Serious Transfusion Incident Report
Blood Matters – Better Safer Transfusion Program
2006–07
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Acknowledgements

The Blood Matters program is founded on the expectation that the provision of relevant information will serve to support the community by promoting better transfusion practice. STIR thanks the Victorian and Tasmanian public health services, hospitals and participating private facilities for their contribution to the program, and acknowledges the STIR Expert Group whose expert input is invaluable in reviewing the incidents and providing recommendations.
## Abbreviations and acronyms

<table>
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<th>Abbreviation</th>
<th>Definition</th>
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</thead>
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<tr>
<td>ABO</td>
<td>ABO blood groups</td>
</tr>
<tr>
<td>ARCBS</td>
<td>Australian Red Cross Blood Service</td>
</tr>
<tr>
<td>ATR</td>
<td>acute transfusion reaction</td>
</tr>
<tr>
<td>DAT</td>
<td>direct antiglobulin test</td>
</tr>
<tr>
<td>DHS</td>
<td>Department of Human Services</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>difficulty breathing</td>
</tr>
<tr>
<td>FFP</td>
<td>fresh frozen plasma</td>
</tr>
<tr>
<td>Hb</td>
<td>haemoglobin (g/L)</td>
</tr>
<tr>
<td>HLA</td>
<td>human leucocyte antigen</td>
</tr>
<tr>
<td>HTR</td>
<td>haemolytic transfusion reaction</td>
</tr>
<tr>
<td>Hypotension</td>
<td>drop in blood pressure</td>
</tr>
<tr>
<td>Hypoxia</td>
<td>low oxygen levels in the blood</td>
</tr>
<tr>
<td>LDH</td>
<td>lactate dehydrogenase</td>
</tr>
<tr>
<td>mL</td>
<td>millilitre</td>
</tr>
<tr>
<td>NHTR</td>
<td>non-haemolytic febrile transfusion reaction</td>
</tr>
<tr>
<td>Rh</td>
<td>Rhesus blood group</td>
</tr>
<tr>
<td>SHOT</td>
<td>Serious Hazards of Transfusion (UK)</td>
</tr>
<tr>
<td>STIR</td>
<td>Serious Transfusion Incident Report</td>
</tr>
<tr>
<td>TACO</td>
<td>transfusion-associated circulatory overload</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>increase in heart rate</td>
</tr>
<tr>
<td>TA-GVHD</td>
<td>transfusion-associated graft versus host disease</td>
</tr>
<tr>
<td>TRALI</td>
<td>transfusion-related acute lung injury</td>
</tr>
<tr>
<td>TTI</td>
<td>transfusion-transmitted infections</td>
</tr>
<tr>
<td>TTP</td>
<td>thrombotic thrombocytopenic purpura</td>
</tr>
<tr>
<td>VHIMS</td>
<td>Victorian Health Incident Management System</td>
</tr>
<tr>
<td>WBIT</td>
<td>wrong blood in tube</td>
</tr>
</tbody>
</table>
The Blood Matters Serious Transfusion Incidents Reporting System (STIR) is a central reporting system for serious adverse events related to blood component transfusion (red cells, platelets, fresh frozen plasma, and cryoprecipitate), including near miss incidents. The system aims to measure and monitor serious transfusion incidents, including near misses, to derive recommendations for better safer transfusion practice, and disseminate these to individual hospitals, health services and the Australian Red Cross Blood Service. More information on the program is outlined in the STIR guide available at: www.health.vic.gov.au/best/downloads/stir_guide.pdf


Using a staggered approach, all Victorian and Tasmanian hospitals were invited to report by August 2007. Including the nine pilot health services, 41 hospitals are now reporting within Victoria and Tasmania, representing 30 per cent of the current transfusing hospitals in both states.

The program is still relatively new, however the data already provide strong messages to inform current and future practice.

Transfusion-related procedural errors were identified as a major theme. Sixty nine procedural error incidents were recorded, representing 45 per cent of all reports to STIR. Fortunately, 74 per cent of these were recognised and intercepted before transfusion proceeded (defined as a “near miss”). Many incidents involved the potential for patients to be given the wrong transfusion, which could have resulted in fatal consequences, and many of these involved patient misidentification. Correct patient identification, from sampling and blood grouping to product administration, is the cornerstone of safe transfusion practice. This finding is consistent with one of the 2007-08 priorities of the Australian Commission on Safety and Quality in Health Care. The work of the Commission for 2007–08 is focused on current and complex areas of health that would benefit from national consideration and action. The commission identified nine priority programs of work, with patient identification targeted as priority four. www.safetyandquality.org/internet/safety/publishing.nsf/Content/programs-lp

Executive Summary

The Blood Matters Serious Transfusion Incidents Reporting System (STIR) is a central reporting system for serious adverse events related to blood component transfusion (red cells, platelets, fresh frozen plasma, and cryoprecipitate), including near miss incidents. The system aims to measure and monitor serious transfusion incidents, including near misses, to derive recommendations for better safer transfusion practice, and disseminate these to individual hospitals, health services and the Australian Red Cross Blood Service. More information on the program is outlined in the STIR guide available at: www.health.vic.gov.au/best/downloads/stir_guide.pdf


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Introduction

The statewide ‘Better Safer Transfusion’ (BeST) Program was established in mid 2004 to improve transfusion safety and appropriateness of use of blood and blood products in Victorian Hospitals. It is an initiative of the Department of Human Services, Victoria and the Australian Red Cross Blood Service (ARCBS), and an extension of the successful Blood Matters project (2002–04) that involved 13 hospitals throughout Victoria and Tasmania.

Blood Matters demonstrated the ability of coordinated hospital-based initiatives to improve the safety of blood transfusions in hospitals. The approaches used in Blood Matters that lead to safer transfusion practice have formed the foundations for continued improvement under the BeST Program. These effective practice improvement ideas have now spread across Victoria and to other jurisdictions.

In response to clinicians and with support of the program executive, in 2008 BeST has renamed the program to Blood Matters-better safer transfusion program to ensure the program name is recognised for its priorities and aims.

One of the Blood Matters program aims was to establish a haemovigilance system for Victoria. At the time of initiating the system, no Australian system existed for collecting haemovigilance data. It was therefore necessary to design a system, and Blood Matters set about this based using experience gained from international haemovigilance programs. The United Kingdom Serious Hazards of Transfusion (SHOT) Scheme and the New Zealand Haemovigilance Program served as important examples for their wealth of experience and close alignment with Australian health service models.

The Blood Matters Serious Transfusion Incident Reporting System (STIR) is designed to measure and monitor serious transfusion incidents, including near misses, and to derive recommendations for better safer transfusion practice through the monitoring of these incidents. A definition of haemovigilance that aligns with the aims of the Blood Matters program is, ‘…a system of surveillance and alarm, which encompasses all steps of the transfusion process, from blood collection to the follow-up of recipients.’

The transfusion process is a complex system often involving numerous health professionals with varying degrees of experience. Since transfusion procedures are well-practised routines, they are often performed as automatic behaviours, vulnerable to interruption and unanticipated occurrences (Kaplan et al). Locally it is unknown how often these interruptions and unanticipated occurrences occur and whether there is harm to the patient as a result.

The Blood Matters program is pleased to provide the report of the 2006-07 Victorian and Tasmanian serious transfusion incident reporting (STIR) data. STIR is a voluntary reporting system with thirty percent of facilities (n= 41 hospitals, including nine private facilities and 32 public facilities) participating in the year of its inception. All major blood users in Victoria, Tasmania and ACT continue to be encouraged to report into STIR so that aggregated data are strengthened and a more complete picture of relevant local risks in transfusion in Australia is developed.
Method

Data are received by STIR as an initial notification through an e-form located on the Blood Matters website. On receipt, a form relevant to the specific incident type (clinical or procedural) is provided to the hospital or health service by the STIR office. This is returned to STIR with detailed information about the incident. Patient-identifying data are not provided. In 2006-07, information was logged manually into Excel spreadsheets. 2008 has already seen the introduction of a database to assist streamlining the process of reporting and reviewing, with work ongoing towards an entirely electronic process.

Sentinel events are reported in accordance with the existing sentinel event procedure. STIR is notified by the department that an incident has occurred and liaises with the key transfusion contact to ensure STIR forms are completed and submitted in conjunction with sentinel event investigations and root cause analysis.

All reports are reviewed by a rotating subgroup of the STIR expert group consisting of a haematologist, transfusion scientist and/or transfusion nurse to ascertain alignment with the STIR criteria, review the diagnosis, and attach imputability (causality) and severity ratings for relevant incidents. Recommendations are made to the reporting institution following this review. The STIR expert group also reviews all sentinel events involving blood products from the sentinel event program. In 2007, the group reviewed four sentinel event reports. Recommendations from reviews are outlined further in the report.

The future will see STIR incorporated into the Victorian Health Incident Management System (VHIMS), assisting health services reporting into this system, avoiding duplication of reporting. STIR will continue in its current format for those health services outside of the VHIM scope.

Total of blood issues from the transfusion service for both states are highlighted in table 1.

Table 1: Number of blood components issued for Victoria and Tasmania 2006-07

<table>
<thead>
<tr>
<th>Products</th>
<th>Victoria</th>
<th>Tasmania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red cells</td>
<td>391,702</td>
<td>31,112</td>
</tr>
<tr>
<td>Platelets</td>
<td>52,440</td>
<td>3836</td>
</tr>
<tr>
<td>Fresh frozen plasma</td>
<td>59,961</td>
<td>2727</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>34,213</td>
<td>2844</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>538,316</strong></td>
<td><strong>40,519</strong></td>
</tr>
</tbody>
</table>

Number of Components issued 2006-07 ARCBS Data (Table 1)
Reports for 2006-07

Table 2: Types of incidents at notification

<table>
<thead>
<tr>
<th>Category</th>
<th>Reports received by STIR</th>
<th>Number</th>
<th>Per cent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute transfusion reaction</td>
<td></td>
<td>77</td>
<td>49</td>
</tr>
<tr>
<td>Near miss</td>
<td></td>
<td>26</td>
<td>17</td>
</tr>
<tr>
<td>Wrong blood in tube</td>
<td></td>
<td>25</td>
<td>16</td>
</tr>
<tr>
<td>Incorrect blood component transfused</td>
<td></td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>Transfusion-related acute lung injury (TRALI)</td>
<td></td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Bacterial</td>
<td></td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Delayed transfusion reaction</td>
<td></td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Transfusion-associated graft versus host disease</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Post-transfusion purpura</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Viral</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>155*</td>
<td>100</td>
</tr>
</tbody>
</table>

*One notification report may correspond with more than one type of incident. Percentages are based on number of reports returned.

Reports are entered into STIR as either “confirmed at time of reporting” or remain suspected, awaiting further investigation or test results.

Confirmed n = 93
Suspected n = 61

Table 3: Types of blood components implicated at notification

<table>
<thead>
<tr>
<th>Product</th>
<th>Number</th>
<th>Per cent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Cells</td>
<td>94</td>
<td>61</td>
</tr>
<tr>
<td>Platelets</td>
<td>17</td>
<td>11</td>
</tr>
<tr>
<td>Other^</td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>Fresh frozen plasma</td>
<td>14</td>
<td>9</td>
</tr>
<tr>
<td>Red Cells, Platelets*</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Fresh frozen plasma, Cryoprecipitate*</td>
<td>2</td>
<td>1.3</td>
</tr>
<tr>
<td>Platelets, Cryoprecipitate*</td>
<td>1</td>
<td>0.7</td>
</tr>
<tr>
<td>Missing data</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>154</td>
<td>100</td>
</tr>
</tbody>
</table>

* one incident may have multiple components that potentially may have been involved.

^ other includes all pre-transfusion specimens
Incident demographics (2006-07)

Twenty-three per cent of incidents occurred between the hours of 8 pm and 8 am, with 10 per cent occurring between midnight and 8 am. Although no local denominator data exist regarding the proportion of transfusions occurring at various times over the twenty four hour day, incidents relating to these ‘out of hours’ periods appear over-represented in STIR reports compared with ‘in hours’ transfusions. This is consistent with data from international haemovigilance systems such as SHOT. There was no correlation to any day of the week or weekdays/weekends.

More incidents (n=58, 37 per cent of all reports) occurred in a general ward area than any other clinical area. This appears to correlate with the proportions of transfusions given in the wards and is similar to information from international haemovigilance programs. However, no local denominator data exist for formal comparison.

Patient demographics

Incidents were reported for 154 patients; 51.9 per cent of these involved female patients. Patient age ranged from 1 day to 95 years (mean 48 years) and 25.3 per cent of incidents were in patients of 18 years or less. This appears to reflect more robust reporting to STIR from hospitals that care for children, rather than a higher incidence of events in children per se.

Diagnoses

The STIR Expert Group amended the diagnosis on 15 occasions, in addition to 13 alterations by health services following initial notification. These occurred mostly in the category of acute transfusion reactions, and the majority of alterations were to the definition of the event. Some perceived ambiguities in the definitions are being addressed with modification of the reporting form.

Outcomes

Patient outcomes described in table 4 are those attributed by the initial health service report, and not the expert review group. Patient outcome is only documented in acute/delayed reactions, incorrect blood component transfused, bacterial and TRALI reports.

<table>
<thead>
<tr>
<th>Patient Outcomes</th>
<th>101 events^ (65%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full recovery with no ill effects</td>
<td>78 (77%)</td>
</tr>
<tr>
<td>Full recovery with requirement for extended length of stay</td>
<td>11 (11%)</td>
</tr>
<tr>
<td>Died</td>
<td>5 (5%)*</td>
</tr>
<tr>
<td>Missing data</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>Outcome not recorded</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Recovered with morbidity</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

^two reports correspond with more than one type of event
*death attributed to other causes other than the transfusion adverse event in all cases.
Imputability (Causality) and severity

Since 2007 the expert panel has commenced a process of attribution of event causality and severity ratings. This followed careful consideration of the applicability of the STIR definitions to incident types (for example, for those events where there was potential for, but no actual negative patient outcome) and enables a validation step of the data presented to STIR. Future reports for incidents where investigation is completed will reflect validated data using the following definitions that were developed from the Root Cause Analysis Education–Clinical Risk Management, Department of Human Service Victoria (Table 5 and 6).

Table 5: Imputability (Causality)

<table>
<thead>
<tr>
<th>Imputability/Causality</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not assessable</td>
<td>When there is insufficient evidence for an imputability definition.</td>
</tr>
<tr>
<td>Excluded</td>
<td>When there is conclusive evidence that the cause of the incident is attributable to other causes and not the transfusion.</td>
</tr>
<tr>
<td>Possibly</td>
<td>When the evidence is indeterminate for attributing the incident to either the transfusion or other causes.</td>
</tr>
<tr>
<td>Probably</td>
<td>When the evidence is clearly in favour of attributing the incident to the transfusion.</td>
</tr>
<tr>
<td>Certainly</td>
<td>When the evidence is conclusively attributable to the transfusion.</td>
</tr>
</tbody>
</table>

Table 6: Severity Rating

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Relatively infrequent, clear-cut events that occur independently of a patient’s condition; commonly reflect hospital system and process deficiencies; and results in or have the realistic potential to result in, an unexpected death or a permanent disabling injury or psychological harm to a person and includes reportable Sentinel Events</td>
</tr>
<tr>
<td>2</td>
<td>Events that result in a temporary loss of function (sensory, motor, physiological or intellectual) which are unrelated to the natural course of the patient’s illness and differ from the expected outcome of person’s management</td>
</tr>
<tr>
<td>3</td>
<td>Events that result in a person requiring increased treatment, but not hospitalisation or an increased length of stay</td>
</tr>
<tr>
<td>4</td>
<td>Events that result in minor injury requiring only first aid treatment or no injury</td>
</tr>
</tbody>
</table>

RCA Education – Clinical Risk Management, Department of Human Service Victoria
Reaction categories and informative report examples:

Acute transfusion reaction (ATR)

**Definition**
A reaction occurring at any time during or up to 24 hours following a transfusion of blood or components, excluding cases of acute reactions known to be due to incorrect component being transfused.

**Current acute reaction types defined:**

**Haemolytic transfusion reaction (HTR)**
HTR is clinically suspected if one or more of the following is present:
- fever and/or other symptoms (including dyspnoea, hypotension, tachycardia, back pain)
- failure to achieve expected rise of the haemoglobin (Hb) post-transfusion or a drop in Hb > 20 g/L within 24 hours (excluding all causes for ongoing bleeding)
- rise in lactate dehydrogenase (LDH) > 50 % within 24 hours
- rise in bilirubin, free haemoglobin (plasma or urine).
HTR is confirmed by a positive direct antiglobulin test (DAT) and a positive red cell cross match.
In the absence of a positive DAT, retrospective phenotype incompatibility of transfused units, or a positive crossmatch in addition to clinical scenario consistent with acute haemolytic transfusion reaction, may provide diagnosis.

**Non-haemolytic febrile transfusion reaction (NHTR)**
Moderate/severe febrile transfusion reaction
- chills/rigor
- headache
- nausea and vomiting and
- fever (> 38.5°C or a change of 1.5°C above baseline)

**Allergic reaction**
One or more of the following:
- rash
- allergic dyspnoea (stridor, cyanosis, wheezing)
- angioedema (swelling beneath the skin, may affect the eyes, lips and throat)
- urticaria (hives, itchy rash) and without hypotension during or within 24 hours.

**Anaphylactoid/anaphylaxis reaction**
Allergic reaction with associated hypotension or shock associated with transfusion.
Transfusion-associated circulatory overload (TACO)
Respiratory distress, tachycardia and increased blood pressure within 12 hours of the completion of the transfusion. Typical signs of cardiogenic lung oedema in the chest X-ray and a positive fluid balance, or known compromised cardiac status, support a diagnosis of TACO.
Seventy seven notifications were received under the category of acute reaction. Allergic/anaphylactoid reactions accounted for 35 (45 per cent) of acute reaction reports as determined by the notifying hospital or reviewer. All types of fresh products were implicated in the allergic/anaphylactoid reactions. Of these, 12 (34 per cent) were associated with platelets, 10 (29 per cent) with red cells and 9 (26 per cent) with FFP and there were 4 (11 per cent) where multiple products were administered and the reviewers were unable to determine which product was responsible.

Allergies as reported by the hospitals were ascertained for severity and defined as in table 7 below.

<table>
<thead>
<tr>
<th>Allergy Type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild - single symptom or single drug treatment (other than adrenaline) required</td>
<td>14</td>
</tr>
<tr>
<td>Moderate - multiple symptoms with polypharmacy treatment not including adrenaline</td>
<td>9</td>
</tr>
<tr>
<td>Severe - multiple symptoms with polypharmacy treatment including adrenaline and/or increased length of stay or level of care</td>
<td>9</td>
</tr>
<tr>
<td>Anaphylaxis - as above for severe allergy including severe hypotension or cardiac arrest</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
</tr>
</tbody>
</table>

Case Study 1: Anaphylactoid reaction

A patient with leukaemia developed an acute reaction following completion of a platelet transfusion. The patient developed, fever, dyspnoea, itching/rash, hypotension, oxygen de-saturation to 86%, tachycardia and oedema of left eye. This case required management with oxygen, antihistamines, steroids and adrenaline. It was assessed as probably related to the blood product and a severity score of 2. The patient made a full recovery with no ill effects.

Points to consider

- Mild allergic reactions can progress to anaphylaxis. They should be assessed and treated at the first signs of the reaction and the product discontinued.
- An alert in the patient’s history should reflect that an allergic reaction has occurred during a transfusion so that future products can be administered with caution.
- Patients who have anaphylaxis to a blood product require assessment by a haematologist prior to transfusing further units whenever possible, and should be investigated for possible IgA deficiency with presence of anti-IgA antibodies.
Transfusion-related acute lung injury (TRALI)

Definition
Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates occurring during or within 24 hours of transfusion, with no other apparent cause.

Three reports of possible TRALI were notified, all developed significant respiratory distress during or following a transfusion: two cases implicated red cells and one a platelet pool. These were all investigated by Australian Red Cross Blood Service (ARCBS) for HLA antibodies and genotype.

Case Study 2: Suspected TRALI
A patient receiving red cells developed a fever, rigors and chills during the transfusion, and then progressed with significant oxygen desaturation. Transfusion was ceased. Oxygen therapy was required for a further 12 hours after the event. At the time of this report ARCBS are investigating this case as a possible TRALI. The patient went on to make a full recovery.

Points to consider
• The true incidence of TRALI is as unknown, yet it is felt to be an under-recognised event. It has been reported involving all types of fresh components. TRALI should be considered in any patient who exhibits severe respiratory distress requiring substantial ongoing oxygen support or admission to a critical care area as a result of a transfusion of a fresh component.
• These incidents should be notified to the ARCBS to enable thorough investigation of both the patient and product (for example, by review of the blood donor and donation information) and also reported to STIR.
• Identifying this significant serious side effect could lead to greater understanding of the disease and promote clinician awareness and subsequent product and/or practice improvements.
Transfusion-transmitted infections (TTI)

Definition
A post-transfusion infection resulting from transfusion of a bacterially, virally or parasitically contaminated component if the following criteria were met at the end of the investigation:

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

Three reports of potential bacterial contamination were notified and all have been reviewed. Review has analysed two reports as possibly related and one certainly related to the blood component. The components implicated in these reports were red cells and platelets. There were no reports of any transfusion-transmitted infection resulting from viral or parasitically contaminated product.

Case Study 3: Confirmed bacterial contamination
A transfusion-dependent patient admitted to the day ward for transfusion of red cells became unwell during transfusion. Symptoms were recognised as potentially due to bacterial contamination, and both component and patient were cultured. Both cultures grew Streptococcus pneumoniae. The patient required admission to an inpatient clinical ward and a course of intravenous antibiotics, eventually making a full recovery.

Points to consider
• Always consider the possibility of a bacterial contaminated component if the patient exhibits fever and associated symptoms with the transfusion of any fresh blood component, particularly if the increase in temperature is marked, and associated with signs of cardiovascular compromise. Early recognition and treatment are important to ensure the patient is correctly treated, including with appropriate antibiotic cover.
• Suspected reactions due to bacterial contamination should be urgently communicated to the ARCBS. Many donations are separated into multiple components, and immediate quarantine and recall of all associated components is required in this setting. This is to prevent transfusion of these associated components to additional patients, and also because testing of these components these may be crucial as part of the investigation.

NOTE:
Bacterial screening of all platelet products
From 28 April 2008, all platelet components issued by ARCBS are screened for bacterial contamination.

Worldwide, bacterial contamination of platelets is recognised as the most significant residual infectious risk of transfusion in developed countries. As a cause of death from transfusion, bacterial sepsis is second only to ABO incompatibility.
Incorrect blood component transfused (IBCT)

**Definition**
Patient was transfused with a blood component or plasma product that did not meet the appropriate requirements or which was intended for another patient.

Eighteen notifications of incorrect blood component were received. Seventeen were reviewed. Of these, three were sentinel events and reported through the sentinel event program, including one ABO incompatibility episode with plasma. There were also three incidents where red cells were correctly crossmatched and issued, but transfused to the incorrect patient. In all cases, by chance, the ABO and Rh group of the transfused product was compatible with the recipient: for example, a group A, Rh D positive patient received two units of group A, Rh D negative blood issued for another patient.

Of the 17 incidents reviewed, these were then categorised as outlined in table 8. The category ‘components that did not meet specific requirements for patient’ contains examples of modifications to the blood product required for the patient which were either missed through lack of request from the clinical team, missed at issue stage by the institutional blood bank or not available at the hospital when required.

### Table 8: Incorrect blood component types

<table>
<thead>
<tr>
<th>IBCT Types</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components that did not meet specific requirements for patient</td>
<td>12</td>
</tr>
<tr>
<td>Incorrect blood component to incorrect patient-ABO compatible</td>
<td>3</td>
</tr>
<tr>
<td>Incorrect blood component to incorrect patient-ABO incompatible</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>17</strong></td>
</tr>
</tbody>
</table>

Of the 17, there were 12 that had more then one process issue as outlined in table 9 below.

### Table 9: Location of incorrect blood component incident

<table>
<thead>
<tr>
<th>Process issues with IBCT incidents*</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Blood Bank</td>
<td>20</td>
</tr>
<tr>
<td>Prescription</td>
<td>14</td>
</tr>
<tr>
<td>Collection/Administration</td>
<td>6</td>
</tr>
<tr>
<td>Inventory</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>47</strong></td>
</tr>
</tbody>
</table>

* 12 incidents had multiple process issues

‘Wrong blood episodes’ are preventable incidents. The common theme through the reports of incorrect blood component transfused reported to STIR was failure to positively identify the patient correctly either due to incorrect identification procedures or failure to follow hospital policy.
Case Study 4: Patient misidentification

Patient A bled during surgery. An emergency transfusion was prescribed afterwards in the Intensive Care Unit for a Hb of 72g/L. Patient A was given approximately 100 mL of blood which had been crossmatched and labelled for Patient B. It was discovered 40 minutes into the transfusion and the transfusion was ceased. Fortunately both patients were Group B, Rh D positive, as was the unit issued. Both patients were under the care of the same nurse. Blood administration procedures were not followed; blood was only checked against the paperwork at the ward desk and no identity of product against patient was undertaken at the bedside as required by hospital protocol.

Case Study 5: Patient misidentification

A patient admitted via the emergency department required emergency surgery. During resuscitative efforts in theatre the patient was mistakenly transfused two units of blood issued for another patient in the adjacent theatre. The blood issued was compatible with the patient’s ABO group. The units were checked against the patient’s paperwork but there was no identity check with the patient. It was then discovered the patient had no identity wristband and had not been identified according to hospital protocol for management for an unknown patient.

Case Study 6: Patient misidentification and prescription error

Two patients (patients A and B) had the same name. Medical staff treating patient A considered possible transfusion. Pathology results of patient A reviewed and transfusion indicated. However, this was documented incorrectly in patient’s B file, including prescribing the transfusion for patient B, who then received the transfusion. Correct crossmatched blood administered but transfusion inappropriate as was not indicated for patient B. Fortunately no harm resulted to either patient.

Case Study 7: Prescription error

A patient was admitted with possible thrombotic thrombocytopenic purpura (TTP). Haematology consultation and documentation advised cryo-depleted plasma, however the attending doctor incorrectly prescribed cryoprecipitate which was administered. The diagnosis proved not to be TTP. No harm resulted for the patient.

Points to consider

- All steps of the transfusion process are vital to ensure administration of correct product to correct patient. Hospital guidelines or procedures should reflect all the necessary steps from prescription through to administration.
- Staff must be adequately trained in patient identification procedure for administering a blood product, including the special cases of the unconscious and unknown patient.
- Knowledge of transfusion, blood products and product modification varies amongst clinicians. Ensure clinicians who are prescribing blood products are aware of what products and any modifications are required for certain disease processes, or how to get assistance with prescribing. Assistance for prescription and product identification is available through the Blood Matters website www.health.vic.gov.au/bloodmatters and the ARCBS website www.transfusion.com.au
Near miss incidents

**Definition**

Any incident that had the potential to cause harm, but did not, due to timely intervention and or luck or chance. For example any incident which is recognised before transfusion took place 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.

Near misses are included in the system due to the importance of recognising issues prior to harm (Lundy7 et al). They provide an opportunity to learn without harm to the patient and also allow for system weaknesses to be identified and the opportunity to address them.

Twenty-six notifications of near miss with transfusion were received, with 23 reports reviewed. Near misses covered many different facets of the transfusion process from the institutional blood bank laboratory to the bedside, as outlined in table 10 below.

**Table 10: Near miss classification**

<table>
<thead>
<tr>
<th>Area</th>
<th>Number of reports</th>
<th>Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labelling/documentation</td>
<td>8</td>
<td>• Incorrect patient labels used to collect blood from pathology.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Incorrect labels placed on blood bag by institutional blood</td>
</tr>
<tr>
<td></td>
<td></td>
<td>bank laboratory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Incorrect patient details on request for product(s).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Patients of the same name with labels transposed on the pre-transfusion specimen.</td>
</tr>
<tr>
<td>Storage and handling</td>
<td>4</td>
<td>• Platelets refrigerated (2-6° centigrade) instead of room temperature (20-24° centigrade) storage.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Collection of the wrong component from the satellite fridge.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• No O Rh D negative red cells available for urgent use when</td>
</tr>
<tr>
<td></td>
<td></td>
<td>anticipated in off site fridge.</td>
</tr>
<tr>
<td>Inappropriate component issued</td>
<td>5</td>
<td>• Non-irradiated blood issued when patient required irradiated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>components</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Incorrect ABO group FFP issued</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Expired product issued</td>
</tr>
<tr>
<td>Incorrect prescription or</td>
<td>3</td>
<td>• Verbal order transcribed in error</td>
</tr>
<tr>
<td>request for blood</td>
<td></td>
<td>• Blood requested based on spurious results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Failure to request blood once abnormal haemoglobin known</td>
</tr>
<tr>
<td>Administration</td>
<td>3</td>
<td>• Failure to provide a standard blood filter in the administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>line</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Incorrect administration rate in a neonate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• No patient identification check-incorrect blood unit</td>
</tr>
</tbody>
</table>
Case Study 8: Blood component issue

Staff from theatre recovery arrived to pick up blood from the institutional blood bank laboratory, but it was not ready to be issued. The blood release order with the patient details was left on the blood bank bench and the staff returned to recovery. Recovery staff returned to collect the blood, they picked up an incorrect blood bank release order that was also on the bench and blood was issued on that release order (wrong patient, wrong blood). At patient identification the error was noted and the product returned to blood bank.

Case Study 9: Blood component issue

Verbal request to pathology by medical staff for fresh frozen plasma (FFP) for patient A, however blood bank issued FFP for patient B. Lack of documentation from verbal order failed to indicate whether requested for incorrect patient or if verbal order was transcribed incorrectly. Transfusion did not proceed.

Points to consider

• Always clarify requests that are transcribed from a verbal order, and document in medical notes and pathology register as appropriate.

• Ensure all clinical staff collecting blood from blood bank or the blood fridge are effectively trained and credentialed in the practice.

• Unexpected abnormal results must be reviewed with the patient’s current clinical condition and recent history taken into account. If in doubt, repeat.

• Ensure that all clinical staff are aware of where to access blood and the procedure involved in an emergency.
Wrong blood in tube (WBIT)

**Definition**
This is a special category of a near miss incident where it is detected that the labelled blood sample has been collected from an incorrect patient, however the transfusion did not then proceed.

This near miss category has potential for catastrophic harm, particularly if an historical blood group is not available. These incidents may be further categorised: the sample may have been taken from the wrong patient and labelled as the intended recipient, or the sample taken from the intended recipient and labelled for another patient.

Twenty-five notifications of the category WBIT were received, with 20 reviewed. All instances were discovered by the laboratory as an historical record was available to compare results. This means the patient had a previous blood group available in the pathology records for comparison. WBIT events are likely more frequent, but may be missed until a second transfusion episode because not all patients for whom blood is crossmatched will proceed to transfusion. Positive patient identification and care can prevent a potential disaster.

**Case Study 10: Wrong blood in tube-patient misidentification**
Pre-transfusion sample from the clinical unit was sent to the laboratory. The historical group was B Rh D positive and the sample was A Rh D negative. Further investigation revealed that a staff member had pre-labelled tubes in anticipation of taking the blood but was called to another patient to insert an intravenous cannula and take samples. The pre-labelled tubes were used erroneously.

**Case Study 11: Wrong blood in tube-patient misidentification**
An unlabelled specimen was picked up at a patient’s bedside and labelled even though the staff member had not taken the blood. It was labelled with the intended patient’s details but in fact the specimen had been taken from another patient. The historical group was different. On further investigation it was discovered that standard practice was for one staff member to collect the blood samples and one to ‘help out’ by labelling tubes and sending to sample processing.

**Points to consider**
- Positive patient identification is a vital prerequisite for all pre-transfusion sampling and should be applied for the collection of all pathology specimens. A patient’s pathology results are often the basis for clinical intervention. If the first step is incorrect, incorrect treatment maybe given or blood of an incorrect and dangerous group administered.
- Standard practices must always be written from a patient safety perspective, since those formulated to save time as a priority can often result in poor unsafe practice as they are vulnerable to unexpected occurrences.
Recommendations

For all serious adverse events associated with transfusion, follow up review by a transfusion committee (or at senior medical director level if a committee if not available), is vital in ongoing review of transfusion practice within hospitals. The availability of a transfusion nurse as a trained resource to provide education to clinical staff is most helpful in implementing transfusion improvement processes, as evidenced in the 2003–06 evaluation of the transfusion nursing role in Victoria.

Procedural Recommendations

- All staff administering transfusions should be trained (and credentialed) in the correct procedure, particularly the importance of patient identification. This is especially critical in emergency and hectic situations, where procedural errors can quickly compound to unsafe patient care.
- Medical staff training should be directed, at both junior and senior levels, to ensure appropriateness of transfusion, to improve medical documentation of transfusion requirements and incorporation of clinical history on request forms.
- Institutions should train staff to improve awareness of product terminology, to avoid incorrect products being ordered. Access to relevant and up to date transfusion educational resources is essential for clinical staff wherever transfusion is practised. Two websites with examples of education tools and product information are www.health.vic.gov.au/bloodmatters and www.transfusion.com.au

Policy recommendation

- Elective transfusions administered overnight can have serious consequences. Clinical signs of a reaction can be missed, both due to the environmental factors (for example, reduced lighting) and the often reduced staffing levels (both nursing and medical) which can affect the physical monitoring of the transfusion. Overnight transfusions also disturb sleep patterns for patients. The UK Serious Hazards of Transfusion (SHOT) report has highlighted that the risks associated with human error increase when transfusing at night. The STIR report highlighted 23 per cent of reports with transfusions occurring between 8pm and 8 am. Health services should incorporate into their policy/guidelines that wherever possible overnight transfusions in stable, non-bleeding patients should be avoided.

Reaction recommendation

- Allergic reactions accounted for over 40 per cent of acute reactions. When a patient experiences a severe allergic reaction or anaphylaxis, an alert should be visible in the patient’s history so that future transfusions can be administered with caution, and pre-medication used if appropriate.
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STIR Contacts

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Enquiries: stir@dhs.vic.gov.au
Website: www.health.vic.gov.au/best

STIR Expert Group Members
The system is overseen by the STIR expert group of the Blood Matters Program Advisory Committee of the Department of Human Services Victoria. Blood Matters is a partnership between the department and the Australian Red Cross Blood Service.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
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<tbody>
<tr>
<td>Dr Erica Wood (chair)</td>
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<td>Director of Anaesthesia and Perioperative Medicine, Eastern Health</td>
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</tr>
<tr>
<td>Dr Chris Hogan</td>
<td>Consultant Haematologist, Melbourne Health</td>
</tr>
<tr>
<td>Mr Geoff Magrin</td>
<td>Senior Scientist, Haematology Department, Bayside Health</td>
</tr>
<tr>
<td>Dr Ellen Maxwell</td>
<td>Director of Haematology, Melbourne Pathology</td>
</tr>
<tr>
<td>Mr Richard Rogers</td>
<td>Blood Bank Scientist, Cabrini Health</td>
</tr>
<tr>
<td>Dr Carole Smith</td>
<td>Consultant Haematologist, Austin Health</td>
</tr>
<tr>
<td>Ms Slav Curcic</td>
<td>Transfusion Nurse, Austin Health (from 2008)</td>
</tr>
<tr>
<td>Dr Merrole-Cole Sinclair</td>
<td>Consultant Haematologist, Bayside Health (now at St Vincent's Hospital)</td>
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</tr>
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<td>Transfusion Nurse, Blood Matters Program, Department of Human Services, Victoria</td>
</tr>
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<td>Transfusion Medicine Scientist, Australian Red Cross Blood Service, Victoria</td>
</tr>
<tr>
<td>Mr Deane Wilks</td>
<td>Manager, Quality and Safety Programs, Department of Human Services, Victoria</td>
</tr>
</tbody>
</table>
Appendix 1: STIR Guide and forms
Serious Transfusion Incident Reporting (STIR) system

This guide provides instruction on how to report a serious transfusion incident in Victoria.

STIR Expert Group Members

The system is overseen by the STIR expert group of the Better Safer Transfusion (BeST) Program Advisory Committee of the Department of Human Services Victoria.

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The Better Safer Transfusion (BeST) Program wishes to acknowledge the use of reference material obtained from the 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.

Comments and suggestions are welcome and can be forwarded to:

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Initial reporting form (eform) – Serious Transfusion Incident Report
Initial reporting form (red form) – Serious Transfusion Incident Report
Serious Transfusion Incident Reporting: system overview

Purpose

The Better Safer Transfusion Program Serious Transfusion Incident Reporting (STIR) system is a new statewide system commencing in 2007 to capture serious hospital transfusion incidents, including near misses. The data is collated and reported with recommendations for improvements for better, safer transfusion practice.

The system is one part of the Better Safer Transfusion (BeST) Program and links with other haemovigilance activities such as appropriateness of use of blood and components.

Organisation

The BeST Advisory Committee provides advice to the Director Quality and Safety Branch, Department of Human Services (the department), on strategic direction for the Victorian STIR system. An expert group that reports into the advisory committee reviews the deidentified data collected.

The STIR reporting system is integrated with the separate, statewide sentinel events reporting system to minimise duplication of reporting for defined sentinel events. Data reported is confidential and does not include patient identifiers; patient identification information is kept by the reporting hospital only.

All hospital/health services are invited to report both serious transfusion incidents and near misses.

Scope of the system

The system reports on incidents relating to fresh blood and components, namely red cells, platelets, fresh frozen plasma, and cryoprecipitate. This includes products from volunteer donors, family donors and autologous collections.

The system is a statewide incident reporting mechanism, with data from both public and private organisations collected. This system has been designed to meet the current statewide definitions for incidents.

Incident

Actions or conditions which could have, 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 clinical incident can also be a near miss: incident that had the potential to cause harm but didn’t due to timely intervention and or luck or chance.

Categories of transfusion incidents

The system captures ten defined categories of serious transfusion incidents. These are:

1. incorrect blood component transfused
2. acute transfusion reactions
3. delayed transfusion reactions
4. transfusion-associated graft-versus-host disease (TA-GVHD)
5. transfusion-related acute lung injury (TRALI)
6. post-transfusion purpura (PTP)
7. bacterial/other infection
8. post transfusion viral infection
9. wrong blood in tube (near miss incident)
10. other near miss incidents

*Definitions of each incident category are detailed in the section ‘Incident category definitions’.*

**System aims**

- To measure and monitor serious transfusion incidents including near misses during blood and component utilisation in Victoria.
- To derive recommendations for better safer transfusion practice and disseminate these to Victorian hospitals, health services and the Australian Red Cross Blood Service.

**Measures**

- Proportion of Victorian hospitals reporting into the system
  - monitored as trends over time
  - at the end of each year, hospitals that report no incidents will be asked to complete a form that states they had NO incidents.
- Number of total incidents reported
  - monitored as trends over time
  - the indicator is number of incidents (divided by) number of units issued.
- Number of incidents by category of incident, monitored as trends over time.

**Components of the system**

The flowchart in the next section describes the components of the system and the responsible authority for each stage of reporting.

The system consists of two sets of forms. An initial form is used to notify BeST of an incident (including near misses) titled ‘Serious Transfusion Incident Report’. The ‘eform’ is available at www.health.vic.gov.au/best, and there is a paper copy also available. The quality/risk manager is responsible for coordinating completion of the form and forwarding of it to BeST. An example of both forms is available in the appendix.

The second form is required to provide more detail about the incident. The relevant form is provided to the hospital or health service by BeST upon receipt of a report of an incident. There are nine different forms depending on the incident reporting. The forms are titled as follows:

- Procedural Reporting Form – incorrect blood component transfused (IBCT)
- Clinical Reporting Form – transfusion reaction including: acute transfusion reactions and delayed transfusion reactions.
- Clinical Reporting Form – transfusion-related acute lung injury (TRALI) and Transfusion-associated circulatory overload (TACO)
- Clinical Reporting Form – transfusion-associated graft-versus-host disease (TA-GVHD)
• Clinical Reporting Form – post-transfusion purpura (PTP)
• Clinical Reporting Form – bacterial/other infection
• Clinical Reporting Form – viral infection
• Procedural Reporting Form - other near miss
• Procedural Reporting Form – wrong blood in tube (WBIT).

Sentinel events are reported in accordance with the existing sentinel event procedure, through the department. BeST is notified by the department that an incident has occurred and BeST liaises with the key transfusion contact to ensure forms are completed in conjunction with sentinel event investigations and root cause analysis.

**Completing and returning the forms**

Paper based or electronic forms are to be completed and returned to BeST. An ‘eform’ is available through the BeST website, www.health.vic.gov.au/best/tools/stir.htm, and submits automatically to STIR.

**Feedback**

Sentinel event specific reports will be provided to the reporting organisation, by the Clinical risk management program.

Annual STIR reports will be published by the BeST program and widely disseminated, with hospital identifiers removed.

**Advisory Committee terms of reference**

These can be found at the BeST website at www.health.vic.gov.au/best.
Serious Transfusion Incident Reporting (STIR) System Flowchart

Step 1: Transfusion incident reported on usual institutional incident form

Step 2: Quality/Risk Manager receives report

Step 3: BeST ‘Serious Transfusion Incident Report’ completed and forwarded to:
   (a) BeST Office
   (within 3 business days)
   (b) Relevant staff & committees of reporting institution
       ARCBS\(^a\) notified if appropriate

Step 4: BeST forwards relevant second layer form (within one week)

Step 5: (a) Second layer form completed and forwarded to BeST (within four weeks)
       (b) RCA\(^b\) arranged if appropriate

Step 6: Incident data entered by BeST into database

Step 7: Data verified and collated by expert BeST group and reported back annually or earlier if required

Step 8: Data reviewed by institution, action plan developed

Responsibility:
- Clinical staff
- Quality/Risk Manager
- Hospital key transfusion contact
- (a) BeST
- (b) Quality/risk manager
- BeST
- (a) Hospital key transfusion contact
- (b) Quality/risk manager
- BeST
- Quality/risk manager institutional staff and committees

Note 1: Hospitals should develop a policy and procedure to support the reporting of serious transfusion incidents. Nomination of a key transfusion contact is part of this procedure.

Note 2: Sentinel events are reported to the department through the sentinel event program. BeST will liaise with the key transfusion contact to have the initial and subsequent BeST forms completed in conjunction with the root cause analysis.

Abbreviations
\(^a\)ARCBS – Australian Red Cross Blood Service; \(^b\)RCA – root cause analysis
Incident category definitions

Acute transfusion reaction (ATR)

A reaction occurring at any time during or up to 24 hours following a transfusion of blood or components, excluding cases of acute reactions known to be due to incorrect component being transfused.

Possible acute reaction types:

Haemolytic transfusion reaction (HTR)

HTR is clinically suspected if one or more of the following is present:
- fever and/ or other symptoms (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).

HTR is confirmed by a positive direct antiglobulin test (DAT) and a positive red cell cross match. In the absence of a positive DAT, retrospective phenotype incompatibility of transfused units or a positive crossmatch in addition to clinical scenario consistent with acute haemolytic transfusion reaction may provide diagnosis.

Non-haemolytic febrile transfusion reaction (NHTR)

Moderate/severe febrile transfusion reaction
- chills/rigor
- headache
- nausea and vomiting
- and
- fever (>38.5°C or a change of 1.5°C above baseline)

Allergic reaction

One or more of the following;
- rash
- allergic dyspnoea (stridor, cyanosis, wheezing)
- angioedema
- urticaria
- and without hypotension during or within 24 hours.

Anaphylactoid/anaphylaxis reaction

Allergic reaction with associated hypotension or shock associated with transfusion.

Transfusion-associated circulatory overload (TACO)

Respiratory distress, tachycardia and increased blood pressure within 12 hours of the completion of the transfusion. Typical signs of cardiogenic lung oedema in the chest x-ray and a positive fluid balance, or known compromised cardiac status support TACO.
Delayed transfusion reaction (DTR)
A reaction occurring more than 24 hours following a transfusion of blood or components. These are usually delayed haemolytic reactions due to the development of red cell alloantibodies. Simple serological reactions are excluded such as antibody development without a positive direct antiglobulin test (DAT) or evidence of haemolysis.

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 the transfusion, without other apparent cause. The diagnosis is supported by skin/bone marrow biopsy appearances and the presence of circulating donor lymphocytes.

Transfusion-related acute lung injury (TRALI)
Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates occurring during or within 24 hours of transfusion, with no other apparent cause.

Post-transfusion purpura (PTP)
Thrombocytopenia arising five to twelve days following transfusion of red cells associated with the presence in the patient of antibodies directed against the human platelet antigen (HPA) system.

Transfusion- transmitted infections (TTI)
A post-transfusion infection resulting from transfusion of a bacterially, virally or parasitically contaminated component if the following criteria were met at the end of the investigation:
- there was no evidence of infection prior to transfusion and
- at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection, or
- at least one component received by the infected recipient was shown to have been contaminated with the agent of infection.

Incorrect blood component transfused (IBCT)
Patient was transfused with a blood component or plasma product that did not meet the appropriate requirements or which was intended for another patient.
Near miss incidents

Any incident, that had the potential to cause harm, but didn’t due to timely intervention and or luck or chance. For example any incident which is recognised before transfusion took place 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 it is detected that the labelled blood sample has been collected from an incorrect patient, however the transfusion did not then proceed.
Organisational readiness checklist

This checklist is a tool to assist organisations to review their operational capacity against the generic structural and process elements essential to achieving an effective serious transfusion incident reporting system. Please tick the appropriate box and add comments as appropriate.

<table>
<thead>
<tr>
<th>Senior management commitment</th>
<th>YES</th>
<th>NO</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior management has approved the incident reporting policy that includes transfusion incidents.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior management has established a transfusion governance reporting and monitoring requirement.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality/risk manager nominated to liaise with STIR team on reports made.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training requirements are determined and scheduled.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incident reporting policy</th>
<th>YES</th>
<th>NO</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>A hospital-wide incident reporting policy, that includes serious transfusion incidents, has been developed by management and staff and signed by the appropriate, delegated person.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The incident reporting policy has been communicated to staff.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The incident reporting policy is reviewed periodically.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incident operational management</th>
<th>YES</th>
<th>NO</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>The roles and responsibilities of the Quality/risk manager for serious incidents are clearly defined and documented</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A transfusion safety and quality committee (howsoever named) has been established or, for small rural/regional health services, included as a standing agenda item for an existing committee.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The terms of reference and membership of the transfusion committee or equivalent are clearly defined and communicated.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff and management understand the function of the transfusion committee or equivalent.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The transfusion committee or equivalent has an executive sponsor in the organisation and clear reporting lines to an overarching organisational safety and quality committee.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reports on key transfusion issues are made available to the chief executive officer and the board of directors or board of management as per organisational policy.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STIR</th>
<th>YES</th>
<th>NO</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion administration procedures/policy documentation enables staff to readily identify serious transfusion incidents and the mechanism for reporting.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Brief bibliography


This reference has a very good haemovigilance recommended reading list – pp 100-102.


Serious Transfusion Incident Report (STIR)

The * symbol indicates required information.

The ? symbol indicates field level help is available.

Any data submitted using this electronic form via the Internet is secure and will be encrypted using SSL (Secure Socket Layer).

The Serious Transfusion Incident Reporting (STIR) system is a central reporting system for serious adverse events with transfusion of blood or blood components including near-miss incidents.

Please use this form to report serious incidents with transfusion of fresh blood and blood components.

Confidentiality of data is fundamental to the success of this scheme. We have not requested unique patient identification details. We will contact you to obtain additional details if necessary.

Key details of incident
- Hospital code 
- Patient details – Male / Female 
- Description of Age – SELECT – 

Details of product – including autologous
- Please tick (you may check more than one box) – Red Cells / Platelets / Fresh frozen plasma / Cryoprecipitate / Other 
- Other (please specify) 
- Date of Implicated Transfusion 
- Time of implicated transfusion 

Nature of Incident
1. Incorrect Blood component transfused
2. Acute transfusion reaction (including anaphylaxis)
3. Delayed transfusion reaction
4. Transfusion-related acute lung injury (TRALI)
5. Post-transfusion purpura (PTP)
6. Bacterial / other infection
7. Post transfusion viral infection
8. Wrong blood in tube (WBIT)
9. Other near-miss incident

- Has your hospital blood bank/pathology provider been informed? – Yes / No

For more information on serious transfusion incidents, please see the Summary table on incidents on the BeST Website (opens in new window).

Patient outcome
- Tick box – No obvious clinical problem / Morbidity due to an adverse event / Death following adverse event

Comment on patient outcome

Report made by Quality/Risk Manager
- First Name
- Surname
- Title
- Organisation
- Postal Address
- Date of Report
- Email address
- Telephone number

Submit Form

Last reviewed: 20 March 2007

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Serious transfusion incident report

The Serious Transfusion Incident Reporting (STIR) system is a central reporting system for serious adverse events and near misses during the transfusion of blood or blood components. Please use this form to report serious transfusion incidents.

Confidentiality of data is fundamental to the success of this system. We have not requested unique patient identification details. We will contact you to obtain additional details if necessary.

### Key details of adverse event

#### Patient details
- **Age:**
- **Sex:**

#### Details of product – including autologous (please tick)
- Red cells
- Fresh frozen plasma
- Platelets
- Cryoprecipitate
- Other (please specify):

#### Date of implicated transfusion:

#### Time of implicated transfusion:

### Has your hospital blood bank/pathology provider been informed?
- [ ] Yes
- [ ] No

### Nature of incident

#### INCIDENT

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Suspected</th>
<th>Confirmed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Incorrect blood component transfused</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Acute transfusion reaction (including anaphylaxis)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Delayed transfusion reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Transfusion associated graft versus host disease (TA-GVHD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Transfusion related acute lung injury (TRALI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Post-transfusion purpura (PTP)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Bacterial/other infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Post-transfusion viral infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Wrong blood in tube (WBIT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Other near miss incident</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*PTO for Summary table of serious transfusion incidents to assist in completion of this question.*

### Patient outcome (Tick box)

- [ ] No obvious clinical problem
- [ ] Morbidity due to adverse event
- [ ] Death following adverse event

#### Comment:

### Report made by Quality/Risk Manager

- **Surname:**
- **Postal work address:**
- **Initial and title:**
- **Date of report:**
- **Email:**
- **Tel. number:**
Summary table of incidents for information

<table>
<thead>
<tr>
<th>Problem</th>
<th>Typical features</th>
<th>Diagnostic tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Incorrect Blood or component transfused</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABO incompatible</td>
<td>May be none - or major collapse as for 2</td>
<td>Check identity and group of patient and unit [inc. Rh(D)]. May have +ve DAT.</td>
</tr>
<tr>
<td>ABO compatible</td>
<td>May be none. As for 2 if patient has atypical red cell alloantibodies.</td>
<td>Check identity and group of patient and unit [inc. Rh(D)]. May have +ve DAT.</td>
</tr>
<tr>
<td>2. Acute Transfusion Reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute haemolytic transfusion reaction</td>
<td>Dyspnoea, chest pain, fever, chills, JBP, ↓ urine output, DIC</td>
<td>Haemoglobinuria/uria, ↓Hb, +ve DAT, serological incompatibility, spherocytes on blood film.</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>↓BP, dyspnoea, +/- bronchospasm, +/- rash.</td>
<td>Occasionally patient has severe IgA deficiency.</td>
</tr>
<tr>
<td>4. Transfusion-associated graft-versus-host disease (TA-GVHD)</td>
<td>Progression of fever, rash, T liver enzymes, diarrhoea, pancytopenia (1-6 weeks post transfusion)</td>
<td>Skin biopsy + cytogenetic or HLA analysis. DNA analysis (eg RFLP, minisatellite probes) to establish presence of third party lymphocytes.</td>
</tr>
<tr>
<td>5. Transfusion-related acute lung injury (TRALI)</td>
<td>Acute respiratory distress (non cardiogenic) Hypoxia, bilateral pulmonary infiltrates.</td>
<td>This reaction must be reported urgently to Australian Red Cross Blood Service. Call 9694 0200 24 hours a day.</td>
</tr>
<tr>
<td>6. Post-transfusion purpura</td>
<td>Immune-mediated thrombocytopenia arising 5-12 days post-transfusion.</td>
<td>HPA type patient. HPA antibodies (usually HPA-1a negative with anti-HPA-1a)</td>
</tr>
<tr>
<td>7. Reaction to a bacterially contaminated component</td>
<td>Rapid onset of circulatory collapse, fever.</td>
<td>This reaction must be reported urgently to Australian Red Cross Blood Service. Call 9694 0200 24 hours a day.</td>
</tr>
<tr>
<td>8. Post transfusion viral infection</td>
<td>Depends on virus. Eg. Jaundice, malaise, rash. Weeks to months post transfusion.</td>
<td>This reaction must be reported urgently to Australian Red Cross Blood Service. Call 9694 0200 24 hours a day.</td>
</tr>
<tr>
<td>9. Wrong blood in tube (WBIT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Other near miss</td>
<td>Examples include: (a) Request errors such as wrong component requested, special requirements incorrectly specified or product requested for wrong patient, (b) Laboratory sample handling or testing errors (c) laboratory component selection, handling or storage errors, (d) component issue, transportation, collection or administration errors.</td>
<td></td>
</tr>
</tbody>
</table>

Please email report to: stir@dhs.vic.gov.au
Procedural reporting form – incorrect blood component transfused (IBCT)

1. Date the adverse event occurred?

2. Patient diagnosis/reason for admission?

3. Indication for transfusion:

4. Was the implicated transfusion commenced between?
   - [ ] 8am–8pm
   - [ ] 8pm–midnight
   - [ ] midnight–8am

5. Was the transfusion episode?
   - [ ] an emergency
   - [ ] elective
   - [ ] unknown

6. Where underlying adverse event occurred:
   - [ ] Blood bank/laboratory
   - [ ] Theatre
   - [ ] Intensive Care Unit
   - [ ] Maternity/Delivery suite
   - [ ] Emergency Department
   - [ ] Ward
   - [ ] Out Patient clinic
   - [ ] Ambulatory care centre
   - [ ] Other (please specify):

7. Adverse event involved: (tick one or more)
   - [ ] Medical staff
   - [ ] Technical staff
   - [ ] Nursing staff
   - [ ] Other (please specify):

8. Brief description of how the adverse event occurred? (What happened?)

9. Australian Red Cross Blood Service: (tick one or more)
   - [ ] Incorrect blood group/antigen phenotype
   - [ ] Incorrect serology results supplied
   - [ ] Inappropriate component supplied
   - [ ] Incorrect labeling of component
   - [ ] Other (please specify):
   - [ ] N/A

10. Prescription, sampling and request: (tick one or more)
    - [ ] Sample taken from wrong patient
    - [ ] Prescription of inappropriate and/or incompatible component(s)
    - [ ] Details on request form incorrect
    - [ ] Inappropriate request (for example, failure to request irradiated product)
    - [ ] Details on sample incorrect
    - [ ] Other (specify):
    - [ ] N/A
11. Had the person who took the sample received any documented training in taking samples for blood grouping/cross-matching?
- Y
- N
- Don't know

12. Hospital blood bank/pathology provider: (tick one or more)

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical error</td>
<td>Missed incompatibility/error in cross-matching</td>
</tr>
<tr>
<td>Clerical error</td>
<td>Incorrect serological reasoning</td>
</tr>
<tr>
<td>Failure to follow protocol</td>
<td>Labeling error</td>
</tr>
<tr>
<td>Failure to consult/heed historical record</td>
<td>Selection/issue of inappropriate component</td>
</tr>
<tr>
<td>Tested wrong sample</td>
<td>Failure to irradiate or provide irradiated product</td>
</tr>
<tr>
<td>Blood grouping error</td>
<td>Failure to clear satellite refrigerator increasing number of units in fridge for multiple patients: increasing risk of collection of wrong blood.</td>
</tr>
<tr>
<td>Antibody screening error</td>
<td></td>
</tr>
<tr>
<td>Antibody identification error</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td>Other (please specify)</td>
</tr>
</tbody>
</table>

13. Collection and administration: (please tick)

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection of wrong component</td>
<td>Wristband missing or incorrect</td>
</tr>
<tr>
<td>Failure to detect error earlier in the chain</td>
<td>Failure of bedside checking procedure</td>
</tr>
<tr>
<td>N/A</td>
<td>Other (please specify)</td>
</tr>
</tbody>
</table>

14. Were there two people checking the transfusion?

- Y
- N
- N/A

If no, please explain: __________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

15. Was the component unit checked at the bedside?

- Y
- N
- N/A

If no, please explain: __________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

16. Other information: (please specify)

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

Effect of the event:

17. What were the complications of the transfusion (more than one may be ticked as required)?

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Progression of underlying condition</td>
</tr>
<tr>
<td>Deteriorating renal function</td>
<td>Electrolyte imbalance</td>
</tr>
<tr>
<td>Septicemia</td>
<td>Respiratory distress (pulmonary oedema)</td>
</tr>
<tr>
<td>Septicemia</td>
<td>Cardiac problems</td>
</tr>
<tr>
<td>Persistent viral infection</td>
<td>Deteriorating hepatic function</td>
</tr>
<tr>
<td></td>
<td>Coagulopathy</td>
</tr>
<tr>
<td></td>
<td>Potential risk of Rh (D) sensitization in a female of child-bearing potential</td>
</tr>
<tr>
<td></td>
<td>Acute symptomatic confirmed infection (viral, bacterial, protozoal)</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
</tr>
</tbody>
</table>
18. Did the patient require?  
- [ ] Intensive care unit (ICU) admission  
- [ ] High dependency unit (HDU) admission  
- [ ] Ventilation  
- [ ] Dialysis  
- [ ] Already in ICU on dialysis  
- [ ] None of the above

19. Specify treatment given:  
- [ ] Unable to determine (please explain why)  
- [ ] Oxygen ________ litres/minute  
- [ ] Ventilator  
- [ ] Antihistamine (please specify)  
- [ ] Steroids (please specify)  
- [ ] Pressor agents (please specify)  
- [ ] Other (please specify)

20. Causality:  
In clinical consideration of the adverse event reported was it determined the sign(s) and symptom(s) were related to the transfusion (please tick one option)  
- [ ] No relationship  
- [ ] Possibly  
- [ ] Probably  
- [ ] Certainly

21. Outcome for the patient:  
- [ ] Full recovery with no ill effects  
- [ ] Full recovery with requirement for extended length of stay/ ICU admission  
  (Please indicate if ICU admission required as result of transfusion reaction)  
- [ ] Recovered with minor morbidity  
- [ ] Recovered with major morbidity  
- [ ] Died  
- [ ] Outcome not recorded

22. Did the indications for this transfusion meet hospital guidelines?  
- [ ] Y  
- [ ] N  
If no, please explain:  
________________________________________________________________________  
________________________________________________________________________  
________________________________________________________________________  
________________________________________________________________________

23. Were hospital procedures followed?  
- [ ] Y  
- [ ] N  
If no, what was the deviation?  
________________________________________________________________________  
________________________________________________________________________  
________________________________________________________________________  
________________________________________________________________________

24. Has the case been reviewed by the hospital transfusion committee or its equivalent?  
- [ ] Y  
- [ ] N  
- [ ] Hospital does not have a transfusion committee/equivalent  
If no, has the case been reviewed by the hospital chief medical officer or other appropriate senior medical officer?  
- [ ] Y  
- [ ] N

25. Has the case been reviewed by the hospital quality team?  
- [ ] Y  
- [ ] N  
- [ ] Hospital does not have a quality team
26. As a result of this case have changes to the hospital's procedures been identified or recommended?  
☐ Y ☐ N  
If yes, please specify ________________________________________________________________

Questions 27–42 to be completed by laboratory scientist

27. Please state the ABO/Rh(D) group of the patient: ____________________________

28. Please state the ABO/Rh(D) group of the unit: ____________________________

29. Does the person who performed the pre-transfusion testing/issuing component, normally work in blood bank?  
☐ Y ☐ N  
If yes, please specify ________________________________________________________________

30. Was the current group checked against historical grouping records prior to blood component/product issue?  
☐ Yes – against manual record  
☐ Yes – against computerised record  
☐ Against both  
☐ No (if no, please explain why not) ____________________________________________________

31. Was pre-transfusion testing performed?  
☐ Y ☐ N  
If yes, please specify ________________________________________________________________

32. Historical antibody record:  
☐ Positive ☐ Negative ☐ No history  
If positive, state specificity of antibody(ies) ______________________________________________

33. Antibody screen result:  
☐ Positive ☐ Negative ☐ Not tested  
If positive, state specificity of antibody(ies) ______________________________________________

How many panel cells were used for antibody identification________________________________

34. Was the antibody specificity identified correctly?  
☐ Y ☐ N

35. Would the antibody specificity usually be confirmed at a reference centre?  
☐ Y ☐ N

36. Does the patient have special transfusion requirements?  
☐ CMV – components ☐ Irradiated components ☐ Other (specify)  
Do the special requirements appear in the patient's historical record?  
☐ Y ☐ N

Were the special requirements indicated on the request form?  
☐ Y ☐ N

Were the special requirements met?  
☐ Y ☐ N

If no, why not ________________________________________________________________

37. Was the pre transfusion sample retested?  
☐ Y ☐ N

Was the same result obtained?  
☐ Y ☐ N

If no, please explain ________________________________________________________________
38. Was a direct antiglobulin test (DAT) done post transfusion? □ Y □ N
   If positive, was an eluate done? □ Y □ N
   Please give specificity of the eluate ____________________________________________________________________

39. Antibody screen result: □ positive □ negative
   If positive, please give the specificity of the antibody(ies) ____________________________________________________________________

40. Were all tests performed according to hospital policy? □ Y □ N

41. Was the post transfusion crossmatch compatible? □ Y □ N
   If no, please explain ____________________________________________________________________

42. Was a urine sample collected? □ Y □ N
   If yes, was there evidence of:
   □ Raised urobilinogen
   □ Haemoglobinuria

Quality/Risk Manager:
Name ____________________________________________________________
Title ____________________________________________________________
Date completed ___________________________________________________
Tel ______________________________________________________________
Email ____________________________________________________________

Please complete and send report to:
Project Officer, Better Safer Transfusion (BeST) Program
Quality and Safety Branch
GPO Box 4057
Melbourne VIC 3001