FACTORS ASSOCIATED WITH NEAR MISS EVENTS OF TRANSFUSION PRACTICE AMONGST DOCTORS IN HOSPITAL UNIVERSITI SAINS MALAYSIA

DR KIMBERLY FE JOIBI

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF PATHOLOGY (HAEMATOLOGY)

UNIVERSITI SAINS MALAYSIA

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SUPERVISORS:

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LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

Symbols / Abbreviations	Meaning
%	Percentage
ADU	Avoidable, delayed or undertransfusion
BCSH	British Committee for Standards in Haematology
BE	Blood Establishment
BEST	Biomedical Excellence for Safer Transfusion
CI	Confidence Interval
CIRS	Critical Incident Reporting System
CoE	Council of Europe
EDTA	Ethylenediaminetetraacetic acid
et al	et alia (and others)
EU	European Union
FDA	Food and Drug Administration
FMEA	Failure Mode and Effect Analysis
GDBS	Global Database on Blood Safety
GSH	Group, Screen and Hold
GXM	Group and Crossmatch
HBB	Hospital Blood Bank
HO	House Officers
HPRA	Health Products Regulatory Authority
HREC	Human Research Ethics Committee
HSE	Handling and Storage Errors
HTC	Hospital Transfusion Committee

Symbols / Abbreviations	Meaning
IAKH	Interdisziplinäre Arbeitsgemeinschaft für Klinische Hämotherapie (Interdisciplinary Task Force for Clinical Hemotherapy)
IBCT	Incorrect Blood Component Transfused
IC	Identification Certificate
ICU	Intensive Care Unit
ID	Identification
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
MERS-TM	Medical Event Reporting System for Transfusion Medicine
mls	milliliters
MLT	Medical Laboratory Technologist
MMC	Malaysian Medical Council
MO	Medical Officers
n	number
NHCC	National Haemovigilance Coordinating Centre
NHO	National Haemovigilance Office
NHS	National Health Service
NPSA	National Patient Safety Agency
OR	odds ratio
PDN	Pusat Darah Negara
PHS	Portuguese Hemovigilance System

Symbols / Abbreviations	Meaning
PKKT	Pusat Pengetahuan, Komunikasi dan Teknologi (Centre for Knowledge, Communication and Technology)
PPS	Pegawai Perubatan Siswazah (House officers)
PS	Power and Sample Size
RBC	Red blood cells
RBRP	Right Blood Right Patient
RFID	Radio Frequency Identifier
RhD	Rhesus D
RN	registration number
ROC	Receiver Operating Characteristics
SD	Standard deviation
SHOT	Serious Hazards of Transfusion
SPSS	Statistical Package for the Social Science
STC	State Transfusion Committee
STIR	Serious Transfusion Incident Report
TACO	Transfusion-associated circulatory overload
TESS	Transfusion Error Surveillance System
TRALI	Transfusion-related acute lung injury
UK	United Kingdom
UPT	Unit Perubatan Transfusi
US	United States
USM	Universiti Sains Malaysia
WBIT	Wrong Blood in Tube
WHO	World Health Organisation

FAKTOR-FAKTOR YANG MEMPENGARUHI KESILAPAN NYARIS DALAM AMALAN TRANSFUSI DARAH DI KALANGAN DOKTOR DI HOSPITAL UNIVERSITI SAINS MALAYSIA (HOSPITAL USM)

ABSTRAK

Pengenalan: Kesilapan nyaris dalam amalan transfusi darah didefinisikan sebagai kesilapan yang berpunca daripada amalan yang tidak mematuhi prosedur yang telah ditetapkan, namun berjaya dikesan sebelum proses transfusi darah berlaku. Ia boleh menyebabkan kesilapan transfusi jika gagal dikesan dan pemantauannya penting untuk mengelakkan berulangnya kesilapan yang sama. Hasil daripada audit tahunan yang dijalankan di Unit Perubatan Transfusi (UPT) Hospital USM, pegawai perubatan siswazah (PPS) merupakan kakitangan yang paling kerap terlibat dengan kesilapan nyaris. Objektif: Tujuan kajian ini adalah untuk mengenal pasti punca- punca utama dan faktor-faktor yang mempengaruhi insiden kesilapan nyaris di kalangan doktor di Hospital USM. Metodologi: Bahagian pertama kajian ini adalah kajian rentas yang menganalisa data semua permohonan ujian kumpulan darah dan saringan antibodi (GSH) dan ujian penyesuaian silang (GXM) yang dihantar ke UPT dari tahun 2011 sehingga 2017. Bahagian kedua adalah kajian kes-kontrol yang mengkaji hubungkait faktor sosiodemografik, tempat kerja dan pengalaman dengan insiden kesilapan nyaris di kalangan PPS dengan menggunakan model logistik. Kes terdiri daripada 42 PPS yang terlibat dengan kesilapan nyaris. Kontrol terdiri daripada 124 PPS yang dipilih secara rawak daripada senarai PPS yang menghantar permohonan ke UPT, tetapi tidak terlibat dalam kesilapan nyaris. Keputusan: Kajian menunjukkan terdapat 83 kesilapan nyaris di

kalangan 242 004 permohonan GSH dan GXM dengan prevalens 0.034 % (CI, 0.027% - 0.042%). Kadar kesilapan nyaris bersamaan dengan satu insiden untuk setiap 2916 permohonan. Purata kesilapan nyaris tahunan adalah 11.9. Kesilapan nyaris klinikal (89.2%) didapati lebih banyak daripada kesilapan nyaris makmal (10.8%). Kesilapan melabel (33.7%) adalah lebih banyak daripada kesilapan kutipan (10.8%). Kajian menunjukkan PPS terlibat dengan kebanyakan insiden kesilapan nyaris (83.1%). Insiden kebanyakkannya berlaku di wad perubatan dan wad obstetrik dan ginekologi, dengan 26 kes (31.3%) setiap satu. Kajian ini menunjukkan faktor umur PPS mempunyai hubungkait yang signifikan dengan kesilapan nyaris. PPS yang setahun lebih tua mempunyai kurang kemungkinan terlibat dengan kesilapan nyaris sebanyak 30% (CI, 0.51 - 0.96). Kesimpulan: Prevalens kesilapan nyaris di Hospital USM adalah agak rendah. Namun, kesilapan nyaris yang gagal dikesan akan memberi implikasi buruk terhadap pesakit. Oleh itu, hasil kajian ini menunjukkan antara penambahbaikan yang boleh dilaksanakan termasuk memperbaiki amalan pengambilan sampel di wad, memastikan juruteknologi makmal menerima latihan yang mencukupi dan memastikan PPS menerima pendidikan transfusi yang sesuai.

(363 patah perkataan)

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ABSTRACT

Introduction: A near miss in transfusion practice is defined as a deviation from standard procedures, discovered before transfusion and has the potential to lead to a transfusion error. Near miss investigation is vital to prevent future occurrences. Unpublished yearly audit of our centre showed that house officers were often involved in near miss events. Objectives: This study aims to identify the common causes and associated factors of near miss events amongst doctors in Hospital USM. Methodology: The first part of this study is a cross-sectional study which required the data collection from all requests for Group, Screen and Hold (GSH) and Group and Crossmatch (GXM) tests sent to Transfusion Medicine Unit Hospital USM from 2011 until 2017. Second part is a case-control study which analyses the association of sociodemographic, workplace and experience factors with near miss events amongst house officers (HO) using logistic regression. Case group included 42 HO involved in near miss and control group consisted of 124 randomly selected HO who sent requests to our unit and were not involved in near miss. Results: We reported 83 near miss events among 242 004 GSH and GXM requests with a prevalence of 0.034 % (CI, 0.027% - 0.042%). Rate of near miss events were one event for every 2916 requests. Mean reporting rate was 11.9 events per year. Clinical near miss predominates with 89.2% over laboratory near miss of 10.8% from total near miss. Mislabelled events (33.7%) were more than miscollected events (10.8%). HO were

involved with most events (83.1%). Most events occurred in Medical and Obstetrics and Gynaecology wards with 26 cases (31.3%) each. We found a significant association between the age of HO with near miss events. HO who are a year older decrease the odds of having a near miss event by 30% (CI, 0.51 - 0.96). Conclusion: The prevalence of near miss events in our centre were relatively low. However, the consequences if a near miss goes undetected are detrimental to the patient. Our study has shown among areas for improvement include improving sampling practices in clinical areas, adequate training of laboratory technicians and providing proper transfusion education to house officers.

(356 words)

CHAPTER 1

INTRODUCTION

1.0 INTRODUCTION

Blood transfusion generally refers to the usage of whole blood and its components which includes packed cells, fresh frozen plasma, cryoprecipitate and platelets for therapeutic reasons. It is among the common therapy used in medical practices for various reasons for example packed cells transfusion for treatment of symptomatic anaemia, plasma products for the correction of coagulation abnormalities in bleeding patient and platelet transfusions in symptomatic thrombocytopenic patients (Benjamin and McLaughlin, 2012; Estcourt *et al.*, 2017; Ghartimagar, 2017).

No doubt procuring blood product is essential in a hospital setting. However, the process of blood procurement involves multiple essential procedures and steps that must be taken to ensure a safe blood product is delivered to the patient. The whole chain of transfusion process involves several steps starting from the blood donation procedure, processing of the blood components and infective screening of donated blood. It is followed by the ordering of blood components, pre-transfusion testing processes, release of blood components to the wards or clinics, transportation of blood components to intended places and lastly the transfusion process itself (Fastman and Kaplan, 2011; Hazzazi *et al.*, 2014; PDN, 2016).

In the year 2018, Transfusion Medicine Unit of Hospital USM received approximately 12 036 requests for 'Group, Screen and Hold' (GSH) tests and 13 444 requests for 'Group and Crossmatch' (GXM) tests. Because of the lengthy process and multiple steps involved in delivering a blood component to a patient, added with increasing demands for blood transfusion, there is the possibility of errors occurring in any of these steps (Kaur *et al.*, 2019). Hence, there is a need for a surveillance programme that functions to

monitor, oversee and report any adverse events occurring in any of the steps as mentioned earlier. This programme is also known as haemovigilance. Haemovigilance reporting includes not only reports on transfusion error but includes mistransfusion and near miss (PDN, 2016).

Near miss is defined as error or deviation from standard procedures or policies that is discovered before the patient receives a transfusion and this may lead to a mistransfusion if a transfusion was to take place (Nascimento, 2011). A mistransfusion is defined as the delivery of inappropriate or wrong blood component to an intended patient (Bellone and D. Hillyer, 2013).

Predictors of near misses and actual errors are hypothesised to be similar. Analysis can be focused more on near miss events in comparison to actual errors because it occurs more frequently than actual errors (Tanaka *et al.*, 2010). Therefore, although near miss events are not actual errors of transfusion, reporting and investigation of near miss events is vital in detecting steps and factors that have high chances of causing actual transfusion errors. Information such as causes of near miss events, their location and medical personnel involved help narrow down target areas for improvement. It allows for focus on rectifying any problem that arises (Kaur *et al.*, 2019).

Doctors were among the most common profession associated with near miss incidents in transfusion medicine in several international studies (Lundy *et al.*, 2007; PHB Bolton-Maggs (Ed) D Poles et al., 2017). Study on factors associated particularly with doctors involved in near miss events of transfusion practice, has never been done before. Few other studies analysed mostly prevalence and causes of near miss (Ardenghi *et al.*, 2007;

Kaur *et al.*, 2019; Lundy *et al.*, 2007). Some mainly discussed factors associated with doctors or nurses in near miss events of medical field in general or general laboratory test requests and not specifically towards those occurring in transfusion practice (Chow *et al.*, 2005; Tanaka *et al.*, 2010). By analysing and identifying other possible factors associated with near miss events amongst doctors, we can further improve the safety of our blood products.

It is hoped that information from this study can be utilised in implementing better efforts to improve the standard of haemovigilance in our centre. This information can help us to decide or plan for future interventions and implement proper corrective action with the main objective of having zero transfusion error in our centre.

CHAPTER 2

LITERATURE REVIEW

2.0 LITERATURE REVIEW

2.1 Blood transfusion overview

Blood transfusion is defined as a form of medical treatment or therapy in which blood products and its component are administered into the patient via intravenous access (Merriam-Webster, 2019). Its functions and indications depend on the type of blood products or components transfused. Commonly transfused blood products and components include packed cell, fresh frozen plasma and platelets.

Since the early 20th century, blood transfusion, particularly packed cell, have been used widely to treat cases of anaemia. They provide mainly three valuable benefits; replenishing volume, providing rheological property and ensuring adequate oxygenation (Yaddanapudi and Yaddanapudi, 2014). Common indications for packed cell transfusion include cases of symptomatic acute and chronic anaemia. Example of cases requiring packed cell transfusion are severe haemorrhages, anaemia-induced acute coronary syndrome and critical illnesses with haemoglobin values below the transfusion trigger determined by respective centres (Yaddanapudi and Yaddanapudi, 2014).

For blood products such as fresh frozen plasma, it is mainly utilised to correct cases with factor deficiencies. Examples include cases like congenital factor deficiency, bleeding disseminated intravascular coagulation, bleeding patients with liver disease or those treated with Vitamin K antagonists (Liumbruno *et al.*, 2009). Platelet transfusion is indicated in specific cases of thrombocytopenia such as bleeding thrombocytopenic patients or as a prophylaxis in preventing spontaneous bleeding in certain conditions. Some example are those with platelet count less than 10 x 10^9/l in therapy-induced

hypoproliferative thrombocytopenia, or patients with platelet count less than 20 x 10^9/l planned for central venous line insertion (Kaufman *et al.*, 2015).

The complete blood transfusion process does not only involve the act of transfusing blood products into the patient. The process starts with the donation process and ends with the patient receiving the blood products (Figure 2.1).

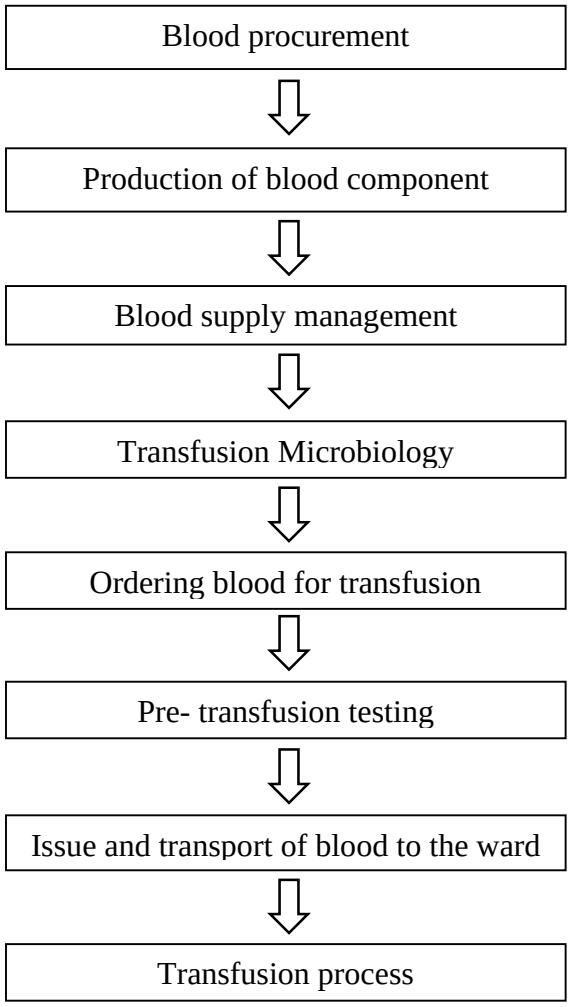

Figure 2.1: Summary of blood transfusion process

The first step, which is the blood procurement process includes donor recruitment, identification of blood donor, collection of blood, and ensuring a proper registry is available. This process is followed with production of blood component, which include its preparation, proper labelling and screening of the donor sample. Next is ensuring efficient blood supply management is in place and this consists of good stock forecasting and ensuring optimal inventory of frequently used blood products, for example, packed cell, fresh frozen plasma, cryoprecipitate and platelet (PDN, 2016). Adequate availability of special blood products, for example, Safe O blood products or RhD negative blood stock is equally important. Proper storage of blood is also part of the transfusion process (Kaur *et al.*, 2019; PDN, 2016).

Transfusion microbiology is also part of the transfusion process. Every transfusion medicine unit should have a good screening procedure, established verification process and a proper algorithm for the release of blood products. Next is the process of ordering blood for transfusion. This process includes; taking consent, positive patient identification, taking and labelling of patient's blood sample, filling in request forms and appropriate rejection of requests from blood bank unit (PDN, 2016).

After the patient's sample arrive in respective blood bank for testing, the next process is pre-transfusion testing. Pre-transfusion testing is described as a multistep process intended at preventing potentially fatal haemolytic transfusion reactions. It begins in the ward with identification of intended recipient and collection of an appropriately labelled blood sample. Once received in the laboratory, requests are registered, blood bank staff reviews the recipient's transfusion history, and performs testing (Boisen *et al.*, 2015). This testing includes ABO and RhD group determination, screening for antibodies, and

if antibodies are present, subsequent identification of antibodies. It is followed by the donor's sample and the patient's sample crossmatching if ordered (PDN, 2017). The two common test requests sent to blood bank are GSH (Group, Screen and Hold) and GXM (Group and Crossmatch). In GSH, sample are ABO and rhesus grouped with antibody screening for unexpected red cell antibodies performed. Sample is kept for 48 hours, in the event that it may be used for crossmatching if the patient needs a transfusion. In GXM, patient's sample are grouped, antibody screened and crossmatched to be issued to the patient (PDN, 2017). Once a blood component is ready to be issued, it will be collected and transported to respective wards. Proper care and storage during transportation should not be dismissed.

Final step is the transfusion process itself. This step includes identification check before transfusing, close patient monitoring, proper record keeping, and ensuring the appropriate duration of transfusion (PDN, 2016).

There are plenty of opportunities for error to happen because of the elaborateness of the multistep transfusion process (Fastman and Kaplan, 2011). There has been an increasing trend of error reporting, and this can be attributed partly due to increasing awareness. Additionally, new audit policies that made changes in error reporting has resulted in more underreported errors being recognised (Koh and Alcantara, 2009). Regardless, given these statistics, ensuring the delivery of safe products to the patients should be of utmost importance as there is the possibility of fatal outcomes.

2.2 Regulatory aspects of blood safety

Given the concern for blood safety, there is a need for a strict regulatory framework. Internationally, the World Health Organisation (WHO) and the Council of Europe (CoE) have outlined a set of principles which are not legally compulsory. They mainly serve as guidance on transfusion practice for many countries (Allard and Contreras, 2016). Guidelines and laws on safe transfusion practice differs between countries. In the United Kingdom (UK), the European Union (EU) Blood Directives set the standards of safety and quality for collection, testing, processing, storage and distribution of blood and its components (Allard and Contreras, 2016).

In the South-East Asia region, WHO collects, and analyses officially submitted data from member states within this region. In a 5-year review published, data submitted into the WHO Global Database on Blood Safety (GDBS) was analysed with the hopes of providing information on the current status of blood transfusion services. This data can be used to help the respective member country to assess areas in which improvement is needed. The data is also used to design optimal recommendations for these countries, to plan and execute activities as well as assessing their progress (World Health Organization, 2018).

In Malaysia, guidelines for safe transfusion practice are outlined by the National Blood Centre in Kuala Lumpur (PDN, 2016). As delineated in this guideline, each hospital should set up a Hospital Transfusion Committee (HTC), and it should be functionally active. An HTC has many roles, including monitoring and ensuring appropriate usage of blood and its components by developing local policies. It also plays a role in ensuring constant availability of blood products by coordinating with blood transfusion service. It

is also involved in developing hospital blood ordering schedule and standard operating procedures. One of its function involves providing transfusion training to involved medical personnel and developing good hospital haemovigilance programme to monitor any adverse transfusion events (Liumbruno and Rafanelli, 2012; PDN, 2016)

The crucial requirements for a hospital transfusion unit or laboratory include having a thorough quality management system following the principles of 'good practice'. It entails having strict requirements for storage and distribution of blood components. It is also necessary to have good traceability, adequate training of blood transfusion staff and haemovigilance (Allard and Contreras, 2016).

2.3 Haemovigilance

Haemovigilance refers to the set of surveillance system encompassing the whole chain of transfusion process, starting from blood donation process, processing of blood and its components, their provision and transfusion to patients, and including their follow up. It involves collection and analysing data on unwanted reactions resulting from the transfusion process. In the long run, it aims to prevent recurrences of similar incidents in the future (International Society of Blood Transfusion (ISBT); World Health Organization, 2019). The primary intent of this system is to improve the safety of the transfusion process, for policy informing, improving standards and using data obtained to aid the formulation of guidelines (World Health Organization, 2016).

Haemovigilance plays a significant role in blood safety and has already been established in many countries around the world. WHO GDBS reported that in 2016, national haemovigilance system had been in place in 70 countries. Within the WHO regions, the

region with the highest percentage of haemovigilance systems was Europe (77%) followed by South-East Asia (46%), the Eastern Mediterranean (35%), the Western Pacific (32%), Africa (26%) and the Americas (14%) (Liang *et al.*, 2018).

Different countries have different national haemovigilance system models. As an example, in countries like France, Germany and Switzerland, it is managed by Competent Authority. In Japan, South Africa and Singapore, the system is managed by blood manufacturers while Professional Organisation manages the ones in the UK and the Netherlands. Public Health Authority manages the national haemovigilance system in Canada, and Private/ Public Partnership manages it in the United States (Liang *et al.*, 2018)

On a global scale, there is the International Haemovigilance Network (IHN) which has transpired from European Haemovigilance Network. It aims to establish and sustain a joint system related to the safety of blood products and of haemovigilance of transfusion practice throughout the world. The IHN worked together with the ISBT working party on haemovigilance in recommending standard definition for haemovigilance system (Jain and Kaur, 2012).

In Malaysia, there is coordination at the national level with regards to haemovigilance. There are national policies and guidelines on recommended principles of how blood banks should be operating, and the way procedures should be done (Ayob, 2010). Transfusion practices monitoring in Malaysia is regulated centrally by the Ministry of Health via its Quality Program. This monitoring includes National Indicators, Quality Assessment Program and external audits (Ayob, 2010).

Haemovigilance reporting in Malaysia includes reporting of all adverse events occurring during blood collections, processings, testings, transfusions and outcome of transfusions. Near misses and incidents related to equipment and products are also included. Each hospital must have a system in place to compile and scrutinise data of all adverse incidents. Regular reports should be handed to respective HTC, State Transfusion Committee (STC) if available and National Haemovigilance Coordinating Centre (NHCC) of which is under the responsibility of the National Blood Centre. Both HTC and STC are responsible for taking corrective and preventive actions as well as aid allocation of enough resources at the hospital and state level (PDN, 2016).

Haemovigilance plays a significant role in identifying the hazards of transfusion and in the long run, able to demonstrate the efficacy of interventions. For example, Serious Hazards of Transfusion (SHOT) reporting in the UK, has successfully demonstrated the significance of transfusion-related acute lung injury (TRALI) as a plausible lethal transfusion risk. It also successfully corroborated the benefit of taking fresh frozen plasma from male donors. SHOT reporting has also made it possible to verify the advantageous effects of other strategies. An example was a reducing number of transfusion-associated graft-versus-host disease and post-transfusion purpura cases seen after using leucodepleted blood product in patients at risk (Bolton-Maggs and Cohen, 2013).

Over the last two decades, haemovigilance systems have developed around the globe and resulted in positive outcomes and changes. There was a significant reduction in ABO associated transfusion errors, TRALI and allergic reactions. There was also a significant increase in blood product's traceability and reduction in wastage of blood products. Additionally, there was an increase reporting of transfusion-associated circulatory

overload (TACO), adverse donor reactions and post-donation information (Liang *et al.*, 2018).

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2.4 Adverse events in transfusion medicine

ISBT have proposed definition for adverse events reporting in transfusion medicine with the intent for use in monitoring unwanted transfusion events. This definition is also useful when observation from different haemovigilance system are done (ISBT, 2011).

ISBT defined adverse event as an unwanted occurrence that happened before, during or after the process of blood transfusion, which may be linked with the administration of the blood component. It can occur as a result of an incident or an error and may or not result in a reaction in the intended patient (Escoval, 2014; ISBT, 2011).

An incident is a situation where the patient received a transfusion with a blood product which did not fulfil the requirements for a suitable transfusion for that patient or was intended for another patient. Therefore, it includes transfusion errors and transgression from standard operating practices and hospital policies. Adverse reactions may or may not be a consequence of this (ISBT, 2011). Illustration representing the general definition of adverse events is shown in Figure 2.2.

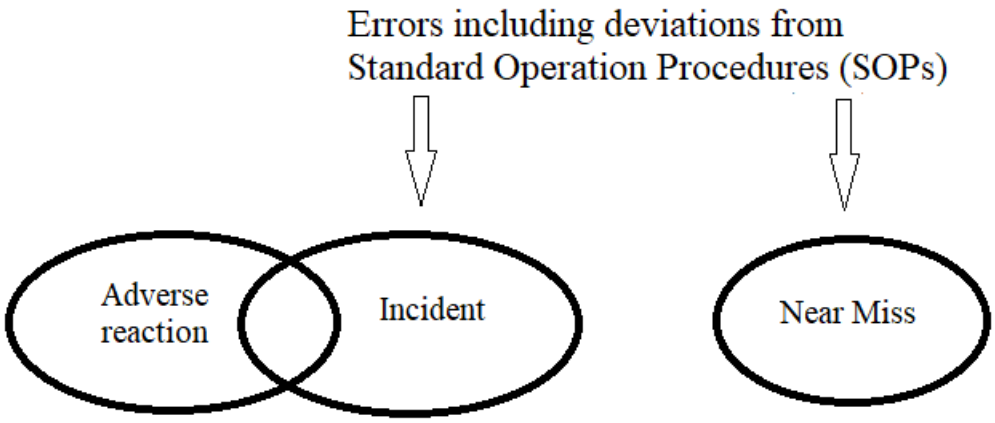

Figure 2.2: General definitions of adverse events. It is adapted from Proposed Standard Definitions For Surveillance of Non-Infectious Adverse Transfusion Reactions by ISBT (ISBT, 2011).

2.5 Near miss

2.5.1 Near miss overview

Near miss in its general sense was coined from air-traffic control to define an unwanted incidence which almost happens but somehow because of judgment or luck, did not occur instead (Sheikhtaheri, 2014; Tanaka *et al.*, 2010). This term is also a concept that can be used in various clinical situation. For example, in maternal mortality, it refers to unwanted events that led to detriment effects to the mother, almost causing death, but she survived (Chhabra, 2014). Likewise, in other clinical areas such as medication-related error, near miss implies medication error that did not harm the patient (Claffey, 2018).

In transfusion medicine, a 'near miss' is a deviation from standard procedures that is discovered before a transfusion has taken place. Hence, a mistransfusion or reaction in the recipient is prevented from occurring (Escoval, 2014; ISBT, 2011; Nascimento, 2011). They reveal the crucial monitoring points in the transfusion chain process of a centre (Nascimento, 2011).

Mistransfusion describes the situation where a patient receives a blood product that did not fulfil the needed requirement or a blood product that was meant to be transfused to another patient (Ohsaka, 2009). It is the result of blunder and failure in performing the necessary stipulated procedure along the chain of the transfusion process, starting from the decision for transfusion until the delivery of blood product to the patient (Bellone and D. Hillyer, 2013).

Though near misses are not considered 'substantial errors', information on them provides pivotal data on areas of improvement to prevent actual errors in the future (Das *et al.*, 2017; Sheikhtaheri, 2014). Therefore, most transfusion medicine services in the world report on cases of near miss as part of their haemovigilance programme. Near miss incidents are reflections on potential cases of transfusion errors. Therefore, thorough investigations on these incidents provide valuable information for better service (Sheikhtaheri, 2014).

Predictors of near misses and actual errors are postulated to be similar (Sheikhtaheri, 2014). A more extensive analysis of these predictors of future errors can be done with near miss reports in comparison to actual errors because it occurs more frequent (Sheikhtaheri, 2014; Tanaka *et al.*, 2010). Therefore, although near miss events are not actual errors of transfusion, reporting and investigation of near miss events is essential in detecting steps and factors that have high chances of causing fatal transfusion errors (Elhence *et al.*, 2012; Tanaka *et al.*, 2010). A continuous reporting of near miss events is essential to aid learning from near miss cases as these events do not cause actual harm towards patient. Furthermore, reporters may be more willing to voluntarily report a near

miss as they are not at risk for humiliation, blame or legal consequences because no actual harm to the patient has occurred (Sheikhtaheri, 2014).

Near miss reporting investigations thus allows us to analyse the frequency and expected patterns of error. For example, we can obtain information on which step of the transfusion process they frequently occur and the typical location for potential errors. We can also analyse which healthcare staff are more frequently involved and investigate the common risk factors or causes for near miss. These data help determine appropriate corrective and preventive actions to ensure transfusion safety (Sheikhtaheri, 2014).

2.5.2 Near miss reporting

Near miss incidents in transfusion medicine are being reported each year worldwide. However, different countries have different system of reporting with each system having the primary goal of improving haemovigilance in respective countries. Among the leading haemovigilance system in Europe was established in France and the United Kingdom (Ayob, 2010).

The concept of 'Haemovigilance' first appeared in France in the early 1990's. The French Blood Agency first developed it as a national level surveillance and alert system for unwanted incidents in the transfusion process (Sen *et al.*, 2014). Haemovigilance in France consisted of three levels; local, regional and national. Hospital haemovigilance officer is required to inform adverse transfusion events through a form and a website called "e-fit". These reports are received by the Regional Haemovigilance Coordinator and subsequently forwarded to the haemovigilance manager at national level (De Vries and Faber, 2012).

SHOT program established in the UK first started in 1996. It has the responsibility to gather data of adverse events in transfusion medicine, including near miss cases. The data gathered is disclosed at an annual symposium and made available in report form. As a result, several impactful changes were made in blood transfusion practices resulting in better transfusion safety. They have also resulted in the government endorsing other initiatives such as national transfusion audit and education initiatives to improve transfusion safety (Bolton-Maggs *et al.*, 2012).

In Ireland, since 2010, all near miss events that happened in 'Blood Establishment' (BE) or Hospital Blood Bank (HBB) will be required to report to their National Haemovigilance Office (NHO). The NHO, in turn, will be submitting the report as serious adverse events to the Health Products Regulatory Authority (HPRA) who annually reports to the European Commission. Cases of 'Wrong Blood in Tube' (clinical near miss events) were also required to be reported to the NHO starting in 2019 (Irish Blood Transfusion Service, 2019).

2.5.2(a) Near miss reporting in Malaysia

In Malaysia, cases of near miss events of transfusion practice, from all hospitals in Malaysia, are required to be reported to the National Haemovigilance Coordinating Centre (NHCC) of the National Blood Centre. The report should include the root cause analysis for all near miss events reported together with implemented corrective and preventive actions (PDN, 2016).

2.5.2(b) Near miss reporting in Hospital USM

Transfusion Medicine Unit of Hospital USM receives requests for tests including; ABO and rhesus grouping, Group, Screen and hold (GSH), Group and Crossmatch (GXM), red blood cells (RBC) phenotyping, Direct Coombs Test, Indirect Coombs Test, antibody identification tests, antibody titre determination and cold agglutinin titre test. All requests from wards or clinics require designated request forms to be filled in. Additionally, requests should also be entered into *MyTransfusi* online system by respective staff or clinicians.

MyTransfusi is Hospital USM's online laboratory information system. It is developed in 2011 by Centre for Knowledge, Communication and Technology (PPKT) Hospital USM for Transfusion Medicine Unit of Hospital USM. This information system functions as a support service to be managed by the Transfusion Medicine Unit. According to *MyTransfusi* User Guideline and Manual, the *MyTransfusi* system consists of 4 modules which includes Blood donation Module, Microbiology Module, Immunohematology Module, and Component Module. Each module has its respective functions (Salamah *et al.*, 2018).

Immunohematology Module is the main module of *MyTransfusi* system. This system functions as a medium to be used by the ward or clinic to request tests. It is also useful for the laboratory to receive and record online test requests and to report tests' results. Therefore, it enables wards to access results online without relying on forms. It is also used to double-check on a component request of a patient before releasing the blood component. Lastly, this module can be integrated with information from other modules,

functioning as inventory for all blood products as well as analysis of laboratory statistics (Salamah *et al.*, 2018).

In Hospital USM, all near miss events should be recorded, adequately investigated and reporting made following a standard procedural step. Blood bank personnel involved plays a role in ensuring all steps are properly done and appropriate notification given to the involved party. Our centre divides near miss into two types which are near miss occurring in the ward and laboratory near miss.

According to Hospital USM Standard Operating Procedure for the Management of Near Miss (2017), near miss occurring in wards are categorised as clinical near miss. It is detected when there is discrepancy between the ABO grouping of a newly received sample and pre-existing ABO grouping of the same patient recorded within *MyTransfusi* system. According to our centre's standard operating procedure, when this occurs, this event should be investigated by the on-call medical officer. Implicated sample need to be rejected, and the ward should send a new sample (Salamah *et al.*, 2017).

Likewise, near miss occurring in blood bank, also known as laboratory near miss, is also detected when there is a discrepancy between the ABO grouping of a newly received sample and pre-existing ABO group of the same patient in *MyTransfusi* record. In contrast, laboratory near miss occurred resulting from mistakes from the laboratory side during sample receipt, testing, result interpretation and during release of test results or blood component. Investigation should be done according to the standard operating procedure of our centre. Implicated sample need to be discarded, and wards should be informed to send a new sample (Salamah *et al.*, 2017).

2.5.3 Near miss Incidences

The latest annual SHOT review in 2017 reported that the number of near miss cases increased to n=1359 in 2017 in comparison to 2016, which was n=1283. The increase was attributed to possible unsuccessful efforts or increased rate of detection due to certain policies for example group-check sample (Bolton-Maggs *et al.*, 2018). Near miss events were reported to be approximately ten times more frequent than actual incidents (Simon *et al.*, 2009). The Annual SHOT 2017 reported that there were 606 near miss incidents where potential ABO-incompatible transfusion might occur. In contrast, there were only four cases of ABO-incompatible transfusions from 2016 and 2017 data (Bolton-Maggs *et al.*, 2018). A higher number of near miss further supported the notion that analysing near miss data is more feasible due to the wealth of information available (Arnold, 2017).

A 3-year pilot research project in near miss event reporting conducted in Ireland also utilises the Medical Event Reporting System for Transfusion Medicine (MERS-TM) to collect and analyse data. Comparing between the two years in which this study was conducted, there is an increasing number of near miss reported in the second year (479 reports). It almost doubles the number of cases in the first year of study (280 reports). This particular study also suggests that near miss events were 18 times more often in comparison to actual adverse events (Lundy *et al.*, 2007).

As a means of improving the blood transfusion safety requirement in Germany, a critical incident reporting system (CIRS) for Germany was established in 2009. An analysis of the reports submitted to this registry from 2009 until 2013 showed that near misses were 46% and true errors were 53% of total error of mismatched recipient and blood product.

In contrast to previously mentioned reports, this report showed a higher number of true errors (Frietsch *et al.*, 2017).

A previous prospective study that was conducted in Transfusion Medicine Unit in Hospital USM from January until December 2009 showed a rate of near miss of 0.4%. This study mainly takes into account all mislabelled and miscollected samples, of which mislabelled cases were more frequent (66.3%) as opposed to miscollected samples (33.7%) (Noor Haslina *et al.*, 2011).

2.5.4 Types of Near Miss

There are different versions of near miss categorisation depending on each country's standardised haemovigilance reporting. United Kingdom's SHOT categorised near miss into the following; incorrect blood component transfused (IBCT), handling and storage errors (HSE), right blood right patient (RBRP), adverse events related to anti-D Immunoglobulin and avoidable, delayed or undertransfusion (ADU) (Bolton-Maggs *et al.*, 2018).

A Portuguese retrospective analysis of near miss events divided the events based on error type and the stage of the transfusion process in which a near miss has occurred. They reported on near miss occurring before reaching the blood bank (clinical decision of transfusion, requests and sampling), near miss in hospital blood bank and near miss after issuance of blood product (Maria Antónia, 2014). The German Interdisciplinary Task Force for Clinical Hemotherapy (IAKH) mainly described near misses occurring in the mismatched categories. These categories included either wrong blood given to the patient

or the wrong patient, given another blood product intended for others (Frietsch *et al.*, 2017).

Two prospective studies in India on near miss and actual errors divided near miss into three phases of laboratory testing, namely pre-analytical errors, analytical errors and post-analytical errors (Elhence *et al.*, 2012; Sidhu *et al.*, 2016). Pre-analytical phase includes any events occurring from collection of samples until laboratory transport. Analytical phase starts from receipt of specimen into the laboratory until completion of testing producing results. Post-analytical phase refers to reporting of the result of a test and distribution of the blood product (Elhence *et al.*, 2012).

In Malaysia, the NHCC in National Blood Centre or Pusat Darah Negara (PDN), requires all transfusion-related adverse event to be reported. A specific form 'Reporting Form for Transfusion-related Adverse Event' is required to be filled in. PDN reporting of errors and incidents in transfusion process is divided into cases of 'IBCT and near misses in transfusion process' and 'other incidents related to transfusion process' (Appendix A). Actual errors and near miss are classified into ward errors, testing (blood bank) errors and errors of blood administration in the ward. The category 'Other incidents related to transfusion process' include recipient sharing the same ID, possible blood grouping error in another health facility, error in previous admission and other unspecified situation (PDN, 2016).

In a previous study that was done in our centre, only two areas of near miss were investigated, namely mislabelled and miscollected samples. In this study, mislabelled samples were defined as samples that did not meet the criteria of acceptance by the

laboratory. Miscollected samples were samples in which the blood group obtained from ABO grouping testing were different from the blood grouping from previous testing (Noor Haslina *et al.*, 2011).

2.5.5 Location of near miss

A prospective study on near miss and actual errors in India have divided near miss into mainly two distinct groups according to the location of the event, namely, clinical services and transfusion services. Clinical services describe near miss occurring mainly in clinical departments either in the clinic or wards. Transfusion services near miss referred to those occurring in blood bank (Sidhu *et al.*, 2016). Similarly, a Portuguese Hemovigilance System (PHS) report have also divided the location of near miss into two major groups. They consisted of those occurring in clinical areas and those in the hospital blood bank without mentioning specific wards or departments (Maria Antónia, 2014).

Canadian's Transfusion Error Surveillance System (TESS) and Australia's Serious Transfusion Incident Report (STIR), however, specified respective places of near miss events. For example, the emergency department, the intensive care unit (ICU), the laboratory, the maternity ward or others (Public Health Agency of Canada, 2015; Strauss *et al.*, 2018; Victoria State Government, 2018).

2.5.6 Role of medical personnel in contributing towards near miss events

A study reporting on near miss events in a hospital blood bank in Pakistan described various personnel being involved. They included postgraduate trainee or interns, nursing staff, and trained phlebotomists (Karim *et al.*, 2017). A prospective study in India