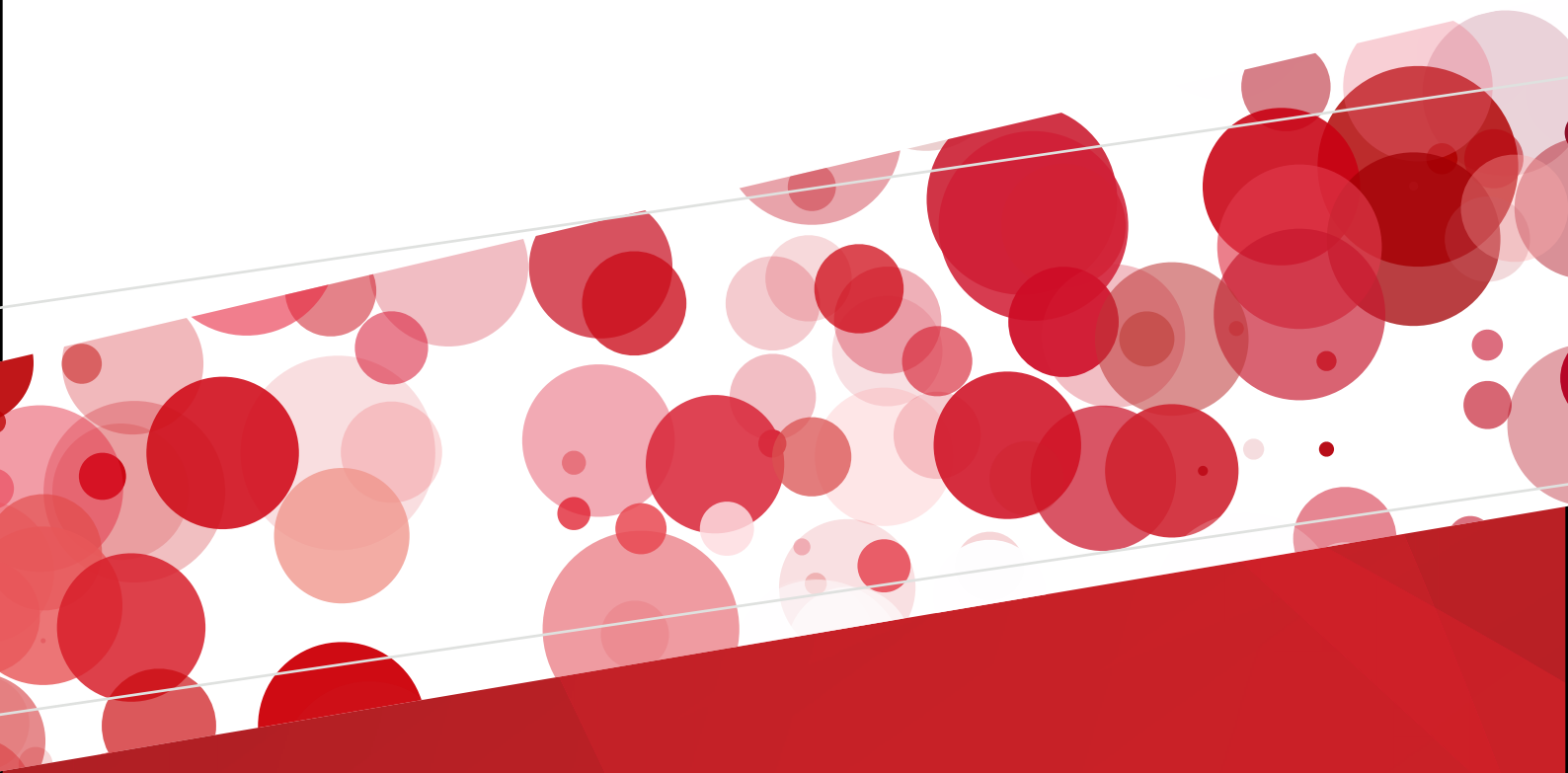
Serious Transfusion Incident Reporting (STIR) annual report 2020–21

Blood Matters program



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Blood Matters program

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Acknowledgements

The Serious Transfusion Incident Reporting (STIR) program is part of the work of the Blood Matters program, a collaboration between the Victorian Department of Health and Australian Red Cross Lifeblood. It is founded on the expectation that providing haemovigilance information supports the community by promoting better transfusion practice.

Without the support and contribution of the participating health services, both public and private, in the four participating jurisdictions, Victoria, Tasmania, Australian Capital Territory and Northern Territory, the program would not have continued to provide 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	Definition
ABO	the most important of the blood grouping systems
AHTR	acute haemolytic transfusion reaction
ATR	acute transfusion reaction
BP	blood pressure
BloodNet	BloodNet is a web-based system that allows staff in health facilities across Australia to order blood and blood products in a standardised way and to do so, quickly, easily and securely from Australian Red Cross Lifeblood
COVID-19	Coronavirus SARS-CoV2, an infectious disease caused by a coronavirus, causing respiratory illness in those infected
Cryo	cyroprecipitate
DAT	direct antiglobulin test
DHTR	delayed haemolytic transfusion reaction
DSTR	delayed serologic transfusion reaction
FFP	fresh frozen plasma
FNHTR	febrile non-haemolytic transfusion reaction
FY21	financial year 2021, 1 July 2020 to 30 June 2021
HLA	human leukocyte antigen
IBCT	incorrect blood component transfused
ICU	intensive care unit
IV	intravenous
LDH	lactate dehydrogenase
Lifeblood	Australian Red Cross Lifeblood
NBA	National Blood Authority
NSQHS	National Safety and Quality Health Service
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RhD Ig	RhD immunoglobulin
RhD iso	RhD isoimmunisation
SHOT	Serious Hazards of Transfusion – haemovigilance program in the UK
SR	severity rating
STIR	Serious Transfusion Incident Reporting
TACO	transfusion-associated circulatory overload
TAD	transfusion-associated dyspnoea
TA-GVHD	transfusion-associated graft versus host disease
TRALI	transfusion-related acute lung injury
TTI	transfusion-transmitted infection
WBIT	wrong blood in tube

Executive summary

The Blood Matters program is pleased to present the *Serious Transfusion Incident Reporting (STIR) annual report 2020–21*. The STIR program is part of a larger program of work to help health services improve the care of patients receiving blood and blood products in Victoria, Tasmania, Northern Territory and Australian Capital Territory. This report provides information on serious transfusion reactions and incidents reported from these four jurisdictions.

Although reporting to STIR is voluntary, the National Safety and Quality Health Service's (NSQHS) 'Blood management standard' requires participation in haemovigilance activities and reporting in accordance with national guidelines.

This year, STIR received 180 notifications, with nine withdrawn by the health service and 14 excluded by the expert group, leaving a total of 157 investigations in this report. Of the 105 health services registered with STIR, 33 (31 per cent) submitted reports. Considering the workload due to COVID-19, this level of reporting has been appreciated and demonstrates an ongoing commitment to incident reporting.

Blood Matters has developed key messages (p. 11) to be shared with clinical and governance staff *to help determine if work is needed in these areas and to raise awareness of the issues*.

Health services need to ensure appropriate procedures are in place for the identification of patients at all critical steps of the transfusion process, regardless of urgency or situation, and that staff understand and follow these procedures. Wrong blood in tube and incorrect blood component transfused incidents are both often associated with incorrect or incomplete patient identification steps. This is a recommendation that has been made over several years and is ongoing.

Key messages

Area	Recommendation
Patient identification	Correct patient identification is essential to several steps in the transfusion process. Incorrect or inadequate patient identification can lead to serious incidents. All staff need to understand what positive patient identification is and how it is to be performed: that is, asking the patient to state their name and date of birth where possible to compare to ID band and any documentation.
Clinical	Always suspect a transfusion reaction in the initial investigation of patient deterioration in the setting of current or recent transfusion. Treatment of life-threatening signs and symptoms is the priority in this situation and investigations occur once the patient has been stabilised (case study 1). Investigation of the reaction should include both clinical and laboratory components to eliminate possible reaction types. Clinical signs and symptoms alone may not help to eliminate all possible reaction types (case study 2). Health services should use checklists to assist in assessment of patient risk of TACO or to step clinical staff through the bedside check.
Governance	As seen in STIR reports delayed serologic transfusion reactions occur regularly. Pathology providers may not share information on antibody history when a patient moves between health services. This puts the patient at risk of a reaction if a known antibody can no longer be recognised on testing. We recommend a national database to record patient red cell alloantibodies, which would assist laboratories to share information on patient antibody history. Health services should ensure policies and procedures to prevent TA-GVHD are reviewed and up to date, and that these procedures decrease the risk of an at-risk patient receiving a non-irradiated product. Health services should ensure policies and procedures for RhD immunoglobulin administration are in line with recently updated guidelines, and that staff are aware of the guidelines and any changes in procedures (<https://www.blood.gov.au/sites/default/files/Guideline for the prophylactic use of Rh D immunoglobulin in pregnancy care.pdf>). Consider using electronic systems to identify patients and label specimens. These systems must have simple processes that cannot easily be overridden, in order to ensure safety mechanisms work (case study 12). See *ANZSBT guidelines* <https://anzsbt.org.au/guidelines-standards/anzsbt-guidelines/> for further information on developing electronic medical records for transfusion.

Area	Recommendation
Blood administration	Processes for collecting blood from blood fridges must be robust to ensure the correct product is collected each time. Identifiers must be taken to the fridge and checked at the time of collection, with the staff member documenting removal from storage (case study 8). Positive patient identification is essential in several steps in the transfusion process. It is important staff are aware of the importance of correctly performing this task. They should involve the patient in the process, wherever possible, by asking them to state their name and date of birth. This is an opportunity to pick up errors in patient identification earlier in the process, for example errors in details on the wristband (case study 9).

Introduction

Transfusion is a common procedure within health services. Transfusion reactions are reported to occur commonly, such as allergic and febrile non-haemolytic reactions, while others are much less common, such as TRALI, anaphylaxis or acute haemolytic transfusion reactions. The severity of these reactions can be mild, in some cases allowing, after treatment, for the transfusion to continue, to life-threatening reactions. STIR definitions encourage the reporting of more severe reactions and so may not represent a true overview of all reactions that occur.

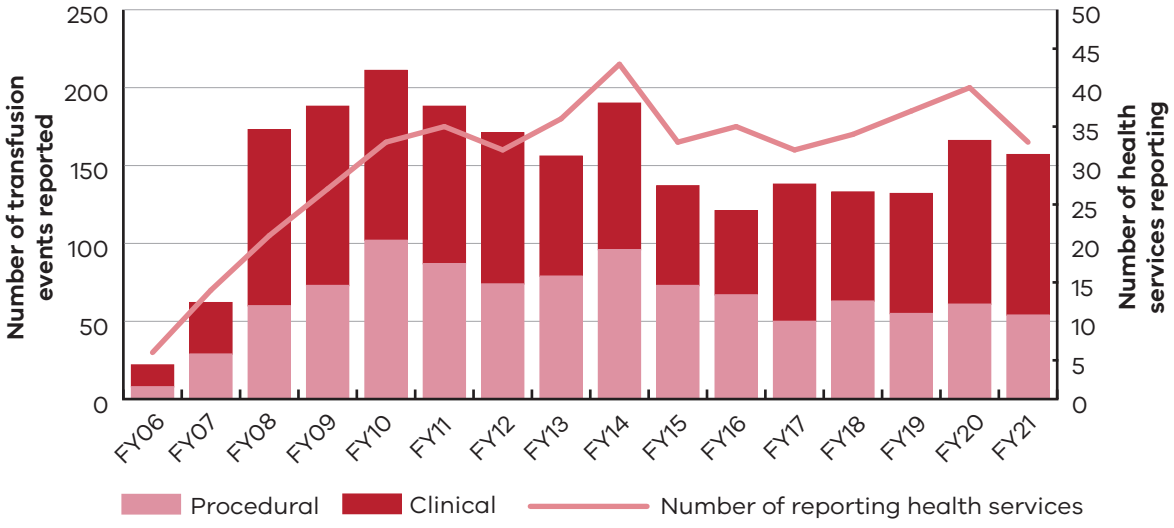
STIR reporting is also voluntary, and so may not receive all reports of reactions or incidents that meet our guidelines. We encourage health services to report to STIR all appropriate reactions and incidents to assist in understanding the true incidence of reactions within Australia and to assist the health service meet the requirements for the National Safety and Quality Health Service (NSQHS) Standards, for accreditation.

This report covers investigations from the period 1 July 2020 to 30 June 2021 (FY21). Despite COVID-19 workload and secondment of some quality staff to clinical areas, health services continue to report to STIR. Unlike some other international haemovigilance programs, reporting to STIR is voluntary and we appreciate that health services continue to place value on reporting.

In FY21, STIR received 180 notifications from 33 health services, with 157 reports being validated after review. These validated investigations form the basis of this annual report. The non-validated investigations were either withdrawn by the health service prior to review or were excluded after expert review. See 'Table 4: Reasons for withdrawal of notifications to STIR'.

STIR validated 103 clinical reports (reactions) and 54 procedural reports (errors and near misses). Figure 1 shows FY21 reports compared with previous years.

Figure 1: Number of validated clinical and procedural reports and health services reporting each financial year, FY2006 to FY2021



As shown in Figure 1, clinical events were reported more frequently than procedural events. This may represent improvements in safety systems and education of staff in relation to transfusion, helping to reduce the incidence of adverse procedural events. However, we are unable to confirm this definitively. In most instances, procedural events are preventable. Blood Matters continues to assist health services to recognise risks and develop systems to help prevent errors (see 'Key messages').

Currently there are 105 health services registered with STIR, 72 public and 33 private. In addition, general practices may report RhD Ig incidents using an aggregate code. Not all health services will have reports that fit STIR criteria each year. STIR focuses on more serious events. Reactions that may be reportable within the health service may not require STIR reporting.

The National Blood Authority (NBA), via BloodNet, provide data on blood product issues for the year (Table 1). Overall, there has been a slight increase in the number of blood products issued compared with the previous year.

Table 1: Total blood issues per jurisdiction 2020–21 (FY21)

Issues 2020–21	Victoria	Australian Capital Territory	Tasmania	Northern Territory
Total red cells	177,231	10,067	12,564	4,322
Total platelets	36,749	1,512	2,659	982
Total FFP	21,875	796	1,536	642
Total cryoprecipitate	31,770	3,512	2,687	753
Total	**267,624**	**15,887**	**19,446**	**6,699**

NBA data is also used to estimate the frequency of reactions for Victorian health services, as shown in Table 2.

Table 2: Estimated frequency of clinical reactions per product in Victoria (n = 95)

Product	Blood issues (Vic.)	Validated clinical events	Frequency
Red cells	177,231	62	1:2,859
Platelets	36,749	25	1:1,470
FFP	21,875	8	1:2,734
Cryoprecipitate	31,770	1	1:31,770

There were no SR 1 events or root cause analyses reported in FY21.

Method

Reporting to STIR requires multiple steps at both the health service level and at Blood Matters.

Health services should review the event/reaction and determine the likelihood it is transfusion related and the type of event or reaction it is, including whether it fits STIR criteria.

At Blood Matters, several validation steps take place, to ensure as much as possible all STIR criteria are met and all available information is available to expert reviewers.

STIR is currently working to improve the process of feedback to health services when events are determined to be either not assessable or excluded. Emails to the reporter are sent with information when this occurs.

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

Withdrawn reports

Notifications to STIR may be withdrawn for several reasons. For FY21, health services withdrew nine reports for reasons as shown in Table 4.

Another 14 reports were excluded after expert review. This may occur if the information provided indicates there may be another reason, other than the transfusion, that caused the patient's signs and symptoms, or because there is not enough information provided to make a determination.

The STIR expert group will provide timely feedback to reporters when an investigation is found to be not assessable or is excluded in future. This will be an email to the reporter to inform them of the decision.

Table 4: Reasons for withdrawal of notifications to STIR

Financial year	Duplicate	Not in scope	Deemed not transfusion related by health service	Not completed	Excluded after expert review	Total STIR notifications	Total withdrawn n (%)
2012–13	2	4	–	4	–	166	10 (6)
2013–14	1	6	4	16	–	227	27 (12)
2014–15	9	11	6	8	4	175	38 (22)
2015–16	6	11	5	5	4	152	31 (20)
2016–17	5	4	2	1	5	155	17 (11)
2017–18	3	5	–	2	15	158	25 (16)
2018–19	5	16	3	1	14	171	39 (23)
2019–20	9	11	4	2	22	214	48 (22)
2020–21	2	3	2	2	14	180	23 (13)

Validation and reconciliation

Validation of data is an important component of the STIR program, with all returned investigation forms reviewed by an individual member of the expert group. If the reviewer has any uncertainty, the investigation may have a second review or go to the group for consensus review and validation. All SR 1 and SR 2 events are reviewed by the group to ensure consistency of reporting.

Expert review of investigations may lead to a change in the type of incident or in the severity rating assigned, determined on the information provided, as shown in Table 5 and Table 6.

Table 5: Changes to incident type following STIR expert group review

Original incident type	Validated as: Febrile non-haemolytic	Validated as: ATR ana-phylactic	Validated as: Acute hypotensive	Validated as: TACO	Validated as: DSTR
Acute haemolytic	1	–	–	–	–
ATR – allergic	–	1	–	–	–
ATR – other	1	–	1	–	–
ATR bacterial	1	–	–	–	–
ATR TACO	–	–	–	1	–
DHTR	–	–	–	–	1
TAD	–	–	–	1	–

In addition, three reported near misses were reclassified as other procedural, RhD administration and WBIT.

Table 6a: Type of clinical report at notification versus as validated

Type: Clinical report	As notified by health services	As validated
ATR	60	61
DHTR	7	7
DSTR	22	23
TA-GVHD	0	0
TRALI	2	1
TACO	10	10
TAD	2	1
PTP	0	0
RhD isoimmunisation	1	1
TTI bacterial	2	0
TTI viral	0	0
Total reports	**104**	**104**

Numbers may not add up as one report may record more than one type of incident at notification for example, IBCT with ATR

Table 6b: Type of procedural report at notification versus as validated

Type: Procedural report	As notified by health services	As validated
IBCT	7	7
Other, procedural	2	3
WBIT	16	17
Near miss	9	6
RhD administration	21	22
Total reports	**55**	**55**

Numbers may not add up as one report may record more than one type of incident at notification for example, IBCT with ATR

For FY21, there were four reports with multiple notification categories, with final validation resulting in two reports with more than one type of incident type (ATR /TACO and a DSTR/ procedural other).

Severity ratings

The severity rating of events is assigned by the reporter at the time of notification, and also by the reviewer. Appendix 3 provides definitions. When these do not align, a third person will review and determine, or if unable to decide will take the investigation to the expert group. Where either party determines the severity is SR 1 or 2, the investigation goes to the expert group for review and validation.

A small number of events are not assigned a severity rating (WBIT, near miss, and RhD administration). This is because although there is potential for serious harm in some cases, no harm has occurred.

The majority of reports (89/114, 78 per cent) validated caused no or little harm to the patient (SR 3 or 4). There were 23 events that were determined to be SR2 with no SR1 events validated.

Table 7: Changes to the severity rating following expert review

Incident type (number)	Incident severity rating submitted as	Incident severity rating validated as
Allergic/anaphylactic reaction (2)	SR4	SR3
Allergic/anaphylactic reaction (2)	SR4	SR2
Febrile non-haemolytic transfusion reaction (1)	SR4	SR3
Febrile non-haemolytic transfusion reaction (1)	SR4	SR2
DHTR (1)	SR4	SR3
DSTR (1)	SR4	SR3
TACO (2)	SR4	SR3
TRALI (1)	SR4	SR2
RhD iso (1)	SR4	SR2

Demographics

Figure 2 shows the number of registered and reporting health services and total number of reports for each jurisdiction.

Figure 2: Number of validated reports per reporting jurisdiction

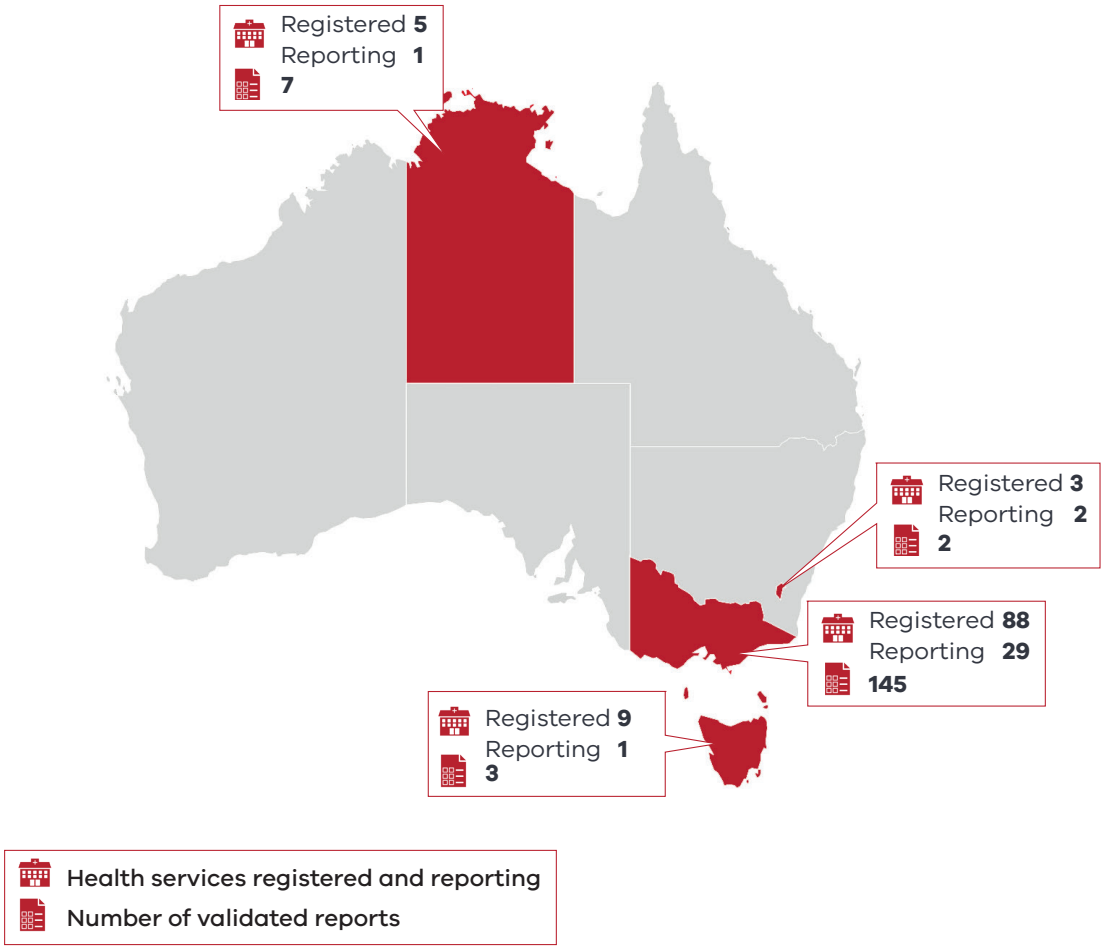


Table 8 shows the demographics for validated reports in FY21. Considering all notification categories except RhD-related incidents, the mean age was 51 years, with 72 (53 per cent) females compared with 64 (47 per cent) males. For all RhD incidents the average age was 32 years.

Red cells remain the most reported product associated with reactions and incidents.

Table 8: Demographics for all validated reports (excluding RhD incidents)

Demographic	Statistic
Age	51 (range 0–93 years)
Gender	Male: 63 (47%) Female: 71 (53%)
Blood products notifications	Red cells: 72 Platelets: 28 Fresh frozen plasma: 9 Cryoprecipitate: 1 Multiple products: 3
Other	Includes WBIT n = 17, near miss n = 3, TACO [buffy coat granulocytes] n = 1

Sentinel events

This year there were no sentinel events reported to STIR. This is supported by the Safer Care Victoria 2020–21 Sentinel events annual report <https://www.safercare.vic.gov.au/publications/sentinel-events-annual-report-2020-21>, in which there were no reported sentinel events related to transfusion.

Future

Recently, the STIR expert group reviewed STIR definitions of reporting categories and compared them with international haemovigilance programs. Most definitions were consistent with international definitions. Where there were differences, these were reviewed, and decisions made on whether to change them. Where changes have occurred, these will be reported in the information following.

Clinical reports

In this reporting period, there were 103 validated clinical investigations.

As in previous years, acute transfusion reactions (not including pulmonary complications or bacterial contamination) are most common, with febrile non-haemolytic and allergic reactions being most often reported in this category.

Figure 3: Validated clinical reactions FY21

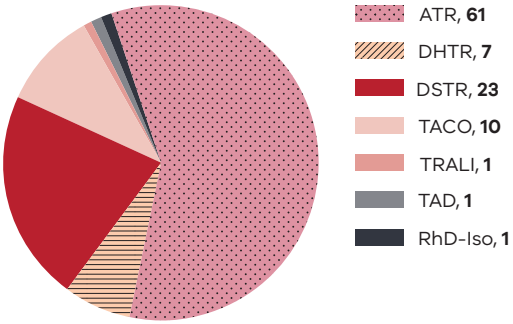


Table 9: Breakdown of ATR clinical reports

Reaction	Number
Febrile non-haemolytic transfusion reaction	25
Allergic/anaphylactic/anaphylactoid	31
Acute haemolytic	1
Hypotensive	1
Other	2

Table 10: Validated reaction type by blood component

Blood component	FNHTR	Allergic	Hypotensive	AHTR	TACO*	TRALI	TAD
Red cells	22	3	1	1	8	–	–
Platelets	3	18	–	–	1	1	1
FFP	–	7	–	–	–	–	–
Cryo	–	1	–	–	–	–	–
Multi	–	2	–	–	–	–	–

*TACO – plus one buffy coat granulocytes

Table 10 shows the products reported given prior to reactions. There was one reaction reported that was associated with the use of buffy coat granulocytes. The expert group agreed that this was likely TACO, associated with a relatively large number of blood products given. As would be expected, allergic reactions occur more commonly with platelets and plasma, rather than red cells. TACO and FNHTRs are more often reported with the use of red cells.

Febrile non haemolytic transfusion reactions (FNHTR)

FNHTRs are one of the most reported reactions to STIR. These reactions can involve mild symptoms that resolve with antipyretics and can allow the transfusion to continue. More severe reactions with rigours and higher fever can occur and should involve testing to ensure a more severe reaction type, such as acute haemolytic or transfusion-transmitted bacterial infection, has not occurred.

Expert group review of the definition used by STIR for reporting of FNHTRs has determined that an increase in the temperature from current 38.5 degrees Celsius and/or 1.5 degrees Celsius rise in temperature, to 39 degrees Celsius and/or 2 degrees Celsius rise in temperature will make STIR reporting consistent with other haemovigilance group definitions, for example ISBT and SHOT, and commenced July 1, 2022.

Within a health service the definition of FNHTR may have a lower temperature for reporting and investigation, however, not all FNHTRs will be reportable to STIR. Reporting should only include those that meet STIR definition or where there is other serious signs and symptoms associated.

The majority of FNHTR reports to STIR this year are related to red cells, older patients (> 50 years) and men (68 per cent), as shown in Table 11.

Table 11: Data summary – febrile non-haemolytic transfusion reaction, n = 25

Characteristic	Number (%)
Age: < 1 year	–
Age: 1–18 years	1 (4)
Age: 19–29 years	2 (8)
Age: 30–49 years9	1 (4)
Age: 50–69 years	8 (32)
Age: 70–79 years	10 (40)
Age: 80+ years	3 (12)
Gender: male	17 (68)
Gender: female	8 (32)
Implicated blood product: red cells	22 (88)
Implicated blood product: platelets	3 (12)

There were two reports that had a severity rating 2, which may occur when patients being transfused in an ambulatory setting require admission following the reaction. Imputability is generally low for this reaction type, with 19 of 25 (76 per cent) being possibly related to the transfusion (Table 12).

Table 12: Severity rating and imputability – febrile non-haemolytic transfusion reaction

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	–	–	–	–
SR 2	–	1	1	2
SR 3	1	2	6	9
SR 4	–	2	12	14
Total	**1**	**5**	**19**	**25**

Table 13: FNHTR by associated signs and symptoms

Signs and symptoms	Number
Fever	23
Chills	13
Tachycardia	8
Rigours	6
Hypertension	3
Dyspnoea/difficulty breathing	3
Headache	1
Back pain	1
Nausea/vomiting	1
Hypotension	1
Chest pain/discomfort	1
Itching/rash	1

Fever, chills and rigours and tachycardia are common with FNHTRs. In a small number of patients, more severe signs and symptoms that need to be investigated occur, such as hypotension, dyspnoea or chest pain/discomfort (Table 13). Investigation to ensure the fever is not associated with a more serious reaction is always recommended. Bacterial cultures, and/or investigations for signs of haemolysis help eliminate bacterial contamination or an acute haemolytic transfusion reaction as the possible cause of fever and may help to identify an underlying cause, such as infection.

Table 14: FNHTR and associated treatment

Treatment	Number
Antipyretics	21
IV fluids	4
Oxygen	2
Inotropes/pressor agents	1
Assisted ventilation	1
(other – anti-emetic)	2
(other – antibiotics)	1

SHOT (2020 report) noted several inappropriate treatments given for reactions. Treatment should be based on the signs and symptoms and cover the most serious and likely reactions. Most commonly, they describe inappropriate treatment with steroids and antihistamine (over 40 per cent of purely febrile reactions were given an antihistamine and/or a steroid) in patients without signs of allergic reactions. There is no evidence of clinical benefit in patients with only febrile type symptoms and may further immunosuppress already immunocompromised patients.

In the STIR data for this reporting period, it is pleasing to see that treatment for FNHTR did not include antihistamines or steroids. The majority received antipyretics, with a small number requiring oxygen, inotropes and/or assisted ventilation, this could be due to other clinical conditions occurring at the same time as the transfusion reaction (Table 14).

Allergic / anaphylactic reactions

Allergic/anaphylactic reactions were the largest proportion of clinical reactions reported at 30 per cent. One-third of these reports related to anaphylaxis or severe allergic reactions to blood components. STIR definitions do not include reporting for minor allergic reactions, for example, rash without other signs or symptoms.

Approximately one-third of all reports (35 per cent), both allergic and anaphylactic occur in those aged under 18 years of age (Table 15). The most common implicated product for both allergic and anaphylactic reactions is platelets (58 per cent overall), followed by FFP (26 per cent overall).

Table 15: Data summary – allergic/anaphylactic

Characteristic	Allergic, n = 24 (%)	Anaphylactic, n = 7 (%)
Age: < 1 year	–	–
Age: 1–18 years	8 (33)	3 (43)
Age: 19–29 years	–	–
Age: 30–49 years	5 (21)	1 (14)
Age: 50–69 years	7 (29)	1 (14)
Age: 70–79 years	1 (4)	1 (14)
Age: 80+ years	3 (13)	1 (14)
Gender: male	17 (71)	4 (57)
Gender: female	7 (29)	3 (43)
Implicated blood product: cryoprecipitate	1 (4)	–
Implicated blood product: fresh frozen	6 (25)	2 (29)
Implicated blood product: platelets	14 (58)	4 (57)
Implicated blood product: red cells	2 (8)	1 (14)
Implicated blood product: multiple products	1 (4)	–

Severity ratings for allergic and anaphylactic reactions are high due to the type of reactions and STIR not requiring reporting of incidents of rash only. Seventy-five per cent of allergic reactions were SR 3 or higher. For anaphylactic reactions, 86 per cent of reactions were determined to be SR 2 (Tables 16a and b).

Table 16a: Allergy – Severity rating and imputability

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	–	–	–	–
SR 2	1	2	2	5
SR 3	4	7	2	13
SR 4	1	5	–	6
Total	**6**	**14**	**4**	**24**

Table 16b: Anaphylactic – Severity rating and imputability

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	–	–	–	–
SR 2	2	2	2	6
SR 3	1	–	–	1
SR 4	–	–	–	–
Total	**3**	**2**	**2**	**7**

A small number of allergic reactions were associated with signs and symptoms not generally associated with allergic reactions, such as fever, chills and rigours and back pain. The most common sign or symptom was itching/rash, followed by dyspnoea/difficulty breathing (Table 17).

Table 17: Allergic transfusion reactions by associated signs and symptoms

Signs and symptoms	Allergy (%)	Anaphylactic (%)
Itching/rash	21 (88)	5 (71)
Dyspnoea/difficulty breathing	8 (33)	3 (43)
Tachycardia	8 (33)	2 (29)
Restlessness/anxiety	5 (21)	2 (29)
Hypotension	5 (21)	3 (43)
Respiratory wheeze	4 (17)	3 (43)
Nausea/vomiting	4 (17)	1 (14)
Hypertension	2 (8)	2 (29)
Fever	1 (4)	1 (14)
Chest pain/discomfort	1 (4)	–
Chills	–	1 (14)
Rigours	–	2 (29)
Back pain	–	1 (14)

Treatment included antihistamines and or steroids in 68 per cent of all reactions. Inotropes/pressor agents were required for all anaphylactic reactions, and a third of allergic reactions. Oxygen was used for 21 per cent of allergic and 43 per cent of anaphylactic reactions, with one patient reported as requiring intubation (Table 18).

Table 18: Reported treatments for allergic/anaphylactic

Treatment	Allergy [n = 24] (%)	Anaphylactic [n = 7] (%)
Antihistamines	17 (71)	4 (57)
Steroids	15 (63)	6 (86)
Inotropes/pressor agents	8 (33)	7 (100)
IV fluids	6 (25)	3 (43)
Oxygen	5 (21)	3 (43)
Antipyretics	3 (13)	–
Intubation	–	1 (14)
Other – anti-emetic	2 (8)	–

Case study 1: Possible anaphylactic reaction to FFP

A 33-year-old male coming off bypass after mitral and aortic valve replacement was administered two bags of FFP, given over 15 minutes in total. About five minutes post-transfusion, the patient developed severe refractory hypotension, BP 41 systolic, diastolic unrecordable. It was noted the patient had also received protamine approximately 20 minutes prior to the reaction.

He was administered adrenaline, metaraminol, methylene blue and IV fluids; and blood pressure improved while still in theatre. The patient was transferred to ICU on an adrenaline infusion.

Post-transfusion tryptase level was 18.5 mcg/L (normal < 11mcg/L, per health service).

At the time, anaphylaxis was not necessarily considered as the most likely cause, given the other potential causes (post-cardiopulmonary bypass, vasoplegia, long bypass time, sepsis) and the lack of response to adrenaline. In view of the positive tryptase, it is suspected FFP was the most likely cause due to the proximity of the event to its administration and the absence of any reaction with the first dose of protamine.

STIR expert group validation: Possible anaphylactic/anaphylactoid, SR 2

Comments

A transfusion reaction should always be suspected in the initial investigation of patient deterioration in the setting of current or recent transfusion. Treatment of life-threatening signs and symptoms is the priority in this situation and investigations occur once the patient has been stabilised. As in this case, there may be other medications or treatments that may be involved in the patient deterioration, and it may be difficult to determine definitively if the transfusion was the cause.

Hypotensive

STIR commenced accepting reports of hypotensive reactions July 1, 2020. STIR has received two notifications of hypotensive reactions, with one validated as a possible hypotensive reaction.

The STIR definition is:

> An isolated fall in systolic BP of 30 mmHg or more occurring during or within one hour of completing transfusion AND a systolic BP 80 mmHg or less in the absence of allergic or anaphylactic symptoms. More serious reactions might include hypotension, as previously defined, leading to shock (for example, acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms (based on SHOT definition).

Case study 2: Possible hypotensive reaction to red cells

An 85-year-old man was admitted with symptomatic anaemia, with a background of known iron deficiency anaemia (previously investigated). He was ordered and administered two units of red cells. Approximately 20 minutes into the second unit of red cells, the patient developed hypotension (BP pre 140/70; post 70/40), without other signs and symptoms. The initial treatment was for a potential allergic reaction with antihistamine given. No other treatment for the hypotension was described.

STIR expert group validation: possible acute hypotensive, SR 4

Comments

Hypotension may be a sign associated with several reaction types and investigation to eliminate these alternative causes for hypotension is important. The health service performed a compatibility check, which showed the unit was compatible with the post-transfusion patient sample and the DAT was negative, indicating a haemolytic reaction was unlikely. This was supported by a negative haemolysis screen and normal blood film. Patient and product blood cultures eliminated bacterial contamination as a possible cause. An IgA level, taken on a pretransfusion specimen, was normal and tryptase was within normal limits, indicating an allergic reaction was unlikely.

Acute haemolytic transfusion reaction (AHTR)

Acute haemolytic transfusion reactions are reported infrequently to STIR, with few of these resulting from an ABO incompatible transfusion. Incorrect blood component transfused notifications occur more often with a slightly larger number of these being ABO incompatible. These ABO incompatible IBCT investigations occur with all fresh products, not only red cells, while acute haemolytic reactions as reported are almost exclusively associated with red cells.

In this reporting period there was one acute haemolytic reaction validated by the expert group and related to an anti-Kell antibody not evident on pretransfusion testing (Table 19).

Table 19: Data summary – acute haemolytic

Characteristic	AHTR (n = 1)
Age	50–69 years
Gender	female
Implicated blood product	Red cells
Severity rating	SR 2
Imputability	Certainly

Acute transfusion reaction – other

Reactions are classified as 'ATR – other' when the information provided indicates the transfusion is likely to be the cause of signs and symptoms described, and there is no indication of other causes for the signs and symptoms. These reactions do not fit into other transfusion reaction categories.

In this financial year, there were two events validated as transfusion reactions that did not fit into our usual reporting categories but were thought to be associated with the transfusion event.

Delayed haemolytic

Definitions for reporting of delayed haemolytic and serologic reactions were reviewed by the expert group. The NBA definition is antibodies manifest 24 hours to 28 days post-transfusion. At the time of adding the delayed definitions to STIR in 2017, there was much discussion of the timeframe for reporting. While most antibodies will appear in this timeframe, they may not be found until later when the patient attends for other treatments. For this reason, STIR has decided to maintain the current definition of occurring up to three months post-transfusion.

Table 20: Data summary – delayed haemolytic and serologic reactions

Characteristic	Delayed haemolytic reaction, n = 7 (%)	Delayed serologic reaction, n = 24 (%)
Age: < 1 year	–	–
Age: 1–18 years	–	1 (4)
Age: 19–29 years	1 (14)	1 (4)
Age: 30–49 years	–	5 (21)
Age: 50–69 years	3 (43)	4 (17)
Age: 70–79 years	3 (43)	6 (25)
Age: 80+ years	–	7 (29)
Gender: male	1 (14)	10 (42)
Gender: female	6 (86)	14 (58)
Implicated blood product: red cells	7	24

Table 21a. Severity rating and imputability – delayed haemolytic reaction

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	–	–	–	–
SR 2	–	1	–	1
SR 3	2	1	–	3
SR 4	3	–	–	3
Total	**5**	**2**	**–**	**7**

Table 21b: Severity rating and imputability – delayed serologic reaction

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	–	–	–	–
SR 2	–	–	–	–
SR 3	1	1	–	2
SR 4	15	5	1	21
NA	1	–	–	1
Total	**17**	**6**	**1**	**24**

Case study 3: Development of new antibody, with haemolysis, in patient with multiple antibodies

A 70-year-old woman was admitted via the emergency department with non-ST-elevation myocardial infarction associated with chronic blood loss and anaemia. She had a history of both previous transfusion and pregnancy.

On this admission she received four units of red cells, six days later she was found to have developed a Jk(a) antibody, that was not evident pretransfusion. The patient had a history of two other antibodies (anti-E and anti-Leb). Post-transfusion it was found two of the transfused units were Jk(a) positive. The patient had indications of haemolysis with a raised LDH and reticulocytes, and low haptoglobin, signs of jaundice and anaemia. Blood bank testing demonstrated a positive DAT with anti-Jk(a) eluted from the red cells.

Comments

Patients with one red cell antibody are more at risk of developing further antibodies. It is unclear when the patient initially developed this antibody. Some antibodies can become undetectable, but when the patient is presented with the cogent antigen, responds quickly and leads to haemolysis.

The most commonly reported antibodies in both haemolytic and serologic reactions are Jka, E and c (Table 22). These antibodies are not always associated with haemolysis.

Table 22: Antibodies implicated in delayed haemolytic and serologic reactions

Antibody	Haemolytic (number)*	Serologic (number)*
Jka	2	9
E	3	6
c	2	4
Fya	–	3
Kpa	–	2
Cw	–	2
C	1	1
Fyb	1	1
M	–	1
S	–	1
Wr	–	1
Unknown	–	1

*Number is greater than reports as some reports had more than one antibody identified.

Delayed serologic

Delayed serologic reactions are reported more often than haemolytic reactions.

Case study 4: New antibody found at time of next admission

A 77-year-old woman received a transfusion of two units of red cells for anaemia and ongoing blood loss. She had a history of previous transfusion and uncertain history of pregnancy reported.

About six weeks later, the patient was readmitted for another unrelated procedure. At this time she was found to have a positive DAT and an anti-c antibody. She had a previous known anti-E. The units transfused were identified as c positive.

STIR expert group validation: DSTR, certainly SR 4

Comments

There was no indication that the patient had any haemolysis associated with this transfusion. The antibody was identified at the time of readmission to the same health service and could be related back to the transfusion received.

Patients who have developed one antibody are at risk of developing further antibodies with ongoing transfusions. The incidence of antibody development is debated and ranges between the percentages of 1–6 per cent in single transfused and up to 30 per cent in multitransfused patients (Zalpuri et al. 2012). The likelihood of a particular patient becoming immunised after a particular blood transfusion is known to be highly variable, therefore regular blood bank testing is important to identify new antibodies, to ensure compatible blood for patients.

Transfusion-associated circulatory overload (TACO)

TACO in many instances is a preventable transfusion reaction. Assessment of the patient for risk factors, transfusing only the minimum amount of blood necessary and not rushing non-urgent transfusions all assist in minimising the risk.

TACO (n = 18) and transfusion delays (n = 12) are the most common causes of transfusion-related deaths in the UK in 2020 and accounted for 30/39 deaths (76.9 per cent). SHOT reporting of pulmonary complications (TACO, TRALI, TAD) in 2020 had these complications as a contributing factor in the deaths of 23 patients. Some of these could have been prevented and measures must be taken to address these. Vigilance, effective communication, collaboration among staff and use of a TACO checklist are all useful in reducing these incidents (SHOT 2020).

Blood Matters TACO checklists, swingtags and posters can be found on the Serious Transfusion Incident Reporting system website <https://www.health.vic.gov.au/patient-care/serious-transfusion-incident-reporting-system>.

In this reporting period, there were 10 TACO investigations validated (see Table 23). While there were no deaths attributed to TACO, there were three SR 2 events validated, as shown in Table 24. These events are serious and often require increased high-level care of the patient, including admission to intensive care units (ICU).

Review of reporting definitions for TACO showed that several haemovigilance programs included reports of TACO occurring up to 12 hours post-transfusion. Currently the NBA reporting criteria are for up to 6 hours post-transfusion. The decision was made for STIR reporting to remain at up to 6 hours post-transfusion to remain consistent with NBA reporting requirements.

Table 23: Data summary – TACO

Characteristic	TACO [n = 10] (%)
Age: < 1 year	–
Age: 1–18 years	1 (10)
Age: 19–29 years	–
Age: 30–49 years	2 (20)
Age: 50–69 years	2 (20)
Age: 70–79 years	1 (10)
Age: 80+ years	4 (40)
Gender: male	3 (30)
Gender: female	7 (70)
Implicated blood product: red cells	8 (80)
Implicated blood product: platelets	1 (10)
Implicated blood product: buffy coat granulocytes	1 (10)

Table 24: Severity rating and imputability

Severity rating	Imputability: certainly	Imputability: probably	Imputability: possibly	Total
SR 1	–	–	–	
SR 2	–	2	1	3
SR 3	–	2	5	7
SR 4	–	–	–	–
Total	**–**	**4**	**6**	**10**

Case study 5: TACO associated with the use of buffy coat granulocyte transfusion

A 34-year-old woman admitted with cellulitis, necrotising fasciitis, requiring surgical debridement (day before transfusion), and pseudomonas bacteraemia on a background of lymphoma was given buffy coat granulocyte transfusions for major infection, on a background of neutropenia. She had no history of pre-existing cardiac or respiratory disease.

During the administration of the eighth bag of buffy coat granulocytes (volume approximately 750 mL total, given over approximately one hour) she developed dyspnoea and reduced oxygen saturation, tachycardia, rigours and chills, fever, nausea and vomiting, and back pain. The buffy coat granulocyte transfusion was ceased, and no further bags administered.

Assessing her fluid balance was difficult as recording of output was incomplete, but she had had significant inputs over the last few days prior to this transfusion (5,840 mL, and 4,422 mL).

A chest X-ray showed 'interval pulmonary venous congestion with air space opacities in the perihilar regions bilaterally consistent with acute pulmonary oedema'. Transthoracic echo, undertaken in ICU, showed hyperdynamic left ventricle, no large pericardial effusion.

The patient required oxygen therapy and admission to ICU, there was no reported diuretic given. The health service noted the deterioration in condition could be associated with underlying sepsis in the patient.

STIR expert group validation: possible TACO, SR 2

Comments

While buffy coat granulocyte transfusions are not common, this blood product commonly results in transfusion reactions. Buffy coat granulocyte transfusions provide granulocytes to support patients with severe infections and neutropenia, where the neutropenia is reversible and the infection has not responded to appropriate antibiotic or antifungal therapy. Multiple buffy coat granulocyte bags are required to provide an adequate dose. Adverse events such as febrile reactions, occasional severe pulmonary reactions and HLA (human leucocyte antigen) alloimmunisation can be associated with buffy coat granulocyte transfusions. In this case the patient would appear to have potentially had positive fluid balances in the days prior to the infusion, with the 750 mL of buffy coat granulocytes leading to overload during the transfusion. The fever and rigours are unlikely related to the TACO but could be caused by either the buffy coat granulocytes or the underlying sepsis. While respiratory reactions to buffy coat granulocytes are common, in this case the chest x-ray supports the diagnosis of TACO.

Transfusion-related acute lung injury (TRALI)

Table 25: Data summary – TRALI

Characteristic	TRALI (n = 1)
Age:	1–18 years
Gender:	female
Implicated blood product:	platelets
Severity rating:	SR 2
Imputability:	Probably

In this financial year, there was one case of TRALI validated by the expert group after consultation with Lifeblood as to their findings in this case (Table 25).

The true incidence of TRALI is difficult to ascertain due to possible under recognition and under reporting. Literature has a wide range of 1:1200 to 1: 190,000 for incidence and mortality of five to 24 per cent. Approximately 80 per cent of cases are antibody or immune mediated, the remaining 20 per cent are non-immune, associated with biological response modifiers.

While Lifeblood will test for anti-HLA or anti-HNA antibodies in donors, these are not necessarily always found in all cases. Where antibodies are found it allows for deferral of these donors from future donation.

TRALI is rarely reported to STIR. In the 2020 SHOT report there were two cases documented. Internationally there has been work to refine the definition of TRALI.

In Australia strategies to reduce the risk of TRALI have included the use of male only clinical plasma, with plasma from female donors being used to make processed products. This is used as a mitigation strategy as female donors are more likely to have leucocyte alloantibodies due to pregnancy and the processing of plasma helps to reduce the risk of TRALI with processed products. Platelet and red cell products are suspended in an additive solution, that minimises the amount of plasma in these products. These steps help to reduce the risk of antibody mediated TRALI but does not completely remove risk.

There has been no established treatment for TRALI beyond supportive care and monitoring. Research is ongoing into potential strategies for treatment.

Case study 6: probable TRALI

A six year-old female was receiving random donor platelets, for low platelet count on the background of a haematologic condition, in an ambulatory day ward. The bag was administered over approximately 50 minutes, in a patient without obvious risk of overload.

At the end of the transfusion the patient developed dyspnoea, reduced oxygen saturation and tachycardia. It was noted she had mottled skin. She was administered oxygen and intramuscular adrenaline, as initially allergy was suspected.

Chest X-ray showed 'diffuse ground glass air space opacification throughout both lungs in keeping with pulmonary oedema'. The patient was admitted, resulting in a temporary increase in care and an increased length of stay. The reaction was reported to Lifeblood as a possible TRALI and information from Lifeblood did not have donor testing available but supported the diagnosis of TRALI on clinical grounds.

STIR expert group validation: TRALI, probably, SR2

Transfusion-associated dyspnoea (TAD)

TAD is characterised by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress, not explained by the patient's underlying condition or any other known cause, is the most prominent clinical feature.

For this report there was one TAD validated by the expert group (Table 26).

Table 26: Data summary – TAD

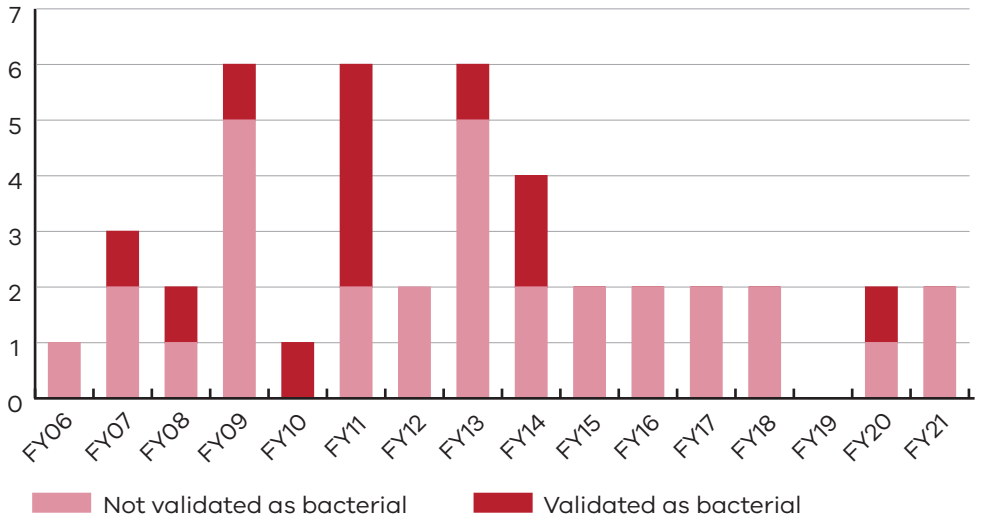
Characteristic	TAD (n = 1)
Age	1–18 years
Gender	male
Implicated blood product	platelets
Severity rating	SR 2
Imputability	Possibly

Transfusion-transmitted infection, bacterial

STIR receives a very small number of reports of possible bacterial reactions to blood products, 42 since reporting commenced to end of FY21.

Figure 4 shows reports to STIR of possible bacterial contamination compared with confirmed reports, in total 12 were confirmed as bacterial contamination (the last one in FY20). In this case the patient had received both a red cell and platelet transfusion prior to the reaction.

Figure 4: Bacterial contamination – notifications



The risk of septic reaction is very small with red cells estimated at < 1:2.5 million, while with platelets the risk is estimated at 1:250,000, due to the differences in storage (Lifeblood).

Lifeblood originally introduced universal bacterial contamination screening of platelet components in 2008. In 2021, Lifeblood was able to move to seven-day shelf-life platelets. By implementing a strategy of taking a larger sample volume at a later time (36 hours), there is an increased ability to detect low levels of bacterial contamination and therefore safely extend the shelf life from five to seven days. Cultures continue for seven days, and platelet components are released as negative to date.

STIR has had only 12 validated investigations over the life of the program, of these seven related to red cell transfusion, six related to platelet transfusion, and in one the patient received both red cells and platelets prior to the reaction.

While a small number of notifications are received for suspected bacterial contamination and associated infection in the patient, it is rare that this is confirmed (1 in 3–4 STIR notifications). Confirmation by culturing the same organism from the patient and component is required. Where bacterial contamination is suspected it is important to keep the blood bag and giving set (sealed) for further investigation.

STIR bulletin no. 7 was Transfusion-transmitted bacterial infection and current mitigation strategies in Australia <https://www.health.vic.gov.au/publications/transfusion-transmitted-bacterial-infection-and-current-mitigation-strategies-in>, providing an overview of the current risk of bacterial infection related to blood component transfusion.

In this period, although STIR received two reports of possible bacterial contamination, neither was validated as this (one FNHTR, the other ATR other).

Transfusion-transmitted infection, other

STIR receives even fewer reports of these types of reactions. The risk of contamination is very small for all blood products, due to careful donor selection and testing at Lifeblood, and is reflected in the minimal reports received.

In FY21, there were no reports of other transfusion-transmitted infections to STIR.

Transfusion-associated graft versus host disease (TA-GVHD)

There have been no reports of TA-GVHD to STIR since its inception.

Australian guidelines for the Prevention of Transfusion-Associated Graft Versus Host Disease (TA-GVHD) are available and irradiation of cellular components provides safety to patients at risk.

In the IBCT category we receive regular reports of patients receiving non-irradiated blood products when there has been a requirement for irradiation for the patient. Despite this, we have not seen TA-GVHD occur.

Prevention of TA-GVHD has been by irradiating products for at-risk patients to prevent the proliferation of viable T lymphocytes which are the immediate cause of TA-GVHD. Despite this, TA-GVHD still occurs in individuals with no known risk factors, most likely due to similarity of donor and recipient major histocompatibility antigens, for example where the donor is homozygous for an antigen present in the recipient. (ANZSBT guidelines)

More recently the British Society for Haematology have reviewed their guidance and note that leucodepletion and age of product, with most cases occurring in patients who have received product aged greater than 14 days, confer some protection against TA-GVHD. ANZSBT are in the process of reviewing the Australian guidelines.

RhD isoimmunisations

From 1 July 2020, STIR commenced accepting reports of alloimmunisation to the RhD antigen.

The STIR guide defines these as cases of RhD-negative women who become sensitised and are found to have developed immune anti-D, which is detected during pregnancy, either at booking or later in the pregnancy, or following and attributable to pregnancy. This definition is in line with the SHOT definition.

Case study 7: RhD isoimmunisation

There has been one report to STIR of an RhD isoimmunisation in this year. In this case the antibody was detected at 40 weeks gestation (titre 1:2,048).

The reporting health service was not the one that had cared for the woman during her pregnancy. The woman had been transferred from a regional health service with her infant after the birth of the newborn, who required extended care, including phototherapy and admission to neonatal intensive care unit due to haemolytic disease of the newborn. The long-term outcome for the infant was not recorded.

The mother was group A, RhD negative and the baby group A, RhD positive. It was documented as unknown if she had had any sensitising events during the pregnancy, but she had received all appropriate routine prophylaxis. The woman was known to have had a previous spontaneous miscarriage, but no details of RhD immunoprophylaxis.

Testing from the first health service at time of delivery showed an anti-E and anti-D.

The comment was:

> Anti-E detected. In the event of transfusion, E Negative blood should be given. Anti-D detected. This is probably a passive antibody due to the prophylactic administration of anti-D gamma globulin

The antibody was not titred to assess its strength.

At the reporting health service, a sample from the woman detected anti-E and anti-D. The anti-D titre was 2048, so concluded that the patient was isoimmunised, and that the anti-D was NOT due to prophylaxis. Last prophylaxis was given seven weeks prior to this testing and a level this high would not be expected.

Comments: The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZOG) in conjunction with the National Blood Authority (NBA), published updated guidelines for the use of RhD immunoglobulin in pregnancy care in 2021 and while it does not specify titration or quantification of significant antibodies, the *ANZSBT guidelines for transfusion and immunohaematology laboratory practice* state:

> When a red cell antibody is detected, its specificity must be identified, clinical significance determined and risk of HDFN assessed. If the antibody is clinically significant, the level should be measured by titration or quantitation.

Laboratories often rely on clinical staff to provide information on if and when RhD immunoglobulin was administered. If there is inaccuracy in this information, isoimmunisation may be missed, and the pregnancy continue without appropriate monitoring.

Post-transfusion purpura

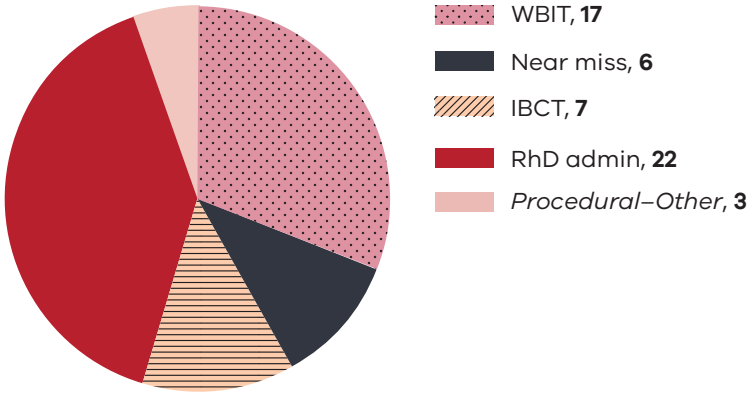
There have been no reports of post-transfusion purpura in FY21.

Expert group review of reporting definitions found that the haemovigilance programs reviewed all defined PTP as characterised by thrombocytopenia arising 5-12 days following transfusion. STIR will change definition from seven to 10 days to five to 12 days to be in line with other reporting systems.

Procedural reports

This report includes 55 procedural reports validated by expert review. As per Figure 5 WBIT reports remain high, but this year have been bypassed by RhD administration errors. Procedural errors are most often avoidable with good, well-understood procedures that are followed.

Figure 5: Validated procedural reports FY21



Incorrect blood component transfused

For this financial year there were seven IBCT events validated (Table 27). There were no ABO incompatible transfusions reported. Of these reports four relate to errors originating in the laboratory. Two reports related to errors in documentation in the electronic medical record (EMR), either not signing for a product administered, leading to a second unit transfused or not cancelling an administration order that was no longer required, leading to an inappropriate transfusion (Table 27). This is not reflected in Table 28 where events occurred, as this is reported as the area the patient is in at the time of the incident. This may not reflect that an error in the laboratory or in a pathology collection area led to the incorrect transfusion. Incorrect checking at the time of administration may not pick up on these errors earlier in the chain, allowing the incorrect product to be administered.

Table 27: Types of IBCT events FY21

Event	Count
ABO compatible	2
Specific requirements not met	1
Inappropriate platelet/plasma product	1
Other red cell antigen incompatibility	1
Inappropriate	2

Table 28: Where events occurred

Location	Count
ICU	2
Day unit	1
Ward	2
Blood bank	1
Unknown	1

Case study 8: IBCT ABO compatible

A woman requiring advanced resuscitation for ante-partum haemorrhage in the operating theatre received red cells urgently. The units were taken from a blood fridge, assuming they were the emergency O negative units. While the units were O negative, they had been cross-matched for another patient. The checking process at both collection and administration did not identify the unit was cross-matched for a different patient. A staff member, unfamiliar with the collection process for blood products, did not complete checks, as policy required at the blood fridge. As the unit was group O negative, it was assumed to be correct by the nurses performing bedside checks. However, they did not notice the other patient's name attached to the bag.

There was no harm to the patient, as the unit was compatible for her.

Comments

All staff should be made familiar with the requirements for collecting blood from blood fridges, and completion and signing of the blood register. The assumption that previous steps in the transfusion chain have occurred correctly is never wise. The blood checks at the patient side are the last chance to pick up errors earlier in the chain. All steps need to be completed, even in the event of urgent transfusion. It is important that all documentation attached to the product is checked so that incorrect products are not administered.

Procedural – other

Procedural – other includes incidents where a patient received the correct blood product/s despite one or more prescription, identification or administration errors occurring. This also includes problems in any aspect of the transfusion process, not fitting into IBCT or near-miss categories. Examples include:

- transfusions that run over the four-hour time period for administration
- administration of blood where there is a mismatch in one or more patient identifiers for example 'DOB 5/3/64' instead of '3/5/64'
- transposed patient (compatibility) labels on blood bags, meaning that the donation number on the patient (compatibility) label did not match the donation number on the Lifeblood label.

Table 29 categorises the types of Procedural other events validated by STIR and following Serious Hazards of Transfusion categories.

Table 29: Types of validated procedural other events FY21

Category	Number
Inappropriate transfusion (includes delayed, under or over transfusion)	–
Right blood, right patient (RBRP)	2
Handling and storage errors (HSE)	–
Errors relating to information technology (IT)	1

Case study 9: Incorrect patient identification procedure leads to transfusion with incorrect date of birth

A patient was administered a unit of red cells on day two of admission. A phlebotomist who attended the patient for specimen collection after the transfusion, found that the date of birth, as documented on the patient identification was incorrect.

All documentation that came with the red cell unit included matching (but incorrect) date of birth. The patient had previous specimen collection that did not pick up the error and the error was not noted at time of administration of the blood.

STIR expert group validation: Procedural other, certainly, SR4

Comments

The patient was conscious and alert, and the health service noted the patient had not corrected the staff prior to the transfusion. This may indicate that the correct process for patient identification was not followed, that is asking the patient to state his name and date of birth. Presumably, the patient, if asked, would have stated his correct date of birth, providing the staff the opportunity to note the error.

Near miss

Near miss events are an opportunity to find where there are potential risks in the transfusion chain without harm to the patient. Near misses are an important learning opportunity for health services and provide an opportunity to assess what are the current risks. We continue to support reporting of near-miss events for this reason.

Table 30 shows the types of reports to STIR for the reporting period.

Table 30: Types of validated near-miss events FY21

Event	Count
Labelling/documentation	4
Laboratory	1
Storage and handling	1

Case study 10: Spiking component prior to blood checks leads to waste

Two patients were admitted to the emergency department, both requiring blood products. The first patient was prescribed red cells and platelets. He had received a unit of red cells and was awaiting platelet transfusion. The second patient was prescribed multiple products post-trauma. A unit of FFP arrived via pneumatic chute system. This was assumed by the RN to be platelets for the first patient, however, was actually FFP for second patient. No checks were undertaken at time of collection from chute. The bag was spiked prior to bedside checks. When checks were then performed, the error was discovered and the unit was removed, with no FFP administered. The unit was wasted and delayed treatment for the second patient.

Comments

The health service indicated this process of spiking the bag prior to checks was against policy. Blood checks should always take place at the bedside, immediately prior to spiking the blood bag. In this way, any errors can be remedied prior to starting the transfusion and wastage can be avoided.

Collection of blood products from a site distant to the laboratory, such as a pneumatic chute, should have processes in place for staff to perform checks to ensure they are collecting blood for the right patient. Assumptions that the product delivered is for a particular patient have led to collection of incorrect products, as reported to STIR, including ABO incompatible transfusions, and administration of the incorrect product when bedside checks have been incomplete.

Wrong blood in tube (WBIT)

Wrong blood in tube events continue to be reported regularly and remain a focus for improvement in health services. In communications with transfusion nurses, they report difficulties finding successful improvement strategies for these errors. Specimen collection occurs in all areas and many clinical staff engage in this process. Ensuring all staff are aware of the safe procedure for collection and labelling of specimens and that they follow this procedure each time seems difficult.

Strategies to address WBIT events have included such things as:

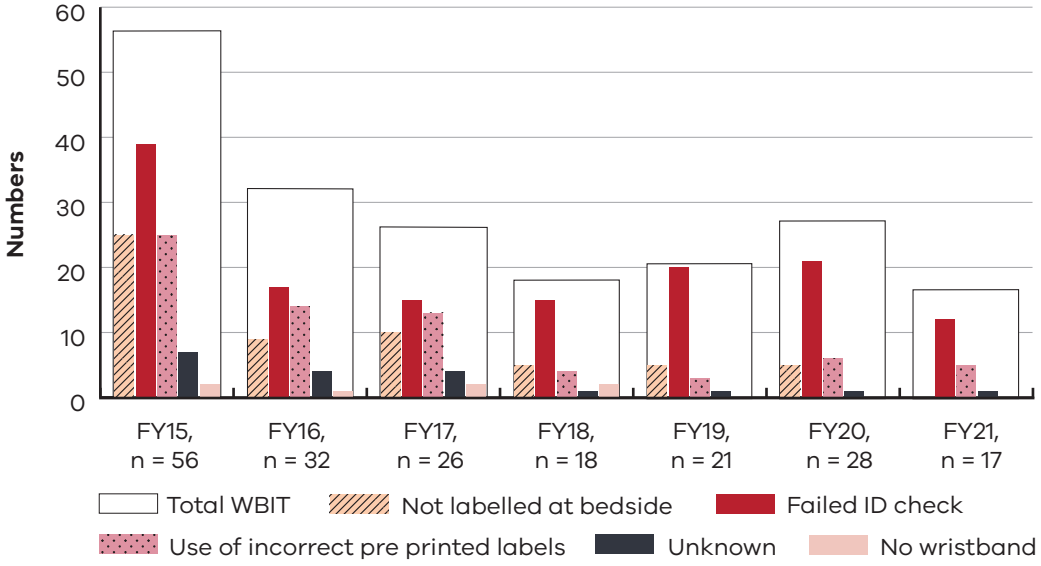
- zero tolerance procedures for blood bank specimens
- education for all staff involved in the process
- champions in clinical areas
- policy/procedure review
- staff reflection tools for those that make major mislabelling/WBIT errors
- reporting incidents and/or data to managers and clinical governance committees or data on executive dashboards
- working with communicating for safety committees
- observational audits.

One health service reports that the implementation of an electronic system that requires scanning of the patient identification band to assist in patient identification, printing of specimen labels at the time of collection and at the patient side, and electronic form and sign off, has helped to significantly reduce the number of WBIT events.

Where events still occur, they are largely related to areas that continue to use paper-based forms, or in the use of near patient testing for example, blood gases. This is supported in a paper by Kaufmann et al. 2019, which showed a significant difference in the incidence of WBIT in manual systems compared with electronic systems (1:3046 versus 1:14,606).

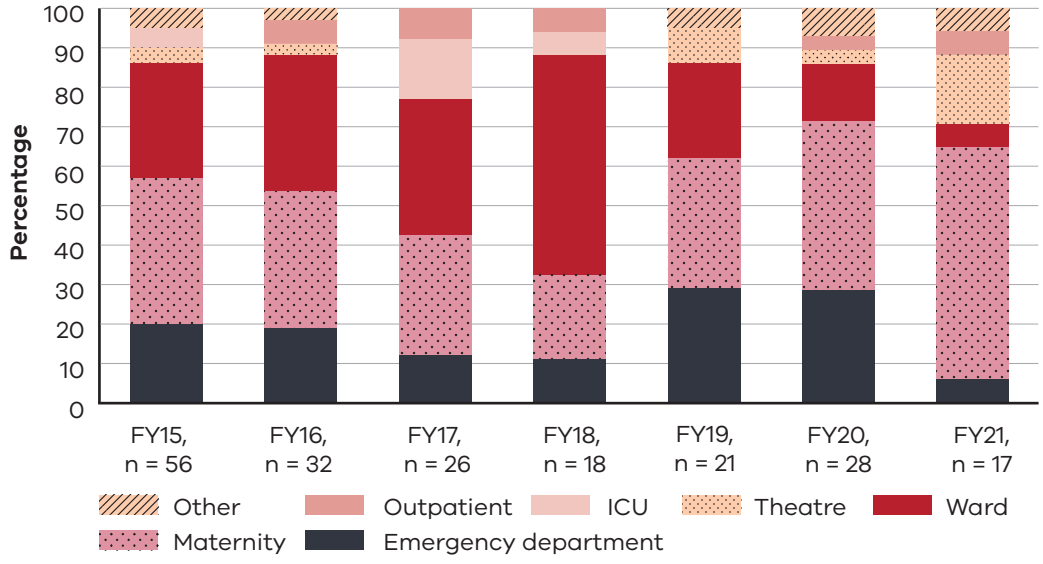
In this reporting period, WBIT is the second most reported procedural event after RhD immunoglobulin, representing 31 per cent of all procedural errors.

Figure 6: Factors contributing to WBIT incidents (multiple responses per event)



There are a number of contributing factors in WBITs (Figure 6). It is pleasing to see that patients not wearing a wristband for identification has not been reported in the last three years. A new variable, namely the use of EMR contributing to WBITs was added into the investigation forms commencing July 2020. Four reports identified EMR as contributing to the incident.

Figure 7: Location of WBIT errors



In most years, the WBIT errors commonly occur in the emergency department and maternity units. The SHOT program in the UK noted in their 2020 report that the majority of reported WBIT errors occurred in maternity. As noted in previous STIR reports, emergency and maternity are both areas where there can be high stress workloads and patients who are not able to participate in the patient identification process. Workflows may also contribute to specimen collection occurring prior to patient identification and wearing of ID bands.

This year 10 of the 17 reported WBIT events came from the maternity area (Figure 7). While a portion of these relate to cord bloods being attributed to the mother, this is not always the cause of WBITs in this area. Unusually, this year there were more WBITs reported in theatre than in the emergency department.

Table 31: How the WBIT was discovered

Category	Number (%)
Recognised prior to testing	6 (35)
Discrepancy noted when comparing sample results with historical record	6 (35)
Recognised post-testing but prior to issue	1 (6)
Significant change in MCV compared with prior testing	1 (6)
Recognised post-issue but prior to transfusion	0
Other	3 (18)
Total incidents	**17**

Case study 11: Specimen labelling away from the patient side

Two patients were transferred to the birth suite with both having blood samples taken at the time of intravenous cannula insertion. In both cases the staff members removed the unlabelled specimens from the patient room, in order to print labels for the specimens. When an emergency occurred both staff left the unlabelled specimens on the staff desk, coming back and labelling and sending the specimens after the event.

In processing the specimens, the blood bank became aware that the historical group for one patient was different to current results. The birth suite staff were alerted and both patients had repeat blood samples taken.

The health service was using the EMR for ordering of pathology specimens, however it was common practice to take specimens at the time of cannulation before an electronic order had been generated. It was also noted that the area lacked enough label printers for the workload.

The health service is now investigating the ability of midwives to initiate pathology orders, to enable collection of specimens at time of cannula insertion. They were also purchasing additional printers for the area and educating both midwives and obstetricians on the collection process via a variety of methods.

STIR expert group validation: WBIT, certainly

Comments

It is important EMRs assist staff to follow safe processes for the collection of specimens. Where common practices are at odds with the process, review and risk assessments need to take place. As this health service is doing, finding ways of working that are both safe and follow usual clinical practice is essential to make sure the process stays safe. Education needs to include, not just what to do, but why it is important to follow the process; what are the safety aspects of the workflow.

Where labels are not readily available at the patient side, handwritten documentation of patient identification should occur prior to removal of any specimens from the patient side.

Where an electronic sampling system is in place, it should assist the staff to follow all safety steps for example, enough printers to take to the bedside for printing and labelling at the bedside.

Case study 12: Incorrect choice of printer for specimen labels and incomplete checking of labels used leads to WBIT

An anaesthetist in operating theatre 1 was ordering a group and screen for patient A. However, the printer chosen for printing the patient labels was located in operating theatre 2, where patient B was also having a group and screen taken. The nursing staff did not check the labels they were using against patient details (no positive patient identification) prior to collecting samples or after specimens were labelled. The samples from theatre 2 were sent to the laboratory, with the wrong patient identification.

The error was recognised prior to testing.

STIR expert group validation: WBIT, certainly

Comments

Care must be taken when choosing printers in the EMR setting for printing of either requests or labels. When removing labels for use from printers it is important that these are checked against the patient identification, using positive patient identification whenever possible. Labels sent to the incorrect printer, or labels left behind form a previous collection can both lead to WBIT events.

RhD immunoglobulin incidents

In 2021 the Guideline for the prophylactic use of Rh D immunoglobulin in pregnancy care <https://www.blood.gov.au/sites/default/files/Guideline%20for%20the%20prophylactic%20use%20of%20Rh%20D%20immunoglobulin%20in%20pregnancy%20care.pdf> was published. This was a joint project between the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the National Blood Authority, Australia (NBA).

In 2020, Blood Matters commenced providing targeted education to midwives in a '5 in 5' format, five individual hour-long sessions run over five days. We are also working on other education opportunities with the ANMF to provide education to this group of clinicians, including highlighting the new guidelines.

Blood Matters has also developed an infographic to highlight the essential steps for RhD immunoglobulin administration, available on the Blood Matters website <https://www.health.vic.gov.au/patient-care/blood-matters-program>.

Incidents related to missed doses of RhD immunoglobulin or errors in timing or dosing continue to be reported to STIR. In this period there were 22 validated reports, representing 40 per cent of all procedural errors, as shown in Table 32 intended administration and Table 32 Types of RhD incidents.

Table 32: RhD Ig errors – intended administration (n=22)

Intended administration	Number (%)
Antenatal prophylaxis	18 (82)
Sensitising event	2 (9)
Postnatal	2 (9)

Table 33: Types of RhD Ig incidents

Type of incident	Number n = 22 (%)
Administered, not required (Rh negative mother with known RhD-negative baby)	1 (4)
Administered, not required (RhD positive woman)	4 (18)
Administered, not required (woman with immune Anti-D)	–
RhD Ig dose omitted	11 (50)
Delay in administration (> 72 hours)	3 (14)
Wrong or inadequate dose	1 (4)
Other: near miss (RhD positive patient prescribed RhD Ig)	2 (8)

Case study 13: Miscommunication leads to inappropriate RhD Ig administration

A woman in early pregnancy, home pregnancy test positive, commenced passing frank blood and small clots. She was diagnosed as undergoing a miscarriage. The medical officer contacted the laboratory and asked for a verbal report on the patient blood group. During this communication there was a misunderstanding about the blood group, with the medical officer understanding the woman was RhD negative. The medical officer then ordered RhD Ig for the patient. Information on the accompanying paperwork reported the woman as RhD positive, however no one questioned this at the time of administration and the dose was given.

STIR expert group validation: RhD Ig administration, inappropriate, SR4

Comments

Care must always be taken in the reporting of blood groups. Where at all possible documented blood groups, rather than relying on verbal or transcribed results, are the preferred method of communicating results. When administering the product, it is important to check all accompanying paperwork to ensure any discrepancies are found and addressed prior to administration.

Case study 14: Missed RhD Ig administration

At 38 weeks it was noted that a woman had not received any RhD Ig prophylaxis despite a RhD-negative blood group, no action was taken at this time. At delivery this was reported, but unclear in the medical record if the woman had received a dose at delivery.

The health service noted the woman had multiple failure to attend for appointments and routine bloods were not taken until later in her pregnancy.

There was no report of the infant blood group but testing of the woman just prior to delivery did not demonstrate any antibodies. Follow up testing was not provided.

In another report the routine dose was missed at the 28-week appointment, but given at 35 weeks when found, the 36-week dose was then administered at 38 weeks. Although there was delay in providing prophylaxis the health service had given treatment once the issue was identified.

Comments

Missed doses of RhD Ig are relatively commonly reported. A process such as sign off by the person reviewing blood results assists health services to ensure administration where needed is not missed. In several cases the health service has noted that the woman involved has had some complex care issues, but any process should work in all situations to ensure complete care is given.

Education of the woman to ensure she understands the importance of attending appointments and/or following up with blood tests is necessary to ensure compliance. In the above case, even when a blood test was available it does not appear there was follow up to ensure she received RhD Ig as required.

Cell salvage

As in previous years there have been no reports of incidents related to either intra or post-operative cell salvage use.

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Appendix 1: STIR expert group members

Members 1 July 2020 to 30 June 2021 (FY21)

Name	Title and Affiliation
Dr Amanda Davis (CHAIR)	Consultant Haematologist, Alfred Hospital, Victoria
Dr Giles Kelsey	Consultant Haematologist, Royal Melbourne Hospital
Ms Christine Akers	Transfusion Nurse, Blood Matters Program, Victoria
Ms Linley Bielby	Program 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
Ms Clare Hennessy	Transfusion Nurse Consultant, Eastern Health (resigned)
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 Glenda Mann	Blood Bank Scientist, Cabrini Health, Victoria
Ms Rae French	Scientist, Blood Matters Program, Victoria
Ms Meryanda Jodoin	Transfusion Clinical Nurse Consultant, Quality & Risk, Bendigo Health

Appendix 2: STIR publications and promotions

STIR annual report launch -September 22, 2020

ISBT36th International Congress, 2020 poster: Increasing safety and awareness of RhD immunoglobulin through haemovigilance reporting

ISBT 36th International Congress, 2020 oral presentation: Incorrect blood component transfused – is it changing over time?

STIR bulletins:

- Transfusion-transmitted bacterial infection and current mitigation strategies in Australia, August 2021
- Emergency issue of O RhD negative emergency red cell units – not without risk, January 2021
- Passive transfer of antibodies in patients receiving intravenous immunoglobulin (IVIg), December 2020
- Electronic medical records and transfusion, June 2020

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

Number	Category	Topic
1	Allergic	Possible anaphylactic reaction to FFP
2	Hypotensive	Possible hypotensive reaction to red cells
3	DHTR	Development of new antibody, with haemolysis, in patient with multiple antibodies
4	DSTR	New antibody found at time of next admission
5	TACO	TACO associated with the use of buffy coat granulocyte transfusion
6	TRALI	Probable TRALI
7	RhD isoimmunisation	RhD isoimmunisation
8	IBCT	ABO compatible transfusion
9	Procedural other	Incorrect patient identification procedure leads to transfusion with incorrect date of birth
10	Near miss	Spiking component prior to blood checks leads to waste
11	WBIT	Specimen labelling away from the patient side
12	WBIT	Incorrect choice of printer for specimen labels and incomplete checking of labels used leads to WBIT
13	RhD Ig administration	Miscommunication leads to inappropriate RhD Ig administration
14	RhD Ig administration	Missed RhD Ig administration

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 dyspnooea (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)

Appendix 6: Text-equivalent descriptions

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

- 180 notifications from health services
- 9 notifications withdrawn before investigation returned
- 171 investigation forms sent to STIR expert group for review
- 37 investigations required second review
- 14 investigations excluded by expert review
- 157 validated reports included for analysis

Figure 2: Number of validated reports per reporting jurisdiction

- Victoria: 88 registered; 29 reporting; 145 validated reports
- Australian Capital Territory: 3 registered; 2 reporting; 2 validated reports
- Tasmania: 9 registered; 1 reporting; 3 validated reports
- Northern Territory: 5 registered; 1 reporting; 7 validated reports