Department of Health

health

# Serious transfusion incident report 2008–09

State Government Victoria

Australian Red Cross BLOOD SERVICE

blood matters
better safer transfusion program

# Serious transfusion incident report 2008–09

## Acknowledgements

The Blood Matters – better safer transfusion program (Blood Matters) is a collaboration between the Victorian Government Department of Health (the department) and the Australian Red Cross Blood Service (the Blood Service). Its aim is to improve transfusion practice in hospitals and is founded on the expectation that the provision of relevant information will serve to support the community by promoting better transfusion practice.

The Serious Transfusion Incident Reporting (STIR) program thanks the participating Victorian, Tasmanian, Australian Capital Territory and Northern Territory public health services, hospitals and private facilities for their contribution to the program, and acknowledges the STIR expert group, whose input is invaluable in reviewing the incidents and providing recommendations.

### Accessibility

If you would like to receive this publication in an accessible format, please phone 03 9096 9037 using the National Relay Service 13 36 77 if required.

The document is also available in PDF format on the Internet at www.health.vic.gov.au/bloodmatters

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# Contents

# Abbreviations and acronyms

| | |
|---|---|
| ABO | ABO blood groups |
| ANZSBT | Australian and New Zealand Society of Blood Transfusion |
| ATR | acute transfusion reaction |
| DAT | direct antiglobulin test |
| Dyspnoea | difficulty breathing |
| FFP | fresh frozen plasma |
| FNHTR | febrile non-haemolytic transfusion |
| Hb | haemoglobin (g/L) |
| HLA | human leucocyte antigen |
| HTR | haemolytic transfusion reaction |
| Hypotension | low-drop in blood pressure |
| Hypoxia | low oxygen levels in the blood |
| IAT | indirect antiglobulin test |
| LDH | lactate dehydrogenase |
| mL | millilitre |
| Rh | Rhesus blood group |
| RCNA | Royal College of Nursing, Australia |
| SHOT | Serious Hazards of Transfusion (UK) |
| STIR | Serious Transfusion Incident Reporting |
| TACO | transfusion-associated circulatory overload |
| Tachycardia | increase in heart rate |
| TA-GVHD | transfusion-associated graft versus host disease |
| The Blood Service | Australian Red Cross Blood Service |
| TRALI | transfusion-related acute lung injury |
| TTI | transfusion-transmitted infections |
| TTP | thrombotic thrombocytopenic purpura |
| VHIMS | Victorian Health Incident Management System |
| WBIT | wrong blood in tube |

# Executive summary

The Blood Matters Serious Transfusion Incident Reporting system (STIR) is a voluntary, central reporting system for a defined set of serious adverse events relating to transfusion. These include procedural and clinical reactions related to transfusion of fresh blood components, and near miss events associated with pre-transfusion sampling.

The system monitors these events and derives recommendations to assist in improving transfusion practice and ensure a safe transfusion for the patient. The STIR process includes review by a group of clinicians and scientists with expertise in transfusion medicine.

This is the second report of the STIR program. It presents a summary and analysis of data from expert medical reviewers for the period 1 January 2008 to 30 June 2009, and also includes events from 2007 where full documentation and review occurred in 2008. The data presented here provide strong messages to inform current and future transfusion practice. Avoidable transfusion adverse events continue to occur throughout the transfusion process, and all areas of the transfusion process require training and support to ensure systems function effectively and provide a safe transfusion for the patient.

Included in the report is a transfusion safety checklist – a short and practical tool developed for health services to use for assessment of their own systems. This tool is derived from the accumulated STIR data and reflects practice and issues within contributing organisations and jurisdictions.

# Introduction

Blood Matters is a collaboration between the Victorian Government Department of Health and the Australian Red Cross Blood Service. The program is pleased to provide the 2008–09 report of the Serious Transfusion Incident Reporting (STIR) system.

Transfusion safety is paramount to the overall aim of Blood Matters. Monitoring and reporting on adverse events of transfusion are a part of its overall haemovigilance strategy, from blood collection to the follow-up of recipients.

STIR is a voluntary reporting system for clinical adverse events associated with transfusion, with contributions from public and private facilities (hospitals and transfusion laboratories) that transfuse blood products. It aims to identify hazards in the clinical practice of transfusion and to develop strategies and recommendations to improve the overall safety of the transfusion process.

Each reported event is reviewed by the STIR expert group which consists of medical specialists, transfusion nurse consultants and transfusion laboratory scientists.

The STIR system complies with the Victorian Government Department of Health privacy policy. No patient names are collected with STIR notifications and only deidentified aggregate data are reported.

In 2008–09 reports were received from 58 hospitals in four jurisdictions: Victoria, Tasmania, Australian Capital Territory and Northern Territory. In Victoria the reporting hospitals represented 68 per cent of the currently transfusing hospitals in the state, based on denominator data of blood components issued to those laboratories for transfusion. For hospitals currently not reporting to STIR, it cannot be assumed that no transfusion incidents occurred, but simply that none were reported to STIR during this period.

# Transfusion safety checklist

This transfusion safety checklist has been included in this report as a tool for health services. It can be used to ensure compliance with relevant areas to support safety of transfusion recipients. The issues and areas addressed in the checklist are based on data received and analysis and recommendations of the STIR expert group.

| Issue | Strategies implemented by health service to address the issues | Yes | No | WIP* | N/A# |
|---|---|---|---|---|---|
| Incorrect blood component | All patients receiving a transfusion must be identifiable by wristband or photo identification. | | | | |
| | A guideline exists for management of a massive transfusion episode and that coordination of the administration is undertaken, ensuring correct patient identification, correct documentation and ongoing communication with the laboratory. | | | | |
| | Transfusion compatibility reports, unless necessary for traceability, should be phased out of the transfusion process. All information required to be checked against the patient is contained on the label attached to the blood bag or on the blood bag. | | | | |
| Satellite blood fridge | Careful consideration should be given to whether a satellite fridge is absolutely necessary. | | | | |
| | If a satellite fridge is deemed necessary, procedures must be in place for monitoring alarms and the registering of blood contained within the fridge. All staff with access to the fridge are trained and competent for removal of products. | | | | |
| Patient identification in blood sampling | A policy or guideline outlining how to positively identify all patients undergoing blood sampling is available for all staff. | | | | |
| | Clinical staff performing phlebotomy procedures undertake formalised training in patient identification and blood-sampling labelling. | | | | |
| | Blood-sampling error rates are monitored and areas for improvement targeted and explored. | | | | |
| Management of transfusion reactions | A process exists to ensure that the laboratory is informed of all transfusion reactions. | | | | |
| | Clinicians are made aware of the signs and symptoms of transfusion reactions and how to report these to the transfusion service and hospital governance department. | | | | |
| Training and credentialing staff in transfusion practice | Clinicians undertake transfusion education or formalised assessment of transfusion practice at least every two years. | | | | |
| Hospital transfusion committee or equivalent | Transfusion improvement activities and transfusion safety issues are discussed at a hospital committee meeting that reports to or has hospital executive representation. | | | | |

# Method

Data are received by STIR as an initial notification through an e-form located on the Blood Matters website <www.health.vic.gov.au/best/tools/stir.htm>. On receipt of initial notification, the STIR office provides the reporting institution with a form relevant to the specific incident type (clinical or procedural). This is returned to STIR with detailed information about the incident, and this is entered into a Microsoft Access database for analysis and review. Patient or personnel-identifying data are not collected.

Sentinel events are reported in Victoria in accordance with the existing sentinel event procedure. STIR is notified by the department that an incident has occurred and liaises with the health services to provide an investigation form to assist with investigations and root-cause analysis.

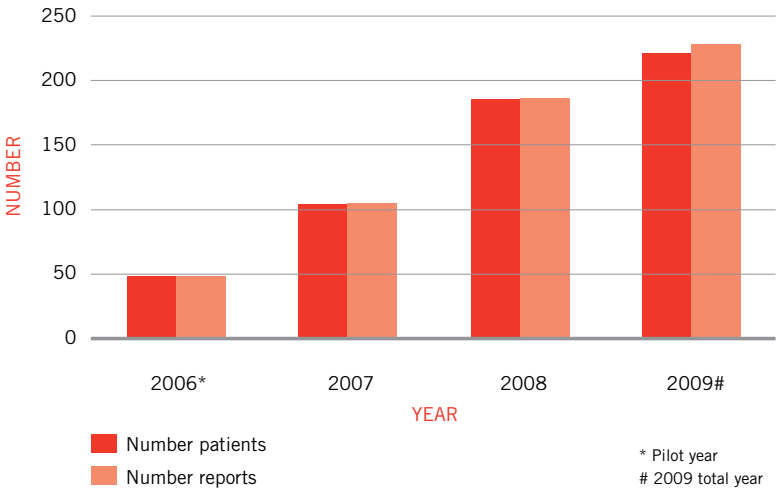
Each report is reviewed by a subgroup of the STIR expert group consisting of a haematologist, transfusion scientist and transfusion nurse to ascertain alignment with the STIR reporting, review the diagnosis, and attach imputability (causality) and severity ratings for relevant events.

The STIR expert group also reviews all sentinel events involving blood products from the Victorian Government Department of Health Sentinel Event Program. In 2008–09, the group reviewed three sentinel event reports and recommendations from these reviews are outlined further in the report. Recommendations are made by the STIR expert group to the sentinel event program, which in turn provides these to the reporting institution.

In the future STIR will be incorporated into the Victorian Health Incident Management System (VHIMS). It is anticipated that this will occur during 2010, assisting health services reporting to this system, and avoiding duplication of reporting. STIR will continue in its current format for health services outside the scope of VHIMS.

Figure 1 highlights the events reported to the STIR program since 2006 and demonstrates number of patients and number of reports.

## Figure 1 – Reports received by STIR 2006–09



# Imputability and causality

In 2007 the expert group introduced a process of attribution of event causality and severity ratings. This followed careful consideration of the applicability of the STIR definitions to incident types and enables validation of the data presented to STIR. The 2008–09 results reflect validated data using definitions developed from the Root Cause Analysis Education – Clinical Risk Management, Department of Health, Victoria (Table 1 and 2).

## Table 1 – Imputability and causality rating

| Imputability/ causality | Definition |
|---|---|
| Not assessable | There is insufficient evidence for an imputability definition. |
| Excluded | There is conclusive evidence that the cause of the incident is attributable to other causes and not the transfusion. |
| Possibly | The evidence is indeterminate for attributing the incident to either the transfusion or other causes. |
| Probably | The evidence is clearly in favour of attributing the incident to the transfusion. |
| Certainly | The evidence is conclusively attributable to the transfusion. |

## Table 2 – Severity rating

| Severity rating | Incident |
|---|---|
| 1 | Relatively infrequent, clear-cut events that occur independently of a patient's condition; commonly reflect hospital system and process deficiencies; and result 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 |
| 2 | 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 the person's management |
| 3 | Events that result in a person requiring increased treatment, but not hospitalisation or an increased length of stay |
| 4 | Events that result in minor injury requiring only first aid treatment or no injury |

# Report for 2008–09

Total of blood issues from the Australian Red Cross Blood Service for all current reporting jurisdictions is provided in Table 3 and gives a numerical context for the STIR data.

### Table 3 – Total of blood issues per jurisdiction

| Products | Victoria | Tasmania | ACT | Northern Territory |
|---|---|---|---|---|
| Red cells | 309,556 | 22,696 | 18,702 | 9,187 |
| Platelets | 46,397 | 3,492 | 3,212 | 1,381 |
| Fresh frozen plasma | 55,223 | 2,343 | 3,983 | 1,443 |
| Cryoprecipitate | 29,145 | 2,152 | 1,677 | 448 |
| **TOTAL** | **440,321** | **30,683** | **27,574** | **12,459** |

Together with the issue data for Victoria and number of events notified per component type, an event frequency has been estimated (see Table 3). While the denominator is blood components issued by the Blood Service to hospital laboratories, the number of components actually transfused to recipients is unknown. This is a major limitation of assigning rates of reactions by component type. In Victoria organisations reporting to STIR represent approximately 68 per cent of transfusion activity by volume of components issued. However the number of events reported does provide some reflection of relative risk, at least as far as these appear to cause clinically apparent reactions investigated by reporting hospitals.

### Table 4 – Frequency of events per product issued

| Products | Victoria issues | Events*^ | Frequency |
|---|---|---|---|
| Red cells | 309,556 | 92 | 1:3364 |
| Platelets | 46,397 | 27 | 1:1718 |
| Fresh frozen plasma | 55,223 | 10 | 1:5522 |

*Victorian notifications only

^ Two events not included as multiple products implicated.

Number of components issued 2008–09, Blood Service Data (Table 3)

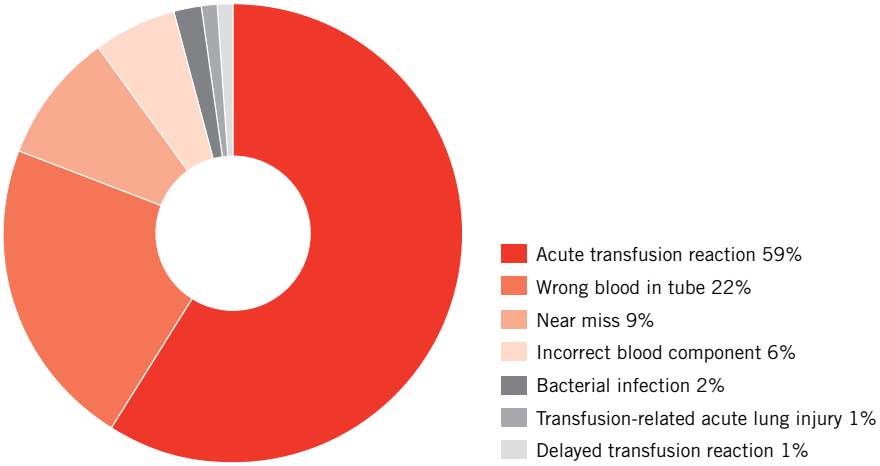
# Types of incidents at notification

Figure 2 highlights the notifications into STIR during the period of this report.

It should be noted that a notification report may correspond with more than one type of event. Percentages are based on number of reports returned.

There were no reports of transfusion-associated graft-versus-host disease (TA-GVHD), post-transfusion purpura (PTP) or viral infection through the STIR system in 2008–09

### Figure 2 – STIR notifications




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

Confirmed n = 136  Suspected n = 141

# Types of components implicated at notification

### Table 5 – Blood Components

| Product | Number | Percentage |
|---|---|---|
| Red cells | 165 | 60 |
| Other^ | 56 | 21 |
| Platelets | 32 | 11.5 |
| Fresh frozen plasma | 14 | 5 |
| Cryoprecipitate | 1 | 0.5 |
| Red cells, platelets, fresh frozen plasma, cryoprecipitate* | 6 | 2 |
| **TOTAL** | **274** | **100** |

* One event may have involved multiple components.

^ Other includes all events involving pre-transfusion specimens.

# Event demographics

Sixty per cent of all reported events occurred between 8 am and 8 pm; 25 per cent of all events occurred between the hours of 8 pm and midnight; and 15 per cent occurred between midnight and 8 am. Similar to our initial data from 2006–07, events relating to these 'out of hours' periods appear over-represented in STIR reports compared with 'in hours' transfusions.

Similar numbers of events were reported during weekdays and Saturdays (12–21 per cent). However fewer events occurred on Sunday (7 per cent), possibly suggesting that less transfusion activity occurs on this day, which may correlate with patterns of elective surgery.

More acute transfusion reactions (ATR) events (n=108, 66 per cent of all ATR 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.

With wrong blood in tube (WBIT) events, the emergency (n=20, 32 per cent), maternity (n= 14, 23 per cent) and general ward (n=14, 23 per cent) departments were the three areas where a sample error occurred more often than all other clinical areas. However no hospital actual transfusion rates in these areas exist for formal comparison.

# Patient demographics

Events were reported for 274 patients; 52 per cent of these incidents involved female patients. Patient age ranged from 0 days to 98 years (mean 48 years) and 21.9 per cent of events were in patients of 18 years or less. This large percentage of reports in patients under the age of 18 years 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 category of event on 43 occasions (16 per cent of initial reports), in addition to six 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.

# Outcomes

Patient outcomes described in Table 6 are those attributed by the health service report. Fortunately for a majority of events the patient made a full recovery, with only a small percentage requiring ICU admission or increased length of stay. The patient outcome is only documented for events reported initially as acute or delayed reactions, incorrect blood component transfused, suspected bacterial contamination and transfusion-related acute lung injury (TRALI).

## Table 6 – Patient outcomes

| Patient outcomes^ | Reports |
|---|---|
| Full recovery with no ill effects | 147 |
| Full recovery with requirement for extended length of stay | 21 |
| Died* | 5 |
| Missing data | 8 |
| Outcome not recorded | 6 |

^one report corresponds with more than one type of event.

*death attributed to causes other than the transfusion adverse event in all cases.

# Review by health service

As part of a thorough investigation and to assist in complete data capture, the STIR expert group recommends that all reports are reviewed by either the hospital transfusion committee (HTC) or equivalent, where a HTC doesn't exist, if meeting prior to STIR submission date, or by the chairperson of HTC or a senior medical officer, outside normal institutional meeting times. Involvement of the hospital quality or governance team will assist with highlighting system deficits that are noted with events and assist with hospital-wide change processes, if required. Tables 7–9 highlight how the reports for were reviewed prior to submission for this reporting period.

## Table 7 – Review by hospital transfusion committee

| Has the case been reviewed by the hospital transfusion committee? | | |
|---|---|---|
| Case review | **Count** | **Percentage** |
| Yes | 184 | 67 |
| No | 46 | 17 |
| Not answered | 5 | 2 |
| To be discussed at next meeting | 38 | 14 |
| Hospital does not have a transfusion committee | 1 | 0 |
| | **274** | **100** |

## Table 8 – Review by senior medical officer

| If no, has the case been reviewed by the hospital chief medical officer or other appropriate senior medical officer? | | |
|---|---|---|
| Case review | **Count** | **Percentage** |
| Yes* | 33 | 12 |

*Includes 6 cases where both hospital committee and senior medical officer reviewed the case.

## Table 9 – Review by hospital quality team

| Has the case been reviewed by the hospital quality team? | | |
|---|---|---|
| Case review | **Count** | **Percentage** |
| Yes | 139 | 51 |
| No | 120 | 44 |
| Not answered | 3 | 1 |
| Will be reviewed | 9 | 3 |
| Hospital does not have a quality team | 3 | 1 |
| | **274** | **100** |

This current data indicates that some events are not undergoing a review process prior to submission. This should be addressed by health services and will be an area of review for the Blood Matters program.

# 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.

One hundred and sixty-three notifications were received in the category of ATR in 2008–09. Febrile non-haemolytic transfusion reactions (FNHTR) accounted for a total of 84 reports (51 per cent), with reviewers reclassifying 23 incident reports into this category.

Allergic/anaphylactoid reactions accounted for 67 (41 per cent) of ATR reports as determined by the notifying hospital or reviewer. Sixty-one allergic reports were assessed for severity and imputability. All types of fresh components were implicated in the allergic/anaphylactoid reactions. Of these, 29 were associated with red cells, 21 with platelets, 12 with fresh frozen plasma and one with cryoprecipitate, and there were four occasions where multiple components were administered and it was not possible to determine which product was responsible.

Allergies as reported by the hospitals were ascertained for severity and are set out in Table 10. Mild allergic response to blood products appears prominent in the paediatric population but it is unclear whether this reflects reporting issues or true biological responses to transfusion.

### Table 10 – Allergy severity

| Allergy type | Number |
|---|---|
| Mild – single symptom or single drug treatment (other than adrenaline) required | 29 |
| Moderate – multiple symptoms with polypharmacy treatment not including adrenaline | 12 |
| Severe – multiple symptoms with polypharmacy treatment including adrenaline or increased length of stay or level of care | 14 |
| Anaphylaxis – as above for severe allergy including severe hypotension or cardiac arrest | 12 |
| **TOTAL** | **67** |

### Case study

A post-operative cardiac bypass grafts surgery patient received fresh frozen plasma for abnormal coagulation parameters in the setting of ongoing bleeding. Within 10 minutes of infusion, the patient developed facial swelling, tachycardia, significant hypotension and hypoxia. Within minutes a ventricular fibrillation cardiac arrest ensued. The patient was successfully resuscitated with direct cardioversion, oxygen and intravenous adrenaline, and made a successful recovery from both the anaphylaxis and surgery.

Investigations: The patient was investigated for immunoglobulin A (IgA) deficiency, with testing for immunoglobulin levels and anti-IgA antibodies. IgA levels were normal and no anti-IgA antibodies were detected. The anaphylaxis was probably due to reaction to other plasma proteins within the fresh frozen plasma.

## Australian Red Cross Blood Service

**Febrile non-haemolytic transfusion reaction**

Usual aetiology: Alloimmunisation to donor human leucocyte antigen or other antigens. Cytokine accumulation during storage.

Incidence: 0.1–1 per cent of transfusions with universal leucodepletion (as of November 2008 is now Australia-wide). Most frequent in patients previously alloimmunised by transfusion or pregnancy.

Main clinical features: Temperature rise of ≥ 1°C during or shortly after transfusion and in the absence of any other pyrexic stimulus. Chills, rigors and headache.

Investigation: Clinical assessment.

Intervention: Consider and exclude other causes. Give antipyretic.

Source: Blood component information, Australian Red Cross Blood Service, available from www.transfusion.com.au

**Anaphylactoid reactions or anaphylaxis**

Usual aetiology: The majority of these reactions have been reported in IgA deficient patients who have antibodies against IgA or IgE classes of immunoglobulins. Also IgE-mediated allergy to plasma proteins, rarely to donor medications.

Incidence: 1:20,000–50,000 transfusions.

Main clinical features: May be fatal. Onset characterised by coughing, bronchospasm, laryngospasm, respiratory distress, vascular instability, nausea, abdominal cramps, vomiting, diarrhoea, shock and loss of consciousness.

Investigation: Check recipient pre-transfusion sample for IgA deficiency and presence of antibodies against IgA.

Intervention: Stop transfusion immediately. Maintain airway and intravenous line. Administer adrenaline and corticosteroids. Treat hypotension. Inform the Blood Service. Where appropriate, use autologous, washed, or components from IgA-deficient donors if future transfusion required.

Source: Blood component information, Australian Red Cross Blood Service, available from www.transfusion.com.au

### Case study

A patient with a low haemoglobin received a transfusion of red cells. Thirty minutes post-transfusion, the patient developed a fever, chills, back pain and nausea and vomiting. There was no documentation that any treatment was required and there was not enough information about the patient's admission to be certain whether this event was related to the transfusion or the patient's underlying condition.

Investigations: The investigation was compromised by inability to culture the blood component pack as it was misplaced and not available for testing. However, bacteria were isolated from the patient's blood culture. The review group agreed this was a possible febrile non-haemolytic transfusion reaction, especially as the patient did not apparently require any intervention, but could not rule out a possible bacterial contamination.

## Transfusion safety tip

Thorough and prompt investigation of acute transfusion reactions can assist in determining a diagnosis, initial treatment and also a management plan for the patient for any future transfusion requirements.

Some cases may be 'diagnoses of exclusion' when typical clinical features are absent or not recorded, or relevant investigations not performed. Wherever bacterial contamination of blood components is suspected, it is essential to return blood packs to the issuing laboratory for urgent Gram stain and culture. Delay in returning component packs for investigation can lead to introduction of contamination with environmental organisms, and can make interpretation of culture results very difficult. Patient cultures should also be performed promptly.

Notification of transfusion reactions to the pathology provider who issued the blood components will assist with the investigation. This also enables prompt notification of the Blood Service where applicable. In some cases further testing of patients, donors or products is required, quarantine of components may be necessary, and donor deferral may need to be considered. Consultation with a haematologist or transfusion medicine specialist may also be helpful.

# 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.

Four reports of DTR were notified with three investigation forms reviewed. Each of these events occurred 5–9 days post-transfusion. Symptoms and signs included typical features of haemolysis (fever, haemoglobinuria, jaundice, failure to increment haemoglobin post-transfusion, raised bilirubin and LDH levels) and one incidental finding of a positive antibody screen on later pre-transfusion testing.

STIR reports highlight the complexities in managing these patients. Difficulties can occur with red cell alloantibodies that can fall to low levels and be undetectable in subsequent testing months or years later. These typically include antibodies in the Kidd (Jk) system. It is especially difficult when patients present for testing at different institutions over time, without previous information being available to the laboratory performing the current test.

Access for transfusion laboratories to patient results through a regional or national database of antibody results may prevent re-exposure to antigen-positive units and the consequences of some delayed haemolytic transfusion reactions.

### Case study

A patient undergoing major vascular surgery received multiple red cell units. The initial pre-transfusion antibody screen was negative. The patient was transfused uneventfully, but five days post-transfusion developed fever, jaundice and haemoglobinuria.

Investigations: The post-transfusion investigations included a positive direct antiglobulin test. Anti-E and anti-Jkb were detected. The patient recovered without any additional management but will now require antigen-negative blood for future transfusions.

## Australian Red Cross Blood Service

**Haemolysis: delayed (usually extravascular)**

Usual aetiology: Usually occurs in previously red cell alloimmunised patients in whom antigens on transfused red cells provoke anamnestic production of red cell antibody. Usual timeframe is 2–14 days after transfusion.

Incidence: 1:4,000–9,000.

Main clinical features: Signs may include unexplained fever, development of a positive DAT, jaundice and unexplained decrease in haemoglobin.

Investigation: DAT and IAT. Liver function tests. Markers of haemolysis (urinary haemosiderin, haptoglobin et cetera).

Intervention: Most delayed haemolytic reactions have a benign course and require no treatment. Perform antibody identification and provide antigen negative blood if further transfusion is needed. Inform the Blood Service.

Source: Blood component information, Australian Red Cross Blood Service, available from www.transfusion.com.au

# 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.

Two reports of suspected TRALI were notified in 2008–09.

One report was a complex case and is outlined in the case study below. This case may have been TRALI but transfusion-associated circulatory overload (TACO) could not be excluded. In addition, the evidence was indeterminate for attributing the incident to the transfusion or other causes. It was classified by both reviewers as a 'possible' TRALI.

One case notified in 2007, but investigated in 2008, was classified initially by the reviewers as a probable TRALI, but on further investigation it was thought to be most likely TACO.

### Case study

A patient presented with critical bleeding from a gastric ulcer was admitted to the intensive care unit (ICU) post-operatively. Bleeding remained an issue and multiple blood products (17 units of red cells, 3 apheresis platelets and 4 units of fresh frozen plasma) were administered over the patient's first 24 hours, during emergency resuscitation and surgery. Three hours following admission to ICU, the patient received eight units of cryoprecipitate. Over the next 24 hours the patient's respiratory status deteriorated, culminating in significant desaturation.

Investigations: Due to the complexity of the patient's condition and the numerous blood products administered in the 24-hour period, it was difficult to ascertain any implicated transfusion. The patient developed adult respiratory distress syndrome (ARDS), with typical changes on chest x-ray. The Blood Service, institutional haematologist and ICU team felt this case could have possibly been acute pulmonary oedema (volume overload), ARDS or TRALI. Donor investigations were not performed due to the large number of products involved and the uncertainty of the diagnosis, in a situation where donor investigation would not have altered the patient's management.

## Australian Red Cross Blood Service

**Transfusion-related acute lung injury (TRALI)**

Usual aetiology: Specific mechanism of action is not clear. HLA or granulocyte antibodies in donor plasma reacting with recipient HLA or granulocyte antigens may play a role. Rarely, the reverse may be the case.

Incidence: Variably reported. 1:5,000–190,000 transfusions.

Main clinical features: Onset of fever, tachycardia, hypotension, hypoxia and pulmonary oedema within six hours of transfusion.

Investigation: Clinical assessment and investigation (for example chest x-ray, oxygen saturation and laboratory investigations. TRALI is a clinical diagnosis. Diagnosis may be supported by demonstration of HLA or granulocyte antibodies in donor or recipient serum together with a positive crossmatch.

Intervention: Stop transfusion immediately. Provide cardiovascular and respiratory support. Inform the Blood Service.

Source: Blood component information, Australian Red Cross Blood Service, available from www.transfusion.com.au

## Transfusion safety tip

During a critical bleeding episode, multiple blood products may be administered, often concurrently. Maintaining good documentation of which products were administered, and at what times, can be essential in assisting with investigation of reactions, should they occur.

In some critical bleeding episodes it maybe helpful to have a staff member dedicated to managing the transfusion requirements, including documentation, and responsible for communicating with the institutional blood bank for ongoing product requirements and blood samples for investigation.

# 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 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.

Five reports of potential bacterial contamination were notified during the reporting period and for each of these investigation forms were returned and reviewed. No cases were confirmed as bacterial contamination events. Two reports were considered possibly related to the blood component, two reports were excluded and for one report there was not enough evidence to assess the event as attributable to the transfusion. The components implicated in these reports were red cells and platelets.

There were no reports of any TTI resulting from viral or parasitically contaminated product.

**Case study**

A patient was admitted with cardiogenic shock, and developed a fever during a transfusion of red cells. The indication for transfusion was unclear from the investigation report. As part of the transfusion reaction investigation microbial cultures were performed on samples from both patient and the red cell unit. Culture results demonstrated a coagulase-negative staphylococcus from each sample; however, the investigation report from the health service did not state that molecular tests were performed to confirm whether these were the same organism. The event was categorised as only possibly related to the transfusion, since 10 days earlier the patient had a positive culture for coagulase-negative staphylococcus.

Investigations: Samples from both patient and blood bag were evaluated with microscopy, culture and sensitivity. The patient did not require any escalation in treatment; was already in intensive care and receiving supportive management of fever. The health service could not rule out there had been some contamination of the unit with the patient's blood. The patient made a full recovery.

### Case study

A patient attended an out-patient treatment area for post-transplant review and for red cell transfusion. Within an hour of the transfusion the patient became acutely unwell with hypotension requiring a medical emergency call and was admitted to ICU overnight for further management, including intravenous antibiotics. Patient cultures isolated organisms *Klebsiella pneumoniae* ssp, *pneumoniae* and *stenotrophomonas*.

Investigations: The pack was unable to be cultured due to an insufficient sample. Patient cultures were removed from the peripherally-inserted central catheter (PICC) which was subsequently removed as it was suspected this may have been the source of the infection. Coagulase-negative *staphylococcus* were isolated from the tip of the catheter. This event was categorised by the reviewers as possibly related to the transfusion. The patient made a full recovery.

## Australian Red Cross Blood Service

**Infection – bacterial**

Usual aetiology: Bacteria may enter the blood during collection or preparation of components. Occasionally bacteria may enter the blood during the collection or preparation of components or due to contamination of the ports during thawing of frozen products in a water bath. Both gram-positive and gram-negative organisms have been identified. Organisms capable of multiplying at low temperatures and those using citrate as a nutrient are most often associated with red cell contamination, especially Yersinia enterocolitica. Greatest risk is for platelets stored at room temperature. In order to minimise the risk of bacterial contamination of platelets, the Blood Service performs screening by culture for bacterial contamination on all platelet components.

Incidence: For clinically apparent reactions, variously reported in international literature to be at least 1:75,000 for platelets and at least 1: 500,000 for red cells.

Main clinical features: Can be acute, severe life-threatening. May be fatal. Onset of high fever, severe chills, hypotension or circulatory collapse during or soon after transfusion should suggest the possibility of a bacterial contamination and endotoxin reaction.

Investigation: Clinical assessment. Blood cultures from the patient. Culture and gram stain of the component. Keep blood bag and giving set (sealed) for further investigation.

Intervention: Stop transfusion immediately if suspected. Start broad spectrum antibiotics once cultures have been taken. Cardiovascular support. Inform the Blood Service.

Source: Blood component information, Australian Red Cross Blood Service available from www.transfusion.com.au

## Transfusion safety tip

Any clinical risks of TTI are minimised by routine and additional thoughtful clinical observation before, during and after transfusion of blood and blood products.

Careful sample handling and cultures of both product and patient are important elements to the investigation of a suspected bacterial contamination. Information on management of samples should form part of institutional guidelines for managing transfusion reactions, to assist staff in investigating a suspected bacterial contamination.

# Incorrect blood component transfused (IBCT)

Sixteen notifications of IBCT were received through the STIR program for 2008–09. Fourteen investigation forms were reviewed. Three sentinel events were reported through the sentinel event program and STIR that fitted the category of incorrect blood component. All were ABO incompatibility episodes, two involving red cells and one a plasma transfusion.

Each of the events has been categorised as outlined in Table 11. The category 'components that did not meet specific requirements for patient' contains examples of important patient-specific transfusion component modifications which were missed – either through lack of explicit request from the clinical team or at issue of components for transfusion by the institutional blood bank.

### Table 11 – Incorrect blood component transfused events

| IBCT types | Number |
|---|---|
| Components that did not meet specific requirements for patient | 6 |
| Incorrect blood component to incorrect patient – ABO compatible | 5 |
| Incorrect blood component to incorrect patient – ABO incompatible* | 3 |
| Other | 3 |
| **TOTAL** | 17* |

*This includes two reported to STIR and the sentinel event program and one only reported through the sentinel event program.

'Wrong blood episodes' are preventable events. The common theme through the reports of IBCT reported to STIR and the sentinel event program was failure to positively identify the patient correctly either due to incorrect identification procedures or failure to follow hospital policy during all steps of the transfusion process.

### Case study

A sole scientist on duty overnight transcribed blood grouping results directly from an auto-analyser computer screen without matching the patient's identity with the result on the screen.

The transcription was unnecessary as this routinely occurs via an electronic upload from the auto-analyser. There had been no patient specimens run on the analyser for some hours and it was incorrectly assumed the result on the screen belonged to the recent test; in fact it was for a recipient tested five hours previously. Thus the results and blood group interpretation were incorrectly recorded on the laboratory information system.

The group recorded was group O, Rh D-positive, when in fact the patient was group AB, Rh D-positive. Four units of O Rh D positive red cells were electronically matched and fortunately were compatible.

This pathology laboratory had a procedure in place that for any manual entry of blood grouping results an immediate saline spin crossmatch must also be performed. However in this case it was not performed.

### Case study

A patient received red cells that had been crossmatched and issued for another patient on the same ward. The error was detected soon after commencement of the infusion and the patient received only a small quantity of the incorrect blood. Fortunately the unit of red cells was group O, Rh D-negative and also met all other compatibility requirements for the patient.

The health service also noted the failure of the pre-transfusion bedside checking procedure and instituted recommendations to improve this process.

The unit had been selected from a satellite fridge, where multiple units were stored for multiple patients. At the time of this event there was no procedure for checking blood in or out of the satellite fridge. The health service has now established such a policy.

### Case study

A patient experienced a significant post-partum haemorrhage overnight, requiring transfusion of red cells. Due to a communication error staff thought that no group O, Rh D-negative red cells were available. No sample was collected for a pre-transfusion specimen and the on-call scientist was not called.

On the basis of patient information and a previous blood bank card, group O, Rh D-positive red cells were selected by the clinical staff and administered. It was hospital policy to direct staff to give group-specific units if the patient's blood group was known. However, in this instance the blood was issued with the patient's historical record on a card, not on the basis of current or historical laboratory testing results. The error of issuing group-specific blood without patient testing was detected by the pathology provider the following day.

Multiple procedural errors contributed to this event. Fortunately the patient did not suffer any harm because the blood administered was ABO-compatible. This health service has changed policy to comply with safe transfusion practices and ensured all staff are familiar with pre-transfusion sampling, testing and emergency issue policies.

## Transfusion safety tip

### 1. Compliance with bedside identity check

All staff should be familiar with the requirement to review the wristband of a patient or obtain verbal confirmation of the patient details prior to administering any blood product. These details should exactly match the product and its accompanying paperwork, prior to transfusion proceeding.

Compatibility reports or transfusion report forms that accompany blood products when issued from the laboratory are often being used as the patient identification step when checking the product in the clinical area, instead of direct patient identification. The UK Serious Hazards of Transfusion (SHOT) in 2008 recommended that the compatibility report should be discontinued except in hospitals where it is integral to traceability of the product.

### 2. Training of staff in transfusion administration practices

Health services should address training and assessment of nursing and other staff in awareness of and adherence to guidelines for administration of blood products.

A blood safety training initiative has been developed by the South Australian Department of Health BloodSafe program. This e-learning program has been designed to provide clinical and other staff (such as porters and orderlies) with an opportunity to develop their knowledge of blood and to encourage safe transfusion practice and the appropriate use of blood components. It is available for use nationally. Further details are available at www.bloodsafelearning.org.au

### 3. Use of satellite (non-laboratory) blood storage refrigerators

The use of satellite blood fridges and retrieval of the wrong unit of blood from the fridge has been implicated in two previous sentinel events reported to STIR. Given the number of events involving the administration of the wrong blood to the wrong patient where a satellite fridge was a significant contributing factor, STIR recommends health services review their need for blood fridges outside the laboratory and where possible remove these from use.

# Near miss events

Twenty-six notifications of near miss events were received and all were reviewed. Some were outside current STIR criteria for near miss, in that the transfusion did proceed, although without harm to patient. Although no patient adverse events occurred, these cases have been included in the report as they provide important transfusion process improvement messages.

Near misses covered many different facets of the transfusion process from the institutional blood bank laboratory to the bedside, as outlined in Table 12 below.

### Table 12 – Near miss events

| Area | Number of reports | Types |
|---|---|---|
| Labelling/ documentation | 11 | Failure to label specimen sample adequately and sign declaration<br>Transposing of two samples<br>Pre-transfusion specimen labelling not adhering to zero tolerance policy that rejects specimens non-compliant with institutional labelling policy<br>Two patient samples in one blood tube |
| Storage and handling | 2 | Expired blood still available to clinical staff<br>Blood removed from blood fridge returned to fridge an hour later, unit was destroyed as storage condition could not be guaranteed |
| Inappropriate component issued | 1 | Blood issued for patient with similar surname, failure to use other identity checks |
| Incorrect prescription or request for blood | 1 | Incorrect dose of intravenous immunoglobulin prescribed per weight of patient |
| Administration | 6 | Missed administration of Rh D immunoglobulin prophylaxis<br>Blood administered over more than four-hours time limit for red cells<br>Failure to use in-line filter in administration<br>Administration rate faster than prescribed |
| Laboratory | 5 | Failure to have blood available resulting in delay of transfusion<br>Transcription error in laboratory system |

### Case study

Night staff commenced a transfusion. Observations at 15 minutes were not recorded and the prescribed rate was not adhered to. Staff did not check on the transfusion and morning shift staff found the transfusion in progress six and a half hours after commencement. The transfusion was discontinued and the pack discarded. The ward was busy overnight with several admissions and the health service reported that the staff skill mix was not optimal and that hospital guidelines were not adhered to. There was no apparent harm to the patient.

### Case study

Staff from the emergency department requested a unit of red cells from the institutional blood bank. The scientist removed the unit from the fridge, checking against patient's surname but did not check the other patient details against the request. The scientist did not know that two patients with the same surname had blood crossmatched. In dispensing the product, the scientist scanned the unit barcode which gave details of the patient for whom the unit had been crossmatched. These details matched the patient details on the red cell unit tag but they were not checked against the request. The red cell unit was issued to the clinical area. During bedside checks clinical staff found the blood was not for the patient they had but for another patient with the same surname. That patient's first name, DOB and UR number were different. The transfusion did not proceed.

### Case study

Institutional blood bank staff were requested to supply blood for a patient in theatre. The unique hospital record number was neither provided nor requested, and no patient label was provided at the time of collecting the blood, just the patient name. Blood bank staff looked for the first name, not the surname and subsequently released blood intended for another patient. It was of note that the surname of the blood issued was similar to the first name of the patient for which the blood was requested. The health service has made changes to their policy to explicitly state that a patient label must be supplied before blood is released for transfusion. Blood bank have also made policy changes. The current blood bank policy of requiring written patient identification from all wards and departments has now been extended to include theatre (which previously only provided verbal patient identification due to blood being sent direct there via a pneumatic chute system).

### Case study

A sample for blood group and screen was received in the institutional blood bank. Testing demonstrated mixed field blood group. The patient had no history of transfusion or transplant. Routine blood samples were taken on this patient at time of admission, including a group and hold.

Staff in the area do not routinely use the vacutainer system for blood collection when they are taking blood tests at the time of intravenous cannulation. Instead they will use a syringe to withdraw blood from the cannula or three-way tap.

The blood is then inserted into specimen tubes by attaching a clean needle and spiking each tube. To avoid needle sticks the tubes sit in a rack on the side of the IV trolley ready for use and are spiked while still sitting in the rack.

In this instance it appears someone had drawn blood from a patient and added it to tubes in the rack but had not collected all the used tubes from the rack at the end of the procedure. The next person took blood and filled the tubes. They were unable to see that the group and screen tube was already partially filled as they did not pick it up from the rack until after they had added the blood and it would have been hidden among other tubes.

In this way they managed to get blood from two different patients into the same tube.

## Transfusion safety tip

Transfusion is a process with multiple steps and participants, with errors possible at any stage: sampling, testing, collection of product and administration. The potential for errors in the clinical pathway highlights the importance of ensuring that prescription of products is appropriate and to minimise unnecessary transfusions.

Having clear, easy to follow guidelines and policies that outline responsibilities and processes for each of these steps and staff trained to undertake these procedures, should ensure detection of errors early on in the transfusion process, if an event occurs.

# 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.

Sixty-one initial notifications of the category WBIT were received in 2008–09 with 57 investigation forms returned and reviewed.

It is difficult to assign a severity score for WBIT events as by definition they caused no actual harm to the patients since transfusion did not proceed. However, they cause inconvenience and in some cases delays and their potential for harm means that they possibly could result in severe morbidity or mortality. These events are a 'good catch' and an important opportunity for learning.

The Centre for Health Innovation, Centre for Research Excellence in Patient Safety and the Transfusion Outcomes Research Collaborative (TORC, a partnership between Monash University Department of Epidemiology and Preventative Medicine and the Australian Red Cross Blood Service) are undertaking a study entitled 'Reducing patient harm in transfusions'. This project in human factors related to pre-transfusion blood sampling errors is funded by the Victorian Managed Insurance Agency (VMIA) and is investigating the multiple process errors and systems factors which lead to the occurrence (or prevention) of WBIT. Outcomes from the research will be valuable in informing recommendations from STIR to assist in reducing WBIT of crossmatch specimens and reduce potential harm to transfusion recipients. STIR provided input into the study design and steering committee for the project.

The following cases demonstrate the issues with labelling pre-transfusion specimens in varied clinical situations.

Maternity/delivery suite, emergency and general wards were three clinical areas where WBIT appeared to occur more often than other areas. The use of maternal labels only on cord blood samples for blood grouping of the infant continues to be a problem.

### Case study

A doctor called the laboratory enquiring about results on a patient. Laboratory staff stated they had never received samples for that patient. It was subsequently identified that the specimen and request were labelled with a different patient's details from the same clinical area.

A doctor noted he had wrong labels which he had used to label a pre-transfusion request. The patient attended the outpatient area and required blood tests. The doctor completed the request form. However no labels were available in the patient history so the doctor asked the ward clerk to print out labels. When the doctor removed labels from the printer he picked up labels for another patient and used these to label the request and attached the labels to the slip for labelling of the tubes. The patient was sent to the pathology collection area with a request slip for collection of bloods. The blood was taken but it was not picked up at this point that labels did not match the patient's identity. The pathology collector asked the patient if he was John. Both patients had the first name John. The outpatient clinic area rang pathology to notify the error in labelling for the patient.

### Case study

Patient X attended for routine antenatal screening including a glucose challenge test. After initial blood sampling she was given a glucose solution to drink, and waited in the area for one hour prior to further blood sampling. Patient Y was attending at the same time for a glucose tolerance test, and she also required a blood group and screen.

Patient Y's blood group was reported as group A, Rh D-positive. She had no historical data available at the hospital. Two months later repeat blood tests, including another group and screen, reported Patient Y as group A, Rh D-negative. Further investigation showed that patient Y had a previous blood group done at another pathology service and reported as group A, Rh D-negative. Patient X had a historical blood group of A, Rh D-positive.

Patient Y was contacted as soon as possible to discuss the need for RhD immunoglobulin prophylaxis, which was not given at 28 weeks as the blood group at this time indicated she did not need it. However the patient insisted the father of the baby was also Rh D-negative and refused Rh D immunoglobulin. When investigating this event, it was very difficult for staff involved in the incident to recall specifics about the collection two months later.

The second WBIT associated with this event was taken at exactly the same time and day as the first specimen, with specimens being taken by two different collectors. It appears they may have taken the wrong slips to the wrong patients and neither realised. Patient X had an historic group of A positive, the same group as found with the first WBIT.

## Transfusion safety tip

In transfusion sampling, identification of the patient is paramount to ensuring the test result is for the correct patient. Blood is issued for transfusion and administration on the basis of pre-transfusion testing results and fatal complications may occur.

Transfusion sampling should be seen as a critical task as it is an early step in the transfusion process. Therefore:

- Design of work spaces and workflow areas should enable safe completion of the critical transfusion sampling step.
- Adequate time to do the sampling should be provided.
- Staff responsible for transfusion sampling should understand this early step is critical.

Asking patients to state their full name and date of birth and not just confirm (respond to) their details is the important part of positive patient identification. Hospital guidelines and policies should reflect this.

# Recommendations

A transfusion safety checklist, endorsed by the STIR expert group, has been included on page 7 of this report, as a tool for health services. It can be used by health services to facilitate compliance and assist in implementing processes to ensure the safety of all transfusion recipients.

A number of the recommendations and safety tips are reiterations of content within existing national guidelines (reference to RCNA/ANZSBT *Guidelines for the administration of blood components*, 2004) and these guidelines should be utilised by health services for guideline and practice improvement development.

## Training of staff in transfusion administration practices

STIR recommends that the health services address training and assessment of nursing and other staff in awareness of and adherence to guidelines for administration of blood products.

## Use of satellite blood fridges

Given the number of events involving the administration of the wrong blood to wrong patient, where a satellite fridge was a significant contributing factor the STIR Expert Group strongly recommends health services review the need for a satellite fridge and where possible remove it from clinical practice.

## Review of STIR reports prior to submission

The STIR group recommends that all reports are reviewed by either the hospital transfusion committee (HTC) or equivalent, where a hospital transfusion committee doesn't exist. If the HTC or equivalent meets prior to submission of data then it is recommended that the report be reviewed by the chairperson of the HTC or a senior medical officer.

## Transfusion Safety Tips

- All staff should be familiar with the requirement to review the wristband of a patient or obtain verbal confirmation of the patient details prior to administering any blood product. These details should exactly match product and paperwork, prior to transfusion proceeding.
- Thorough and prompt investigation of acute transfusion reactions can assist in determining a diagnosis, initial treatment and also a management plan for the patient for any future transfusion requirements.
- Notification of transfusion reactions to the pathology provider who issued the blood components will assist with the investigation. This also enables prompt notification of the Blood Service where applicable. In some cases further testing of patients, donors or products is required, quarantine of components may be necessary, and where donor deferral may need to be considered. Consultation with a haematologist or transfusion medicine specialist may also be helpful.
- Maintaining good documentation of which products were administered, and at what times, can be essential in assisting with investigation of reactions, should they occur.
- Any clinical risks of transfusion-transmitted infection are minimised by routine and additional thoughtful clinical observation before, during and after transfusion of blood and blood products.
- A blood safety training initiative has been developed by the South Australian Department of Health, BloodSafe program. This e-learning program has been designed to provide clinical and other staff (such as porters and orderlies) with an opportunity to develop their knowledge of blood and to encourage safe transfusion practice and the appropriate use of blood components. It is available for use nationally. Further details are available at www.bloodsafelearning.org.au
- In transfusion sampling, identification of the patient is paramount in ensuring the test result is for the correct patient. Blood is issued for transfusion and administration on the basis of pre-transfusion testing results and fatal complications may occur. Therefore:
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  - Staff responsible for transfusion sampling should understand this early step is critical.

Asking patients to state their full name and date of birth and not just confirm (respond to) their details is the important part of positive patient identification. Hospital guidelines and policies should reflect this.

# References


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# STIR publications and promotions 2008–09

Transfusion laboratory workshop – Royal Melbourne Institute of Technology (RMIT) *'Transfusion science workshop February 2008: clinical aspects of transfusion reactions'.*

Annual Scientific meting of Australia and New Zealand, the Australian & New Zealand Society of Blood Transfusion and the Australasian Society of Thrombosis and Haemostasis, Adelaide October 2008, *'Serious transfusion incident reporting: a growing process'*.

Australian Institute of Medical Scientists, Melbourne, 2008. *Blood Matters: improving the safe and appropriate use of blood*.

European Haemovigilance Network meeting, Rome February 2009, *The Serious Transfusion Incident Reporting (STIR) system in Australia.*

Australian Capital Territory Transfusion Champions forum, June 2009, *Serious Transfusion Incident Reporting System (STIR).*

Development of education modules for Blood Matters website, 2008 *Essential elements of STIR part 1 and part 2*, <www.health.vic.gov.au/best/tools/stir.htm>.

STIR also promoted throughout 2008–09 with attendance at hospital transfusion committees in Victoria and Tasmania by the Blood Matters secretariat and the transfusion medicine team at the Blood Service.

# STIR contacts

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# STIR expert group members 2008–09

The system is overseen by the STIR expert group of the Blood Matters – better safer transfusion (BeST) Program Advisory Committee of the Department of Health, Victoria. Blood Matters is a collaboration between the department and the Australian Red Cross Blood Service.

Dr Erica Wood (chair), Transfusion Medicine Specialist, Australian Red Cross Blood Service,

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Ms Karen Botting, Program Manager, Blood Matters Program, Department of Health

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