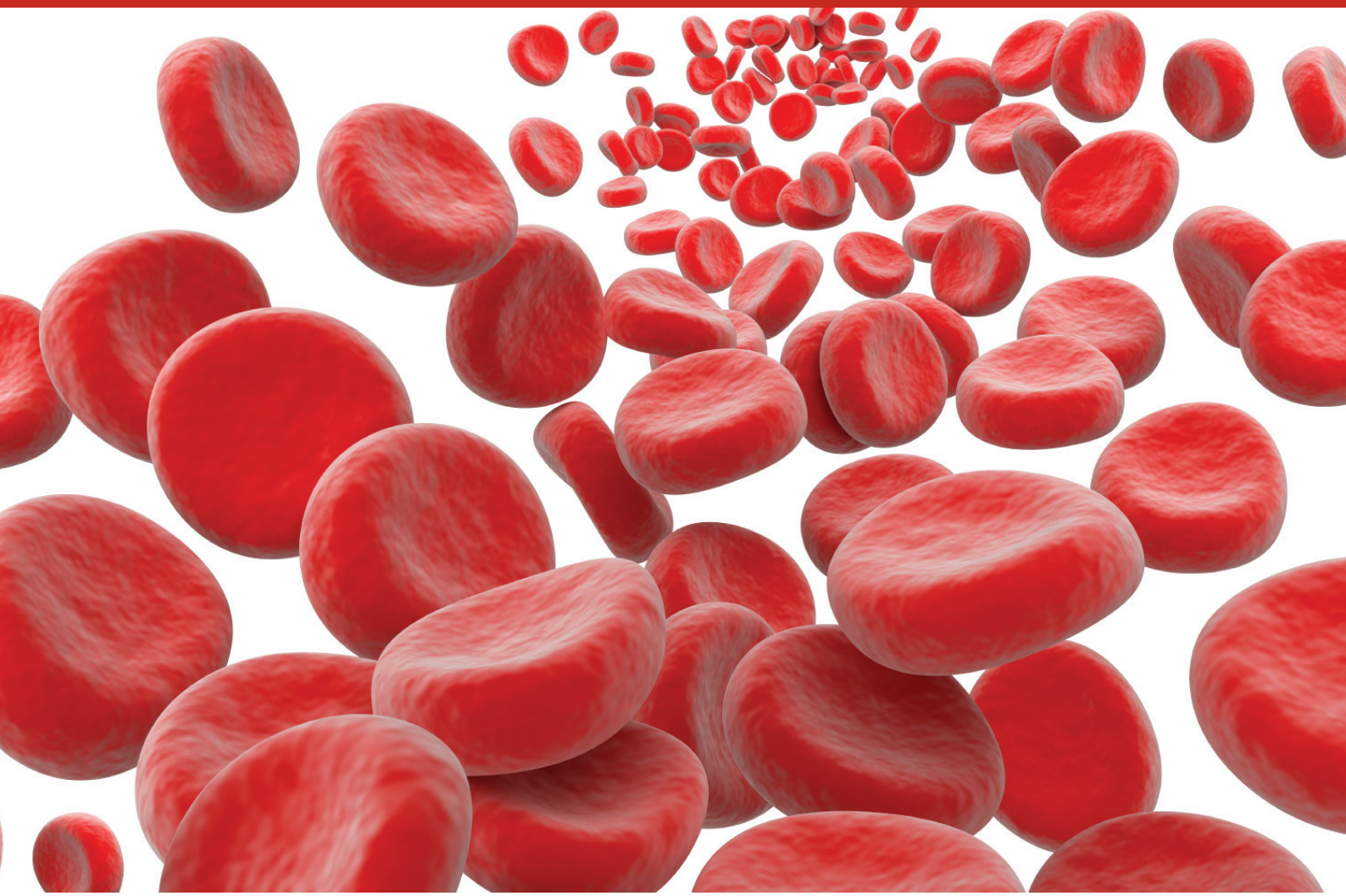
Serious transfusion incident report 2011–13



Department of Health & Human Services

Australian Red Cross BLOOD SERVICE

State Government Victoria

Serious transfusion incident report 2011–2013

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Contents

Abbreviations, acronyms and definitions

AAA	abdominal aortic aneurism
ABO	ABO blood groups
ACT	Australian Capital Territory
ALI	acute lung injury
ANZSBT	Australian and New Zealand Society of Blood Transfusion
ACSQHC	Australian Commission on Safety and Quality in Healthcare
AHTR	acute haemolytic transfusion reaction
ATR	acute transfusion reaction
BRMs	biological response modifiers
CMO	Chief Medical Officer
CMV	cytomegalovirus
CT scan	computerised tomography scan
DAT	direct antiglobulin test
DCT	direct Coombs test
DIC	disseminated intravascular coagulation
DHTR	delayed haemolytic transfusion reaction
Dyspnoea	difficulty breathing
ECMO	extra corporeal membrane oxygenation
ED	emergency department
FBE	full blood examination
FDA	Food and Drug Administration
Fi02	fraction of inspired oxygen
FFP	fresh-frozen plasma
FNHTR	febrile non-haemolytic transfusion reaction
GP	General Practitioner
Hb	haemoglobin (g/L)
HLA	human leucocyte antigen
HNA	human neutrophil antigen
HTR	haemolytic transfusion reaction
Hypotension	low blood pressure
Hypoxia	low oxygen levels in the blood
IAT	indirect antiglobulin test

IBCT	incorrect blood component transfused
ICU	intensive care unit
IV	intravenous
IVIg	intravenous immunoglobulin
LDH	lactate dehydrogenase
LPS	lipopolysaccharide
MCV	mean corpuscular volume
mL	millilitre
NATA	National Association of Testing Authorities
NBA	National Blood Authority
NSQHS	National Safety and Quality Health Service
NT	Northern Territory
PBM	patient blood management
Pa02	arterial partial pressure of oxygen
PTP	post-transfusion purpura
Rh	Rhesus blood group
RCA	root cause analysis
RCNA	Royal College of Nursing, Australia
Serology	the properties and reactions of blood serum
SHOT	Serious Hazards of Transfusion (UK)
Sp02	oxygen saturation
STIR	Serious Transfusion Incident Report
TACO	transfusion-associated circulatory overload
Tachycardia	increase in heart rate
TA-GVHD	transfusion-associated graft-versus-host disease
the Blood Service	Australian Red Cross Blood Service
TRALI	transfusion-related acute lung injury
TTI	transfusion-transmitted infections
URN	unit record number
VAED	Victorian admitted episode data
WBIT	wrong blood in tube

Executive summary

Health services must comply with the new Australian Commission on Safety and Quality in Health Care (ACSQHC) National Safety and Quality Health Service Standards (ACSQHC 2011). Pathology laboratories undergo accreditation with the National Association of Testing Authorities, which completes the regulation loop for blood.

Standard 7 'Blood and Blood Products' includes the requirement for health services to ensure reporting and management of transfusion-related adverse events. Blood Matters collects haemovigilance data and provides recommendations for improved practice through the Serious Transfusion Incident Reporting (STIR) system.

From February 2006 to 30 June, 2013, STIR received 1,207 notifications of transfusion episodes resulting in 1,221 adverse events and incidents, with 55 institutions reporting at least one event.

Fifty-six per cent were associated with red cell transfusion, and acute reactions were the most frequently reported event type (49 per cent of total events). Consequences ranged from no clinical impact to serious adverse events.

Failure of checks and non-compliance with local policy and guidelines accounted for 43 per cent of all events, with 'wrong blood in tube' the most common at 26 per cent and 'incorrect blood component transfused' at seven per cent, including eight ABO group incompatible transfusions.

Failure of correct patient identification was the most common compliance failure for all process-related events, with 244 (20 per cent) cases related to incorrect patient identification.

Safety and quality is integral in transfusion medicine and it is the responsibility of all participants in the transfusion chain to minimise adverse events. Participation in haemovigilance activities and compliance with Standard 7 can help health services provide safer transfusion for their patients.

The STIR de-identified aggregate report provides summary findings, demographics, case studies and recommendations for dissemination of information to health services (for review and action) and the community.

We are pleased to provide the 2011–13 STIR report to assist health services in providing a safe transfusion journey for patients, as well as improving compliance with national standards and guidelines.

We would also like to acknowledge all those who have taken part in the preparation of this report.

Introduction

The Blood Matters program commenced in 2002 as a collaboration between the Victorian Department of Health & Human Services and the Australian Red Cross Blood Service, with the aim of improving clinical transfusion practice. The program introduced voluntary haemovigilance activities to Victorian hospitals (approximately 155 public and private) that undertake transfusion through clinical audit (from 2005), and monitoring of serious transfusion adverse events (from 2006).

STIR uses standard definitions and case report forms for adverse reactions and process-related incidents. All cases are reviewed by a multidisciplinary expert group.

Blood Matters is committed to the national blood stewardship principles (Australian Health Ministers Conference 2010). These principles include collecting and managing transfusion-related adverse event information according to jurisdictional requirements. Further information on the *National stewardship expectations for the supply of blood and blood products* statement can be found at <www.nba.gov.au/policy/stewardship-statement.html#policy/stewardship-statement.pdf>.

Starting in 2013, Victorian public and private health services are accredited against the ACSQHC Standards (ACSQHC 2011), which includes a standard (Standard 7) covering blood and blood products. Further information on the national standards is available at <www.safetyandquality.gov.au/our-work/accreditation/>.

Standard 7, Criteria 7.3 and 7.6 require that:

- blood and blood product adverse events are included in the incidents management and investigation system
- health service organisations participate in relevant haemovigilance activities conducted by the organisation at state or national level
- the clinical workforce documents any adverse reactions to blood or blood products.

These particular criteria in Standard 7, along with the *National stewardship expectations*, all highlight the importance of promoting the safe management of blood and blood products, and participation in haemovigilance programs.

The STIR system complies with the Victorian Department of Health & Human Services privacy policy. Other participating jurisdictions have signed memorandums of understanding that include privacy requirements. No patient names are collected with STIR notifications, reviewers are blinded to the organisations that submit events and only de-identified aggregate data is reported publicly.

This report reviews data from incident and reaction investigations received between 1 July 2011 and 30 June 2013.

Details of number of reports, demographics, imputability, severity and component implicated are tabled with a review of the data.

For each category of event, case studies are presented and information from the Australian Red Cross Blood Service is included to help investigate and manage acute transfusion reactions.

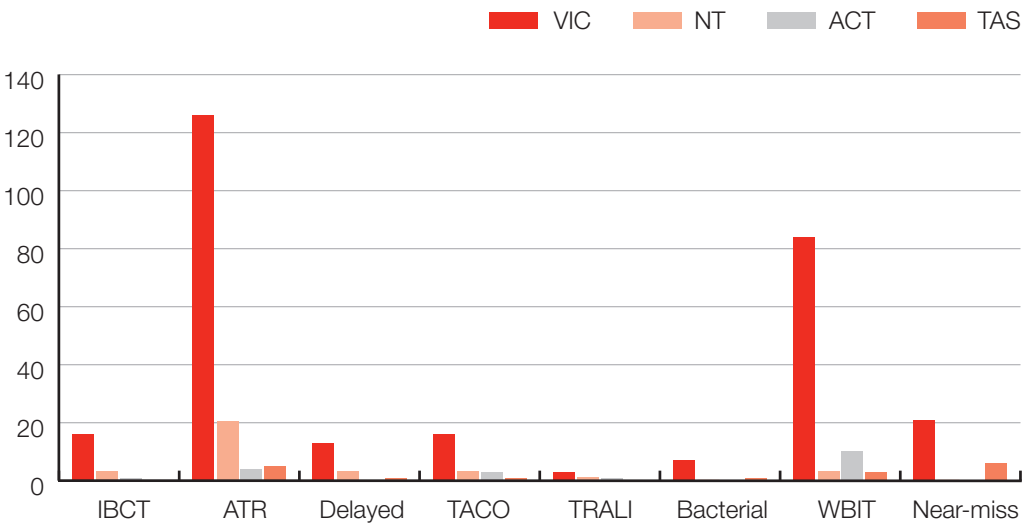
Further information is available at <www.transfusion.com.au//adverse_transfusion_reactions>.

There were 356 reports received from 43 hospitals in four jurisdictions: Victoria, Tasmania, Australian Capital Territory (ACT) and the Northern Territory (NT) (Figure 1) for the report period.

In Victoria those hospitals, public and private, that have agreed to report to STIR represent 90 per cent of the current transfusing hospitals in the state, based on denominator data of Victorian Admitted Episode Data (VAED) transfusion episodes for 2011–13 (Department of Health 2013).

For hospitals currently not reporting to STIR, it cannot be assumed that no transfusion incidents occurred, simply that none were reported during this period.

Figure 1: Jurisdictional STIR reports 2011–13 (event type at notification)



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 the analysis and recommendations of the STIR Expert group.

Issue	Strategies implemented by health service to address the issues	Yes	No	WIP*	N/A#
TACO under-reported and under-recognised; associated with potentially high mortality	Improve monitoring and assessment of at-risk individuals, especially those with pre-existing cardiac failure prior to transfusion				
	Investigate and implement the use of a single-unit guideline for high-risk clinical areas <www.blood.gov.au/single-unit-transfusion>				
Transfusion reactions not investigated	Develop policy or guidelines for transfusion reaction investigations for clinical staff				
	Educate staff on the importance of thorough investigation of a reaction to assist with diagnosis, management and future transfusion requirements				
	Review of transfusion reaction investigations is undertaken by the transfusion committee or equivalent and/or by other relevant positions for example chief medical officer, quality or governance unit				
Patient identification issues with sampling, request and administration	Investigate the use of technology such as 2D barcode scanning for sampling and administration practices for transfusion to reduce patient identification or product errors				
	Develop laboratory guidelines and enforce a ‘zero tolerance’ for non-conforming pre-transfusion specimens on arrival in the laboratory				
	Educate clinical staff and laboratory staff in transfusion practice, using BloodSafe eLearning Australia or local education initiatives <www.bloodsafelearning.org.au>				

WIP: work in progress

NA: not applicable

Method

During 2011–13, the STIR system continued to refine its processes for receiving data from health services to ensure it remains streamlined and accurate.

Notification still occurs via an e-form on the Blood Matters website.

On receipt of the initial e-form, Blood Matters provides the reporting institution with a form relevant to the specific incident type. STIR incidents are classified as either a clinical reaction or a procedural event. On return of the second-level form, the information is imported into a Microsoft Access database for analysis and review. Figure 2 outlines all reports received by STIR per calendar year.

Each report is reviewed by members of the STIR Expert group. The group assesses reports to:

- ascertain alignment with STIR definitions
- review the diagnosis
- attach an imputability (causality) score and a severity score for relevant incident types.

This group also reviews any reported sentinel events involving blood products.

In 2011–13, there were no blood-associated sentinel events reported to STIR.

There was one event reported to the sentinel event program in May 2011, which was reviewed later in 2011. The recommendations from that review are outlined further in this report (under incorrect blood component transfused), as it was not previously reported.

Recommendations from the Expert group are reported back to the sentinel event program and the reporting institution for consideration.

Figure 2: Reports received by STIR 2006–13

Withdrawn reports

During the reporting period, 29 reports (seven per cent) were withdrawn by health services following initial notification.

For example, further investigation may have determined that the transfusion was not implicated in the event. This scenario occurred on six occasions involving initially reported ATR (two), delayed (one), TRALI (two) and WBIT (one).

Health services streamlined processes about what to report to STIR, and so withdrew cases that did not strictly fit criteria or were not serious in outcome.

For example, six FNHTR events were withdrawn by one health service. A further three WBIT events were withdrawn after the investigative process identified they were unlikely to be WBIT events; and two ATR reports were withdrawn due to the low level of severity.

Four reports included products currently not within STIR scope, namely IVIg-Octagam and RhD immunoglobulin. Health services were encouraged to report these events directly to the manufacturers of the implicated products and the Blood Service.

All other withdrawn reports (n = eight) were either duplicates, overdue investigations, or the health service felt they did not have access to sufficient data to complete the investigation. This could be due to an inability to locate a patient's history, delay in pathology results, no pathology tests requested or staff turnover.

Report for 2011–13

In Victoria, public and private health services that have agreed to report to STIR represent approximately 90 per cent of transfusion activity, based on denominator data of VAED (Department of Health 2013) transfusion episodes 2012–13.

This information with total blood issues from Blood Service data assist in providing an estimate of relative risk of clinical reaction, as outlined in Table 2.

Table 1: Total blood issues per jurisdiction (Blood Service data)

Products	Victoria	Tasmania	ACT	NT	Total all jurisdictions
Red Cells	412,453	29,762	27,099	11,320	480,634
Platelets	70,954	6,231	3,300	1,771	82,256
FFP	75,646	5,335	6,192	2,333	89,506
Cryoprecipitate	37,740	4,802	3,361	704	46,607
Total	**596,793**	**46,130**	**39,952**	**16,128**	**699,003**

Source: 2011–13 Australian Red Cross Blood Service, National Reporting Team

Table 2: Frequency of events per product issued (Blood Service data v products v clinical reaction)

Products	Victoria	Events	Frequency
Red cells	412,453	120	1:3,437
Platelets	70,954	39	1:1,819
FFP	75,646	17	1:4,450
Cryoprecipitate	37,740	3	1:12,580

Currently the National Blood Authority (NBA) is coordinating a national data linkage project with blood product use and admitted episode data.

This project will create a national minimum dataset containing blood transfusion activity, blood test results and admitted activity data. Victoria is undertaking the first phase of this project, ascertaining red cell utilisation with 18 hospital pilot sites in Victoria.

We hope that datasets like this will give a clearer picture of the clinical use of blood and, together with haemovigilance data, help to provide a relative risk profile of transfusion.

Types of incidents at notification

There were 356 notifications reported for this period, resulting in 361 adverse events.

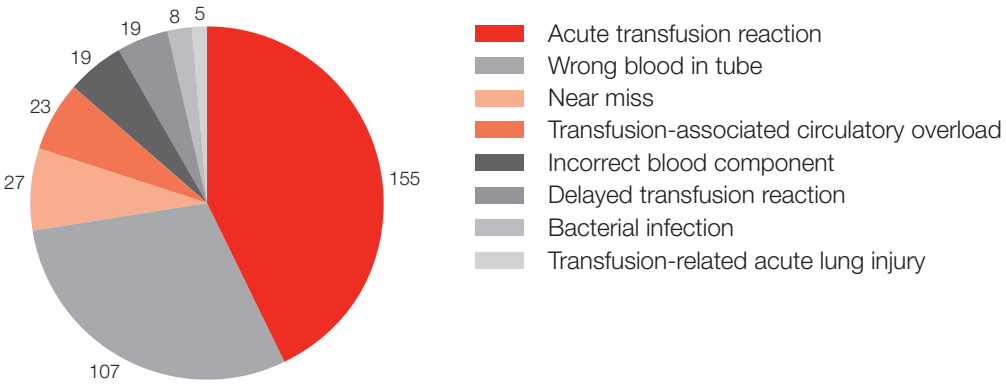
Figure 3 highlights the type of events reported.

One notification report may correspond with more than one category of event as percentages are based on the number of reports returned. There were no reports to the STIR system in 2011–13 of transfusion-associated graft-versus-host disease (TA-GVHD), post-transfusion purpura or viral infection.

The definitions of each category are based on current international definitions for clinical reactions to blood and blood products, sourced from the Serious Hazards of Transfusion *Definition of current SHOT categories and what to report* (2012) and consensus from the STIR Expert group, September 2013.

These are outlined in a revised *STIR guide* (Blood Matters 2013) available through the Blood Matters website <docs.health.vic.gov.au/docs/doc/Blood-Matters-Serious-Transfusion-Incident-Reporting-guide-2013>.

Figure 3: STIR notifications



Events can be reported as confirmed or suspected, that is awaiting further test results or an ongoing investigation. In 2011–13, 198 reports notified to STIR were confirmed with 163 suspected at time of reporting.

Red cells continue to be the most commonly implicated blood product (Table 3).

Table 3: Types of blood products implicated at notification [product data]

Products	Count	%
Red Cells	171	48%
Other*	102	29%
Platelets	38	11%
Fresh frozen plasma	26	7%
Cryoprecipitate	2	1%
Multiple products^	17	5%

* Other includes all events involving pre-transfusion specimens
^ One event may have involved multiple components

Event demographics

Acute transfusion reactions continues to be the largest dataset for STIR (ATR, n = 155, 43 per cent of all reports).

The most common clinical areas to report acute reactions, including TACO, were general wards.

Critical care areas such as intensive care units (ICU) and emergency departments (ED) reported most cases of suspected TRALI which aligns with a theory that TRALI occurs more often in patients who are often acutely unwell or 'primed' for the acute lung injury.

Eighty-two per cent of all reported ATR occurred between 8 am and 8 pm (core hours), while 11 per cent occurred between 8 pm and midnight and a further six per cent between midnight and 8 am (8 pm–8 am, out of core hours).

Best practice highlights that elective transfusions should not occur out of core hours, when there is greater risk to patients because wards are poorly illuminated and fewer staff are available to monitor the transfusion (SHOT 2008).

Seventy per cent of procedural error-related events (IBCT, near miss, WBIT) occurred during core hours, with 30 per cent occurring out of core hours.

Incorrect blood component transfused (IBCT) category (total 19) originated out of the laboratory 20 per cent of all IBCT reports, the general ward and ED were the two most common clinical areas to have a procedural error with an IBCT.

Wrong blood in tube (WBIT) (total 107) was prominent in three clinical areas, general ward (n = 37, 35 per cent), ED (n = 37, 35 per cent) and maternity services (n = 23, 21 per cent). This data continues to highlight an ongoing concern with the collection of pre-transfusion samples, although an improvement in maternity services is encouraging.

Patient blood management (PBM) is the management and preservation of patients' own blood to reduce or avoid the need for a blood transfusion.

The aim of PBM is to improve outcomes for each patient by minimising or avoiding unnecessary exposure to blood. In 2012–13 the NBA released *Patient blood management: module 3 – medical* and *Patient blood management: module 4 – critical care*.

These modules cover specific transfusion recommendations for patients who are critically ill, with kidney disease, cardiac disease, gastroenterology, haematology and oncology diseases. These specialities often use multiple blood products for patient management.

During 2011–13, there were 165 events reported to STIR that involved critical care patients (20 adverse events occurring within ICU) and medical patients (145 adverse events occurring on the ward or day wards).

The implementation of the PBM guidelines may assist in reducing unnecessary exposure, thus reducing potential adverse events and improving outcomes for these groups of patients.

Patient demographics

Fifty-seven per cent of reported events involved female patients. Patient age ranged from one day to 98 years (mean 53 years), with 10 per cent of events involving patients of 18 years or less.

Diagnoses

The STIR Expert group amended the reported category of events following review on 36 occasions with 20 excluded as a transfusion adverse event. All others were reclassified.

Health services amended their initial notification on one occasion. An amendment occurs either because of new evidence or because the evidence and information provided indicates it would fit more correctly into another category.

Outcomes

Health services highlight patient outcomes in cases reported as acute and delayed reactions, IBCT, suspected bacterial contamination, TACO and TRALI.

In this report a higher percentage of events requiring an extended length of stay and causing minor morbidity was seen (Table 4) compared with previous reports.

However, this may be a reflection of better alignment with STIR definitions by health services rather than the adverse events causing more harm.

Table 4: Patient outcomes reported at notification

Patient outcomes	Reports
Full recovery with minor morbidity or requirement for extended length of stay	151
Full recovery with no ill effects	70
Died*	9

* Death attributable to other causes in all cases

Review by health services

In all the previous reports STIR has recommended that all events reported should be reviewed by either the hospital transfusion committee or equivalent, or by the chair of the committee, or a senior medical officer outside of normal meeting times.

This ensures good governance and assists hospitals to meet National Standard 7.3.2: adverse blood and blood product incidents are reported to and reviewed by the highest level of governance in the health service organisation. In 2011–13, 90 per cent (n = 319) of events had been reviewed or scheduled to be reviewed by the transfusion committee.

In addition, another four per cent were reviewed by the chief medical officer or hospital clinical governance unit. There were no plans to review six per cent of events reported.

STIR also encourages the involvement of the hospital quality team to ascertain system-wide deficits and implement hospital-wide process change.

Imputability and severity

In 2007, the STIR Expert group introduced a process of attributing event imputability (causality) and severity scoring.

This followed careful consideration of the applicability of the STIR definitions to incident types, and enables a validation step of the data presented to STIR. For near-miss events, a potential severity is attributed.

The definitions used for all events other than near miss and wrong blood in tube (WBIT) were developed using the Department of Health & Human Services's 'Root cause analysis (RCA) education: clinical risk management' training program (see Tables 5 and 6).

Table 5: Imputability/causality rating

Imputability/causality	
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

Table 6: Severity rating

Severity	Incident
1	Relatively infrequent, clear-cut events that occur independently of a patient's condition; commonly reflect hospital 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

Source: Department of Health 2012

Acute transfusion reaction

Data summary	
Category	Acute transfusion reaction
	Total number of events: 137
Gender	Male: 65
	Female: 72
Age	< 1 year: 0
	1–18 years: 17
	19–29 years: 11
	30–49 years: 31
	50–69 years: 47
	70–79 years : 14
	80+ years: 17
Time of transfusion	In hours : 111
	Out-of-hours: 21
	Missing data: 5
Imputability	Certainly: 21
	Probably: 72
	Possibly: 35
	Excluded: 1
	Not assessable: 8
Severity	SR1: 1
	SR2: 19
	SR3: 38
	SR4: 73
	Not assessable: 6
Blood product implicated	Red cells: 88
	Platelets: 28
	FFP: 16
	Cryoprecipitate: 0
	Other: 5

This category includes reactions occurring at any time during a transfusion or up to 24 hours after a transfusion of fresh blood or blood products, This excludes cases of acute reactions known to be due to IBCT (Blood Matters 2013).

This category includes allergic reactions, febrile non-haemolytic transfusion reactions (FNHTR) and acute haemolytic transfusion reactions (AHTR). TACO and TRALI are reported separately.

This category received 155 notifications. After validation, 137 events were confirmed. One event was reclassified as TRALI, and the remaining events (n = 17) were not identifiable.

Allergic reactions

The most commonly reported event in this category was allergic, including anaphylactic, reactions (n = 61, 45 per cent). In this reporting period there were more severe allergic or anaphylactic reactions than in previous reports (n = 27, 81 per cent of all allergic reports).

As previously noted this probably reflects improved reporting from health services rather than more harmful events.

For the severe/anaphylaxis category, there must be multiple symptoms present requiring polypharmacy treatment, including adrenaline and/or increased length of stay or level of care.

Table 7: Allergy severity

Allergy type	Number
Mild – single symptom or single drug treatment (other than adrenaline) required	18
Moderate – multiple symptoms with polypharmacy treatment not including adrenaline	24
Severe – multiple symptoms with polypharmacy treatment including adrenaline and/or increased length of stay or level of care	11
Anaphylaxis – as above for severe allergy including severe hypotension or cardiac arrest	8
Total	**61**

Case study

A young female patient with severe anaemia and suspected haemolytic uremic syndrome was receiving therapeutic plasma exchange with cryo-depleted plasma. Within a minute of commencing the transfusion the patient developed restlessness, anxiety, itching rash, nausea and vomiting and was found to have hypotension, tachycardia and febrile more than 1.5° C above baseline.

The patient was severely distressed and an emergency call was undertaken. The patient was managed by the resuscitation team and admitted to intensive care due to the reaction.

The patient required ongoing plasma exchange and during the next treatment experienced a further allergic response fortunately milder than the initial reaction. However there was no evidence the hospital investigated IgA levels or tryptase levels, which may have been useful in planning future exposure to blood and blood products.

Australian Red Cross Blood Service advice:

Severe allergic reactions

When to suspect these adverse reactions?

Reactions usually begin within 1 to 45 minutes after the start of the transfusion. Patients present with a sudden onset of severe hypotension, cough, bronchospasm (respiratory distress and wheezing), laryngospasm, angioedema, urticaria, nausea, abdominal cramps, vomiting, diarrhoea, shock and loss of consciousness. This may be a fatal reaction.

This occurs in 1:20,000 to 1:50,000 of transfusions. (Roback 2011; Callum et al. 2011).

Usual causes?

Anaphylactic transfusion reactions can occur when IgE antibody in the patient interacts with an allergen, usually a plasma protein in the blood component.

The following mechanisms have been implicated in anaphylactic reactions:

- IgA-deficient patients who have anti-IgA antibodies
- Patient antibodies to plasma proteins (such as IgG, albumin, haptoglobin, transferrin, C3, C4 or cytokines)
- Transfusing an allergen to a sensitised patient (for example, penicillin or nuts consumed by a donor)
- Rarely the transfusion of IgE antibodies from a donor to an allergen present in the recipient.

Investigation

Anaphylaxis usually has a typical clinical presentation. Occasionally the differential diagnosis is acute haemolysis. Direct antiglobulin test (DAT), blood count and repeat ABO grouping may be indicated. Check the recipient's pretransfusion sample for IgA deficiency and presence of anti-IgA antibodies.

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What to do?

Stop transfusion immediately and follow other steps for managing suspected transfusion reactions. This may become a medical emergency. Maintain open airway and intravenous line, support blood pressure. Administer supplemental oxygen, antihistamines, adrenaline and corticosteroids as required, resuscitation may also be necessary.

Consult a haematologist before administering additional blood packs. To prevent recurrent anaphylaxis the following options may be considered:

- pre-medication with steroids and antihistamine.

If patient is IgA deficient with anti-IgA, the use of IgA-deficient or washed blood components is recommended.

Source: Australian Red Cross Blood Service available from <www.transfusion.com.au//adverse_transfusion_reactions>.

Febrile non-haemolytic transfusion reactions

Febrile non-haemolytic transfusion reactions (FNHTR) (39 per cent, n = 59) was the second largest dataset in the acute transfusion reaction category.

The FNHTR definition includes one or more of the following: chills/rigor, headache, nausea and vomiting, including fever > 38.5° C or > 1.5° C above baseline during or within four hours of the completion of the transfusion and excludes any other identifiable cause such as infection, or haemolytic transfusion reaction (Blood Matters 2013).

Case study

A chronically transfused patient presented for their red cell transfusion.

Two hours after commencing the transfusion the patient developed fever, rigors, back pain, headache, nausea and vomiting, hypotension and tachycardia.

The transfusion was ceased, the patient was medically managed and no increase in care was required.

The health service diagnosed it as a probable febrile non-haemolytic transfusion reaction and STIR Expert review agreed.

Australian Red Cross Blood Service advice:

Febrile non-haemolytic reaction

When to suspect this adverse reaction?

Patients present with an unexpected temperature rise (≥38ºC or ≥1ºC above baseline, if baseline ≥37ºC) during or shortly after transfusion.

This is usually an isolated finding. Occasionally the fever is accompanied by chills.

Chills, rigors, increased respiratory rate, change in blood pressure, anxiety and a headache may accompany this reaction but occur in several more serious transfusion reactions also, the most serious being acute haemolytic reaction, transfusion associated sepsis and TRALI.

FNHTR is a diagnosis of exclusion.

This occurs in 0.1% to 1% of transfusions with leucocyte depletion (Roback 2011).

Usual causes?

Cytokine accumulation during storage of cellular components (especially in platelet units) is thought to be the most common event leading to symptoms of FNHTRs.

Cytokines are released by white cells and pre-storage leucodepletion has reduced this risk.

FNHTR is also caused by the presence of recipient antibodies (raised as a result of previous transfusions or pregnancies) reacting to donor human leucocyte antigens (HLA) or other antigens.

These antigens are present on donor lymphocytes, granulocytes, or platelets.

Investigation

Clinically assess the transfused patient for fever, chills, rigors and headache.

Acute haemolytic reaction may need exclusion.

Direct antiglobulin test (DAT), blood count and repeat ABO grouping may be indicated.

Consider investigations for transfusion associated sepsis.

In patients with repeated FNHTR, investigation for HLA antibodies may be useful.

What to do?

Stop transfusion immediately and follow other steps for managing suspected transfusion reactions. Treat the fever with an antipyretic. However, avoid aspirin in thrombocytopenic and paediatric patients.

Consider and exclude other causes, as fever alone may be the first manifestation of a life threatening reaction.

Rule out acute haemolytic reaction, transfusion associated sepsis and Transfusion-related acute lung injury (TRALI).

Recommencement of the transfusion, at a slow rate, is possible if other causes of a fever have been excluded.

Source: Australian Red Cross Blood Service available from <www.transfusion.com.au//adverse_transfusion_reactions>.

Acute haemolytic transfusion reactions

Acute haemolytic reactions were reported on five occasions.

Case study

A patient presented with anaemia and infective endocarditis.

Near the end of the transfusion of a red cell unit, the patient developed fever, chills and tachycardia, and an investigation was commenced.

The post-transfusion serological compatibility test highlighted a missed antibody that was not detectable on screening cells but evident on panel at post-transfusion.

The antibody detected was anti-Cob but unfortunately the unit was not available for testing to determine crossmatch compatibility. This rare antibody had been implicated in mild haemolytic transfusion reactions in international literature (Poole 2007).

Australian Red Cross Blood Service advice:

Acute haemolytic reaction

When to suspect this adverse reaction?

It characteristically begins with an increase in temperature and pulse rate. Symptoms may include chills, rigors, dyspnoea, chest and/or flank pain, discomfort at infusion site, sense of dread, abnormal bleeding and may progress rapidly to shock. Instability of blood pressure is frequently seen. Transfused patients develop oliguria, haemoglobinuria and haemoglobinaemia.

In anaesthetised patients, hypotension and evidence of disseminated intravascular coagulation (DIC) may be the first sign. This may be a fatal reaction.

Usual causes?

Acute haemolytic transfusion reactions occur at an incidence of 1:76,000 transfusions (1) and may be associated with:

- ABO/Rh mismatch
- Red cell alloantibodies (non-ABO) as a result of patient immunisation from previous pregnancy or transfusion
- Rare cases when Group O donor platelets with high titres of anti-A and/or anti-B are transfused to a non-Group O recipient

There is immunologic destruction of transfused red cells, due to incompatibility of antigen on transfused cells with antibody in the recipient circulation.

The most common cause is transfusion of ABO/Rh incompatible blood due to clerical errors or patient identification errors such as improper labelling of samples, administering blood to the wrong patient or testing errors. As little as 10 mL of incompatible blood can produce symptoms of an acute haemolytic reaction. ABO/Rh incompatibility occurs in about 1:40,000 transfusions.[1]

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Another cause of this type of transfusion reaction can be the presence of red cell alloantibodies (non-ABO) in the patient's plasma which have not been previously identified. Occasionally a patient may have an antibody at levels below the detection capabilities of the antibody screening method or a clerical error occurs in the labelling of patient samples. Rarely is it caused by emergency uncrossmatched blood being given to an alloimmunised patient.

Investigation

Clinically assess patients for common features of haemolysis occurring within 4 hours of transfusion. Check clerical records, such as ABO typing of patient and unit. Repeat patient ABO grouping in both pre- and post-transfusion samples. Perform Direct Antiglobulin Test (DAT) and Indirect Antiglobulin Test (IAT), renal function, and tests for haemolysis (eg, serum haptoglobulin).

What to do?

Stop transfusion immediately and follow other steps for managing suspected transfusion reactions. Seek urgent medical assistance. Maintain blood pressure and renal output. Induce diuresis with intravenous fluids and diuretics. This may become a medical emergency so support blood pressure and maintain an open airway.

Do not administer additional blood packs until cleared by haematologist or Transfusion Service Provider.

Source: Australian Red Cross Blood Service available from <www.transfusion.com.au//adverse_transfusion_reactions>.

Transfusion-associated circulatory overload

Data summary	
Category	Transfusion-associated circulatory overload
	Total number of events: 19
Gender	Male: 8
	Female: 11
Age	< 1 year: 0
	1–18 years: 2
	19–29 years: 1
	30–49 years: 2
	50–69 years: 1
	70–79 years: 5
	80+ years: 8
Time of transfusion	In hours: 9
	Out of hours: 10
Imputability	Certainly: 1
	Probably: 9
	Possibly: 9
	Excluded: 0
	Not assessable: 0
Severity	SR1: 0
	SR2: 1
	SR3: 16
	SR4: 2
	Not assessable: 0
Blood product implicated	Red cells: 19
	Platelets: 0
	FFP: 0
	Cryoprecipitate: 0

Events of transfusion-associated circulatory overload (TACO) are confirmed by any four of the following occurring within six hours of transfusion (Blood Matters 2013):

- acute respiratory distress
- tachycardia
- increased blood pressure
- acute or worsening pulmonary oedema evident on chest X-ray
- evidence of positive fluid balance.

There were 21 reports of TACO that were classified by health services at initial notification, three reports were excluded by the review group; and one transfusion-transmitted infection (TTI) was reclassified to TACO.

This is an increase from previous reporting and fits with international data that demonstrates more cases of TACO are being recognised and reported. The Food and Drug Administration reports that in the US in 2011, TACO was the second most common cause of death related to transfusion (Alam et al. 2013).

Identification of individuals who are at risk is key to preventing its occurrence and ensuing that each transfusion is appropriate for the individual. Those at risk are the very young, the elderly and patients with existing cardiac dysfunction, renal impairment and/or hypoalbuminaemia.

Thorough assessment of the patient prior to commencing the transfusion, vigilant monitoring during the transfusion episode, slowing the transfusion rate if possible and also minimising the volume to be infused may all help to prevent TACO.

The NBA has recently released guidance on the development of a single-unit transfusion policy and how-to guide to apply this at your health service. The introduction of single-unit transfusions may be a valuable improvement to reduce the incidence of TACO in certain clinical situations.

Further information is available here: <www.blood.gov.au/single-unit-transfusion>.

Case study

A paediatric patient in sickle cell crisis was admitted for a red cell exchange.

One unit of red cells was administered and at the end of the transfusion the patient developed reduced oxygen levels and difficulty breathing at a rate of 50 breaths per minute.

The patient was managed with oxygen and diuretics and a chest X-ray confirmed acute pulmonary oedema.

In the preceding 24 hours the patient had received multiple blood and blood products, which may have contributed to the circulatory overload.

Australian Red Cross Blood Service advice:

Transfusion-associated circulatory overload (TACO) reaction

When to suspect this adverse reaction?

The clinical features of TACO can include dyspnoea, orthopnoea, cyanosis, tachycardia, increased blood pressure and pulmonary oedema and may develop within 1 to 2 hours of transfusion. Patients over 60 years of age, infants and severely anaemic patients are particularly susceptible (Roback 2011; Callum et al. 2011).

TACO occurs in less than one per cent of patients receiving transfusions (Roback 2011).

Usual causes?

This is usually due to rapid or massive transfusion of blood in patients with diminished cardiac reserve or chronic anaemia.

Investigation

TACO is frequently confused with TRALI as a key feature of both is pulmonary oedema and it is possible for these complications to occur concurrently.

Hypertension is a constant feature in TACO whereas it is infrequent and transient in TRALI.

Perform a chest X-ray and if septal lines, cephalisation and enlarged vascular pedicles (> 65 mm) are present, these findings are more consistent with circulatory overload (Benson, Moss and Sillman 2009).Clinically assess patients for distended neck veins, S3 murmur on cardiac examination and peripheral oedema as these are also consistent with circulatory overload.

What to do?

Stop transfusion immediately and follow other steps for managing suspected transfusion reactions.

Place the patient in an upright position and treat symptoms with oxygen, diuretics and other cardiac failure therapy.

In susceptible patients at risk for TACO (paediatric patients, patients with severe anaemia and patients with congestive heart failure), transfusion should be administered slowly and consideration given to use of a diuretic.

Source: Australian Red Cross Blood Service available from <www.transfusion.com.au//adverse_transfusion_reactions>.

Transfusion-related acute lung injury

Data summary	
Category	Transfusion-related acute lung injury
	Total number of events: 1
Gender	Male: 1
	Female: 0
Age	< 1 year: 0
	1–18 years: 0
	19–29 years: 0
	30-49 years: 0
	50–69 years: 0
	70–79 years: 1
	80+ years: 0
Time of transfusion	In hours: 0
	Out of hours: 1
Imputability	Certainly: 0
	Probably: 0
	Possibly: 1
	Excluded: 0
	Not assessable: 0
Severity	SR1: 0
	SR2: 0
	SR3: 1
	SR4: 0
	Not assessable: 0
Blood product implicated	Red cells: 1
	Platelets: 0
	FFP: 0
	Cryoprecipitate: 0

TRALI is a clinical diagnosis; it may be immune or non-immune. Serological confirmation is not required for diagnosis.

The *STIR guide* (Blood Matters 2013) defines clinical TRALI features as:

- acute respiratory distress with hypoxia
- bilateral pulmonary infiltrates, evidenced on radiology imaging, occurring during or within 24 hours of transfusion, with no other apparent cause of acute lung injury (ALI)
- no evidence of TACO.

There were five reports of suspected TRALI reported to STIR in 2011–13. Following expert review, all cases were reclassified to acute haemolytic reaction (one), TACO (two), or other causes (two). However, one case submitted as an ATR was re-categorised to TRALI following review.

As TRALI remains the leading cause of transfusion-related mortality in both the United Kingdom (SHOT 2012) and the USA (FDA 2012), the Blood Service takes action to reduce the risk of TRALI.

One research group in Queensland is undertaking important research in this area, and the following information has been provided by Dr John-Paul Tung, Research Fellow for the Blood Service.

TRALI is a frequent cause of transfusion-related morbidity and mortality (FDA 2012, SHOT 2012). It is diagnosed clinically by the development of hypoxaemia ($PaO_2/FiO_2 < 300$ or $SpO_2 < 90$ per cent on room air) and pulmonary oedema (bilateral infiltrates on chest radiograph) either during or within six hours of transfusion (Klienman et al. 2004).

While the mechanism(s) by which TRALI develops remain to be fully elucidated, current evidence indicates a two event mechanism (Silliman 2006). The first event is the underlying clinical condition of the patient, which results in pulmonary endothelial activation and accumulation of primed adherent neutrophils in the lungs.

The second event is the transfusion of blood products which induce activation of the primed neutrophils resulting in the release of reactive oxygen species and enzymes that damage the lungs resulting in TRALI.

It is hypothesised that the type, strength or concentration of the patient and blood product factors must together overcome an activation threshold for TRALI to develop (Bux and Sach 2007).

Two classes of factors in blood products may cause TRALI: either antibodies directed against patient leucocytes, or what are collectively termed biological response modifiers (BRMs).

The antibodies may be directed against human neutrophil antigens (HNA), or human leucocyte antigens (HLA) class I or class II. Collectively, these antibodies previously accounted for approximately three-quarters of TRALI cases (Middleburg et al. 2008).

However these anti-HNA and anti-HLA antibodies are more frequently reported, and in higher concentrations, in multiparous women which formed the basis of successful TRALI risk-reduction strategies, such as the preparation of clinical plasma either exclusively or predominantly from male donors (Triulzi et al. 2009)

BRMs accumulate during routine storage of cellular blood products, and take the form of bioactive lipids (such as lyso-phosphatidylcholines, arachidonic acid and hydroxyeicosotetranoic acids) and proteins (such as soluble CD40 ligand and cytokines) (Reesink et al. 2012). However, the identities of specific BRMs and the precise mechanisms by which they mediate the development of TRALI need to be determined before we can develop suitable risk-reduction strategies for this form of TRALI.

Research is ongoing, particularly into BRM-mediated TRALI. Of particular note is the research being undertaken in Australia by a collaboration between the Australian Red Cross Blood Service and the Critical Care Research Group of the Prince Charles Hospital and the University of Queensland. This group reported the first large animal model of TRALI using a sheep model of BRM-mediated TRALI (Tung et al. 2012, Tung et al. 2011).

In this model, TRALI developed via a two-event mechanism, with the first event being lipopolysaccharide (LPS) as a model of bacterial infection, and the second event being the transfusion of the soluble fraction of date-of-expiry human blood products (either day-five platelets or day-42 red cell concentrates).

This model was unique in that it was the first time that TRALI had been defined in an animal model by the development of both hypoxaemia and pulmonary oedema, as occurs clinically.

An advantage of a large animal model of TRALI is the level of sophisticated monitoring that can be undertaken, and this model recorded respiratory and haemodynamic function continuously throughout the experiments.

Comparison of this data between sheep that developed TRALI due to transfusion of the soluble fraction of either day-42 red cell concentrates or of day-five platelets showed that more severe changes were associated with the former.

Ongoing work by this group is investigating the role that leucodepletion may have played in TRALI incidence, as well as the role of various potential BRMs.

That BRMs may be related to storage has led to further research by this group into the possible association between age of transfused blood products and poor clinical outcomes, including TRALI, in sheep transfusion models in the settings of haemorrhage, haemorrhage followed by trauma, sepsis and smoke-induced acute lung injury followed by extracorporeal membrane oxygenation.

Case study

Suspected TRALI cases are often complex and difficult; the following case outlines this complexity.

A female patient presenting with a stroke developed worsening anaemia during admission and was appropriately managed with red cell transfusions. During transfusion of one unit the patient developed dyspnoea, restlessness, anxiety, tachycardia and decreased oxygen saturation.

The patient required ventilation and admission to intensive care for ongoing care. The patient's blood bank investigation was complicated by detection of cold agglutinins, though no red cell alloantibodies were identified and all red cell transfusions were compatible. A haemolytic transfusion reaction was excluded but further testing was not able to conclusively differentiate between TACO and TRALI. Multiple STIR reviewers agreed there could be a possibility of TRALI but could not rule out other causative factors.

Australian Red Cross Blood Service advice:

Transfusion-related acute lung injury

When to suspect this adverse reaction?

Acute onset of fever, chills, dyspnoea, tachypnoea, tachycardia, hypotension, hypoxaemia and noncardiogenic bilateral pulmonary oedema leading to respiratory failure during or within six hours of transfusion.

TRALI has been implicated in transfusion of unfractionated plasma-containing components (red cells, platelets and plasma).

Its incidence is variably reported between 1:1,200 to 1:190,000 transfusions (Roback 2011), with estimates around 1:10,000 most commonly reported. TRALI is thought to be the most common cause of transfusion-associated fatalities (Callum et al. 2011).

Usual causes?

The most widely held pathogenesis theory is that human leucocyte antigen (HLA) or human neutrophil antigen (HNA) antibodies found in the donor's plasma are directed against the recipient's leucocyte antigen.

The antigen–antibody reaction activates neutrophils in the lung microcirculation, releasing oxidases and proteases that damage blood vessels and make them leak. Biological response modifiers, such as biologically active lipids can accumulate in some cellular components during storage and may also induce TRALI in susceptible patients (Callum et al. 2011).

Investigation

TRALI has many clinical features in common with fluid overload or cardiogenic pulmonary oedema and careful clinical assessment is required.

Acute haemolytic reaction or transfusion-associated sepsis may have similar initial clinical findings. Direct antiglobulin test (DAT), blood count and repeat ABO grouping may be indicated.

continued…

Once TRALI is clinically suspected, test the donor and recipient serum for HLA and HNA antibodies and perform an HLA type on the recipient as demonstration of these antibodies supports diagnosis. TRALI testing is specialised and contact with the Blood Service is necessary. Chest X-ray will show bilateral interstitial infiltrates.

What to do?

Stop transfusion immediately and follow other steps for managing suspected transfusion reactions.

Provide cardiovascular and airway support. Administer supplemental oxygen and employ ventilation as necessary. Diuretics are not beneficial. This may become a medical emergency; support blood pressure and maintain an open airway.

Notify your Transfusion Service Provider to contact the Blood Service so we can quarantine and test related components from the same donor and prevent TRALI in other recipients.

Source: Australian Red Cross Blood Service available from <www.transfusion.com.au/adverse_transfusion_reactions>.

Delayed haemolytic transfusion reaction

Data summary	
Category	Delayed haemolytic transfusion reactions
	Total number of events: 15
Gender	Male: 2
	Female: 13
Age	< 1 year: 0
	1–18 years: 1
	19–29 years: 1
	30–49 years: 2
	50–69 years: 6
	70–79 years: 2
	80 years: 3
Time of transfusion	In hours: 12
	Out of hours: 3
Imputability	Certainly: 11
	Probably: 4
	Possibly: 0
	Excluded: 0
	Not assessable: 0
Severity	SR1: 0
	SR2: 4
	SR3: 3
	SR4: 7
	Not assessable: 1
Blood product implicated	Red cells: 15
	Platelets: 0
	FFP: 0
	Cryoprecipitate: 0

This is defined as a haemolytic reaction occurring more than 24 hours after a transfusion of fresh blood or blood products.

These are usually due to the development or re-emergence of red cell alloantibodies. Delayed haemolytic transfusion reactions (DHTRs) are defined as reactions with or without fever and other symptoms/signs of haemolysis more than 24 hours after transfusion; confirmed by one or more of the following:

- a fall in Hb or failure of increment
- rise in bilirubin
- incompatible crossmatch not detectable pre-transfusion.

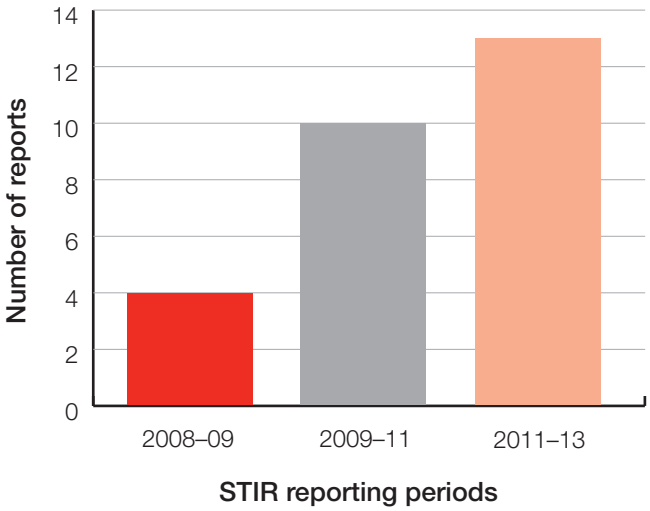
Simple serological reactions are excluded such as antibody development without a positive direct antiglobulin test (DAT) or evidence of haemolysis (Blood Matters 2013).

Reporting of delayed haemolytic reactions has been increasing with each STIR aggregated report as outlined in Figure 4.

It is assumed that laboratories are becoming more aware of the STIR system for reporting these types of events, rather than more events occurring, due to increased educational initiatives at health services.

As a percentage of the overall events this category represents four per cent of all reports.

Figure 4: Delayed haemolytic reports



Seventeen reports were received and reviewed, with 15 reports confirmed by the expert reviewers.

Symptoms and signs included typical features of haemolysis: jaundice (n = 3), failure to maintain the increment in haemoglobin post-transfusion (n = 15), haemoglobinuria (n = 1), raised bilirubin (n = 1).

A post-transfusion antibody screen was reported for all events, with 14 (93 per cent) found to be positive.

As recommended in previous reports, access for transfusion laboratories to patient's results through a regional or national database of antibody results may prevent re-exposure to antigen positive units and the consequences of some delayed haemolytic transfusion reactions.

Case study

Patient presented to the emergency department following referral from the GP with a low Hb for investigation. The patient's Hb was 67 g/L on presentation with symptoms of lethargy and trouble sleeping. The patient was admitted for a two-unit transfusion and referral to the surgical team for ongoing investigation of chronic anaemia.

Pre-transfusion screening was unremarkable and transfusions were administered without any issue. Investigation of anaemia occurred over the next eight days prior to discharge with a referral to a haematologist.

The patient re-presented to the emergency department six days post discharge, again lethargic and now with dark urine and a day history of left flank pain and feeling unwell. Hb was 83g/L on admission and presented with a temperature of 39°C.

A provisional diagnosis of urosepsis was made and the patient admitted for IV antibiotics, although cultures remained negative.

The laboratory noted haemolysis on blood specimens and investigated for a delayed haemolytic transfusion reaction, which was confirmed. Antibodies were detected and blood was sent to the Australian Red Cross Blood Service Red Cell Reference laboratory for further antibody investigation.

The patient was transferred to another health service with a delayed haemolytic reaction and acute renal failure. Follow up investigation found antibodies against three red cell antigens Jk(a), c and E, with the Jk(a) antibody the most likely cause of the haemolytic reaction. Future red cell transfusion must be with antigen-negative units.

Australian Red Cross Blood Service advice:

Delayed haemolytic reaction

When to suspect this adverse reaction?

Patients may present with unexplained fever and anaemia usually 2 to 14 days after transfusion of a red cell component. The patient may also have jaundice, high bilirubin, high LDH, reticulocytosis, spherocytosis, positive antibody screen and a positive Direct Antiglobulin Test (DAT) (Roback 2011; Callum et al. 2011).

It occurs in 1:2,500 to 1:11,000 of transfusions (Roback 2011; Popovsky 2007).

Usual causes?

After transfusion, transplantation or pregnancy, a patient may make an antibody to a red cell antigen that they lack. If the patient is later exposed to a red cell transfusion which expresses this antigen a DHTR may occur. DHTRs may also occur with transfusion transmitted malaria and babesiosis (Callum et al. 2011).

The clinical severity of a DHTR depends on the immunogenicity or dose of the antigen. Blood group antibodies associated with DHTRs include those of the Kidd, Duffy, Kell and MNS systems, in order of decreasing frequency (Roback 2011).

Investigation

Request a Direct Antiglobulin Test (DAT), antibody screen, liver function tests (LDH) and markers of haemolysis (eg serum haptoglobin, bilirubin).

What to do?

Most delayed haemolytic reactions have a benign course and require no treatment; however life-threatening haemolysis with severe anaemia and renal failure may occur. (Callum et.al. 2011) If an antibody is identified, you may request antigen-negative blood if further transfusion is needed.

Source: Australian Red Cross Blood Service available from <http://www.transfusion.com.au//adverse_transfusion_reactions>.

Transfusion-transmitted infections (bacterial)

Data summary	
Category	Transfusion-transmitted infections (bacterial)
	Total number of events: 1
Gender	Male: 0
	Female: 1
Age	< 1 year: 0
	1–18 years: 0
	19–29 years: 0
	30–49 years: 0
	50–69 years: 0
	70–79 years: 0
	80+ years: 1
Time of transfusion	In hours: 1
	Out of hours: 0
Imputability	Certainly: 1
	Probably: 0
	Possibly: 0
	Excluded: 0
	Not assessable: 0
Severity	SR1: 0
	SR2: 1
	SR3: 0
	SR4: 0
	Not assessable: 0
Blood product implicated	Red cells: 1
	Platelets: 0
	FFP: 0
	Cryoprecipitate: 0

This class of event is defined as a post-transfusion infection resulting from transfusion of a bacterially contaminated component if the following criteria were met at the end of the investigation (Blood Matters 2013):

- there was no evidence of infection prior to transfusion, and
- at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection, or
- at least one component received by the infected recipient was shown to have been contaminated with the agent of infection.

Eight reports of suspected bacterial contamination were notified during the reporting period.

However, there was only one confirmed case that fitted the STIR definition and was confirmed with the Blood Service.

This case was initially reported as a febrile non-haemolytic transfusion reaction but as cultures of both product and patient were positive and confirmed the same bacteria; it was reclassified to a TTI (bacterial) by the hospital prior to submission of the investigation forms. This case demonstrates the usefulness of undertaking a thorough investigation when any acute transfusion reaction occurs to cover many possible diagnoses.

Case study

A patient presented for surgery with significant comorbidities, including anaemia of chronic disease. Haemoglobin 86g/L on admission and two units of red cells were ordered pre-surgery.

The first unit was commenced and 140 mL was transfused.

The patient developed a fever, the unit was ceased and the second unit not given.

Within 45 minutes of the reaction, cultures of both patient and product had been undertaken and within a day both had positive results of a Gram-positive coagulase-negative staph.

The organism isolated was identified as *staphylococcus epidermidis*.

The Blood Service was notified and confirmed a true bacterial contamination.

The patient required a temporary increase in care and an increased length of stay and was managed with appropriate antibiotics.

Australian Red Cross Blood Service advice:

Transfusion-transmitted infections (bacterial)

When to suspect this adverse reaction?

Clinical features of transfusion associated sepsis suggesting the possibility of bacterial contamination and/or endotoxin reaction may include rigors, high fever, severe chills, hypotension, tachycardia, nausea and vomiting, dyspnoea, or circulatory collapse during or soon after transfusion.

In severe cases, the patient may develop shock with accompanying renal failure and disseminated intravascular coagulation (DIC). This reaction may be fatal (Roback 2011; Callum et al. 2011).

For clinically apparent reactions, bacterial infections are reported to occur in at least 1:75,000 platelet transfusions and at least 1:500,000 red cell transfusions (Eder et al. 2007; Kuehnert 2009).

Bacterial infection is more common with:

- platelets (as these are stored at room temperature)
- previously frozen components thawed by immersion in a water bath
- red cell components stored for several weeks.

Usual causes

Blood components may be contaminated by:

- bacteria from the donor's skin during the collection procedure
- unrecognised bacteraemia in the donor
- contamination from the environment
- contamination during the preparation of components
- contamination of ports during the thawing of frozen products in a water bath.

Both Gram-positive and Gram-negative organisms have been implicated in transfusion-associated sepsis with serious morbidity and mortality occurring most frequently with Gram-negative bacteria (Roback 2011).

continued…

Organisms capable of multiplying at low temperatures and those using citrate as a nutrient are most often associated with red cell contamination, especially *Yersinia enterocolitica*.

Investigation

Request for blood cultures from the patient, and perform culture and Gram stain on the remainder of the blood component.

The key to diagnosing transfusion-related sepsis is culturing the same organism from the patient and component.

Keep the blood bag and giving set (sealed) for further investigation.

What to do?

Stop transfusion immediately and follow other steps for managing suspected transfusion reactions.

Seek urgent medical assistance as this may become an emergency.

Start broad-spectrum antibiotics once cultures have been taken, including cover for staphylococcal infections.

Provide cardiovascular support.

Send blood pack to the Transfusion Service Provider for urgent culture and Gram Stain.

Advise Transfusion Service Provider to notify the Blood Service to ensure quarantining and testing of related components from the same donation/donor.

Source: Australian Red Cross Blood Service available from: <http://www.transfusion.com.au/adverse_transfusion_reactions>.

Incorrect blood component transfused

Data summary	
Category	Incorrect blood component
	Total number of events: 19
Gender	Male: 7
	Female: 12
Age	< 1 year: 4
	1–18 years: 1
	19–29 years: 3
	30–49 years: 2
	50–69 years: 6
	70–79 years: 2
	80+ years: 1
Time of transfusion	In hours: 16
	Out of hours: 3
Imputability	Certainly: 16
	Probably: 0
	Possibly: 2
	Excluded: 0
	Not assessable: 1
Severity	SR1: 0
	SR2: 1
	SR3: 7
	SR4: 10
	Not assessable: 1
Blood product implicated	Red cells: 16
	Platelets: 0
	FFP: 2
	Cryoprecipitate: 0
	Other: 1

This category describes an event where a patient is transfused with a fresh blood component that did not meet the appropriate requirements or which was intended for another patient (Blood Matters 2013) such as:

- incorrect blood transfused – ABO incompatible and ABO compatible
- special requirements not met
- unnecessary or inappropriate transfusions.

Nineteen notifications of IBCT were received through the STIR system.

Incorrect blood components transfused has been categorised in the following Table 8 to outline the themes where a patient receives a product that was not intended for them or did not met patient requirements.

Table 8: Incorrect blood component transfused events

IBCT types	Number
Components that did not meet specific requirements	6
Antigen-antibody issue	5
Inappropriate red cell product	3
Inappropriate plasma/platelet product	1
Incorrect blood component to incorrect patient – ABO compatible	3
Incorrect blood component to incorrect patient – ABO incompatible	1

The ABO incompatible transfusion reported involved a unit of group A FFP administered to a patient who was blood group B. There was no reported haemolysis associated with this event, with minor symptoms that could be associated with a mild allergic reaction. This event did not meet the guidelines for reporting as a sentinel event.

During this reporting period, one sentinel event was reviewed by the STIR expert group that aligned with the criteria for an IBCT. This sentinel event was reported outside the reporting period (May 2011) and is counted in the previous STIR report 2009–11; however, the full root cause analysis was not available at that time and consequently will be presented below.

The health service has shared their story and STIR review of the recommendations provided by the health service agreed the measures outlined were appropriate to reduce the chance of recurrence.

We thank the health service for sharing their story and providing an opportunity for others to benefit from this knowledge in their own health service.

Incorrect blood component transfused – lessons from a health service

Patient A was brought into the emergency department via ambulance with sudden onset of chest pain. The patient was seen immediately and various diagnostic tests performed.

The patient's condition deteriorated which resulted in transfer to a resuscitation cubicle that had been occupied by Patient B who was moved to another area.

Blood samples had been taken from Patient B with three tubes sent to pathology for processing and one tube not processed at the same time as it was undecided whether a crossmatch sample would be needed. This tube was left in the resuscitation bay, *unlabelled*, when Patient A was moved into this area.

Patient A had a CT scan that showed a dissecting abdominal aortic aneurysm. The medical officer ordered a crossmatch.

The unlabelled tube of blood from Patient B was labelled with Patient A's details and sent to pathology for crossmatching. The blood group for this sample was A RhD positive.

The pathology service queried the sample for two reasons:

- the staff member did not sign the specimen collection declaration on the request form as per protocol, and
- there was a variation in the haemoglobin level from an earlier sample.

The patient's condition continued to deteriorate and they needed to be transferred to another health service. The pathology service was urged to provide the red cells in accordance with the crossmatch sample provided for Patient A. Four units of A RhD positive red cells were subsequently supplied.

The hospital transfused one unit of the red cells while Patient A was in the emergency department and the second unit commenced just prior to transfer.

The remaining two units were sent with the patient. On arrival at the receiving hospital the incompatible blood error was discovered when Patient A was crossmatched and found to be an O RhD positive blood type. Patient A died soon after arrival with cause of death attributed to ruptured AAA.

How the health service addressed the issues

As a result of this error, the health service informed the pathology service of the hospital's position relating to provision of blood in emergency situations – that is, the hospital executive supports the pathology service in its adherence to its protocols regardless of the nature of the situation/emergency.

continued…

The health service has a zero tolerance policy for any specimen labelling errors and recommends that O negative blood be used in an emergency when there is concern about the integrity of the sample or any delay.

The *Blood and blood products policy* and *Blood collection method protocol* were reviewed to ensure compliance with best practice and national guidelines in relation to taking and labelling of blood.

The BloodSafe e-Learning Australia package was included in the 'Registrar and junior medical officer education competency suite' with participation monitored and reported through to the transfusion governance committee (BloodSafe eLearning Australia).

Observational audits of the specimen collection and labelling process were increased to twice a year from annual audits in the emergency department with immediate feedback to staff if any breach in compliance with the protocol was detected.

Emergency department staff introduced double-positive patient identification of the specimen collection process for all transfusion specimen requests. One staff member must be a senior nursing staff member at time of collection and both clinical staff sign the specimen declaration that a positive identification process has been correctly undertaken.

Recommendations from a state and national level.

The STIR group reviewed this case and highlighted that there was both non-compliance to protocol in the clinical area in specimen collection and in the pathology service in issuing the blood.

Recommendations included:

- All specimens should be labelled at the bedside at the time of collection by the collector. Any unlabelled samples found should be discarded.
- When the pathology service raises doubt as to the validity of the pre-transfusion specimen and when recollection is not possible or the urgency of the situation warrants immediate blood product provision, the pathology service should always issue O RhD negative blood.
- Clinicians must be made aware of and adhere to specimen labelling protocols and be aware of pathology protocols for non-conforming specimens and the issue of blood in an emergency.

When correct patient identification processes are followed when labelling blood samples and pathology departments enforce zero tolerance on non-conforming samples WBIT errors are decreased and the risk of transfusing ABO incompatible blood is greatly reduced.

These recommendations are to be part of new national guidelines currently being developed by the Australian and New Zealand Society for Blood Transfusion (ANZSBT). As also recommended in the 2009–11 STIR report, the STIR Expert group recommends the investigation and use of technology such as 2D barcode technology systems to assist in patient identification processes and sample collections to further reduce system errors (Miller et al. 2013).

Case study

Following activation of the massive transfusion guideline, O RhD negative units were issued, two transfused and two not.

When retrospectively entering data into the laboratory system once patient details were available, it was noted that two of the units issued had expired 11 days previously.

This was clarified with the Blood Service. The clinical team and patient's family were informed and changes were made to the process for issuing O-negative units through the laboratory information system to ensure all checks are undertaken prior to issuing, to prevent an expired unit from being dispensed.

There was no harm to the patient.

Case study

Following an ABO-mismatched peripheral stem cell transplant from an O RhD negative donor to an A RhD negative patient, the patient required transfusion.

An A RhD negative red cell unit was issued and administered.

It was normal process for the blood group support to be changed to a blood group compatible to both patient and donor (in this case O RhD negative) on the day of transplant.

This did not occur and despite alerts in the system the red cells were issued and administered.

There was no harm to the patient and the health service has made changes to both the laboratory information system for tracking transplant patients and to the clinical area for transfusion support in the transplant setting with a staff competency package and check list to include all transfusion support information.

Case study

A transfusion of a unit of red cells that was neither irradiated or CMV-negative occurred despite requesting the same.

These modifications had been missed both when issuing the blood, where alerts were overlooked, and then on administering the unit where the requirements for modifications were not known to those checking the product.

At the time of the report there was no harm to the patient.

The health service has made changes to how blood is requested, with education to promote compliance, alteration to the request form and the layout of information. The health service is also developing a competency package for laboratory staff to reduce the risk of overlooking alerts in the system, to improve the process for issue of blood.

Near-miss incidents

Data summary	
Category	Near-miss
	Total number of
Gender	Male: 12
	Female: 15
Age	< 1 year: 1
	1–18 years: 0
	19–29 years: 1
	30–49 years: 4
	50–69 years: 9
	70–79 years: 8
	80+ years: 4
Time of transfusion	In hours: 21
	Out of hours: 6
Blood product implicated	Red cells: 21
	Platelets: 1
	FFP: 0
	Cryoprecipitate: 2
	Other: 3

This category includes any incident that had the potential to cause harm but did not, due to timely intervention, luck or chance. For example, any incident that is recognised before transfusion but which, if undetected, could have resulted in the determination of wrong blood group (includes antenatal screening as well as pre-transfusion testing), or issue, collection, or administration of an incorrect, inappropriate or unsuitable component (Blood Matters 2013).

Twenty-seven notifications were received. Near-misses occur in all areas of the transfusion process, although without consequence for the patient, in all events reported to STIR. The following examples outlined in Table 9, provide a snap shot of the type of near-misses that are occurring and where in the transfusion process.

Case study

A blood collection form requesting a unit of red cells for Mr C in the emergency department was presented to laboratory scientist, the scientist reviewed the patient information and transfusion record in the laboratory information system.

The blood was issued, but the wrong unit was selected and handed to the staff member. On double-checking at the bedside it was noted the unit was allocated to Mr T.

It was returned to the laboratory and the laboratory scientist correctly located the blood for Mr C and the transfusion proceeded.

This health service has made changes to the identification check undertaken by scientists from the collection form to issue, and changes to the laboratory information system to ensure a less manual process to reduce human error.

Table 9: Near-miss events

Types of near-miss events and examples	Number of reports
Laboratory, including inappropriate/incorrect component issued Emergency blood issued on historical group only, on processing specimen patient identification error noted, blood issued incompatible, transfusion not commenced Two units sent to ward area with labels transposed Conflicting transfusion grouping results in two laboratory information system from one pathology provider Manual entry in the laboratory information system incorrect Incorrect RhD grouping Antenatal screening missed anti-Kell antibodies Issued incorrect blood to clinical area	10
Labelling/documentation/identification Mislabelled blood unit following irradiation Incorrect labels in patient file resulting in incorrect sampling Patient of the same name blood removed from blood fridge Incorrect units removed from blood fridge Patient having a transfusion with no wrist band in place, transferred from ward to critical care area	8
Storage and handling Incorrect storage of products released for massive transfusion resulting in wastage Two units returned to fridge after being out of storage control for greater than two hours, subsequently collected for transfusion six hours after return to fridge	4
Incorrect prescription or request for blood Using previous patients identification left in an emergency bay for request of products Requesting red cell units, when haemoglobin result > 120g/L	2
Administration/delay in management Haemolysis in line after using five per cent dextrose to prime the line Failure of patient identification check, incorrect unit hung for transfusion	3

Case study

A health service ordered two units of AB RhD positive, irradiated and CMV-negative units from the Blood Service.

The delivery arrived with the units of blood; but there was a discrepancy on one label of the blood bag, displaying two donation numbers and labelled as O RhD positive.

As part of policy and normal practice, the blood group of the unit was checked by the health service, confirming blood group as AB RhD positive, the unit was quarantined.

Reported and investigated by the Blood Service who has made significant changes to labelling post irradiation as a result of this near-miss.

Case study

Urgent blood collection form arrived in the blood bank from the emergency department with no previous written or verbal request for blood.

Specimens were also left for processing.

The blood bank checked the historical group using patient details from the collection form and noted an antibody that made the emergency O RhD negative blood incompatible.

The blood bank communicated with the emergency department noting this problem and offering historical group-matched blood (A RhD positive) that is antigen negative as an alternative.

This blood was sent to the emergency department unlabelled.

The specimens were processed and staff noted a clerical discrepancy between the specimens and the collection form first given to the blood bank.

Specimens processed showed the patient to be O RhD positive and that the collection form was for the wrong patient.

Fortunately the blood in the emergency department had been hung but the transfusion not yet commenced.

The hospital undertook an in-depth case review as to the serious breaches of protocol that resulted in a near miss of an incompatible ABO transfusion.

Wrong blood in tube

Data summary	
Category	Wrong blood in tube
	Total number of events: 107
Gender	Male: 47
	Female: 60
Age	< 1 year: 6
	1–18 years: 3
	19–29 years: 15
	30–49 years: 29
	50–69 years: 17
	70–79 years: 22
	80 + years: 15
Time of sampling	In hours: 69
	Out of hours: 38
Blood product implicated	Red cells: 8
	Platelets: 0
	FFP: 1
	Cryoprecipitate: 0
	Other: 98

This is a special category of a near-miss incident where the error is picked up prior to transfusion. It means that:

- samples are taken from the wrong patient but labelled as per the intended patient
- or, sample taken from the intended patient but labelled as per another patient
- or, mismatch between paperwork request and specimen.

There were 107 notifications of wrong blood in tube (WBIT) events received for this reporting period. WBIT are near-misses as by definition they cause no actual harm to the patients since the errors are identified often prior to testing (Blood Matters 2013).

WBITs were most likely to occur in the ward (n = 37, 35 per cent) and the emergency department (n = 37, 35 per cent).

Thirty-one per cent were discovered through differences in historical blood group and/or differences in MCV. Interestingly, on nine (eight per cent) occasions clinical staff detected the WBIT and rang the laboratory outlining the error prior to testing.

Missed patient identification continues to be an issue with sampling patients for transfusion, and as noted in some of our cases this issue also affects blood samples collected for treatment other than transfusion.

It was reported in 70 per cent (n = 75) of cases that the correct checking procedure of patient identification was not followed, and that in 29 per cent of cases (n = 31) the sample was not labelled at the bedside contributing to the error.

The majority of the WBITs reported are where there is a mismatch between the patient details on the request and the details on the tube, clearly indicating an error in the process. Fortunately the laboratory discarded these mismatched samples prior to testing.

More and more laboratories are adopting a ‘zero tolerance’ policy where if a sample and/or request does not conform to policy, the sample will be discarded and a recollect will be required.

Case study

A patient presented to a clinical area for treatment and had a group and hold taken, this was reported as A RhD positive.

Staff questioned this as a previous crossmatch three months earlier was O RhD positive as outlined in his records, when two units were allocated but not required.

Now with a change from the historical test result, the sample was repeated twice by separate staff all confirming positive patient identification, all subsequent samples were grouped as A RhD positive.

It is assumed the WBIT was the sample collected three months earlier but the health service was unable to ascertain how that occurred due to time delay.

Case study

A sample for a full blood examination (FBE) was sent to the laboratory and on processing it, the scientist noted significant discrepancies with recent results.

Blood group analysis was performed on the sample and was noted to be AB RhD positive, the historical record for the patient was O RhD positive.

The health service noted it was collected from the correct patient who required a FBE, however it was labelled with another patient's details and labelled away from the patient with no direct checking procedure with the patient being undertaken.

Case study

A request and specimen for group and hold was received by the laboratory and no discrepancies were noted.

Prior to testing, a phone call was received from a midwife who said the specimen did not come from the patient whose details were on request and specimen. Both were discarded by the laboratory.

On investigation by the health service it was discovered the specimen and request had been labelled away from the bedside and that no patient identity check had been used to confirm that the request details and the patient matched. No other patient was put at risk.

Recommendations

Recommendation 1

TACO is under-reported and under-recognised, but associated with potentially high mortality for transfusion recipients. STIR recommends health services transfusing must ensure there is improved monitoring and assessment of at risk-individuals, especially those with pre-existing cardiac failure prior to transfusion.

STIR recommends health services should investigate and implement the use of a single-unit guideline for high-risk clinical areas to help prevent TACO.

Information on a single-unit guideline, including tools and resources is available through the National Blood Authority website <www.blood.gov.au/single-unit-transfusion>.

Recommendation 2

As recommended in the previous STIR report, STIR recommends the development of a regional or national database of antibody results that may assist in preventing re-exposure to antigen-positive units and the consequences of some acute and/or delayed haemolytic transfusion reactions.

Recommendation 3

Patient identification issues with sampling, request and administration still occur too frequently. STIR recommends health services investigate the use of technology such as 2D barcode scanning for sampling and administration practices for transfusion to reduce patient identification/product errors if possible.

To reduce ongoing blood sampling errors STIR recommends laboratories should strictly follow guidelines to identify pre-transfusion specimens and enforce a ‘zero tolerance’ for non-conforming pre-transfusion specimens on arrival in the laboratory.

STIR recommends education of clinical staff and laboratory staff in transfusion practice from sampling to administration to assist in reducing errors related to patient identification.

Free courses are available through BloodSafe eLearning Australia <www.bloodsafelearning.org.au>.

Recommendation 4

Patient blood management (PBM) is the management and preservation of patients’ own blood to reduce or avoid the need for a blood transfusion.

The aim of patient blood management is to improve outcomes for each patient by recognising anaemia, risk factors for procedural bleeding and minimising or avoiding unnecessary exposure to blood components.

STIR recommends the implementation of the PBM guidelines for specific clinical areas to reduce unnecessary patient exposure to blood products.

The guidelines, including tools and resources for implementation, is available through the National Blood Authority website <www.blood.gov.au/implementing-pbm>.

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STIR publications and promotions 2011–13

October 2011, Sydney: Annual Scientific Meeting of Haematology Society of Australia and New Zealand, the Australian and New Zealand Society of Blood Transfusion and the Australasian Society of Thrombosis and Haemostasis. Presentation: 'Serious Transfusion Incident Reporting (STIR): five years on'.

September 2011, Launceston: Transfusion Science Day, Presentation: 'Blood Matters lessons learnt from Serious Transfusion Incident Reporting (STIR)'.

January 2012, Sydney: Royal College of Pathology Association Pathology, update poster: 'STIR: a state approach to Haemovigilance'.

February 2012, Montreal, Canada: International Haemovigilance Seminar, presentation: 'Recognising and reporting acute transfusion reactions: experience from STIR'.

April 2012, Brisbane: Queensland Transfusion Forum, presentation: 'STIR what's it all about? Blood Matters a recipe for Haemovigilance'.

June 2012, Beijing China: 1st Annual International Symposium of Haematology (AISH), presentation: 'Haemovigilance in the hospital and statewide'.

October 2012, Melbourne: Annual Scientific Meeting of Haematology Society of Australia and New Zealand, the Australian and New Zealand Society of Blood Transfusion and the Australasian Society of Thrombosis and Haemostasis, poster: 'When the signs and symptoms of an acute reaction don't fit the definition'.

October 2012, Melbourne: Annual Scientific Meeting of Haematology Society of Australia and New Zealand, the Australian and New Zealand Society of Blood Transfusion and the Australasian Society of Thrombosis and Haemostasis, poster: 'Overseeing a haemovigilance program: the value of an expert group'.

February 2013, Brussels, Belgium: International Haemovigilance Seminar, presentation: 'Recognising and reporting acute transfusion reactions: experience from STIR'.

June 2013, Xi'an, China: Annual International Symposium of Haematology (AISH), presentation: 'Measuring and monitoring the hazards of clinical transfusion practice and the challenge of improving outcomes for Victoria'.

STIR was presented at local education workshops, professional meetings and attendance at hospital transfusion committees to promote the system and lessons from the members of the STIR expert group.

STIR contacts

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STIR Expert group members 2011–13

The system is overseen by the STIR expert group of the Blood Matters Advisory Committee of the Department of Health & Human Services Victoria.

The Blood Matters Advisory Committee includes clinician and consumer representation and advise and review the STIR system. Blood Matters is a collaboration between the department and the Blood Service.

Dr Erica Wood (chair – resigned in 2013) Associate Professor, School of Public Health and Preventive Medicine Monash University, Victoria

Ms Helen Atkinson, Transfusion Nurse, Royal Hobart Hospital, Tasmania

Mr Gerald Bates, Laboratory Manager, Launceston General Hospital, Tasmania

Mr Peter Beard, Data Manager, Blood Matters Program, Department of Health & Human Services, Victoria

Ms Linley Bielby, Program Manager, Blood Matters Program, Department of Health & Human Services, Victoria

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

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

Dr Amanda Davis (chair – commences 2014), Consultant Haematologist, Alfred Hospital, Victoria

Ms Clare Hennessy, Transfusion Nurse Consultant, Eastern Health

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Ms Bridget Glazebrook, Data Manager, Blood Matters Program, Department of Health & Human Services, Victoria

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Mr Scott McArdle, Transfusion Nurse, St Vincents Health

Dr Tina Noutsos, Consultant Haematologist, Royal Darwin Hospital, Northern Territory

Ms Jo Perillo, Education Coordinator, Blood Matters Program, Department of Health & Human Services, Victoria

Mr Richard Rogers, Blood Bank Scientist, Cabrini Health

Dr Carole Smith, Consultant Haematologist, Austin Health

Ms Lisa Stevenson, Transfusion Nurse, Blood Matters Program, Department of Health & Human Services, Victoria

Ms Theresa Williamson, Acting Manager, Quality and Safety Programs, Department of Health & Human Services, Victoria