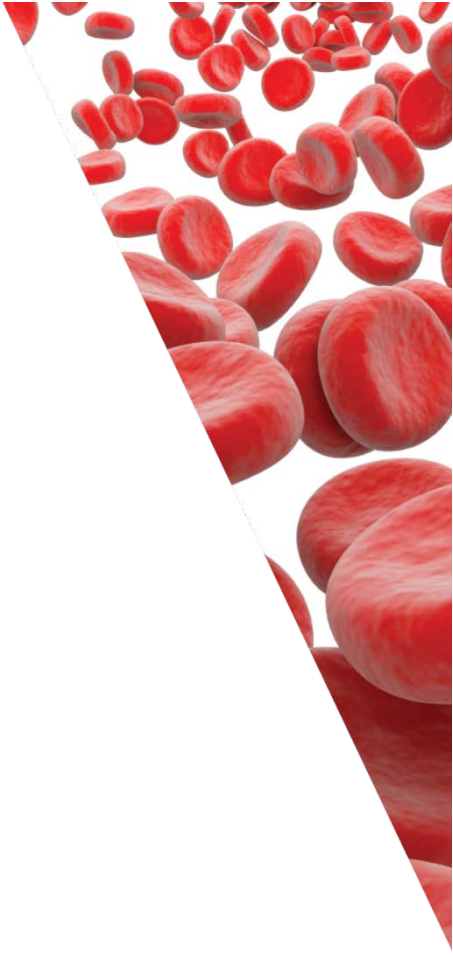

Serious transfusion incident reporting guide

(Version 4)

Revised 2017

blood matters

Australian Red Cross BLOOD SERVICE

VICTORIA State Government | Health and Human Services

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Contents

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Version 1	3 May 2007	Karen Botting
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Abbreviations

ABO	ABO blood groups
ALI	acute lung injury
anti-D	Rh D Immunoglobulin
ATR	acute transfusion reaction
BP	blood pressure
CMV	cytomegalovirus
DAT	direct antiglobulin test
DHTR	delayed haemolytic transfusion reaction
DSTR	delayed serologic transfusion reaction
FFP	fresh frozen plasma
FNHTR	febrile non-haemolytic transfusion reaction
Hb	haemoglobin
HIV	human immunodeficiency virus
HPA	human platelet antigen
HTR	haemolytic transfusion reaction
IBCT	incorrect blood component transfused
LDH	lactate dehydrogenase
NBA	National Blood Authority
PTP	post transfusion purpura
Rh	Rhesus blood group
SHOT	Serious Hazards of Transfusion
STIR	serious transfusion incident reporting
TACO	transfusion-associated circulatory overload
TAD	transfusion-associated dyspnoea
TA-GVHD	transfusion-associated graft versus host disease
The Blood Service	Australian Red Cross Blood Service
The department	Department of Health & Human Services
TRALI	transfusion-related acute lung injury
TTI	transfusion-transmitted infection
WBIT	wrong blood in tube

Serious transfusion incident reporting: system overview

Introduction

The Blood Matters Program Serious Transfusion Incident Reporting (STIR) system is a voluntary state-wide system to capture serious hospital transfusion incidents, including near misses. All data is de-identified, with no patient details collected except for age and gender. Health services are identified by a code number assigned by the STIR office and these numbers are not used in any reporting.

Since its inception in 2007 the system has expanded to include health services from Victoria, Tasmania, Australian Capital Territory and Northern Territory. Health services from both the public and private sectors participate.

The *National Safety and Quality Health Service standards* (Australian Commission on Safety and Quality in Health Care 2011) include Standard 7 covering blood and blood products. Criteria 7.3 and 7.6 require that:

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

These criteria highlight the importance of participation in haemovigilance programs and promoting the safe management of blood and blood products.

The Blood Matters program provides advice to the Director, Cancer, Specialty Programs, Medical Research and International Health Branch, Department of Health & Human Services (the department), on the strategic direction of the Victorian STIR system. An expert group that reports to the Blood Matters Advisory Committee reviews the de-identified data.

Validated data is extracted from STIR and provided to the National Haemovigilance report overseen by the National Blood Authority (NBA).

Purpose

The STIR system provides a reporting mechanism for serious incidents related to transfusion. This central database is used to provide local information on the number and type of serious reactions that occur. The data collected by STIR is collated, aggregated and reported with recommendations for improvements for better, safer transfusion practice.

The system is one part of the Blood Matters program and links with other haemovigilance activities such as appropriate use of blood and products and patient blood management.

Scope of the system

The system reports on incidents and near misses relating to fresh blood and components, namely red cells, platelets, fresh frozen plasma and cryoprecipitate, and includes products from volunteer donors, family donors and autologous collections. In 2015, the scope of STIR was expanded to include procedural incidents related to cell salvage and Rh D immunoglobulin. Further, the NBA reviewed the types of transfusion-related adverse events collected as part of the national haemovigilance reporting; and added TAD and DSTR categories, as found in Australian Haemovigilance Minimum Data Set (August 2015). The new data set takes effect as of 1 July 2017.

The STIR reporting system is integrated with the separate state-wide Sentinel Events program to minimise duplication of reporting for defined sentinel events. Sentinel event information, with

recommendations from the health service, is reviewed by the expert group to provide comment and additional recommendations if required.

Incident

An incident is defined as actions or conditions that could have led, or did lead, to unintended and/or unnecessary harm to a person receiving care.

A clinical incident can be either:

- an **adverse event** resulting in harm to a person receiving care, or
- a **near miss** that had the potential to cause harm but didn't due to timely intervention, luck or chance.

Reporting categories for transfusion incidents

The system captures two main categories of serious transfusion incidents: clinical and procedural which are reported via data collection forms:

- Clinical reporting forms –
    - acute transfusion reactions – this includes febrile non-haemolytic reactions, allergic or anaphylactic reactions and acute haemolytic reactions
    - transfusion-related acute lung injury (TRALI)
    - transfusion-associated circulatory overload (TACO)
    - transfusion-associated dyspnoea (TAD)
    - delayed haemolytic transfusion reactions (DHTR)
    - delayed serologic transfusion reactions (DSTR)
    - transfusion-associated graft-versus-host disease (TA-GVHD)
    - post-transfusion purpura (PTP)
    - bacterial/other infection
    - post-transfusion viral infection
- Procedural reporting forms –
    - incorrect blood component transfused (IBCT)
    - wrong blood in tube (near-miss incident)
    - cell salvage incidents
    - Rh D immunoglobulin (anti-D) incidents
    - other near-miss incidents.

Definitions of each incident category are detailed in the 'Incident category definitions' section.

Components of the system

Appendix 1 includes a flowchart that describes the components of the system and the responsible authority for each stage of reporting.

Each hospital is coded in accordance with privacy principles. Codes are available through the Blood Matters program.

The system for reporting to STIR involves the following steps.

Local

The incident should be reviewed at the local level.

Following review, determine the STIR definition for reporting the incident.

All clinical incidents should be reported to the transfusion laboratory in a timely manner. If bacterial contamination, TRALI or PTP is suspected, the incident should also be reported, without delay, to the Australian Red Cross Blood Service (the Blood Service).

The Blood Matters secretariat will inform the Blood Service of any reports of bacterial contamination or TRALI to assist the Blood Service to monitor incidents and any safety or quality issues.

If there is uncertainty about the reaction and which category it may fit into, health services can contact the Blood Matters secretariat to discuss.

Notification

Health services can notify STIR of an event via the notification e-form linked on the Blood Matters website <https://stir.transfusion.com.au>.

This should occur within four weeks of the incident. If this is not possible please contact the Blood Matters secretariat to discuss.

This initial notification requires key details of the incident, including hospital code, date and time of incident, product type and minimal patient identifiers (age and gender); nature of the incident, clinical or procedural and what is being reported; information on patient outcome (if known) and contact details of the reporter.

The reporter receives a return email that includes a unique report identification number.

Investigation

Following the initial notification to STIR a second fillable MS Word form is emailed to the reporter to collect more detailed information specific to the incident. This should assist the health service with further investigations if needed and provide information for review by the STIR expert group.

It is expected this form will be completed and returned via email to the Blood Matters secretariat within four weeks. The data is imported into an MS Access database and de-identified.

Additional information not covered in the questions in the form can also be sent through. This can include results of investigations, transfusion reaction reports or an explanation of a complicated incident. Please identify any additional information with unique event identifier provided and delete any patient identifiers.

Sentinel events

Sentinel events are reported in accordance with the existing sentinel event procedure, through the department.

Blood Matters STIR expert group is notified by the department after the sentinel event investigation and root cause analysis.

The STIR expert group then reviews the incident and the health service recommendations, and provides feedback through the Sentinel Event program.

Health services can report through STIR as well, as our investigation form may assist with the investigation into the sentinel event.

Withdrawn notifications

If a report is deemed, on further investigation, not to be a transfusion-related incident or meet STIR criterion, it can be withdrawn. Contact the Blood Matters secretariat to discuss.

The Blood Matters secretariat may choose to withdraw incidents if appropriate, after discussion with the health service.

Feedback

STIR de-identified aggregate reports will be published by the Blood Matters program and widely disseminated.

Sentinel event specific reports will be provided to the reporting organisation, by the Sentinel Event program through the Department.

A summary report for health services will be made available as requested or on a six-monthly basis. These summary reports will include information on number and types of events reported for the reporting period, including the total number reported for the health service, as well as total number of reports to STIR. The report will also provide information on the number of withdrawn reports and any alteration to event types reported, and level of severity by the expert group on review.

Individual follow up with health services may occur on occasion for clarification and feedback.

Future

Further advancements of the system are currently being investigated and updates to both scope and reporting methods will be notified to users when available.

Incident category definitions

Clinical reactions

Acute transfusion reaction (ATR)

Acute transfusion reactions occur at any time during a transfusion or up to 24 hours following a transfusion of a blood component.

An acute reaction known to be due to an incorrect component being transfused should be reported using the IBCT procedural form.

TRALI, TACO and TAD should be reported using the TRALI/TACO form.

Suspected bacterial contamination should be reported using the Bacterial form.

Acute transfusion reactions include the following.

Febrile non-haemolytic transfusion reaction (FNHTR)

FNHTRs with the following characteristics should be reported:

- fever (> 38.5° C or a change of 1.5° C above baseline), occurring during or within four hours of the transfusion with one or more of the following –
    - chills/rigor
    - headache
    - nausea/vomiting.

Allergic reactions

These reactions are where the most likely cause of the allergy is the transfusion. Consider other causes for the allergic reaction, for example drug reactions.

Moderate reactions are where one or more of the following occur within four hours of transfusion; and **where there is no evidence of significant** hypotension:

- rash
- allergic dyspnoea (stridor, cyanosis, wheezing)
- angioedema
- urticaria.

Anaphylactoid/anaphylaxis reactions may also involve respiratory and/or cardiovascular signs or symptoms, occurring during, or within four hours of transfusion, and excluding any other identifiable cause. Signs and symptoms may include:

- hypotension (drop in systolic BP > 30 mmHg) or requiring vasopressor treatment
- syncope or loss of consciousness
- laryngeal tightness or stridor
- cough, wheeze or bronchospasm
- hypoxemia

(National Blood Authority Australia, 2015)

Acute haemolytic transfusion reaction (HTR)

Acute HTR is suspected if the patient has fever and other signs/symptoms of haemolysis (including dyspnoea, hypotension, tachycardia, back pain, dark urine) within 24 hours of transfusion and one or more of the following:

- failure to achieve expected rise of the Hb post-transfusion or a drop in Hb > 20g/L within 24 hours (excluding all causes for ongoing bleeding)
- rise in LDH > 50 per cent within 24 hours
- rise in bilirubin, free haemoglobin (plasma or urine).

Transfusion-associated circulatory overload (TACO)

Cases of TACO are confirmed by any four of the following which occur within six hours of transfusion:

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

The following should also be reported:

- cases where TACO is suspected even if the available information suggests that fewer than four of the five defining criteria for TACO are met
- cases with features of TACO which occur between six and 24 hours should also be reported.

(SHOT, 2017)

Transfusion-related acute lung injury (TRALI)

TRALI may be immune or non-immune mediated. Serological confirmation is not required for diagnosis.

All cases of TRALI should be reported to the Blood Service at the first available opportunity to quarantine and test related components from the same donor and prevent potential reactions in other recipients.

Clinical TRALI features should include:

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

(SHOT, 2017 and National Blood Authority Australia, 2015)

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 should be the most prominent clinical feature and should not be explained by the patient's underlying condition or any other known cause.

(SHOT, 2017 and National Blood Authority Australia, 2015)

Delayed haemolytic transfusion reaction (DHTR)

A reaction occurring more than 24 hours following a transfusion of blood or blood components in which haemolysis occurs due to the development of red cell antibody. Delayed HTRs may present with unexplained fever, anaemia and/or jaundice, usually two to 14 days after transfusion of a red blood cell component. The reaction may be confirmed by **one or more** of the following:

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

(SHOT, 2017 and Australian Red Cross Blood Service, 2014)

Delayed serological transfusion reaction (DSTR)

A DSTR occurs when, after a transfusion, there is demonstration of clinically significant antibodies against red blood cells (as described in the ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice, 1st Edition, 2016, https://www.anzsbt.org.au/pages/anzsbt-guidelines.html) which were previously absent, as far as is known, and when there are no clinical or laboratory features of haemolysis. This term is synonymous with alloimmunisation.

(NBA: Australian Haemovigilance Minimum Data Set, 2015)

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

The development of the classical symptoms of fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia, occurring less than 30 days following transfusion, without other apparent cause.

The diagnosis is supported by skin/bone marrow biopsy appearance or confirmed by the identification of donor-derived cells, chromosomes or DNA in the blood and/or affected tissues.

(SHOT, 2017)

Post-transfusion purpura (PTP)

PTP is characterised by sudden and self-limiting thrombocytopenia (typically platelet counts < 10 x 10^9/L) arising five to twelve days following transfusion of red cells or platelets. It is associated with the presence of antibodies directed against the human platelet antigen (HPA) system.

(SHOT, 2017 and Australian Red Cross Blood Service, 2014)

Transfusion-transmitted infections (TTI)

All TTIs should be reported to the Blood Service at the first available opportunity to quarantine and test related components from the same donor and prevent potential infection in other recipients.

A TTI should be reported where the recipient has evidence of infection post transfusion and there was no evidence of infection with the agent of infection prior to transfusion and:

- at least one component received by the recipient was donated by a donor who had evidence of the same transmissible infection, **or**
- at least one component received by the recipient was shown to have been contaminated with the agent of infection.

These may be reported via the bacterial/other form for all bacterial, parasitic (such as malaria) or other infections, not including serious viral infections.

Use the viral infection form for viral infections, such as HIV, hepatitis or CMV.

Incident category definitions

Procedural events

Incorrect blood component transfused (IBCT)

This includes reports of incidents in which:

- the component did not meet the specific requirements for the patient
- transfusion of a component intended for another patient (ABO compatible)
- all unintentional incompatible transfusions, including ABO incompatible
- transfusion of product other than that prescribed (e.g. platelets instead of FFP)
- unnecessary or inappropriate transfusion.

Include all events even if:

- only a small quantity of blood was transfusion
- no adverse reaction occurred

N.B. This does not include anti-D administered to the wrong patient or inappropriately. Anti-D errors should be reported via the specific anti-D form.

(SHOT, 2017)

Near-miss incidents

A near miss is an incident that is discovered before the start of the transfusion and that could have led to a wrong transfusion or a reaction in a recipient if transfusion had taken place.

For example any incident that is recognised before transfusion, but which, if undetected, could have resulted in the determination of wrong blood group, or issue, collection, or administration of an incorrect, inappropriate or unsuitable component.

(SHOT, 2017)

Wrong blood in tube (WBIT)

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

These events have the potential to cause harm to patients, because while labelling is consistent and passes zero-tolerance guidelines, the blood group may be different to that of the named patient.

This includes specimens where:

- samples are taken from the wrong patient but labelled as per the intended patient, or
- sample is taken from the intended patient but labelled as per another patient.

Cell salvage

Incidents and near misses involving the use of intraoperative and/or postoperative cell salvage where the incident may be due to:

- operator error

- machine failure
- administration error
- adverse reactions to the reinfused product.

(SHOT, 2017)

Rh D immunoglobulin (anti-D)

Includes incidents related to anti-D request or administration for women of childbearing potential or following transfusion of Rh D mismatched red cells or platelets. This includes incidents where:

- anti-D is omitted or administered late
- anti-D is administered to a Rh D positive woman
- anti-D is administered to a woman with immune anti-D
- anti-D is administered erroneously to the mother of a Rh D negative infant
- anti-D is administered to the wrong patient
- the incorrect dose of anti-D is administered
- failure of prophylaxis
- an expired product is administered

Adverse reactions to anti-D are not reportable to STIR but should be reported to the manufacturing company and the Blood Service.

Appendix 1: Serious transfusion incident reporting flowchart

Health Service

- Transfusion incident reported and investigated
- Reported to relevant clinical staff and Blood Service if appropriate
- Fits STIR definitions

Health Service

- Reported to STIR via Blood Matters website https://stir.transfusion.com.au

STIR

- Initial incident data assessed for validity by STIR secretariat
- Acknowledgement email automatically sent with ID number for incident
- Investigation form sent to reporters email

Health Service

- Investigation form to be completed within 4 weeks and returned via email to STIR

STIR

- Data verified and collated by STIR and reviewed by expert group
- Summary reports developed for all reporting health services 6 monthly or as requested
- Annual de-identified aggregate reports developed with findings and recommendations

References

National Blood Authority Australia 2015, The Australian haemovigilance minimum data set, version 1. https://www.blood.gov.au/system/files/aust-haemovigilance-min-data-set.pdf

Serious Hazards of Transfusion (SHOT) 2017, *Definitions of current SHOT categories and what to report,* accessed June 2017, <www.shotuk.org/sabre/>.

Australian Red Cross Blood Service 2017, 'Adverse events', accessed June 2017, <www.transfusion.com.au/>.

Wiersum, JC, Wood, E, Bolton-Maggs, PHB and Schipperus, MR. 2014. *Definitions in haemovigilance:guiding principles and current state of development of international reference definitions.* ISBT Science Series. 9, 91-97.

New Zealand Blood Service, 2015. National Haemovigilance Program Annual report 2015. https://www.nzblood.co.nz/clinical-information/haemovigilance-programme/haemovigilance-annual-report-2012/ National Blood Authority 2015, Australian