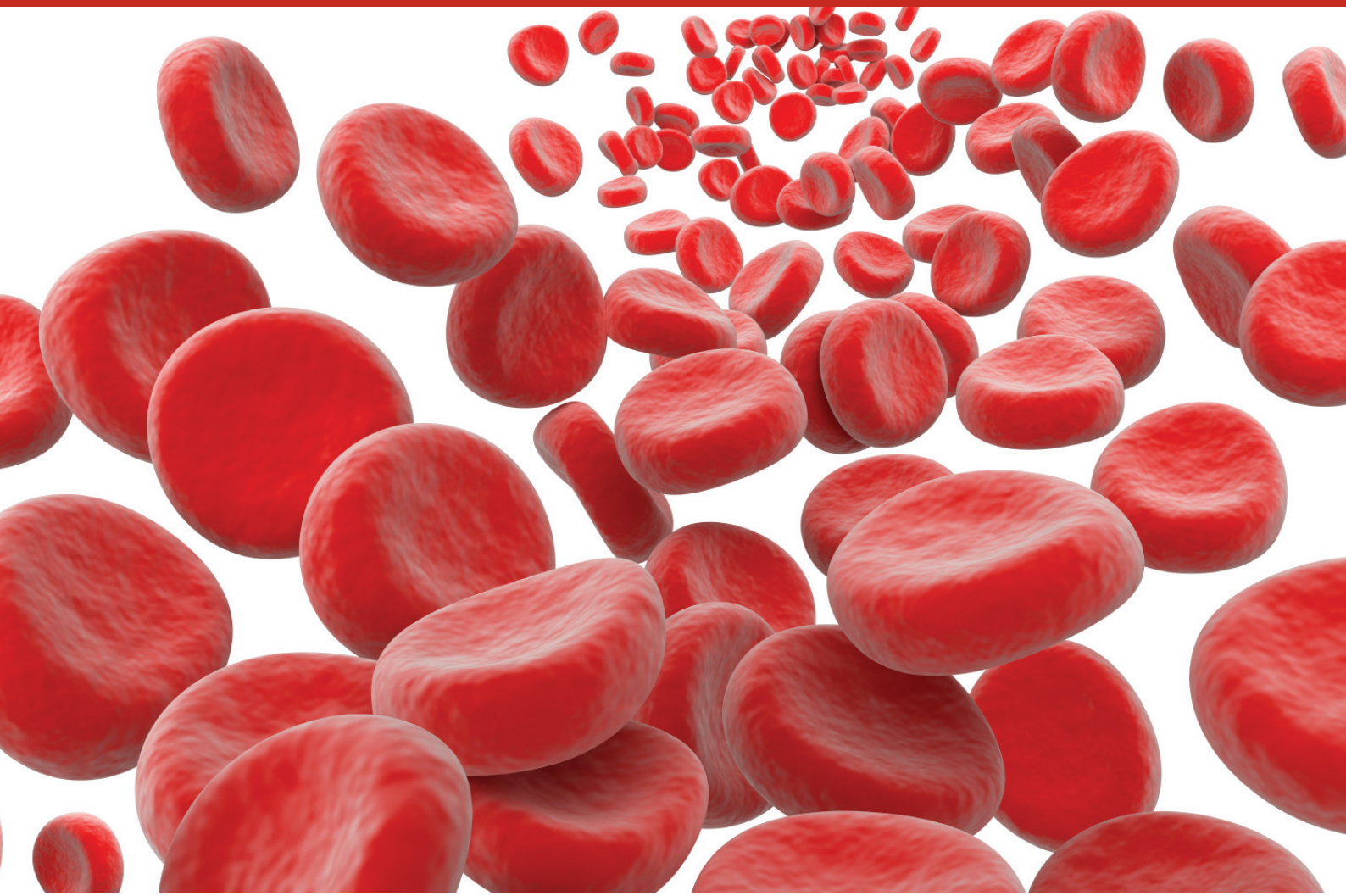
# Serious transfusion incident report 2013–14



Australian Red Cross BLOOD SERVICE

VICTORIA State Government | Health and Human Services

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# Serious transfusion incident report 2013–14

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Approved January 2016 (1601006)

# Acknowledgements

The Blood Matters program is a collaboration between the Victorian Department of Health and Human Services (the department) and the Australian Red Cross Blood Service (the Blood Service). It is founded on the expectation that the provision of relevant haemovigilance 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 and private health services for their contribution to the program. Blood Matters recognises and appreciates the in-kind support of the STIR expert group, whose input was invaluable in reviewing the incidents and providing recommendations.

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# Abbreviations, acronyms and definitions

| | |
|---|---|
| ABO | ABO blood groups |
| AHTR | acute haemolytic transfusion reaction |
| anti-D | Rhesus D immunoglobulin |
| ACSQHC | Australian Commission on Safety and Quality in Health Care |
| ATR | acute transfusion reaction |
| Blood Service | Australian Red Cross Blood Service |
| DAT | direct antiglobulin test |
| DHTR | delayed haemolytic transfusion reaction |
| ED | emergency department |
| FBE | full blood examination |
| FFP | fresh frozen plasma |
| FNHTR | febrile non-haemolytic transfusion reaction |
| FY | financial year |
| GP | general practitioner |
| Hb | haemoglobin |
| IBCT | incorrect blood component transfused |
| ICU | intensive care unit |
| LDH | lactate dehydrogenase |
| MCV | mean corpuscular volume |
| NBA | National Blood Authority |
| PICU | paediatric intensive care unit |
| PTP | post-transfusion purpura |
| Rh | rhesus blood group |
| SHOT | Serious Hazards of Transfusion |
| STIR | Serious Transfusion Incident Reporting program |
| TACO | transfusion-associated circulatory overload |
| TaGVHD | transfusion-associated graft-versus-host disease |
| TRALI | transfusion-related acute lung injury |
| VMIA | Victorian Managed Insurance Authority |
| WBIT | wrong blood in tube |

# Executive summary

We are pleased to provide the STIR report for the financial year from 1 July 2013 to 30 June 2014. This report covers one year, whereas previous reports have provided information on notifications to STIR that occurred over a two-year period. STIR regularly provides information to reporting health services on the number and type of notifications they make. During 2013–14, there were 190 notifications. Three notifications were for multiple events, giving a total of 193 events received from 43 health services across four jurisdictions, including both public and private health services.

Health services that submit data to STIR are able to comply with the Australian Commission on Safety and Quality in HealthCare (ACSQHC) Standards (Standard 7, 'Blood and blood products') by reporting adverse events related to transfusion at a state and national level. This data is also valuable in helping to determine the types and frequency of adverse transfusion events occurring in the Australian population. If you are not currently contributing to STIR, please contact Blood Matters on stir@redcrossblood.org.au to arrange to participate.

Fifty per cent (97 out of 193) of notifications were related to transfusion reactions. Acute reactions were the most common, with allergic/anaphylactic reactions (40 of 80, 50 per cent) and febrile non-haemolytic transfusion reactions (24 of 80, 30 per cent).

Fifty per cent (96 of 193) of notifications related to procedural events. The most common was wrong blood in tube (WBIT) at 75 per cent (72 of 96) of all procedural events. This is a persistent issue across current and previous reports.

The STIR expert group recommends that health and pathology services ensure zero tolerance policies for discrepant specimen labelling are in place and enforced.

A focus on staff education regarding specimen collection should include patient identification and specimen labelling processes to ensure compliance with policy. Health services should also consider using electronic systems to assist in correct patient identification and specimen labelling.

As noted in previous reports, the majority of notifications are related to red cell use (79 of 193, 41 per cent) and women were more often affected (109 of 193, 57 per cent) than men.

We would like to acknowledge those who have contributed to this report by submitting data to STIR, or by assisting in the preparation of this report.

# Recommendations

Blood Matters and the STIR expert group recommend that the Department of Health and Human Services advise health services of the following clinical and procedural recommendations to improve the safety related to administration and management of blood products.

## Clinical recommendations

1. Where patients experience severe allergic/anaphylactic/anaphylactoid reactions to blood products, laboratories should test the pre-transfusion sample for IgA level.
2. All patients are assessed pre-transfusion for cardiovascular risk/tolerance of increase fluid volume to prevent transfusion-associated circulatory overload (TACO).
3. Education of staff administering transfusion and patients receiving transfusion about the signs and symptoms of TACO, to assist early recognition.
4. Appropriate and mandated visual observation and clinical assessment of patients are undertaken during and post-transfusion for early identification of any patient compromise. This should include those patients receiving transfusion in day procedure areas.
5. Implementation of a single-unit transfusion policy, where appropriate, to reduce all transfusion-related risks, including TACO.
6. Implementation and education of policy that ensures appropriate reporting lines for transfusion-related incidents, both within the health service and to external bodies, for example, the Australian Red Cross Blood Service.

## Procedural recommendations

1. All staff involved in the collection of blood specimens should have training, not only in collection technique, but also in the process of patient identification and specimen labelling.
2. Zero tolerance policies must be in place regarding acceptance of all pathology specimens to ensure compliance with collection policy at all times, and to reduce the risk of unnecessary transfusions due to incorrect full blood examination (FBE) results.
3. Health services should consider the use of technology to assist staff in patient identification and specimen labelling processes.
4. Educate staff regarding correct checks at the patient side. This must emphasise patient identity checks, and confirmation that the product details match the prescription.

# Transfusion safety checklist

Health services can use this transfusion safety checklist to measure compliance and support safety for transfusion recipients. The issues and areas addressed in the checklist are based on data received and analysed, leading to the recommendations by the STIR expert group.

| Issue | Strategies to address the issue | Yes | No | WIP* | NA# |
|---|---|---|---|---|---|
| Incorrect blood component administration | Blood administration guidelines and education must emphasise the need for:<br>• positive patient identification, matching stated identity with wristband and matching this to the product<br>• checking the product is correct to the prescription and meets patient requirements e.g. irradiation<br>• the checking process is performed by two staff who perform independent checks of the patient and product together immediately prior to spiking the product. | | | | |
| | Investigate the use of technology to assist with the blood administration process and reduce system errors. | | | | |
| Patient identification in blood sampling | Blood sampling guidelines and education must emphasise the need for:<br>• positive patient identification, matching stated identity with wristband and matching this to the request form<br>• labelling of specimens at the bed/ patient side. | | | | |
| | Health services with obstetric and newborn services must have a process in place for clinical staff to label sample tubes correctly with the neonate's details.<br>Where there are multiple births, processes must be in place to accurately identify cord blood specimens from each neonate. | | | | |
| | Health services with emergency departments must have a process in place for identification of all patients, especially those who are unable to identify themselves, that is reliable and clear to all. | | | | |

| Issue | Strategies to address the issue | Yes | No | WIP* | NA# |
|---|---|---|---|---|---|
| Laboratory standard operating procedures for blood bank | Training and assessment of laboratory staff should address awareness of and adherence to operating procedures and guidelines for the issue of blood products and testing of pre-transfusion samples. | | | | |
| Blood product prescription | Where indicated (stable, non-bleeding patient), transfusion of a single unit of RBC, followed by clinical reassessment to determine the need for further transfusion is appropriate. This will potentially reduce the patient exposure to blood and thereby risk of a reaction. | | | | |
| Management of transfusion reactions | Blood administration guidelines should include the requirements and the importance for visual and physical monitoring of the patient during a transfusion. | | | | |
| | Clinical staff must be made aware of the importance of involving the pathology/ blood bank staff early in an acute suspected transfusion reaction. | | | | |
| | Procedures should include information for clinicians on when to report reactions to the Blood Service, manufacturers and STIR. | | | | |
| Training/ credentialing staff in transfusion practice | The BloodSafe eLearning tool should be used in adjunct with a health service-based education program for transfusion practice. Information on the courses from BloodSafe eLearning Australia is available at: <https://www.bloodsafelearning.org.au/>. | | | | |
| Health service transfusion committee or equivalent | All adverse events with blood should be reviewed by the reporting health service prior to submission to STIR. Ideally this review should be by either the health service transfusion committee or equivalent (if meeting prior to STIR submission date) or by the chair of the committee or a senior medical officer, outside of normal institutional meeting times. | | | | |

* Work in progress
# Not applicable

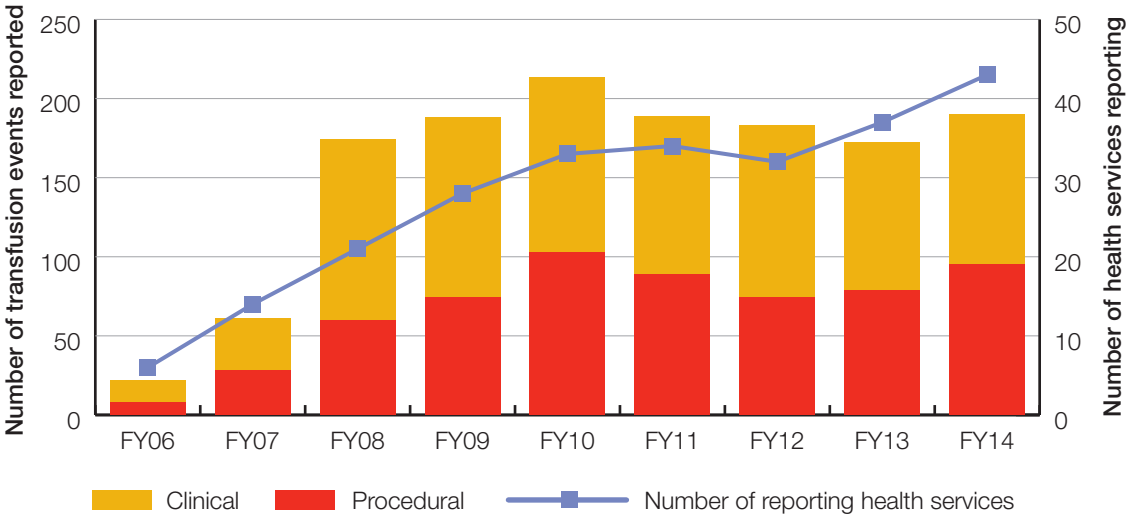
# Introduction

This report covers the period 1 July 2013 to 30 June 2014 and includes information from 43 health services from four Australian jurisdictions: Victoria, Tasmania, Australian Capital Territory and the Northern Territory.

STIR received 190 notifications including incidents, reactions to blood components and near misses. Several notifications covered more than one incident leading to a total of 193 reports.

This report discusses some main themes evident over the reporting period.

**Figure 1: Number of clinical and procedural reports and health services reporting to STIR each financial year**

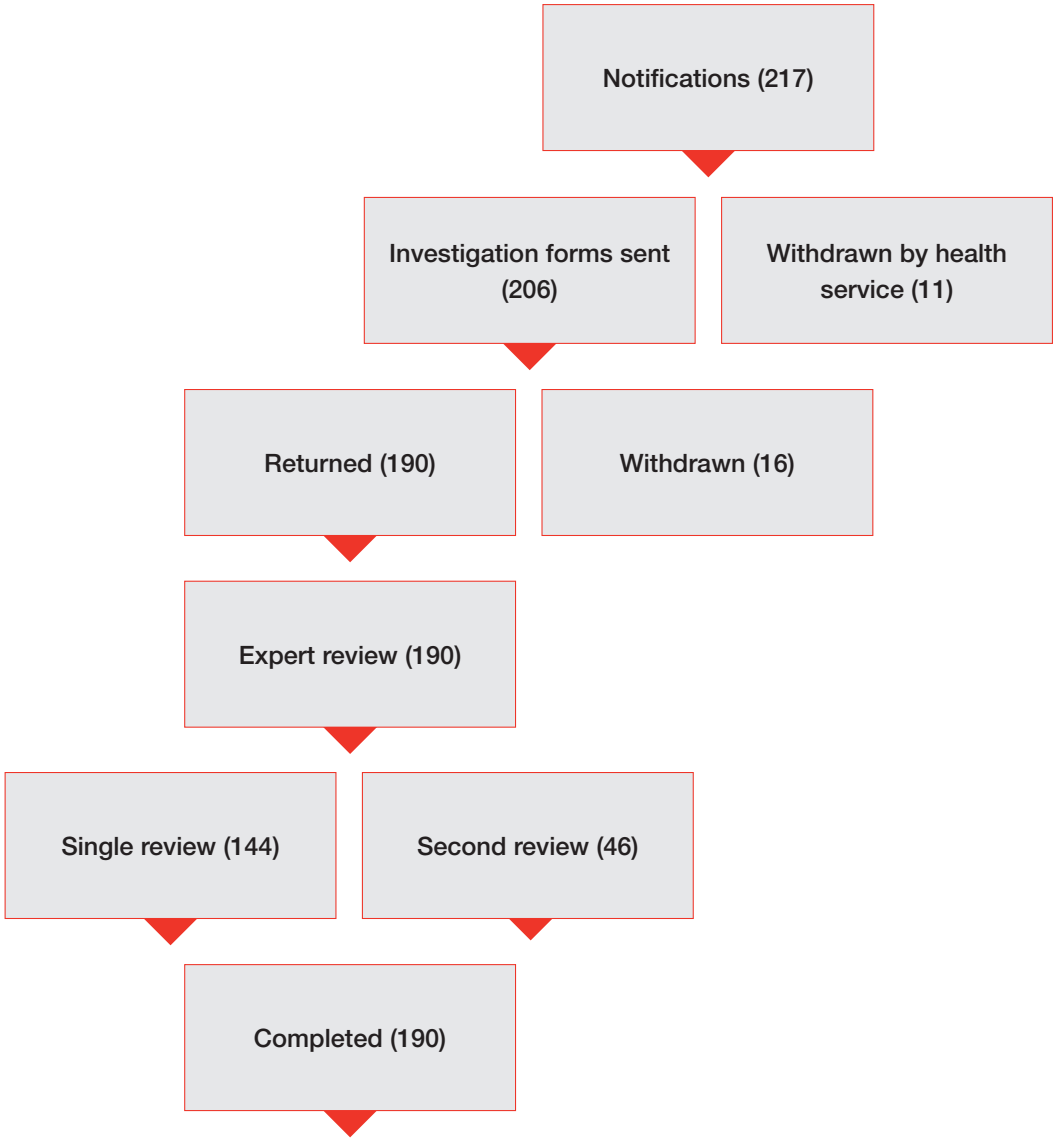



## Method

STIR receives data via an e-form located on the Blood Matters website www.health.vic.gov. au/bloodmatters/tools/stir. When the STIR office receives the initial notification, it provides the reporting institution with a form relevant to the specific incident type (clinical reaction or procedural event). The reporting institution returns this form to STIR with detailed information about the incident which is entered into a database for analysis and review. Patient or personnel identifying data is not collected. Reports are subsequently reviewed by the STIR expert group which consists of medical, nursing and scientific staff with expertise and/or an interest in transfusion. The STIR experts assign imputability (causality) and severity scores for each event. Please see Appendix 3 for these definitions.

Figure 2 outlines the various stages in the STIR review process, and lists the number of cases that reached each of these stages. One hundred and ninety-three incidents, reactions and near misses were fully reviewed and these form the basis of this report.

Figure 2: Steps in STIR reporting process




## Withdrawn reports

Reports may be withdrawn for a number of reasons, including duplicate notification, the health service deciding the event does not fit STIR criteria, or the health service being unable to complete the investigation form. In the 2013–14 reporting period there were 27 reports withdrawn. This represents 12 per cent of all notifications over this period, see Table 1. ‘Not in scope’ refers to reports where the administered product was not within the current reporting guidelines, for example intravenous immunoglobulin.

**Table 1: Reasons behind the withdrawal of reports (2012–13 data have been included for comparison)**

| Financial year | Duplicate | Not completed | Not in scope | Not transfusion related |
|---|---|---|---|---|
| 2012–13 | 2 | 4 | 4 | 0 |
| 2013–14 | 1 | 16 | 6 | 4 |

## Demographics

Table 2 outlines the demographics for notifications received. It shows that more notifications were associated with female patients than males, and that the majority of reports were related to red cells. These results are consistent with those of previous reports, although as a percentage of all reports red cells has been decreasing, from 66 per cent of reports in the pilot program to 41 per cent of reports in this period.

**Table 2: Demographics for all notification types**

| Demographic | | Number = 193 | Per cent |
|---|---|---|---|
| Age | Range | 0 days to 96 years | |
| | Mean/median | 49/51 years | |
| Gender | Male | 81 | 43 |
| | Female | 109 | 57 |
| Type of incident at notification | **Clinical** | | |
| | Acute transfusion reaction (ATR) | 80 | 41 |
| | Delayed haemolytic transfusion reaction (DHTR) | 3 | 2 |
| | Transfusion-associated circulatory overload (TACO) | 12 | 6 |
| | Bacterial Sepsis | 2 | 1 |
| | **Procedural** | | |
| | Incorrect blood component transfused (IBCT) | 12 | 6 |
| | Wrong blood in tube (WBIT) | 72 | 37 |
| | Near miss | 12 | 6 |
| Type of blood product identified | Red cells | 79 | 41 |
| | Platelets | 24 | 12 |
| | Fresh frozen plasma | 17 | 9 |
| | Cryoprecipitate | 1 | <1 |
| | Multiple (2 or more) products | 7 | 4 |
| | Other* | 65 | 34 |

NB: Three notifications were for multiple events.

* Includes WBIT events

# Clinical reports

For this period 97 of the 193 reports (50 per cent) were related to clinical reactions to blood products (see Figure 3). The majority of reports (80 of 97, 82 per cent) were acute transfusion reactions (ATRs) (see Figure 4). After expert review these ATRs include febrile non-haemolytic transfusion reactions (FNHTRs) (24 of 80, 30 per cent), allergic/anaphylactic reactions (40 of 80, 50 per cent), and acute haemolytic reactions (two of 80, three per cent). Three ATR reports were changed, after expert review to TACO. The remainder, 11 (14 per cent) of reactions were deemed to be due to other causes after expert review.

**Figure 3: Clinical reactions reported**

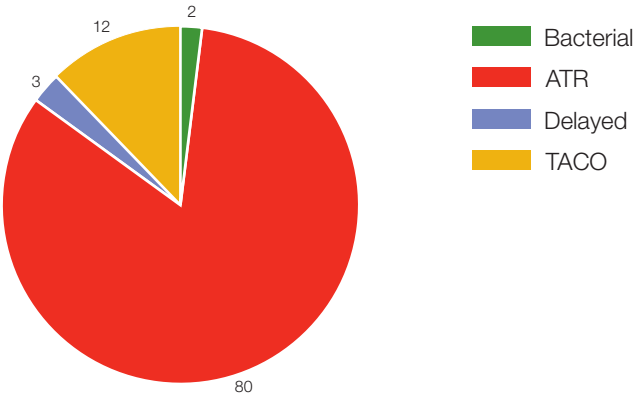
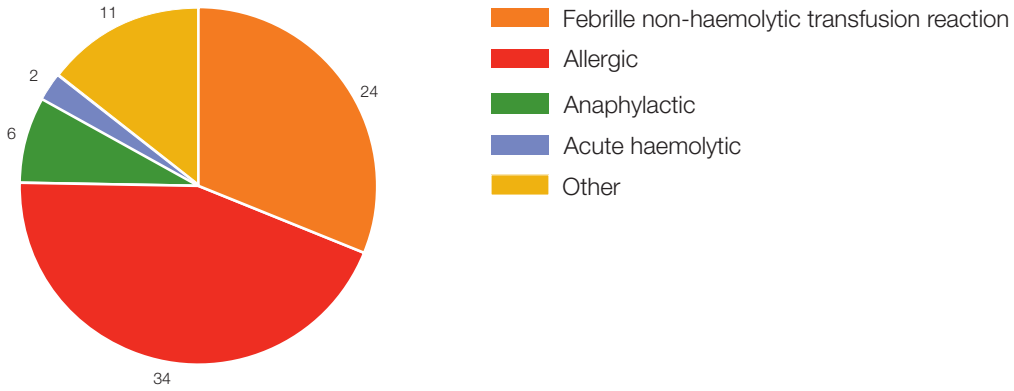



**Figure 4: Acute transfusion reactions after expert review**



## Allergic reactions

There were a total of 40 allergic/anaphylactic/anaphylactoid transfusion reactions reported to STIR in 2013–14. After expert review, 28 (70 per cent) were categorised as mild/moderate, six (15 per cent) as severe, and another six (15 per cent) as anaphylactic/anaphylactoid.

**Table 3: Allergy severity**

| Severity | Description | Number (%) |
|---|---|---|
| Mild | A single symptom or single drug treatment (other than adrenaline) required | 14 (35) |
| Moderate | Multiple symptoms with polypharmacy treatment, not including adrenaline | 14 (35) |
| Severe | Multiple symptoms with polypharmacy treatment, including adrenaline and/or increased length of stay or level of care | 6 (15) |
| Anaphylaxis | As above for severe allergy, including severe hypotension or cardiac arrest | 6 (15) |

IgA deficiency is recognised as the most common human immunodeficiency. Although the majority of IgA-deficient individuals are asymptomatic, some IgA-deficient individuals have a higher prevalence of respiratory and gastrointestinal tract infections. From a transfusion medicine perspective, the presence of anti-IgA in an IgA-deficient recipient is a possible cause of anaphylactic transfusion reactions (Goldman, 2012).

Approximately 20 per cent of anaphylactic transfusion reactions in a Caucasian population may be associated with anti-IgA in IgA-deficient recipients (Vamvakas 2007). Although the causes of allergic/anaphylactic transfusion reactions are diverse, these reactions are more frequent in IgA-deficient recipients and have been associated with the presence of anti-IgA. Therefore when a severe/anaphylactic reaction has occurred, testing for IgA levels plus or minus testing for antibodies, on a pre-transfusion sample, is important to find patients at risk of further reactions.

The STIR investigation form for acute transfusion reactions includes a question relating to IgA testing. For 2013–14, only five of the 12 patients (42 per cent) in the severe/anaphylactic group had IgA testing reported. No results were provided, so it is not known if any of these patients was IgA deficient.

## Transfusion-associated circulatory overload

There were 12 reports of transfusion-associated circulatory overload (TACO) in this period. This is in keeping with trends from previous years, with 19 cases reported in the preceding two-year period. TACO has been reported as a separate category since February 2011. TACO is the leading cause of major morbidity and mortality in the UK (Bolton-Maggs and Cohen 2013). For many patients, circulatory overload is a recognised risk of transfusion and measures are taken to prevent it, such as the prescription of diuretics and a slow infusion rate. Unfortunately, these measures are not always sufficient or implemented appropriately and TACO occurs, reportedly in less than one per cent of patients transfused (Roback JD 2011). In massive transfusion situations it may be impossible to slow the transfusion rate and TACO can result.

### Case study

A 15-year-old, 60 kg male patient with no history of cardiac or respiratory disease was admitted to ICU post-trauma. The patient experienced critical bleeding which led to the activation of the massive transfusion protocol. The patient received nine units of red cells, two units FFP, and two bags of platelets, along with 900 mL of fluid volume.

The patient developed respiratory wheeze and dyspnoea with restlessness and anxiety. His oxygen saturation decreased, his sputum became pink and frothy and he was tachycardic.

Transfusion was ceased and the need for further emergency blood assessed. Oxygen therapy was commenced; however, the patient required intubation and assisted ventilation. He also required inotrope support for hypotension. Chest X-ray supported the diagnosis of TACO.

The patient recovered after a period in ICU.

Medical review of patients between units can be useful in preventing TACO as well as assessing the need for further transfusion. Over-transfusion is an avoidable precipitating factor for TACO and following a single-unit policy as prescribed by the National Blood Authority Patient Blood Management guidelines may assist in reducing this risk. In day areas, where medical staff may not be as readily available, it is important patients are also reviewed for the reasons described above. If the patient is at increased risk of TACO, consideration should be given to inpatient admission for transfusion. Nursing staff administering the product also need to be aware of patients at increased risk of TACO, and be aware of the clinical indications when monitoring patients during a transfusion.

### Case study

A 92-year-old woman with anaemia related to ongoing gastrointestinal bleeding (Hb 77 g/L) and a history of congestive cardiac failure was admitted by her GP to a day ward for transfusion of three units of red cells. Each unit was administered over three hours successively without medical review. At the end of the third unit the patient developed dyspnoea, restlessness and reduced oxygen saturation. She was treated with oxygen therapy, diuretics and salbutamol. Chest X-ray supported the diagnosis of TACO.

The patient recovered after an extended stay. This case triggered a review of the governance of patients attending the day unit within the health service.

TACO can be a causative factor of patient mortality. The 2013 SHOT report found that TACO contributed to the deaths of 12 patients. No patient deaths attributable to TACO have been reported to STIR, however a number of patients have required increased care, including ICU admission.

Risk factors for TACO include:

- cardiac failure
- renal impairment
- hypoalbuminaemia
- pre-existing fluid overload
- age more than 70 years
- low body weight.

Where possible, single-unit transfusion followed by clinical review of the patient should be considered for those at risk of TACO.

## Delayed haemolytic transfusion reaction

Delayed haemolytic transfusion reaction (DHTR) usually occurs two to 14 days after transfusion, transplantation or feto-maternal haemorrhage, when a patient makes an antibody to a red-cell antigen that they lack. If the patient is subsequently exposed to that antigen (through transfusion) haemolysis can occur. In this reporting period, there were three DHTRs reported at notification. Following expert review, one of these was later determined to be an allergic reaction. In two reports an antibody was detected post-transfusion that had not been evident pre-transfusion. DHTRs should be suspected in the absence of an appropriate haemoglobin increment, or due to the development of jaundice. A direct antiglobulin test (DAT), antibody screen, liver function tests (including LDH) and markers of haemolysis (for example, serum haptoglobin, and bilirubin) will assist in investigation of possible DHTRs.

## Bacterial sepsis

There were two reports of bacterial sepsis related to transfusion in this period. In both reports the same organism was isolated from the patient's blood stream and the component pack (*Staphylococcus aureus* and *Acinetobacter baumannii*). Both patients recovered with appropriate antibiotic support and without the need for transfer to the ICU.

All suspected bacterial contamination should be reported to the Australian Red Cross Blood Service as soon as possible so that other products associated with the suspect donation can be recalled.

## Other

For this period there were no reports of TRALI, TA-GVHD, PTP or viral infections.

## Clinical recommendations

1. Where patients experience severe allergic/anaphylactic/anaphylactoid reactions to blood products laboratories should test the pre-transfusion sample for IgA level.

2. All patients are assessed pre-transfusion for cardiovascular risk/tolerance of increased fluid volume to prevent TACO.

3. Education of staff administering transfusion and patients receiving transfusion about the signs and symptoms of TACO, to assist early recognition.

4. Appropriate and mandated visual observation and clinical assessment of patients are undertaken during and post-transfusion for early identification of any patient compromise. This should include those patients receiving transfusion in day procedure areas.

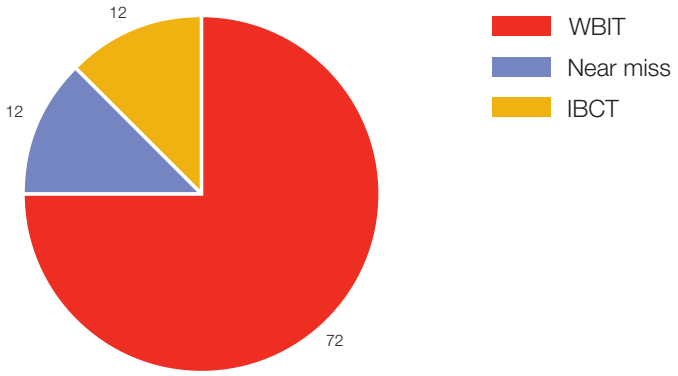
5. Implementation of a single-unit transfusion policy, where appropriate, to reduce all transfusion-related risks, including TACO.

6. Implementation and education of policy that ensures appropriate reporting lines for transfusion-related incidents, both within the health service and to external bodies for example Australian Red Cross Blood Service.

# Procedural reports

In this reporting period there were 96 reports of procedural events. Of these the largest proportion, (72, 75 per cent), were wrong blood in tube (WBIT) events as shown in Figure 5.

**Figure 5: Procedural reports**

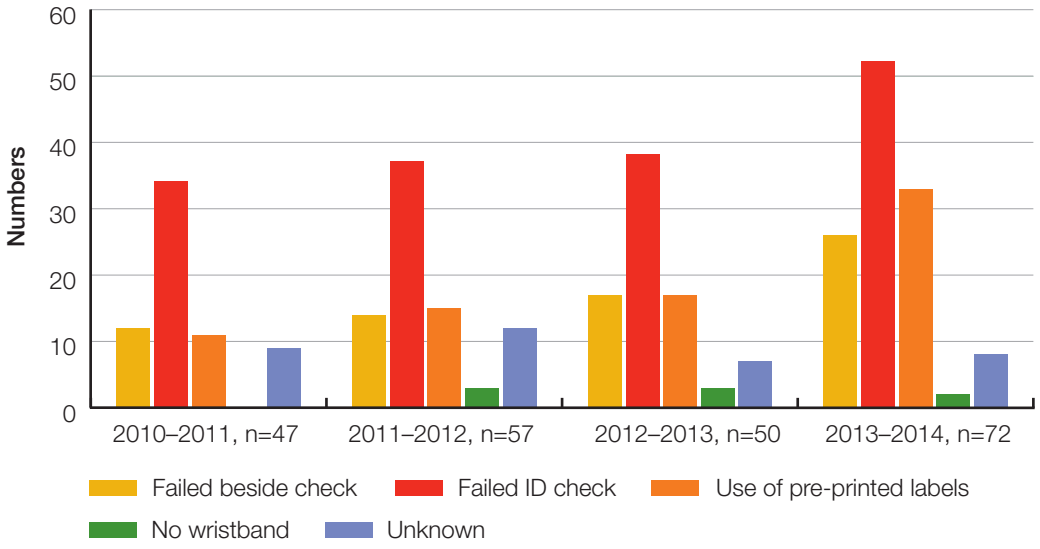



## Wrong blood in tube

These events occur when the blood in the tube is not that of the patient whose details appear on the tube and request. The major risk inherent in wrong blood in tube (WBIT) events is that they will not be detected due to the fact that labelling of sample and request form is consistent. That they will pass zero tolerance sample labelling criteria, and there is no historical blood group result available to highlight a grouping discrepancy. If this were to occur, an incorrect blood group could be attributed to a patient, and this could lead to an ABO incompatible transfusion. It is acknowledged that 'silent' errors may occur where although the specimen is a WBIT, the blood group matches the patient's own blood group (VMIA 2010). The number of these types of errors is unknown.

WBIT events can be prevented if patient identification and specimen labelling policies are adhered to, for example where possible, always asking the patient to state their name and date of birth, checking details against the request slip/ID band, and labelling at the patient side. However, where the process for collection of specimens relies predominantly on the collector to remember and perform certain steps, errors will continue. New technology to assist the specimen collector in patient identification and specimen labelling may reduce the number of errors, but should be introduced with care to avoid new errors related to the technology. Figure 6 shows factors that contribute to these errors occurring. More than one factor can be included in a single reported event. The most common is failure of a correct patient identity check.

**Figure 6: Factors contributing to the incident**




Staff involved in WBITs included medical (18, 25 per cent), nursing (42, 58 per cent), pathology collection staff (one of 72, one per cent), and other/unidentified (11, 15 per cent). From this data, nursing staff appear to be over-represented in collecting the samples involved in WBITs, however, nurses (as opposed to medical staff) are more likely to collect the specimens when pathology collectors are unavailable. Pathology collection staff, who it may be assumed take large number of specimens, are relatively rare contributors to WBIT numbers.

Wrong blood in tube incidents most commonly involve the sample from the correct patient being labelled as per another patient (47, 65 per cent). In a small number of reports the sample was from the wrong patient and labelled as the correct patient (six, eight per cent). The remaining reports were classified as 'other' (19, 26 per cent), the majority being discrepancy between labelling of request form and specimen (zero tolerance). These types of reports are no longer being collected. The reporting of WBIT errors to STIR has changed as of January 2015 to exclude those reports where paperwork/request form and the specimen details do not match as these should be rejected prior to processing with the application of a zero tolerance labelling/documentation policy. This policy should be applied to all specimens, not only blood-banking specimens. It is particularly important for full blood examination (FBE) specimens as a wrong result can lead to inappropriate transfusion.

Errors in specimen collection most commonly occur in three main areas: maternity (24, 30 per cent), emergency (19, 26 per cent) and wards (21, 29 per cent) as Figure 7 demonstrates. A frequent labelling issue particular to maternity occurs when the baby's specimen is labelled with the mother's identifiers. This seems to be especially problematic when babies are routinely not given their own identifiers, requiring modification of the mother's identifier for labelling of request and specimen. Table 4 highlights how the incident was discovered.

**Figure 7: Where WBIT errors occur**

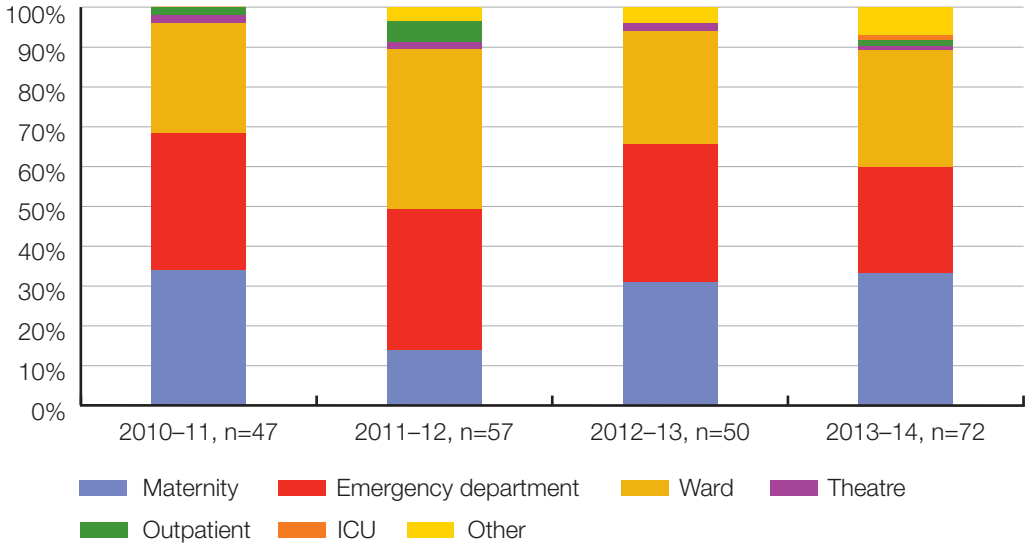



**Table 4: How was the incident discovered?**

| Category | Number | *Percentage |
|---|---|---|
| Recognised prior to testing | 47 | 65 |
| Discrepancy noted when comparing sample results with historical record | 23 | 32 |
| Recognised post testing but prior to issue | 3 | 4 |
| Significant change in MCV compared with prior testing | 0 | 0 |
| Recognised post issue but prior to transfusion | 0 | 0 |
| Other | 1 | 1 |
| Unknown | 2 | 3 |
| **Total** | **72** | |

*Some health services submitted multiple methods of incident discovery, percentage will be greater than 100.

### Example of a health service's response to WBIT

One organisation where a significant number of WBIT events were detected established a working party to understand the causes and find a solution.

The organisation reviewed data pertaining to breeches in the zero tolerance labelling and documentation policy to gain an insight into the systemic and cultural issues surrounding safe sample collection. Root cause analyses of WBIT events and observational audit of specimen collection indicated that staff were not following positive patient identification practices during sample collection. Human factors, including a sense of comfort that staff know their patients well, fatigue, work load, high stress and trust in the performance of colleagues were identified as contributors to WBIT and major mislabelling events. A false sense of security that two people perform checks, with each assuming the other is doing the check correctly, and an over-reliance on laboratory staff to detect errors made at the bedside, also contribute to a culture of inadequate patient identification practices during specimen collection.

Many organisations have a no-blame culture associated with unintentional and non-deliberate errors; however, there is a need to clarify where and how professional responsibility fits into the no-blame culture (Walton 2006). Such a culture should not negate the ability of an organisation to develop and implement strategies to reduce errors, and provide corrective action when such errors occur.

A level of professional accountability is required to reduce WBIT and other major mislabelling events. Self-reflection is used widely in healthcare to consciously and critically analyse one's own practice.

The use of a self-reflection tool for specimen mislabelling events is a simple and effective way for staff to reflect on their practice, understand their professional responsibility and identify opportunities to improve practice to prevent an incident recurrence. It also assists staff in recognising preventable harm including additional venepuncture, delay in results or treatment and the risk of an incorrect diagnosis and/or treatment.

The self-reflection tool supports incident management processes and de-identified information can be used for broader learning.

The health service now reports a decreased number of WBIT and specimen labelling errors in the areas where the self-reflection tool has been implemented. It plans to further implement the tool throughout the health service.

See Appendix 4 for two examples of staff reflection tools used at two different health services.

## Incorrect blood component transfused (IBCT)

Incorrect blood component transfused includes incidents such as:

- the patient receiving a blood component intended for another patient
- a component which did not meet the patients special requirements
- a component other than that prescribed
- a component unnecessary at the time.

During this reporting period there were 12 incidents reported to STIR. Table 5 notes the types of IBCT events.

In addition, one near-miss was changed to IBCT. This related to several units of cross-matched blood placed in a remote blood fridge. The units were removed from storage for over 30 minutes and then returned to the blood fridge. The units were returned to the pathology service's blood inventory as unused and subsequently cross-matched for other patients and administered. The pathology service did not have a process in place to recognise when units of blood may have been out of storage for longer than 30 minutes. Clinical staff did not follow health service policy on removal and return of units to the blood fridge.

**Table 5: Types of IBCT events**

| Category | Number reported |
|---|---|
| Antigen-antibody issues | 1 |
| Components that did not meet specific requirements for patient | 5 |
| Inappropriate platelet/plasma product | 3 |
| Inappropriate red cell product | 3 |
| Incorrect blood component to incorrect patient | 1 |

### Case study

A patient in ICU post-surgery for a small bowel obstruction had received two of four FFP units prepared the day before. On the day of the incident, an order had been made to administer a unit of platelets. The nurse caring for the patient requested FFP from the blood bank in error. FFP was sent and two nurses then checked the patient details, but not the product details. The FFP was administered and the error not found until later. There was no harm to the patient in this instance, however the patient was exposed to unnecessary risk and could have reacted to the component.

Errors may occur in any part of the transfusion chain including supply from the Blood Service, health service blood bank or pathology service, at the time of prescription, specimen collection or request for product, during collection of product or at administration.

In each event report it is noted that the checks were performed at the patient side in the majority of cases (10 of 12 checks), one of 12 started in the medication room, and was completed at the bedside, and in all cases two staff members were involved in the checks. The pre-administration check is the final opportunity to detect errors that have occurred earlier in the chain and therefore vigilance and adherence to policy is vital.

In this reporting period, IBCT events did not result in serious harm to patients. One patient had planned surgery delayed as a precaution and another was put at risk of developing an anti-K antibody, however there was no evidence of this at the time this report was developed. Another patient had the date of a planned bone marrow transplant changed as a precaution.

### Time out in the emergency department: how one institution responded to IBCT events

Over a 12-month period there had been an increase in the number of incidents and near misses in the emergency department, where patients had been put at risk of receiving an ABO incompatible transfusion.

Despite a number of root cause analyses and clinical reviews there was no real change in practice. Transfusion and clinical staff were concerned that another incident would occur.

A working party was developed to try to improve practice. The working party included:

- nurse manager
- clinical nurse manager of quality and risk at the emergency department, who could give the working party the authority to implement strategies
- deputy director of the department, to provide medical input and act as a conduit for information about changes to the medical team
- hospital transfusion nurse, for specialist clinical input
- clinical nurse specialists and educators from the department, for their experience in the area and as the staff members responsible for the onsite implementation of recommendations
- senior registered nurses, who understand the day-to-day workings of the area and provide local knowledge of workflow.

The purpose of the group was to revise and improve current practices for the ordering, checking and administration of blood in the emergency department. The first step in this process was to look at factors that might be contributing to the errors, barriers to following the correct procedures in all instances, and challenges to change.

Key improvements:

- The resource nurse was made responsible for ensuring patient ID bands were applied to patients at the first opportunity. This was recognised as an important step but without a key person responsible for this, it was not always done.
- The use of a transfusion trolley with the minimum equipment required to start a transfusion was instigated to deal with the often crowded environment. This gave staff an area in the patient cubicle, at the bedside, to perform the pre-transfusion checks, which could then be removed at completion of the checks.
- A certain staff member is designated the task of pre-administration checks in emergency and massive transfusion situations. During the checking process they don a fluorescent vest with ‘Blood checking, do not disturb’ printed across the back. All staff are empowered to point this out if this designated staff member is interrupted. The interrupting staff member is encouraged to look elsewhere for assistance or wait for the process to be completed before asking questions.

Since the implementation of this practice in late 2013 there have been no further incidents of IBCT in the emergency department. Blood administration audits performed in the area indicates that staff continue to use the practice.

## Near miss

Near-miss events are an opportunity to detect system failures without patients coming to harm. Near misses provide an opportunity to implement strategies to prevent future errors before they occur. Table 6 describes the types of near-miss events reported during this period. Unfortunately, not all near misses are reported. If the error is recognised before the patient is affected, staff may see no need to do so.  For this reason we could assume that the near-miss category is under-reported.

**Table 6: Types of near-miss events**

| Category | Number reported |
|---|---|
| Inappropriate component issued | 1 |
| Labelling/documentation | 6 |
| Laboratory | 2 |
| Administration | 1 |
| Incorrect prescription or request for blood | 2 |

**Procedural recommendations**

1. All staff involved in the collection of blood specimens should have training, not only in collection technique, but also in the process of patient identification and specimen labelling.
2. Zero tolerance policies must be in place regarding acceptance of all pathology specimens to ensure compliance with collection policy at all times, and to reduce the risk of unnecessary transfusions due to incorrect full blood examination (FBE) results.
3. Health services should consider the use of technology to assist staff in patient identification and specimen labelling processes.
4. Education of staff regarding correct checks at the patient side. This must emphasise patient identity checks, and confirmation that the product details match the prescription.

# Future

This is the first of what is to become an annual report for STIR.

In 2015, STIR commenced collecting reports of incidents related to anti-D administration and cell salvage. We hope to be able to provide information regarding these notifications in future reports. As mentioned previously, STIR will no longer be collecting reports related to zero tolerance where sample and request form labelling is discrepant, as these should be detected prior to laboratory acceptance under zero tolerance policies.

A review of STIR notifications and reporting to ensure alignment with the updated Australian National Haemovigilance Data Dictionary (ANHDD) will be undertaken. This will allow STIR to provide complete data for the National Haemovigilance Report. Classifications of transfusion reactions are currently under review by the NBA including incorporating two new categories, transfusion-associated dyspnoea and hypotensive reactions.

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# Appendix 1

Expert group members 2013–14

Amanda Davis, (chair) Consultant Haematologist, Alfred Health, Victoria

Christine Akers, (secretary) Transfusion Nurse, Blood Matters Program, Victoria

Helen Atkinson, Transfusion Nurse, Royal Hobart Hospital, Tasmania

Gerald Bates, Laboratory Manager, Northern Tasmanian Pathology Service, Launceston General Hospital, Tasmania

Linley Bielby, Program Manager, Blood Matters Program, Victoria

Merrole Cole-Sinclair, Director of Haematology, St Vincent's Hospital, Victoria

Philip Crispin, Consultant Haematologist, Canberra Hospital, Australian Capital Territory

Erica Wood, Associate Professor, School of Public Health and Preventative Medicine, Monash University, Victoria

Bridget Glazebrook, Data Manager, Blood Matters Program, Department of Health, Victoria

Clare Hennessy, Transfusion Nurse Consultant, Eastern Health, Victoria

Chris Hogan, Medical Director Pathology Services, Australian Red Cross Blood Service

Giles Kelsey, Consultant Haematologist, Royal Melbourne Hospital, Victoria

Geoff Magrin, Scientist, Victoria

Ellen Maxwell, Director of Haematology, Melbourne Pathology, Victoria

Scott McArdle, Transfusion Nurse, Australian Red Cross Blood Service

Tina Noutos, Haematologist, Royal Darwin Hospital, Northern Territory

Jonathan Prescott, Acting Manager, Quality and Safety Programs, Department of Health, Victoria

Richard Rogers, Blood Bank Scientist, Cabrini Health, Victoria

Carol Smith, Haematologist, Austin Health, Victoria (resigned)

Theresa Williamson, Manager, Quality and Safety Programs, Department of Health, Victoria (resigned)

Anissa Yttrup, Transfusion Nurse, Barwon Health, Victoria

# Appendix 2

## STIR publications and promotions

Audit of acute transfusion reaction knowledge and management 2013

HAA, Gold Coast, October 2013. 'STIR Process mapping: Demystifying the haemovigilance reporting and expert review process'.

*Serious transfusion incident report 2011–13*, with supporting powerpoint presentation.

STIR was promoted in numerous education sessions delivered at health services throughout Victoria in 2013–14.

# Appendix 3

## Imputability and severity scores

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

| Severity | Incident |
|---|---|
| 1 | Relatively infrequent, clear-cut events that occur independently of a patient's condition; commonly reflect health service system and process deficiencies; result in, or have the realistic potential to result in, an unexpected death or a permanent and disabling injury 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 is unrelated to the natural course of the patient's illness and differ from the expected outcome of the patient's management. |
| 3 | Events that result in a person requiring increased treatment, but not hospitalisation or an increased length of stay. |
| 4 | Events that result in minor injury requiring only first aid treatment or no injury. |

# Appendix 4

## Wrong blood in tube: staff reflection tools


### WRONG BLOOD IN TUBE / MAJOR PATHOLOGY MISLABELLING STAFF REFLECTION TOOL

Incidents related to pathology specimen labelling have been identified as a high risk requiring urgent action. The consequence of these incidents has the potential to significantly harm our patients. Many of the incidents relate to incorrect patient identification.

Health Professionals are accountable for ensuring the correct patient identification processes are followed.

You have been provided with this reflection tool to assist you and your manager with understanding the cause of these errors and to identify where practice in this area can be improved.

Please complete this reflection tool within 24 hours of becoming aware that you have been involved in a pathology specimen labelling incident.

It is expected that all staff involved in pathology specimen collection are familiar with and meet compliance with **ACTH Standard Operating Procedure: Patient Identification: Pathology Specimen Labelling.**

*RISKMAN ID#:*_____ *CLINICAL AREA:*_____

*NAME:* _____ *DESIGNATION:*_____

RETURN COMPLETED FORM to:
By:

**Note:** Any information used to assist with Quality Improvement will be de-identified.

| Q | **REFLECTION QUESTIONS** (most are a tick or circle response, some require a written response) |
|---|---|
| 1 | **How often do you perform pathology specimen collection? (circle)**<br>**Daily** **Weekly** **Occasionally** **Rarely** |
| 2 | **What was the specimen collection request?** |
| 3 | **What was the incident? (circle)**<br>a) Wrong Blood in Tube (WBIT): patient identifiers on both request form and the specimen tube match exactly but there is another patient's blood in the tube.<br>b) Major pathology mislabeling: patient identifiers on the request form and the specimen tube are from different patients. |
| 4 | **What was your role? (Circle)**<br>**a)** Specimen collector?<br>**b)** Specimen collection witness? (Go to Q7)<br>**c)** Other? (Describe) |
| 5 | **Did you have the completed and labelled request form with you at the time of collection?**<br>**Yes** **or** **No** → If 'No' why? |
| 6 | **Did you label the specimen tubes while still with the patient?**<br>**Yes** **or** **No** → If 'No' - why & where did you label the tubes/container? |
| 7 | **Describe how you confirmed correct patient identification, including on the request form and the specimen tube/container?** |
| 8 | **Describe the purpose of the witness (where relevant)?** |
| 9 | **How should the witness confirm it is the correct patient's specimen in the tube?** |
| 10 | ***Refer to the Standard Operating Procedure: Patient Identification: Pathology Specimen Labelling.***<br>**What step(s) in the procedure were not followed and why?** |

| | |
|---|---|
| | |
| 11 | **What preventable harm did the patient experience as a result of this incident? (Circle)**<br>a) Another venepuncture/procedure for specimen recollection?<br>b) Delay in results?<br>c) Delay in treatment?<br>d) Incorrect diagnosis?<br>e) Other (describe): |
| 12 | **What did you say to the patient when you had to recollect the specimen?** |
| 13 | **How was the error detected?** |
| 14 | **Describe the possible outcome if the error had not been identified.** |
| 15 | **Describe the barriers that prevented the correct procedure being followed in this case.** |
| 16 | **What would you do differently in the future?** |
| 17 | **Do you have any suggestions for how the system could be improved to help staff prevent these errors/incidents?** |
| 18 | **Other comments:** |
| | **Manager/CNC/Supervisor**<br>Name_____ Designation_____<br>**Comment:**<br><br>**Date:** |


**Thank you for your cooperation**

**Please arrange an appointment to discuss this reflection tool with your CNC/Manager**

## WBIT questionnaire

| |
|---|
| Name: |
| Date: …… / …… / …… |
| Ward: Unit: |
| Riskman Incident Number: |
| Were you the person who took the blood sample?<br>Yes ☐ No ☐<br>If you answered NO are you able to say who did take the specimen? |
| Did you label the blood sample?<br>Yes ☐ No ☐<br>If you answered NO are you able to say who did? |
| Did you check the patient's wristband against the blood request form?<br>Yes ☐ No ☐ |
| Did you label the blood tube **before** the blood specimen was taken?<br>Yes ☐ No ☐ |
| Did you label the sample at the bedside?<br>Yes ☐ No ☐ |
| Do you check all three labels on the blood sample, blood request and patient post procedure?<br>Yes ☐ No ☐ |
| Describe the circumstances immediately before and after you took the blood sample. |

**Have you had education on taking blood samples (mark all applicable)?**

At health service? Yes ☐ No ☐

At university? Yes ☐ No ☐

Elsewhere? Yes ☐ No ☐

If elsewhere please stipulate:

.....

.....

.....

**If at health service was it:**

BloodSafe e-learning package? Yes ☐ No ☐

Transfusion safety in-service? Yes ☐ No ☐

Other? Yes ☐ No ☐

If Other please stipulate:

.....

.....

.....

**Have you had education on identifying a patient (mark all applicable)?**

- At health service? Yes ☐ No ☐
- At university? Yes ☐ No ☐
- Elsewhere? Yes ☐ No ☐

If elsewhere please stipulate:

.....

.....

.....

**Are you aware of how to locate the health service policy and procedure for taking a specimen for cross match?**

Yes ☐ No ☐

## Action

1. **Please complete this questionnaire and return to Transfusion Nurse/Quality officer by email or internal mail.**
2. You are now required to complete the blood sampling section of the BloodSafe e-learning package.