Haemovigilance in NSW

A Review of Blood and Blood Product incident notifications in NSW public hospitals: 2005-2016

NSW GOVERNMENT
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Clinical Excellence Commission
Board Chair: Associate Professor Brian McCaughan, AM
Chief Executive: Ms Carrie Marr

Any enquiries about or comments on this publication should be directed to:
Clinical Excellence Commission
Locked Bag 8
HAYMARKET NSW 1240
Phone: (02) 9269 5500
Email: CEC-BloodWatch@health.nsw.gov.au

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INTRODUCTION

> "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"
>
> World Health Organisation [1]

National Perspective on Haemovigilance – National Blood Authority

> 'Blood products and transfusion are not risk free. Despite significant improvements in product safety through careful donor selection and product screening, transfusion errors and reactions still occur in all hospitals in all countries. Often they result from human error and can lead to patient morbidity, longer bed stays, remedial interventions, diversion of scarce resources, and in some cases death [2].'

The National Blood Authority (NBA) carries out 'national blood arrangements relating to safety measures, quality measures, contingency measures and risk mitigation measures for the supply of blood products and services'. The NBA established the National Haemovigilance Program in 2008 under the governance of a Haemovigilance Advisory Committee. Following the Initial Australian Haemovigilance report in 2008 [2], subsequent reports have been published in 2010, 2013, 2015 and 2016 respectively, reporting national haemovigilance data between 2009 and 2014 [3, 4, 5, 6].

The aim of the Haemovigilance Program is to identify factors contributing to the risks of transfusion, promote safe transfusion practice and product improvements, and to position Australian transfusion risks and trends in a global perspective. This is supported by the National Stewardship Statement 2010 which outlines the expectations of Health Ministers in relation to blood stewardship, including the requirement for health providers to collect and manage transfusion-related adverse event information [Appendix I].

National Perspective on Haemovigilance – Australian Commission on Safety and Quality in Health Care

The National Safety and Quality Health Service Standards (NSQHS) [7] are a quality framework used in Australian health facilities as part of the national health accreditation processes and requirements. Standard 7 – Blood and Blood Products, provides the framework for health organisations to implement and monitor processes to ensure safe and effective use of blood and blood products.

Haemovigilance is a key feature of this and the standard includes the following haemovigilance related criteria:

7.3.1 Reporting on blood and blood product incidents is included in regular incident reports

7.3.2 Adverse blood and blood product incidents are reported to and reviewed by the highest level of governance in the health service organisation

7.3.3 Health service organisations participate in relevant haemovigilance activities conducted by the organisation or at state or national level

7.6.1 Adverse reactions to blood and blood products are documented in the patient clinical record

7.6.2 Action is taken to reduce the risk of adverse events from administering blood or blood products

7.6.3 Adverse events are reported internally to the appropriate governance level and externally to the pathology provider, blood service or product manufacturer whenever appropriate

The Australian Commission on Safety and Quality in Health Care have published version 2 of the NSQHS [8] and healthcare facilities will be accredited against these from January 2019. In version 2, Standard 7 has been renamed as 'Blood Management Standard 7'. Haemovigilance remains a key feature of this revised standard, including a specific sub-section called 'reporting adverse events', items 7.7 and 7.8.

Haemovigilance in New South Wales

NSW is the most populous state in Australia with a population of just under 7.6 million in 2015. Supporting this population are over 200 public hospitals, as well as over 100 private facilities, a large percentage of which transfuse blood and blood products. Usage of fresh blood products in NSW accounts for approximately 30% of the total national issue. The mean issue of red cells to NSW is currently 16,232 units per month (to December 2016). Since July 2012, the mean number of red cell units, the most commonly prescribed fresh blood product issued to all NSW hospitals, has decreased by 18%.

Blood management in NSW is supported by Blood Watch, a program of the Clinical Excellence Commission. Through a collaborative approach with key partners including clinicians, local health districts, and the NSW Ministry of Health, the program provides leadership and support in quality care, clinical safety and supply security of blood and blood products to achieve world class transfusion medicine practice in NSW.

Incident management activities and responsibilities are outlined in NSW Health policy directives; Incident Management [9], with further requirements for specific blood and blood product related incidents outlined in the policy; Blood - Management of Fresh Blood Components [10]. This includes responsibility for reporting Haemolytic Transfusion Reactions (HTR) as a result of ABO incompatibility (a national sentinel

event) as well as reporting requirements to the Blood Service for other specific adverse outcomes of transfusion. Local management and review is conducted via facility or network Transfusion Committees (or equivalent governance committees) and/or Clinical Governance departments.

NSW public hospitals use a centralised incident reporting platform to report incidents and 'near miss' events, including those related to the clinical handling, management and administration of blood and blood products. The current platform used in NSW is the Incident Information Management System (IIMS).

Beginning in 2008, NSW has supplied a collated review of haemovigilance related notifications as extracted from IIMS to the NBA for inclusion in the National Haemovigilance Reports. The information supplied however, was not mapped in line with the Australian National Haemovigilance Data Dictionary (ANHDD) [11]. This has meant that data from NSW, although included in the report, could not be analysed in the context of the national data set.

In 2013, Blood Watch committed to evaluating IIMS data from 2011/12 and 2012/13. The aim of this was to determine if the data could be mapped to the ANHDD, and provided to the National haemovigilance program for inclusion in the national data set. A small expert advisory group was engaged, and relevant notification details, including all free text fields, were analysed.

A total of 2,929 incident reports submitted over the 2 year period were reviewed with 469 incidents mapped to the ANHDD and submitted to the NBA for inclusion in the Australian Haemovigilance Report 2015 [5].

Following this initial mapping exercise, the scope of the haemovigilance data analysis project was expanded in order to inform knowledge and clinical practice improvement related to transfusion safety in NSW hospitals. This report provides the results of this analysis and provides recommendations for improving recognition, management and reporting of adverse events and outcomes in transfusion medicine.

METHOD

De-identified data of notifications with Blood and Blood Products category selected as either a Primary or Other incident type between June 2005 and July 2016 was extracted from IIMS. The total number of notifications was 22,343. This extract was then reviewed for accuracy of the categorisation and 2,093 notifications were excluded from further analysis.

Notifications that were excluded include:

- Accident/occupational health and safety
- Patient/staff member bleeding/blood loss
- Obstetric trigger tool data set notifications (e.g. PPH or postpartum blood transfusion)

- Other medications inappropriately described as a blood or blood product (e.g. Recombinant factor VIIa, parenteral iron preparations)

IIMS notifications are commonly described as incidents. For the purpose of this review, blood and blood products IIMS notifications have been categorised as either incident type notifications or complication type notifications. Incident type notifications are adverse or 'near miss' events occurring in the transfusion process, while complication type notifications describe pathophysiological reactions to blood and blood products.

Included notifications were first broadly categorised this way, and then further grouped according to defined subtypes (developed in the initial data mapping exercise). Defined subtypes, where relevant, were defined in line with definitions in the ANHDD. These classifications are outlined in Tables 1 and 2.

Table 1 Incident type notifications and definitions

Incident type	Related activity
Administration process	Bedside product verification, patient monitoring and related administration procedures in the clinical setting
Clinical Management	The delivery of care and/or patient assessment leading to avoidable, inappropriate or delayed use of blood products
Documentation	The clinical documentation of prescription, care delivery, monitoring, and consent
Equipment	Blood product related storage and transport equipment, most commonly outside of the transfusion laboratory e.g. satellite fridges or vacuum tube delivery systems
Incorrect blood component transfused (IBCT)	Blood products ordered and/or administered to the wrong patient, the incorrect product ordered and/or administered for the clinical indication, and products not meeting transfusion requirements based on clinical need (e.g. irradiation)
Labelling and identification	Patient identification procedural issues, and labelling of specimens, request forms, and other relevant documentation
Laboratory process	Pre-transfusion testing, dispensing, and laboratory procedural non-compliance
Non laboratory dispensing	Blood product collection, delivery and storage, including from satellite storage, by non-transfusion laboratory staff

Incident type	Related activity
Wastage	Blood products requiring discard due to errors in ordering, storage or handling (not related to equipment failure) and other clinical procedure non compliance
Wrong Blood in Tube (WBIT)	Confirmed events where blood collected for transfusion testing does not belong to the person identified on the specimen label

Table 2 Complication type notifications and definitions

Complication type	Description
Febrile non haemolytic transfusion reaction (FNHTR)	Temperature > 10 C above baseline +/- chills or rigors during or within 4 hours of completion of transfusion
Haemolytic Transfusion Reaction - immediate (HTR)	One or more of the following within 24 hours of transfusion • fever +/- other systemic symptoms • inadequate rise in post transfusion Hb • drop in Hb of ≥ 20g/l in 24 hours • rise in LDH ≥ 50% in 24 hours • haemoglobinuria, ↑ bilirubin, ↓ haptoglobin
Delayed Haemolytic Transfusion Reaction (DHTR)	As per Immediate HTR but 1 – 28 days post transfusion
Severe allergic/anaphylactoid reaction	Allergic - Rash, pruritus, urticaria, dyspnoea, angioedema Anaphylactoid – as allergic with systemic signs e.g. hypotension and ↓LOC
Transfusion-Associated Circulatory Overload (TACO)	Acute symptoms of circulatory overload with respiratory distress, ↑HR, and ↑BP during or within 12 hours of completion of transfusion
Transfusion-Related Acute Lung Injury (TRALI)	Non cardiogenic acute respiratory distress, and diffuse bilateral infiltrations on CXR during or within 6 hours of completion of transfusion (exclude TACO)
Transfusion-Transmitted Infection (TTI)	Detection of infective agent (bacteria, virus, parasite) in a transfused blood component and/or recipient's blood
Unclassifiable	The incident description does not fit within the currently applied definitions but is of sufficient severity requiring inclusion in

Complication type	Description
	compliance with IHN principles of Unclassified or Previously Unrecognised Complications of Transfusion (PUCT); or The incident detail is insufficient for inclusion into another category

Some notifications can be classified as both an incident and a complication notification type, where an incident resulted in a complication for the patient. For the purposes of this review, in most instances the complication type notification classification was applied, and a subgroup of preventable complications was identified post analysis (see results for complication notification types for further detail).

In some cases, multiple incident type notifications could be identified in one notification. In these instances a consensus between reviewers agreed on the application of one primary subtype ensuring all notifications represented a unique count.

Notifications prior to 2011 were retrospectively mapped to the ANHDD definitions, although not submitted to the National Program. All notifications since 2011 have been reported in line with the ANHDD. Over the relevant time period, between 10 to 12% of notifications could be mapped. Important key differences in Blood and Blood Product incident notifications in NSW, as compared to those submitted to the national program, meant the large majority of notifications in NSW are not considered relevant for national reporting.

The reasons for this are:

- NSW IIMS notifications include fresh blood components and plasma derived blood products. Only notifications related to labile (fresh) blood products; red cells, platelets, and plasma, are mapped and reported to the national program
- The only incident type reported to the National Program is Incorrect Blood Component Transfused (IBCT) which is between 0.7% - 3.9% of all incident type notifications in NSW
- All other notifications reported to the National Program are complication types which are an average of 10% of total notifications in NSW annually

Notification details, SAC score, contributory factors, or outcomes were not reviewed for accuracy of reporting, and no peer or hospital comparisons were made.

RESULTS

Overall notifications

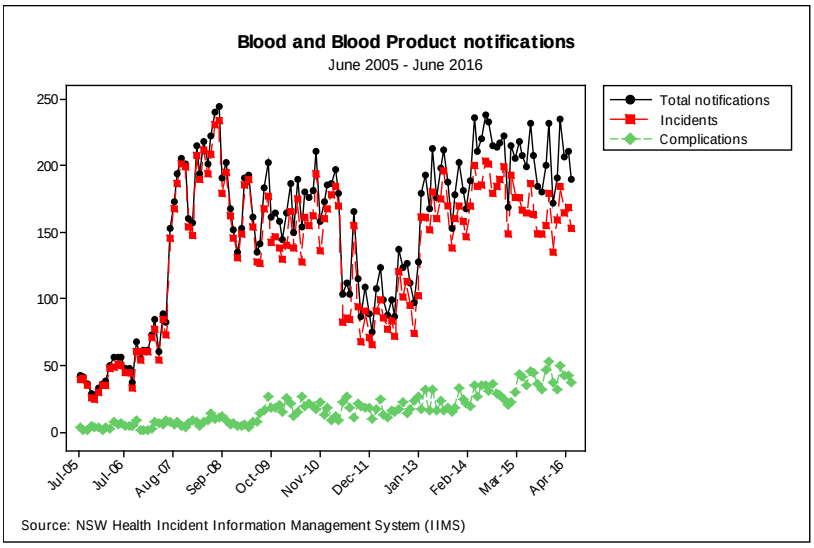
Notifications included for review

The total number of notifications made to IIMS with Blood and Blood Products accurately denoted as the primary or other incident type from 1st July 2005 to 30th June 2016 was **22,591**.

Blood and Blood Product notifications in IIMS 2005 - 2016												
	2005/06	2006/07	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	Total
Total	659	767	2303	2167	2019	2052	1192	1737	2339	2570	2455	22591
Incidents	610	715	2224	2085	1795	1845	997	1507	2056	2203	1949	20042
Complications	47	52	79	82	224	207	195	230	283	368	496	2548
Mapped to ANHDD	NA	94*	133*	142*	234*	242*	239	230	237	265	281	2286

** Post submission analysis, ANHDD compliant data set not submitted for national reporting for these years*

Chart 1. Blood and Blood Product notifications per month July 2005 – June 2016



Over the reporting period, the rate of all notifications has increased, with a rapid increase in incident type notifications identified from 2007-8, accounting for a mean of 90% of all notifications.

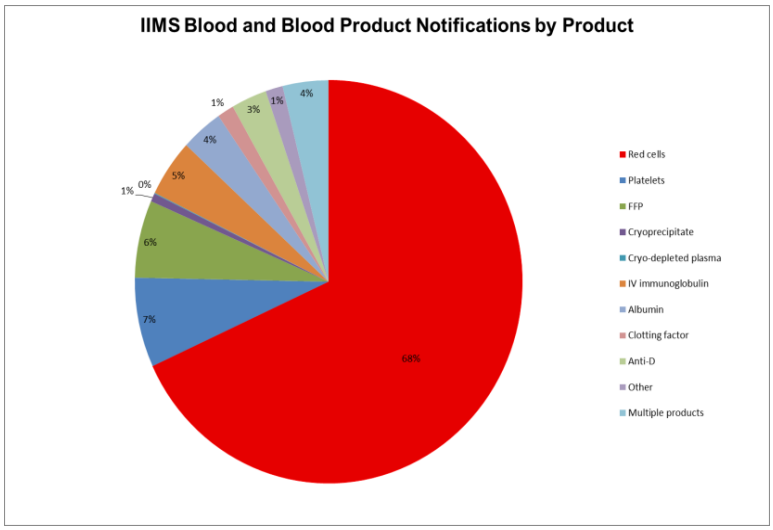
The rate of incident type notifications reported demonstrates a wide variation over time. Complication type notifications demonstrate a stable, slower rate of increase over the same time period.

The increase in overall notifications demonstrates an increased level of awareness of the importance of haemovigilance activities across the health system in NSW.

Notifications by type of blood product

Notifiers can enter any 'near miss' or actual adverse event or outcome for **all** blood and blood product types. Not all notifications involve a blood product, and many notifications involve more than one product type. These are transfusion chain incidents which are process errors in transfusion-related activities, for example, pathology specimen for transfusion labelling or testing errors, some clinical management type incidents, and documentation errors.

Chart 2. Notifications by blood product 2005 – 2016



Where identified, 68% of notifications are for red cells which are the most commonly administered fresh blood product.

Approximately 58% of all notifications are transfusion chain errors and no blood product is identified.

Incident severity and root cause analysis (RCA) review

Notifications are rated for outcome severity locally using a Severity Assessment Code (SAC). There are four SAC ratings, ranging from SAC 1 (extreme risk) to SAC 4 (low risk). Blood and blood product notifications analysed ranged in severity across all ratings.

Approximately 1% of blood product notifications were rated as SAC 1 or SAC 2, meaning the majority of reported notifications involved little or no harm to the patient. All SAC 1 notifications require an RCA to be undertaken to identify causality and/or contributory factors as well as opportunities to improve system safety.

Of the 36 blood and blood product RCAs reviewed, thirteen (36%) were performed following the death of a patient with transfusion as a causal contributor to mortality. Table 4 outlines the primary transfusion relationship to the root cause as identified.

In 2012-13, there were 11 SAC 1 notifications with subsequent RCA investigations: all identified Incorrect Blood Component Transfused (IBCT) as the primary transfusion-related issue. All of these IBCT events were procedural errors in patient identification at the time of administration. In 4 of the 11 events, the

patient died, however, the IBCT was found not to be contributory. Instead, the underlying significant trauma or disease factors were found to be the contributory factors to mortality. There have been no SAC 1 notifications since July 2014.

Table 3: Notifications by SAC Ratings 2005 – 2016

SAC Rating	Count
SAC 1	45
SAC 2	181
SAC 3	9202
SAC 4	11790
No SAC Allocated	718

Table 4. Primary transfusion-related root causes (SAC 1)

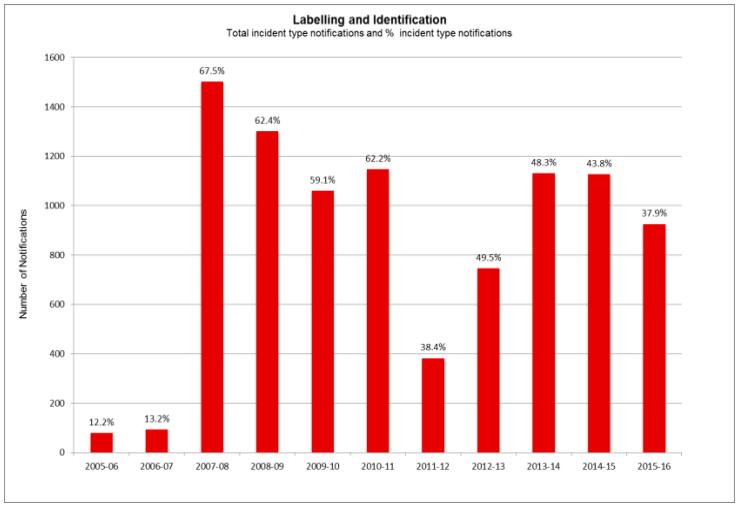
Primary transfusion relationship with root cause	Count
Incorrect Blood Component Transfused (IBCT)	32
Transfusion-Transmitted Infection	2
Transfusion-Related Acute Lung Injury (TRALI)	1
Delayed Transfusion Reaction (DTR)	1
TOTAL (Reviewed)	36

Incident type notifications

Incident type notifications increased by 72% between 2005-06 and 2015-16. The incident type notification with the most significant increase over this time is labelling and patient identification which increased from 12.2% of incident type notifications in 2005-06, to a peak of 67.5% of incident type notifications in 2007-08.

This increase correlates with the implementation of pathology labelling and zero tolerance policies across a large number of health services in NSW.

Chart 3. Labelling and Identification incident type notifications 2005 – 2016



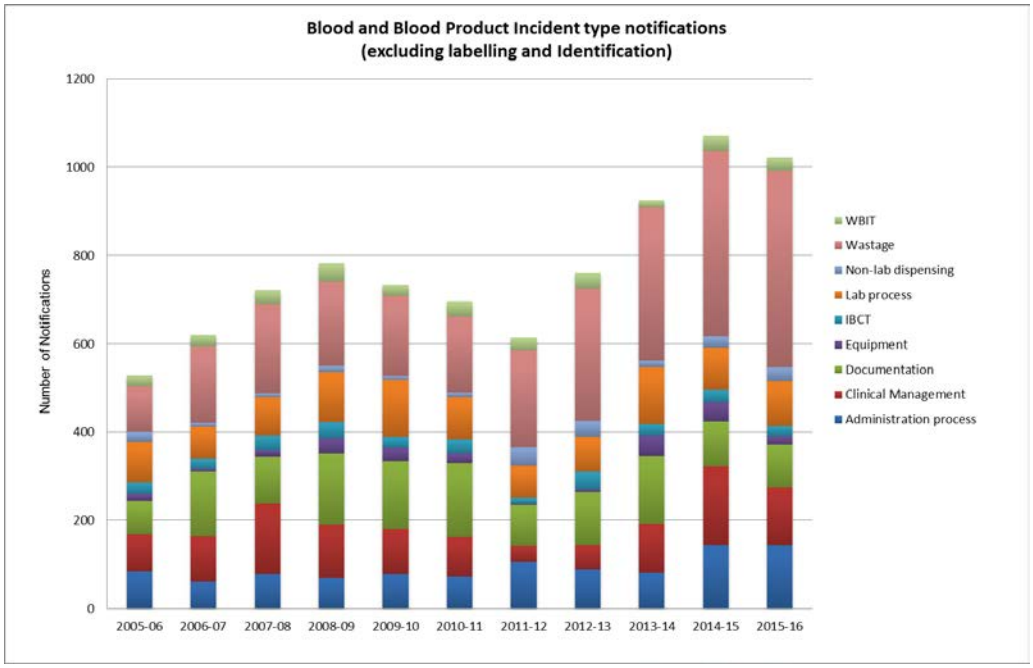
A key component of these local policies was a targeted campaign of reporting these errors in IIMS, most commonly by laboratory services, and trended data used locally for targeted education.

The transfusion sector in Australia continues to recognise this as a high risk area and, despite these types of incidents considered no-harm events, labelling and identification errors continue to be an important component of the haemovigilance related reporting culture across NSW hospitals.

Incident type notifications – excluding labelling

Notification of other incident types has increased by approximately 75% since 2005-6 as demonstrated in Chart 4 (excluding labelling and identification incident types).

Chart 4. Incident type notifications (excluding labelling and identification incident types) 2005 – 2016



Administration process

In 2011-12, administration incident type notifications increased from a mean of 75 notifications per year, to a mean of 114 notifications per year. In 2012, NSW Health mandated the completion of the BloodSafe eLearning: Clinical Transfusion Practice [12] course for all staff involved in the prescription, handling and administration of blood and blood products. This standardised education across all hospitals and clinical groups increased awareness of best practice, and hence the importance of notification of procedural errors. Since 2012, there have been nearly 78,000 completions of BloodSafe eLearning courses by NSW Health staff.

Wastage

Between 2005-06 and 2010-11, the mean number of wastage incident types notifications was 170, increasing to a mean of 346 notifications per year since 2011-12[1]. This increase in wastage related

[1] It should be noted that more accurate and sophisticated wastage data reporting is now available through alternative sources, and that this only refers to reported incident data.

incident type correlates with both the mandating of standardised transfusion education for clinical staff using BloodSafe eLearning, as well as the National Blood and Blood Product Wastage Reduction Strategy 2013-17 [13] and the associated work of the NSW Wastage Reduction Working Party. It highlights an increased awareness of wastage of blood products related to clinical handling, ordering and storage (outside of the transfusion laboratory setting and storage related equipment failure).

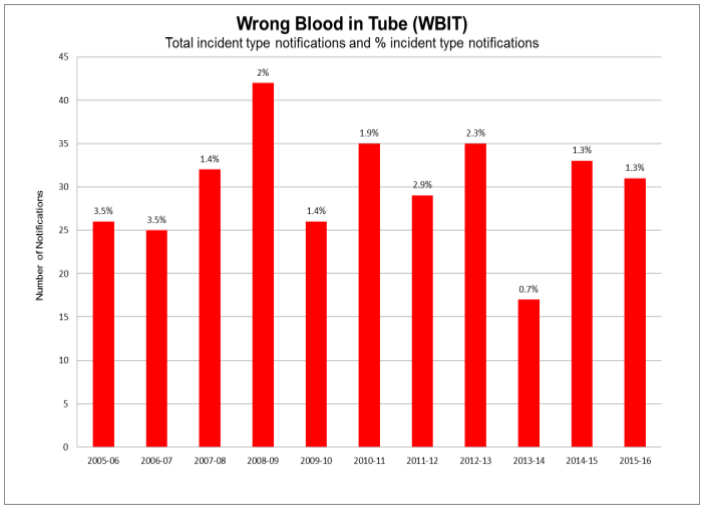
Wrong Blood in Tube (WBIT)

Wrong blood in tube (WBIT) incident types account for only a small percentage of all incident type notifications, however are considered a significant risk to patient safety in transfusion medicine. They are an example of a procedural error (incident) potentially causing a complication. The reaction potentially caused by a WBIT is an ABO incompatible haemolytic transfusion reaction, a potentially fatal complication of transfusion.

WBITs are considered separately to labelling and identification errors as they are confirmed events where it is known that the blood sample does not belong to the person as identified on the specimen label. WBITs are known to have contributed to transfusion-related deaths in Australia as a result of significant ABO haemolytic transfusion reactions [14], as well as the potential of other causes of harm. Examples of incident type notifications classified as WBITs include:

- Transfusion specimens – Blood group testing not matched to the correct patient, commonly identified when patient blood grouping inconsistent with historical blood group
- Other specimens - Patient transfused blood or blood product based on pathology results of another person, commonly identified during post transfusion testing results

Chart 5. WBIT incident type notifications 2005 – 2016



The rate of WBIT notifications has remained stable with a mean of 30 notifications per year since 2005-6. Some hospitals allocate a potential SAC of 1 or 2 for WBITs, but they are identified prior to harm reaching the patient. There have been no notified deaths as a result of a WBIT since 2005-06 in NSW Health.

Incorrect Blood Component Transfused (IBCT)

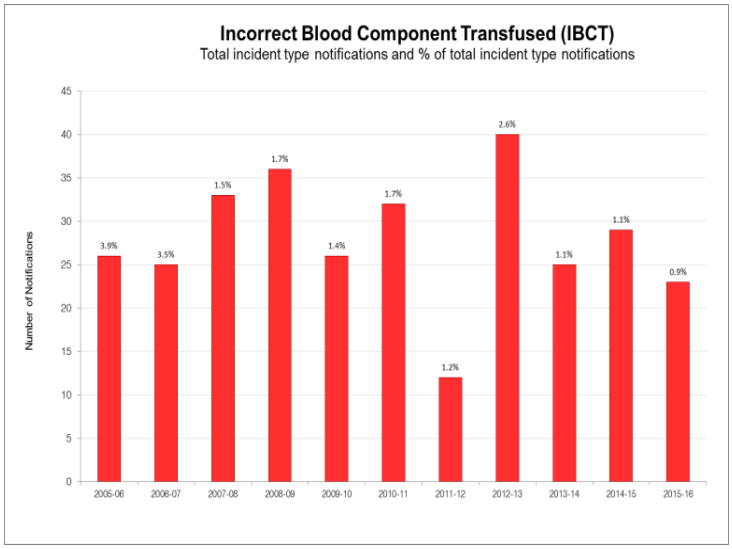
Incorrect blood component transfused (IBCT) is another low rate notification, but is also a significant patient risk in transfusion medicine. IBCT occurs where a patient receives a blood component that is either destined for someone else, or not to specification.

Where the blood component was destined for another person, this represents an example of procedural error potentially causing an ABO incompatible haemolytic transfusion reaction. This type of IBCT error can be the end result of a WBIT incident (see previous) but, more commonly results from patient identification procedural errors at the point of transfusion are the main factors. Historically, deaths have been reported in NSW and nationally as a result of IBCTs and this report demonstrates improvement in this area [15, 16, 17]. These types of errors result in patients receiving a blood product ordered and cross matched for another person. They do not always result in harm as patients may incidentally have the same or compatible blood group.

Specific risks identified through this analysis include:

- Same/similar patient names
- Co-located patients, such as 4 bed rooms/bays
- High traffic clinical environments (e.g. ED)
- Unknown and/or unconscious patients (e.g. patients under anaesthesia)

Chart 6. IBCT incident type notifications 2005 – 2015



The rate of IBCT notifications has remained stable over time with a mean of 28 IBCT incident types notified per year since 2005-06. IBCTs account for a high number of SAC 1 notifications (see Incident severity and RCA review previously).

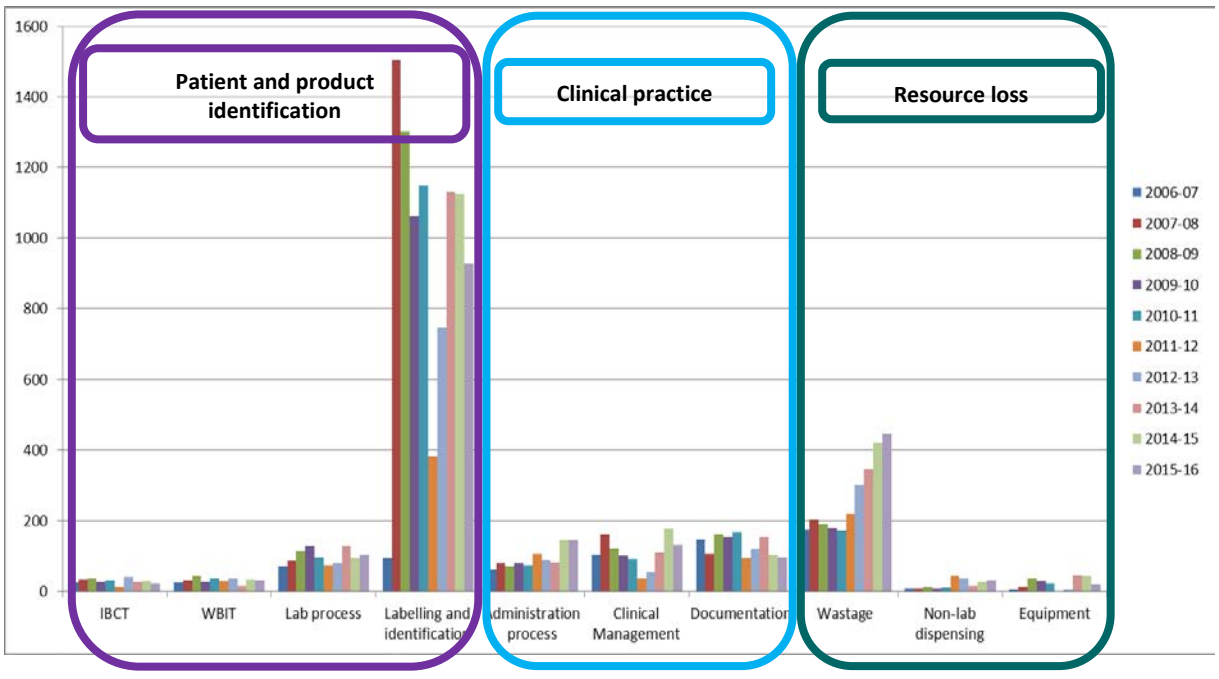
Data analysis identified the growing number of notifications where special product modifications are not met, known as not to specification. Certain patient populations require modifications (of fresh products) used for transfusion. One example, gamma-irradiation of fresh blood products indicated for patients

undergoing allogeneic bone marrow transplant, has been flagged as an increased trend in notifications. Gamma-irradiation of blood products prevents a rare but fatal transfusion complication: Transfusion Associated Graft versus Host Disease (TA-GVHD). TA-GVHD is reportable to the National Program; however, there have not been any notifications in NSW since the implementation of the IIMS platform.

Overall review of the incident type notifications over time shows three distinct 'clusters' of incident types. These are:

- Patient and product identification type errors where the primary error type includes instances where the patient identification process is incorrect, or the product selection is inappropriate
- Clinical practice type errors in the process of prescribing and administration
- Resource loss errors resulting in increased wastage of blood products.

Chart 7. Cluster categorisation of incident type notifications over time 2005 – 2016



Complication type notifications

Notifications of complications of transfusion have increased by 71% since 2008-09 and were 13% of total blood and blood product notifications in 2015 -16. This increase represents improved capacity for reporting, rather than an increase in episodes of complications of transfusion. The two most commonly reported complication type notifications are:

- Febrile Non-Haemolytic Transfusion Reactions (FNHTRs), which increased from a mean of 27 notifications per year between 2005-06 and 2008-09, to a mean of 158 notifications per year since 2009-10. FNHTRs are reported for most blood and blood products; however, red cells are the most common. The reported incidence of FNHTRs is 0.1 to 1% of transfusions (with leucocyte depleted products) [18]
- Severe allergic reactions have increased from a mean of 15 notifications per year between 2005-06 and 2008-09, to a mean of 52 notifications per year. As with FNHTR, severe allergic reactions are reported for most blood and blood products; however, plasma and platelets are the most common. The reported occurrence of severe allergic reactions is 1:20 000 – 1:50 000 [19]

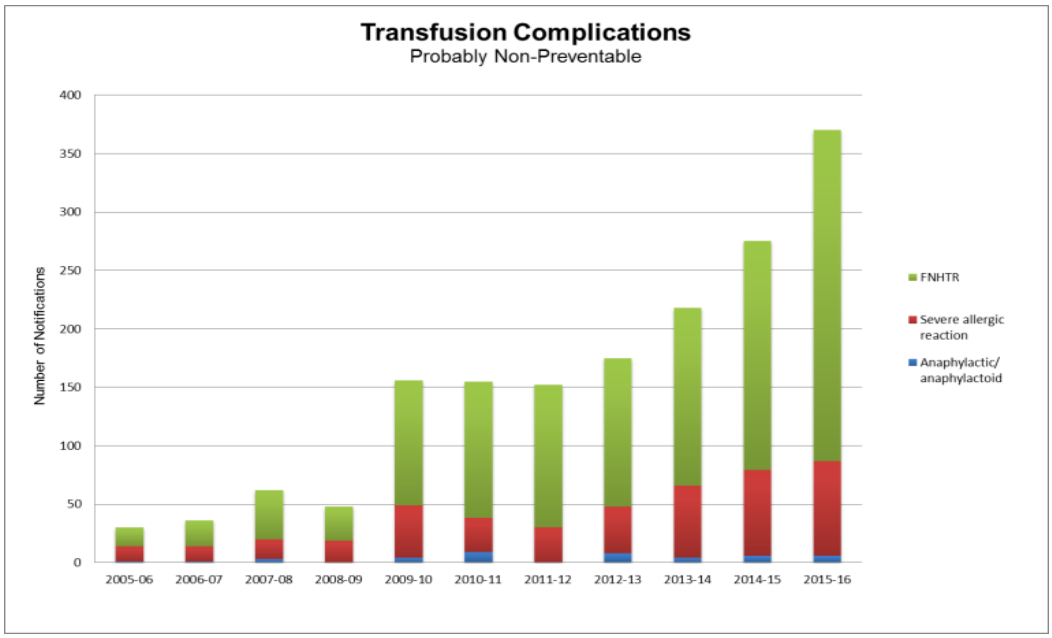
Through the course of review, it was determined that complication type notifications could be further grouped based on the concepts of 'preventability'. Assessing the preventability of transfusion-related complications allows us to identify and concentrate on specific procedural risks as a part of the incident management processes, rather than adopting a 'one size fits all' model of risk assessment and mitigation.

The specific framework identified and used for this review is based on the UK Serious Hazards of Transfusion (SHOT) model [20] using 'Probably Not Preventable' and 'Possibly Preventable' groupings.

'Probably Not Preventable' complications of transfusion

FNHTR, severe allergic type, and anaphylactic/anaphylactoid reactions are included as 'Probably Not Preventable' complications of transfusion as both product and patient characteristics are the major contributing factors. Chart 8 demonstrates the number of 'Probably Not Preventable' complication type notifications per year since 2005.

Chart 8. 'Probably Not Preventable' complication type notifications 2005 – 2016



‘Possibly Preventable’ complications of transfusion

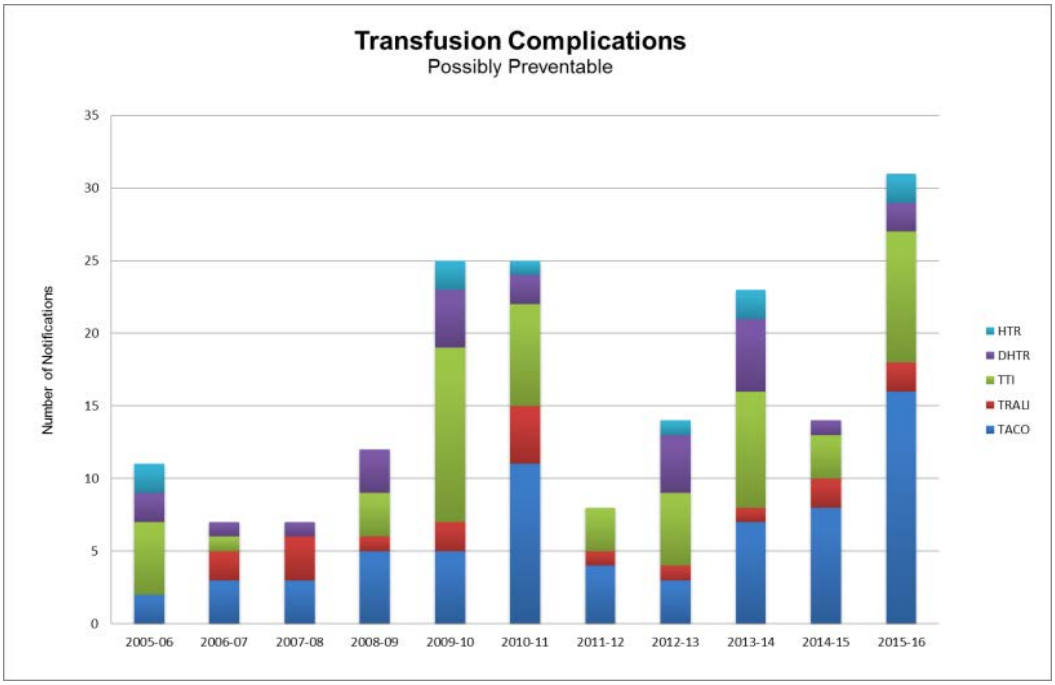
‘Possibly Preventable’ complication notification types are less commonly entered into IIMS, ranging between a combined count of 7 and 25 notifications per year.

Transfusion-Associated Circulatory Overload (TACO)

TACO is the most commonly reported ‘Possibly Preventable’ complication; however, it is probable that there is significant under reporting. It is considered one of the leading causes of transfusion-related death and major morbidity internationally [21]. The risk of developing TACO can be significantly reduced by appropriate use and single unit dosing, as well as adequate patient risk assessment.

Patients most at risk of TACO include those with severe anaemia (including critical haemorrhage), patients with low body weight (including the frail elderly, neonates and paediatric patients), and patients with congestive cardiac failure [21].

Chart 9. ‘Possibly Preventable’ complication type notifications 2005 – 2016



Transfusion-Related Acute Lung Injury (TRALI)

TRALI is cited as the most common cause of transfusion associated fatalities, presenting as an acute, non-cardiogenic, respiratory failure syndrome within 6 hours of transfusion [22]. It is thought that TRALI cases occur as a result of a combination of patient and donor factors, such as high acuity/ICU patients, and the passive transfer of specific antibodies through transfusion. Plasma is the most common product associated with TRALI, although platelets and red cells have also been identified. The incidence of TRALI is variably reported. The most commonly reported incidence is 1:10 000 transfusions [22].

In NSW, there were 20 notified cases of suspected TRALI in IIMS between 2005 and 2016. One patient death has been reported; however, it was determined that the death was unlikely to be related to transfusion. As for TACO, TRALI is often described as under-reported in the national and international literature [22].

TRALI is considered preventable by donor specific exclusion criteria; it is not the result of procedural errors in transfusion. The main TRALI risk reduction strategies have been implemented in Australia by the Blood Service and include the use of male only clinical plasma for clinical use, for example FFP and cryoprecipitate. Since July 2016, apheresis platelets (higher plasma content than pooled platelets) are collected only from male and nulligravida female donors (female donors who have never been pregnant [22]).

All suspected TRALI cases must be reported to the Blood Service.

Transfusion-Transmitted Infection (TTI)

TTIs are not commonly notified using IIMS in NSW. However, the general public consider the risk of virus transmission to be significant. There were no viral TTIs reported in IIMS between 2005 and 2016. The Blood Service publishes residual risk estimates for transfusion-transmissible viral infections. These are available at: https://www.transfusion.com.au/adverse_events/risks/estimates

There have been 59 TTI complication type notifications in IIMS since 2005-06, though only a small number of these have been confirmed. All notifications involved bacterial transmission, with 2 reported deaths, one in 2006 and the other in 2007. Both deaths involved acutely unwell patients who developed sepsis and multi organ failure following bacterial transmission from platelet products. Platelets are at particular risk of bacterial contamination as they are stored at 20 - 24^{0}C.

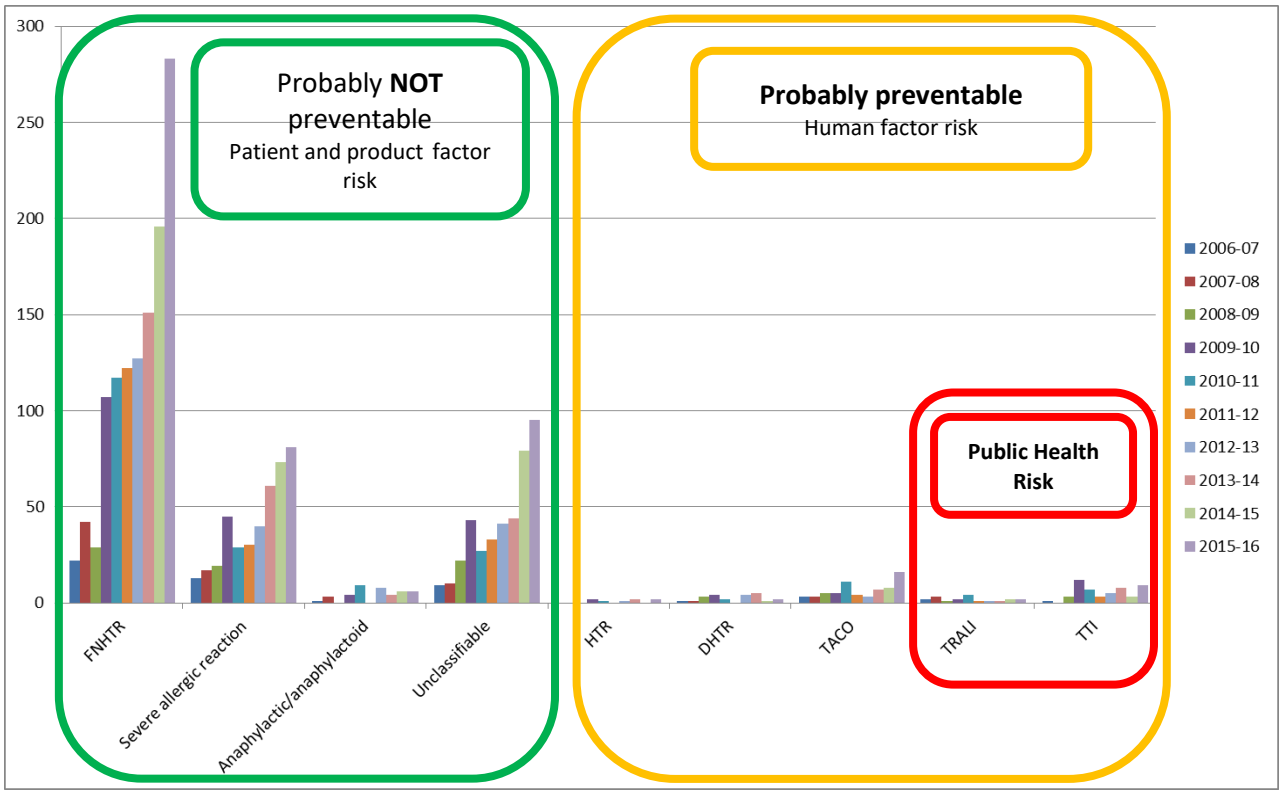
Inappropriate storage may contribute to the incidence of TTIs but, like TRALI, it is often not the result of procedural errors within the clinical setting. TTIs are more commonly linked to donor carriers (either blood borne or skin contaminants).

As well as donor specific exclusion criteria, and screening for specific blood borne infections, several interventions have been implemented by the Blood Service since 2006/7. These include the use of a diversion pouch to collect the first 20-30mL of blood at donation, as well the implementation of bacterial screening protocols [23, 24]. Since 2010, all TTI notifications were related to an 'initial positive' screen (as

performed at the Blood Service) and the associated blood product recall, noting that some products are transfused prior to recall and the recipient requires a further clinical assessment. All notifications in IIMS since 2010 were no harm events, with no confirmed transmission of infections reported.

All suspected TTI cases must be reported to the Blood Service.

Chart 10.Cluster categorisation of complication type notifications 2005 – 2016



CONCLUSION & RECOMMENDATIONS

Since the implementation of the IIMS platform in 2005 and following implementation of the Blood Watch program, there has been a significant increase in the number of transfusion-related incident notifications in NSW. The increase in overall notifications demonstrates an increased level of awareness of the importance of haemovigilance activities across the health system in NSW. Importantly, the increase in notifications has occurred simultaneously with a decrease in incident severity and patient harm. Following this review, several recommendations for improvement have been made:

At point of care – Local Health Districts/Speciality Health Networks

- Continue to foster the notification of haemovigilance related incidents, even those where no harm has occurred
- Continue to monitor haemovigilance events to ensure local risks are identified, and implement and monitor strategies to reduce risks related to transfusion
- Implement and monitor appropriate use of transfusion protocols and other transfusion-related improvement initiatives, to ensure the benefit of transfusion outweighs the risks of transfusion for patients so exposed

System wide – Blood Watch

- Development of standardised clinical resources to support:
    - Recognition and clinical management of adverse events of transfusion
    - Incident management resources including investigation follow-up and clear guidance on reporting requirements
- Annual analysis and release of NSW haemovigilance snapshot data
- Annual analysis and data submission in compliance with the ANHDD
- Develop and implement a process to improve reporting of suspected TRALI and TTI events to the Blood Service
- Haemovigilance data reconciliation with the Blood Service

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APPENDIX I

AUSTRALIAN HEALTH MINISTERS' CONFERENCE STATEMENT ON NATIONAL STEWARDSHIP EXPECTATIONS FOR THE SUPPLY OF BLOOD AND BLOOD PRODUCTS

The Australian Health Ministers' Conference (AHMC) has determined that a clear statement is needed on governments' stewardship expectations for the providers of blood and blood products within the health sector. Stewardship, in this context, means responsible, sustainable and appropriate use of blood and blood products.

Blood and blood products are provided under the *National Blood Agreement* 2003 to which all Commonwealth, State and Territory Governments are signatories. Achieving a blood supply that can meet the growing needs of an ageing population at an affordable cost requires the commitment from blood donors to be matched by an equal commitment from other parties in the supply chain.

All governments are committed to:

- Providing an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services; and
- Promoting safe, high quality management and use of blood products, blood related products and blood related services in Australia.

A key component of the blood sector and one which plays an invaluable part is that of the health providers of blood and blood products. Hospitals, doctors, laboratories and other health providers serve a vital role in ensuring these key resources reach the patients in need.

In fulfilling this role, Ministers expect that these health providers will contribute to the sustainability of the blood supply by adopting these stewardship measures for their own organisation and requiring their adoption by any other party to whom they supply blood.

Blood Stewardship Principles

Blood should be managed in ways that ensure:

- All blood products are used in a clinically appropriate manner in accord with relevant professional guidelines and standards;
- Informed patient consent procedures are implemented for all patients;
- Processes, programs and facilities are in place to minimise the wastage of blood products;
- Facilities are accredited with the appropriate bodies to meet all quality and safety obligations; and
- Transfusion related adverse event information is collected and managed according to jurisdictional requirements.

National blood product planning, management and governance are supported by:

- Health providers having an ordering and receipt verification process in place which provides adequate financial accountability as required by governments; and
- Inventory data is provided on a regular and timely basis to assist in supply and demand planning, especially in times of national shortages.

Governments and the National Blood Authority will continue to manage the Australian blood supply to meet the needs of the community. Health providers play a vital role in making sure that products are available to meet clinical need, when and where required. The contribution of these health providers to safe and appropriate use, including minimisation of cost and wastage in the supply, is equally important. Ministers look to health providers to increase their efforts in these areas to ensure that Australia has a sustainable and affordable blood supply into the future.

Statement Approved by the Australian Health Ministers' Conference, 12 November 2010.

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

Clinical Excellence Commission
Locked Bag 8
Haymarket NSW 1240
p. +61 2 9269 5500
e. CEC-SPC@health.nsw.gov.au
w. www.cec.health.nsw.gov.au