Serious transfusion incident reporting guide

Revised 2015
Contents

STIR expert group members iv
Acknowledgments iv

Abbreviations v

Serious transfusion incident reporting: system overview 1
Introduction 1
Purpose 1
Scope of the system 1
Incident 1
Reporting categories for transfusion incidents 2
Components of the system 2
Future 3

Incident category definitions 4
Clinical reactions 4
Procedural events 7

Appendix 1: Serious transfusion incident reporting flowchart 9

References 10

Version control

<table>
<thead>
<tr>
<th>Version number</th>
<th>Date</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 1</td>
<td>3 May 2007</td>
<td>Karen Botting</td>
</tr>
<tr>
<td>Version 2</td>
<td>5 August 2013</td>
<td>Lisa Stevenson</td>
</tr>
<tr>
<td>Version 3</td>
<td>17 December 2014</td>
<td>Chris Akers</td>
</tr>
</tbody>
</table>
STIR Expert Group Members

The system is overseen by the STIR expert group of the Blood Matters program, Department of Health, Victoria.

Dr Amanda Davis (chair), Consultant Haematologist, Alfred Hospital, Victoria
Ms Christine Akers, Transfusion Nurse, Blood Matters Program, Department of Health, Victoria
Ms Helen Atkinson, Transfusion Nurse, Royal Hobart Hospital, Tasmania
Mr Gerald Bates, Laboratory Manager, Launceston General Hospital, Tasmania
Mr Peter Beard, Data Manager, Blood Matters Program, Department of Health, Victoria
Ms Linley Bielby, Program Manager, Blood Matters Program, Department of Health, Victoria
Dr Philip Crispin, Consultant Haematologist, The Canberra Hospital, Australian Capital Territory
Dr Merrole Cole-Sinclair, Director of Haematology, St Vincent’s Hospital
Ms Bridget Glazebrook, Data Manager, Blood Matters Program, Department of Health, Victoria
Ms Clare Hennessy, Transfusion Nurse Consultant, Eastern Health & Education Coordinator Blood Matters Program
Dr Chris Hogan, Medical Director Pathology Services, Australian Red Cross Blood Service
Mr Geoff Magrin, Senior Scientist, Haematology Department, Alfred Health
Dr Ellen Maxwell, Director of Haematology, Melbourne Pathology
Mr Scott McArdle, Transfusion Nurse, St Vincents Health
Dr Tina Noutsos, Consultant Haematologist, Royal Darwin Hospital, Northern Territory
Mr Richard Rogers, Blood Bank Scientist, Cabrini Health
Dr Carole Smith, Consultant Haematologist, Austin Health
Mr Jonathan Prescott, Acting Manager, Quality and Safety Programs, Department of Health, Victoria
Dr Erica Wood Associate Professor, School of Public Health and Preventive Medicine Monash University, Victoria

Acknowledgments

The Blood Matters program wishes to acknowledge the use of reference material obtained from the National Blood Authority, *Australian Haemovigilance report 2010*, United Kingdom Serious Hazards of Transfusion (SHOT) scheme and the New Zealand National Haemovigilance Programme and the STIR working group for their innovation and design of the system.

Address queries to:
Ms Linley Bielby, Program Manager, Blood Matters, 03 9694 0102
Ms Chris Akers, Transfusion Nurse, Blood Matters, 03 9694 3523
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO</td>
<td>ABO blood groups</td>
</tr>
<tr>
<td>ALI</td>
<td>acute lung injury</td>
</tr>
<tr>
<td>anti D</td>
<td>Rh D Immunoglobulin</td>
</tr>
<tr>
<td>ATR</td>
<td>acute transfusion reaction</td>
</tr>
<tr>
<td>BP</td>
<td>blood pressure</td>
</tr>
<tr>
<td>CMV</td>
<td>cytomegalovirus</td>
</tr>
<tr>
<td>DAT</td>
<td>direct antiglobulin test</td>
</tr>
<tr>
<td>DTR</td>
<td>delayed transfusion reaction</td>
</tr>
<tr>
<td>FFP</td>
<td>fresh frozen plasma</td>
</tr>
<tr>
<td>FNHTR</td>
<td>febrile non-haemolytic transfusion reaction</td>
</tr>
<tr>
<td>Hb</td>
<td>haemoglobin</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>HTR</td>
<td>haemolytic transfusion reaction</td>
</tr>
<tr>
<td>IBCT</td>
<td>incorrect blood component transfused</td>
</tr>
<tr>
<td>LDH</td>
<td>lactate dehydrogenase</td>
</tr>
<tr>
<td>PTP</td>
<td>post transfusion purpura</td>
</tr>
<tr>
<td>STIR</td>
<td>serious transfusion incident reporting</td>
</tr>
<tr>
<td>TACO</td>
<td>transfusion associated circulatory overload</td>
</tr>
<tr>
<td>TA-GVHD</td>
<td>transfusion associated graft versus host disease</td>
</tr>
<tr>
<td>The Blood Service</td>
<td>Australian Red Cross Blood Service</td>
</tr>
<tr>
<td>The department</td>
<td>Department of Health &amp; Human Services</td>
</tr>
<tr>
<td>TRALI</td>
<td>transfusion related acute lung injury</td>
</tr>
<tr>
<td>TTI</td>
<td>transfusion transmitted infection</td>
</tr>
<tr>
<td>WBIT</td>
<td>wrong blood in tube</td>
</tr>
</tbody>
</table>
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 a new standard (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, Sector Performance, Quality and Rural Health, Department of Health and 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.

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, data collection now includes incidents related to cell salvage and Rh D immunoglobulin.

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:

- an adverse event – incident that resulted in harm to a person receiving care
- a near miss – incident 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. The data collection forms include:

- **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)
  - delayed transfusion reactions
  - 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 or TRALI 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 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

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 form is emailed to the reporter to collect more details about the incident. This should assist the health service with further investigations if needed and provide information for review by the STIR expert group.

The form is an electronic MS Word form and is forwarded to the reporter via email. The form is specific to the nature of the incident being reported at initial notification. 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.

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.

Withdrawals

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 necessary, 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.

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 definition 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 blood or blood component.

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

Report reactions 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.

(National Blood Authority Australia, 2013)

Anaphylactoid/anaphylaxis reaction
An allergic reaction with associated hypotension (drop in systolic BP > 30 mmHg) during or within four hours of transfusion.

Alternatively this may include intractable hypotension or shock with loss of consciousness associated with transfusion and excluding any other identifiable cause.

(National Blood Authority Australia, 2013)

Haemolytic transfusion reaction (HTR)
HTR is clinically suspected if one or more of the following is present with a positive direct antiglobulin test (DAT) post transfusion and a positive red cell cross match:

- fever and/ or other symptoms of a haemolytic reaction (including dyspnoea, hypotension, tachycardia, back pain)
- 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 four 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 cases 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, 2012)

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:
• acute 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, 2012 and National Blood Authority Australia, 2013)

Delayed transfusion reaction (DTR)
A reaction occurring more than 24 hours following a transfusion of blood or blood components, but which is not TA-GVHD, PTP or a TTI, which have specific investigation forms (see below).

Delayed reactions are usually delayed haemolytic reactions due to the development of red cell alloantibodies. 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.

Simple serological reactions such as antibody development without a positive DAT or evidence of haemolysis are excluded.
(SHOT, 2012 and Australian Red Cross Blood Service, 2014)
**Transfusion-associated graft-versus-host disease (TA-GVHD)**

The development of the classical symptoms of fever, rash, liver dysfunction, diarrhoea and pancytopenia occurring one to six weeks following transfusion, without other apparent cause.

The diagnosis is supported by skin/bone marrow biopsy appearances and the presence of circulating donor lymphocytes.

(SHOT, 2012)

**Post-transfusion purpura (PTP)**

PTP is characterised by sudden and self-limiting thrombocytopenia (typically platelet counts < 10 x 10⁹/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.

(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.

(National Blood Authority Australia, 2013)
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)
• ABO incompatible transfusions (due to any cause)
• transfusion of product other than that prescribed (e.g. platelets instead of FFP)
• unnecessary or inappropriate transfusion.
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, 2012)

Near-miss incidents
Any incident that had the potential to cause harm, but didn't due to timely intervention, luck or chance.
For example any incident that is recognised before transfusion, but which, if undetected, could have resulted in the determination of wrong blood group, or issue, collection, or administration of an incorrect, inappropriate or unsuitable component.

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, 2012)

Rh D immunoglobulin (anti-D)
Includes incidents related to anti-D request or administration for women of child bearing potential or following transfusion of RhD 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 reaction to the product.
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

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
- Biennial de-identified aggregate reports developed with findings and recommendations
References


