Serious transfusion incident report 2015–16



This page has been left blank for the purpose of double-sided printing.

Serious transfusion incident report 2015–16

To receive this publication in an accessible format phone 9694 0102 using the National Relay Service 13 36 77 if required, or email stir@redcrossblood.org.au

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne. © State of Victoria, Department of Health and Human Services December, 2017. ISBN 978-1-76069-232-2

Available at https://www2.health.vic.gov.au/hospitals-and-health-services/patientcare/ speciality-diagnostics-therapeutics/blood-matters/serious-transfusion-incidents (1712018)

Contents

Acknowledgements	iv
Abbreviations, acronyms and definitions	v
Executive summary	vi
Key messages and recommendations	vii
Transfusion safety checklist	viii
Introduction	1
Method	2
Data for 2015–16	3
Demographics	6
Clinical reports	10
Febrile non-haemolytic transfusion reaction (FNHTR)	12
Allergic/anaphylactic reactions	14
Acute haemolytic reaction	18
Transfusion transmitted infection, including bacterial sepsis	20
Transfusion-associated circulatory overload (TACO)	21
Transfusion related acute lung injury (TRALI)	23
Delayed haemolytic reactions	24
Transfusion associated graft versus host disease (TAGvHD)	27
Post-transfusion purpura (PTP)	27
Procedural reports	28
Incorrect blood component transfused (IBCT)	28
Wrong blood in tube (WBIT)	32
RhD administration	35
Near miss	38
Cell salvage	40
Sentinel events	41
Future	41
References	42
Appendix 1: Expert group members	43
Appendix 2: STIR publications and promotion	44
Appendix 3: Imputability and severity scores	45

Acknowledgements

The Blood Matters program is a collaboration between the Victorian Department of Health and Human Services (the department) and the Australian Red Cross Blood Service (the Blood Service). It is founded on the expectation that providing relevant haemovigilance information will promote better transfusion practice.

The Serious Transfusion Incident Reporting (STIR) program thanks the participating Victorian, Tasmanian, Australian Capital Territory and Northern Territory public and private health services for their contribution to the program. Blood Matters recognises and appreciates the generous in-kind support of the STIR expert group, whose input was invaluable in reviewing the incidents and providing recommendations.

Abbreviations, acronyms and definitions

ABO	ABO blood groups
AHTR	acute haemolytic transfusion reaction
anti-D	Rhesus D immunoglobulin
ACSQHC	Australian Commission on Safety and Quality in Health Care
ATR	acute transfusion reaction
Blood Service	Australian Red Cross Blood Service
DAT	direct antiglobulin test
DHTR	delayed haemolytic transfusion reaction
ED	emergency department
FBE	full blood examination
FFP	fresh frozen plasma
FNHTR	febrile non-haemolytic transfusion reaction
GP	general practitioner
Hb	haemoglobin
IBCT	incorrect blood component transfused
ICU	intensive care unit
LDH	lactate dehydrogenase
MCV	mean corpuscular volume
NBA	National Blood Authority
PICU	paediatric intensive care unit
PTP	post-transfusion purpura
Rh	rhesus blood group
SHOT	Serious Hazards of Transfusion
STIR	Serious Transfusion Incident Report program
ТАСО	transfusion-associated circulatory overload
TA-GVHD	Transfusion associated graft versus host disease
TRALI	transfusion-related acute lung injury
VMIA	Victorian Managed Insurance Authority
WBIT	wrong blood in tube

Executive summary

We are pleased to provide the STIR report for the financial year from 1 July 2015 to 30 June 2016. We gratefully acknowledge all those hospitals who have contributed to this valuable reporting system by submitting data to STIR, and those who have assisted in preparing this report.

We also express some concern regarding possible underreporting, noting that only 35 of the 93 health services registered with STIR reported events in this financial year. This is somewhat surprising, given the emphasis placed on a reporting process for transfusion reactions and incidents encouraged in the National and Quality Health Services (NSQHS) Standards developed by the Australian Commission on Safety and Quality in Healthcare (ACSQHC).

There is also ongoing concern regarding the number of procedural errors, which continue to be the majority of events reported to STIR. This is despite making the definition of wrong blood in tube (WBIT) more concise from 1 January 2015. WBIT reporting now only includes instances where the tube and request form is labelled with patient A details but contains the blood of patient B.

Errors in patient identification are a common factor in procedural events. In order to avoid these errors, hospitals should continue to focus on staff education and training, audit practice and explore new technology to improve safety. New technology can be explored in all aspects of transfusion practice, from the collection of blood samples to administration of blood. Many people would realise the extent to which technology in laboratories has improved the safety of blood provision.

This report also focuses on errors relating to RhD administration. STIR has collected these events since January 2015. In the last 12 months, there have been 14 errors reported. A serious adverse event occurred whereby misinterpretation of a result led to incorrect RhD administration and failure to recognise a foetus suffering from haemolysis. This case and other similar misinterpretations highlight the importance of access to RhD testing and education regarding correct interpretation of results prior to RhD administration.

In terms of clinical events, we highlight the report of 10 cases of transfusion-associated circulatory overload, two of which were severity rating 2. This transfusion reaction has been recognised as a leading cause of death from transfusion, and may be underreported to STIR. There are several approaches that greatly minimise the risk from this transfusion reaction, and we encourage health services to educate their medical staff regarding these risk reduction strategies.

Furthermore, a case study in this report demonstrates the risks of haemolytic transfusion reactions due to patients who move between hospitals without hospital blood banks knowing their transfusion history or presence of historical red-cell alloantibodies. This could easily be avoided with the establishment of a national database for red-cell alloantibodies, such as that used by New Zealand.

STIR also continues to support a coordinated, national haemovigilance program rather than separate systems in different states and territories. This would provide a more robust process for assessing transfusion safety in Australia, and many developed countries around the world have this type of program.

Key messages and recommendations

Clinical recommendations

Health services should have a process in place for investigating all reactions to blood and blood products. This should include appropriate testing, as required, such as tryptase and IgA levels in severe allergic reactions, chest X-ray in reactions associated with breathlessness, such as TACO or TRALI, and bacterial cultures in febrile reactions. De-identified results of testing should be made available with STIR investigation forms as appropriate.

Education of staff should include the pillars of patient blood management, including appropriateness of transfusion. Blood components should only be used where the benefit to the patient outweighs the risk.

Unless required to treat life-threatening bleeding, a slow infusion rate should be used for all blood products to minimise the risk of reactions such as TACO and allergic reactions.

Procedural recommendations

Correct patient identification should be completed at all steps of the transfusion process. Procedural errors demonstrate how poor patient identification contributes to these incidents. Correct patient identification includes the confirmation of full name, date of birth and hospital number, or an alternative recognised system for identifying patients where patient identity has not yet been established.

Staff involved in the prescription and/or administration of RhD immunoglobulin should be educated in order to understand test results and appropriate indications for use of RhD immunoglobulin.

Laboratory services need to have alerts within the laboratory information system to alert staff when an inappropriate blood product due to ABO or RhD incompatibility is being issued. This should be in place for both ABO and RhD discrepancies to avoid inappropriate crossing of blood groups. Non-essential alerts should be minimised.

Transfusion safety checklist

Health services can use this transfusion safety checklist to measure compliance and support safety for transfusion recipients. The issues and areas addressed in the checklist are based on data received and analysed, leading to the recommendations by the STIR expert group.

Issue	Strategies to address the issue	Yes	No	WIP*	NA
Patient identification	Staff must positively identify the patient at every step of the transfusion process e.g. collection of pretransfusion specimens, administration of blood products. This includes the requirement to have a request form with all patient identifiers to take to the bedside. WBITs regularly occur when staff label both the specimens and request away from the patient side after collection.				
Patient identification	Policies should include the need for staff to use full patient identification (full name/DOB/hospital number/address) as specified by the health service for all communications regarding the transfusion, both written and verbal.				
Patient identification	 The health service should provide a guideline/policy on the process of patient identification in the following situations: patient unable to participate in the process unknown patients patients where staff are unable to access the ID band and patient unable to participate, e.g. in theatre patients in isolation, where access is limited baby or child who requires a transfusion 				
Training/ credentialling staff in transfusion practice	 Regular staff education should include the following: patient identification collection of pretransfusion samples patient blood management and appropriate guidelines for the use of blood products recognition of potential transfusion reactions initial management and investigation of potential transfusion reactions 				
Training/ credentialling staff in transfusion practice	Staff involved in the prescription and/or administration of RhD immunoglobulin should receive education relating to the use, prescription and testing required, as well as how to interpret the results of any testing. The Blood Service publishes RhD Immunoglobulin Clinical Modules <https: enrol="" index.<br="" learn.transfusion.com.au="">php?id=247></https:>				
Training/ credentialling staff in transfusion practice	BloodSafe eLearning should be used in conjunction with health service-based education programs for transfusion practice. View information on the courses from BloodSafe eLearning Australia <https: www.bloodsafelearning.org.au=""></https:> The Blood Service also has tools for education of junior medical staff <https: jmo_education="" transfusion.com.au=""></https:>				

Issue	Strategies to address the issue	Yes	No	WIP*	NA
Laboratory standard operating procedures for blood bank	The laboratory information system should alert staff when an inappropriate blood product due to ABO or RhD incompatibility is being issued. This should be in place for both ABO and RhD discrepancies to avoid inappropriate crossing of blood groups. Non-essential alerts should be minimised.				
Laboratory standard operating procedures for blood bank	When taking orders for products or dispensing products, laboratory staff must request full patient identification (full name/DOB/hospital number/address) as specified by the health service, for each communication or request. Clinical staff, no matter the urgency, must use appropriate details for the request and confirm or correct errors when details are repeated back.				
Laboratory standard operating procedures for blood bank	Laboratories dispensing RhD immunoglobulin should consider a policy of the laboratory having results on site or communication, on letterhead, from an outside laboratory of the patient blood group and antibody status, before the product is dispensed.				
Blood product prescription	Health services should have processes in place to ensure appropriate communication to the laboratory of important information regarding patient specific requirements or previous reactions, if known.				
Blood product prescription	The prescription must be clear and unambiguous. Standardised terminology for blood components is not yet agreed nationally but prescribers should be encouraged to avoid acronyms that may be ambiguous or misleading. (ANZSBT, 2011) Consistency in dosing, in particular, is required and health services should consider standardising their prescribing to units, bags or doses.				
Governance	All adverse events involving blood should be reviewed by either the health service blood management committee or equivalent, or by the chair of the committee or a senior medical officer. Involvement of the hospital quality or governance team will assist with highlighting system deficits and assist with hospital-wide process changes, if required. Any serious transfusion events should be reported through to STIR, if appropriate.				
Governance	Protocols should include who is responsible for investigating reactions and incidents and following up, including reporting to STIR.				

Introduction

Blood Matters is pleased to present the annual Serious Transfusion Incident Report for 1 July 2015 to 30 June 2016 (FY16). The Blood Matters Serious Transfusion Incident Reporting (STIR) system is a voluntary reporting system for a defined set of serious adverse events relating to transfusion in Victoria, Tasmania, Australian Capital Territory and Northern Territory. There are 93 health services registered with STIR across the four jurisdictions, comprising both public (70 per cent) and private (30 per cent) health services. Thirty-five of these health services (39 per cent) submitted a total of 153 notifications, including incidents, reactions to blood components and near misses. The total number of investigations analysed following events withdrawn or excluded was 122 (referred to as validated investigations).

Validation occurs for all returned investigations, with each being reviewed by staff with experience or expertise in transfusion. All serious incidents/reactions (SR1 or SR2 events) or incidents where there is disagreement on the severity or type of reaction are also reviewed by the STIR Expert Group to ensure consistency in reporting.

Blood Matters and the STIR program support initiatives developed in haemovigilance, patient blood management and appropriate use of blood components and products through education, auditing and haemovigilance activities.

STIR aims to provide local information on the number and type of serious reactions that occur and to collate and report on these reactions with recommendations for improvements for better, safer transfusion practice.

The number of validated reports and health services reporting to STIR each financial year is outlined in Figure 1. Numbers of notifications continued to drop in this year, while the number of reporting health services has increased compared with the last report.

Definitions for all reporting categories are available on the Blood Matters website, Serious Transfusion Incident reporting guide 2017 https://www2.health.vic.gov.au/ hospitals-and-health-services/patient-care/speciality-diagnostics-therapeutics/bloodmatters/serious-transfusion-incidents>.

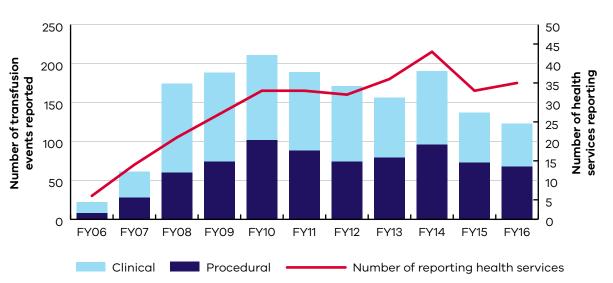
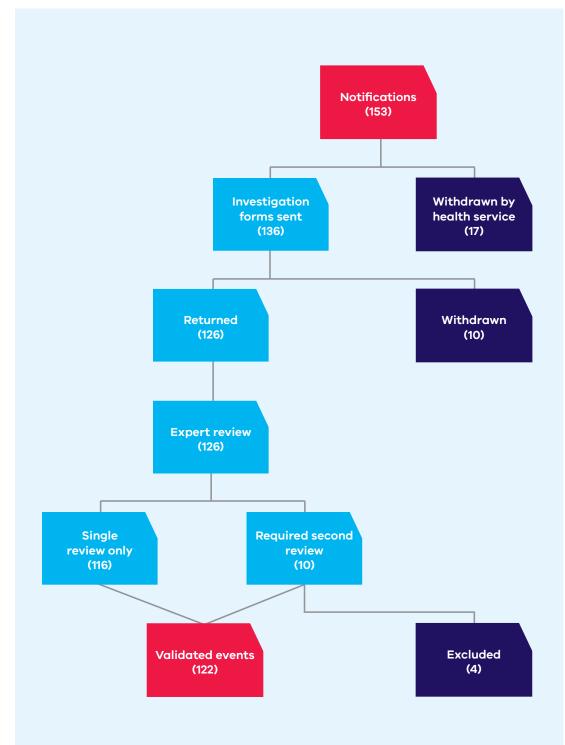


Figure 1: Number of validated clinical and procedural reports and health services reporting to STIR each financial year

Method

Figure 2 shows the steps in the STIR reporting process.

Figure 2: Steps in STIR reporting process



Data for 2015-16

The National Blood Authority (NBA) via BloodNet provides total blood issue data as shown in Table 1. Blood issues includes distributed units minus units lost due to wastage, damage or other reasons. Table 2 shows an estimate of the relative risk of transfusionrelated events via the frequency of events per product issued.

Products	Victoria	Tasmania	ACT	Northern Territory
Red cells	176,907	11,354	10,570	4,208
Platelets	34,231	2,262	1,625	822
Fresh frozen plasma	32,397	1,855	1,239	642
Cryoprecipitate	22,999	1,911	2,808	679

Table 1: Total of blood issues per jurisdiction 2015-16

Table 2: Frequency of clinical events per product issued in Victoria

Product	Blood issues (Victoria)	Validated clinical events*	Frequency
Red cells	176,907	37	1:4781
Platelets	34,231	13	1:2633
FFP	32,397	5	1:6479
Cryoprecipitate	22,999	_	_

*Victorian notifications only

As reported by Politis C et al. from the ISTARE haemovigilance database, based on data from 2006 to 2012, the incidence of all adverse reactions to blood was 77.5 per 100,000 components issued. STIR data may underrepresent the number of reactions to blood components, because STIR collects more serious errors and may miss reports of less severe reactions. For example, STIR has a higher temperature threshold for the reporting of febrile non-haemolytic transfusion reaction (FNHTR) than the NBA. Reporting to STIR is voluntary whereas reporting to ISTARE is mandated in some countries.

For the purposes of this report, STIR received 153 initial notifications, with 122 validated investigations being included. Initial notifications may not be included in the final report for a number of reasons, as defined in Table 3.

Eight included reports were reclassified after expert review, as shown in Table 4. Reactions reported as 'other' by the health service were most often changed by the reviewers. One was changed to acute haemolytic, and one to allergic, and two were changed to FNHTR. Other changes included two FNHTR being reclassified as other, and one acute haemolytic being changed to delayed haemolytic.

Table 3: Reasons for withdrawal of reports	Table 3: Reasons f	for withdrawal	of reports
--	--------------------	----------------	------------

Fiscal year	Duplicate	Not in scope	Deemed not transfusion related	Not completed	Expert review excluded	Total
2012–13	2	4	0	4		10
2013–14	1	6	4	16		27
2014–15	9	11	6	8	4	38
2015–16	6	11	5	5	4	31

Table 4: Incident type following expert review

		Ir	Incident type following expert review					
		Acute tro	ansfusion	reactions	(ATR)			
		Acute Haemolytic	Allergic	FNHTR	Delayed	Other	TRALI	TACO
	ATR							
Incident type at notification	Acute Haemolytic	1			1			
otifi	Allergic		17					
e at r	FNHTR			11		2		
type	Delayed		1		3			
dent	Other	1	1	2		5		
lnci	TRALI							
	ТАСО							10
	Total	2	19	13	4	7	0	10

Expert reviewers also assess the severity of the clinical reactions reported. In 16 events, expert reviewers increased the severity rating (SR) from that reported by the health service (Table 5).

The STIR expert group routinely reviews all SR1 and SR2 events to assess and validate these events. Any root cause analysis (RCA) reported to STIR, either directly or via the Department of Health and Human Services (the department), is reviewed by the expert group, which makes recommendations or comments. In FY16 there was one RCA that was determined to be unrelated to the transfusion (see the section on sentinel events). There were no SR1 events reported.

Appendix 3 provides definitions of severity ratings.

		Severity rating follo	owing expert review	Total
Severity rating at notification		SR2	SR3	
ATR	SR4	2	8	10
IBCT	SR4	1	2	3
TACO	SR4		3	3
Total		3	13	

Table 5: Changes to severity rating following expert review

Demographics

Table 6: Demographics for all validated reports

Incident type	Number (%)	Age average, (range)	Male	Female
Clinical reports				
FNHTR	13 (24)	75 (16–100)	10	3
Allergic	19 (35)	34 (1 month–79 years)	12	7
Acute haemolytic	2 (4)	82 (76–88)	1	1
ATR (other causes)	7 (13)	72 (41–85)	6	1
Bacterial sepsis	0 (0)	_	_	-
ТАСО	10 (18)	54 (1 month–82 years)	5	5
TRALI	0 (0)	_	_	-
Delayed haemolytic	4 (7)	72 (55–96)	0	4
TAGvHD	0 (0)	_	_	_
PTP	0 (0)	_	_	_
Clinical subtotal	55 (45)	57 (1 month-100)	34	21
Procedural reports				
IBCT	10 (15)	45 (1 day–77 years)	4	6
WBIT	32 (47)	43 (0–94)	12	20
RhD immunoglobulin	14 (21)	33 (19–42)	0	14
Cell salvage	0 (0)	_	-	_
Near miss	12 (18)	53 (2 weeks–92 years)	3	9
Procedural subtotal	68 (56)	43 (0–94)	19	49
Total*	*122	49 (0–94)	53	*69

*One report was validated as two incidents: IBCT and delayed haemolytic

The most common clinical events reported to STIR are allergic reactions (35 per cent) and FNHTR (24 per cent). The 2015 NBA haemovigilance report showed that the most frequent adverse events were FNHTR at 53.9 per cent and allergic reactions at 24.3 per cent of all reports for 2010–11 to 2013–14. The difference may be because different jurisdictions use different definitions, with STIR only accepting reports where the fever is greater than 38.5 degrees Celsius, or the rise in temperature is greater than 1.5 degrees Celsius.

The most commonly reported procedural event remains WBIT (47 per cent). Events related to RhD immunoglobulin represent 21 per cent of reported procedural events. In the 2014–15 STIR report, this was eight per cent for the six months of data included (RhD reporting commenced in January 2015).

As in previous years, more reports relate to procedural events than clinical reactions. Clinical reactions were more often reported in men than women (34 versus 21 reports), while procedural reports occurred more often in women than men (69 versus 53 reports). This may be in part due to the reporting of RhD immunoglobulin and also WBIT, where a third of reports relate to the maternity/obstetric area.

	Blood product type					
Incident type	Red cells	Platelets	FFP	Cryoprecipitate	Multiple products	Other
Clinical reports						
FNHTR	12	1				
Allergic	4	11	4			
Acute haemolytic	2					
ATR – other causes	6	1				
Bacterial						
ТАСО	8				2	
TRALI						
Delayed haemolytic	4					
TAGvHD						
PTP						
Clinical subtotal	36	13	4	0	2	0
Procedural reports						
IBCT	8	1	1			
WBIT						32
RhD immunoglobulin						14
Cell salvage						
Near miss	10				1	1
Procedural subtotal	18	1	1	0	1	47
Total	54	14	5	0	3	47

Table 7: Blood product implicated by validated incident type

As outlined in Table 7, notifications continue to most commonly be associated with the use of red cells, both in clinical and procedural events. One exception is allergic reactions which are most often associated with platelets, as seen in previous reports.

FNHTR remain most commonly associated with red cells, however universal leucodepletion of red cells should reduce the risk. There was only one report in this period where platelets, which express human leucocyte antigens (HLA) class 1, were associated with FNHTR. TACO is most often associated with red cell transfusions, but also a small number of events in which the patient received multiple products.

Health service review of reported incidents continues to occur in almost all reported incidents, often with more than one type of review. This has improved over time as reporting mechanisms within health services improve.

Outcomes

Table 8 shows patient outcome post transfusion, as reported by health services.

Patient outcome*	ATR (n = 41)	Delayed (n = 4)	TACO (n = 10)	IBCT (n = 10)
No increase in care (apart from the transfusion incident investigations)	14	_	2	8
Temporary increase in care	20	4	5	1
Permanent increase in care	_	_	_	_
Increase length of stay	3	_	1	_
ICU admission due to transfusion reaction	1	_	-	_
Haemodialysis/haemofiltration	_	_	_	_
Death due to transfusion reaction	_	_	_	_
Death not due to transfusion reaction	5	_	3	_
Outcome not recorded	2	_	_	_
Not yet discharged	7	1	_	1

Table 8: Outcome for the patient this admission, post transfusion (multiple answers may be given)

*For all reports except near miss, RhD immunoglobulin, TA-GVHD and WBIT events.

There have been no reports of deaths attributed to transfusion in the investigations received by STIR. This is similar to the NBA 2013–14 data which reported no deaths, but 4.5 per cent of events resulting in a life-threatening outcome. In the Serious Hazards of Transfusion (SHOT) report from the UK for 2016, there were 26 deaths reported as related to the transfusion, with three certain and eight probably related. The three certain deaths related to TACO in one instance and delayed transfusion in the other two.

Severity rating

No SR1 events were reported for FY16. The severity ratings and number of clinical events is shown in Figure 3.

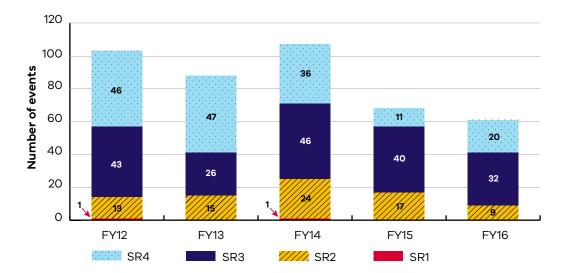


Figure 3: Severity ratings - clinical events and IBCT only

Severity ratings are not assigned to procedural events other than IBCT. In near miss and WBIT events the error is found due to luck, serendipity or good processes, and a negative outcome for the patient is averted.

Since 2016, the STIR expert group has reviewed all SR1 and SR2 events before final validation.

Clinical reports

Figures 4 and 5 outline the clinical reports received and comparisons to previous years.

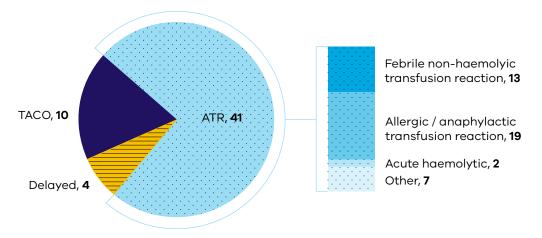


Figure 4: Clinical reactions reported FY16

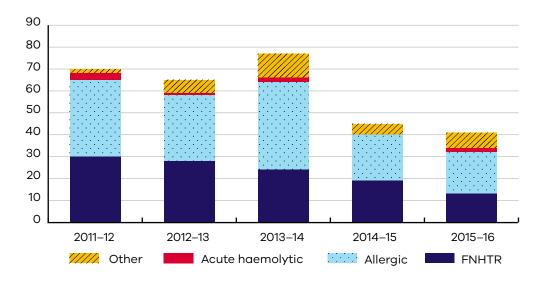


Figure 5: Comparison of ATR validated reports to previous years

In Figure 5, 'other' refers to reports where a transfusion reaction cannot be excluded, but information is not available to make a definitive diagnosis.

For reports submitted between July 2011 to June 2016, 385 investigation forms (acute reaction, delayed reaction and TRALI/TACO) have responded to the question 'Did the reason for transfusion meet hospital guidelines?' Of these 14 (4 per cent) were reported as not meeting hospital guidelines (Figure 6).

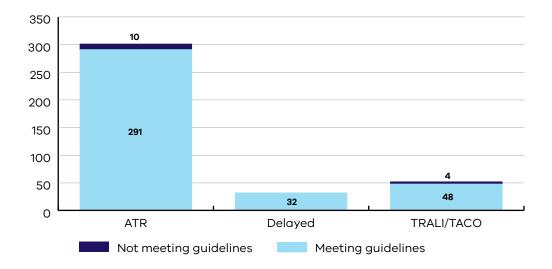


Figure 6: Did the reason for transfusion meet hospital guidelines FY12-FY16?

Of note, there were more reports of fresh frozen plasma (FFP) (7 of 41, 17 per cent) not meeting hospital guidelines for ATRs, and more reports of red cells (4 of 36, 11 per cent) not meeting guidelines for TRALI/TACO.

Determining transfusion appropriateness can be complex, and is beyond the scope of the expert reviewers' examination of investigation forms. Therefore, there may be a number of inappropriate transfusions that are reported as meeting hospital guidelines (see allergic reactions case study).

Febrile non-haemolytic transfusion reaction (FNHTR)

Data summary – validated data Febrile non-haemolytic transfusion reaction, n=13				
Gender		Time of transfusion		
Male	10	In hours (8am-8pm)	8	
Female	3	Out of hours (8pm-8am)	5	
Age		Imputability		
<1 year:	_	Certainly:	_	
1–18 years:	1	Probably:	_	
19–29 years:	_	Possibly:	13	
30–49 years:	_	Excluded:	_	
50–69 years:	_	Not assessable:	_	
70–79 years:	6	Severity		
80+ years:	6	SR1: unexpected death or a		
Blood product implicated		permanent and disabling injury		
Red cells:	12	SR2: temporary loss of function		
Platelets:	1	SR3: increased treatment,	5	
FFP:	_	but no increased length of stay		
Cryoprecipitate:	_	SR4: no injury or minor requiring	7	
Multiple products	_	only first aid treatment		
		Not assessable:	1	

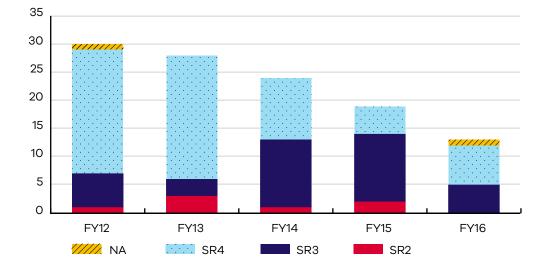


Figure 7: Number of febrile non-haemolytic transfusion reactions per fiscal year

Figure 7 shows the following trends:

- The number of investigations is declining over time. This may be due to greater adherence to STIR definitions.
- More males than females are reported as experiencing FNHTR.
- This year there were no SR2 events reported.
- All reports from this year are attributed as possibly FNHTR related to the transfusion.

Allergic/anaphylactic reactions

Data summary – validated data Allergy, n=19	1		
Gender		Time of transfusion	
Male:	12	In hours:	16
Female:	7	Out of hours:	3
Age		Imputability	
<1 year:	2	Certainly:	3
1–18 years:	7	Probably:	11
19–29 years:	2	Possibly:	5
30–49 years:	1	Excluded:	_
50–69 years:	4	Not assessable:	-
70–79 years:	3	Severity	
80+ years:	_	SR1: unexpected death	
Blood product implicated		or a permanent and disabling injury:	-
Red cells:	4	SR2: temporary loss of function:	5
Platelets:	11	SR3: increased treatment, but	12
FFP:	4	no increased length of stay:	
Cryoprecipitate:	-	SR4: no injury or minor requiring	1
Multiple products/other:	_	only first aid treatment:	
		Not assessable:	1

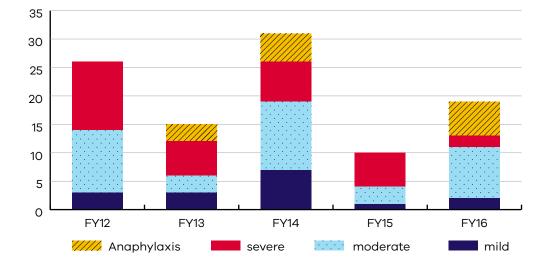


Figure 8: Number of allergic/anaphylactic reactions reported per year

Figure 8 shows the following trends:

- The number of allergic reactions is higher than last year, with an average of 20 reports per year.
- This year there were more anaphylactic-type reactions reported than previous years. Mild reactions are a small percentage of reported reactions.
- Seventy-four per cent of reactions were deemed probably or certainly related to the transfusion. The rest were all possibly related. The information for these reactions may have been unclear on what other medications or treatments may have caused the reaction.
- Platelets are the most commonly implicated product in allergic reactions. This is similar to data from the ISTARE haemovigilance database (Politis C et al. 2016) where the most frequently implicated products were apheresis and whole-blood derived platelets and granulocytes.

Case study 1: Allergic

A 51-year-old woman with infective endocarditis and a history of aortic valve replacement was in the operating theatre for cardiac surgery. During the procedure, the patient was administered a unit of red cells. She developed tachycardia, bronchospasm, facial redness and angioedema. The patient was intubated and ventilated for the surgery and required administration of intravenous esmolol and adrenaline. At the time of the reaction, she had received propofol, and bioglue had been used.

Investigations included an IgA level (performed on a pretransfusion sample), which was 1.8 g/L (ref range for adult 0.7-3 g/L). A tryptase was taken two hours post the event with a level of 41.1 reported (reference range is < 11.4 ng/mL).

Comment

Two of the most-recognised mediators of allergic and anaphylactic reactions are tryptase and histamine. Elevations in these can sometimes be detected in the blood of patients who show symptoms of an allergic reaction.

IgA deficiency can also be associated with anaphylactic transfusion reactions if the patient has developed anti-IgA antibodies, although this is relatively rare.

The measurement of serum tryptase after allergic reactions remains under-used, even after life-threatening episodes of anaphylaxis. (NICE, 2014) Since 2011, there have been 18 confirmed anaphylactic reactions reported to STIR. Of these, eight (44 per cent) had a tryptase level reported as taken and five (28 per cent) an IgA level.

The rise in tryptase levels starts to be detected in serum within minutes of anaphylaxis, but the level will gradually revert to normal over the next six to 24 hours depending on the height of the increase, and often correlates with the severity of the anaphylaxis (NICE 2014).

Case study 2: Allergic

A 64-year-old woman with a history of alcohol-related liver cirrhosis was admitted with decompensated liver disease. The patient required a diagnostic ascetic tap, and prior to the procedure was administered a bag of FFP for an INR of 1.5.

Thirty minutes into the transfusion, the patient became dyspnoeic and hypoxic, resulting in a MET call. There was no evidence of wheeze or angioedema, but the patient did develop an urticarial rash. She was administered antihistamine, steroids and oxygen. A chest X-ray, taken at the time, was clear. The patient had a temporary increase in care, but no long-term problems described.

Comment

It is unclear if international normalised ratio (INR) reflects the true risk of bleeding in patients with liver disease (Rai et al. 2012; Northlip and Caldwell 2013). An elevated INR or thrombocytopenia is not a contraindication to paracentesis, and in most patients there is no need to transfuse fresh frozen plasma or platelets prior to the procedure (Moore KP and Aithal GP 2006).

The actual risk of bleeding following paracentesis is very low (Moore KP and Aithal GP 2006; McVay and Toy 1991). There is little evidence of theoretical, laboratory or clinical benefit to prophylactic FFP prior to procedures to correct a mildly elevated INR in this group (Northlip and Caldwell 2013).

The administration of FFP can also be associated with a number of risks such as allergic reactions, TACO and TRALI.

Acute haemolytic reaction

Data summary – validated data Acute haemolytic, n=2			
Gender		Time of transfusion	
Male:	1	In hours:	1
Female:	1	Out of hours:	1
Age		Imputability	
<1 year:	_	Certainly:	1
1–18 years:	_	Probably:	1
19–29 years:	_	Possibly:	_
30–49 years:	_	Excluded:	_
50–69 years:	_	Not assessable:	_
70–79 years:	1	Severity	
80+ years:	1	SR1: unexpected death or a	_
Blood product implicated		permanent and disabling injury:	
Red cells:	2	SR2: temporary loss of function:	_
Platelets:	_	SR3: increased treatment, but	2
FFP:	_	no increased length of stay:	
Cryoprecipitate:	_	SR4: no injury or minor requiring	_
Multiple products/other:	_	only first aid treatment:	
		Not assessable:	_

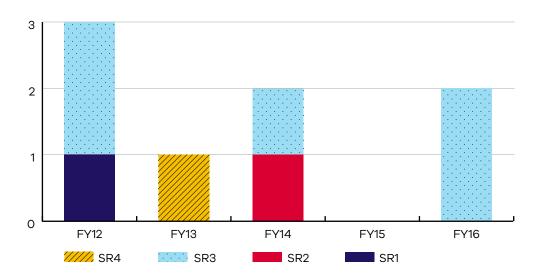


Figure 9: Number of acute haemolytic reactions reported per year

Figure 9 shows the following trends:

- Numbers of reported acute haemolytic reactions remain small.
- When reported, the severity of the reaction is often higher, usually at least SR3. There have been no further SR1 events reported since FY12.
- Neither report in FY16 related to ABO-incompatible transfusions.

Case study: Acute haemolytic

A 76-year-old man was admitted with anaemia (Hb 59g/L) likely due to gastrointestinal bleed. He had a rising troponin and the clinical decision was made to transfuse the patient. However, the patient had a record of anti-e and anti-C antibodies.

The laboratory had no antigen-negative red cells available at the time, and the clinical staff, in consultation with a haematologist, made the decision to go ahead and transfuse antigen-e positive units.

Clinical staff were aware that although the units were ABO and RhD compatible, they were still incompatible for this patient. They monitored the patient closely throughout the transfusion. The patient did develop signs of a reaction two hours into the transfusion, with fever, rigors, hypertension, tachycardia and haemoglobinuria, requiring a temporary increase in care.

Comment

In this case the transfusion was known to be incompatible for the patient, but it was undertaken with forethought, taking into consideration the patient's condition and the risks associated with waiting for compatible units to be available.

The clinical staff consulted with the haematologist appropriately prior to the transfusion and monitored the patient closely during the transfusion. This allowed prompt treatment of the reaction that occurred, thus minimising the known risk.

Transfusion transmitted infection, including bacterial sepsis

There were no reports of bacterial sepsis associated with transfusion in this reporting period.

In the 2013–14 NBA report, there were 27 reports of transfusion-transmitted infection, with 12 of these excluded, unlikely or not assessable. Only six cases were confirmed bacterial (five to platelets, one to red cells).

The Blood Service has commenced reconciling reports of serious adverse events received with jurisdictional haemovigilance programs. Three reports of suspected bacterial sepsis were initially received from health services within the STIR jurisdiction, and all were consequently excluded following the validation process by either the health service or reviewer. In FY16, there were no reports of bacterial sepsis confirmed by the Blood Service in jurisdictions reporting to STIR.

Transfusion-associated circulatory overload (TACO)

Data summary – validated data Transfusion-associated circulatory overload, n=10				
Gender		Time of transfusion		
Male	5	In hours	7	
Female	5	Out of hours	3	
Age		Imputability		
<1 year:	1	Certainly:	1	
1–18 years:	_	Probably:	3	
19–29 years:	_	Possibly:	6	
30–49 years:	3	Excluded:	-	
50–69 years:	3	Not assessable:	_	
70–79 years:	2	Severity		
80+ years:	1	SR1: unexpected death or a		
Blood product implicated		permanent and disabling injury		
Red cells:	8	SR2: temporary loss of function	2	
Platelets:	_	SR3: increased treatment, but	7	
FFP:	_	no increased length of stay		
Cryoprecipitate:	_	SR4: no injury or minor requiring	1	
Multiple products	2	only first aid treatment		
		Not assessable:		

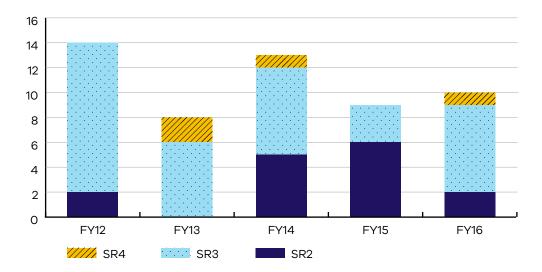


Figure 10: Number of transfusion related circulatory overload reported per year

Figure 10 shows the following trends:

- There are relatively small numbers of TACO reports, which possibly reflects underreporting of this type of reaction.
- Although there have been no deaths directly attributable to TACO, a small number of events have been assigned a severity rating of SR2, where the patient has experienced a temporary loss of function. The majority of events continue to be either SR2 or SR3, indicating more severe reactions are being reported.
- Most often, TACO is reported in relation to red-cell transfusion.
- Currently, information about the volume of other intravenous fluids administered to patients in the previous 24 hours is not available. With changes to investigation forms starting 1 July 2017, more information on which to validate TACO reports will become available.

Preventive measures

With improved practice and monitoring, it is believed TACO events can be avoided. Risk factors for TACO should be considered when balancing risk versus benefit of a transfusion.

Risk factors include:

- age greater than 70 years
- concomitant medical conditions cardiac failure, renal impairment, fluid overload, hypoalbuminaemia
- low body weight
- too-rapid transfusion rate.

In the most recent SHOT report (based on 2015 data), there were seven deaths reported where TACO was considered a contributory factor. There have been no deaths reported to STIR that can be directly attributed to TACO to date.

TACO is recognised as one of the leading causes of death in overseas haemovigilance reports. In the *Australian haemovigilance report 2015*, covering data from 2013–2014, there were 28 reports of TACO and no deaths recorded.

It is often difficult to attribute a patient's symptoms to TACO if they have had other fluids infused, or have other clinical conditions that make them prone to fluid overload.

STIR has designed an information swing tag and poster, based on the SHOT checklist. These will be given to health service laboratories, with instructions to attach the swing tag to all units issued to patients for a one-month period. The campaign is designed to highlight the risk factors for development of TACO, the preventive measures, and monitoring for signs and symptoms.

The use of single-unit transfusion in patients who are haemodynamically stable and not bleeding is recommended as one way to reduce the risk of TACO. Review of patients after a unit of red cells should include assessment of the need for further units, and fluid assessment, particularly in people at increased risk.

Transfusion related acute lung injury (TRALI)

The Blood Service has commenced reconciling reports of serious adverse events received with jurisdictional haemovigilance programs.

In FY16, there were no reports of TRALI to STIR, and there were no reports of TRALI confirmed by the Blood Service in STIR jurisdictions. Two events are still under review at time of publication, one of these occurred at a STIR reporting health service.

Delayed haemolytic reactions

Data summary – validated data Delayed haemolytic, n=4				
Gender		Imputability		
Male	_	Certainly:	3	
Female	4	Probably:	1	
Age		Possibly:	-	
<1 year:	_	Excluded:	-	
1–18 years:	_	Not assessable:	-	
19–29 years:	_	Severity		
30–49 years:	_	SR1: unexpected death or a	_	
50–69 years:	2	permanent and disabling injury		
70–79 years:	1	SR2: temporary loss of function	1	
80+ years:	1	SR3: increased treatment, but	3	
Blood product implicated		no increased length of stay		
Red cells:	4	SR4: no injury or minor requiring	-	
Platelets:		only first aid treatment		
FFP:		Not assessable:	-	
Cryoprecipitate:				

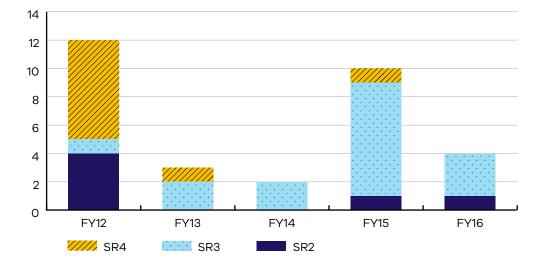


Figure 11: Number of delayed haemolytic transfusion reactions reported per year

Figure 11 shows the following trends:

- Numbers reported remain small, but severity of reactions is high. This is probably due to STIR reporting requirements.
- Currently, STIR does not accept reports of delayed serologic reactions. This occurs when the patient has developed a new red cell alloantibody, but does not demonstrate signs of anaemia or haemolysis. However, from 1 July 2017 delayed serologic reactions will be included in STIR reporting.
- All reports received were deemed certainly or probably related to the transfusion.

Case study 1: Delayed haemolytic

A 72-year-old woman was admitted via emergency with an acute on chronic subdural haemorrhage requiring surgical evacuation.

The patient had blood tests, including a group and screen, prior to surgery. At this time, her blood group was O positive, with a negative antibody screen.

Post-surgery the patient required transfusion for symptomatic anaemia, Hb 71 g/L. An electronic cross-match was performed and the patient was administered two units of red cells and a bag of pooled platelets for low platelet count.

Post transfusion the patient demonstrated an appropriate Hb increment. However, over the next week the patient demonstrated worsening anaemia (Hb 60–70 g/L) without signs of bleeding. Investigation showed a positive haemolysis screen with a new panreacting antibody screen. Enquires to the Blood Service confirmed the patient had a historical record of anti-Jk3, found when she attended a different health service.

Anti-Jk3 may cause severe haemolysis after transfusion, but is only implicated in mild cases of haemolytic disease of the newborn (HDN) (Dean L 2005). Only about one per cent of donor units will lack the corresponding antigen, so liaison with the Blood Service to find appropriate units is necessary.

Investigation by the transfusion team found that the patient, who did not speak English, and her daughter had told medical staff at the time of admission that the mother had a known red cell alloantibody and that it could be difficult to find blood for her. This information was not documented in the medical record or passed on to the pathology service.

Since the medical officer who requested and prescribed blood for the patient had not assessed her transfusion history, and there was no historical record at the health service of this red cell alloantibody, a blood product that did not meet the patient's specific requirements was dispensed and administered to her, resulting in a delayed haemolytic reaction.

...continued next page

Comment

Establishing a national red cell alloantibody database would make available accurate records of patients' red cell alloantibodies.

This would assist patients who move from one health service to another and have testing and provision of blood from different laboratory services.

Communicating important clinical information between staff in a health service can be challenging, and there is no guarantee that information gained from patients and their carers will be documented and shared with the appropriate staff to follow up.

It is not reasonable to expect that patients will know or provide documentation relating to their red cell antibody status, especially in situations of stress or when they are unable to participate in their care.

STIR strongly supports the establishment of a national red cell alloantibody database.

Transfusion associated graft versus host disease (TA-GVHD)

No events reported.

Post-transfusion purpura (PTP)

No events reported since 2011.

The NBA 2013–14 haemovigilance data reported six PTP events, of which one was excluded, and none where confirmed (three possible, two probable).

Procedural reports

Figure 12 shows the procedural events reported to STIR.

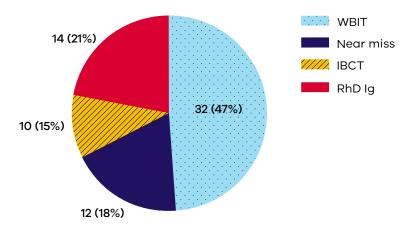


Figure 12: Procedural events FY16

Incorrect blood component transfused (IBCT)

Data summary – validated data Incorrect blood component transfusion, n = 10			
Gender		Time of transfusion	
Male	4	In hours	6
Female	6	Out of hours	4
Age		Imputability	
<1 year:	2	Certainly:	8
1–18 years:	_	Probably:	1
19–29 years:	_	Possibly:	1
30–49 years:	2	Excluded:	
50–69 years:	4	Not assessable:	
70–79 years:	2	Severity	
80+ years:	_	SR1: unexpected death or a	-
Blood product implicated		permanent and disabling injury	4 8 1
Red cells:	8	SR2: temporary loss of function	2
Platelets:	1	SR3: increased treatment, but	2
FFP:	1	no increased length of stay	
Cryoprecipitate:	_	SR4: no injury or minor requiring only first aid treatment	6
		Not assessable:	_

Table 9: Types of IBCT events: FY16

Category	Number reported
Antigen-antibody issues	3
Components that did not meet specific requirements for patient	2
Inappropriate platelet/plasma product	2
Inappropriate red cell product	_
Incorrect blood component to incorrect patient	
ABO compatible	3
ABO incompatible	_

Figure 13: Number of incorrect blood component transfused reports per fiscal year

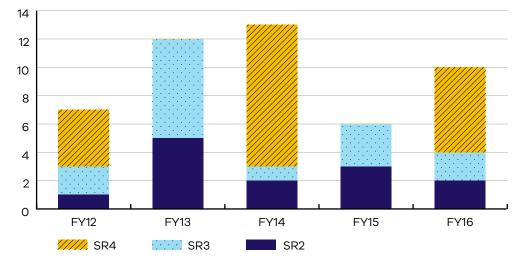


Figure 13 shows the following trends:

- Incorrect blood component transfused continues to be reported regularly.
- Over time the numbers and types of events have remained relatively constant.
- ABO incompatible transfusions continue to occur periodically, although there were none reported in FY16.
- Many of the reports received have a low severity rating as they do not cause harm to the patient, but these events indicate faulty systems or communications that allow the wrong product to reach the patient.
- Most often the product involved in these events is red cells, where if an ABO incompatible product were to be administered there could be fatal consequences.

Case study 1: IBCT – Antigen or antibody issue

A 30-year-old woman was ordered a single unit of red cells for Hb 87. The patient blood group was AB RhD negative. The laboratory issued a unit of red cells that was A RhD positive.

The unit was administered to the patient and the error was not found until two days later after further blood group testing.

The health service noted that as part of a wastage review, AB red cells had recently been removed from the inventory. As a result, the laboratory had noted an increase in alerts when patients who are group AB have group A red cell units cross-matched to them.

They felt this led to a degree of complacency among staff when the alerts appeared, and such alerts were overridden without reading them, hence the discrepancy in RhD group was not noted.

Further steps in the laboratory processes did not assist the staff in recognising the discrepancy. When the blood was sent to the ward for administration the addition of a comment to the compatibility report that the unit was deemed compatible meant the nursing staff did not question the discrepancy in RhD group.

As a result of this incident, the health service made changes to reduce unnecessary alerts, and make staff respond to the more important alerts, including consultation with senior scientist or haematologist when crossing groups in women of childbearing age.

The compatibility report has also been changed to acknowledge where units are different to both ABO and/or RhD groups. Education of staff is ongoing and more information on blood group compatibility is being added.

Case study 2: IBCT – Correct component to incorrect patient (ABO compatible):

A 77-year-old man in the operating room post trans-catheter aortic valve implantation, with retroperitoneal haematoma, and bleeding from groin puncture had a Code Blue called.

A unit of platelets was requested urgently for the patient. The prescription was completed and labelled with labels found on the bench in the theatre. The same labels were used on the collection slip (used to identify patient and product to collect from the laboratory). The blood bank dispensed platelets matching the patient information provided.

In theatre, the staff performing the bedside checks were unable to access the patient ID band, due to positioning and checked against the prescription only. The labels used were from the previous patient who had been in the operating room. There was no harm to the patient in this instance as the product was compatible.

Comment

Laboratory staff can only provide product on the identifiers given to them. When there is an error in patient identification on the ward, they are unable to identify this if identification is consistent.

Staff in areas such as the operating room need to have a method of accurately identifying patients, particularly when they are unable to access patient ID bands. The use of medical records, sheets of labels or other documentation not directly attached to the patient are risky alternatives.

One suggestion is to check the details of an addressograph label against the patient ID band when the patient arrives, and then attach this to the patient's forehead, upper chest or shoulder where it can be accessed, is out of the surgical field and not covered by sterile drapes.

This can then be used to check patient ID while the patient is unconscious, and ID bands are out of reach. In the future, use of barcode technology or RFID to assist in patient identification is likely to improve patient safety.

Wrong blood in tube (WBIT)

Data summary – validated data Wrong blood in tube, n = 32			
Gender		Sample collected	
Male	12	In hours	22
Female	20	Out of hours	10
Age		Urgency of transfusion	
<1 year:	3	Emergency	3
1–18 years:	1	Routine	23
19–29 years:	8	Unknown	6
30–49 years:	8	Location	
50–69 years:	5	Theatre	1
70–79 years:	2	Ward	11
80+ years:	5	ICU	-
		Ambulatory care	2
		Emergency department	6
		Maternity/delivery suite	11
		Home transfusion	0
		Other (external hospital prior to transfer)	1

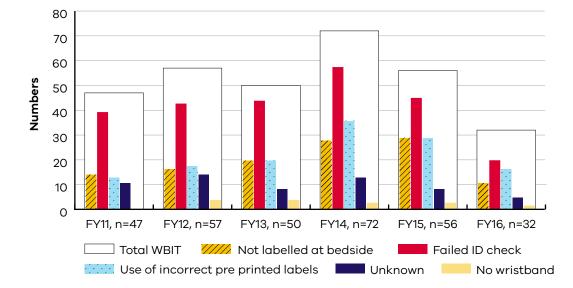


Figure 14: Factors contributing to WBIT incidents (multiple responses per incident)

Note: More than one response may be selected per incident

Failure of the patient identity check (Figure 14) is still reported as the most common contributing factor to WBIT incidents, followed by use of incorrect preprinted patient labels.

ANZSBT guidelines for transfusion and immunohaematology laboratory practice (2016) state: Handwritten labelling of specimens is strongly recommended in the absence of a full electronic system that securely identifies the patient and prints labels on demand at the bedside. Preprinted addressograph (or similar) labels are not recommended but may be accepted at the discretion of the laboratory director.

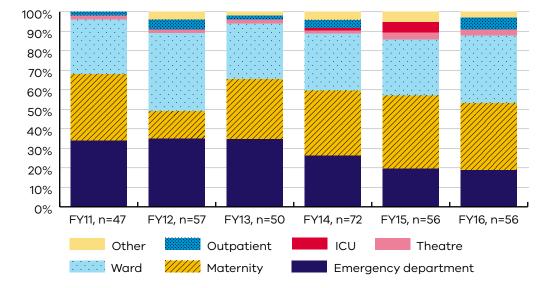


Figure 15: Where WBIT errors occur

Maternity services continue to contribute the greatest proportion of WBIT events, while events in the emergency department appear to be reducing (Figure 15). Educating maternity staff on correct patient identification and labelling is likely to help health services to reduce these numbers.

Table 10 shows how the incident was discovered.

Category	Number	Percentage (%)
Recognised prior to testing	11	34%
Discrepancy noted when comparing sample results	12	38%
Recognised post testing but prior to issue	5	16%
Significant change in MCV compared with prior	3	9%
Recognised post issue but prior to transfusion	0	0%
Other	4	13%
Total incidents	32	

Table 10: How the incident was discovered: FY16

Note: More than one response may be selected per incident

Case study: WBIT – collecting blood specimens from a patient in ICU

The nurse was given a request form without full patient identifiers attached. The nurse collected the bloods, without any verbal identification of the patient's identity or verifying the identity on the patient's name band.

When the nurse went to label the specimens, s/he approached the doctor who had a patient medical record in hand. The nurse assumed the record belonged to the patient from whom the specimens were taken and labelled both the request form and specimens with labels from this record before sending them to the laboratory.

Approximately 10 minutes later the nurse realised a mistake may have been made and checked the labels used, which actually belonged to the patient in the next cubicle. At this point appropriate steps were taken to notify the laboratory and treating team.

Comment

Fortunately, in this instance the error was recognised prior to any results being available or acted upon. Approximately 34 per cent of WBIT incidents are recognised prior to testing occurring, which indicates clinical staff are recognising their error after they have sent the specimen to the lab.

Even in areas where staff are caring for one patient at a time, it is still important to complete all patient identity checks prior to the collection of specimens. If the patient is conscious and alert, they are an integral part of the checking procedure and must be asked to state their name and date of birth, with this checked against the identification band.

RhD administration

Data summary – validated data RhD immunoglobulin, n=14			
Gender		Intended administration*	
Male	_	Antenatal prophylaxis	6
Female	14	Sensitising event	3
Age		Post-natal	6
<1 year:	_	Type of incident	
1–18 years:	_	Administered, not required (Rh negative mother with Rh negative baby)	2
19–29 years:	5	Administered, not required (Rh positive woman)	2
30–49 years:	9	Administered, not required (woman with immune Anti-D)	1
50–69 years:	_	RhD dose omitted	2
70–79 years:	_	Delay in administration (>72 hrs.)	
80+ years:	_	Wrong or inadequate dose	
Location		Storage and handling error (near miss)	
Hospital	14	Other: released or administered to incorrect patient, reaction	7
Community	_		
General Practitioner	_		
Other	_		

*One investigation form reported inappropriate prophylaxis and post-natal administration.

Trends include the following

- Numbers of reports remain relatively small and the types of events reported are similar to the last fiscal year.
- Many reports in the "other" category relate to issues of patient identification i.e. product is requested for one patient, but then administered to a different patient. In each of these instances the patient who received the product actually required product and it appears no patient missed receiving a required dose. However, in order to track product in the event of a recall, documentation needs to be accurate.
- There have been no reports of a woman developing an anti-D through omission of doses but, not all reports include this information. Omission of doses most often appears to be recognised by the health service at the time of delivery when antenatal prophylaxis has been missed.

Case study 1: Postnatal RhD immunoglobulin to a woman with a RhD negative infant

A 42-year-old woman who is RhD negative and delivered a RhD negative infant was discharged correctly from the health service without a dose of RhD immunoglobulin.

However, she was subsequently administered a dose of RhD immunoglobulin (Ig) postnatally. The patient had been discharged and was being attended by a midwife in her home. The midwife noted there was a positive fetomaternal haemorrhage (FMH) test and misinterpreted the comment in the report to indicate that RhD Ig was required.

The patient was asked to re-present to the hospital emergency department (ED). In the ED the patient was prescribed and administered a dose of RhD Ig, without further checking of pathology results.

The health service is working to clarify the coded comments for FMH testing to try and minimise misinterpretation.

Case study 2: Anti D administered to a woman with immune anti-D

A woman in her third pregnancy was being cared for under a shared-care arrangement. Blood tests were undertaken at an outside laboratory. The outside laboratory failed to contact the health service to report the result as they were using an incorrect fax number. Furthermore, without consultation with the medical officer, no titre was performed.

A hard copy of the results was sent, addressed to the chief medical officer at the health service. At the woman's 28-week visit to the health service, the midwife requested a copy of the results from the laboratory, but it is unclear whether she saw the results. At this time the woman was administered RhD Ig.

At the woman's 34-week visit, the results were viewed by a midwife and medical officer, however they misinterpreted the result to be due to passive anti-D. A second dose of RhD Ig was given.

Prior to elective caesarian section, a strong anti-D was found (titre of 2,048) and was reported. The woman was contacted and asked to return to the health service. Cardiotocography (CTG) was performed, and found a sinusoidal trace (known to be associated with severe fetal anaemia).

An emergency caesarian section was performed and at birth meconium liquor was noted. The infant made an initial gasp and required some initial intermittent positive pressure ventilation with a heart rate < 100.

The infant was transferred to NICU on 60 per cent oxygen and CPAP; he was later intubated and ventilated. Testing showed he had an initial Hb 70 g/L and bilirubin of 161, requiring a double volume red cell exchange. Despite these circumstances and the elevated RhD titre, the woman was given a postnatal dose of RhD Ig.

As a result of this incident the health service has revised their RhD Immunoglobulin procedure, which now requires all women who are Rh negative to have a group and antibody screen performed by the onsite laboratory.

This ensures consistent methods of reporting 'notifiable' anti-D results to the correct clinician. The health service procedure stipulates how this reporting should take place, but external labs are not privy to these methods and may report results differently. Labs may need instruction from clinical staff before performing further testing, such as titres, on a positive result.

The red cell antibody testing procedure has also been revised to reflect this change and clinical staff are undergoing extra training.

Near miss

Data summary – validated data Near miss, n=12			
Gender		Time of incident	
Male	3	In hours	11
Female	9	Out of hours	1
Age		Urgency of transfusion	
<1 year:	1	Emergency	4
1–18 years:	1	Routine	8
19–29 years:	1	Unknown	
30–49 years:	2	Location	
50–69 years:	3	Theatre	3
70–79 years:	2	Ward	4
80+ years:	2	ICU	1
Blood product implicated		Ambulatory care	
Red cells:	11	Emergency department	
Platelets:		Maternity/delivery suite	1
FFP:		Home transfusion	
Cryoprecipitate:	1	Other (pathology)	3

The types of near miss events reported are noted in Table 11.

Table 11: Types of near miss events

Category	Number reported
Inappropriate component issued	2
Labelling/documentation	4
Laboratory	2
Administration	2
Incorrect prescription or request for blood	2
Storage and handling	_

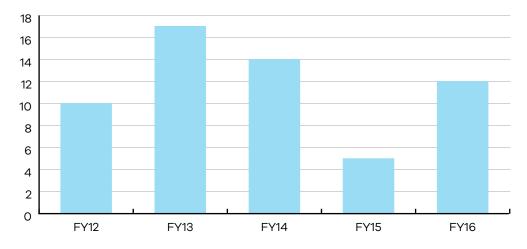


Figure 16: Number of near miss reports per year

Figure 16 shows the following trends:

- There has been an increase in the reported near-miss events this year compared with last year.
- A number of reports seem to relate to communication issues between clinical staff and the laboratory (see case studies).
- Most reports related to the use of red cells, as in previous years.

Case study 1: Near miss

An urgent cross-match request was received via telephone for a patient in theatre.

The scientist taking the call either misheard or incorrectly recorded the patient details.

Units were then cross-matched and sent to the operating room, but for a different patient with a similar name.

The error was detected when completing the pre-transfusion checks.

Case study 2: Near miss

Ward nurse (RN) contacted the pathology service to request red cell units be prepared for transport with a patient being transferred by ambulance to another hospital.

The RN only provided the patient's surname, which the scientist misheard. When the scientist repeated the incorrect surname back to the nurse, the error was not corrected.

There were two patients in the same ward with similar names; both had valid cross-matched red cells available. Red cells, cross-matched for the incorrect patient (as heard by the scientist), were prepared and packed up ready for transfer with the patient.

A 'Request for blood and blood products' form was sent when collecting the blood. The details on this did not match the details on the product. The blood bank scientist requested a new 'Request for blood and blood products' form, but was told by the RN that there was no time for this as the ambulance was ready to go.

The discrepancy in patient details was found at the time of checking of the blood by the ambulance officers and the product was not transfused.

Comment

In both of the above cases, patient identification at the time of request for product was inadequate.

Patient identification needs to be accurate, and short cuts are not acceptable, such as only using the patient's name. Full patient identifiers should always be used by the requesting staff member, full name, date of birth and hospital number, where available.

Laboratory staff should repeat details back to the requesting clinician to ensure they have been heard and documented correctly. Blood product should not be dispensed if there is a discrepancy in patient details.

Technological solutions include the use of online ordering systems, where there is complete documentation of all the details of the patient and product required. This can include prompts to ensure appropriateness of transfusion and may help reduce such errors.

Cell salvage

Cell salvage has been included in STIR investigations since 2015, but no reports have been made to STIR yet.

Sentinel events

The STIR expert group are requested to review sentinel events related to blood and blood products.

During this period the expert group reviewed an event related to the provision of blood and blood products where death occurred.

The expert group found that the health service had provided a suitable plan for the care for this patient in regard to the difficulties in providing cross-matched blood, and that blood loss and lack of available blood did not seem to have contributed to the death.

Future

The Blood Matters team and the STIR expert group remain in contact with the department to assess the ability of STIR to be incorporated into VHIMS data systems, reducing the need for doubling up of reporting and ensuring notification of STIR reportable events.

Review of all investigation forms to ensure collection of data is useful to reviewers and appropriate for the reaction being reported is completed.

Two new event categories have been added to STIR: transfusion-associated dyspnoea (TAD) and delayed serologic transfusion reactions (DSTR). These are available for reporting commencing 1 July 2017.

References

Australian and New Zealand Society of Blood Transfusion and Royal College of Nursing 2011, *Administration of blood products,* 2nd edition, Australia.

Australian and New Zealand Society of Blood Transfusion 2016, *Guidelines for transfusion and immunohaematology laboratory practice,* 1st edition, Australia.

Bolton-Maggs PHB (ed), Poles D et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group 2017, The 2016 annual SHOT report, https://www.shotuk.org/shot-reports.

Dean L 2005, *Blood groups and red cell antigens*, National Center for Biotechnology Information, Bethesda (MD) <https://www.ncbi.nlm.nih.gov/books/NBK2269>.

King G 2014, *Serum Tryptase,* Medscape, http://emedicine.medscape.com/article/2093911-overview-viewed-20/6/17.

McVay PA, Toy PT 1991, 'Lack of increased bleeding after paracentesis and thoracentesis in patients with mild coagulation abnormalities', *Transfusion* vol. 31, p. 164.

Merck Manuals online http://www.merckmanuals.com/professional/appendixes/normal-laboratory-values/blood-tests-normal-values viewed 20/6/17

Moore KP and Aithall GP 2006, 'Guidelines on the management of ascites in cirrhosis', *GUT*, vol. 55, suppl V.

Murphy MF, Stanworth SJ, Yazer M 2011, 'Transfusion practice and safety: current status and possibilities for improvement', *Vox Sanguinis*, vol. 100, p. 46–59.

National Blood Authority 2015, *Australian Haemovigilance Report 2015,* https://www.blood.gov.au/system/files/documents/nba-haemovigilance-report-2015.pdf>

National Institute for Health and Care Excellence (UK) 2014, *NICE clinical guidelines*, no. 183: drug allergy – diagnosis and management of drug allergy in adults, children and young people, section 7, measuring serum tryptase after suspected anaphylaxis, National Clinical Guideline Centre (UK), London.

Northlip P and Caldwell S 2013, 'Coagulation in liver disease: a guide for the clinician', *Clinical Gastroenterology and Hepatology*, p. 1064–1074.

Politis C et al. 2016, 'The ISTARE haemovigilance database', *Vox Sanguinis,* vol. 111, p. 409-417.

Rai R, Nagral S and Nagral A 2012, 'Surgery in patient with liver disease', *Journal of Clinical and Experimental Hepatology*, vol. 2, no. 3, p. 238–246.

Runyon BA 1986, 'Paracentesis of ascitic fluid: a safe procedure', *Arch Intern Med*, vol. 146, p. 2259.

Blood Matters Program and STIR expert group 2016, *STIR Annual Report 2014–15,* https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/speciality-diagnostics-therapeutics/blood-matters/serious-transfusion-incidents

Appendix 1: Expert group members

Amanda Davis, (chair) Consultant Haematologist, Alfred Health, Victoria Christine Akers, (secretary) Transfusion Nurse, Blood Matters Program, Victoria Helen Atkinson, Transfusion Nurse, Royal Hobart Hospital, Tasmania Gerald Bates, Laboratory Manager, Northern Tasmanian Pathology Service, Launceston General Hospital, Tasmania Linley Bielby, Program Manager, Blood Matters Program, Victoria Karen Botting, Senior Program Advisor, Blood Pharmaceutical Organ and Tissue Donation Programs, Department of Health & Human Services Merrole Cole-Sinclair, Director of Haematology, St Vincent's Hospital, Victoria Philip Crispin, Consultant Haematologist, Canberra Hospital, Australian Capital Territory Bridget Glazebrook, Data Manager, Blood Matters Program, Department of Health, Victoria Adrienne Wynne, Education Coordinator, Blood Matters Program, Victoria Clare Hennessy, Transfusion Nurse Consultant, Eastern Health & Education Coordinator, Blood Matters Program, Victoria Chris Hogan, Medical Director Pathology Services, Australian Red Cross Blood Service Giles Kelsey, Consultant Haematologist, Royal Melbourne Hospital, Victoria Geoff Magrin, Scientist, Events and Education officer, Australian Institute of Medical Scientists, Victoria Ellen Maxwell, Director of Haematology, Melbourne Pathology, Victoria Scott McArdle, Transfusion Nurse, Australian Red Cross Blood Service Tina Noutos, Haematologist, Royal Darwin Hospital, Northern Territory Richard Rogers, Blood Bank Scientist, Cabrini Health, Victoria

Erica Wood, Associate Professor, School of Public Health and Preventative Medicine, Monash University, Victoria

Anissa Yttrup, Transfusion Nurse, Barwon Health, Victoria

Appendix 2: STIR publications and promotion

Australian College of Midwives Conference, October 2015. Poster: 'Collecting blood samples: can we do it better?'

HAA, October 2015. Poster: 'Wrong blood in tube – Is there any improvement?'

International Haemovigilance Network, March 2016. Poster: 'Blood specimen collection in the obstetric setting: mum and bub are not the same.'

Appendix 3: Imputability and severity scores

Imputability/causality	Definition
Not assessable	When there is insufficient evidence for an imputability definition.
Excluded	When there is conclusive evidence that the cause of the incident is attributable to other causes and not the transfusion.
Possibly	When the evidence is indeterminate for attributing the incident to either the transfusion or other causes.
Probably	When the evidence is clearly in favour of attributing the incident to the transfusion.
Certainly	When the evidence is conclusively attributable to the transfusion.

Severity	Incident
1	Relatively infrequent, clear-cut events that occur independently of a patient's condition; commonly reflect health service system and process deficiencies; result in, or have the realistic potential to result in, an unexpected death or a permanent and disabling injury or psychological harm to a person and includes reportable sentinel events.
2	Events that result in a temporary loss of function (sensory, motor, physiological or intellectual) which is unrelated to the natural course of the patient's illness and differ from the expected outcome of the patient's management.
3	Events that result in a person requiring increased treatment, but not hospitalisation or an increased length of stay.
4	Events that result in minor injury requiring only first aid treatment or no injury.

