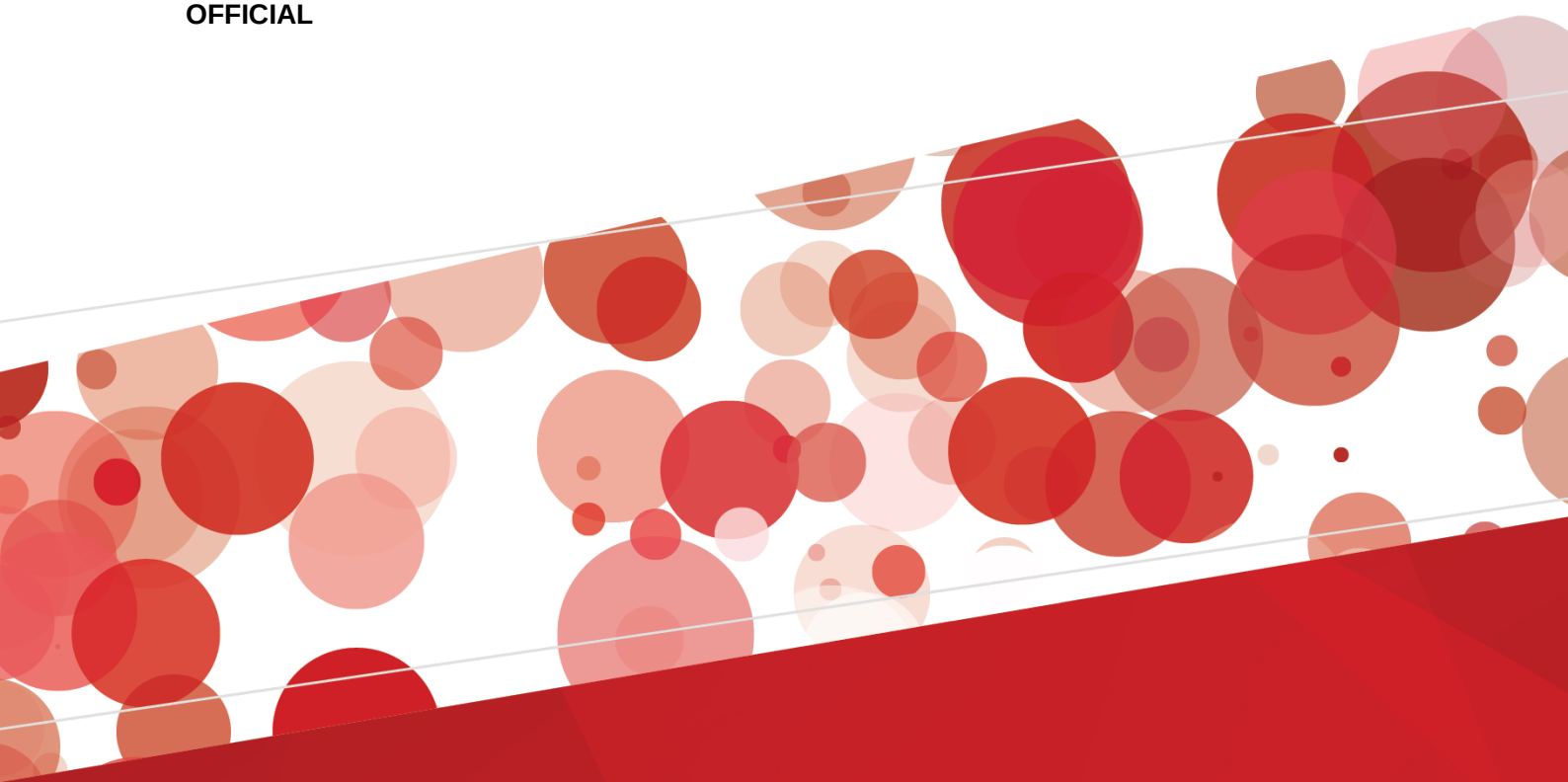
Serious Transfusion Incident Report (STIR) annual report 2022–23

Blood Matters program

OFFICIAL



VICTORIA State Government

Australian Red Cross Lifeblood

Blood Matters

Serious Transfusion Incident Report (STIR) annual report 2022–23

Blood Matters program

To receive this document in another format, phone 03 9694 0102, using the National Relay Service 13 36 77 if required, or email Blood Matters bloodmatters@redcrossblood.org.au.

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

ISSN 2651-8872 (online/PDF/Word) or (print)

Available at Blood Matters Serious Transfusion Incident Reporting
<https://www.health.vic.gov.au/patient-care/serious-transfusion-incident-reporting-system>

Contents

Acknowledgements

The Serious Transfusion Incident Reporting (STIR) system is part of the work of the Blood Matters program. Blood Matters is a collaboration between the Victorian Department of Health and Australian Red Cross Lifeblood (Lifeblood). STIR provides haemovigilance information to support safer transfusion practice.

Public and private health services in Victoria, Tasmania, Australian Capital Territory and Northern Territory contribute to the system. This allows us to keep providing information and recommendations for best practice.

Blood Matters recognises and appreciates the generous in-kind support of the STIR Expert Group, whose input is invaluable in reviewing the incidents and providing recommendations and direction for the work.

Abbreviations and acronyms

Abbreviation/acronym	Definition
AHTR	acute haemolytic transfusion reaction
ANZSBT	Australian and New Zealand Society of Blood Transfusion
ATR	acute transfusion reaction
BP	blood pressure
BPM	beats per minute
DHTR	delayed haemolytic transfusion reaction
DSTR	delayed serologic transfusion reaction
ED	emergency department
EMR	electronic medical records
FBE	full blood examination
FFP	fresh frozen plasma
FNHTR	febrile non-haemolytic transfusion reaction
FY23	financial year 23, 1 July 2022 – 30 June 2023
Hb	haemoglobin
HDFN	haemolytic disease of the foetus and newborn
IBCT	incorrect blood component transfused
ICU	intensive care unit
IM	intramuscular
INR	international normalised ratio
IT	information technology
IV	intravenous
Lifeblood	Australian Red Cross Lifeblood
LIS	laboratory information system
MCV	mean corpuscular volume
MET	medical emergency team
NBA	National Blood Authority
NIPA	non-invasive pre-natal analysis
NIPT	non-invasive pre-natal testing
PTP	post transfusion purpura
RACP	Royal Australasian College of Physicians
RBC	red blood cells

Abbreviation/acronym	Definition
RhD Ig	RhD immunoglobulin
SAPSE	serious adverse patient safety event
SDC	Statutory Duty of Candour
SHOT	Serious Hazards of Transfusion
SR	severity rating
STIR	Serious Transfusion Incident Reporting system
TACO	transfusion-associated circulatory overload
TAD	transfusion-associated dyspnoea
TA-GVHD	transfusion-associated graft versus host disease
TRALI	transfusion-related acute lung injury
WBIT	wrong blood in tube

Executive summary

This year's report includes 209 validated investigations, 68 procedural events and 141 clinical reactions.

Wrong blood in tube events (WBIT) (27), followed by RhD Ig administration errors (15) and incorrect blood component transfused (IBCT) (10), are the most-reported procedural events.

Positive patient identification can largely prevent both IBCT and WBIT events. Health services should train all staff on positive patient identification and the two-person, double-independent checking process.

In settings with transfusion-specific electronic solutions for patient identification, health services must ensure that staff are trained and use the system as intended. The ANZSBT guidelines include information on how to implement and use electronic medical records in transfusion practice.

Clinical reactions to blood components may not always be preventable. However, health services can reduce risks to patients by ensuring transfusions occur only if there is demonstrated clinical need. When transfusion is necessary, health services should use the smallest dose to achieve the desired aim.

Health services that manually transcribe results should consider using electronic systems. Alternatively, staff should use results that are electronic or printed (on letterhead). As pathology providers increasingly adopt ISBT 128 labelling, donation identification numbers on blood components are becoming longer and more complex. Health services should consider using more reliable methods than manual transcription. This will help to guarantee correct documentation for traceability.

The next section sets out key messages from received and validated STIR investigations.

We thank all health services that report to STIR for their ongoing support.

Key messages

Area	Message
Clinical management of reactions	Treatment should be based on the symptoms and signs that occur at the time of the reaction. Diagnosis of type of reaction may require further investigations, blood tests and/or X-rays, to determine the actual or most likely cause of the reaction. Case study 1
Clinical management – determining the need for transfusion	Only use blood components where there is an indication of need. Do not use to treat a number (Hb, INR). Each transfusion should be an independent decision based on the patient's current clinical condition. Case study 2
Clinical management – large-volume FMH and product/route selection	Health services providing maternity and obstetric care should have clear guidelines regarding the suitability of RhD Ig products and administration route for the different products. It should also be clear when to use the IV product, either due to patient factors, for example thrombocytopenia, or due to the dose required. Case study 16
Patient/product identification and matching	The two-person (double) independent check is still not routinely performed or completely understood. Health services need to provide training on this topic to ensure the right product is given to the right patient. Case studies 6 and 9
Documentation – recording and sharing of information	STIR has repeatedly advocated for the development of a national antibody registry. While this is currently available in Western Australia, this is not a nation-wide system. Patients move between health services, and the information regarding known antibodies is not always available to each health service providing care. This puts patients at risk of receiving an incompatible blood component. Case study 4

Area	Message
Documentation-transcription errors	Do not manually transcribe results from one system to another. STIR receives multiple reports of errors associated with this process each year. Incorrectly transcribing a blood group can lead to incorrect or missed blood components or products (such as RhD immunoglobulin). Health services should consider electronic transfer of results, or easy access to systems containing those results when clinical staff work in a separate system. Case study 15

Introduction

STIR received 245 notifications of adverse events from 50 health services for the period 1 July 2022 to 30 June 2023.

Of these reports, 17 were withdrawn by the health service or not completed. Another 19 were excluded after expert review.

This resulted in 209 validated investigations. Of these, there were 141 clinical reactions and 68 procedural errors. Figure 1 shows the number of validated reports from 2009–10 to current.

Of the 114 health services registered with STIR, 50 (44%) submitted reports this year.

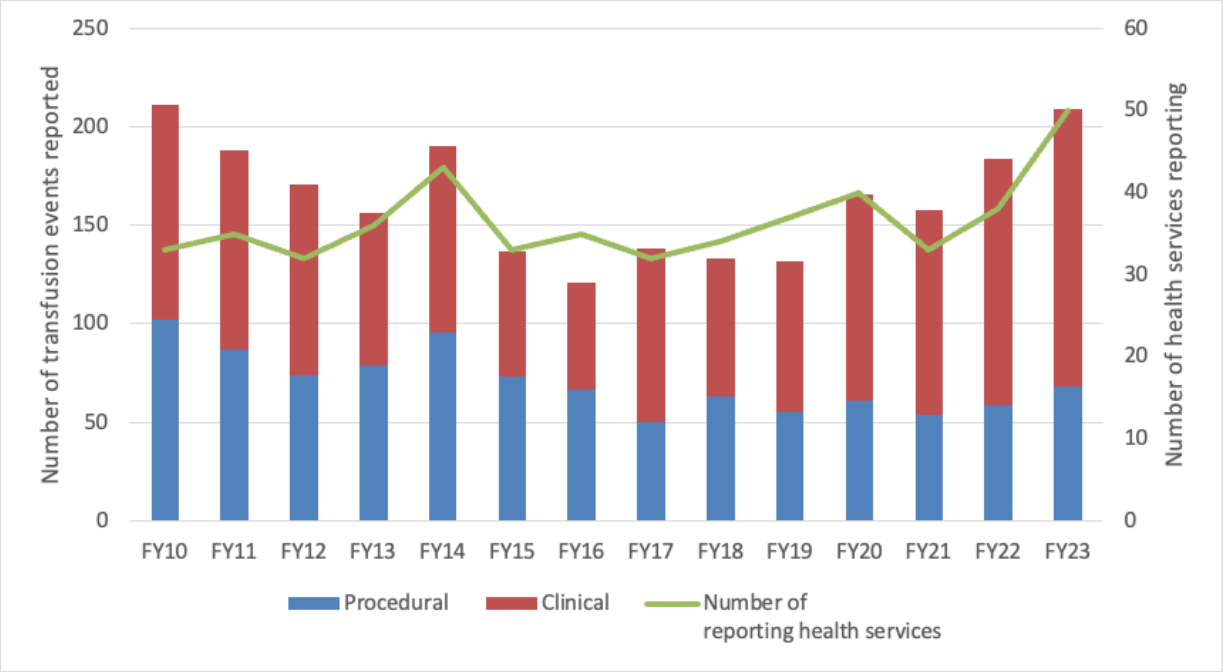
This is the largest number of health services to report to STIR since its inception.

In this period, there was 1 severity rating (SR) 1 event.

This is defined as an event that has the realistic potential to result in an unexpected death or a permanent and disabling injury or psychological harm to a person.

No sentinel events were reported.

Figure 1: Number of validated clinical and procedural reports and health services reporting each financial year, from 2009–10 to 2022–23



The National Blood Authority (NBA) provides information on the number of blood components sent to the jurisdictions reporting to STIR each year (Table 1).

Table 2 shows the estimated frequency of clinical reactions for Victoria, noting reporting is voluntary and only the more serious adverse reactions are reported to STIR.

Table 1: Total blood issues per jurisdiction 2022–23

Components issued 2022–23	Victoria	Australian Capital Territory	Tasmania	Northern Territory
Red blood cells (RBC)	187,059	10,497	14,439	5,158
Platelets	38,927	1,450	3,052	979
Fresh frozen plasma (FFP)	27,267	878	1,450	334
Cryoprecipitate	34,629	3,074	2,207	1,014
Total	**287,882**	**15,899**	**21,148**	**7,485**

Table 2: Estimated frequency of clinical reactions per component in Victoria (n = 130)

Component	Blood issued (Vic.)	Validated clinical events[1]	Frequency
RBC	187,059	96	1:194
Platelets	38,927	29	1:1342
FFP	27,267	15	1:1818
Cryoprecipitate	34,629	2	1:17,314

Method

Table 3: Steps in the reporting and validation of health service notifications

Step	Number of notifications/investigations/reports
STIR notification	• 245 notifications from health services
Notification withdrawal	• 17 notifications withdrawn before investigation returned
Primary investigation	• 228 investigation forms sent to STIR expert group for review
Second review	• 31 investigation forms required second review
Expert Group exclusion	• 19 investigations excluded by Expert Group review
Validation	• 209 validated reports included for analysis

Withdrawn reports

The percentage of withdrawn reports has remained relatively constant over the last three years (Table 4).

Health services withdraw reports for several reasons, most often due to being outside STIR's scope.

Although a transfusion reaction may occur, only the more serious reactions are reportable to STIR. Continued education on appropriate reporting is required.

[1] Multiple blood products may be selected for one reaction.

Duplicate notifications occur when usual communications at the health service level have failed to note a previously reported event, particularly when there are several staff reporting to STIR.

The investigation is excluded, and the reporter notified where the expert review finds there is evidence that the patient's underlying condition or other medications is likely to be the cause of the reaction, or there is not enough information to determine cause.

Table 4: Reasons for withdrawal of notifications to STIR

Financial year	Duplicate notification	Not in scope	Deemed not transfusion related by health service	Not completed	Excluded after expert review	Total STIR notifications	Total withdrawn (%)
FY15	9	11	6	8	4	175	38 (22)
FY16	6	11	5	5	4	152	31 (20)
FY17	5	4	2	1	5	155	17 (11)
FY18	3	5	-	2	15	158	25 (16)
FY19	5	16	3	1	14	171	39 (23)
FY20	9	11	4	2	22	214	48 (22)
FY21	2	3	2	2	14	180	23 (13)
FY22	5	6	4	1	14	216	30 (14)
FY23	4	8	3	2	19	245	36 (15)

Validation and reconciliation

A member of the Expert Group reviews all investigations returned to STIR. For each event, the member assigns a reaction or event type, severity rating and imputability.

For more severe reactions, where the health service or the reviewer assigned SR 1 or SR 2, the entire Expert Group reviews the investigation to ensure consistency in reporting.

Expert review of the information provided may lead to a change in the incident type or severity rating assigned.

This is shown in Tables 5 and 6. Severity ratings are assigned for each investigation, except RhD immunoglobulin (RhD Ig) administration errors, near-miss and wrong blood in tube (WBIT) incidents.

In these events, there is the potential for severe adverse outcomes, but they have either been avoided by finding the error before the blood component or product reached the patient, or the potential future impact is unknown.

We notify the reporter when changes occur.

Table 5: Changes to clinical incident type following STIR Expert Group review

Original incident type	Validated as: TACO	Validated as: DSTR	Validated as: FNHTR
ATR	1	-	-
ATR, TACO, TAD	3	-	-
TRALI	5	-	-
DHTR	-	1	-
DSTR, TACO	-	1	-
ATR other	-	-	2

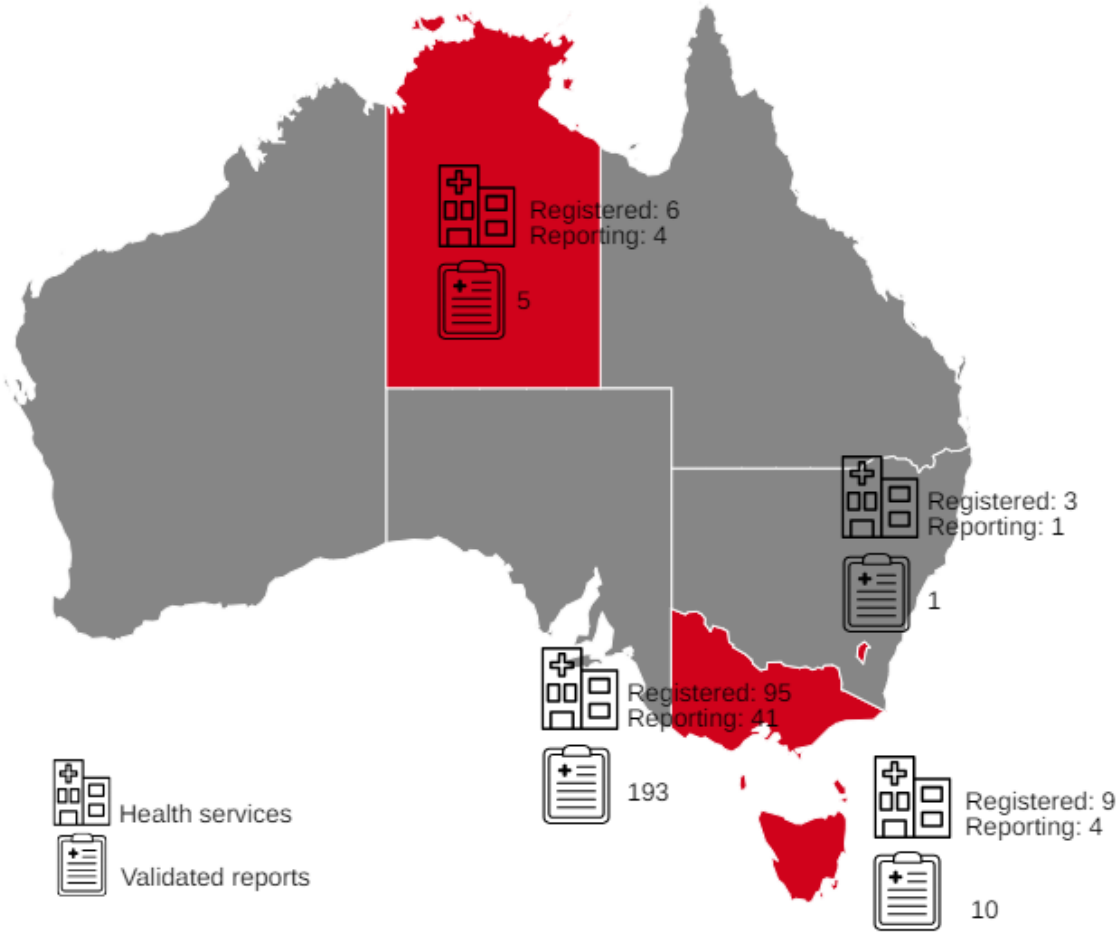
Table 6: Changes to the severity rating following STIR Expert Group review

Incident type (number)	Incident severity rating submitted as	Incident severity rating validated as
Acute haemolytic transfusion reaction (2)	SR4	SR3
Allergic/anaphylactic/anaphylactoid transfusion reaction (6)	SR4	SR3
Febrile non-haemolytic transfusion reaction (3)	SR4	SR2
Febrile non-haemolytic transfusion reaction (3)	SR4	SR3
Delayed haemolytic transfusion reaction (1)	SR4	SR2
Delayed haemolytic transfusion reaction (1)	SR4	SR3
TACO (1)	SR3-2	SR1
TACO (1)	SR4	SR2
TACO (5)	SR4	SR3

Demographics

Figure 2 shows the number of registered and reporting health services and total number of reports for each jurisdiction. As previously noted, more health services reported to STIR this year. All jurisdictions that are associated with STIR have submitted reports this year.

Figure 2: Number of validated reports per reporting jurisdiction



To maintain confidentiality, STIR collects limited patient information. The age and sex of the patient are the only patient identifiers collected. Information on component type is also collected.

When reporting component type there is a category ‘other’, that is commonly used for WBIT and RhD Ig incidents.

Table 7 shows the demographics for FY23 validated reports.

Table 7: Characteristics for all validated reports (excluding RhD-related incidents)

Characteristic	Statistic
Age	Average 55 (range 0–97 years)
Sex	Male: 97 (50%) Female: 98 (50%)
Blood component notifications: (Multiple blood components may be selected for one reaction)	RBC: 130 Platelets: 33 Fresh frozen plasma (FFP): 19 Cryoprecipitate: 2

Characteristic	Statistic
Other	Includes WBIT n = 22, near miss n = 3, TACO (buffy coat) n = 1, Procedural other (organ transplant) n = 1

Sentinel events

Sentinel events comprise a subset of adverse patient safety events that are wholly preventable and result in serious harm to, or death of, a patient (refer to ACSQH's 'Incident management and sentinel events' webpage[2]).

For transfusion, such an event is 'haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death'.

In this financial year there were no sentinel events reported.

One SR1 event was reported by a health service and validated by the Expert Group, but this did not meet the definition for reporting as a sentinel event.

Statutory duty of candour

Health services are required to provide a patient with a statutory duty of candour (SDC) when the patient has suffered a serious adverse patient safety event (SAPSE) while receiving health care. The SDC builds on the principles and elements of open disclosure within the *Australian open disclosure framework*, currently used for all cases of harm and near miss.

When a patient has suffered a SAPSE, the health service is legally required to provide the patient and their next-of-kin/carer with

- a written account of the facts regarding the SAPSE
- an apology for the harm suffered by the patient
- a description of the health service's response to the event
- the steps the health service took to prevent recurrence of the event.

Health services must comply with any timelines and requirements set out in the *Victorian duty of candour guidelines*[3] (legislative instrument).

If the event is classified as a sentinel event, health services must also comply with any relevant timelines within the Victorian sentinel event guide.

To assist health services to determine if an event is a SAPSE, Safer Care Victoria has developed a *Victorian duty of candour framework*.[4] This includes case examples and patient considerations.

In general, a SDC is required when a SAPSE is unplanned or unexpected, and it results in increased treatment and care, or a permanent reduction of function that is unrelated to the natural course of the person's illness or underlying condition.

---

[2] <https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/incident-management-and-sentinel-events>

[3] <https://www.safercare.vic.gov.au/sites/default/files/2022-10/Victorian%20Duty%20of%20Candour%20Guidelines%20-%20FINAL.docx>>

[4] <https://www.safercare.vic.gov.au/sites/default/files/2022-10/Victorian%20Duty%20of%20Candour%20Framework%20-%20FINAL.docx>

Events reported to STIR with a SR1 or 2 generally meet this criterion.

Adverse event reviews are valuable quality and safety improvement processes. However, there is evidence to suggest that clinicians are reluctant to provide information to a review for fear of medico-legal consequences.

Amendments to the *Health Services Act 1988* (the Act) introduced protections for adverse event reviews, called a SAPSE review.[5] If the provisions within Division 8 of Part 5A of the Act are followed and a SAPSE review panel is formed, the review process is protected. Any documents created are not admissible in legal proceedings. There are also protections for SAPSE review panel members and participants of the SAPSE review.

The resulting SAPSE review report must be offered and produced to the patient and their next of kin/carer when accepted. It must also be made available to the Secretary of the Department of Health on request.

These reforms foster a culture that identifies errors and harm and discusses them openly. They also ensure a better understanding of events, along with comprehensive and effective recommendations for improvements.

[5] <https://www.safercare.vic.gov.au/sites/default/files/2022-10/Protections%20for%20serious%20adverse%20patient%20safety%20event%20%28SAPSE%29%20reviews%20-%20FINAL.docx>

Clinical reports

Clinical reactions to blood components remain the largest proportion of reports received by STIR.

This year, 141 (67%) of all validated reports were clinical. The types of reactions are shown in Figure 3. Table 8 shows the breakdown of the types of validated acute transfusion reactions (ATR).

The type of reaction by blood component is shown in Table 9, with red blood cells (RBC) contributing to most-reported reactions.

Figure 3: Validated clinical reactions FY23

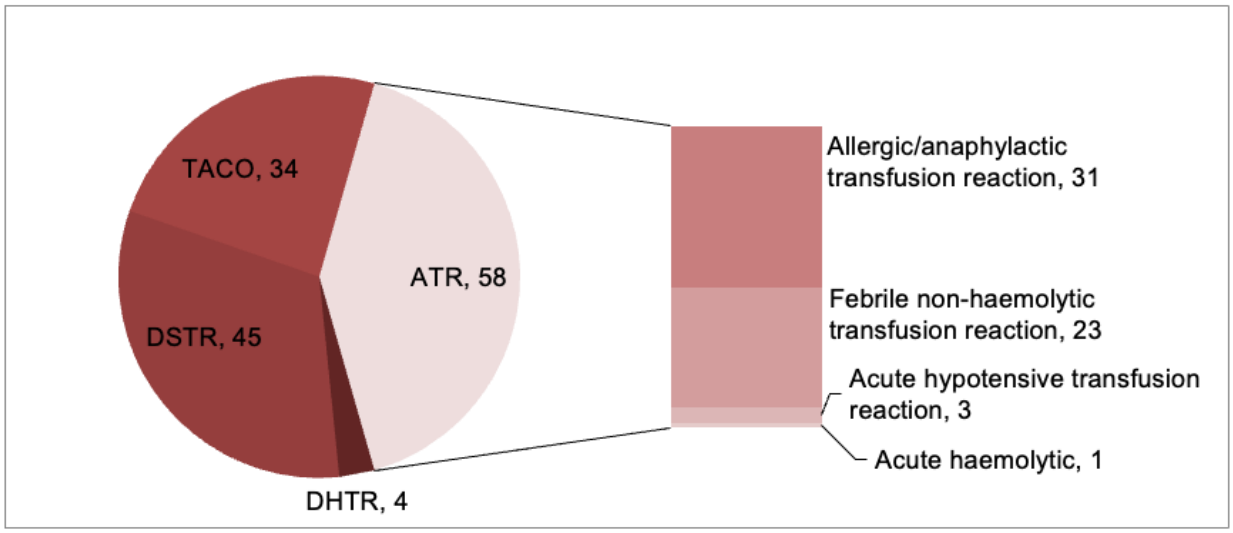


Table 8: Types of validated clinical reports, number and percentage

Reaction	n (%)
Allergic/anaphylactic/anaphylactoid	31 (22)
Febrile non-haemolytic transfusion reaction (FNHTR)	23 (16)
Acute hypotensive transfusion reaction	3 (2)
Acute haemolytic (AHTR)	1 (1)
Transfusion associated circulatory overload (TACO)	34 (24)
Delayed haemolytic transfusion reaction (DHTR)	4 (3)
Delayed serologic transfusion reaction (DSTR)	45 (32)
Total	**141**

Table 9: Validated reaction type by blood component

Blood component	FNHTR n = 23	Allergic/ Anaphylactic n = 31	Hypotensive n = 3	AHTR n = 1	TACO n = 34
Red blood cells (RBC)	21	7	2	1	28
Platelets	3	16	1	-	6
Fresh frozen plasma (FFP)	-	12	-	-	4
Cryoprecipitate	-	2	-	-	-
Other (Buffy coat granulocytes)	-	-	-	-	1

Multiple blood products may be implicated in one reaction.

Febrile non-haemolytic transfusion reactions (FNHTR)

FNHTR are reported regularly to STIR, however imputability is generally low (Table 11). The STIR definition reflects the higher threshold required for reporting only more serious reactions. This definition does not reflect the criteria for reporting and responding to a potential transfusion reaction for clinical staff within the health service.

FNHTR is a diagnosis of exclusion. It should only be reported where there are no other clinical conditions that could cause fever, for example concurrent chest infection or febrile neutropenia, and where investigation has ruled out other potential serious causes of transfusion-related fever such as bacterial contamination or haemolytic reaction.

This year there were 21 FNHTR reported to STIR. The STIR Expert Group added two additional FNHTR due to changes of reaction type, resulting in 23 validated reports. Most reports related to the use of RBC (n = 21, 91%). Refer to Table 10: Data summary.

Table 10: Data summary – febrile non-haemolytic transfusion reaction, n = 23

Characteristic	Number (%)
Age: < 1 year	-
Age: 1–18 years	1 (4)
Age: 19–29 years	2 (9)
Age: 30–49 years	3 (13)
Age: 50–69 years	10 (43)
Age: 70–79 years	5 (22)
Age: 80+ years	2 (9)
Sex: male	11 (48)
Sex: female	12 (52)
Implicated blood component: RBC	21 (91)
Implicated blood component: platelets	3 (13)

Table 11: Severity rating and imputability – febrile non-haemolytic transfusion reaction

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	-	-	-	-
SR 2	-	1	2	3
SR 3	-	1	5	6
SR 4	-	4	10	14
Total	**-**	**6**	**17**	**23**

Case study 1: Febrile non-haemolytic transfusion reaction

A male patient undergoing extensive pelvic surgery required a massive transfusion for intraoperative bleeding. He received a significant number of RBC, FFP and cryoprecipitate.

Approximately 45 minutes into the 13th unit of RBCs, he became febrile with rigors and tachycardia without a significant drop in blood pressure (BP).

There were no respiratory symptoms or signs described.

The health service noted this could have been post-operative systemic inflammatory response syndrome, as the patient continued to require medical emergency team (MET) calls for hypotension, tachycardia and fever over the next 2 days.

Laboratory investigation showed there was no incompatibility between patient and the potentially implicated RBC unit, and both the patient and RBC unit were cultured and tested negative.

Treatment was with an antipyretic alone.

Expert Group determination: FNHTR, probably, SR3

It is often difficult to distinguish fever related to the transfusion from fever related to other conditions the patient may have.

This health service investigated the cause of the fever to rule out more serious problems such as a bacterial contamination (blood cultures of both the patient and blood component), or a haemolytic reaction (rechecking blood grouping and antibody screening for patient and component).

They acknowledged that an underlying condition could have contributed to the fever. However, the possibility of a FNHTR could not be excluded.

Treatment appeared to be appropriate for this patient with an antipyretic being given.

In some investigations received, where fever is the predominant symptom, patients are given unnecessary antihistamine and steroid, without any indication of allergic symptoms.

Allergic/anaphylactic reactions

Allergic transfusion reactions made up 22% (n = 31) of clinical reactions reported to STIR this year. Anaphylactoid/anaphylactic reactions comprised 4% (n = 5) of these, as outlined in Table 12.

The most commonly reported component associated with allergic/anaphylactic reactions was platelets (n = 16, 52%) and FFP (n = 12, 39%).

The Australian and New Zealand Society of Blood Transfusion (ANZSBT) and Royal Australasian College of Physicians (RACP) 'Top five recommendations on low value practices in transfusion'6 (2022) states in point number 5: 'Do not transfuse standard doses of fresh frozen plasma to correct a mildly elevated (< 1.8) international normalised ratio (INR) prior to a procedure'.

The guideline recognises the increased risk of transfusion reactions. Refer to Case study 2.

The 2023 Blood Matters audit, run in conjunction with Australian Red Cross Lifeblood Clinical Education Team, found 42% of FFP use was in episodes deemed non-aligned to guidelines. For more information, refer to the Blood Matters FFP audit.[7]

Tables 13a and 13b outline the severity rating and imputability of allergic and anaphylactic reactions respectively. Table 14 refers to the reported symptoms and signs and Table 15 includes the reported treatments.

Table 12: Data summary – allergic/anaphylactic

Characteristic	Allergic, n = 26 (%)	Anaphylactic, n = 5 (%)
Age: < 1 year	-	-
Age: 1–18 years	3 (12)	2 (40)
Age: 19–29 years	2 (8)	-
Age: 30–49 years	7 (27)	-
Age: 50–69 years	6 (23)	1 (20)
Age: 70–79 years	7 (27)	1 (20)
Age: 80+ years	1 (4)	1 (20)
Sex: male	14 (54)	2 (40)
Sex: female	12 (46)	3 (60)
Implicated blood component: RBC	7 (27)	1 (20)
Implicated blood component: fresh frozen plasma	11 (42)	1 (20)
Implicated blood component: platelets	13 (50)	3 (60)
Implicated blood component: cryoprecipitate	1 (4)	-

Note: multiple blood products may be involved.

[6] <https://evolve.edu.au/recommendations/anzsbt>

[7] <https://www.health.vic.gov.au/patient-care/blood-matters-audit-reports>

Table 13a: Allergy – severity rating and imputability (n = 26)

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	-	-	-	**-**
SR 2		2	-	**2**
SR 3	1	11	4	**16**
SR 4	1	5	2	**8**
Total	**2**	**18**	**6**	**26**

Table 13b: Anaphylactic – severity rating and imputability (n = 5)

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	-	-	-	**-**
SR 2	1	3	-	**4**
SR 3	-	-	1	**1**
SR 4	-	-	-	**-**
Total	**1**	**3**	**1**	**5**

Table 14: Allergic transfusion reactions by reported signs and symptoms

Signs and symptoms	Allergy n = 26 (%)	Anaphylactic n = 5 (%)
Itching/rash	17 (65)	4 (80)
Hypotension	8 (31)	3 (60)
Dyspnoea/difficulty breathing	5 (19)	3 (60)
Rigors	5 (19)	-
Tachycardia	4 (15)	2 (40)
Respiratory wheeze	4 (15)	2 (40)
Nausea/vomiting	2 (8)	3 (60)
Restlessness/anxiety	2 (8)	2 (40)
Chills	2 (8)	1 (20)
Fever	2 (8)	-
Chest pain/discomfort	2 (8)	-
Hypertension	1 (4)	-

Table 15: Reported treatments for allergic/anaphylactic

Treatment	Allergy, n = 26 (%)	Anaphylactic, n = 5 (%)
Antihistamines	15 (58)	3 (60)
Steroids	13 (50)	3 (60)
Inotropes/pressor agents	6 (23)	5 (100)
Intravenous (IV) fluids	5 (19)	2 (40)
Oxygen	4 (15)	2 (40)
Antipyretics	4 (15)	1 (20)

Case study 2: Anaphylactic reaction to FFP

An elderly man attended for a neurological surgical procedure.

Two days prior to surgery and external to the health service, an INR was taken, with a result of 1.5.

On the day of surgery another INR was taken. However, the patient was prescribed FFP before results were available.

The INR, not seen by medical staff before ordering the transfusion, was 1.3 (normal).

The transfusion was commenced on the ward prior to surgery.

Approximately 15 minutes into the transfusion, the patient developed an extensive itching rash, anxiety, restlessness, and hypotension.

The transfusion was stopped, a MET call made, and the patient was treated with antihistamine, steroids, intravenous (IV) fluids for volume support and two doses intramuscular (IM) adrenaline.

There was a further escalation of care when the blood pressure dropped further.

Investigation showed a normal IgA level (tested on post-transfusion sample, as no suitable pre-transfusion specimen was available) and an elevated tryptase (46.8 mcg/L).

The patient required intensive care unit (ICU) admission for the reaction and surgery was deferred.

Expert Group determination: anaphylactic, certainly, SR2

There is no evidence to support the prophylactic administration of FFP to correct a mildly elevated INR prior to a procedure.

The evidence supports the use of vitamin K and suggests the use of FFP correlated with an increased risk of intra-operative bleeding and/or increased risk of transfusion reactions (ANZSBT 2022).

FFP transfusions do not come without risks, commonly transfusion-associated circulatory overload, allergic reactions, transfusion-related acute lung injury and/or development of antibodies (Shaikh et alt. 2018).

Acute hypotensive transfusion reaction

This year, there were 3 validated hypotensive transfusion reactions, as outlined in Table 16.

One additional event notified as hypotensive reaction was reviewed and validated (reclassified) as a transfusion-associated circulatory overload (TACO) event.

Table 16: Data summary – acute hypotensive

Characteristic	Case 1	Case 2	Case 3
Age	70–79 years	1 - 18 years	70–79 years
Sex	Male	Male	Male
Implicated blood component	RBC	RBC	Platelets
Severity rating	SR3	SR3	SR2
Imputability	Probably	Certainly	Possibly

Case study 3: Hypotensive transfusion reaction

A patient attended an ambulatory day area for required platelet transfusion.

Approximately 12 minutes after commencement of a pooled bag of platelets, the patient became hypotensive (119/69 to 67/40) and experienced a drop in oxygen saturation from 96% on room air to 86–91%.

Pulse was also noted to increase during this time from 85b pm to 109 bpm.

The transfusion was discontinued and a MET was called.

The patient received treatment with oxygen and IV fluids and was admitted for further monitoring and management.

They went on to have RBC transfusion without any problems.

Expert Group determination: Acute hypotensive transfusion reaction, possibly, SR2

Acute haemolytic transfusion reaction (AHTR)

In this reporting period, there was one AHTR validated, involving a patient receiving RBC.

Case study 4: Acute haemolysis associated with a low incidence antigen

A patient with severe iron deficiency associated anaemia required a transfusion of RBC.

The patient was given a unit of crossmatched RBC via an electronic crossmatch.

The patient had no antibodies on pre-transfusion testing and a negative antibody history with the health service.

Approximately 90 minutes into the transfusion, the patient developed chills, became hypertensive and tachycardic and experienced dyspnoea without a drop in oxygen saturation.

At the time of the reaction the patient was treated with oxygen, glyceryl trinitrate and diuretic for possible fluid overload.

However, subsequent testing showed the RBC unit to be incompatible with the patient, with a positive direct antiglobulin test (DAT) and an anti-Wra eluted from the patient's RBC.

Further investigation showed the RBC unit administered to be Wra positive.

Haemolysis was supported by an elevated bilirubin and lactate dehydrogenase. Haptoglobin remained within normal limits.

Expert Group determination: acute haemolytic reaction, certainly, SR3

Even with correct crossmatching procedures an incompatible red blood cell transfusion is still possible due to low incidence antigens. The pathology provider may provide an incompatible unit if they are unaware of the historic antibody.

STIR Expert Group continues to support the development of a national database/registry for red cell antibodies, which would reduce the risk of these reactions.

Delayed haemolytic transfusion reaction (DHTR)

STIR defines DHTR as occurring more than 24 hours and less than 3 months following a transfusion.

To make a diagnosis of DHTR, there should be a demonstrated, clinically significant antibody against a patient's RBC along with additional laboratory features of haemolysis.

For example, this includes a fall in haemoglobin (Hb) or failure to increment, a transient positive direct antiglobulin test or rise in bilirubin and/or lactate dehydrogenase.

Delayed haemolytic reactions are reported less often than delayed serologic reactions. This may be because mild signs of haemolysis can be missed by patients and carers after leaving hospital.

Table 17 summarises reports of delayed haemolytic and serological reactions. Tables 18a and 18b include the severity ratings and imputability for DHTR and delayed serological reactions respectively.

Table 17: Data summary – delayed haemolytic and serologic reactions

Characteristic	Delayed haemolytic reaction, n = 4 (%)	Delayed serologic reaction, n = 45 (%)
Age: < 1 year	-	-
Age: 1–18 years	-	-
Age: 19–29 years	-	-
Age: 30–49 years	-	5 (11)
Age: 50–69 years	2 (50)	14 (31)
Age: 70–79 years	1 (25)	13 (29)
Age: 80+ years	1 (25)	13 (29)
Sex: male	3 (75)	23 (51)
Sex: female	1 (25)	22 (49)
Implicated blood component: RBC	4 (100)	45 (100)
Implicated blood component: platelets	-	2 (4)

Note: More than one component may have been implicated in some cases.

Table 18a: Severity rating and imputability – delayed haemolytic reaction

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	-	-	-	**-**
SR 2	1	1	-	**2**
SR 3	-	1	-	**1**
SR 4	1	-	-	**1**
Total	**2**	**2**	**-**	**4**

Table 18b: Severity rating and imputability – delayed serologic reaction

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	-	-	-	**-**
SR 2	-	-	-	**-**
SR 3	-	-	-	**-**
SR 4	38	6	1	**45**
Total	**38**	**6**	**1**	**45**

Delayed serologic transfusion reaction (DSTR)

DSTR is defined by STIR as occurring within 24 hours to three months after a transfusion, with demonstration of clinically significant antibodies against red blood cells (described in the *ANZSBT guidelines for transfusion and immunohaematology laboratory practice*, 1st edition, revised January 2020).

For DSTR to be validated, the implicated antibody is new, and there are no clinical or laboratory features of haemolysis. This term is synonymous with alloimmunisation.

Alloimmunisation can occur with any RBC transfusion (and less commonly with platelet transfusion), and all events should be reported to STIR.

Table 19 lists the antibodies that have been implicated in the reported DHTRs and DSTRs.

Kell (K and Kp^a) antibodies are the most commonly reported, followed by anti-E.

Kell antibodies can be clinically significant, causing transfusion reactions and haemolytic disease of the newborn.

In this reporting period, 5 of the patients who developed Kell antibodies were women, but all were over 50 years of age (not of child-bearing potential therefore not at risk of HDFN).

Anti-E, C, c and D are all part of the Rh blood group system. Together, they are the next most common antibodies reported, with anti-E being the most common within the group.

The one incident of development of an anti-D occurred in a male who had received two bags of RhD-positive platelets in a critical bleeding event.

Jk^b antibodies were associated with haemolytic reactions, whereas this was less common for Jk^a antibodies (both part of the Kidd blood group system). Jk^a is usually associated with less severe DHTRs and Jk^b with more severe DHTRs.

Table 19: Antibodies implicated in delayed haemolytic and serologic reactions

Antibody	Haemolytic (n = 4)	Serologic (n = 45)
Jk^a	1	10
Jk^b	2	-
E	1	14
c	1	1
C	-	2
D	-	1
Fy^a	-	4
Fy^b	-	1
K	1	15
Kp^a	-	1
Lu^a	-	4
S	-	2
Not documented	-	1

Note: More than one antibody identified in some cases.

RhD isoimmunisation

There were no reports of RhD isoimmunisation in this reporting period.

Reports of RhD isoimmunisation are possibly under-reported.

Some occur due to errors in providing prophylaxis for women at risk, but a number occur despite appropriate prophylaxis.

The supply of RhD immunoglobulin is affected by its own success in preventing immunisation.

Donors to the RhD program are ageing out of the ability to donate. New donors, with RhD antibodies (anti-D), are rare. Lifeblood's anti-D program[8] has a small pool of around 115 donors who meet specific criteria:

- men, or women past childbearing years who are RhD negative
- able to donate plasma.

To maintain their anti-D levels, donors receive regular boosting injections of extensively screened and carefully matched RhD positive RBC. Lifeblood is always looking to recruit new donors. Go to Lifeblood's pregnancy, anti-D and plasma[9] page if you, or someone you know can help.

[8] <https://www.lifeblood.com.au/blood/learn-about-blood/plasma/anti-D>

[9] <https://www.lifeblood.com.au/blood/learn-about-blood/plasma/anti-D>

The Guidelines for the prophylactic use of RhD immunoglobulin in pregnancy care[10] recommend non-invasive prenatal testing (NIPT) testing for all RhD negative women from 11 weeks (Lifeblood recommends 12 weeks) to determine fetal RhD genotype.

This would allow for targeted use of RhD immunoglobulin in RhD negative women shown to have a RhD positive foetus, or those for whom the testing is inconclusive. It would reduce demand for limited RhD immunoglobulin resources.

However, Lifeblood is only currently funded to provide non-invasive prenatal analysis (NIPA) for RhD in the following high-risk pregnancies:

1. RhD negative pregnant women who are anti-D alloimmunised
2. RhD negative pregnant women with obstetric indications, such as severe fetal maternal haemorrhage during pregnancy
3. other unusual but rare scenarios such as allergy to the RhD immunoglobulin.

Transfusion-associated circulatory overload (TACO)

As in previous years, TACO is one of the more commonly reported clinical reactions to STIR, with 34 events validated for FY23.

This may not represent the true incidence of TACO in health services, as less serious cases are not required to be reported.

Clinical staff prescribing and administering blood components and products should be aware of the factors that increase a patient's risk of developing TACO.

Blood Matters provides a TACO checklist, swing-tags and poster[11] that health services can use to increase staff awareness.

Table 20 shows the characteristics of the patients reported to STIR with TACO. Table 21 shows the severity ratings associated with these events.

The Serious Hazards of Transfusion (SHOT) 2022 report had the highest number of TACO reports to date (160, an increase of 29 over the previous year). TACO continued to be a major cause of morbidity and mortality.

In the UK, the Medicines and Healthcare Products Regulatory Agency issued a patient safety alert regarding reducing risks for transfusion-associated circulatory overload12 to address the rising deaths from TACO.

This advises health services of the risks for TACO and the things they can do to address these risks.

Some of these include review and update of policies, procedures and training programs and undertaking regular audits of procedures.

[10] <https://www.blood.gov.au/guideline-prophylactic-use-rh-d-immunoglobulin-pregnancy-care>

[11] <https://www.health.vic.gov.au/patient-care/serious-transfusion-incident-reporting-system-stir>

[12] <https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-reducing-risks-for-transfusion-associated-circulatory-overload-natpsa-slash-2024-slash-004-slash-mhra>

Table 20: Data summary – TACO

Characteristic	TACO, n = 34 (%)
Age: < 1 year	-
Age: 1–18 years	7 (21)
Age: 19–29 years	2 (6)
Age: 30–49 years	3 (9)
Age: 50–69 years	7 (21)
Age: 70–79 years	9 (26)
Age: 80+ years	6 (18)
Sex: male	16 (47)
Sex: female	18 (53)
Implicated blood component: RBC	28 (82)
Implicated blood component: platelets	6 (18)
Implicated blood component: FFP	4 (12)
Implicated blood component: other	1 (3)

Table 21: Severity rating and imputability – TACO

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	-	1	-	**1**
SR 2	2	5	4	**11**
SR 3	2	13	6	**21**
SR 4	-	1	-	**1**
Total	**4**	**20**	**10**	**34**

Case study 5: Probable TACO with other potential causes of respiratory signs

A patient with a previous history of respiratory and cardiac disease presented with a complicated medical condition for investigation and management.

The patient had a prolonged admission during which they were transfused two units of RBC on the ward.

They received IV fluids in the 24 hours prior to transfusion. However, no fluid balance nor weight gains were recorded.

Ten minutes into the second unit of RBC the patient developed reduced oxygen saturation, with no documented other signs or symptoms.

The patient was treated with assisted ventilation, oxygen and diuretics and required ICU admission.

Investigations included a chest X-ray which showed ‘interval development of extensive bilateral consolidation’.

Brain natriuretic peptide (BNP) was 3,345 pg/mL (decreased from 17,462 pg/mL earlier in admission).

Computed tomography pulmonary angiogram showed residual pulmonary embolism, right heart strain, extensive bilateral lung parenchymal changes suggestive of acute respiratory distress syndrome.

Unfortunately, the patient died and documentation indicated the transfusion reaction contributed.

Expert Group determination: TACO, probably, SR1

The STIR Expert Group noted this was a multimorbid patient with multiple possible causes for dyspnoea/hypoxia. TACO was at least contributory, however transfusion-related acute lung injury (TRALI) cannot be excluded.

It is sometimes not straightforward to determine if a ‘reaction’ is related to the transfusion or not.

In this case, the patient had multiple medical problems that may have contributed to their dyspnoea/hypoxia, with TACO or TRALI being in the mix and possibly contributory.

Treatment at the time of the reaction appears to have been appropriate.

Transfusion related acute lung injury (TRALI)

TRALI reports are uncommon to STIR. In FY23, STIR received 5 notifications of TRALI events.

Where TRALI is reported, cross-validation with Lifeblood is undertaken. Of the 5 notifications, none was validated as likely to be TRALI and all were reclassified as TACO.

Transfusion associated dyspnoea (TAD)

STIR defines TAD as respiratory distress (the most prominent clinical feature) within 24 hours of transfusion that does not meet the criteria of TRALI, TACO or allergic reaction.

Respiratory symptoms should not be explained by the patient’s underlying condition or any other known cause.

Confirming TAD is difficult in most instances, and we receive few reports of it.

There are no clear diagnostic markers to differentiate TAD from other causes. It is a diagnosis of exclusion.

For this reporting period, we received 3 TAD notifications. One was reclassified as ATR (allergic) and the other 2 as TACO.

Transfusion-transmitted infection, bacterial

There were no validated reports of bacterial infection associated with transfusion in this period.

When fever is the predominant sign in a transfusion reaction, bacterial infection should always be suspected.

Bacterial culture of both the patient and product will assist in determining if bacterial contamination is likely.

If a health service suspects bacterial contamination of a unit, they should contact Lifeblood at the first opportunity. Lifeblood will need to investigate other associated components from the donation.

Transfusion-transmitted infection, other

There were no validated reports of other infection associated with transfusion in this period.

Transfusion associated graft vs host disease (TA-GVHD)

There have been no reports of TA-GVHD in this or previous years.

However, each year we receive reports of a small number of patients receiving non-irradiated products when the health service has determined the patient fits criteria that make an irradiated product appropriate (incorrect blood component transfused).

The new ANZSBT Guideline for the prevention of transfusion-associated graft-versus-host disease[13] (January 2024) notes the following preventative factors for TA-GVHD:

- transfusions should only be administered in accordance with evidence-based recommendations to prevent complications of unnecessary transfusions
- while leucodepletion removes substantial numbers of leucocytes and the T-lymphocytes responsible for the development of TA-GVHD, it is not considered equivalent to irradiation (either gamma or X-ray irradiation). Pre-storage leucocyte depletion reduces the risk of TA-GVHD but is not recommended as an alternative to irradiation
- cold stored RBC in storage for > 21 days are irradiation equivalent. By day 21, T-cell proliferative capacity is below that thought to be required to induce TA-GVHD. The majority of cases of TA-GVHD cases occur in fresher products, generally <10 days of storage. The same does not apply for platelets stored at room temperature for up to seven days.

The age of the product as well as the pre-storage leucodepletion that all RBC undergo may reduce the risk of TA-GVHD. It may also be that a small number of reports of non-irradiated product being supplied are associated with patients who once required irradiation but no longer do. Irradiation is not necessarily a lifetime requirement for all patients.

Post-transfusion purpura (PTP)

There have been no reports of post-transfusion purpura this year to STIR.

PTP is a rare event. Both the NBA Australian Haemovigilance reports and SHOT in the UK have few reports recorded. SHOT had one case reported in 2022, with the last one prior to this in 2018.

For further information, visit Lifeblood's PTP page.[14]

[13] <https://anzsbt.org.au/wp-content/uploads/2024/02/TAGVHD-Guideines-2024.pdf>

[14] <https://www.lifeblood.com.au/health-professionals/clinical-practice/adverse-events/PTP>

Procedural reports

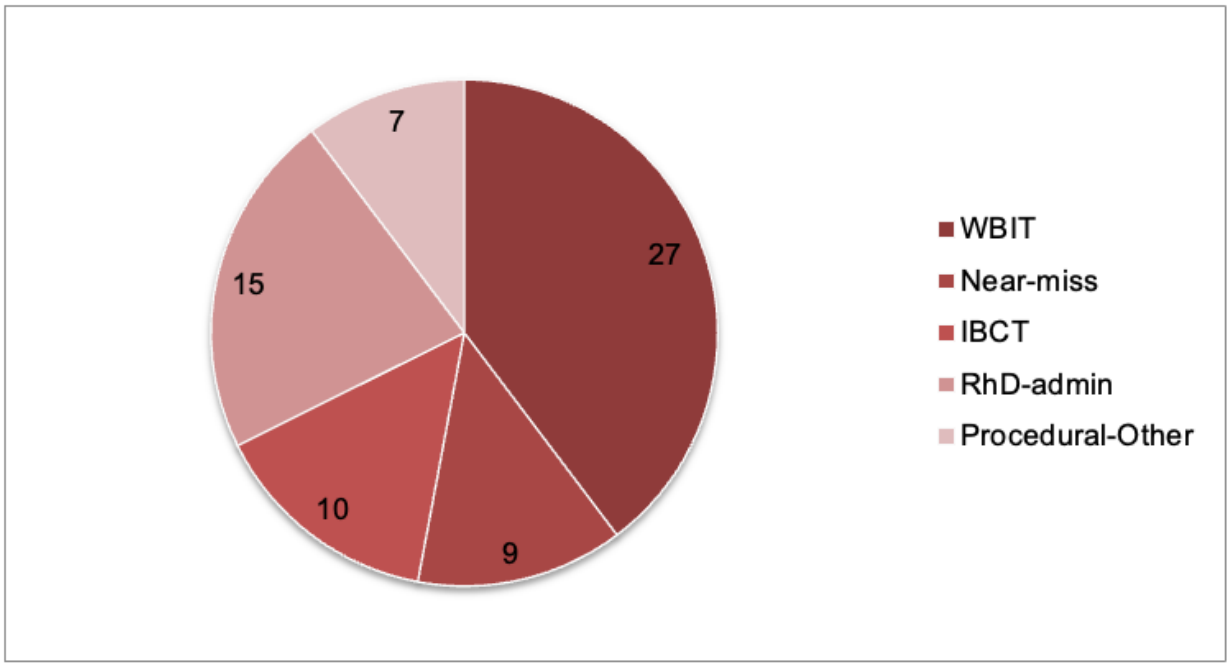
Procedural events made up 33% (n = 68) of validated investigations this year, with wrong blood in tube (WBIT) being the largest number.

Figure 4 shows the number and types of procedural reports validated.

Circumstances contributing to these events require thorough investigation (local, case review or root cause analysis).

Learning from these events helps to identify where things can go wrong and improve systems to prevent or minimise recurrence.

Figure 4: Validated procedural reports FY23



Incorrect blood component transfused (IBCT)

While there are fewer IBCT events validated this year, there have been errors involving failure of bedside checks in detecting discrepancies in patient or component details (see case studies).

Fortunately, these have not resulted in serious adverse outcomes to patients. However, these should always be treated as serious events.

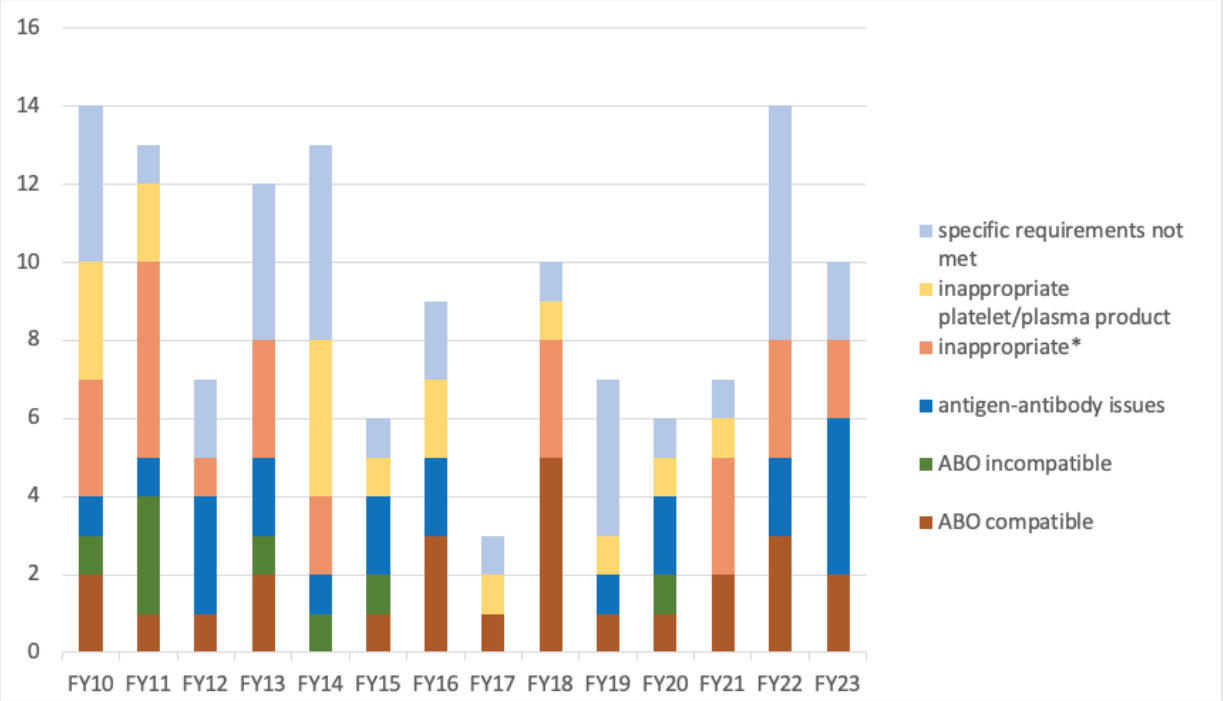
The STIR expert group produced a bulletin (STIR Bulletin 9 Blood product checking)[15] to highlight errors in bedside checking and recommendations for assisting health services to avoid errors.

Figure 5 shows the types of IBCT errors reported since 2010 and Table 23 shows the error types for FY23 validated reports.

There are no ABO incompatible transfusions reported for FY23. Table 24 shows which location within the health service the events occurred.

[15] <https://www.health.vic.gov.au/patient-care/serious-transfusion-incident-reporting-system-stir>

Figure 5: Reported IBCT categories – FY10–FY23



'Inappropriate' was redefined in FY19, with some events being categorised into 'procedural – other'.

Table 23: Types of IBCT events FY23

Event	Count
ABO incompatible	-
ABO compatible	2
Specific requirements not met	2
Antigen-antibody incompatibility, including RhD	4
Inappropriate (no clinical need)	2

Table 24: Where IBCT events occurred

Location	Count[16]
Ward	4
Emergency department (ED)	3
ICU	1
Day unit	1
Operating theatre	1
Other -urgent care unit	1

[16] One report indicated the event occurred in two areas.

Case study 6: Two-person (double) independent checks not followed correctly

This event was initially reported as procedural – other. However, the patient received a unit of RBC labelled and intended for a different patient. The Expert Group therefore reclassified the event.

A nurse collected RBC from the blood bank for patient X, unit group A RhD neg, as documented on the associated paperwork.

After delivery to the ward, 2 nurses took the RBC unit to the patient side to perform checks and administer.

The nurses did not perform 2-person (double) independent checks. One nurse checked the relevant prescription while the other nurse checked the patient identification band.

One nurse stated they had trouble pronouncing the surname of the patient as per the RBC unit compatibility label. They spelled the surname out several times to the second nurse, who answered ‘yes’, when asked if that was the correct patient.

The first nurse did not look to see that the details were correct.

There were no comments on the checking if the patient details matched the details on the RBC compatibility label. If this check was done, no discrepancy in patient name was noted.

Approximately 100 mL of RBC was transfused prior to staff finding the mismatch in identification between the patient wristband and compatibility label on the unit.

The error was picked up by a third nurse performing checks during rounds.

The transfusion was immediately ceased, and the patient was informed of the error.

During investigation, it was noted that the patient said to the nurses that the blood was not intended for them. Fortunately, the unit was ABO compatible with the patient who received it.

The health service is investigating the use of simulation training to educate staff on the correct 2-person (double) independent checking procedure.

Expert Group determination: IBCT SR3, certainly, ABO compatible

The health service noted that while there was no physical reaction from this event, the patient did suffer some psychological distress.

Learnings: The 2-person (double) independent check is still not routinely performed or understood.

Education on the process is important to ensure correct component/product to patient. Simulation training may be a good way to work through the process. It is important to include the patient as part of the checking process (National Standards).

The patient should have been asked to state their name and date of birth, which would have minimised the concern about the pronunciation of the name.

The staff involved did not follow up the reported assertion by the patient that the blood was not for them.

Patients may at times be able to help prevent errors and are certainly an important part of the checking process.

Patient identification checks need to be conducted with the patient, where possible and not to the patient.

Case study 7: Specific requirements for unit transfused not met

A patient with a history of acute leukaemia required a neurosurgical procedure.

The patient was found to be anaemic and required a RBC transfusion.

The RBC unit administered was not irradiated, which the health service policy required for a patient with acute leukaemia.

The prescription did not include the need for irradiation.

Nursing staff do not always understand when special requirements such as irradiation or a cytomegalovirus seronegative product are needed. The prescription should indicate these requirements.

The laboratory had apparently missed the requirement for irradiation for this patient.

Either the requirement was not noted in the laboratory information system (LIS), or the patient was new to the service and information on previous acute leukaemia was not communicated.

System warnings within the laboratory need to be easily seen and followed when the scientist is selecting components for a patient.

Every blood component request to the laboratory for a patient should include special requirements to avoid dispensing inappropriate products.

Electronic medical records (EMR) are one way health services can highlight to clinical staff special requirement indications and communicate these to the laboratory.

Expert group determination: IBCT (specific requirements not met), certainly, SR4

ANZSBT have published updated guidelines for the prevention of transfusion-associated graft versus host disease[17] in January 2024.

Health services should review their policies and guidelines to ensure any necessary changes are made.

The new guidelines indicate when irradiated products may no longer be needed for some patient groups.

There was insufficient information to determine if this patient still required irradiated products.

However, health service policy was not followed.

As noted previously, STIR regularly receives reports of patients not receiving irradiated products when policy indicates they are needed.

Despite this no reports of TA-GVHD have ever been received to STIR.

Procedural – other

This category includes reports of events as shown in Table 25. This year, there were 7 validated procedural – other reports. These are events that have patient care implications, but do not fit into the other categories of events for STIR.

[17] <https://anzsbt.org.au/guidelines-standards/anzsbt-guidelines/>

There have been 2 events reported as procedural – other, but after review changed to IBCT. One event was reported as a near miss but validated as procedural – other.

This category includes reports of events as shown in Table 25.

Right blood, right patient events occur where a patient was transfused correctly despite one or more serious identification (ID) or prescription errors that in other circumstances might have led to an IBCT.

Table 25: Types of validated procedural other events FY23

Category	Number
Delayed, under or over transfusion	1
Right blood, right patient (RBRP)	4
Handling and storage errors (HSE)	2

Case study 8: Unclear communication leads to unnecessary transfusion

A patient was transferred to the ward from ICU.

On the ward, a full blood examination (FBE) was taken. However, before these results were available, a decision was made to transfuse the patient based on a previous result (Hb 71 g/L).

After the unit had been transfused the medical team became aware that the patient had in fact been transfused in ICU prior to the transfer.

Results from the FBE taken on the ward showed Hb was now 91g/L and transfusion was not actually required.

Expert Group determination: Procedural-other, over-transfusion

It is important the communication of transfusion events is part of any hand over and that the decision to transfuse is based on the patients' clinical condition and not only a Hb result.

Case study 9: Incomplete blood component/product checks

Staff checking a second unit of RBC to a patient found the unit number on the compatibility report did not match the details on the RBC bag.

The laboratory had switched compatibility labels on the RBC when preparing the two RBC units for the patient.

The clinical staff performing the bedside checks did not pick up the discrepancy with the first unit and administered the unit.

Expert group determination: Procedural-other, right blood, right patient, certainly, SR4

Bedside checks are the final chance to pick up errors earlier in the transfusion chain. Despite 2-person checks the error was not noted.

Case study 10: Documentation of removal and return to blood fridge

A unit of RBC was returned to the blood fridge more than 30 minutes after it had initially been removed.

A second staff member later removed and used the RBC unit for the patient, unaware it was no longer appropriate to be used.

Expert Group determination: Procedural other, handling and storage errors, certainly, SR4

Health services with blood fridges need to have clear instructions for staff about what to do if returning blood to a blood fridge after 30 minutes.

This includes clear documentation of removal and return times with a method to highlight when the blood is no longer suitable for use.

Blood cannot be returned to storage after it has been out of the blood fridge for more than 30 minutes.

If it is still required for the patient, it should be kept visible at the patient bedside where it can be used within 4 hours of removal from storage.

Blood Matters has developed a '30-min/4-hour' rule poster[18] to assist with interpretation of this rule.

Near miss

This year, there were 9 reports of near-miss events as shown in Table 26.

Near-miss errors provide an opportunity to investigate incorrect or inadequate transfusion processes and identify factors that can harm to the patient.

Table 26: Types of validated near miss events FY23

Event	Count
Administration	2
Labelling/documentation	2
Inappropriate component issued	2
Laboratory	2
Incorrect prescription or request for blood	1

[18] <https://www.health.vic.gov.au/patient-care/prescribing-and-clinical-use-of-blood-and-blood-products>

Case study 11: Inappropriate product issued and almost administered

A patient had undergone a haemopoietic stem cell transplant. They developed graft failure and required irradiated components.

The health service process for requesting irradiated components is to notify the blood bank, which then records the special requirement in the LIS.

Clinical staff need to include the irradiation requirement in the prescription and the staff need to include this when performing bedside checks. However, the health service noted that modifications, such as irradiation or CMV seronegative blood, are not easily visible in the EMR to perform this check.

In this case the order to the blood bank did not include the need for irradiation and as the patient was admitted under a unit other than haematology, the laboratory staff were not alerted and did not check the LIS. The staff administering the RBC were not familiar with the requirements for irradiation and without it being prescribed they did not know they had the wrong component.

Fortunately, the laboratory staff recognised the error quickly and recalled the RBC units before they were administered.

Expert Group determination: near miss, certainly, inappropriate product issued

The health service is working with the EMR team to improve visibility of required blood component modifications within the prescription at the time of transfusion.

Case study 12: Error in collection technique almost caused inappropriate blood group determination

A patient admitted post traumatic injury had the massive haemorrhage protocol activated. They were dispensed 6 O RhD-negative RBC while awaiting initial group and screen (GS) results.

Initial GS resulted as O RhD negative.

The blood bank was planning to thaw group O FFP, but the clinical team requested a delay.

Meanwhile, haematology and biochemistry samples were cancelled by the laboratory and a recollection requested due to possible contamination.

When the blood bank became aware of this, they requested a second group and screen sample. The second sample gave a result of A RhD positive.

On investigation, it was found the initial blood sample was taken upstream on the same limb that the O RhD negative blood was being transfused.

Therefore, sample was contaminated with cells from the transfused units.

The potential for an ABO incorrect FFP transfusion was luckily avoided.

The health service noted the staff member involved was on their first day of trauma rotation.

They have since been educated, and this case has been used as an education example at trauma meetings.

Expert Group determination: Near miss, SR4

Wrong blood in tube (WBIT)

WBIT errors continue to be a significant proportion of the procedural errors received by STIR.

The majority of WBIT specimens are collected by nursing or midwifery staff (Table 27).

When medical staff are involved, errors often occur when they hand off the collected specimen for someone else to label.

While this may be necessary in some cases, there should be a good process for ensuring the staff member labelling and signing for the specimens can complete patient identification procedures and label at the patient side.

Emergency (ED) and maternity departments consistently contribute the most WBIT events, as reported (Figure 6). The number of reports coming from the ED over the last 2 years has increased.

Both areas have high and unpredictable workloads, with patients who may not be able to participate in patient identification, or who are unidentified at the time of specimen collection.

Most often the error is recognised by the laboratory when results are discrepant with historical records (Table 28). This can only occur if the laboratory has a historical record for the named patient.

Factors that contribute to the error (Table 29) are most often reported as ‘The correct checking procedure for patient identification was not followed’ (n = 19; 70%).

Incorrect use of EMR is something that is being reported more often (n = 6; 22%), as health services increasingly move to use of EMR.

Health services should provide education for all staff involved in collection of specimens and easy access to information for staff who may not use the system for specimen collection regularly. This will help to ensure compliance with the process.

One instance (category ‘other’) occurred when the patient gave the incorrect identifiers (see case study 13). Patients also need to be aware of risks around incorrect patient identification.

Table 27: WBIT collectors identified

Staff member	Number (%)
Medical	6 (22)
Nursing	16 (59)
Pathology collector	-
Other: Midwife	4 (15)
Unknown	1 (4)

Figure 6: Location of WBIT errors

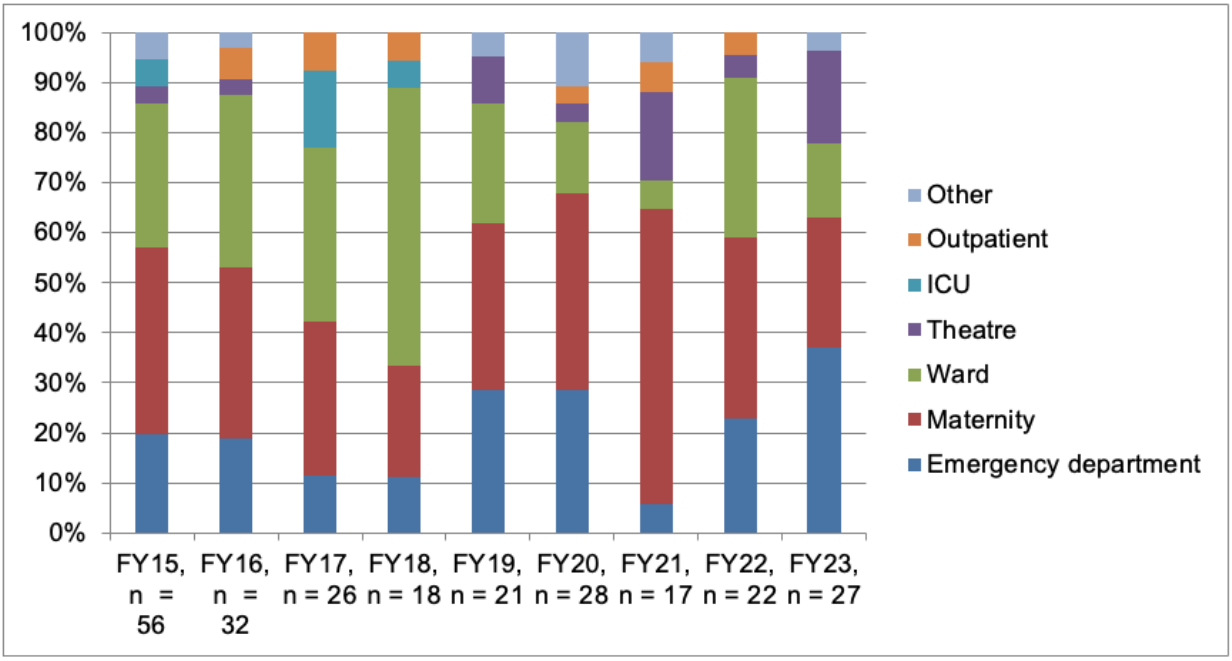


Table 28: How the WBIT was recognised

Category	Number (%)
Recognised prior to testing	2 (7)
Discrepancy noted when comparing sample results with historical record	18 (67)
Recognised post-testing but prior to issue	5 (19)
Significant change in MCV compared with prior testing	1 (4)
Recognised post-issue but prior to transfusion	1 (4)
Other (Kleihauer film reviewed and found to contain baby's cord blood)	1 (4)
Total incidents	**27**

Number is greater than incident number as more than one way of WBIT recognition could be reported.

Table 29: Incident contributing factors

Contributing factor	Number (%)
The correct checking procedure for patient identification was not followed	19 (70)
The sample tube was not labelled at the bedside	6 (22)
Incorrect use of EMR for specimen collection	6 (22)
Unknown	3 (11)
Patient not wearing a wristband	1 (4)
Use of incorrect addressograph labels	1 (4)

Contributing factor	Number (%)
Other, including: • **Lack of experience** • **Handing off specimens for labelling with full checks** • **Patient admitted under wrong identification** • **More than one nurse involved in the collection** • **Colleague labelled away from bedside for the collector** • **Lack of training in specimen collection using EMR**	7 (26)

Number is greater than total WBIT as more than one contributing factor could be selected.

Case study 13: Patients obtaining care under another person's identity

For two WBIT incidents this year, the error was not due to staff procedural errors. In both cases the patient had presented using another person's identifiers.

In one case, the laboratory identified a discrepancy in blood group after processing the sample (sample O RhD positive, historic record A RhD positive).

A repeat specimen was requested which provided the same result (O RhD positive) and raised concern over the patient identity.

Only after this did clinical staff find out that the patient had used another person's details to obtain care.

In the second case a group and save specimen was received, the labelling met zero tolerance policy, and the sample was processed.

As the named patient had no historic blood group, the result was entered into the LIS.

The clinical staff later found that the patient was using false identification and informed the laboratory.

Results were then removed from the LIS. This was initially reported to STIR as a near miss, however the wrong results were attributed to another person due to false identification to obtain care and not incorrect specimen collection processes, therefore is classified as a WBIT.

Expert group determination: both cases were WBIT events, due to patients deliberately misidentifying themselves

Education of patients, as well as staff, on the risks associated with WBIT events appears to be necessary.

If clinical staff become aware of a patient using a false identity it is necessary to educate the patient on the risks of this behaviour and alert the laboratory to address any results that may be incorrectly recorded.

Case study 14: WBIT using an EMR

Specimens were received for a patient undergoing a procedure at a health service that uses an EMR.

The tests were ordered electronically and labels printed at the patient's side, at the time of collection.

The specimens were collected by a nurse and the blood group result was O RhD positive with a positive antibody screen.

Three hours later, a second specimen was received in the laboratory for the same patient.

This specimen was flagged in blood bank, as the electronic form had not been signed (would lead to rejection of the specimen) and it had the same accession number as the first specimen received (different specimens should have different accession numbers).

The blood bank tested the specimen and compared results. The second specimen received had a different blood group (A RhD positive).

The laboratory asked for a re-bleed of the patient and a third specimen confirmed the blood grouping result of the first specimen received (O RhD positive). Specimen 2 was a WBIT.

The health service was unable to follow up with the staff member involved as the sample collection was not signed off in the EMR electronic form and the signature on the specimen was illegible.

It was unclear how labels could have been used for the wrong patient, as they should be printed at the bedside at the time of collection.

There appears to have been no final check of the patient identification with the specimen labelling before sending the specimens.

Expert Group determination: WBIT certainly

Electronic processes for specimen collection have the potential to improve the safety of the collection process when followed correctly. However, errors will occur when staff employ workarounds.

When using an EMR that permits label printing at the bedside, there should be no reason to pre-print labels that can be used incorrectly.

The final check of patient identification with the labelled specimens is an essential patient safety step.

RhD immunoglobulin (RhD Ig) errors

RhD immunoglobulin errors are the second most common procedural error reported to STIR.

The majority relate to antenatal prophylaxis (Table 30) and involve omission of a dose (Table 31), frequently both prophylactic doses, for a RhD negative woman.

Table 30: RhD Ig errors – intended administration (n = 15)

Intended administration indication	Number (%)
Antenatal prophylaxis	10 (67)
Sensitising event	-
Postnatal	5 (33)

Table 31: Types of RhD Ig incidents

Type of incident	Number (%)
Administered, not required (Rh negative mother with known RhD negative baby)	-
Administered, not required (RhD positive woman)	2 (13)
Administered, not required (woman with immune anti-D)	-
RhD Ig dose omitted	6 (40)
Delay in administration (> 72 hours)	2 (13)
Wrong or inadequate dose	3 (20)
Other: Incorrect route of administration of RhD Ig	2 (13)

Case study 15: Transcription error causes missed prophylaxis

On their first visit, the patient's blood group was incorrectly transcribed into the birthing outcomes system, an integrated pregnancy, birthing and neonatal record used by most Victorian maternity hospitals.

This documentation was used at subsequent appointments.

The patient did not receive RhD Ig prophylaxis during the pregnancy.

It was only when she presented in labour that the correct blood group was noted and RhD Ig administered, as the baby's blood group was RhD positive.

The woman's antibody screen was negative at this time.

Expert Group: RhD Ig administration error, certainly, SR4

Several health services have reported transcription errors, which puts women at risk of developing anti-D and future pregnancies being affected by haemolytic disease of the foetus and newborn (HDFN) because they did not receive prophylaxis during their pregnancy.

Access to results from the primary source, rather than transcribed results, is important to prevent these events. Reported events usually relate to missed does of RhD, rather than a woman receiving RhD Ig when not needed due to a transcription error.

Case study 16: Incorrect route of administration for RhD Ig

A woman who had a large fetomaternal haemorrhage required a large dose of RhD Ig (12,000 IU).

She was prescribed Rhophylac to be given intravenously (IV).

The nurse administering the product gave the dose intramuscularly (IM).

Rhophylac comes as 1,500 IU in 2 mL syringes, meaning that 8 syringes are needed to administer 12,000 IU.

IV administration is therefore advisable for patient comfort when doses above 5 mL are required.

If unable to obtain IV access or IV administration is contraindicated, then it is recommended to divide the dose and administer IM at different sites to minimise patient discomfort.

The health service has revised their procedures to clearly identify the dosing and routes of administration for staff.

They are making every effort to ensure this guidance is easily accessible when needed.

In another case, RhD Ig was prescribed to be administered IV to a woman after a large fetomaternal haemorrhage, but the wrong product was given.

RhD Immunoglobulin-VF (the Australian-made RhD Ig product) is only suitable for IM injection, which is clearly stated in the product information.

Where IV administration is required, Rhophylac is always to be used.

Health services with maternity and obstetric care need to have clear guidelines for the different products, routes of administration and in which circumstances each product should be used. For example, this may include thrombocytopenic, or due to the volume of dose to be administered. An example is given in Table 32 below.

Table 32: Suggested product and dosing

Product	Route of admin	Vial size	Possible guide for dosing per ml FMH
RhD immunoglobulin-VF	IM only	625 IU	≤6mls = 1 vial >6-12 mls = 2
Rhophylac	IV or IM IV recommended for patient comfort	1500 IU in 2mls	>12 - ≤ 24mls = 2 vials >24 - ≤ 36mls = 3 vials >36 - ≤ 48mls = 4 vials

Cell salvage

There were no reports of cell salvage errors to STIR this year.

References

Australian and New Zealand Society of Blood Transfusion (2021) *Guidelines for the implementation and use of electronic medical records for transfusion*, ANZSBT.

Australian and New Zealand Society of Blood Transfusion (2022) *Top five recommendations on low value practices*, ANZSBT.

Australian Red Cross Blood Service (2011) *Frequently asked questions about the use of Rhophylac* <https://transfusion.com.au/system/files/resource_library/frequently_asked_questions_about_the_use_of_rhophylac_9558.pdf>, accessed 8 May 2024.

National Blood Authority (2020) *Australian haemovigilance report: data for 2019–20*, National Blood Authority, Canberra.

Narayan S (Ed.), Poles D et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group (2023) *The 2022 Annual SHOT Report*. https://doi.org/10.57911/wz85-3885

Shaikh H, Shaikh S, Lee D and Mewawalla P (2018) 'Fresh frozen plasma: under-dosed and over-transfused', *Vox Sanguinis*, 113(7):296.

Appendix 1: STIR Expert Group members

Name	Title and affiliation
Dr Mandy Davis (Chair)	Consultant Haematologist, Alfred Health, Victoria
Dr Giles Kelsey	Consultant Haematologist, Melbourne Health, Victoria
Ms Christine Akers	Transfusion Nurse, Blood Matters Program, Victoria
Ms Linley Bielby	Manager, Blood Matters Program, Victoria
Dr Philip Crispin	Consultant Haematologist, The Canberra Hospital, Australian Capital Territory
A Prof Erica Wood	School of Public Health and Preventative Medicine, Monash University, Victoria
Ms Bridget Glazebrook	Data Manager, Blood Matters Program, Department of Health, Victoria
Dr Chris Hogan	Director Pathology Services, Austin Health
Dr Ellen Maxwell	Director of Haematology, Melbourne Pathology
Dr Tina Noutsos	Haematologist, Royal Darwin Hospital, Northern Territory
A Prof Merrole Cole-Sinclair	Director of Haematology, St Vincent's Hospital, Victoria
Dr Linda Saravanan	Haematologist, Melbourne Pathology
Ms Mary Comande	Blood Bank Scientist, Royal Children's Hospital
Dr James Daly	Medical Director of Pathology Services, Australian Red Cross Lifeblood
Ms Kaylene Bastin	Education Co-ordinator, Blood Matters Program, Victoria
Dr Kobie von Wielligh	Haematologist, Australian Red Cross Lifeblood
Ms Rae French	Scientist, Blood Matters Program, Victoria
Ms Meryanda Jodoin	Transfusion Clinical Nurse Consultant, Quality & Risk, Bendigo Health
Dr Anna Hutchinson	Haematologist, Royal Hobart Hospital, Tasmania
Dr Zhi Tan	Transfusion Medicine Fellow, Australian Red Cross Lifeblood

Appendix 2: STIR publications and promotions

Bulletins

- Bulletin 9: Blood administration – steps to reduce errors (March 2023)
- Bulletin 10: Wrong blood in tube (WBIT) – what can we do to reduce errors? (July 2023)

Conferences

- Blood 2023 – Poster: A review of delayed haemolytic and delayed serologic reactions reported to Serious Transfusion Incident Reporting program
- Oral presentation – Lessons learnt from the Blood Matters Serious Transfusion Incident Reporting system
- ISBT Gothenburg 2023 – Oral presentation: ABO incompatible transfusions still a significant risk: 15 years of data from the Serious Transfusion Incident Report (STIR) program, Australia.

Appendix 3: Imputability and severity scores

Imputability 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 scores

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 of 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

Appendix 4: Case studies

Appendix 5: STIR timeline

Year	Action
2006	Pilot July to October First notification received 16 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, encourages haemovigilance reporting
2014	Commenced annual STIR report
2015	Commenced RhD Ig and cell salvage reporting (1 January 2015) Change to WBIT reporting to exclude mismatch in labelling (zero tolerance)
2017	Review of all forms Commenced reporting of delayed serological transfusion reaction and transfusion-associated dyspnoea (1 July 2017)
2018	First *STIR bulletin* sent to health services and interested parties
2020	Commenced reporting of RhD isoimmunisations and hypotensive reactions (1 July 2020)
2021	included questions re electronic medical records in investigation forms (1 July 2021)