION BY GENDER – Figure 2.4.1

There were 4049 ATR reported in 2016 and 4245 in 2017. However, in 2016 two hospitals (Hospital Kulim and Hospital Machang) submitted 56 incomplete reports which were excluded from the analysis. Therefore, the final number of reports analysed were 3993.

In 2016, 2271(56.9%) were females, while 1611 (40.3%) were males, and 111 (2.8%) were not documented whereas in 2017, 2511(59.2%) were females, 1715 (40.4%) were males and 19 (0.4%) were not documented.

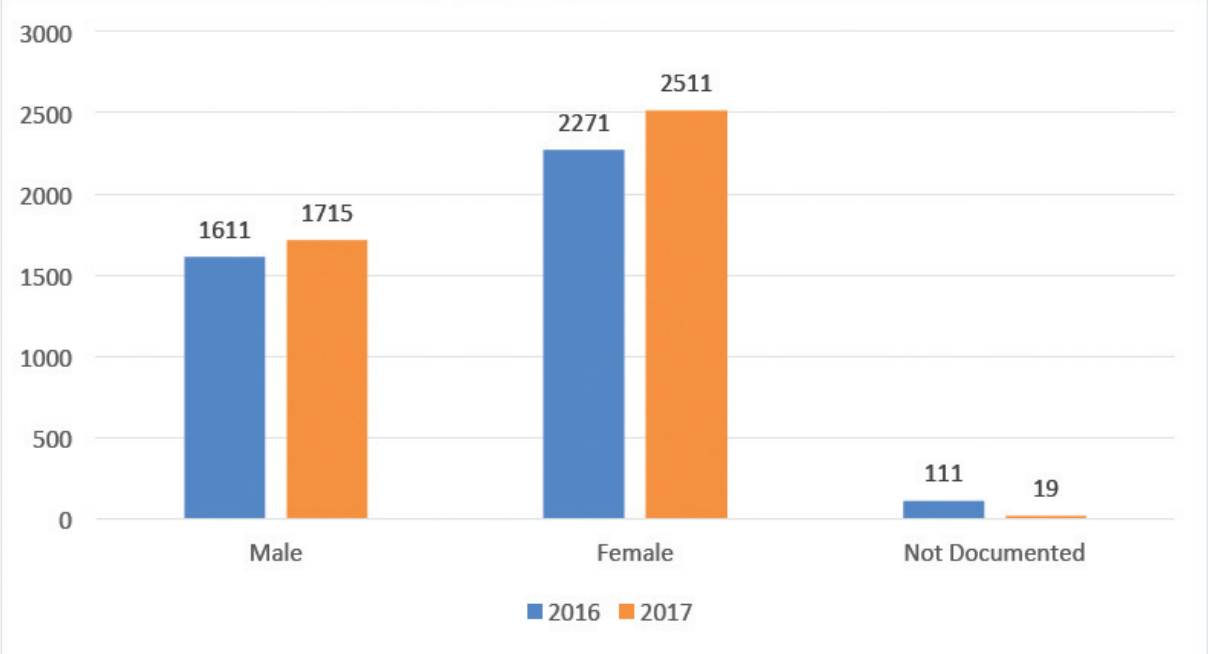


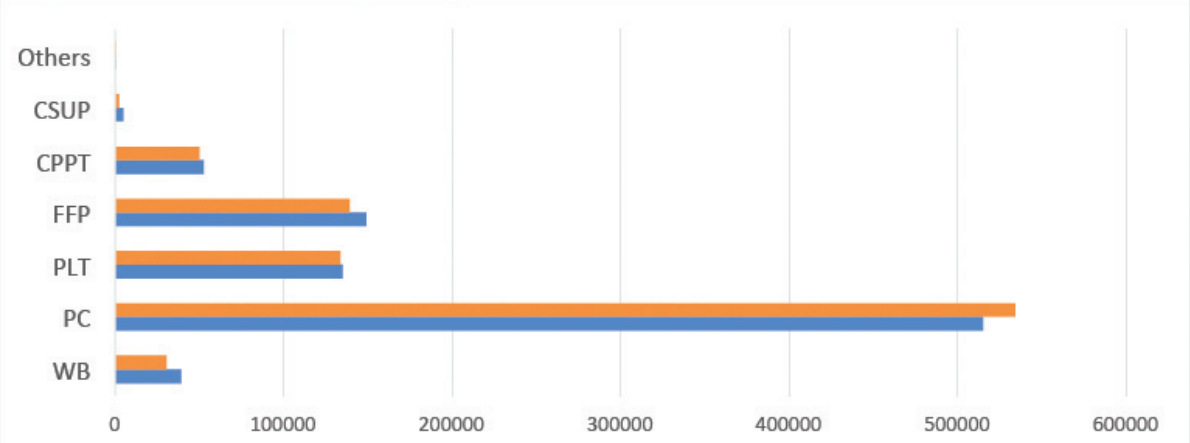
Figure 2.4.1: Gender Distribution of Adverse Transfusion Reaction

2.5 TYPES OF BLOOD COMPONENT TRANSFUSED – Figure 2.5

Blood transfusion is a common practice in any clinical setting. Its clinical benefit in indicated cases is vital to safe the patient life. Thus judicious use of blood should be encouraged for the patient benefits and at the same time help to minimize unnecessary transfusions and hence reduce the risk of adverse transfusion events.

Statistic of blood component transfused derived from Annual Report Blood Transfusion Services 2016 and 2017, showed that type of blood component have been divided into 23 and the total number of blood component transfused were 895,915 and 889,993 respectively. However in this report, the blood components were divided based on principal type which were whole blood, packed red cell, platelet, fresh frozen plasma (FFP), cryoprecipitate, cryosupernatant and others.

The frequency of the blood component transfused were relatively similar for 2016 and 2017. The highest percentage of blood component transfused was packed red cell (57.46%, 60.00%) and the least was cryosupernatant (0.55%, 0.28%). FFP and platelet had similar percentage of usage of approximately 15.00% while whole blood and cryoprecipitate also had similar percentage of usage approximately 5.00% each.



	WB	PC	PLT	FFP	CPPT	CSUP	Others
2017	30435	534002	133564	139322	49869	2475	326
2016	39126	514806	135040	149243	52556	4924	220

Figure 2.5: Type of blood component transfused in 2016 and 2017

2.6 IMPLICATED BLOOD PRODUCTS

An adverse reaction or event is an undesirable response or effect in a patient, temporarily associated with the administration of blood or blood component. Hence, measures and caution should be taken prior to any blood transfusion. Awareness about various clinical features of acute and delayed transfusion reactions with the ability to assess the severity of reactions on time can lead to better prognosis.

In 2017, a total of 889 993 units were transfused, of which 4,441 units were implicated with increment of 302 units (6.8%) compared to year 2016.The total number of implicated blood product was higher than the total number of ATR in view of some cases were transfused with multiple blood product. The average rate of adverse events for 2017 related to the total units of components transfused was 0.46% in 2016 and 0.49% in 2017. There was slight decrement in the ratio of adverse transfusion reaction event to total utilised product in 2016 which was 1:216 compared to 1:202 in 2017.

2.6.1 TYPES OF IMPLICATED BLOOD PRODUCTS – Table 2.6.1

Red cells were still the most common implicated blood product in transfusion reaction based on event rate (75.5%) despite of slight decrement in 2017. However there was limitation to this, as all special red cell components such as washed, filtered, irradiated and leucocyte poor packed cell were categorized under red cells. The occurrence of the adverse event were computed as a summation of all these products although the usage of special red cell products rarely cause an adverse event.

Fresh Frozen Plasma (FFP) was the second most common implicated blood component with the incidence rate remained approximately 10% for both years. There was decrement of adverse events in platelets from 5.9% in 2016 to 3.7% in 2017. Whole blood also showed decrement from 5% to 2.9% respectively. Cryoprecipitate showed marked reduction from 1.4% in 2016 to 0.1% in 2017. However, there was no ATR case reported involving cryosupernatant.

A few reports were incomplete whereby the type of blood product implicated were not stated. This contributed to 135 events in 2017 involving unspecified blood product compared to 21 in 2016.

	Year	2016			2017		
No.	Blood Component	Transfused	Implicated	Percentage % Differences	Transfused	Implicated	Percentage % Differences
1.	Whole blood	39 126	206	4.98	30,435	129	2.90
2.	Red Cells	514 806	3 172	76.64	534,002	3354	75.52
3.	Platelet	135 040	246	5.94	133,564	163	3.67
4.	FFP	149 243	436	10.53	139,322	482	10.85
5.	Cryoprecipitate	52 556	58	1.40	49869	52	1.15
6.	Cryosupernatant	4 924	-	-	2475	-	-
7.	Others	220	-	-	326	127	2.85
8.	Unspecified	-	21	0.50	-	135	3.04
	Total	895 915	4,139		899 993	4,441	

Table 2.6.1: Types of Implicated Blood Products

2.6.2 INCIDENCE OF IMPLICATED BLOOD COMPONENTS – Table 2.6.2a, 2.6.2b

The incidence of implicated blood component(1/units) for both years showed red cell was the most implicated blood component followed by whole blood, FFP, platelet and cryprecipitate as shown in the table below.

No.	Blood Component	Utilized	Implicated	Rate /100,000	1/units
1.	Whole blood	39169	206	526	1: 193
2.	Red Cells	514727	3172	616	1:162
3.	Platelet	135040	246	182	1:549
4.	Fresh Frozen Plasma	154060	436	283	1:353
5.	Cryoprecipitate	59958	58	97	1:1033
6.	Others	220	-	0	0
7.	Unspecified	-	21	-	-
	Total	895 915	4,139	-	-

Table 2.6.2a: Adverse Event Rates for the Types of Individual Blood Component Year 2016

No.	Blood Component	Utilized	Implicated	Rate /100,000	1/units
1.	Whole blood	30,435	129	423	1:236
2.	Red Cells	534,002	3,354	628	1:159
3.	Platelet	133,564	163	122	1:819
4.	Fresh Frozen Plasma	139,322	482	345	1:289
5.	Cryoprecipitate	52,344	51	97	1:1026
6.	Others	326	127	38,957	1:3
7.	Unspecified	0	135	-	-
	Total	899,993	4,441	-	-

Table 2.6.2b: Adverse Event Rates for the Types of Individual Blood Component Year 2017

Chapter 3

Patient Haemovigilance

3.0 Types of Adverse Transfusion Reaction

"Care is an absolute. Prevention is the ideal"

3.1 ADVERSE TRANSFUSION REACTION (ATR) REPORTS – Table 3.1

The adverse transfusion reaction reports received were further classified to confirmed, incomplete and unrelated ATR. No adverse event reports were also received from a few hospitals as NHCC encouraged all hospitals to notify regardless no adverse event occurred.

There were 56 cases out of 4049 cases in 2016 with incomplete data and none in 2017. On the other hand, there were 198 cases (4.39%) in 2016 and 114 cases (2.46%) in 2017 were reported as not related to transfusion. These reactions were caused by underlying illness, due to other complications or procedures unrelated to transfusion. In addition, 456 (11.26%) and 388 (9.14%) were reported as no adverse event in 2016 and 2017 respectively. Hence, reports of incomplete data, unrelated to ATR and no adverse event were excluded in the analysis. Therefore, the number of ATR analyzed for 2016 were 3795 whereas in 2017 were 4131.

ATR Report		Number Of Reports Received	
		2016	2017
Adverse Transfusion Reactions	ATR cases (to be analyzed in the report)	3795	4131
	*Incomplete ATR report	56	0
	Unrelated to ATR	198	114
	SUB TOTAL	4049	4245
No Adverse Event		456	388
Total Number Of Reports Received		4505	4626

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

Table 3.1: Number of Adverse Transfusion Reaction Reports

3.2 ADVERSE TRANSFUSION REACTION (ATR) REPORTS – Table 3.1

The number of actual adverse transfusion reaction reported has increased from 84.23% (3795) in 2016 to 89.16% (4131) in 2017. The commonest incidence for both years were febrile non haemolytic transfusion reaction (FNHTR) and mild allergic transfusion reaction which comprised approximately 40% each. The third common cause of ATR was unclassifiable complication of transfusion with an incidence of 5-10% for both years. Moderate allergic reaction and transfusion associated dyspnoea (TAD) accounted for 1-2% incidence each year. The incidence of transfusion

related acute lung injury (TRALI), delayed haemolytic transfusion reaction (DHTR), non-immune haemolytic transfusion reaction and transfusion transmittable infection (TTI) were infrequent.

No.	Type of ATR	No of cases (2016)	%	No of cases (2017)	%
1.	FNHTR	1718	45.27	1625	39.37
2.	Mild Allergic	1683	44.34	1842	44.59
3.	Unclassifiable Complication of Transfusion	227	5.98	432	10.46
4.	Moderate Allergic Reaction	63	1.66	85	2.06
5.	TAD	41	1.08	94	2.28
6.	TACO	25	0.65	21	0.51
7.	Hypotension Transfusion Reaction	18	0.47	15	0.36
8.	Anaphylaxis	9	0.24	10	0.24
9.	Inconclusive	7	0.18	5	0.12
10.	TRALI	2	0.05	1	0.02
11.	DHTR	1	0.03	0	0
12.	Non Immune HTR	1	0.03	1	0.02
13.	HIV	*1	0.03	0	0
14.	Hepatitis B	0	0	0	0
15.	Hepatitis C	0	0	0	0
16.	Malaria	0	0	0	0
	Total	***3796**		**4131**	

**1 HIV case for 2016 was a case occurred in 2015 which is discussed in this report due to late submission of complete report*

Table 3.2: Incidence of ATR based on type of reaction in 2016 and 2017

3.3 ADVERSE TRANSFUSION REACTIONS REPORTS ACCORDING TO TYPE OF REACTION – Figure 3.3

The reported adverse transfusion reactions for 2016 and 2017 is shown below:

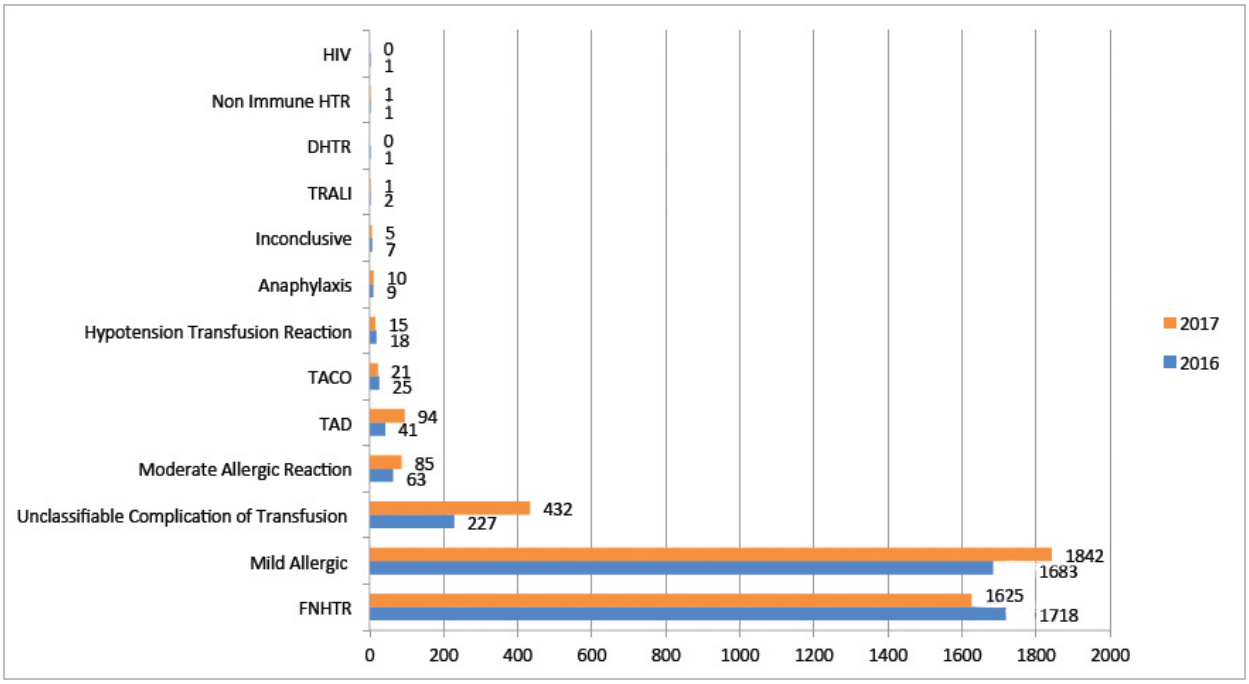


Figure 3.3: Reported Cases of Adverse Transfusion Reactions 2016 and 2017

3.3.1 FEBRILE NON HEMOLYTIC TRANSFUSION REACTIONS (FNHTR)

Febrile Non- Haemolytic Transfusion Reaction is said to occur when there is 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 hemolytic transfusion reaction, bacterial contamination or underlying condition.

Fever in this context is defined as temperature ≥38oC oral or equivalent and a change of ≥1oC from pre-transfusion value.

SHOT UK 2016

As shown in Figure 3.3, FNHTR were the most frequently reported type of adverse transfusion reactions (1718 cases, 45.27%) for 2016. However, there was a reduction in 2017 to 1625 cases (39.37%). All recipients reported good outcome with no morbidity nor mortality.

It is recommended to identify patients at risk particularly those requiring frequent transfusion so that preventive measures such as premedication with antipyretic can be taken. The use of filtered blood is recommended to further reduce the risk of this event.

3.3.2 ALLERGIC REACTIONS – Table 3.3.2

Allergic reaction is defined as 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. Anaphylactic reaction is when, in addition to mucocutaneous symptoms, there is airway compromise or cardiovascular involvement. Laryngeal symptoms include throat tightness, dysphagia, dysphonia, hoarseness and stridor. Pulmonary symptoms include dyspnoea, cough, wheeze/ bronchospasm, hypoxaemia. Cardiovascular symptoms include hypotension, syncope.

SHOT UK 2016

Allergic transfusion reaction is also a common adverse event. It is divided into three types; mild allergic reactions, moderate allergic reactions and severe allergic reactions. Mild allergic reaction was the commonest with no morbidity nor mortality. However, there were few reported cases with severe allergic reaction that required more intervention and further management.

Mild Allergic	Transient flushing, urticaria or rash.
Moderate Allergic	Wheeze or angioedema with or without flushing / urticaria / rash but without respiratory compromise or hypotension.
Severe (Anaphylactic Transfusion Reaction)	Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention AND/OR, directly result in or prolong hospital stay, or **Anaphylaxis** (severe, lifethreatening, generalised or systemic hypersensitivity reaction with rapidly developing airway and/or breathing and/or circulation problems, usually associated with skin and mucosal changes).

Table 3.3.2: Category of Allergic Reactions

Mild allergic reaction was the second most frequently reported case in 2016 after FNHTR which accounts for 1683 cases (44.34%). 63 cases were reported as moderate allergic reactions (1.66%) , and 9 cases were severe allergic transfusion reactions/anaphylaxis (0.24%). On the contrary, mild allergic reaction was accounted as the most common reaction in 2017 which accounts for 1842 cases (44.59%). There were 85 cases (2.06%) of moderate allergic reactions and 10 cases (0.24%) were severe allergic reactions. Overall, there is 4.1% increment in the number of reported allergic reactions cases in 2017 compared to 2016. However, no morbidity or mortality were attributed by allergic reactions for both years.

It is highly recommended to identify patient at risk and offered some preventive steps including premedication with antihistamine prior to transfusion particularly to frequent blood transfusion recipient. Transfusion of washed cellular blood products is recommended for patient who experience severe allergic reaction to blood transfusion.
The patient IgA level need to be investigated as IgA deficient patient with anti-IgA antibody may have severe anaphylaxis reaction in the future. For this patient, we recommend further transfusions to be undergone in a clinical area with resuscitation facilities and to consider pre-medication with steroids and antihistamine. If patient is IgA deficient with anti-IgA, the use of IgA-deficient or washed blood components is indicated.

3.3.3 UNCLASSIFIABLE COMPLICATION OF TRANSFUSION

Unclassifiable Complication of Transfusion is defined as 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 2016

There were 227 cases (5.98%) reported as Unclassifiable Complication of Transfusion in 2016 and the incidence were nearly doubled to 432 cases (10.46%) in 2017. The rise in incidence was caused by the diagnosis of FNHTR that was initially submitted by the hospital blood banks was reclassified to Unclassifiable Complication

of Transfusion by the NHCC team as the temperature rise was less than 10C. No morbidity nor mortality to recipients were reported in both years. Therefore the ability of the medical personnel to understand the criteria for each respective adverse events will help to make an accurate diagnosis.

3.3.4 HYPOTENSION TRANSFUSION REACTION

Hypotension transfusion reaction is defined as decrease in systolic and/or diastolic blood pressure of >30 mmHg occurring during or within one hour of completing transfusion. All other categories of adverse reactions presenting with hypotension must have been excluded together with underlying conditions that could explain hypotension.

NEW ZEALAND BLOOD SERVICE

In 2017, there were 15 cases (0.36%) of transfusion related adverse events classified as hypotension in comparison to 18 cases (0.47%) in 2016. Good recovery reported following this type of adverse event. Majority of the recipient responded well with termination of transfusion and fluid replacement.

3.3.5 TRANSFUSION ASSOCIATED DYSPNOEA (TAD)

Transfusion Associated Dyspnoea is defined as respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction and is not explained by the patient's underlying condition.

SHOT UK 2016

In 2017, 94 cases (2.28%) were reported as transfusion associated dyspnoea which showed a marked increment in comparison to year 2016 which only involved 41 cases (1.08%). Nonetheless, no morbidity or mortality reported. The rise in cases reported might be due to more education in regards of the definition of TAD and its exclusion criteria which has created more awareness of this diagnosis.

3.3.6 TRANSFUSION-ASSOCIATED CIRCULATORY OVERLOAD (TACO)

Transfusion-associated circulatory overload (TACO) is caused by the inability of the circulatory system to handle an increased blood volume. The patient will present with acute pulmonary edema when cardiac output cannot be maintained. Other symptoms include cyanosis, orthopnea, hypertension, headache, tachycardia, chest tightness, and cough. Symptoms usually set in near the end of the transfusion.

SHOT UK 2016

There were 25 cases (0.65%) of TACO documented in 2016 and 21 cases (0.51%) in 2017. One example of reported TACO case which occurred in 2016 is illustrated in this following summary;

This was a case of 42 years old Chinese lady, diagnosed with necrotising fasciitis of right leg. She had history of previous blood transfusion in 2015. Previous transfusion was uneventful. Her initial hemoglobin on presentation was 7.7 g/dl. She was transfused with 1 unit packed cell on 7.6.2016. The packed cell transfusion started on 7.6.2016 at 10 pm. However she became tachypnoeic while approximately 200mls of blood transfused. GCS was full and lung findings noted to have bibasal crepitations over the lower and midzone. Other systemic examinations were unremarkable.

BP was 163/100, with pulse rate of 130 beats per minute, temperature of 36.3oC and SPO2 of 88% room air. She was given IV hydrocortisone 200mg STAT and put on face mask 5L per minute. She was also given IV furosemide 40mg STAT. She had negative balance 206mls on the day of transfusion. However, a day earlier, her input and output charting had positive balance of 1494mls. Chest X ray showed cardiomegaly with congested lung field, both costophrenic angles was blunted. ECHO showed impaired LV function of 40% to 45% and dilated left ventricles. The next day patient already improved and symptoms completely resolved. Patient recovered well and discharged from hospital one week later.

3.3.7 TRANSFUSION -RELATED ACUTE LUNG INJURY (TRALI)

> **Transfusion- Related Acute Lung Injury** (TRALI) is a syndrome characterized by the development of acute respiratory distress with hypoxemia during or up to 6 hours after completion of a blood transfusion. TRALI is a clinical diagnosis based on patient symptoms that has been associated with all types of blood products. Most frequent signs and symptoms include dyspnea, hypoxemia, bilateral pulmonary edema. Other reported findings have been hypotension, tachycardia and fever (1-2°C rise). Characteristic chest X-ray results show evidence of bilateral patchy infiltrates, with alveolar and/or interstitial patterns.
>
> ***SHOT UK 2016***

There were two cases of TRALI (0.05%) reported for year 2016. One of them was a confirmed case with positive serology. Another case in 2016 was a case of possible TRALI in view of no serology confirmation done but clinical history was supported and other causes have been excluded.

On the other hand, there was only one report (0.02%) received for TRALI in 2017 which was possible TRALI in view of supportive clinical history but lack of serology investigation done.

Two cases of TRALI were illustrated as below;

> *A.H, 14 years old boy with underlying Down Syndrome was admitted for Hemolytic Uraemic Syndrome. He was critically ill and was admitted to Intensive Care Unit. In view of his condition, he was decided for plasma exchange transfusion on March 2016. The cycle was started at 1730H and finished at 2030H.*
>
> *Approximately one hour post transfusion he desaturated from 95% down to 56% on face mask. Pre transfusion blood pressure was 139/99 mmHg and during reaction was 115/80 mmHg. He also developed tachycardia of heart rate 108 beats per minute.*

Chest X-ray showed perihilar infiltrates. His input and output fluid balance charting was normal with no positive balance. His blood pressure dropped to 70/50 mmHg and he was resuscitated with fluids and started on single inotrope. He was subsequently intubated in view of impending respiratory collapse and his oxygen saturation improved to normal post intubation. He recovered from TRALI episode however his uraemia symptoms worsened later and he passed away two weeks later. Cause of death was due to underlying illness.

Result for one male donor showed donor had IgG antibodies against HLA class I and II antigens. For class 1 antibodies, anti – A24 was directed against patient. Result for another multiparous female donor showed donor has IgG antibodies against HLA class I and II antigens. Antibodies are not directed against patient.

Impression: Highly likely - case with convincing clinical feature and positive

Mrs FD, 74 years old with multiple co-morbidities Diabetes Mellitus, Hypertension, AVL malfunction and End Stage Renal Failure on regular dialysis was admitted due to symptomatic anaemia with hemoglobin of 6 g/dL. She was planned for 1 unit packed cell transfusion during dialysis. Her transfusion started at 1025H and completed at 1200H with a total 350mls volume transfused. Immediately after transfusion, patient developed hypotension and shortness of breath.

She desaturated from 99% under room air down to 80%. Her blood pressure dropped from 152/76 mmHg down to 86/56 mmHg. She was then intubated due to impending respiratory collapse. Lung findings revealed crackles with no evidence of pleural effusion. Chest X-ray showed generalised patchy infiltrates with no signs of effusion. ECG was normal and excluded any cardiac event.

She was then transferred to intensive care unit for mechanical ventilation support and was put on single inotrope.

She recovered two days later and was extubated uneventfully. She recovered well and discharged with no complications.

Donor involved was a multiparous female and serology investigations taken. However result was negative for any antibody. In view of convincing clinical history with no evidence of fluid overload or any other contributing factors to the symptoms yet negative serology, this case was diagnosed as antibody negative TRALI.

Impression: Antibody negative TRALI – case with convincing clinical picture where serology is negative.

3.3.8 TRANSFUSION TRANSMITTED INFECTION (TTI)

A report was classified as a transfusion-transmitted infection if, following investigation:

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

SHOT UK 2016

All donated blood in Malaysia were screened for Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) and Syphilis. There was no incidence of TTI for 2016 and 2017. However, there was a case (0.03%) of HIV reported in 2015. The complete report was received in 2016 and therefore was included in this report.

The case was illustrated in following summary:

Mr X, a regular donor with history of 10 previous donations in multiple blood collection centres. His last non-reactive donation was on 3/6/2015. However he was found reactive for HIV during subsequent donation on 29/9/15. The donor risk factor identified as history of multiple sexual partners in 2014. The donor did not declare the information during pre-donation counselling as he thought he was well.

Following table showed the summary of his donations:

No of donation Date	Date of donation	Anti-HIV
1	11.2.2010	Non-reactive
2	8.2.2011	Non-reactive
3	5.4.2012	Non-reactive
4	30.9.2013	Non-reactive
5	28.1.2014	Non-reactive
6	16.6.2014	Non-reactive
7	15.9.2014	Non-reactive
8	30.12.2014	Non-reactive
9	3.6.2015	Non-reactive
10	29.9.2015	Reactive

Look back and recall procedure was initiated. The recipients of blood components in the 12 months period prior to the detection of infection were identified.

There was one recipient infected with HIV from blood donated on 3/6/2015. He was a 31 years old with underlying transfusion dependent HbE thalassaemia. He showed no signs or symptoms for HIV or AIDS upon diagnosis and was referred to Infectious Disease Clinic for further management. Two other products Subsequent look back was done for 30/12/2014 donation. However, two of the recipients passed away while one blood component was discarded. Therefore, further look back was done for donation on 15/9/2014. There was one recipient nonreactive for HIV while the other two recipients passed away. Therefore no further look back was done for the other donation.

Following table showed the summary of look back and recall results:

No of Donation	Date of donation	Component	Recipients status
9	3.6.2015	Packed Red cell	**HIV Ag-Ab reactive and PA detected (25.2.2016)**
		FFP	Discarded
		Platelet	Discarded
8	30.12.2014	Packed Red cell	Deceased (25.1.2015)
		Cryoprecipitate	Deceased (29.1.2015)
		Cryosupernatant	Discarded
7	15.9.2014	Packed Red cell	Deceased (2.2.2015)
		FFP	Deceased (31.10.2014)
		Platelet	**HIV Ag-Ab nonreactive (14.3.2016)**

3.3.9 INCONCLUSIVE

There were 7 cases (0.18%) classified as inconclusive in 2016. There were 3 cases recorded from Sarawak, 2 cases from Pahang and 2 cases from Negeri Sembilan. On the other hand, there were 5 inconclusive cases (0.12%) reported in 2017 where 2 cases from Johor and 1 case each from Selangor, Terengganu and Sarawak. All of these cases were inconclusive due to inadequate investigations or insufficient data to achieve the diagnosis for reported adverse transfusion reaction. Example for inconclusive report given as below:

Mrs S, 47 years old female with underlying anaemia and chronic kidney disease was admitted for infected bullous cellulitis. She responded well with IV vancomycin 500mg BD. She was transfused with 1 unit packed cell in view of Hb 6.7gm/dL. Pre transfusion vital signs were all within normal range.

The transfusion started on 15.7.2017 at 1851H and completed uneventfully on 16.7.2017 at 0200H. However 2 hours post transfusion she developed shortness of breath and circulatory shock. She also had raised temperature associated with chills and rigors. BP dropped from 127/88mmHg to 80/56mmHg and she had an episode of cardiorespiratory arrest which revived initially after resuscitation but eventually she died several hours later. Cause of death was reported as septicaemic shock secondary to Hospital Acquired Pneumonia.

Clinician team initially diagnosed as possible TRALI however NHCC viewed this case as inconclusive due to:

1. *Prolonged transfusion of 1 unit packed cell which was nearly 7 hours. Total white cell count raised to 41x109 /L. Blood Culture & Sensitivity done on patient was negative, however date and time taken was not mentioned in the report. No blood culture was done on the blood bag as it was empty.*
2. *Repeated chest X-ray during the event showed consolidation with no evidence of TRALI.*
3. *Donor was a nulliparous female. No history of previous blood transfusion or transplantation.*
4. *HLA test was not done for both patient and donor.*

3.4 OUTCOME OF ADVERSE TRANSFUSION REACTIONS – Figure 3.4

Majority of patients with adverse transfusion reactions had recovered with no ill effects which were 48.27% of cases (1832) in 2016 and 86.86% (3588) cases in 2017. There were 7 cases (0.18%) reported as recovered but with ill effects or morbidity (6 cases of TACO, 1 case of TRALI) in 2016. Meanwhile in 2017, only 1 case (0.03%) was reported as recovered with ill effect which was a case of possible TRALI. There was one case reported with death but not related to transfusion for both years.

Almost half (51.52%) of the reports received did not specify the outcome of adverse reactions in 2016. On the other hand, 86.86% of the reports received in 2017 specified the outcome of recipients. This was possibly due to improvement in quality of reporting with more conscientious follow up done by NHCC.

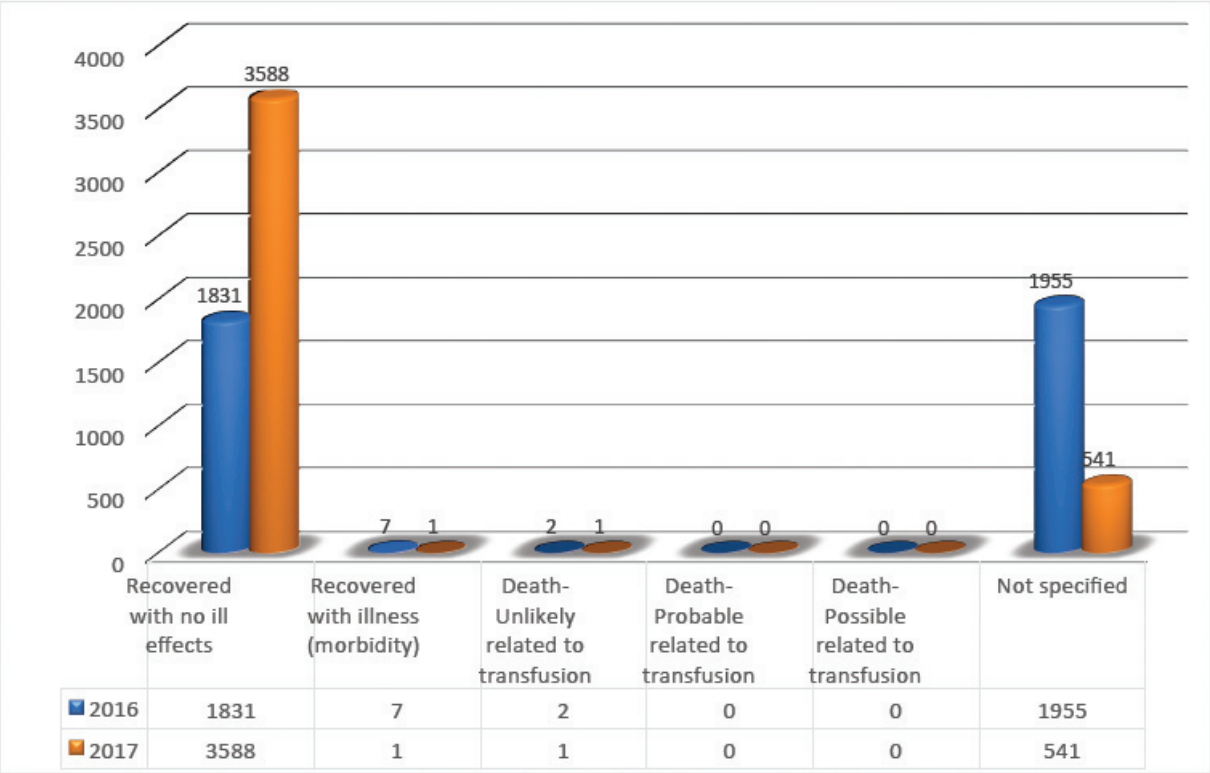


Figure 3.4: Outcome of Adverse Transfusion Reaction 2016 and 2017

3.5 RECOMMENDATIONS

In this annual report, recommendations highlight on the empowerment of knowledge on transfusion related adverse events and standardised data reporting.

1. Establishment of guidelines with standardised definition and criteria for each transfusion related events with proper management accordingly.

2. Empowering the knowledge on recognising and managing transfusion related adverse events among healthcare providers with trainings and courses.

3. NHCC recommends blood bank medical personnels to review, investigate and manage recipients with moderate to severe adverse transfusion events.

4. The reports sent should be verified by specialists to ensure correct diagnosis and management taken.

5. Implementing standardised mechanism of reporting all transfusion related adverse events including the protocol for further investigations of transfusion reactions, use of new format form for reporting (BTS/HV/3/2016) and dateline for reporting.

6. Emphasising the need of reporting all transfusion related events to NHCC by all healthcare providers.

7. NHCC recommends state hospitals to take the role as coordinator for other hospitals in their state to improve quality of reporting as initiated in Sarawak.

8. The scientific use of safe and effective medical and surgical techniques to manage anemia, optimize coagulation, and decrease bleeding should be empowered to decrease the need for blood transfusions and ultimately reduce the adverse event related to blood transfusion. The use of leukocyte reduced blood components could significantly diminishes many of the ATR associated with donor white blood cells. Thus, the study on cost effectiveness of the usage in routine transfusion is recommended.

9. The reduction in the number of participating hospital and low number of reporting on donor haemovigilance 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.

10. Mandatory blood screening for HBV, HCV, HIV and Syphilis is done by serological tests while nucleic acid amplification technique (NAT) have been added in the screening of blood donors to few blood collection centres started in 2007. NAT is a highly sensitive and advanced technique which has reduced the window period of HBV, HCV and HIV. NAT is recommended to be performed in all donated blood to provide extra layer of safety when combined with serology tests. Thus there is currently a work in progress by the transfusion service in Malaysia aim to achieve 100% donor screen with NAT by 2020.

Chapter 4

Patient Haemovigilance

4.0 Near Miss

"Error reduction is like adverse event reduction; it's a continuous battle, not a onetime fix"

4 NEAR MISS (NM) EVENT

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.

TRANSFUSION PRACTICE GUIDELINES, MALAYSIA

4.1 NEAR MISS EVENT REPORTED –Table 4.1

Total number of near miss reported was 260 in 2016 and reduced to 219 in 2017. Hospital blood banks under Ministry of Health (MOH) contributed 83.46% (217) of NM reports in 2016 and 87.67% (192) in 2017. A reduction in the number of NM reports received from Institusi Perubatan Khas and University hospitals of 43 cases in 2016 and 27 cases in 2017.

No.	STATE	2016		2017	
		No of Recipients	No of Near Miss	No of Recipients	No of Near Miss
1.	Selangor	68831	59	68008	47
2.	Sabah	54864	4	59241	1
3.	Johor	49629	26	39491	38
4.	Kedah	27929	6	27902	1
5.	W.Persekutuan	26611	19	22893	9
6.	Perak	22522	13	21935	12
7.	Sarawak	22129	19	21847	16
8.	P.Pinang	17413	31	17420	34
9.	Pahang	17290	6	17324	0
10.	Melaka	16966	0	14563	0
11.	Kelantan	15594	7	10608	16
12.	N.Sembilan	10390	8	8952	7
13.	Terengganu	8346	19	8877	11
14.	Perlis	4053	0	4898	0
15.	Institusi Perubatan Khas/ University Hospital	U/K	43	U/K	27
	Total	**362,564**	**260**	**343,959**	**219**

**U/K = Unknown*

Table 4.1: Near miss events reported

4.2 INCIDENCE OF NEAR MISS EVENTS REPORTED BY HOSPITAL BLOOD BANKS UNDER MINISTRY OF HEALTH – Figure 4.2

The number of recipients for hospital blood banks under MOH for 2016 and 2017 were 362,564 and 343,959 respectively. The incidence of near miss in relation to the number of recipients were 0.07% in 2016 and 0.06% in 2017.

There were three states with more than 30,000 recipients. These states include Selangor, Sabah and Johor. Selangor has the highest number of near miss reported of 59 cases in 2016 and 47 cases in 2017, followed by Johor with 26 cases and 38 cases respectively. Sabah reported the least number of near miss of 4 cases in 2016 and 1 cases in 2017.

There were four states with number of recipients between 20,000 to less than 30,000. These states include Kedah, Wilayah Persekutuan, Perak and Sarawak. For these category, Sarawak showed the highest number on near miss in 2017 of 16 cases, followed by Perak of 12 cases, Wilayah Persekutuan of 9 cases and Kedah with only 1 cases. However in 2016, Sarawak and Wilayah Persekutuan reported 19 cases, while Perak of 13 cases and Kedah with the least number reported of 6 cases.

There were four states with number of recipients between 10,500 to less than 20,000. These states include Pulau Pinang, Pahang, Melaka and Kelantan. Pulau Pinang showed the highest number of near miss reported for both years of 31 cases in 2016 and 34 cases in 2017. This was followed by Kelantan with 7 cases in 2016 and more than double to 16 cases in 2017. Pahang had 6 cases in 2016 and no cases in 2017. There were no cases reported from Melaka for both years.

There were three states with the least number of recipients of less than 10,500. These states were Negeri Sembilan, Terengganu and Perlis. Terengganu showed the highest number of near miss of 19 cases in 2016 and 11 cases in 2017. Negeri Sembilan reported similar number of cases of 8 cases in 2016 and 7 cases in 2017. There were no cases reported from Perlis for both years.

	SGR	SBH	JHR	KDH	WP	PRK	SWK	PNG	PHG	MLK	KTN	NSN	TRG	PLS
2016 No of recipient	68831	54861	49629	27929	26611	22522	22129	17413	17290	16966	15594	10390	8346	4053
2017 No of recipient	68008	59241	39491	27902	22893	21935	21847	17420	17324	14563	10608	8952	8877	4898
2016 No of NM	59	4	26	6	19	13	19	31	6	0	7	8	19	0
2017 No of NM	47	1	38	1	9	12	16	34	0	0	16	7	11	0

Figure 4.2: Incidence of Near Miss and Number of Recipients by State, 2016 and 2017

4.3 INCIDENCE OF NEAR MISS EVENTS IN RELATIONS TO NUMBER OF RECIPIENTS – Table 4.3

Melaka and Perlis have no reported cases of near miss for both years while Pahang had 0.35 cases per 10,000 recipients in 2016 and none in 2017. The incidence of near miss for Sabah was 0.73 cases per 10,000 recipients in 2016 and reduced to 0.17 cases per 10,000 recipients in 2017. Kedah also showed a reduction in incidence of near miss from 2.1 in 2016 to 0.36 cases per 10,000 recipients in 2017. However this probably could be underreported as the average incidence of near miss for Malaysia was nearly 6 cases per 10,000 recipients for 2016 and 2017. If the values are true then preventive steps taken by each state to minimise the error should be shared and learnt by others.

Johor showed double in incidence of NM from 5.2 in 2016 to 9.6 cases per 10,000 recipients in 2017 whereas Kelantan showed an increase of almost four times from 4.5 to 15.1 cases per 10,000 recipients in 2017.

The incidence of near miss in Perak was 5.8 in 2016 and 5.5 cases per 10,000 recipients in 2017 while Negeri Sembilan were 7.7 and 7.8 cases per 10,000 recipients respectively. These states showed a negligible differences of incidence for both years.

Three states showed a minor reduction in the number of near miss. These states were Wilayah Persekutuan, Selangor and Sarawak. The incidence of near miss in Wilayah Persekutuan were 7.1 cases per 10,000 recipients in 2016 and reduced to nearly half (3.9 per 10,000 recipients) in 2017. The incidence of near miss in Selangor which had the highest number of recipients were 8.5 cases per 10,000 recipients in 2016 and reduced to 6.9 cases per 10,000 recipients in 2017. A reduction of incidence were also seen in Sarawak from 8.6 to 7.3 cases per 10,000 recipients.

Pulau Pinang and Terengganu showed three times higher incidence of near miss from average in 2016. The incidence of near miss in Pulau Pinang has increased from 17.8 cases per 10,000 recipients in 2016 to 19.5 cases per 10,000 recipients. Fortunately the incidence of near miss for Terengganu had reduced to almost half from 22.8 cases per 10,000 recipients in 2016 to 12.4 cases per 10,000 recipients in 2017. Safety measures need to be strengthen in order to minimize the incidence of near miss and ultimately prevent incidence of incorrect blood component transfused. However underreporting of near miss by other states could falsely makes these two states to have significantly higher number of NM.

No.	STATE	2016 per 10,000 Recipients	2017 per 10,000 Recipients
1.	Melaka	0	0
2.	Perlis	0	0
3.	Pahang	0.35	0
4.	Sabah	0.73	0.17
5.	Kedah	2.1	0.36
6.	Kelantan	4.5	15.1
7.	Johor	5.2	9.6
8.	Perak	5.8	5.5
9.	W.Persekutuan	7.1	3.9
10.	N.Sembilan	7.7	7.8
11.	Selangor	8.5	6.9
12.	Sarawak	8.6	7.3
13.	Penang	17.8	19.5
14.	Terengganu	22.8	12.4
15.	Malaysia	5.98	5.6

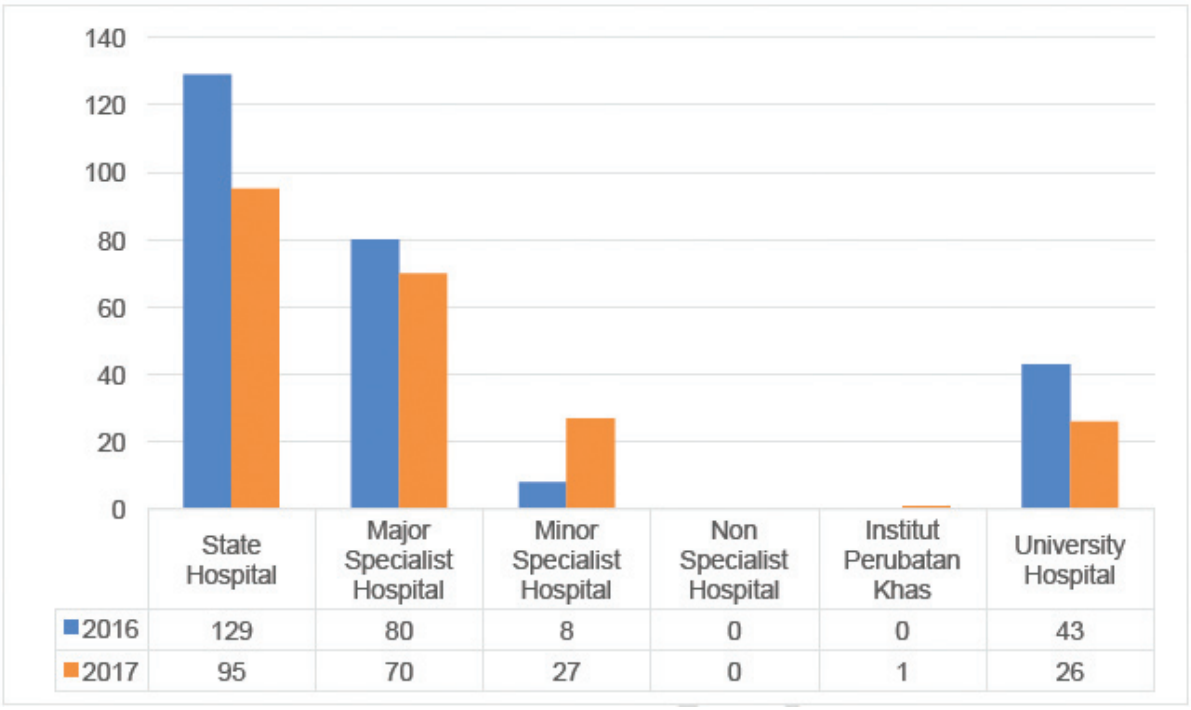
Table 4.3: Incidence of Near Miss Events in Relations to Number of Recipients

4.4 NEAR MISS EVENT REPORTED BY CATEGORY OF HOSPITAL - Figure 4.4

Total of 144 hospitals under MOH, Malaysia were categorized into five types based on the service provided. These are State Hospitals, Major Specialist Hospitals, Minor Specialist Hospitals, Non Specialist Hospitals, Institusi Perubatan Khas and University Hospitals.

In 2016, most cases were reported from State Hospitals (129 cases), followed by Major Specialist Hospitals (80 cases), whereas in 2017 both State Hospitals and Major Specialist Hospitals reported 95 and 70 cases respectively. Data from State Health Informatics Centre, Planning Division, MOH showed top principle cause of hospitalization at these hospitals were pregnancy, childbirth and puerperium which required group screen and hold (GSH) testing in almost every case. Therefore, the probability of error to occur was higher. Furthermore, a Transfusion Medicine Specialist or haematologist is available at these hospitals to identify and report NM event.

There were 8 cases reported from Minor Specialist Hospitals in 2016 and 27 cases in 2017. Lesser cases in 2016 could be due to underreporting. In 2016, 43 cases were reported from University Hospitals and decreased to 26 cases in 2017 while Institusi Perubatan Khas reported 1 case in 2017.



	State Hospital	Major Specialist Hospital	Minor Specialist Hospital	Non Specialist Hospital	Institut Perubatan Khas	University Hospital
2016	129	80	8	0	0	43
2017	95	70	27	0	1	26

Figure 4.4: Near Miss Event Reported by Category of Hospital

4.5 TYPE OF NEAR MISS EVENT - Table 4.5

The SHOT category of WBIT (Wrong blood in tube) includes incidents where:

- Blood is taken from the wrong patient and is labelled with the intended patient's details
- Blood is taken from the intended patient, but labelled with another patient's details.

Either error could result in a transfusion of a component of the wrong blood group to a patient.

SHOT UK 2016

Near miss event was categorized based on the location of incident either ward, blood bank or cause of near miss cannot be determined/ inconclusive. NM that occurred in ward was either during the pre-transfusion sampling or blood administration. NM that happened during pre-transfusion were then divided to sampling error (Wrong blood in tube: WBIT), labelling error (Wrong name on tube: WNOT) and labelling and sampling error at time of blood taking. While near miss that happened during blood administration was divided to failure to check the blood against patient's full identity and others. Near miss in blood bank was either due to technical, transcription, blood issued meant for another patient or wrong blood product supplied. If there were no cause concluded, this case was categorized under Cause of Near Miss Cannot Be Determined/ Inconclusive. Therefore, this will not be analyzed.

The incidence of near miss reported was higher in ward with 85.76% (223) of cases in 2016 and 83.56% (182) cases in 2017 while blood bank showed 7.31% (19) and 10.5% (23) cases respectively. Near miss event under ward category was almost always due to error during pre-transfusion sampling rather than during blood administration for both years. In 2016, the incidence for pre-transfusion sampling was around 30% for each category but in 2017 there was an increase of 50.82% in labelling error.

The incidence of technical error by blood bank reduced from 52.63% in 2016 to 34.78% in 2017 while the incidence of transcription error remained around 35% in both years. However, the incidence of issuing error had doubled from 10.53% in 2016 to 21.74% in 2017. There were 2 cases (8.7%) reported as wrong blood product supplied in 2017.

There was 6.92% in 2016 and 5.94% in 2017 where the cause of near miss was unable to be determined.

	Type of Near Miss	2016	2017
Error in Ward			
1.	Sampling error at time of blood taking	81	51
2.	Labelling error at time of blood taking	64	93
3.	Labelling and sampling error at time of blood taking	78	38
	Sub-total	**223**	**182**
Blood administration in the ward			
1.	Failure to check the blood against patient's full identity	0	1
2.	Others	0	0
	Sub-total	**0**	**1**
Testing (Blood Bank)			
1.	Technical error	10	8
2.	Transcription error	7	8
3.	Blood issued meant for another patient	2	5
4.	Wrong blood product supply (eg: product not irradiated despite fulfill indication)	0	2
	Sub-total	**19**	**23**
Cause of Near Miss cannot be determined/ Inconclusive			
	Sub-total	18	13
	Total	**260**	**219**

Table 4.5: Type of Near Miss Event

4.6 CATEGORY OF HOSPITAL PERSONNEL INVOLVED IN NEAR MISS – Figure 4.6

Majority of hospital personnel involved in near miss for both years were house officers in which there were 213 in 2016 and 177 in 2017. This was to no surprise as house officers were 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. Six medical officers also noted

to oversight the SOP in 2016 and decreased to 3 in 2017. Four staff nurses (SN) were involved in NM in ward during blood sampling in 2016 and one SN in 2017. Another case in 2017 that involved a staff nurse was during blood administration.

Near miss in the blood bank were due to MLTs, as they were involved in all procedures in laboratory. In 2016, there were 19 MLTs while in 2017 the number increased to 23.

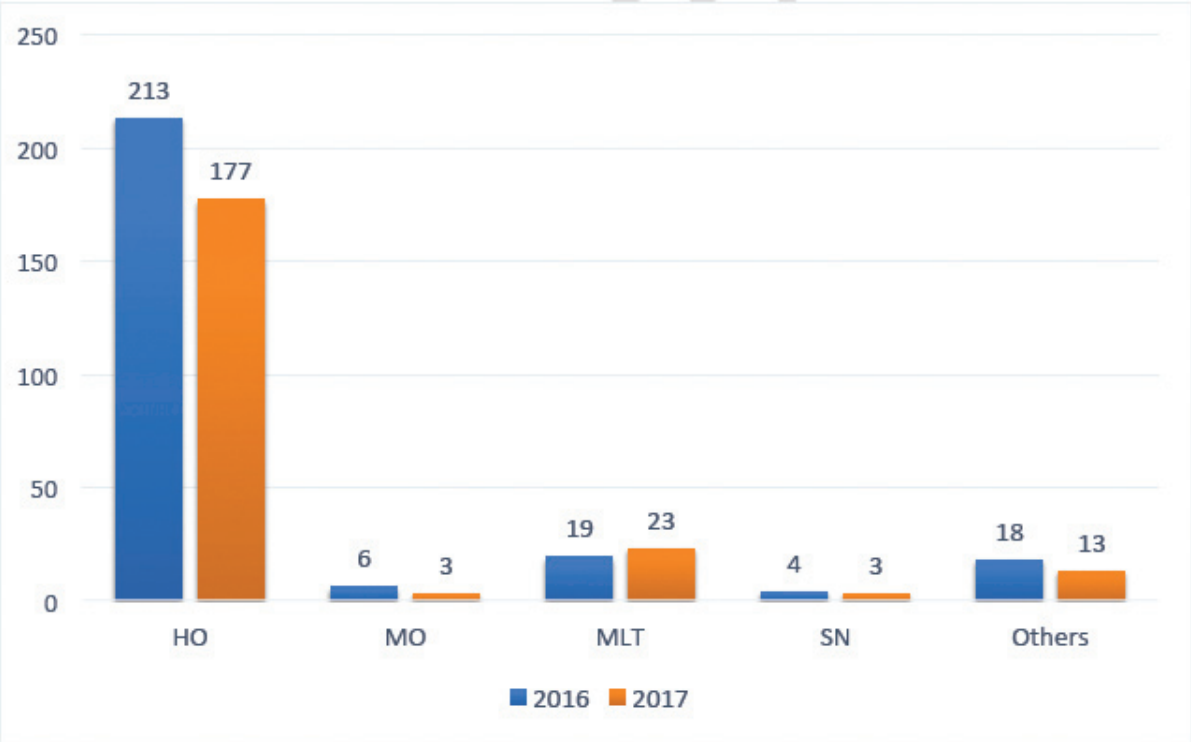


Figure 4.6: Hospital Personnel Involved In Near Miss

4.7 CAUSES OF OTHER INCIDENTS RELATED TO TRANSFUSION PROCESS – Table 4.7

Total number of reported incidents related to transfusion process were 110 cases in 2016 and increase to 186 cases in 2017. Cases that were placed under these categories were:

- Error in registration process: Sharing same ID (IC, UNHCR, Passport)
- Possible blood grouping error in other hospital/clinics
- Error in previous admission
- Others (please specify)

The number of errors in the registration process were 22 cases (20%) in 2016 and dropped to 12 cases (6.45%) in 2017. These were the patients who had been registered to the hospital by using same identification by another patient that was previously admitted.

There were also possible blood grouping error in other hospitals/clinics, which were documented in the patient's record involving antenatal cases and was found discrepant with the patient's actual blood group in the current admission. Total cases were 45 (40.9%) in 2016 and 62 (33.33%) in 2017.

Error of blood grouping in previous admission could be due to either ward or blood bank error that cannot be determined. This comprised of 43 cases (39.09%) in 2016 and 69 cases (37.10%) in 2017.

In 2017, NHCC identified that under the category "Others", 43 cases (100%) were clerical errors during transcribing the patient's blood group from the antenatal book to the GSH form.

	Other Incidents Related to Transfusion Process	2016	2017
1.	Error in registration process: Sharing same ID (IC, UNHCR, Passport)	22	12
2.	Possible blood grouping error in other hospital/clinics	45	62
3.	Error in previous admission	43	69
4.	Others : Clerical error	-	43
	Total	**110**	**186**

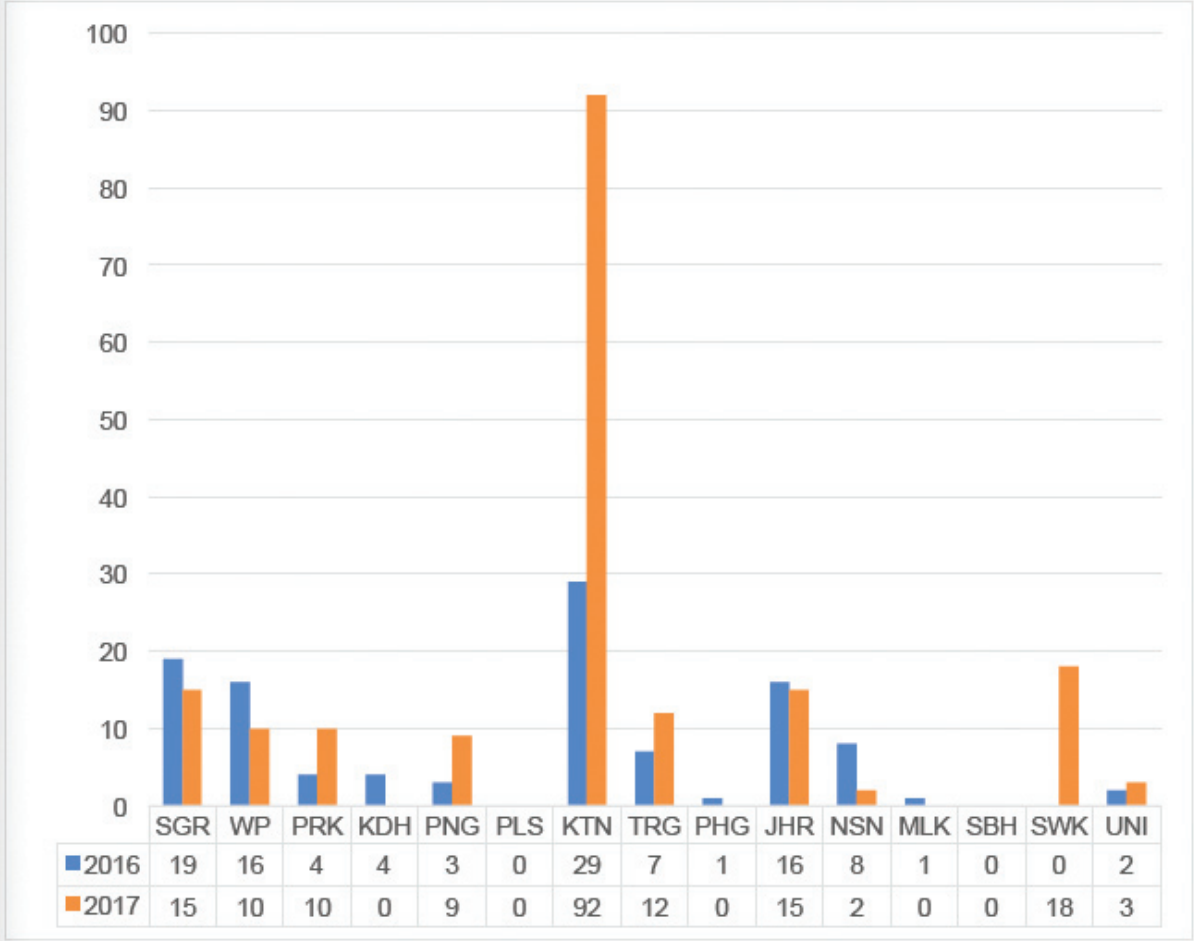
Table 4.7: Causes of Other Incidents Related to Transfusion Process

4.8 THE INCIDENCE OF OTHER INCIDENTS RELATED TO TRANSFUSION PROCESS BY STATES – Figure 4.8

Kelantan had the highest reported number of incidents related to transfusion process in both year with 26.36% of cases in 2016 and almost doubled to 49.46% in 2017. Pulau Pinang and Perak also showed slight increase in number of reporting from 2.73% and 3.64% in 2016 to 4.84% and 5.38% in 2017. Terengganu reported approximately the same percentage of incidents that were 6.36% and 6.45% in 2016 and 2017 respectively. University hospitals on the other hand, reported 1.82% in 2016 and 1.61% in 2017.

The incidents reported by Selangor and Johor were reduced to almost half in 2017. Selangor reported 17.27% incidents in 2016 and 8.06% in 2017 whereas Johor reported 14.55% incidents in 2016 and reduced to 8.06% in 2017. There was a one third reduction of incidents in Wilayah Persekutuan from 14.55% in 2016 to 5.38% in 2017. Negeri Sembilan also showed a reduction in the percentage of incidents from 7.27% in 2016 to 1.08% in 2017.

Sarawak reported 18 cases (9.68%) in 2017 but none in 2016 while Kedah had 4 cases (3.64%) in 2016 but none in 2017. Pahang and Melaka reported 1 case each in 2016 and none in 2017. Perlis and Sabah have no reported cases of incidents in both years.



	SGR	WP	PRK	KDH	PNG	PLS	KTN	TRG	PHG	JHR	NSN	MLK	SBH	SWK	UNI
2016	19	16	4	4	3	0	29	7	1	16	8	1	0	0	2
2017	15	10	10	0	9	0	92	12	0	15	2	0	0	18	3

Figure 4.8: The Incidence of Other Incidents Related To Transfusion Process by States

4.9 Malaysian Patient Safety Goals (MPSG) Performance

To ensure the safety of transfusion of blood and blood products

PATIENT SAFETY GOALS 6

NHCC works along with Patient Safety Counsel to monitor and evaluate the status of patient safety in the country. These goals and indicators are reviewed by the Patient Safety Council regularly every 5 years. There are total of 13 Patient Safety Goals of which safety of transfusion of blood and blood products fall in goal no 6.

The rationale of Patient Safety Goal 6 is mainly to ensure the provision of universal access to safe, quality and efficacious blood and blood products for transfusion, their safe and appropriate use and also ensuring blood donor and patient safety are key elements of a safe and high quality transfusion programme.

Although the number of NM and incident reports received from MPSG were 497 in 2016, the number of reports received by NHCC were only 370. These could be due to lack of reports received mainly from Private and University Hospital and a few from MOH Hospitals.

Chapter 5

Patient Haemovigilance

5.0 Incorrect Blood Component Transfused

The most detrimental error is failing to learn from an error."

5 INCORRECT BLOOD COMPONENT TRANSFUSED (IBCT)

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

SHOT UK 2016

5.1 INCIDENCE OF IBCT IN MALAYSIA – Figure 5.1

The total number of IBCT reported has steadily increased over the years with 38 cases in 2016 and 35 cases in 2017. Total number of recipients were 362,564 in 2016 and 343,959 in 2017. Therefore the incidence for IBCT in Malaysia were 0.01% for either year or about 1 cases of IBCT per 10,000 recipients.

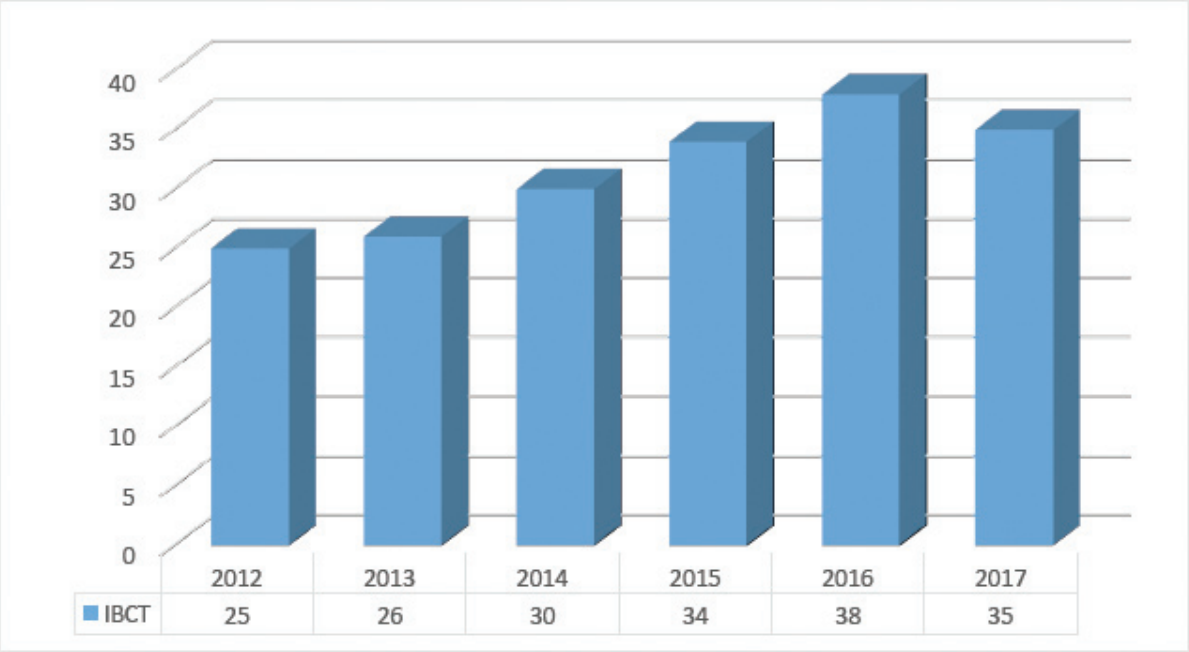


Figure 5.1: Incidence of IBCT in Malaysia

5.2 INCIDENCE OF IBCT BY STATES – Table 5.2

Total number of IBCT reported were 38 in 2016 but reduced to 35 in 2017. Hospital blood banks under Ministry of Health (MOH) contributed 94.74%

(36) of IBCT reports in 2016 and 91.43% (32) in 2017. However, there is an increase in the number of IBCT reports received from Institusi Perubatan Khas and University hospitals of 2 cases in 2016 and 3 cases in 2017.

Four states and 2 University Hospitals showed an increase in IBCT cases over the two years with Kedah 2 cases in 2016 to 7 in 2017 and Johor with 5 cases in 2016 to 8 cases in 2017. These two states showed a remarkable increase in IBCT over the two years by 14.7% and 12.3% respectively. Pulau Pinang from 1 case to 3 cases in 2017, Perak with no cases over several years to 2 in 2017 and finally University Hospitals from 2 cases in 2016 to 3 cases in 2017.

There was a significant drop in IBCT in 2017 from 7 to 2 cases in Wilayah and in Kelantan from 5 to 1 case; a fall in 12.8% and 10.3% respectively. There was also a fall in the number IBCT cases that occurred in other states like in Sabah, Sarawak, Pahang, Terengganu, Melaka, Selangor and Negeri Sembilan. There were no IBCT cases reported from Perlis and the private hospitals over the past two years.

No.	STATE	2016		2017	
		No of Recipients	No of IBCT	No of Recipients	No of IBCT
1.	Selangor	68831	3	68008	1
2.	Sabah	54864	4	59241	3
3.	Johor	49629	5	39491	8
4.	Kedah	27929	2	27902	7
5.	W.Persekutuan	26611	6	22893	2
6.	Perak	22522	0	21935	2
7.	Sarawak	22129	5	21847	4
8.	P.Pinang	17413	1	17420	3
9.	Pahang	17290	1	17324	0
10.	Melaka	16966	1	14563	0
11.	Kelantan	15594	5	10608	1
12.	N.Sembilan	10390	2	8952	1
13.	Terengganu	8346	1	8877	0
14.	Perlis	4053	0	4898	0
15.	Institusi P Khas/ Uni Hosp	U/K	2	U/K	3
	Total	**362,564**	**38**	**343,959**	**35**

**U/K = Unknown*

Table 5.2: Incidence of IBCT by States

5.3 INCIDENCE OF IBCT EVENTS REPORTED BY HOSPITAL BLOOD BANKS UNDER MINISTRY OF HEALTH - Figure 5.3

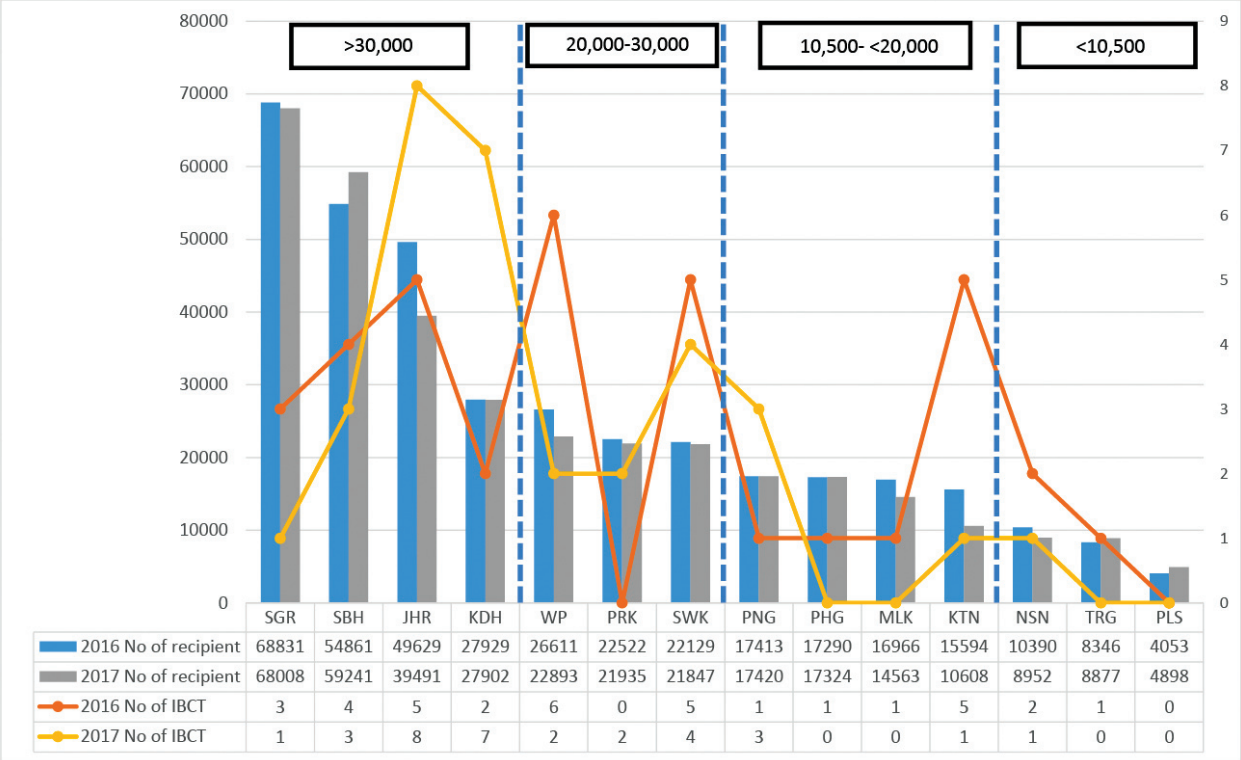
The number of recipients for hospital blood banks under Ministry of Health for 2016 and 2017 were 362,564 and 343,959 respectively. However, the incidence of IBCT in relation to the number of recipients were 0.01% for both the years.

There were three states with more than 30,000 recipients. These states include Selangor, Sabah and Johor. Johor has the highest number of IBCT reported of 5 cases in 2016 and 8 cases in 2017, followed by Sabah with 4 cases and 3 cases respectively. Selangor reported the least number of IBCT of 3 cases in 2016 and 1 cases in 2017.

There were four states with number of recipients between 20,000 to less than 30,000. These states include Kedah, Wilayah Persekutuan, Perak and Sarawak. For these category, Kedah showed the highest number on IBCT in 2017 of 7 cases, followed by Sarawak of 4 cases, Wilayah Persekutuan and Perak of 9 cases each. However in 2016, Wilayah Persekutuan reported 6 cases, while Perak had no cases.

There were four states with number of recipients between 10,500 to less than 20,000. These states include Pulau Pinang, Pahang, Melaka and Kelantan. Pulau Pinang showed the highest number of IBCT reported for 2017 of 3 cases whereas Kelantan of 5 cases in 2016 but I case in 2017. There was 1 case each for Pulau Pinang and Pahang in 2016 but no cases reported for Pahang and Melaka in 2017.

There were three states with the least number of recipients of less than 10,500. These states were Negeri Sembilan, Terengganu and Perlis. Negeri Sembilan showed the highest number of IBCT of 1 case in 2017 but 2 cases in 2016. Terengganu reported 1 case in 2016 but no cases in 2017. There were no cases too reported from Perlis for both years.



	SGR	SBH	JHR	KDH	WP	PRK	SWK	PNG	PHG	MLK	KTN	NSN	TRG	PLS
2016 No of recipient	68831	54861	49629	27929	26611	22522	22129	17413	17290	16966	15594	10390	8346	4053
2017 No of recipient	68008	59241	39491	27902	22893	21935	21847	17420	17324	14563	10608	8952	8877	4898
2016 No of IBCT	3	4	5	2	6	0	5	1	1	1	5	2	1	0
2017 No of IBCT	1	3	8	7	2	2	4	3	0	0	1	1	0	0

Figure 5.3: Incidence of IBCT Events Reported by Hospital Blood Banks under Ministry Of Health

5.4 INCIDENCE OF IBCT EVENTS IN RELATION TO NUMBER OF RECIPIENTS – Table 5.4

The number of IBCT cases reported from MOH hospitals in Malaysia for 2016 and 2017 were 68 cases with total recipients of 706,523. The incidence of IBCT was 9.62 per 100,000 recipients.

Kelantan recorded the highest incidence of IBCT of 22.9 per 100,000 recipients followed by Sarawak of 20.5 per 100,000 recipients. Wilayah Persekutuan and Kedah had incidence of 16.16 and 16.12 per 100,000 recipients respectively. Safety measures need to be strengthen in order to prevent incidence of incorrect blood component transfused. However underreporting of near miss by other states could falsely makes these two states to have significantly higher number of IBCT.

Although Johor has the highest number of IBCT cases reported over the two years which were 13 cases with a rate was 14.59 per 100,000 recipients. Negeri Sembilan and Pulau Pinang has incidence of 15.5 and 11.5 per 100,000 recipients respectively. Sabah and Terengganu has the incidence of 6.13 and

5.8 per 100,000 recipients respectively. Perak, Melaka, Selangor and Pahang have the incidence of less than 5 per 100,000 recipients in which Perak had 4.5 and Melaka 3.2 per 100,000 recipients respectively. Two states with incidence of 2.9 per 100,000 recipients were Selangor and Pahang. Although Selangor had most number of recipients over the two years, the incidence of IBCT was the lowest. However this probably could be underreported as the average incidence of IBCT for Malaysia was nearly 9.62 per 10,000 recipients for 2016 and 2017. If the values are true then preventive steps taken by each of these state to minimise the error should be shared and learnt by others.

Although Perlis was with the least number of recipients, there were no recorded cases of IBCT for both years.

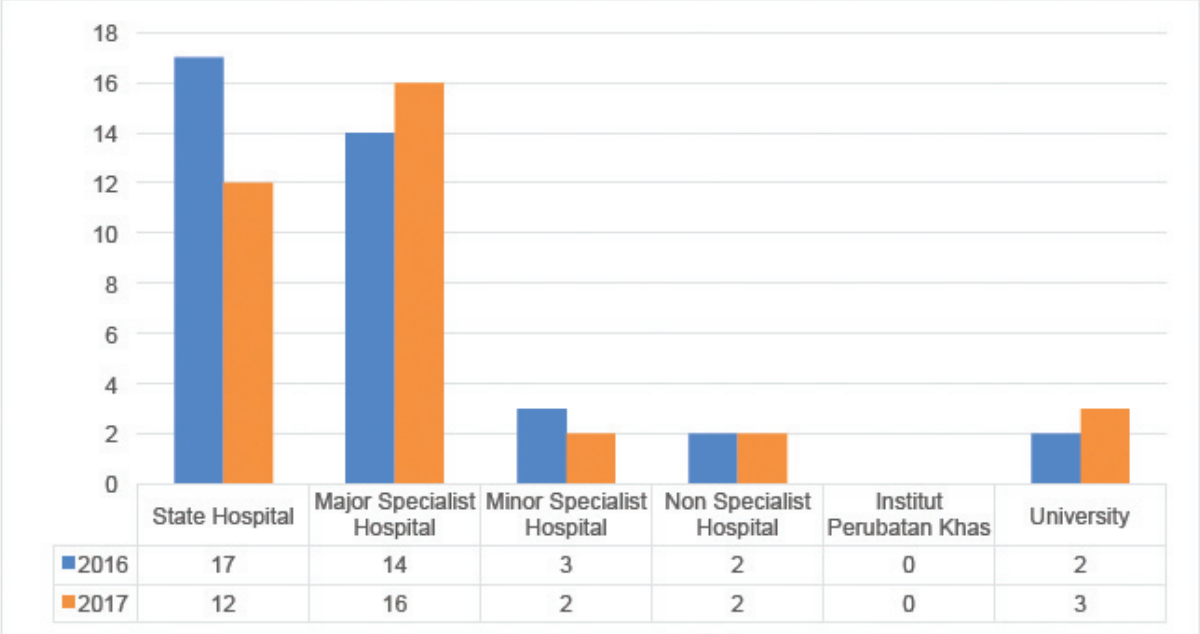
No.	STATE	Total No of IBCT 2016-2017	Total No of recipients 2016-2017	Rate of IBCT per 100,000 Recipients
1.	KTN	6	26202	22.9
2.	SWK	9	43976	20.5
3.	WP	8	49504	16.16
4.	KDH	9	55831	16.12
5.	NSN	3	19342	15.5
6.	JHR	13	89120	14.59
7.	PNG	4	34833	11.5
8.	SBH	7	114102	6.13
9.	TRG	1	17223	5.8
10.	PRK	2	44457	4.5
11.	MLK	1	31529	3.2
12.	SGR	4	136839	2.9
13.	PHG	1	34614	2.9
14.	PLS	0	8951	0
15.	**MALAYSIA**	**68**	**706523**	**9.6**

Table 5.4: Incidence of IBCT Events in Relation to Number of Recipients

5.5 INCIDENCE OF IBCT BY CATEGORY OF HOSPITAL – Figure 5.5

Errors can occur anywhere if we are not vigilant. Over the last two years, reports on IBCT were received more from state hospitals and major specialist hospitals as these hospitals are referral centers for cases waranting for blood transfusion. There were 16 cases from major specialist hospitals, 12 from state hospitals in 2017 whereas in 2016 there were 17 from state hospitals

and 14 were from major specialist hospitals. However there was a reduction of 10.4% of IBCT cases noted in State Hospitals. University Hospitals showed an increase from 2 cases in 2016 to 3 cases in 2017. There were 3 cases from minor specialist hospitals in 2016 and 2 cases in 2017. Nonspecialist hospitals reported 2 cases of IBCT in both years.

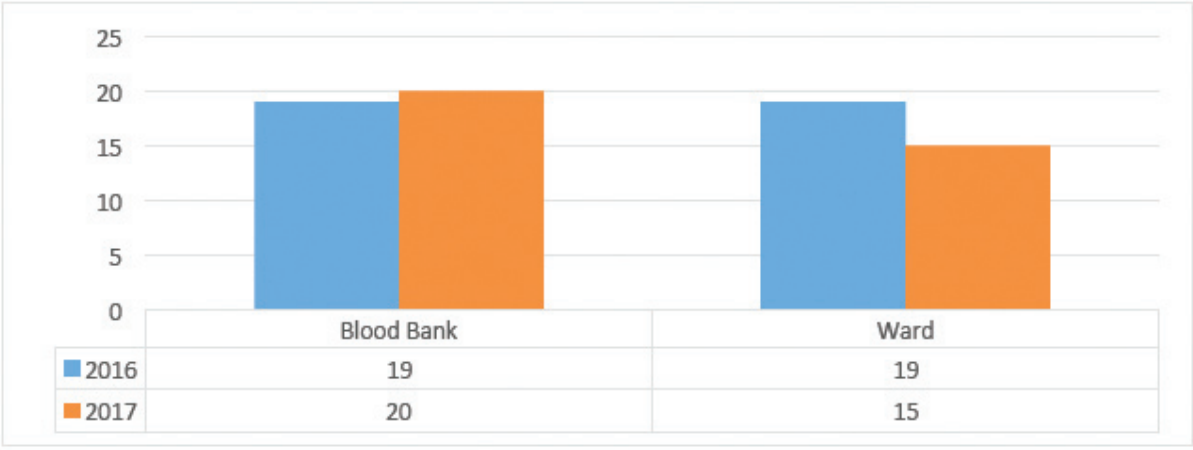


	State Hospital	Major Specialist Hospital	Minor Specialist Hospital	Non Specialist Hospital	Institut Perubatan Khas	University
2016	17	14	3	2	0	2
2017	12	16	2	2	0	3

Figure 5.5: Incidence of IBCT by Category of Hospital

5.6 SITE OF ERROR – Figure 5.6

The number of IBCT in blood bank showed a rise from 19 to 20 cases in 2016 and 2017 respectively. On the other hand, error in ward showed a reduction in the number of cases from 19 to 15.



	Blood Bank	Ward
2016	19	19
2017	20	15

Figure 5.6: Site of Error

5.7 COMPARISON OF CRITICAL POINTS IN IBCT

5.7.1 Blood Bank Error – Figure 5.7.1a, 5.7.1b

Blood Bank Error

This category currently includes: Patients receiving a blood component intended for a different patient, due to - laboratory error which comprises of 3 major step in transfusion test.

a. **Technical error** – which error happens when staff did not adhere to SOP in laboratory setting such as wrong sample selected for testing, ABO/RhD grouping error and incorrect component selected from stock.
b. **Transcription error** – which error happens when staff mistakenly write wrong data entry into the form or IT system.
c. **Issuing error** - procedural errors contributing to the selection and issue of the incorrect blood group

Total number of IBCT were 19 cases for 2016 and 20 cases for 2017. Issuing error seemed to be the main cause of IBCT for both years. Blood issued meant for another patient was the commonest cause of error in issuing while the occurrence of blood issued with wrong phenotype or wrong component were the same over the two years.

Technical error was the second commonest cause of IBCT. There was an increase in the number of cases from 6 in 2016 to 10 in 2017. This either happened because MLT performed test on multiple sample at one time and wrongly read another patient's results or switched samples. Regrouping was only done once the blood was released. In few instances, it was also noted MLTs were not competent enough while performing their task and never seek the assistance of other staffs when they were in a doubt. Staffs not adhering to standard operating procedures (SOPs) and increase in workload may also lead to these errors. On the other hand there were no transcription error in 2017 compared to 5 cases in 2016.

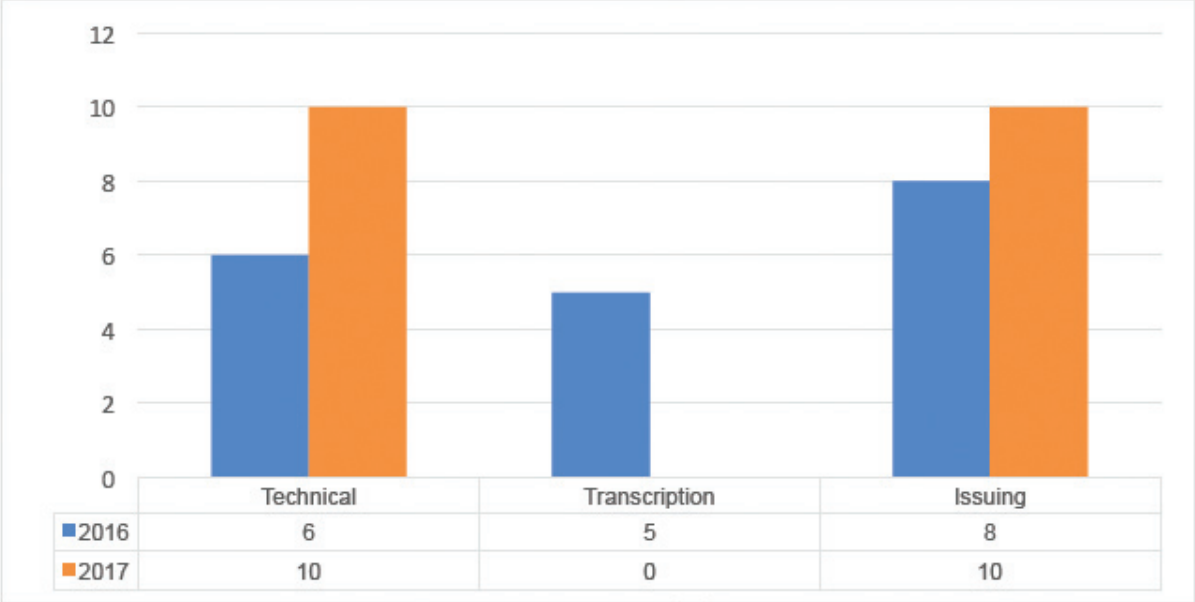


Figure 5.7.1a: Critical Points of Error in Blood Bank

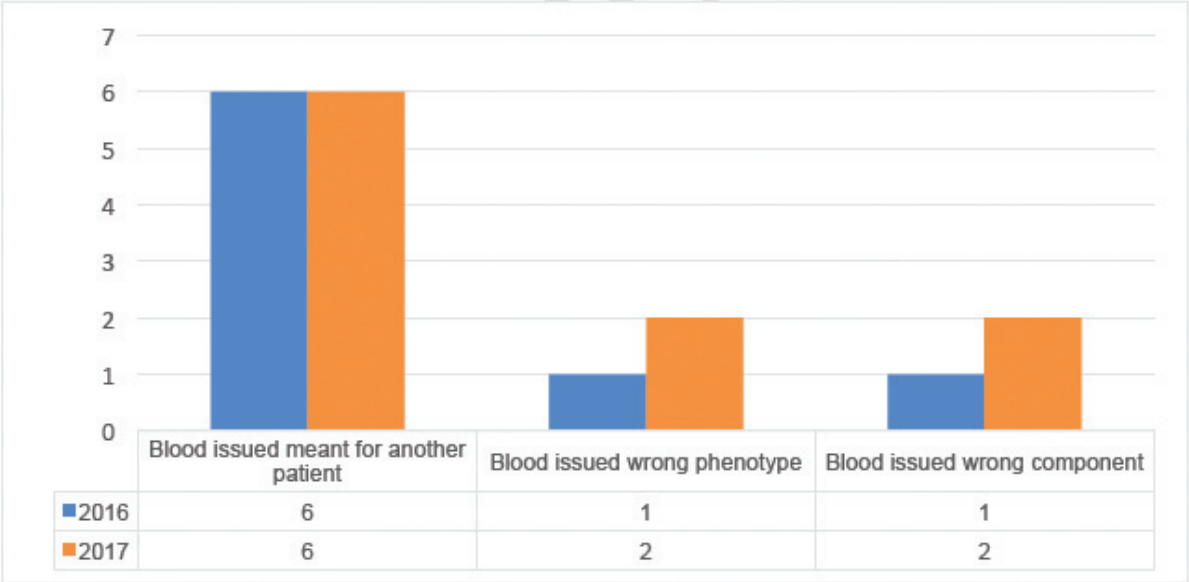


Figure 5.7.1b: Type of Issuing Error

5.7.2 Ward – Figure 5.7.2

IBCT in ward comprised of sampling and/or labeling and administration errors. Sampling and/or labelling errors seemed to be the commonest cause for both years. There were 10 cases in 2016 and reduced to 7 cases in 2017. Meanwhile there was only slight reduction in administration error from 9 cases to 8 cases in both years.

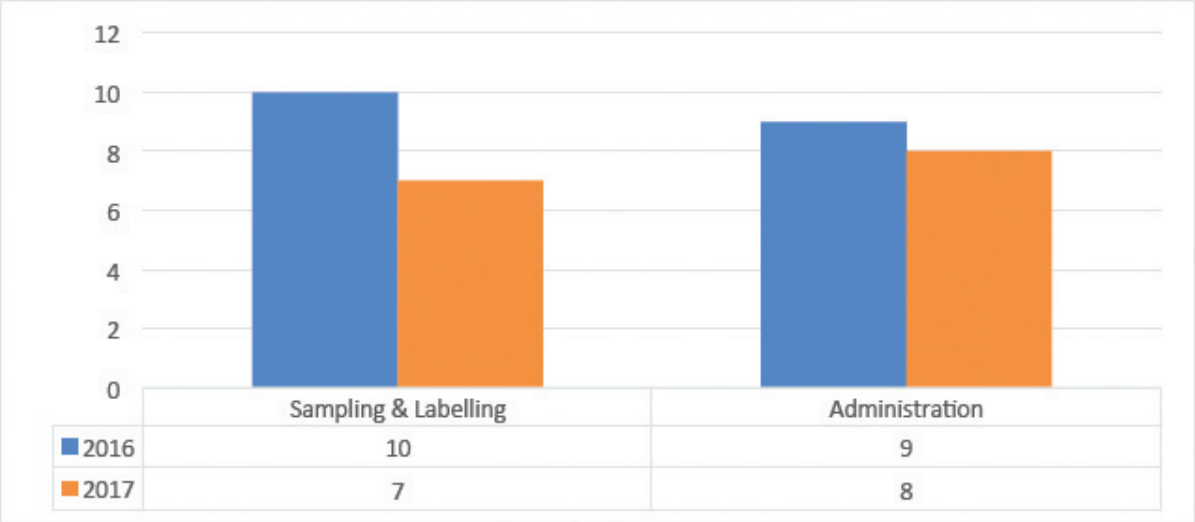


Figure 5.7.2: Critical Points of Error in Ward

5.8 CATEGORY OF STAFFS INVOLVED IN IBCT

5.8.1 Sampling and/or Labelling error – Figure 5.8.1

Staffs involved in the sampling and/or labeling were mainly doctors. There was a reduction in the number of errors done by house officers (HOs) from 7 cases in 2016 to 4 cases in 2017. HOs remained the highest personnel involved in sampling and/or labelling error as they were mainly involved in blood taking and labelling. On the other hand, medical officers contributed to 2 cases while staff nurses were the least with 1 case in each year.

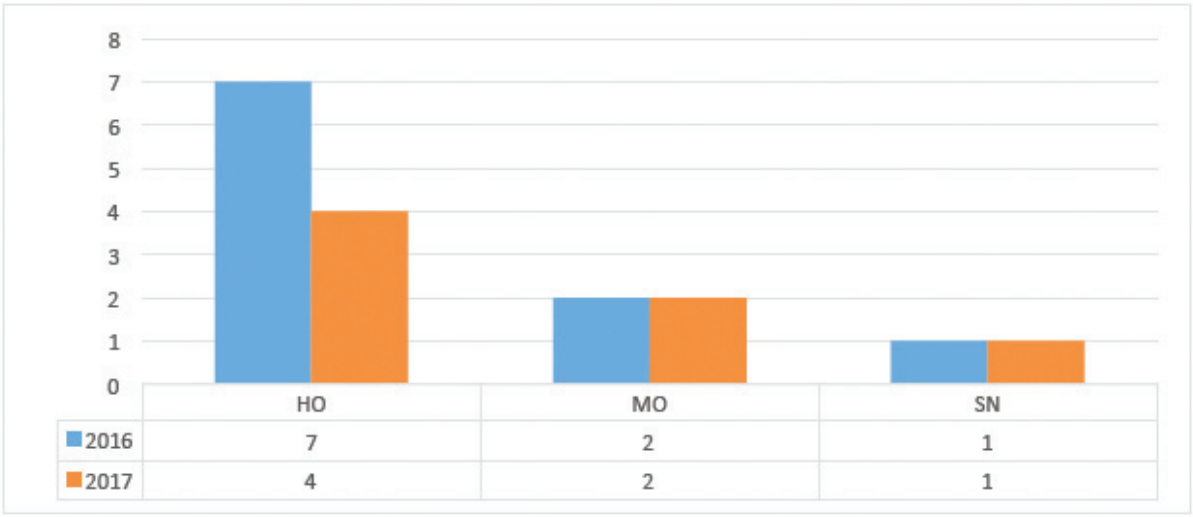


Figure 5.8.1: Category of Staffs Involved in IBCT : Sampling and/or Labelling error

5.8.2 Administration error – Figure 5.8.2

The correct component was collected or delivered but failure of the final identification check at the patient's bedside led to the component being transfused to the wrong patient. Personnel involved were mainly staff nurses with 7 cases for both years while house officers contributed to 2 cases in 2016 and 1 case in 2017. No errors were done by medical officer.

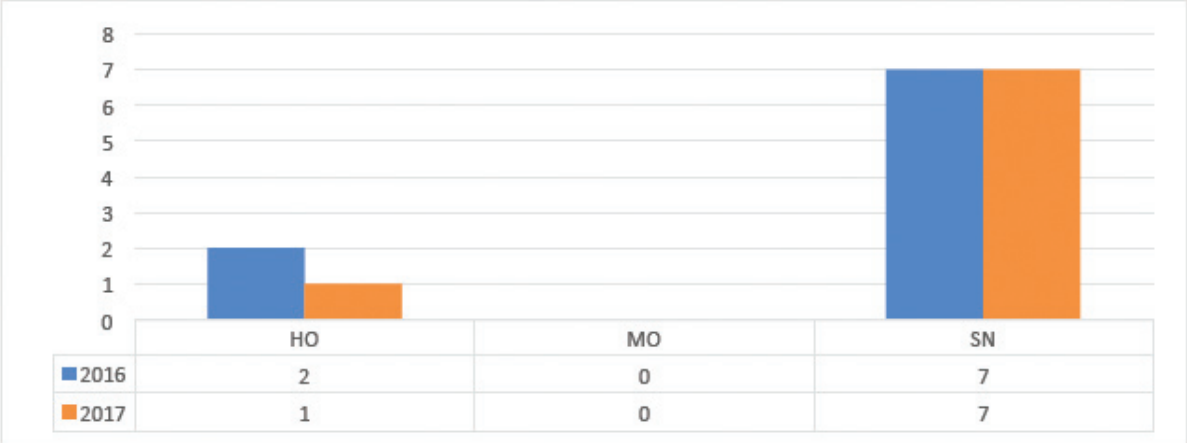


Figure 5.8.2 : Category of Staffs Involved in IBCT : Administration Error

5.9 OUTCOME OF IBCT – Table 5.9 and Figure 5.9

Majority of patients with IBCT had recovered with no ill effects in which were 65.79% of cases (25) in 2016 and 57.14% (20) cases in 2017.

There were 8 cases reported with recovery but required extended length of stay for both years with (21.05%) in 2016 and (22.86 %) in 2017. Meanwhile there were nine deaths recorded for both years due to IBCT of which seven were not related to transfusion while two were probably related to transfusion.

As described in figure 5.9, only 2.63% reports received in 2016 and 5.71% of reports received in 2017 did not specify the outcome of recipients. This was possibly due to improvement in quality of reporting with more conscientious follow up and training done by NHCC.

Outcome	2016		2017	
	Number	%	Number	%
Recovered with no ill effects	25	65.79	20	57.14
Recovered with illness (morbidity)	8	21.05	8	22.86
Death- Unlikely related to transfusion	4	10.53	3	8.58
Death- Probable related to transfusion	0	0	0	0
Death- Possible related to transfusion	0	0	2	5.71
Outcome not recorded	1	2.63	2	5.71
Total	**38**	**100**	**35**	**100**

Table 5.9: Outcome of IBCT

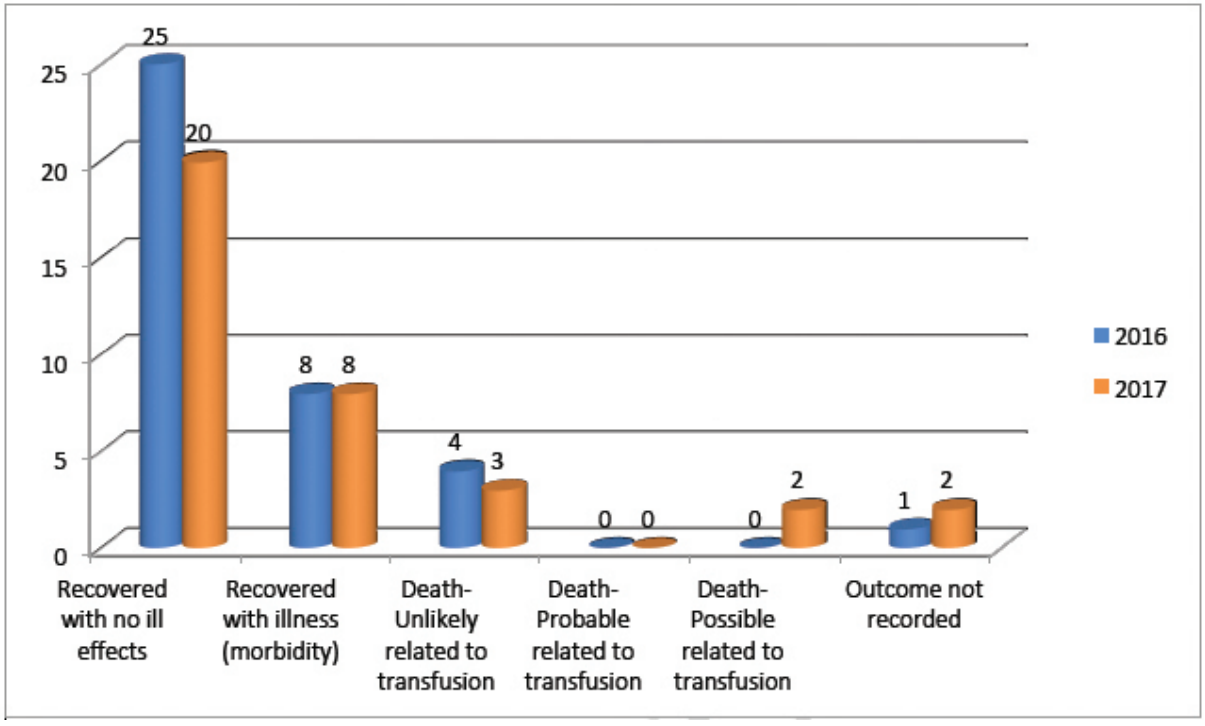


Figure 5.9: Outcome of Adverse Transfusion Reaction

5.10 RECOMMENDATIONS

1. Reporting of near misses, incidents and IBCT are essential as it helps to identify the root cause of error. Each hospital should have an active and functioning transfusion committee with members from all clinical departments, nursing department and blood bank to monitor and ensure the action plan is executed and completed within the agreed timeframe.

This would enable the organizations to take corrective and preventive actions and minimize future occurrence of similar events.

2. A near miss, if not been identified may lead to IBCT. Blood transfusion is a multistep, multidisciplinary process in which the human error is inevitable despite numerous courses and workshops conducted every year. As discussed in the report, WBIT/WNOT was the main source of error in both these mishaps in both years. Most of the time WBIT/WNOT occur when a positive patient identification (PPI) was not follow according to SOP. Ideally, this error can be eliminated by an automated phlebotomy specimen collection system where printing and applying specimen container identification labels to improve sample identification. However due to high cost this technology is not available in MOH blood banks. Nevertheless, in the meantime, some hospitals have implement second verifier during blood sampling and Clinical Transfusion Division (CTD) unit in PDN has started the initiative to do ward round that intend as a "spot-check" every week at random wards including in ED, OT and ICU to see whether the SOP in blood transfusion process is followed. All staffs involved in the transfusion process should be trained about haemovigilance, its objectives, benefits and consequences if not adhered to.

3. Issuing error was the commonest cause of error in blood bank over the two years, blood issued meant for another patient was the commonest error encountered. Hence there should be a checklist and two verifiers need to do so vigilantly at the counter prior to any release of blood or blood products. The need of proper staffing especially MLTs at blood bank too has to be looked into seriously. Many at times, MLTs multitask at one time when errors occur. The need to adhere to SOPs and preventing from taking shortcuts is a must at all times to prevent errors.

4. Technical error seem to be high generally over the two years. This was due to MLTs that process multiple sample at one time and wrongly read the other patient's results. In some cases, second MLT did regrouping but only after the blood had been released and some MLTs were not competent enough to interpret the results. Hence technical staffs should be trained, supervised as well as be made aware of their roles in transfusion safety at all times. Attitude and responsibility of staffs play an important role for the human factor for example testing of more than one sample at a time and test carried out was not interpreted and relied on previous results.

5. On the other hand there were no transcription error in 2017 compared to 5 cases in 2016. This was due to existing SOP was reviewed and detailed out on how to manage blood component request other than red cells as well as there was clear SOP to avoid in various practices among the staffs. Regrouping was done by second person before blood was issued. Enforcement was also taken to ensure data appear in computer tally with that in the request form. Besides that the need to increase staffs especially in areas where there was a shortage as same personnel was doing various tasks at the same time. Close monitoring of staffs on duty by supervisors too had prevented errors from occurring.

6. IBCT and near miss errors are preventable and therefore must be monitored for the purpose of implementing corrective and preventive measures. Positive patient identification during pre-transfusion sampling and strict adherence to SOP by personnel involve in the transfusion process is fundamental to prevent error.

7. State Transfusion Committe should also monitor transfusion practices in their respective states. There shall be a quality management system in all blood banks. Regular internal and external audits in quality and transfusion should be performed in all blood banks to ensure all process and procedures are in accordance with the national guidelines and standards.

8. Public too should be educated on safe transfusion practices and importance of patients using their own identity details by circulating educational flyers on regular basis.

Chapter 6

Donor Haemovigilance

6.0 Adverse Donor Reaction

"A hero is someone who has given his or her life to something bigger than oneself"

6 ADVERSE DONOR REACTION (ADR)

ADR is an undesirable response associated with the donation process of blood and blood components. Majority of donors experience no complication. By monitoring complications, blood establishment can take measures to reduce ADR. Life threatening complications and long term disability are extremely rare after blood donation. Severity of ADR is graded as mild, moderate and severe. In cases which donors require referrals to hospital or hospitalisation, they are automatically classified as severe ADR.

6.1 TYPE OF ADVERSE DONOR REACTIONS

TYPE OF ADVERSE DONOR REACTIONS		DESCRIPTION *ISBT/IHN 2014*
GENERALIZED SYMPTOMS	VASOVAGAL REACTIONS (VVR)	Vasovagal reaction (VVR) describes general feeling of discomfort and weakness with anxiety, dizziness and nausea. It can occur before, during, or immediately after phlebotomy especially when donor stands up abruptly, while in the refreshment area, or later when donor has already left the donation area. It may progress to loss of consciousness (LOC). This is the most common acute complication related to blood donation. The mechanism is from both physiologic and psychological. In severe cases, hypotension and LOC may occur accompanied by loss of bladder control or convulsive movement. It is classified further to mild, moderate and severe and also relating to whether VVR occurs with injury (fall, accidents) or no.

TYPE OF ADVERSE DONOR REACTIONS			DESCRIPTION *ISBT/IHN 2014*
LOCAL SYMPTOMS	BLOOD OUTSIDE VESSELS	HAEMATOMA	Hematoma is an accumulation of blood in the tissues outside the vessels. It is caused by blood flowing out of damaged vessels and accumulating in the soft tissues. Affected donors may present with bruises, discoloration, swelling and local pain. Blood accumulating in deeper tissues may result in serious pain and pressure syndrome. In apheresis donation, hematoma can also be caused by infiltration of soft tissues by red cells during the return phase of the procedure. Large hematoma might cause pressure in surrounding tissues and may contribute to other complications such as nerve irritation or injury. Very rarely, it may also contribute to compartment syndrome.
	BLOOD OUTSIDE VESSELS	ARTERIAL PUNCTURE	Arterial puncture is defined as a puncture of brachial artery or one of its branches by the needle used to bleed donor. The blood collected is usually brighter red in colour. Needle and tubing may pulsate and blood bag fills up quickly. There may be weak pain localized in the elbow region. There is also risk of large hematoma and might lead to compartment syndrome.
		DELAYED BLEEDING	Delayed bleeding is defined as leakage of blood from the venepuncture site after initial bleeding has stopped. Rebleeding may be caused by incorrect location or inadequate pressure applied to the venepuncture site. Premature removal of bandage post donation is mostly the cause. After donation, donor might strain donation's arm by lifting heavy object and increasing the risk of delayed bleeding. Other causes might be due to underlying medical illness or medication such as anticoagulants.

TYPE OF ADVERSE DONOR REACTIONS			DESCRIPTION *ISBT/IHN 2014*
LOCAL SYMPTOMS	BLOOD OUTSIDE VESSELS	NERVE INJURY OR NERVE IRRITATION	At insertion or withdrawal of needle, a nerve might be hit directly causing pressure on the nerve. Swellings from the surrounding tissues from hematoma or inflammation of soft tissues may also cause disturbance to the nerve. Donor may have radiating or electrical sharp pain moving away from the venepuncture site. Tingling or burning sensation may also be felt later after donation has completed, in which it is due to progressive increase in hematoma that presses on the nerve. Certain positions or arm motions may have worse symptoms and rarely donor complains of arm weakness. Usually symptoms resolve within days but may persist for months as the nerve recovers.
		OTHER ARM PAIN	Pain in the arm may be the only presenting complain from donor. This criterion is chosen when all the diagnosis above such hematoma, nerve injury or irritation has been ruled out.
	LOCALIZED INFECTION OR INFLAMMATION (THROMBOPHLEBITIS OR CELLULITIS		Inflammation along the course of the vein may progress to localised infection few days after blood donation. The superficial vein inflammation is called thrombophlebitis whereas the inflammation to surrounding tissues is called cellulitis. Donor may present with warm skin, tenderness, redness and swelling at venepuncture site.
	OTHER MAJOR BLOOD VESSELS INJURY	DEEP VEIN THROMBOSIS	Deep venous thrombosis is defined as thrombosis in deep vein on donor's phlebotomy arm. The superficial venous thrombosis may progress into deeper veins, but this rarely occurs. Other risk factors such as the use of oral contraceptives may present in these donors. They may have swelling and pain at the upper arm and also accompanied by symptoms of superficial vein inflammation.

TYPE OF ADVERSE DONOR REACTIONS			DESCRIPTION *ISBT/IHN 2014*
LOCAL SYMPTOMS	OTHER MAJOR BLOOD VESSELS INJURY	ARTERIOVENOUS FISTULA	Arteriovenous fistula is defined as acquired connection between the vein and artery due to venepuncture lacerations. After venepuncture, a channel may form between the lacerated vein and artery during healing process. Donor may have pulsating mass with palpable thrill and associated bruit. The affected arm feels warm while the distal part is cold from the presence of significant blood shunting. The distal veins may be dilated and pulsating.
		COMPARTMENT SYNDROME	Compartment syndrome is an increased intracompartment pressure leading to muscle and soft tissue necrosis. This is usually caused by arterial puncture, large haematoma or inflammation in soft tissues leading to increase compartment pressure in the donating arm. Blood may accumulate in the frontal deep areas of the forearm. Donor may have painful arm, paresthesia, pallor and later paralysis if not treated.
		BRACHIAL ARTERY PSEUDOANEURYSM	Pseudoaneurysm of brachial artery following blood donation is a very rare complication. This is due to inadvertent complication from arterial puncture. Donor may present with pulsatile swelling in the antecubital fossa and paresthesia of hand.

TYPE OF ADVERSE DONOR REACTIONS		DESCRIPTION *ISBT/IHN 2014*
ALLERGIC REACTION	LOCAL ALLERGIC REACTION	Any red or irritated skin and the venepuncture site caused by allergens or irritants in solutions used to disinfect arm such as iodine or chlorhexidine. It could also be caused by adhesive bandage or latex from the gloves used. Donor may have itchiness and redness or raised rash or hives in the venepuncture area and may expand to cover a larger area of arm. It may last from hours to days post donation.
	GENERALIZED (ANAPHYLACTIC) REACTION	In severe allergic reaction known as anaphylactic reaction, it usually starts few seconds or minutes after procedure begins and can rapidly progresses to cardiac arrest. Donor may present with sudden onset of severe hypotension, cough, bronchospasm from respiratory distress and wheezing, laryngospasm, angioedema, urticaria, rashes, shock or loss of consciousness. This may be a fatal reaction.
SERIOUS COMPLICATIONS RELATED TO BLOOD DONATION		Serious complications relating to blood donation are divided into acute cardiac symptoms, myocardial infarction, cardiac arrest, transient ischaemic attack, cerebrovascular accident or death. In situation where patient complains of chest pain, but the diagnosis of myocardial infarction and cardiac arrest has been ruled out, acute cardiac symptoms is the criterion.

TYPE OF ADVERSE DONOR REACTIONS		DESCRIPTION *ISBT/IHN 2014*
ADVERSE DONOR REACTIONS RELATED TO APHERESIS	CITRATE REACTION	Infusion of citrate anticoagulant during apheresis causes a fall in ionised calcium levels, leading to neuromuscular hyperactivity. If untreated, symptoms may progress to tetany and severe cardiac arrythmias, including cardiac arrest. Operator error with mix up saline and citrate bags may occur with some apheresis equipment and lead to rapid citrate infusion. Donor may present with symptoms like numbness or tingling of lips, feelings of vibrations, numbness or tingling in the fingers, metallic taste, chills, and shivering, light headedness, feeling of tightness, muscle twitching, rapid or slow pulse or shortness of breath. Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalised muscle contractions, shock, irregular pulse and cardiac arrest.
	HAEMOLYSIS	Haemolysis in apheresis donor occur when there is a malfunctioning valves, kinks or obstruction of the tubing, incorrect installation of equipment, or other equipment failures affecting the extracorporeal circuit. Incompatible replacement fluids, such as dextrose D5W may be used in error. Donor may present with pink or red colored plasma, blood in lines or filter may appear dark. The donor may also notice pink or red urine after collection.
	AIR EMBOLISM	Air embolism is presence of air bubble in donor's circulation. Air may enter into the lines due to the incomplete priming of lines, as a result of a machine malfunction or defective collection kits or through incorrect manipulation by staff. Air in the donor's pulmonary circulation may occlude the pulmonary arteries in the lung and cause cardiopulmonary symptoms. Air may pass to the arterial circulation through an atrial septal defect and reduce blood flow to the brain. Donor will has bubbling sound or feeling at the venepuncture site, or present with cough, dyspnoea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea or vomiting.

6.2 TOTAL ADR REPORTED IN MALAYSIA 2016 – 2017 – Table 6.2

Blood donations are generally considered as safe procedures, however due to some several factors or circumstances donor complications do commonly occur in most. Donor's haemovigilance is important as it is a systematic monitoring of data collection and analysis for all adverse reactions from blood donations.

There are 153 hospitals in Malaysia in which 113 (73.9%) hospitals are collection centers for blood donation. Out of 113 blood collection centers in Malaysia, only 8 collection centers reported in 2016 (7.1%) and 15 centers reported in 2017 (13.3%). Reports were received from Kuala Lumpur, Selangor, Johor, Kedah, Penang, Sabah, Sarawak and Kelantan for both 2016 and 2017. A total of 896 reports were received in 2016 and 1100 reports received in 2017. Rate of ADR was about 3 per 1,000 donors for both years.

Year	ADR Reported	Total blood donations	% of ADR	Rate of ADR: 1,000 Donors
2016	896	255,584	0.35%	3.5
2017	1100	337,074	0.33%	3.5

Table 6.2: ADR Reports Received For 2016 And 2017

6.3 PARTICIPATION IN ADR REPORTING 2016 – 2017

In 2016, there were 8 collection centers participated in ADR reporting, while in 2017, there were an increase to 15 collection centers. The participation in ADR reporting for both years are mentioned in the table 6.4.

6.4 TOTAL ADR REPORTS ACCORDING TO COLLECTION CENTERS IN 2016 AND 2017 – Table 6.4

In 2016, the highest percentage of ADR was from Hospital Tuanku Ampuan Rahimah with 0.81%. While in 2017, the highest ADR was from Hospital Segamat with 1.12%.

2016				2017			
Collection centers	Total ADR	Total blood collection	% of ADR	Collection centers	Total ADR	Total blood collection	% of ADR
Pusat Darah Negara	623	180052	**0.35**	Pusat Darah Negara	515	180651	**0.28%**
Hospital Tuanku Ampuan Rahimah	204	25049	**0.81**	Hospital Tuanku Ampuan Rahimah	200	27241	**0.73%**
Hospital Segamat	5	5260	**0.10**	Hospital Segamat	58	4919	**1.12%**
Hospital Sultan Abdul Halim	1	11354	**0.01**	Hospital Sultan Abdul Halim	1	11505	**0.01%**
Hospital Bukit Mertajam	1	1615	**0.06**	Hospital Bukit Mertajam	5	1761	**0.28%**
Hospital Raja Perempuan Zainab II	15	15397	**0.10**	Hospital Raja Perempuan Zainab II	38	15506	**0.25%**
Hospital Duchess of Kent	8	9551	**0.08**	Hospital Melaka	84	30440	**0.28%**
Hospital Sibu	39	7306	**0.53**	Hospital Seremban	10	18464	**0.05%**
				Hospital Jelebu	1	116	**0.86%**
				Hospital Sultanah Ismail	5	11512	**0.04%**
				Hospital Miri	9	8006	**0.11%**
				Hospital Langkawi	14	2859	**0.49%**
				Hospital Kepala Batas	7	2076	**0.34%**
				Hospital Sibu	33	7485	**0.44%**
				Hospital Seberang Jaya	120	14533	**0.83%**

Table 6.4: Total ADR Reports by Collection Centers

6.5 ADR BY TYPES OF DONATION – Table 6.5

For 2016, there were 896 reports received. Out of the total, there were 870 reports (97.1%) from whole blood donation and 26 reports (2.9%) from apheresis donation. For 2017, 1090 reports (99.1%) were from whole blood donation and 10 reports (0.9%) were from apheresis ADR.

Year	Types of donation		Total cases reported
	Whole blood	Apheresis	
2016	870 (97.10%)	26 (2.90%)	896
2017	1090 (99.10%)	10 (0.90%)	1100

Table 6.5: ADR by Types of Donation

6.6 ADR FROM APHERESIS DONATION – Table 6.6

For both years, there were no ADR from apheresis donation received from other states apart from Pusat Darah Negara. Therefore, total number of apheresis donation in Pusat Darah Negara was used as the denominator. The total apheresis ADR received from Pusat Darah Negara was 26 for 2016 and 10 for 2017.

Year	Apheresis ADR reports	Total of apheresis donation in PDN	Percentage of apheresis ADR
2016	26	5928	0.44%
2017	10	4517	0.22%

Table 6.6: ADR Reports for Apheresis Donation

6.7 ADR BY TYPES OF REACTION – Table 6.7

For the following statistics below, both total numbers of whole blood and apheresis donations were combined as the denominator.

Most common ADR were vasovagal reaction (VVR). In details VVR can be classified according to the timing of occurrence (immediate or delayed) and the effects of reaction (injury or non-injury). The second highest ADR reported was haematoma. Other causes of ADR in 2016 and 2017 included vein collapse, compartment syndrome, nerve irritation and nerve injury.

Year	Types of adverse donor reactions			Total cases reported
	Vasovagal	Hematoma	Others (Vein collapse, compartment syndrome, nerve irritation, nerve injury)	
2016	828 (92.41%)	36 (4.02%)	896	896
2017	1062 (96.55%)	32 (2.91%)	1100	1100

Table 6.7: ADR Reports by Types of Reaction

6.8 ADR BY GENDER – Table 6.8

ADR distribution was higher in females. However there was only slight difference of ADR reported among female donors between 2016 and 2017 which was 50.3% and 51.6% respectively. Similarly, there was also slight decrease of ADR reported among male donors between both years which was 49.7% in 2016 and 48.4% in 2017.

Year	Gender		Total cases reported
	Male	Female	
2016	445 (49.67%)	451 (50.33%)	896
2017	532 (48.36%)	568 (51.64%)	1100

Table 6.8: ADR Reports by Gender

6.9 ADR BY AGE GROUP – Table 6.9

According to the table below, the age group 20-39 had the highest ADR reported in both 2016 and 2017 as largest number of donors is among this age group. In comparison, elder age groups (40 to 60 and more than 60) reported lower number of ADR as lesser donors were among these age groups. For 2016, there were 25 reports with no detail of age, thus denominator was changed to 871 instead of 896 reports.

Year	Age group (year old)				Total cases reported
	<20	20-39	40-60	>60	
2016	124 (14.20%)	649 (74.50%)	93 (10.70%)	5 (0.60%)	871
2017	184 (16.70%)	806 (73.30%)	107 (9.70%)	3 (0.30%)	1100

Table 6.9: ADR Reports by Age Group

6.10 ADR BY WEIGHT – Table 6.10

Donors with more than 55kg had the highest number of ADR which was 72.47% in 2016 and 70.9% in 2017 as most donors had body weights above 55kg. For 2016, there were 57 incomplete data for body weights, thus denominator used was 839 reports.

Year	Weight (kg)			Total cases reported
	< 50kg	50kg – 55kg	> 55kg	
2016	88 (10.49%)	143 (17.04%)	608 (72.47%)	839
2017	108 (9.82%)	212 (19.28%)	780 (70.90%)	1100

Table 6.10: ADR Reports by Weight

6.11 ADR ACCORDING TO TYPES OF BLOOD DONORS (FIRST TIME VS REPEATED BLOOD DONORS) – Table 6.11

There was no remarkable difference in the number of ADR between the first time and repeated blood donors. Most donors were first time donors in both 2016 and 2017. However, there were 2 incomplete data in 2016.

Year	Types of blood donors		Total cases reported
	First time	Repeated	
2016	489 (54.70)	405 (45.30%)	894
2017	562 (51.09%)	538 (48.90%)	1100

Table 6.11: ADR Reports by Types of Blood Donors

6.12 ADR WITH PREVIOUS HISTORY OF REACTION – Table 6.12

There was no remarkable difference in the number of ADR between the first time and repeated blood donors. Most donors were first time donors in both 2016 and 2017. However, there were 2 incomplete data in 2016.

Year	Previous history of reaction		Total repeated donors
	First time	Repeated	
2016	70 (17.28%)	335 (82.72%)	405
2017	94 (17.47%)	444 (82.53%)	538

Table 6.12: ADR Reports by Previous History of Reaction

6.13 ADR ACCORDING TO SEVERITY – Table 6.13

Most ADR that occurred were mild reactions. Based on the percentage of reactions, they were mostly vasovagal reactions. Most of them were mild reaction such as mild vasovagal reactions. Among severe reactions, there was 1 case of compartment syndrome and others were severe vasovagal reactions where donors had loss of consciousness and fitting. There were 83 reports with no severity of ADR documented in 2016.

Year	Severity			Total cases reported
	Mild	Moderate	Severe	
2016	712 (87.58%)	93 (11.44%)	8 9 (0.98%)	813
2017	953 (86.64%)	133 (12.09%)	14 (1.27%)	1100

Table 6.13: ADR According To Severity

6.14 RECOMMENDATIONS

1. Donor haemogivilance plays an important role in the safety of blood donation. The pathophysiology of vasovagal reactions in healthy donor is incomplete and further studies needed on other mitigating strategies to reduce the incidence as decrease donor satisfaction could led to negative impact on donor return rate.

2. To prevent adverse donor reactions and ensure donor safety, several measures should be practiced. Among them are proper donor reassurance and education, detailed donor selection, good clinical skills, regular staff training and competency tests.

3. Clinical audits should be conducted among staffs and blood donation process at the center and mobiles. Data collection from blood donation is also vital to identify the top causes of ADR. Besides, implementation of preventive and corrective measures can be done to help promoting safer blood donations.

6.15 REPORTING FORM FOR ADVERSE DONOR REACTION

1. Every adverse event related to blood or blood component donation shall be managed, investigated and documented accordingly.

2. The blood collection personnel shall fill up this form **immediately** after any adverse donor reaction. The head of the blood collection centre shall ensure that this form is filled up correctly.

3. Completed original form shall be retained at the respective blood collection centre and a copy to be sent to the National Haemovigilance Coordinating Centre, Pusat Darah Negara every month.

REPORTING FORM FOR ADVERSE DONOR REACTION

IMPORTANT INFORMATION

1. Every adverse event related to blood or blood component donation shall be managed, investigated and documented accordingly.
2. The blood collection personnel shall fill up this form **immediately** after any adverse donor reaction. The head of the blood collection centre shall ensure that this form is filled up correctly.
3. Completed original form shall be retained at the respective blood collection centre and a copy to be sent to the National Haemovigilance Coordinating Centre, National Blood Centre every month.

SECTION A: DONOR DETAILS

Name :	NRIC / Passport No:
Gender : ☐ Male ☐ Female	Telephone:
Weight (kg):	Barcode:
Date of donation:	Number of previous donations:
Place of donation:	
Collection centre:	State:

SECTION B: DONATION DETAILS

Type of donation : ☐ Whole Blood ☐ Apheresis Machine: ( )	
Time start:	Time end:
Time of Reaction:	Time of recovery:
Volume collected :	Donation terminated early: ☐ Yes ☐ No
Previous history of reactions: ☐ Yes ☐ No If yes, please describe:	

SECTION C: TYPE OF REACTION (Tick ✓ where applicable)

Type of Reactions*				Grading of Severity*		
				Mild	Moderate	Severe
Local Symptoms	Blood Outside Vessels		Haematoma			
			Arterial Puncture			
			Delayed Bleeding			
	Arm Pain	Specified as	Nerve irritation			
			Nerve injury			
		or not specified	Other Arm Pain			
	Localised infection/ inflammation of vein or soft tissue		Thrombophlebitis			
			Cellulitis			
	Other Major Blood Vessel Injury		Deep Vein Thrombosis (DVT)			
			Arteriovenous Fistula			
			Compartment Syndrome			
			Brachial Artery Pseudoaneurysm			
Generalised symptoms	Vasovagal Reaction		Immediate			
			Immediate with injury			
			Delayed			
			Delayed with injury			
Related to Apheresis Donation			Citrate reaction			
			Haemolysis			
			Air embolism			
Allergic Reactions			Local Allergic Reaction			
			Generalized (anaphylactic) reaction			
Other Serious Complications Related to Blood Donation			Acute Cardiac symptoms (other than Myocardial Infarct or cardiac arrest)			
			Myocardial Infarct			
			Transient Ischemic Attack (TIA)			
			Cerebrovascular accident			
Others						

Table adapted from Standard for Surveillance of Complications Related to Blood Donation by the Working Group on Complications Related to Blood Donation, International Society of Blood Transfusion and Working Party on Haemovigilance, European Haemovigilance Network (2014)

SECTION D: MANAGEMENT (To be filled if necessary)

Vital Sign	Pre Donation	During Reaction	Post Recovery
BP (mmHg)			
Pulse (/ min)			

_____

_____

_____

SECTION E: INVESTIGATIONS (for citrate toxicity, moderate/severe vasovagal reactions)

(e.g.: Sodium, Potassium, Calcium, Phosphate & Magnesium Level, RBS, RP and LFT)

RESULTS

☐ Normal ☐ Abnormal

If abnormal please specify: _____

SECTION F: DONOR OUTCOME

G1. Recovered with no ill effects ☐
G2. Recovered with illness ☐ specify if any: _____
G3. Death ☐

SECTION G: FOLLOW UP

_____

_____

_____

Reported by :	Verified by
Designation :	Designation
Date :	Date:

Chapter 7

Donor Haemovigilance

7.0 Seroconvert Donors

"Do not mix the truth with falsehood or conceal the truth when you know it"

7.1 DEFINITION OF SEROCONVERT DONORS (SD)

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

All donors found to be seroconverted with HIV, Hepatitis B, Hepatitis C or Syphilis were counselled by the doctors referred for further management to appropriate physician according to types of infection.

The donor who was confirmed seroconvert was counselled and permanently deferred from future donation. Subsequently, the donor was registered under SUKUSA. Look back procedure for the last negative donation and donation in the six months period prior to the last negative was conducted. The unused blood component was recalled and hospitals that were supplied with the blood component were informed. Finally, the details of look back investigations of seroconverted donor was reported in Seroconvert Donor Notification Form and report was submitted to NHCC.

7.2 METHOD OF REPORTING

There were two parts for Seroconvert Donor reporting which were Part 1 and Part 2. Part 1 included all the donor details such as name, IC or passport number, gender, barcode involved, date of donation, number of previous donation, reported by which physician collection center and date of reporting. Other details were the infectious marker implicated for each disease and the risk factors of TTI. A copy of Part 1 form was completed and sent to NHCC within a month after the donor came for counseling.

Part 2 form included previous donation records for the last negative donation and donations in the 6 months prior to the last negative donation. This form was filled with the types of blood products involved, issued date, the location of blood products supplied, the name, identification number, diagnosis and outcome of recipient.

Both Part 1 and Part 2 need to be submitted to NHCC within a month upon completion of all investigations.

7.3 TOTAL REPORTS RECEIVED FOR 2016 – 2017

Seroconvert donor reports received in 2016 were only from PDN however there were another participated hospital for 2017 which was Hospital Seberang Jaya despite 113 blood collection centres in Malaysia.

There were 19 seroconvert donors cases investigated and closed in 2016. All closed cases reports were sent to NHCC. For 2017, there were 46 seroconvert donors reported for Part 1 but only 3 reported for Part 2.

There were none of recipients who were positive with any infection based on all Part 2 reports received in both years. A few reports were submitted late in view of the time required to complete investigations prior to reporting.

7.4 REPORTS BY AGE GROUP AND GENDER – Table 7.4a, 7.4b

Most seroconvert donors were in the age group of 20-39 years old in both 2016 and 2017 as most blood donors were also in this age group. Furthermore, males seroconvert donors outnumbered the females in both years as shown in Table 7.4b.

Year	Age				Total cases
	<20	20-39	40-60	>60	
2016	0	14 (73.7%)	5 (26.3%)	0	19
2017	2 (4.3%)	37 (80.5%)	7 (15.2%)	0	46

Table 7.4a: Seroconvert Reports by Age

Year	Gender		Total cases reported
	Male	Female	
2016	17 (89.5%)	2 (10.5%)	19
2017	43 (93.4%)	3 (6.6%)	46

Table 7.4b: Seroconvert Reports by Gender

7.5 REPORTS BY PREVIOUS NUMBER OF DONATIONS – Table 7.5

Table 7.5 below shows that regular donors with less than 5 numbers of donations had the highest percentage for seroconversion than regular donors with more than 10 blood donations.

Year	No of Donation			Total cases
	<5	5-10	> 10	
2016	14 9 (73.7%)	4 (21.1%)	1 (5.2%)	19
2017	30 (65.2%)	8 (17.4%)	8 (17.4%)	46

Table 7.5: Seroconvert Reports by Number of Previous Donation

7.6 SD REPORTS ACCORDING TO TYPES OF DONATIONS – Table 7.6

In 2016, all seroconvert donors were whole blood donors. However, in 2017, there was 1 apheresis donor who became seroconvert.

Year	Type of Donation		Total cases reported
	Whole blood	Apheresis	
2016	19 (100%)	0	19
2017	45 (97.8%)	1 (2.2%)	46

Table 7.6: Seroconvert Reports by the Types of Donation

7.7 NUMBER OF REPORTS ACCORDING TO TYPES OF INFECTION – Table 7.7

Highest number of seroconvert donors were positive with syphilis which was 14 (73.6%) in 2016 and 25 (54.4%) in 2017. This was followed by the number of 4 seroconvert donors with HIV infection with percentage of 21.1% in 2016. In 2017, only 1 seroconvert case with HIV infection, but 18 (39.1%) seroconvert cases with HBV infection.

Year	TTI				Total cases
	HBV	HCV	HIV	Syphilis	
2016	1 (5.3%)	0	4 (21.1%)	14 (73.6%)	19
2017	18 (39.1%)	2 (4.3%)	1 (2.2%)	25 (54.4%)	46

Table 7.7: Seroconvert Reports According To Types of Infections

7.8 REPORTS ACCORDING TO RISK FACTORS – Table 7.8

Table 7.8 below summarized the risk factors among seroconvert donors. Highest number of seroconvert donors were those involved in high risk behaviours. About 30% seroconvert donors chose to deny their risk factors during counselling session.

Year	Risk Factors					Total cases
	High Risk Behaviours	Body Piercing, Tattoo, Acupuncture	History Of Blood Transfusion	IV Drug User	Deny Risk Factors	
2016	13 (68.4%)	0	0	0	6 (31.6%)	19
2017	27 (58.7%)	3 (6.5%)	0	0	16 (34.8%)	46

Table 7.8: SD Reports According To Risk Factors

7.9 RECOMMENDATIONS

1. Repeat donor still has a risk to transmit TTI. An open ended questions during counselling with train personnel, donor education and awareness, confidential unit of exclusion are important mitigation steps to be taken to reduce the risk of high risk donor from donating blood.

2. Seroconvert donor notification to NHCC was severely underreporting. This data is essential to estimate the scope, spread and location of infections, monitor trends, evaluate preventive efforts, and improve practices, policy and facility planning. Thus the seroconversion incidents among blood donors should be monitored and reported.

7.10 SEROCONVERT DONOR NOTIFICATION FORM

BTS/SC/1/2016

SEROCONVERT DONOR NOTIFICATION FORM

IMPORTANT INFORMATION

PART 1

1. Every case of seroconverted donor shall be managed, investigated and documented accordingly.
2. Please complete Part 1 of this form and send a copy within ONE (1) month following donor counselling to the National Haemovigilance Coordinating Centre, National Blood Centre.
3. Completed original form shall be retained at the respective blood centre.

DONOR DETAILS

Name :	IC / Passport No :
Gender : Male ☐ Female ☐	Barcode :
Date of donation :	Number of previous donations :
Reported by :	Designation :
Collection centre :	Date of reporting :

1. Infectious markers implicated

HIV HBV HCV Syphilis Others (please specify) :_____

a. Screening (Specify method) :_____
b. Confirmation (Specify method) :_____
c. Date of confirmation (Seroconversion) :_____

2. Risk Factors

c High Risk Sexual Behaviour (Specify) :_____
c Body piercing / Tattoo/ Acupuncture (Please circle the appropriate one)
c History of blood transfusion (Date & Hospital involved) :_____
c Intravenous drug use
Others (please specify) :_____

IMPORTANT INFORMATION

PART 2

1. Please fill up the following for the last negative donation and donation(s) in the six (6) months period prior to the last negative donation.
2. Upon completion of Part 2, please resend the complete form to National Haemovigilance Coordinating Centre, National Blood Centre.
3. Completed original form shall be retained at the respective blood centre.

PREVIOUS DONATION RECORDS

Barcode NO: _____ **Date (DD/MM/YY)** ____/____/____

Donation Centre/ Hospital: _____

Type of Product:	Whole blood	Packed cells	FFP	Platelet	Cryoppt/sup	Others (……..)
Date Issued:						
Issued to Hospital/ward:						
Patient's name:						
Patient ID:						
Ward :						
Patients current status(dead/ alive/ result status) :						
Patient's Diagnosis :						

Barcode NO: _____ **Date (DD/MM/YY)** ____/____/____

Donation Centre/ Hospital: _____

Type of Product:	Whole blood	Packed cells	FFP	Platelet	Cryoppt/sup	Others (……..)
Date Issued:						
Issued to Hospital/ward:						
Patient's name:						
Patient ID:						
Ward :						
Patients current status(dead/ alive/ result status) :						
Patient's Diagnosis :						

*additional pages to be filled if necessary

References

1. *A Guide to establishing a national haemovigilance system WHO 2016*
2. *https://ihn-org.com/about/haemovigilance*
3. *https://www.who.int/bloodsafety/bts_haemovigilance/en/*
4. *Health Informatics Centre, Planning Division, Ministry of Health*
5. *SHOT UK 2016*
6. *New Zealand Blood Service*

National Haemovigilance Coordinating Centre
Pusat Darah Negara
Jalan Tun Razak
50400 Kuala Lumpur, Malaysia
Tel: 03-2613 2688
Fax: 03-26980362

www.pdn.gov.my