Serious transfusion incident report 2016–17

blood matters

Australian Red Cross BLOOD SERVICE

VICTORIA State Government

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Serious transfusion incident report 2016–17

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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

ISSN ISSN 2651-8872 – Online (pdf / word)

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

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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 the provision of relevant haemovigilance information will serve to support the community by promoting 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	human blood group system
AHTR	acute haemolytic transfusion reaction
ATR	acute transfusion reaction
ANZSBT	Australian and New Zealand Society of Blood Transfusion
B12	vitamin
BiPAP	bilevel positive airway pressure
BloodNET	a web-based system that allows health facilities across Australia to order blood and blood products from the Australian Red Cross Blood Service
bpm	beats per minute
CCU	coronary care unit
DHTR	delayed haemolytic transfusion reaction
FBE	full blood examination
FNHTR	febrile non-haemolytic transfusion reaction
FFP	fresh frozen plasma
FY17	financial year 2017 (1 July 2016 to 30 June 2017)
Hb	haemoglobin
HLA	human leucocyte antigen
Ig	immunoglobulin
IBCT	incorrect blood component transfused
ICU	intensive care unit
IU	international units
Lpm	litres per minute
LUCS	lower uterine caesarean section
NBA	National Blood Authority
PICU	paediatric intensive care unit
PTP	post-transfusion purpura
Rh	Rhesus
RhD Ig	Rhesus D immunoglobulin
SHOT	Serious Hazards of Transfusion (UK)
SR	severity rating
TACO	transfusion associated circulatory overload
TAD	transfusion associated dyspnoea
TAGvHD	transfusion associated graft versus host disease
the Blood Service	Australian Red Cross Blood Service
the department	Department of Health and Human Services
TTI	transfusion transmitted infection
TRALI	transfusion related acute lung injury
VHIMS	Victorian Health Incident Management System
WBIT	wrong blood in tube

Executive summary

Serious Transfusion Incident Reporting (STIR) currently receives and manages reports on transfusion incidents from 34 per cent of registered health services. Monitoring and identifying established and emerging complications of transfusion are the key elements required to improve outcomes through effective communication and education. Greater sensitivity and specificity require a larger data set.

Incidents collected and reviewed from July 2016 to June 2017 can now be compared with more than 10 years of data. STIR reviewed 143 events, similar to the previous two years.

The STIR Expert panel of transfusion practitioners review data to ensure consensus and consistency. The 2017 report includes 88 adverse clinical events and 50 procedural errors, with five events excluded after review. Pleasingly, procedural errors (largely preventable) have been in decline since 2014.

Clinical events range from common and mild to rare and severe. Mild febrile reactions unrelated to incompatibility and allergic reactions are the most common with 29 per cent in each category similar to previous years. Approximately 11 per cent of reported clinical events were transfusion associated circulatory overload (TACO), a relatively predictable and manageable complication which may result in or contribute to mortality if left untreated or unrecognised.

Delayed haemolytic transfusion reactions are caused by pre-existing alloantibodies that reduce in strength over years and become undetectable by routine laboratory techniques. These antibodies are stimulated by subsequent transfusion resulting in significant haemolysis and anaemia typically approximately one week following the transfusion. This category accounted for eight per cent of reported complications and is entirely avoidable if the previously positive antibody history had been available to the transfusion laboratory.

Wrong blood in tube (WBIT) remains the highest procedural error (50 per cent) and is caused by failure to follow protocol for bedside blood collection, labelling and positive patient identification. Failure to administer or inappropriate administration of Rhesus D immunoglobulin accounted for 16 per cent of reported errors. Incomplete knowledge of current recommendations is likely to contribute to these events.

Challenges emerging from the findings from the 2017 financial year include the possibility of expanding STIR, promoting the concept of a centralised antibody register, increasing the awareness of TACO and educating about current recommendations for Rhesus D immunoglobulin administration.

Work must continue to maximise procedural awareness of correct blood collection and labelling.

Key messages and recommendations

Clinical recommendations

1. Patient blood management strategies should be considered in all patients, to either eliminate or reduce the need for transfusion, thereby minimising risk to the patient (case study 4).

2. Education is important for all staff involved in blood administration. It should include monitoring, management and reporting of reactions. Several reactions were only found on audit, or when a second reaction was reported/investigated (case study 8). Patients and/or their carers should also receive education regarding potential reactions and what to report to nursing or medical staff.

3. A national database of red cell antibodies would reduce the risk of the occurrence of haemolytic reactions. Pathology services would be able to check for previously identified antibodies undetectable at time of later pre-transfusion testing, and to provide antigen negative red cells for transfusion. Haemolytic reactions often increase the level of care required and/or associated length of stay (case studies 4 and 10).

4. Steroids are of little use in the immediate management of allergic transfusion reactions. Rather, they should be considered for prevention of delayed recurrence or for premedication in patients at high risk of further events.

Procedural recommendations

1. The timing of transfusion should be considered, as 22 per cent of routine transfusions (procedural errors) occurred between 8 pm and 8 am. These times are not ideal for staffing, monitoring of the patient and patient comfort.

   'Transfusion must only take place when it is appropriately resourced; that is, where enough trained staff are available to monitor the patient, the patient can be observed and emergency medical support is readily available. Overnight or out-of-hours transfusion should be avoided unless clinically indicated' (ANZSBT/RCA Guidelines for the administration of blood products, 2018) – that is, when the transfusion cannot be delayed due to the risk to the patient.

2. Transcription of patient results is not recommended, especially handwritten reports into medical records. Where possible, electronic methods that do not require transcription, such as scanning the pathology report to add to the medical record, or direct enquiry of the electronic result is a better option (case study 17).

3. Zero tolerance for specimen labelling issues must be followed. Any errors must result in the recollection of the specimen (case study 14).

4. Patient identification in all circumstances and for all aspects of the transfusion process must include identification of the patient by direct enquiry, where possible, and/or direct comparison of the patient identity on the wristband attached to the patient with the request or order and the identification attached to the blood product. This includes patients in isolation, or the emergency setting (case studies 12 and 13).

5. Prescriptions for blood and blood products must clearly state the product required and any modifications. Staff accepting these prescriptions must ensure they understand exactly what is required (case study 16).

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 by STIR, leading to the recommendations by the STIR Expert group.

Issue	Strategies to address the issue	Yes	No	WIP*	NA#
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.				
	Staff must positively identify the patient at every step of the transfusion process e.g. collection of pre-transfusion 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.				
Training/ credentialling staff in transfusion practice	Regular staff education should include the following: • patient identification • collection of pre-transfusion 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.				

Issue	Strategies to address the issue	Yes	No	WIP*	NA#
Training/ credentialling staff in transfusion practice (cont.)	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://learn.transfusion.com.au/enrol/index.php?id=247>.				
Governance	The health service should have a policy regarding the timing of transfusion, in particular, 'routine transfusions' administered overnight. Staff should be educated about the risks of overnight transfusion where it is not warranted by the patient condition.				
	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 fourth annual Serious Transfusion Incident Report. This report covers the financial year 1 July 2016 to 30 June 2017 (FY17).

In this financial year we celebrated the 10th anniversary of the first report to the STIR program, which occurred on 18 September 2006, during the pilot phase of the program. Since that initial report and investigation, the program has grown from nine reporting categories to 15 categories, which include clinical reactions, procedural incidents and near miss events. In the first year of the program, 41 public health services in Victoria and Tasmania were registered with STIR, currently 93 health services across Victoria, Tasmania, Northern Territory and Australian Capital Territory, both public and private, are registered. See Appendix 4 for timeline of events in STIR development.

During FY17, a systematic review of all investigation forms was undertaken by the STIR Expert group. The aim was to consolidate information, remove questions that served little purpose, and add questions that may better assist the reviewer to determine type and imputability of the reaction. The Expert group are aware of the burden of reporting in the health services and attempted to ensure there was no increase in the number of questions.

During the first part of 2017, STIR revised its data collection and analysis to be consistent with the revised National Blood Authority (NBA) Australian Haemovigilance Minimum Data Set (2015), which came into effect on 1 July 2017. The revision involved minor changes to definitions, as well as the inclusion of two new reporting criteria: delayed serologic reactions and transfusion associated dyspnoea (TAD), which will be reported in the next annual STIR report.

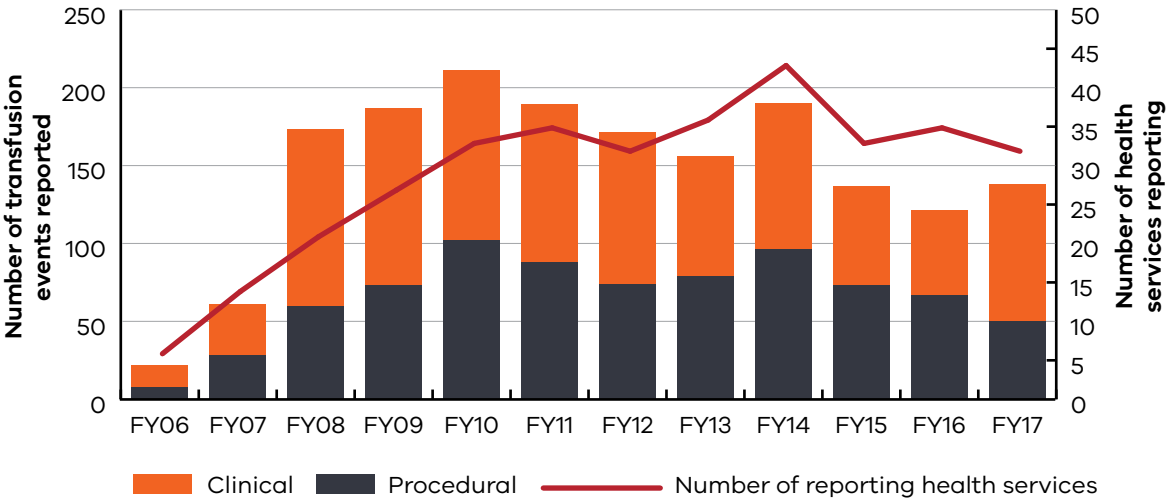
Reporting to STIR is voluntary and all data is de-identified before review, or inclusion in any reports. Health services are encouraged to report to STIR, as doing so may assist in meeting some of the requirements for institutional accreditation.

STIR continues to provide local data on serious transfusion reactions and incidents, case studies that highlight the risks associated with transfusion practice and tools and recommendations for health services to address haemovigilance issues.

The STIR Expert group provide a clinical review and validation system for reports received. These validated reports form part of the national data sent to the NBA for the *National haemovigilance report*.

In this reporting period, 32 health services (34 per cent of all registered health services) submitted a total of 155 notifications, including procedural incidents, clinical reactions to blood components and near misses. The total number of investigations analysed following events withdrawn or excluded was 138 (referred to as validated investigations). This year's reports are compared with previous years in Figure 1.

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



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/blood-matters/serious-transfusion-incidents>.

The NBA via BloodNET provides total blood issue data. Table 1 shows total blood issues per jurisdiction 2016–17 (FY17) (distributed units minus units lost due to wastage, damage or other reasons).

Table 1: Total blood issues per jurisdiction reporting to STIR 2016–17

Product	Victoria	Tasmania	Australian Capital Territory	Northern Territory
Red cells	178,251	10,520	9,645	4,023
Platelets	34,213	2,267	1,530	732
Fresh frozen plasma	27,729	1,445	1,129	505
Cryoprecipitate	25,038	1,275	1,497	817

Blood issue data for Victoria is used to determine the frequency of clinical events per product issued (Table 2). This may not represent the true number of events that occur, due to the voluntary nature of reporting and the fact that STIR intentionally focuses on more serious events. This does, however, give an approximation of the number of serious events occurring.

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

Product	Blood issues (Victoria)	Validated clinical events*	Frequency
Red cells	178,251	44	1:4051
Platelets	34,213	17	1:2012
FFP	27,729	12	1:2310
Cryoprecipitate	25,038	1	1:25,038

**Victorian notifications only (n = 74)*

Method

Figure 2 shows the steps in the reporting and validation of health service notifications to STIR. There are a number of validation steps built into the process. At notification, information is reviewed to ensure the notification meets STIR guidelines. On return of forms, the information provided is checked for clarity and to ensure as much information as possible is available to the reviewer. All forms are sent to members of the Expert group for review, with all severity rating (SR) 1 and 2 events requiring review at the Expert group meeting.

Figure 2: Steps in the STIR reporting process

138 final validated reports included for analysis

Demographics 2016–17

In 2016–17, 155 notifications were made to STIR, 12 were withdrawn by the health service after review of the incident, or discussion with the STIR secretariat for the reasons described in Table 3.

A further five reports were excluded by the reviewers as they were deemed not associated with the transfusion, or where there was insufficient information provided to make a decision.

Table 3: Reasons for withdrawal of reports

Fiscal year	Duplicate	Not in scope	Deemed not transfusion related	Not completed	Expert review excluded	Total
2012–13	2	4	–	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
2016–17	5	4	2	1	5	17

During the Expert review, the incident type may change. If this occurs, there is a second review of the incident to provide a consensus on the final determination. If there is disagreement between the two reviews, the Expert group reviews the incident at one of its regular meetings. As shown in Table 4, there is generally good consensus between the health service determinations of reaction type and the Expert group review. Approximately 10 per cent of reports (n = 9) have the clinical incident type changed after review.

Table 4: Incident type following Expert review: clinical reports only

			Incident type following Expert review							
			Acute transfusion reactions (ATR)							
			Acute Haemolytic	Allergic	FNHTR	Other	Bacterial	Delayed	TRALI	TACO
Incident type at notification	Acute transfusion reactions (ATR)	Acute Haemolytic	1			1				
		Allergic		25						
		FNHTR		1	28	3				
		Other		1	1	4				
		Bacterial		1						
		Delayed		1				8		
		TRALI							2	
		TACO								11
		Total	**1**	**29**	**29**	**8**	**0**	**8**	**2**	**11**

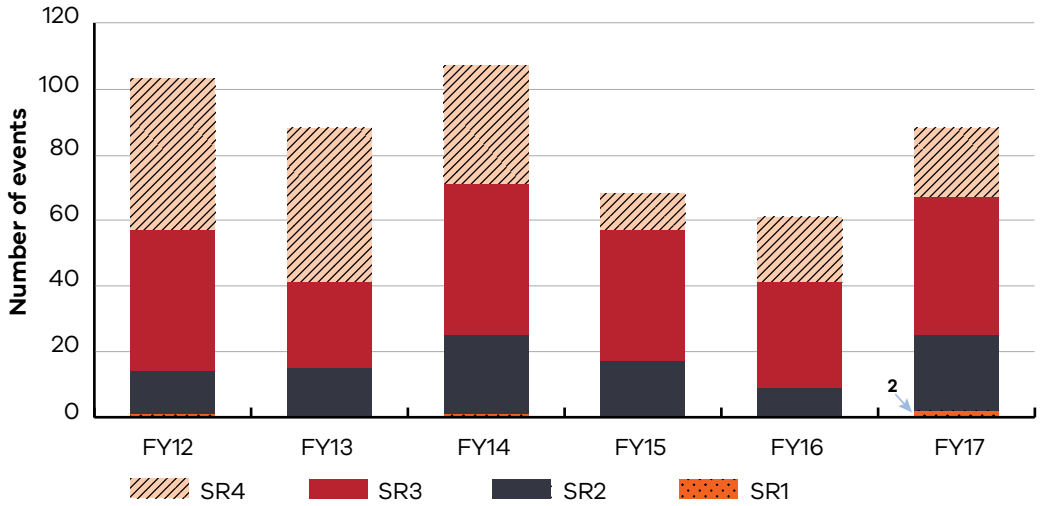
The Expert group also reviews the severity rating of the incident. This may change from that assigned by the health service at the time of initial notification. When the severity rating is changed by the Expert group, this is often an increase in the degree of severity assigned as demonstrated in Table 5.

Table 5: Changes to severity rating following expert review

		Severity rating following expert review			Total
Severity rating at notification		SR1	SR2	SR3	
ATR	SR2–3	1	–	–	1
ATR	SR4	–	3	19	22
DHTR	SR4	–	1	2	3
IBCT	SR4	–	–	1	1
TACO	SR2–3	1	–	–	1
TACO	SR4	–	2	2	4
Total		**2**	**7**	**23**	**32**

In this reporting period, two events were assigned a severity rating 1 (SR1): 'an event that results in or has the realistic potential to result in an unexpected death or a permanent and disabling injury or psychological harm to a person, and includes sentinel events', as shown in Figure 3. One related to an ATR (allergic – see case study 2), the other to TACO, where the patient required intensive care unit (ICU) admission.

Figure 3: Severity ratings (clinical events and IBCT only)



Definitions of severity ratings can be found in Appendix 3.

Validated investigations

The 2016–17 STIR report contains information on the 138 reports validated by Expert review. Demographics for all validated reports are found in Table 6.

Table 6: Demographics for all validated reports

Incident type	Number	Age (average, range)	Gender	
			Male	Female
Clinical reports				
FNHTR	29	60 (15–85)	12	17
Allergic	29	38 (0–95)	13	16
Acute haemolytic	1	46 (46–46)	–	1
ATR (other causes)	8	60 (0–97)	2	6
Bacterial	–	–	–	–
TACO	11	76 (62–91)	7	4
TRALI	2	50 (35–66)	0	2
Delayed haemolytic	8	62 (13–53)	2	6
TAGvHD	–	–	–	–
PTP	–	–	–	–
Clinical subtotal	**88**	**55 (0–97)**	**36**	**52**
Procedural reports				
IBCT	3	38 (1–66)	1	2
WBIT	26	46 (0–82)	13	13
RhD immunoglobulin	8	27 (0–39)	0	8
Cell salvage	–	–	–	–
Near miss	13	58 (0–92)	7	6
Procedural subtotal	**50**	**48 (0–92)**	**21**	**29**
Total	**138**	**52 (0–97)**	**57**	**81**

Similar to previous years, FNHTR and allergic remain the largest proportion of clinical reactions reported.

Two cases of bacterial sepsis were reported, however, neither was verified as confirmed and related to the transfusion. As part of the validation process, any suspected transfusion reactions that could be related to product quality are reported and reconciled with the Blood Service. The determination by STIR that these were not bacterial contaminations was supported by Blood Service findings (see transfusion transmitted infection).

Two cases of suspected TRALI were also reported. Again, these reports were notified and compared with the Blood Service data. In the same period the Blood Service received six reports of potential TRALI.

There were no TAGvHD or PTP incidents reported, and this is consistent with previous years.

This year, there were fewer procedural than clinical events reported. Wrong blood in tube remains the largest proportion of reported procedural events to STIR, indicating ongoing problems with effective patient identification and specimen labelling. As more health services move to electronic methods to assist staff to confirm patient identity and label specimens, it will be interesting to see if there is a sustained reduction in the number of reports received in this category over time.

It is pleasing to see a decrease in the number of IBCT events reported for this year, with no ABO incompatible transfusions reported. However, ongoing vigilance is required to prevent these potentially life-threatening events.

Table 7: Blood product implicated by validated incident type

	Blood product type					
Incident type	Red cells	Platelets	FFP	Cryoprecipitate	Multiple products	Other
Clinical reports						
FNHTR	24	5	–	–	–	–
Allergic	3	11	13	1	1	–
Acute haemolytic	1	–	–	–	–	–
ATR – other causes	5	1	2	–	–	–
Bacterial	–	–	–	–	–	–
TACO	11	–	–	–	–	–
TRALI	–	–	1	–	1	–
Delayed haemolytic	8	–	–	–	–	–
TAGvHD	–	–	–	–	–	–
PTP	–	–	–	–	–	–
Clinical subtotal	**52**	**17**	**16**	**1**	**2**	**0**
Procedural reports						
IBCT	2	–	–	–	–	1
WBIT	4	–	–	–	–	22
RhD immunoglobulin	–	–	–	–	–	8
Cell salvage	–	–	–	–	–	–
Near miss	7	3	–	–	–	3
Procedural subtotal	**13**	**3**	**0**	**0**	**0**	**34**
Total	**65**	**20**	**16**	**1**	**2**	**34**

STIR accepts reports of incidents related to any fresh product (excluding haemopoietic stem cells), as well as incidents involving RhD immunoglobulin. Table 7 reports on the type of incident and associated product. As in previous years, the largest proportion of reports relate to red blood cells. The category 'other' includes RhD immunoglobulin and WBIT events. Only a small number of events included multiple products, most often in emergency situations where products were given quickly, and it was difficult to determine which product the patient was reacting to.

With an increasing focus on patient blood management, relying on effective management and conservation of a patient's own blood and minimising transfusion, the clinical investigation forms include the question, 'Did the transfusion meet hospital guidelines?'.

Of the 88 clinical investigations, only six responded that the transfusion may not have met guidelines. The reasons given are described in Table 8.

Table 8: Reasons reported that transfusion did not meet hospital guidelines

Type of reaction	Reason did not meet guidelines
ATR	The patient's most recent coagulation results were normal, and they were not re-tested before ordering and transfusing FFP
ATR	(2x) ordering could have been single unit
ATR	In retrospect, perhaps this neonate could have been managed with small volume simple transfusions rather than exchange transfusion
TACO	(2x) inappropriate treatment of anaemia (one had Hb 91, other had no pathology)

The Australian and New Zealand Society of Blood Transfusion/Royal College of Nursing Guidelines for the Administration of Blood Products states, 'Overnight or out-of-hours transfusion should be avoided unless clinically indicated.

Clinically indicated refers to instances where the patient would be harmed if the transfusion was delayed, for example, ongoing bleeding. The procedural investigation forms include questions about the timing of the transfusion episode, and whether the transfusion is routine or emergency. As shown in Table 9, 10 of the 43 (23 per cent) procedural incidents reported were routine transfusions, occurring between 8 pm and 8 am.

A further two occurred during the same timeframe, however, it was unknown if they were routine or urgent.

Table 9: Time of procedural incident (IBCT, near miss, WBIT) and urgency of transfusion

	Routine	Emergency	Unknown	Total
8 am–8 pm	21	5	2	28
8 pm–midnight	2	–	1	3
Midnight–8 am	8	–	1	9
Unknown	1	1	–	2
Total	**31**	**6**	**4**	**43**

Outcomes

Table 10 outlines the patient outcome post transfusion, as reported by health services. Although there were three deaths reported (one each for ATR, TRALI and TACO), none were attributed directly to the transfusion. The TRALI death occurred in a woman who was experiencing post-partum haemorrhage, and an amniotic fluid embolus could not be excluded. A significant number of patients required ICU admission post reaction (11 per cent) and/or an increased length of stay (21 per cent).

Table 10: Outcome for the patient this admission, post transfusion (multiple answers may be given)

Patient outcome*	ATR (n = 67)	Delayed (n = 8)	TACO (n = 11)	TRALI (n = 2)	IBCT (n = 3)
No increase in care (apart from the transfusion incident investigations)	17	5	1	–	1
Temporary increase in care	44	2	7	–	1
Permanent increase in care	–	–	–	–	–
Increase length of stay	15	–	3	–	1
ICU admission due to transfusion reaction	3	1	3	2	1
Haemodialysis/haemofiltration	–	1	–	–	–
Death due to transfusion reaction	–	–	–	–	–
Death not due to transfusion reaction	1	–	–	1	1
Not yet discharged	1	1	–	–	–

**For all clinical reports and IBCT.*

Clinical reports

In this year's report, 88 clinical events were validated, with FNHTR and allergic reactions representing the largest proportion (Figure 4). Figure 5 compares the clinical reports received over the years since July 2011.

Figure 4: Clinical reactions reported FY17

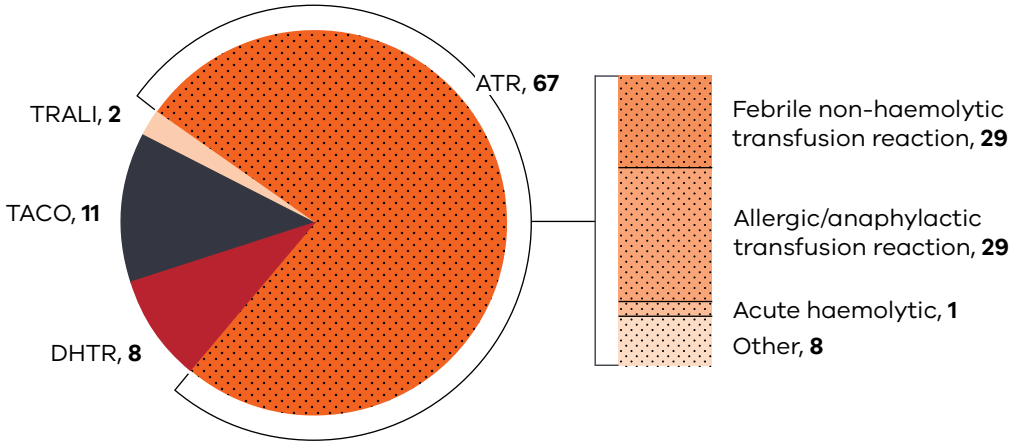
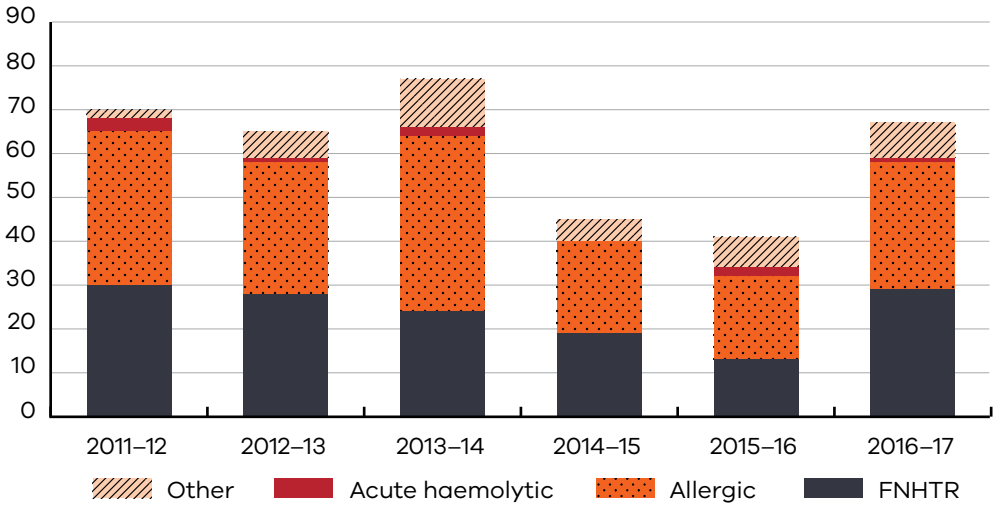


Figure 5: ATR validated reports in FY17 compared to previous years



In Figure 5, 'other' refers to reports where a transfusion reaction cannot be excluded, and information is not available to make a definitive diagnosis or does not currently fit into STIR reporting categories.

Case study 1: Example of ATR other

An example of a validated 'other' ATR event is the case of a premature newborn with anaemia related to a maternal antibody.

An hour into a second unit of red cells, during a red cell exchange, the newborn developed bradycardia (157 to 73 bpm), and hypotension (61/41 to 26/16 mmHg).

The transfusion was ceased. He was treated with intermittent positive pressure ventilation and given calcium gluconate and bicarbonate for metabolic acidosis and hyperkalaemia.

He required continuous positive airway pressure ventilation and was given intravenous antibiotics to cover for possible sepsis.

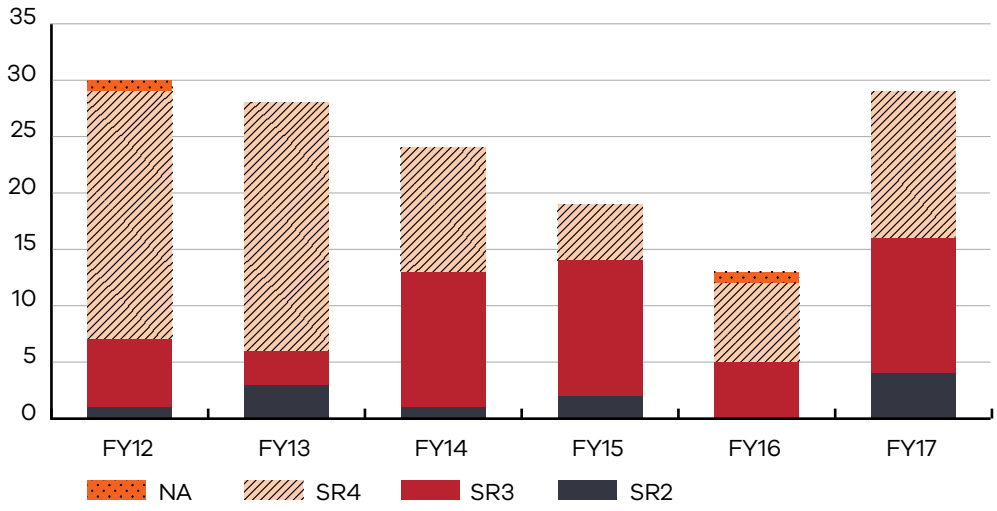
Blood gas investigations showed – pH 7.2, potassium 8.9 and 7.9 mmol/L, and lactate 6.6 mmol/L. Blood cultures of both the patient and the blood bag were negative. There was no evidence of incompatibility with the unit transfused.

The health service reported this was likely a metabolic complication of large volume red cell transfusion in a neonate. STIR review agreed with the health service, and found this was likely related to the transfusion, however it does not fit into the categories currently described by STIR guidelines.

Febrile non-haemolytic transfusion reaction (FNHTR)

Data summary – validated data Febrile non-haemolytic transfusion reaction, n = 29			
Gender		**Time of transfusion**	
Male:	12	In hours (8 am–8 pm):	23
Female:	17	Out of hours (8 pm–8 am):	6
Age		**Imputability**	
< 1 year:	–	Certainly:	–
1–18 years:	1	Probably:	7
19–29 years:	1	Possibly:	22
30–49 years:	6	Not assessable:	–
50–69 years:	10	**Severity**	
70–79 years:	9	SR1: unexpected death or a permanent and disabling injury:	–
80+ years:	2		
Blood product implicated		SR2: temporary loss of function:	4
Red cells:	24	SR3: increased treatment, but no increased length of stay:	12
Platelets:	5		
FFP:	–	SR4: no injury or minor requiring only first aid treatment:	13
Cryoprecipitate:	–		
Multiple products:	–	Not assessable:	–

Figure 6: Number of febrile non-haemolytic transfusion reactions per financial year

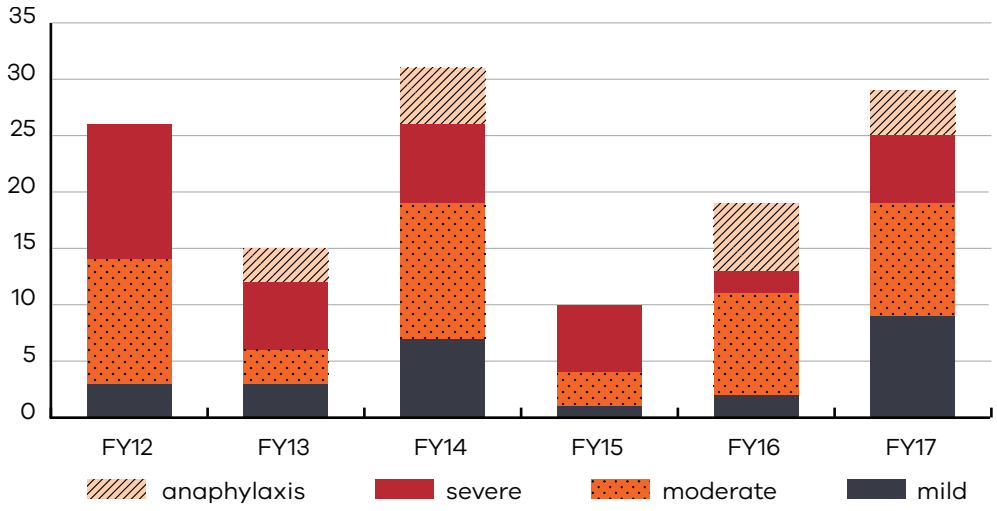


Febrile non-haemolytic transfusion reactions continue to be one of the most commonly reported clinical events to STIR, as shown in Figure 6. It is often difficult to determine if the fever is related to the transfusion of a blood product, or an underlying clinical condition. The imputability of these cases is usually relatively weak, with most being assigned as possibly related. The majority of reports still relate to red cell transfusions.

Allergic/anaphylactic reactions

Data summary – validated data Allergy, n=29			
Gender		**Time of transfusion**	
Male:	13	In hours (8 am–8 pm):	23
Female:	16	Out of hours (8 pm–8 am):	6
Age		**Imputability**	
< 1 year:	1	Certainly:	2
1–18 years:	8	Probably:	10
19–29 years:	2	Possibly:	17
30–49 years:	9	Not assessable:	–
50–69 years:	5	**Severity**	
70–79 years:	1	SR1: unexpected death or a permanent and disabling injury:	1
80+ years:	3		
Blood product implicated		SR2: temporary loss of function:	8
Red cells:	3	SR3: increased treatment, but no increased length of stay:	14
Platelets:	11		
FFP:	13	SR4: no injury or minor requiring only first aid treatment:	6
Cryoprecipitate:	1		
Multiple products:	1	Not assessable:	–

Figure 7: Number of allergic/anaphylactic reactions reported per financial year



The number of allergic reactions reported has increased in this period, as highlighted in Figure 7. Approximately one-third of all reports were severe allergic or anaphylactic reactions to blood products. The majority of reactions occurred with the transfusion of plasma or platelets.

Allergic reactions are the most commonly reported reaction in children. Of the 11 clinical reactions reported in patients aged 18 years and under, nine were allergic.

Table 11: Treatment given for allergic reactions (FY17)

	treatment given at time of reaction				
	antipyretics	antihistamine	steroids	inotopes	Total reactions
mild	0	7	4	1	9
moderate	1	8	8	3	10
severe	0	5	6	5	6
anaphylactic	0	3	4	4	4

As shown in Table 11, a large percentage of patients received steroids as part of the treatment for allergic reactions. This may be appropriate in some cases, but even in mild reactions, 44 per cent of patients received steroids. One case deemed mild also received inotropes. All patients who had a severe allergic or anaphylactic reaction received steroids.

Based on recommendations from SHOT (2017), management for allergic reactions should include:

- give an antihistamine as first line; give adrenaline if anaphylaxis is suspected
- steroids should only be used to prevent a late recurrence. The effect of steroids is delayed by several hours, and will have no immediate effect. The use of steroids may further immunosuppress already immunocompromised patients and increase the risk of side effects such as infection.

Case study 2: Difficulty in attributing the allergic reaction to the transfusion

A 36-year-old woman presented for elective lower uterine caesarean section (LUCS) due to placenta praevia major.

In theatre, she experienced a post-partum haemorrhage of approximately two to three litres.

She was transfused four units of red cells, 10 of cryoprecipitate, 500 mL of blood from cell salvage and 600 mg of tranexamic acid.

The patient had also received carboprost, ergometrin and oxytocin during the surgical period. At extubation, bronchospasm and widespread urticarial rash was noted, and the patient was transferred to ICU.

Investigation showed serum IgE was elevated, tryptase (taken approximately two hours after the last unit of blood) was normal. The chest X-ray was normal; there was no evidence of a haemolytic transfusion reaction on serologic testing.

This was found to be a possible severe allergic reaction, with SR1.

Comments

It can be difficult to definitively attribute allergic reactions to the transfusion in some cases. As described above, the patient had received a number of medications, in addition to the blood products transfused, any of which may have contributed to the allergic reaction in the patient. While tryptase and serum IgE levels can support a diagnosis of allergic reaction, they are not always elevated and do not necessarily confirm the causative agent.

Case study 3: Allergic reaction in a child

A 4-year-old boy receiving treatment for acute lymphocytic leukaemia (ALL), with a platelet count of 13 x109/L and a fever was administered a unit of platelets.

Approximately 30 minutes into the transfusion (30 mL transfused), he developed nausea and vomiting, dyspnoea, respiratory wheeze and facial swelling. He was treated with antihistamines, steroids and oxygen therapy, resulting in a temporary increase in care.

Comments

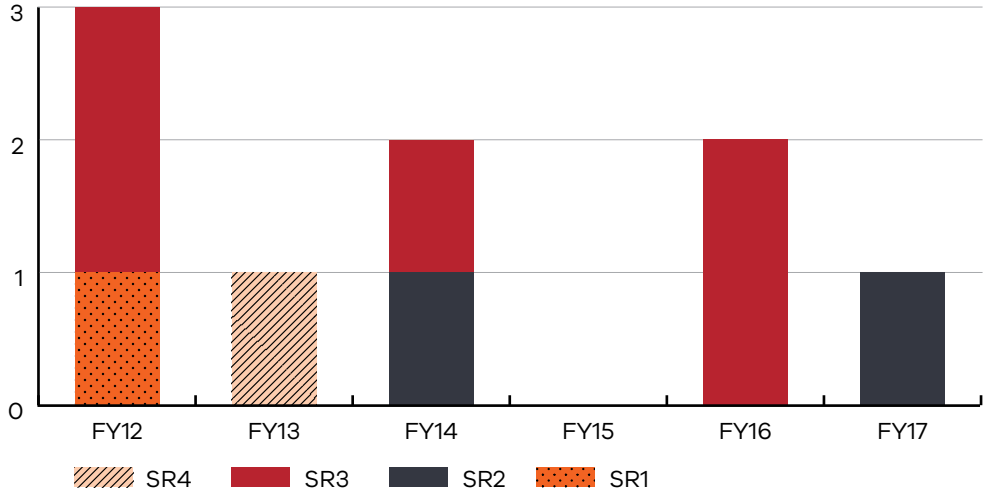
Young children are at greater risk of reactions to blood products for a number of reasons, one of which is their inability to communicate early symptoms to carers. Observation of children is very important to detect early signs, such as irritability, restlessness or where the child is distressed and unable to be consoled.

Acute haemolytic reaction

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

Acute haemolytic reactions are infrequently reported as shown in Figure 8. The one reaction reported in this period occurred in a patient with known antibodies and demonstrates the difficulty of finding suitable blood for some patients (see case study 4).

Figure 8: Number of acute haemolytic reactions reported per financial year



Case study 4: Acute haemolytic reaction in patient with previous delayed haemolytic reaction

A 46-year-old female presented to her general practitioner with chest pain. Investigation showed her Hb was 73 g/L. She was sent to her local hospital where she was transfused three units of red cells with no issues and was discharged home with a Hb of 113 g/L.

Within two to three days she developed fevers, migratory polyarthralgia and icterus (presence of jaundice seen in the sclera of the eye). She also noted fatigue, change in urine (brown colour), and intermittent abdominal pain.

The patient re-presented to her local hospital emergency department a week after discharge and was diagnosed with a delayed haemolytic transfusion reaction (DHTR). Her Hb dropped to 55 g/L and she was transferred to a tertiary health service for investigation and management.

The tertiary health service transfused the patient several days later with the most compatible unit available, however after completion of the unit the patient developed dark urine, fever and back pain. She had an increase in bilirubin (40 mmol/L pre, 876 mmol/L post) and haptoglobin fell < 0.08 g/L. This was diagnosed as an acute haemolytic transfusion reaction (AHTR).

Due to the inability to find suitable red cell units for this patient, she was treated with folate, B12 and erythropoietin injections. She was discharged two weeks later without further transfusion and with a Hb of 69 g/L.

Further investigation found that the patient had a history of anti-c, anti-S and anti-Leb. Testing at the reference laboratory also found anti-I. Previously there had been suspicion of congenital anaemia, however, no follow up testing had been performed.

She had two previous pregnancies and had been transfused two to three units after each birth. She had also received a single unit for anaemia approximately 10 months prior to the transfusion that lead to the delayed haemolysis. This patient was found to be compatible with less than one per cent of donors.

Comments

The initial delayed haemolytic reaction, identified at the local hospital was not reported to STIR, despite this health service being registered with STIR.

It is important to properly diagnose any anaemias, as earlier awareness may have resulted in management changes of her two pregnancies and avoidance of transfusion at these times, as well as the transfusion which resulted in this DHTR.

Transfusion transmitted infection, including bacterial sepsis

In the reporting period, there were two notifications of suspected bacterial contamination. After investigation and review by the Expert group members, they were assigned to another category (allergic), or determined as not assessable.

The Blood Service received more reports of potential bacterial contamination than STIR in the reporting period. This is not surprising, as health services are required to report suspected bacterial contamination immediately to the Blood Service to monitor any safety or quality issues. STIR reporting encourages local review to occur before notification.

STIR and the Blood Service have a process of reconciliation of reports; the findings of the Expert group were supported by the Blood Services own findings in these cases.

Case study 5: Follow up of potential bacterial contamination

A patient with cancer and anaemia was attending the day unit at the health service. The patient was transfused a unit of red cells and became febrile. Treatment included antipyretics, but no blood cultures were taken at the time.

The patient chose not to be further monitored at the day unit as he had family plans. It was presumed the patient had a urinary tract infection and was commenced on oral antibiotics.

As part of the transfusion reaction work up, the unit was sent for culture and returned a positive culture four days later showing gram positive cocci resembling staphylococcus. The Blood Service was not informed of the potential contaminated unit until nearly two weeks after the initial patient reaction.

Comments

The STIR review determined that this event was not assessable with the limited information provided (in particular, no patient blood cultures) and the delay in recognition and reporting. In this reporting period there have been changes made to the STIR reporting forms to try and provide more information to the reviewers to assist determination.

It is important that when there is any suspicion of a bacterial contamination of a product, this is reported to the Blood Service immediately so other components from the same donation can be quarantined and/or recalled. In this instance, the Blood Service determined this to be a possible FNHTR.

Transfusion associated circulatory overload (TACO)

Data summary – validated data Transfusion associated circulatory overload, n = 11			
Gender		**Time of transfusion**	
Male:	7	In hours (8 am–8 pm):	4
Female:	4	Out of hours (8 pm–8 am):	7
Age		**Imputability**	
< 1 year:	–	Certainly:	–
1–18 years:	–	Probably:	7
19–29 years:	–	Possibly:	4
30–49 years:	–	Not assessable:	–
50–69 years:	3	**Severity**	
70–79 years:	4	SR1: unexpected death or a permanent and disabling injury:	1
80+ years:	4		
Blood product implicated		SR2: temporary loss of function:	5
Red cells:	11	SR3: increased treatment, but no increased length of stay:	4
Platelets:	–		
FFP:	–	SR4: no injury or minor requiring only first aid treatment:	1
Cryoprecipitate:	–		
Multiple products:	–	Not assessable:	–

Figure 9: Number of transfusion associated circulatory overload reported per financial year

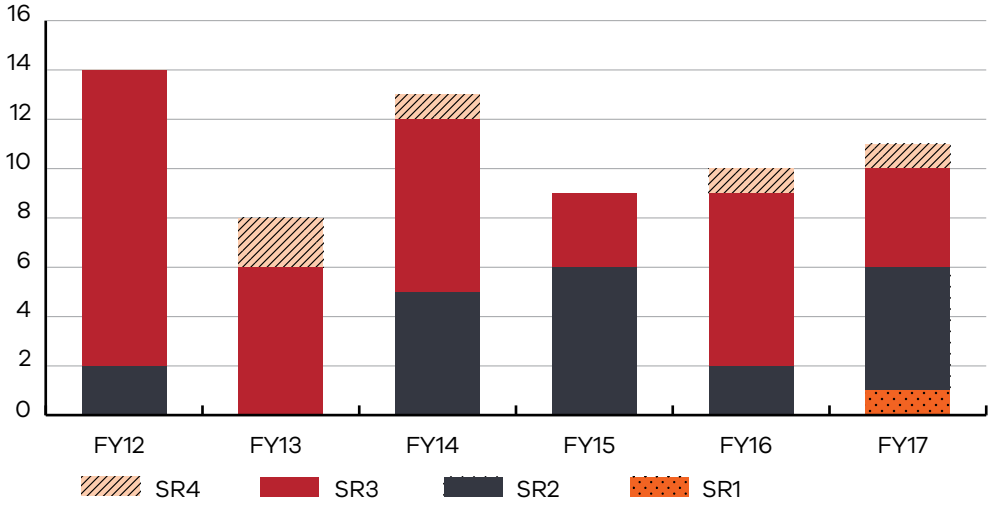


Figure 9 shows the number and severity of TACO reactions reported to STIR. As shown the severity of reactions reported to STIR appears to be increasing with one SR1 event reported in this fiscal year, where the patient required ICU admission.

Case study 6: Pre-transfusion assessment

An 83-year-old woman with iron-deficiency anaemia was referred to a health service for transfusion. She was prescribed two units of red cells, but no formal documentation of her Hb or other results was communicated to the health service.

The patient experienced a fever during the administration of the second unit of red cells, and it was during the investigation of this that the Transfusion nurse discovered the patient had required treatment for overload during the administration of the first unit. The patient had not taken her regular diuretic prior to attending for the transfusion.

The health service found there should have been a review of the request and assessment of appropriate treatment, including the possibility of an iron infusion, before commencing transfusion. Review of the patient to assess condition prior to transfusion may have identified she had not taken her regular diuretics and could have possibly prevented the volume overload by ensuring she had appropriate diuretic cover.

Case study 7: Suspected TACO leading to ICU admission

A 78-year-old man received a transfusion for symptomatic anaemia (Hb 74 g/L).

Forty minutes into the first unit, he developed respiratory wheeze, dyspnoea and decreased oxygen saturation. He was treated with oxygen therapy and diuretics and admitted to ICU. Chest X-ray at the time indicated pulmonary oedema, which continued to progress the next day.

The patient had a history of chronic kidney disease and ischaemic cardiomyopathy with a left ventricular ejection fraction of 38 per cent (normal range > 55 per cent). There was no information provided with the report on fluid balance or other fluids administered within the 24 hours prior to the reported reaction.

Comments

While information was limited, the patient history and relationship of the transfusion to onset of symptoms indicated that this event probably represented TACO. The need for admission to ICU elevated this to an SR1 event.

Case study 8: Follow up of reactions

A 35-year-old woman was day one post-delivery of baby that included post-partum haemorrhage of 600 mL.

She was receiving the second of two units of red cells to treat symptomatic anaemia (Hb 75 g/L) when she developed an increased respiratory rate and decreased oxygen saturation. She had a positive fluid balance at this time and chest X-ray showed pulmonary oedema. She was treated with diuretics and admitted to the coronary care unit (CCU).

It is unusual for TACO to develop in someone this young with a relatively small volume of blood transfused. However, this woman had a history of mitral valve regurgitation and a history of lung toxicity following chemotherapy.

Comments

Although this was a serious reaction, requiring admission to CCU, it was not reported within the health service as a reaction. Instead, it was found several months later during an audit. The patient was treated appropriately at the time; however, to meet the National Safety and Quality Health Service Standards, health services must have incident management and investigation systems in place, which supports the workforce to recognise and report events. Reporting events allows safety and quality improvement, where appropriate, and provides an opportunity to educate staff and the patient if needed. A number of TACO reactions have been reported to STIR where the reaction was only reported after routine auditing within the health service found the event in the medical record.

TACO and fever

Rarely is fever reported as a sign associated with TACO in STIR reports. However, recent studies indicate that a proportion of TACO reports are associated with fever (Parmar et al. 2017).

The cause for this may be unrelated to the transfusion or TACO reaction. An inflammatory response is suggested as a possible cause of fever in some of these patients. In this study, they found that 42 per cent of reported TACO cases (n = 107) recorded fever, with 60 per cent also recording chills and rigors. In 76 per cent of cases, this was the first time a fever had been reported for the patient. In almost half of these, fever was the cause for review, and TACO was found subsequently. Another study (Andrzejewski et al. 2012) reported on 97 TACO cases with one third exhibiting fever (> 38°C).

The cause of fever in these patients is not well understood at this time; however, several hypotheses have been postulated, including an inflammatory aspect. Further study is required to assess if there is a direct relationship between TACO and fever, or there is some other cause.

Transfusion related acute lung injury (TRALI)

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

In this reporting period, two TRALI cases were reported to STIR. Both cases required time and discussion to arrive at a final determination. Both of these cases were reported to the Blood Service, and the STIR Expert group compared its findings with the Blood Service determination. In one case, the final determination was inconclusive: an amniotic fluid embolus was possibly a contributing factor to the recipient's death. In the other, the Blood Service determined this was a possible TRALI, although no HLA class 1 antibodies against the recipient were found. The STIR Expert group has attributed an imputability of possible to both cases (see case study 9).

The reconciliation process between the Blood Service and STIR noted that while STIR received two notifications in the period, the Blood Service received six. In addition to the two reports of TRALI to STIR, another was reported to STIR as TACO (confirmed as TACO by Blood Service, but originally reported as potential TRALI). A fourth report related to stem cells, which is not reportable to STIR as per reporting criteria. The last two reports were from health services that are registered with STIR; however, neither health service reported these events to STIR, as TRALI or any other type of reaction.

Case study 9: Possible TRALI

A 66-year-old woman was undergoing plasma exchange with FFP replacement for vasculitis presenting with pulmonary haemorrhage and rapidly progressive glomerular nephritis. Other than the pulmonary haemorrhage associated with the vasculitis, there was no indication of pre-existing cardiac or respiratory disease.

One hour post procedure, in which 3,000 mL of FFP had been exchanged, the patient's oxygen saturation decreased to 84 per cent on oxygen 3 Lpm. She became dyspnoeic, with a respiratory rate of 28, resulting in a Code Blue.

The patient was treated with frusemide 80 mg intravenously and oxygen 15 Lpm via mask. She was transferred to ICU for non-invasive ventilation (BiPAP) and after three days recovered and returned to the ward.

Delayed haemolytic reactions

Data summary – validated data Delayed haemolytic, n = 8			
Gender		**Imputability**	
Male:	2	Certainly:	1
Female:	6	Probably:	3
Age		Possibly:	3
< 1 year:		Excluded:	
1–18 years:	1	Not assessable:	1
19–29 years:	–	**Severity**	
30–49 years:	1	SR1: unexpected death or a permanent and disabling injury:	
50–69 years:	1		
70–79 years:	3	SR2: temporary loss of function:	2
80+ years:	2	SR3: increased treatment, but no increased length of stay:	3
Blood product implicated			
Red cells:	8	SR4: no injury or minor requiring only first aid treatment:	2
Platelets:	–		
FFP:	–	Not assessable:	1
Cryoprecipitate:	–		

Figure 10: Number of delayed haemolytic transfusion reactions reported per financial year

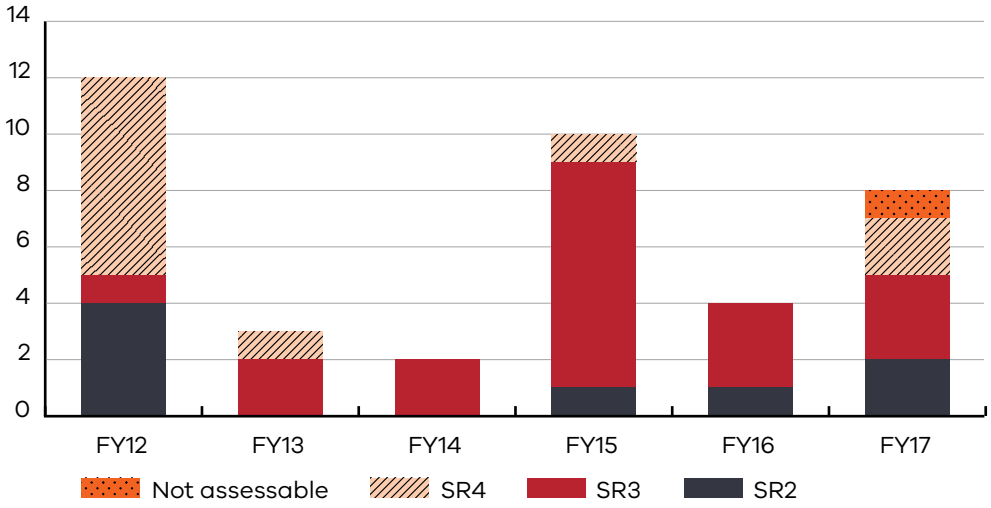


Figure 10 shows the number of delayed haemolytic reactions reported each financial year. The numbers are variable and, as discussed in the acute haemolytic reactions, there may be some that occur but are not reported as the patient is seen at, or transferred to, a different health service from where the transfusion took place.

Case study 10: Difficulties around investigating delayed reactions

A 79-year-old man with cancer was transfused for symptomatic anaemia (Hb 65 g/L). During the transfusion, he developed fever and back pain.

The transfusion team investigated the reaction and classified it as a possible febrile non-haemolytic reaction, with the back pain deemed likely due to an alternative cause. No antibodies were identified in the pre- or post-transfusion samples.

The patient was admitted again six weeks after this transfusion event and a pre-transfusion sample was received. This returned a positive antibody screen with anti-E and anti-c identified.

The patient's history was reviewed, and it was noted that one of the units administered at the time of the initial reaction was positive for both E and c. The haemovigilance team surmised that this may have been a case of antibody reactivation possibly associated with haemolysis which warranted external reporting. The team checked with a number of laboratories who may have seen the patient, but none had any pre-transfusion testing results to share.

Comments

Many patients are seen and/or transfused at more than one health service. Currently in Australia information on antibody development is not easily shared between laboratories, unless you know which laboratory to ask.

Even then, you need to know to ask, and this is most commonly after the patient has had a reaction. A national antibody database, easily accessible by all laboratories, would reduce the chance of haemolytic reactions and assist in making transfusion safer for these patients.

Transfusion associated graft versus host disease (TAGvHD)

There have been no reports of TAGvHD since reporting to STIR commenced.

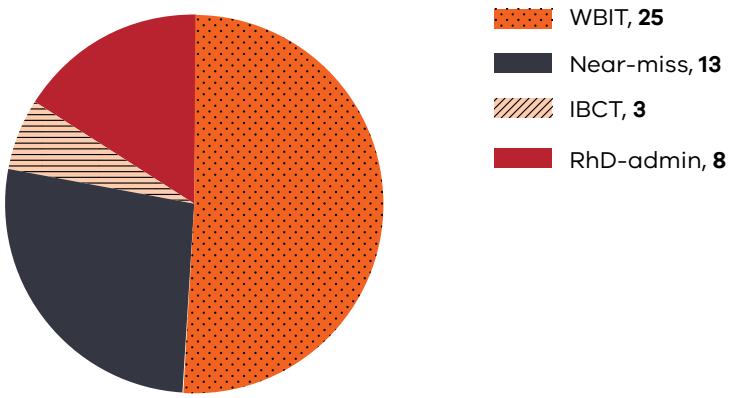
Post-transfusion purpura (PTP)

There were no events reported this year, with the last report occurring in 2009.

Procedural reports

The procedural events reported to STIR can be found in Figure 11.

Figure 11: Procedural reports FY17



Incorrect blood component transfused (IBCT)

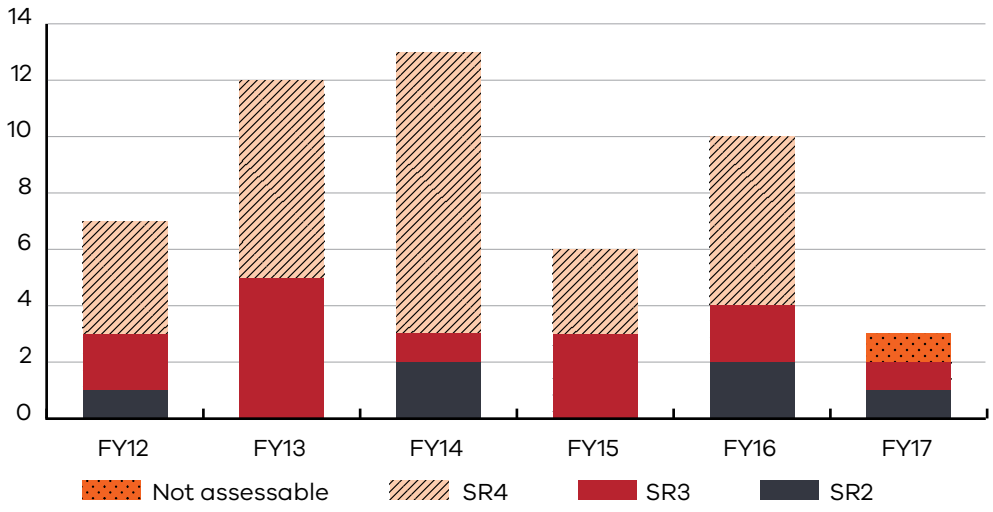
Data summary – validated data Incorrect blood component transfusion, n = 3			
Gender		**Time of transfusion**	
Male:	1	In hours (8 am–8 pm):	1
Female:	2	Out of hours (8 pm–8 am):	2
Age		**Imputability**	
< 1 year:		Certainly:	1
1–18 years:	1	Probably:	–
19–29 years:	–	Possibly:	2
30–49 years:	1	Excluded:	–
50–69 years:	1	Not assessable:	–
70–79 years:	–	**Severity**	
80+ years:	–	SR1: unexpected death or a permanent and disabling injury:	–
Blood product implicated			
Red cells:	2	SR2: temporary loss of function:	1
Platelets:	–	SR3: increased treatment, but no increased length of stay:	1
FFP:	1		
Cryoprecipitate:	–	SR4: no injury or minor requiring only first aid treatment:	–
		Not assessable:	1

Table 12: Types of IBCT events, FY17

Category	Number reported
Antigen-antibody issues	–
Components that did not meet specific requirements for patient	1
Inappropriate platelet/plasma product	1
Inappropriate red cell product	–
Incorrect blood component to incorrect patient: ABO compatible	1
Incorrect blood component to incorrect patient: ABO incompatible	–

The number and types of IBCT events reported (Table 11) is small this year and reflects an overall decrease in the total number of these events being reported. ABO incompatible transfusions are not reported often, and the last one was ABO incompatible FFP in FY15.

Figure 12: Number of incorrect blood component transfused reports per financial year



Case study 11: Poor communication leading to over-transfusion in infant

A paediatric patient, weighing 8.8 kg, was transfused red cells for severe anaemia.

The health service protocol is to order in mL/kg for children weighing less than 20 kg. There were several orders placed for transfusion from different medical teams looking after the patient. At the same time, there were IV access difficulties and the red cells were unable to be commenced as requested.

Electronic orders were used, and it appears some units were not ordered correctly, for example, the amount to transfuse was missing, and nursing staff either had difficulty seeing the complete order or did not follow up on missing information.

The patient was ordered 11.5 mL/kg of red cells but 27 mL/kg was administered. This took his Hb from pre-transfusion 92 g/L to post transfusion 169 g/L.

The patient was transferred to PICU due to bradycardia and metabolic derangements, including elevated potassium. Treatment included 100 mL venesection, resonium, intravenous fluids and salbutamol. The patient was monitored for signs of stroke. Originally discharge had been planned for the day following the transfusion; however, this was delayed with the patient going home three days later.

Comments

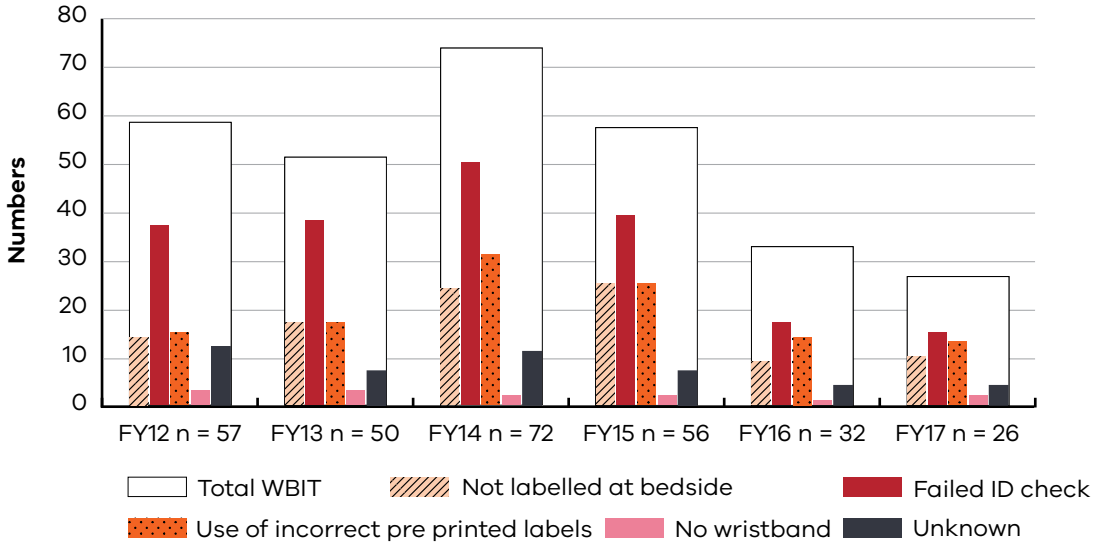
Where electronic systems are in place for ordering or administering blood components, care should be taken to ensure staff know how to use the system correctly and understand that good communication between staff remains paramount.

Wrong blood in tube (WBIT)

Data summary – validated data Wrong blood in tube, n = 26			
Gender		**Time of sample collection**	
Male:	13	In hours (8 am–8 pm):	15
Female:	13	Out of hours (8 pm–8 am):	11
Age		**Urgency of transfusion**	
< 1 year:	2	Emergency:	2
1–18 years:	–	Routine:	20
19–29 years:	4	Unknown:	4
30–49 years:	6	**Location**	
50–69 years:	8	Theatre:	–
70–79 years:	4	Ward:	9
80+ years:	2	ICU:	4
		Ambulatory care:	2
		Emergency department:	3
		Maternity/delivery suite:	8
		Home transfusion:	–
		Other:	–

Wrong blood in tube continues to be the most reported procedural event, with 50 per cent of procedural events falling into this category. The factors contributing to WBIT incidents (Figure 13) remain similar to previous years. Failure of the patient identity check, use of incorrect pre-printed labels, and failure to label specimens at the bedside are the main contributors to these events.

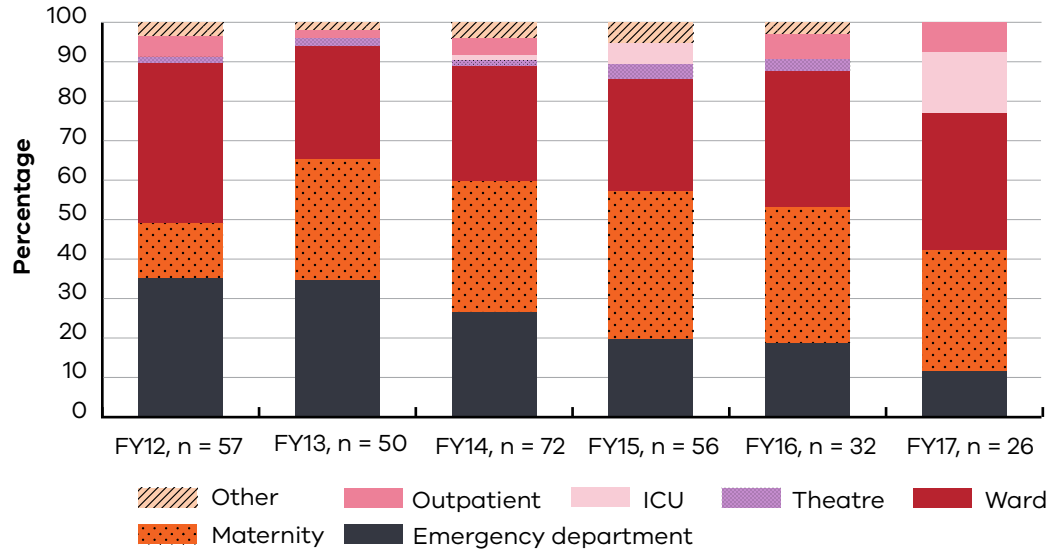
Figure 13: Factors contributing to WBIT incidents (multiple responses per event)



Note: More than one response may be selected per incident. WBIT reporting was changed to exclude mismatch in labelling (zero tolerance) in FY15.

It is pleasing to see a fall in the number of WBIT events associated with the emergency department (Figure 14), however the percentage of events occurring in both maternity and ward areas remains similar to the previous years, with ward areas showing a slight increase.

Figure 14: Where WBIT errors occur



Forty-two percent of WBITs are discovered when the blood group of a sample is found to be different from the patient's historical record (Table 12). This only allows for the recognition of WBIT events when the patient has a historical record at that health service/pathology provider.

Table 13: How the incident was discovered: FY17

Category	Number	Percentage (%)
Recognised prior to testing	8	31%
Discrepancy noted when comparing sample results with historical record	11	42%
Recognised post testing but prior to issue	4	15%
Significant change in MCV compared with prior testing		0%
Recognised post issue but prior to transfusion		0%
Other	3	12%
Total incidents	**26**	**100%**

Case study 12: Patient identification and specimen labelling in patients in isolation/barrier nursed

A patient being nursed in isolation required blood tests, including blood grouping. The nurse caring for the patient wrote up the pathology request, labelling the request with incorrect patient details. The nurse then took samples from the patient. The pathology request form was not compared to the patient identity band at the bedside.

The samples were removed from the room and labelled away from the patient side, comparing samples to request (wrong patient details). The error was found prior to testing, only when it was noted the patient labels were sitting outside the wrong room.

Comments

In all circumstances the patient details on the request must be matched to the patient's stated details and/or identity band. Specimens must not leave the patient side until properly labelled.

Health services must have processes in place for patient identification and specimen labelling that includes what to do in circumstances where patient identification or specimen labelling is difficult, for example, patients in isolation, patients in the operating room.

Case study 13: Use of labels found at bedside for patient identification

Blood specimens including a group and hold were collected from patient A. The collector did not verify patient A's identification at the time, as the collector stated 'there were a lot of people around the patient's bed and the tests were urgent'. The collector labelled the specimen with patient B's details transcribed from patient B's addressograph labels, which the collector found on the work station at the end of patient A's bed.

Comments

A number of reports of either the use of incorrect addressograph labels or transcription from these labels found at the patient bedside have been received by STIR. The use of labels, which are mobile and can easily be placed at the wrong patient side, are not recommended as a substitute for identifying the patient by direct enquiry or via the patient identity band. Fortunately, the error was identified by the laboratory when there was a significant change in FBE results taken the previous day. The transfusion laboratory was alerted to the discrepancy and rejected the group and hold specimen.

Case study 14: Group and hold and other specimens sent to lab with discrepant labelling

A blood bank laboratory received a bag that contained paperwork from patient X and a hand-labelled tube that matched the paperwork. In addition, in the bag were two tubes labelled with addressograph labels from patient Y.

Specimen reception staff spoke to the ward nurse, who confirmed she took patient X's sample, but did not bleed patient Y. The nurse reported not knowing how patient Y tubes got in the bag with patient X paperwork and sample. The nurse advised pathology to proceed with blood group for patient X. Patient Y would require a re-collection. Later, the medical officer called looking for patient Y's results. The medical officer was not aware of the initial problems on receipt of the samples and the need for patient Y re-collection.

Further questioning revealed that a medical student had taken all the bloods for patient X and patient Y. The laboratory cancelled the group and hold for patient X. Testing already performed showed the result to be group A positive. There was no historic group available for this patient but testing of a previous EDTA sample for patient X showed group B positive. Patient Y was confirmed as group A positive on re-collection. The medical student disclosed that he hand-labelled the tube from notes, not from patient wristband or from questioning patient.

Comments

Where there are any discrepancies in the labelling of specimens, all specimens should be rejected. If the error had not been found and patient X had required transfusion, there was serious risk of an ABO incompatible transfusion.

All staff must be educated in both the process of blood taking, as well as the process of patient identification and specimen labelling. An understanding of the risks to the patient should be part of this education.

If students perform tasks such as collecting specimens from patients, they must be supervised during this process.

Case study 15: WBIT picked up two years after bloods taken

A patient had a blood group result of A positive on admission in June 2015, however, when re-admitted in June 2017, the blood group sample showed O positive result. Re-collection confirmed the patient was group O positive, therefore, the initial blood group result in 2015 was a WBIT.

Comments

There may be more WBIT events than reported, because if patients do not attend the health service or require further blood group testing, the original error may not be found.

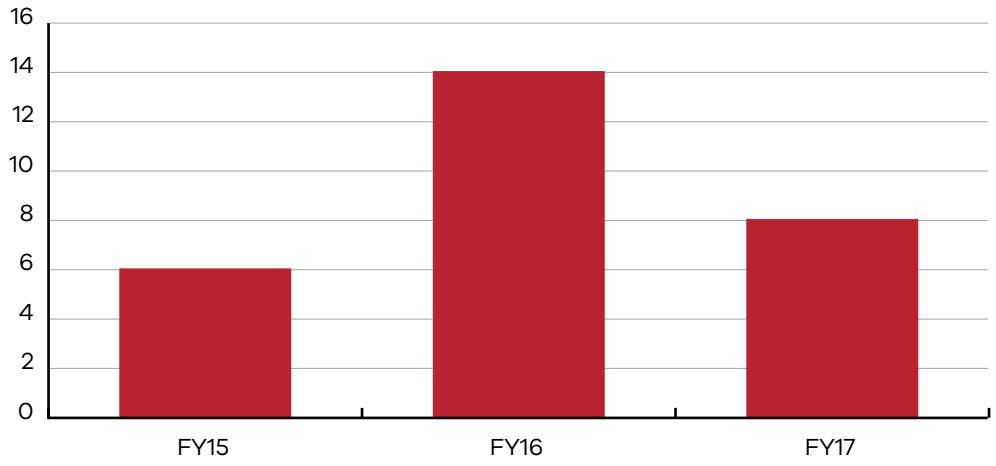
This raises the question of whether all new patients require two separate specimens prior to determination of blood group (as is the practice in some countries).

RhD immunoglobulin administration

Data summary – validated data RhD immunoglobulin, n = 8			
Gender		**Intended administration***	
Male:	–	Antenatal prophylaxis:	5
Female:	8	Sensitising event:	–
Age		Post-natal:	4
< 1 year:	1	**Type of incident**	
1–18 years:	–	Administered, not required (Rh negative mother with Rh negative baby):	1
19–29 years:	2	Administered, not required (Rh positive woman):	1
30–49 years:	5	Administered, not required (woman with immune Anti-D):	–
50–69 years:	–	Rh D dose omitted:	4
70–79 years:	–	Delay in administration (> 72 hours):	–
80+ years:	–	Wrong or inadequate dose:	–
Setting		Storage and handling error (near miss):	–
Hospital:	7	Other: administered to patient instead of Hep B Ig, released to different patient than prescribed:	2
Community:	–		
General practitioner:	–		
Other (private obstetric practice within hospital):	1		

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

Figure 15. Number of RhD immunoglobulin incident reports per financial year



** FY15 contains only six months of data*

The number of reports of RhD immunoglobulin (Ig) incidents this year is relatively small (Figure 15). There is concern that this may under-represent the number of actual incidents that are occurring. Only a small number of health services that provide maternity/obstetric services have reported incidents.

Health services that previously sent reports have not done so in this period after key personnel have resigned and/or not been replaced.

Of concern is that 50 per cent of reports relate to omission of RhD Ig, putting these women at risk of developing an anti-D which could have serious implications for future pregnancies. In the 2017 SHOT report, 426 reports of errors involving RhD Ig were reviewed, of which 327 of 426 (77 per cent) related to omission or late administration of RhD Ig.

It was noted in the SHOT report that there was poor knowledge about indications and delivery of RhD Ig, as well as evidence of a lack of knowledge of basic blood group theory.

Case study 16: RhD immunoglobulin given to baby instead of Hepatitis B immunoglobulin

A baby required hepatitis B immunoglobulin, however the prescription was for immunoglobulin.

The staff members did not refer back to the prescriber to clarify what immunoglobulin, and presumed it was RhD Ig (indicating a lack of knowledge about the indications and use of RhD Ig).

The baby's blood group was B positive and received 625 IU of RhD immunoglobulin.

The baby was monitored for signs of haemolysis following administration. Fortunately, the report did not indicate any problems.

Comments

Education of staff of the reasons for use of RhD Ig and correct and complete prescription of all immunoglobulins, stating type and dose are important to ensure patients receive the correct product. This is not an isolated incident as a similar incident has since been reported at another health service.

Case study 17: Omission of RhD Ig due to incorrect transcription of blood group into the medical record

A woman attending for her first antenatal visit had her blood group transcribed into the medical record as O RhD positive. The external pathology report identified the woman as O RhD negative.

The transcribed blood group was used to identify the woman's blood group at subsequent attendances, and she was not administered RhD Ig in the antenatal period.

At delivery, a blood group and screen were performed, again demonstrating the woman to be O RhD negative. At this time, no antibodies were detected, and the woman was not administered RhD Ig despite the baby being O RhD positive.

The baby required admission to special care nursery, and it was only when the mother queried special care nursery staff why she had not received RhD Ig that the problem was found. The mother was eventually administered a delayed dose nine days post-delivery.

Comments

Transcription errors occur regularly and recording of blood group should only be on the original pathology service documentation. This should always be the source of information for results, not transcribed results.

It is unclear why the woman was not given RhD Ig at the time of delivery, although it may have been overlooked in the need to care for the baby, who required transfer to special care nursery.

Health services should have processes in place to ensure that the need for RhD Ig is not missed despite the circumstance of the birth.

Near miss

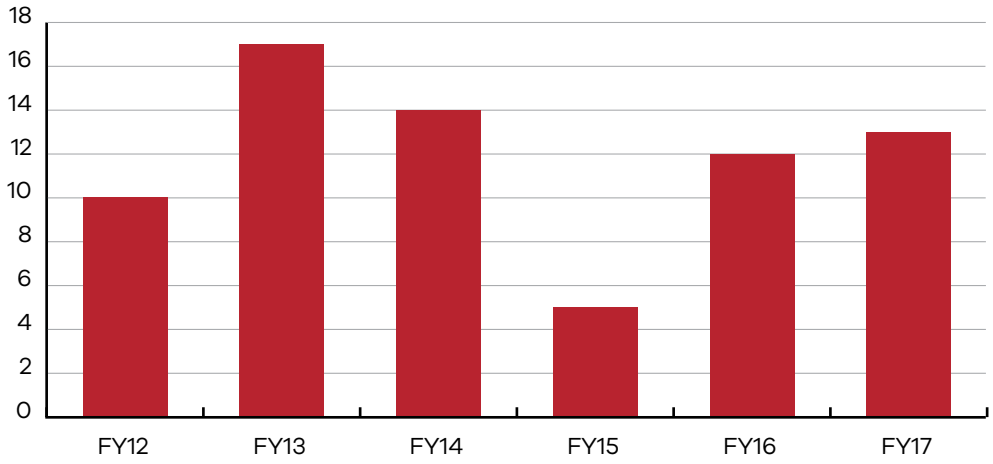
Data summary – validated data Near miss, n = 13			
Gender		**Time of incident***	
Male:	7	In hours (8 am–8 pm):	10
Female:	6	Out of hours (8 pm–8 am):	3
Age		**Urgency of transfusion**	
< 1 year:	1	Emergency:	2
1–18 years:	1	Routine:	10
19–29 years:	–	Unknown:	1
30–49 years:	1	**Location**	
50–69 years:	4	Theatre:	–
70–79 years:	3	Ward:	4
80+ years:	3	ICU:	2
Blood product implicated		Ambulatory care:	–
Red cells:	7	Emergency department:	2
Platelets:	3	Maternity/delivery suite:	–
FFP:	–	Home transfusion:	–
Other:	3	Other (Laboratory)	5

The types of near miss events reported are noted in Table 14.

Table 14: Types of near miss events

Category	Number reported
Inappropriate component issued	1
Labelling/documentation	7
Laboratory	1
Administration	2
Incorrect prescription or request for blood	2
Storage and handling	–

Figure 16: Number of near miss reports per financial year



Near miss reports remain an important aspect of haemogivilance activities. These near misses give health services the opportunity to learn from these errors even when there has been no harm to the patient.

In the 2017 SHOT report, a total of 899 near miss errors were reported that could have resulted in IBCT and 38 per cent of these could have resulted in an ABO-incompatible red cell transfusion. Numbers of reports to STIR are relatively small, with WBIT events being the largest proportion of reports to STIR.

Case study 18: Patient transfused red cells cross matched on another patient's specimen

The incident involved two patients in adjacent ICU cubicles. Patient A had a blood test taken, including group and screen, when being disconnected from dialysis. The dialysis nurse took the specimens and handed them to the ICU nurse, who labelled them.

Patient A was ordered a blood transfusion. Two hours later the nurse rang the laboratory looking for patient A's results. The laboratory could not find specimens for patient A and informed the nurse that if patient A urgently required transfusion a new specimen would be needed.

The nurse took new specimens from patient A and sent them. An hour later the laboratory, expecting the specimens, rang the nurse to see where they were. The nurse was on a break and the nurse from the next cubicle took the call stating she had seen the nurse take and send the specimens. At this point she noted that labels for her patient (patient B) in the next cubicle were sitting by patient A's bed. On enquiring, the laboratory reported receiving specimens for patient B; it became clear that patient A specimens had been incorrectly labelled with patient B labels. All specimen results were cancelled.

Meanwhile, patient B was receiving a transfusion that had been cross-matched against the sample received earlier in the day and which had come from patient A. Fortunately, both patients were group A positive with negative antibody screens.

On both occasions of specimen collection, no one had undertaken positive patient identification, despite the patient being conscious and able to communicate with staff. The assumption was made that labels in the cubicle belonged to the patient. These labels were then used to label both the request form and specimen leading to WBIT.

Cell salvage

Cell salvage has been included in STIR investigations since 2015, however no reports have been made to STIR at this time.

Sentinel events

No sentinel events were reported to STIR for this period.

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.

References

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Appendix 1: Expert group members 2016–17

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

Merrole Cole-Sinclair, Director of Haematology, St Vincent's Hospital, Victoria

Philip Crispin, Consultant Haematologist, Canberra Hospital, Australian Capital Territory

Cindy Flores, Education Coordinator, Blood Matters Program, Victoria (commenced June 2017)

Bridget Glazebrook, Data Manager, Blood Matters Program, Department of Health, Victoria

Clare Hennessy, Transfusion Nurse Consultant, Eastern Health, 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 (resigned June 2017)

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, Head, Transfusion Research Unit Associate Professor, School of Public Health and Preventative Medicine, Monash University, Victoria and Consultant Haematologist, Monash Medical Centre

Adrienne Wynne, Education Coordinator, Blood Matters Program, Victoria (to March 2017) Transfusion Safety Officer, St Vincent Hospital, Victoria (from June 2017)

Anissa Yttrup, Transfusion Clinical Nurse Consultant, Barwon Health, Victoria

Appendix 2: STIR publications and promotions

'Delayed haemolytic transfusion reactions: time for a national registry', poster presented at HAA, November 2016.

'To D or not to D: RhD immunoglobulin incident reporting', poster presented at ISBT, August 2016.

'Patient ID: the consequences of getting it wrong are serious', oral presentation, ISBT, June 2017.

STIR guidelines – updated 2017.

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.

STIR imputability and severity come from Victorian Health Incident Management System (VHIMS) and Department of Health 2012, *Root cause analysis (RCA) education: clinical risk management*.

Appendix 4: STIR history 2006–2017

STIR timeline

2006

- Pilot July–October
- First notification received 18 September 2006
- Nine incident categories

2008

- First STIR report developed and published, covering 1 January 2006 to 31 December 2007
- Four jurisdictions reporting

2011

- Move to electronic notification and report forms

2013

- NSQHS Standard 7: 'Blood and blood products' developed

2014

- Commenced annual reporting of STIR events

2015

- Commenced RhD Ig and cell salvage reporting (1 January 2015)
- Change to WBIT reporting to exclude mismatch in labelling

2017

- Review of all forms
- Commenced reporting of delayed serological transfusion reaction and transfusion associated dyspnoea (1 July 2017)