Introduction

The aim of this Topic guide is to provide guidelines for all staff, including, but not limited to medical, nursing and midwifery and laboratory staff about the accurate reporting of transfusion related incidents into the Safety Learning System (SLS).

Appendix 1 – Reporting requirements for adverse reactions to blood products, page 10
Appendix 2 – Definitions of Adverse Reactions to Blood Products, page 11
Appendix 3 – Definitions for Outcome Severity, page 18
Appendix 4 – Human Blood Tissues Recall Notices, page 19

SA Health services, and their transfusion service providers, have a responsibility to report and investigate all patient incidents involving transfusion of blood and blood product. This will meet the requirements of policy, procedures and national haemovigilance monitoring guidelines and standards.

The SA Health Policy: Patient Incident Management and Open Disclosure outlines the reporting, investigation and response to all patient incidents.

Investigation of incidents related to transfusion includes the investigation of causation and its relationship to product characteristics or transfusion processes that were responsible for any signs and/or symptoms displayed. Incidents may be related to reactions, or other aspects of the transfusion processes.

This is part of a process known as haemovigilance and is a key requirement in the National Safety and Quality Health Service Standards. Standard 7: Blood & Blood Products, 7.3.3. “Health service organisations participate in relevant haemovigilance activities conducted by the organisation or at a state or national level”.

Haemovigilance is defined as: ‘A set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood’. Source: International Society for Blood Transfusion

Safety Learning System Reporting (SLS)

Where practicable, incidents should be entered into the SLS within 24 hours of occurrence.

Please note all SLS fields require completion to assist investigations and reduce data gaps in SA Health data and in haemovigilance submissions to the National Blood Authority. Do not leave fields blank unless they do not apply to the specific incident. If you select “other” as a response to a question, usually a text comment box will open up to allow further detail to be entered. Please provide a brief description in the comment box.

★ This symbol indicates a mandatory field.
Reporting into the SLS – The notifiers section

This section provides an overview of the notifier requirements for SLS. Further information is available in "How to report a patient incident" - Tool 1 of the Patient Incident Management and Open Disclosure Policy Directive”.

The SLS incident classification for “transfusion related incident/event” allows for a range of incident types to be entered. The options span the entire transfusion chain from the initial receipt and handling of blood and blood products to problems and reactions to blood transfusions. The adverse reactions to blood products option is based primarily on the "Australian Haemovigilance Minimum Dataset (August 2015)”, as adjusted for any localised reporting needs. Further detail on this is provided in Appendix 2.

1. Date, time and subject of the incident

Record the date and time; select “patient” as the subject of the incident and add information about the patient affected:
2. **Describe the incident and its outcome**

<table>
<thead>
<tr>
<th>Description of the Incident/Hazard/Event</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What happened?</strong></td>
</tr>
<tr>
<td>Ensure the description is short and factual, as it can be made public under certain circumstances. This should not include names or opinions and must be relevant to the event.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For adverse reactions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter facts as per reaction investigation, reaction report form and/or any other information regarding the event. Where details entered are based only on the reaction report form and lab investigation enter “As per reaction investigation report”. Briefly outline key components of reaction (temp changes, rigors, rash, changes from baseline etc.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For other incident types:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter facts as per incident investigation and/or any other information regarding the event.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What was the outcome of the incident/event?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short, factual description of the outcome. This should not include names or opinions and must be relevant to the event.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For adverse reactions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter outcome as per reaction investigation form and any other information regarding investigation / cause / outcome / if reported to blood service / external product manufacturer (IVIG, other fractionated products)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For other incident types:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter relevant outcome (eg product wasted, treatment delayed, special requirements not met etc)</td>
</tr>
</tbody>
</table>

| Has this incident been disclosed to patient/family? |

It is important that **no** patient or staff identifying details (including name, date of birth or medical record number) are entered into the above sections. Entries in these sections are not able to be altered. Managers and reviewers can add comments, but are encouraged to do so using the managers section. Additions are date and time stamped for audit purposes.

3. **Classify the incident**

Incidents should be classified under the most appropriate Level 3 option, which appear in alphabetical order as follows:

<table>
<thead>
<tr>
<th>Incident Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
</tr>
<tr>
<td>Treatment, procedure</td>
</tr>
<tr>
<td><strong>Level 2</strong></td>
</tr>
<tr>
<td>Transfusion related incident / event</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
</tr>
<tr>
<td>Safety Assessment Code (SAC)</td>
</tr>
<tr>
<td>(Click here to view the Safety Assessment Code Matrix)</td>
</tr>
<tr>
<td><strong>Result</strong></td>
</tr>
<tr>
<td>Administration Error</td>
</tr>
<tr>
<td>Adverse reaction to blood product</td>
</tr>
<tr>
<td>Blood product unavailable</td>
</tr>
<tr>
<td>Dispensing/Issuing</td>
</tr>
<tr>
<td>Handling/Storage</td>
</tr>
<tr>
<td>Inappropriate, Unnecessary or Undertransfusion</td>
</tr>
<tr>
<td>Incorrect blood product given</td>
</tr>
<tr>
<td>Prescribing/Ordering errors</td>
</tr>
<tr>
<td>Pre-transfusion specimen and/or request error</td>
</tr>
<tr>
<td>Treatment / Procedure - failed (transfusion)</td>
</tr>
<tr>
<td>Wrong blood in tube (transfusion sample)</td>
</tr>
</tbody>
</table>

After further investigation, managers and reviewers are able to amend the chosen classification, if required, to provide greater accuracy.
Description and examples of patient incidents for each of the Level 3 options are provided in the table below:

<table>
<thead>
<tr>
<th>Level 3 incident classification option</th>
<th>Description and additional instructions (where required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration Error</td>
<td>Incidents where the rate, timing, equipment, documentation or other processes involved in administering the blood product were implicated.</td>
</tr>
<tr>
<td>Adverse reaction to blood product</td>
<td>Select the correct type of adverse reaction. See Appendix 2 for definitions of the types of adverse reactions. These incidents are required to be reported to the National Blood Authority. This can be amended once further investigation / clinical review has been completed, eg suspected TRALI or false positive bacterial tests (Australian Red Cross Blood Service). An additional question asking for the outcome severity for the patient will appear if this incident type is selected. See Appendix 3 for definitions of the outcome severity categories.</td>
</tr>
<tr>
<td></td>
<td>&gt; No morbidity</td>
</tr>
<tr>
<td></td>
<td>&gt; Minor morbidity</td>
</tr>
<tr>
<td></td>
<td>&gt; Severe morbidity</td>
</tr>
<tr>
<td></td>
<td>&gt; Life Threatening</td>
</tr>
<tr>
<td></td>
<td>&gt; Death</td>
</tr>
<tr>
<td></td>
<td>&gt; Outcome not available</td>
</tr>
<tr>
<td>Blood product unavailable</td>
<td>Incidents where there was a delay or unavailability of blood product in an elective, urgent or life threatening situation.</td>
</tr>
<tr>
<td>Dispensing / issuing</td>
<td>Incidents where there were errors in dispensing or issuing blood and blood products from the laboratory (such as expired / incompatible or incorrect components; incorrectly labelled components or damaged products). These incidents do not involve transfusion of products in error to the patient.</td>
</tr>
<tr>
<td>Handling / Storage</td>
<td>Incidents during the transfusion process where transport, handling and storage may have rendered the blood product less safe for transfusion. An alert reminding the notifier that equipment failure must also be recorded in the appropriate incident stream will pop up if this incident type is selected.</td>
</tr>
<tr>
<td>Inappropriate, unnecessary or undertransfusion</td>
<td>Incidents where the intended transfusion is carried out but the decision leading to the transfusion may have been inappropriate; not required or less than required.</td>
</tr>
<tr>
<td>Incorrect blood product given</td>
<td>Incidents where any of the following occurred:</td>
</tr>
<tr>
<td></td>
<td>• The wrong component was given (eg platelets instead of plasma);</td>
</tr>
<tr>
<td></td>
<td>• An incorrect or incompatible blood group or RhD was transfused (that did not result in an adverse reaction to the patient. If an adverse reaction occurred, then this would be classified in the category above – adverse reaction to blood product);</td>
</tr>
<tr>
<td></td>
<td>• Transfusions with blood components that did not meet specific transfusion requirements such as specific antigen negative, irradiated, human leucocyte/platelet (HLA/HPA) antigen matched, washed, cytomegalovirus (CMV) negative.</td>
</tr>
<tr>
<td></td>
<td>Multiple selections on the above requirements can be made in the one incident. (continued over the page….)</td>
</tr>
</tbody>
</table>
**Incorrect blood product given (continued....)**

This incident type requires completion of the product and product specifics for both what was actually transfused and what was required.

An additional question asking for the outcome severity for the patient will appear if this incident type is selected. *See Appendix 3 for definitions of the outcome severity categories.*

- No morbidity
- Minor morbidity
- Severe morbidity
- Life Threatening
- Death
- Outcome not available

**Prescribing and ordering errors**

Incidents where there are errors in the medical prescription collection slip used to collect blood products from the transfusion laboratory, or transfusion given in the absence of consent documentation, or if blood is given when a refusal of blood product documentation has been signed.

**Pre-transfusion specimen and/or request error**

Incidents where there are errors in the request form and/or specimen label resulting in the rejection of the transfusion specimen.

*Note:* Wrong blood in tube (WBIT) detected through an historical blood group or subsequent testing must be recorded in the WBIT (transfusion sample) field.

**Treatment / procedure failed (transfusion)**

Incidents where the treatment/procedure (blood transfusion) failed due to intravenous access issues; changes in clinical situation; product issues or not being required by the patient resulting in waste or adverse outcome for the patient.

**Wrong blood in tube (transfusion sample)**

Incidents where either blood is taken from the wrong patient and is labelled with intended patient’s detail or blood is taken from the intended patient, but labelled with another patient’s detail and identified after blood group testing. If error is detected prior to testing and the specimen is rejected this should be entered under pre transfusion specimen and / or request error.

### 4. Rate the severity of the incident (SAC rating)

<table>
<thead>
<tr>
<th>Incident Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>★ Level 1</td>
</tr>
<tr>
<td>★ Level 2</td>
</tr>
<tr>
<td>★ Level 3</td>
</tr>
<tr>
<td>★ Safety Assessment Code (SAC)</td>
</tr>
</tbody>
</table>

*Click here to view the Safety Assessment Code Matrix*

<table>
<thead>
<tr>
<th>Consequence</th>
<th>Likelihood</th>
<th>SAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor</td>
<td>Frequent (almost certain)</td>
<td>SAC 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>★ Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>No harm caused to an individual or the organisation</td>
</tr>
</tbody>
</table>

*SAC Rating: Select actual consequence and frequency based on the actual outcome and likelihood that such an event will happen again. E.g. 1: a mild febrile reaction is a frequent event with minor consequence, or 2: ABO incompatible transfusion will be of major consequence but remote (rare) likelihood.*

Indicate whether harm was or wasn’t caused, or if it was a near miss, as per the actual outcome of the incident. If harm was caused, document the type of harm in the outcome section above (see section 2 above).
5. Provide additional information

There are additional questions relating specifically to transfusion incidents to be answered. The questions will vary somewhat depending on the type of transfusion related incident selected. There is one series of questions for adverse events to blood products; a specific set for incorrect blood product given and a final set for the remaining transfusion related incident types. There is much cross-over between these sets, with only the relevant questions appearing for each incident type.

**ADVERSE REACTION TO BLOOD PRODUCT**

<table>
<thead>
<tr>
<th>Transfusion related Incident / Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of transfusion</td>
</tr>
<tr>
<td>Time transfusion commenced</td>
</tr>
<tr>
<td>(hh:mm)</td>
</tr>
</tbody>
</table>

**Contributing Factors**  
This field allows for multiple selections.

**Product Type Given / Involved**  
Complete the primary blood product suspected of causing reaction. Use Concomitant blood products field for other products.

**Adverse reaction to blood product**  
Select type of reaction from list as determined by serology and any other investigations. Use “Uncertain Aetiology” if reaction signs and symptoms are related to other underlying medical condition.  
*Click here for further information* provides a link to the definitions for each adverse reaction type in the live system.

**Concomitant blood products**  
Complete if another product was administered. Select “NOT APPLICABLE” if no other product was involved.

**Modifications for fresh products**  
Select all modifications or select unmodified (based on issued product).

**How likely is it that the adverse reaction can be attributed to the blood component/product?**  
Reflect the imputability of the product causing the reaction here. Complete accurately based on investigations and outcome.

**Outcome severity**  
*Click here for further information* provides a link to the definitions for each outcome severity category in the live system.
### INCORRECT BLOOD PRODUCT GIVEN

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of transfusion</td>
<td></td>
</tr>
<tr>
<td>Time transfusion commenced (hh:mm)</td>
<td></td>
</tr>
</tbody>
</table>

**Contributing Factors**
- This field allows for multiple selections.

**Product Type Given / Involved**
- Complete the primary blood product GIVEN.

**Product type required**
- Complete the primary blood product REQUIRED.

**Product specifics given**
- Select all modifications or select unmodified (based on product GIVEN).

**Product specifics required**
- Select all modifications or select unmodified (based on product REQUIRED).

**Specify the Incident / error involved**
- Select type of error involved in giving the wrong blood product.

**How likely is it that the adverse reaction can be attributed to the blood component/product?**
- Reflect the imputability of the product causing the reaction here. Complete accurately based on investigations and outcome.

**Outcome severity**
- Select the outcome severity for the patient here (this is based on national reporting standards, additional to the SAC). **Click here for further information** provides a link to the definitions for each outcome severity category in the live system.
ALL OTHER INCIDENT TYPES

(Administration Error; Blood Product Unavailable; Dispensing / Issuing Error; Handling / Storage Error; Inappropriate, unnecessary or undertransfusion; Prescribing and Ordering Error; Pre-transfusion specimen and/or request error; Treatment / Procedure Failed (Transfusion); Wrong Blood in Tube (Transfusion Specimen).

<table>
<thead>
<tr>
<th>Transfusion related Incident / Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of transfusion</td>
</tr>
<tr>
<td>Time transfusion commenced (hh:mm)</td>
</tr>
</tbody>
</table>

- **Contributing Factors**: This field allows for multiple selections.
- **Product Type Given / Involved**: Complete the primary blood product involved in the incident.
- **Specify the Incident / error involved**: Select type of error involved in the incident.
- **Modifications for fresh products**: Select all modifications or select unmodified (based on issued product).

The final sections following this (additional information and notifier details) are common across all SLS incident categories and do not require further elaboration in this guide.
The managers section of the SLS

This section provides an overview of the manager requirements for SLS. Further information is available in “How to manage a patient incident - Tool 3 of the Patient Incident Management and Open Disclosure Policy Directive”.

1. Recording the investigation of the incident

The Patient incident manager reviews the report of the incident that has taken place in his/her area of responsibility. SLS automatically notify the relevant BloodSafe nurse(s). Contact the local SLS Administrator if this is not occurring.

Each incident must be analysed by harm caused, interventions required, possible causation, potential frequency, and potential risk, based on contributing factors.

For adverse reactions, serology testing will be involved and the clinical details investigated and confirmed. Once this is complete, imputability is assessed and the final reaction category can be entered. Accurate completion is based on investigation and post reaction serological results.

Use the Progress notes section to record details of the investigation. BloodSafe nurses can add comments to the reviewers section. The Patient incident manager can request that the transfusion services and SA Pathology review the incident. All reviewers and others involved in the investigation must upload copies of their investigation, relevant laboratory results etc into SLS (see Adding Documents - below).

Managers and BloodSafe nurses can amend the classification of inaccurate incidents after investigation, if required. This is important to improve data quality and the accuracy of reports generated.

All SLS reports / events should be monitored and where applicable improvement plans initiated by the site Blood Management / Transfusion Committee / Quality Committee.

2. Adding documents

On the management section of the SLS:

> click on the “Documents” tab in the menu
> select “Attach new document”
> select file type (FORM) and provide a title for the document, eg “Transfusion Reaction Investigation”
> browse your files and select the scanned document
> click on “Save”
> review document to ensure it is uploaded correctly
Appendix 1 – Reporting Requirements For Adverse Reactions to Blood Products

Internal reporting

Report all suspected adverse transfusion reactions to:

> the medical officer responsible for the patient’s care
> Safety Learning System (SLS). The minimum detail required for the system is the reaction classification, product type(s), modifications / special requirements, SAC rating, imputability (likelihood), outcome severity, causation (contributing factors).

In addition there are requirements to complete:

> an SA Pathology “Notification of Transfusion Reaction Form” (available from SA Pathology and Local Health Network (LHN) intranet pages), or
> EPAS reaction document (in EPAS documents as “Transfusion Reaction Note”) or
> Q-Pulse Opportunity for Information (OFI) system (SA Pathology only) for some laboratory incidents.
> Equivalent forms prescribed by the private pathology service (for country health services with private pathology services)

These forms have been designed to gain as much information about the adverse reaction as possible. All fields should be completed accurately.

Return the appropriate form with blood pack(s), specimen samples and any other supporting information as per health service / Transfusion Service provider requirements.

Scan and attach relevant documents to the Documents tab on the Managers section of the SLS patient incident report.

A copy should be retained in the medical records as per LHN procedure.

The EPAS Transfusion Reaction Note can be viewed in the “Documents Tab” of EPAS once submitted.

External reporting

Any serious reaction or event related to blood product quality, bacterial contamination or other manufacturing issue must be reported by SA Pathology to

> the Australian Red Cross Blood Service,
> where applicable to the product manufacturer (using the fractionated products –Adverse Drug Reaction Form).

Reporting Sentinel Events

Any suspected haemolytic transfusion reaction resulting from ABO incompatibility must be reported to the Department of Health and Ageing by the local Manager of Safety, Quality and Risk or delegated staff via email (HealthSentinelEvents@sa.gov.au) and a briefing provided to the CEO of the LHN or statewide service, as outlined in the Patient Incident Management and Open Disclosure Policy Directive.

Laboratory Investigations

Transfusion Services undertake reaction investigation and reporting as outlined in their standard operating procedures (SOP).

Where laboratory investigations are inconclusive and underlying patient aetiology (sepsis, medical conditions or treatments) are suspected to be responsible for the event, the cause should be investigated, the transfusion service provider notified of suspected causation and the outcome documented in the SA Pathology “Notification of Transfusion Reaction Form”. The completed form should be scanned and attached to the incident report in SLS.

Clinical Management of the Adverse Reaction to blood products

Refer to SA Health, local policy / procedures / guidelines for specific reporting processes, forms and transfusion service contacts related to the clinical management of transfusion reactions.

Transfusion reaction management guidelines can also be found in Flippin’ Blood Edition 2, July 2012.
Appendix 2 Definitions of Adverse Reactions to Blood Products

Definitions for the following adverse reactions to blood products are provided below. These definitions are derived from the “Australian Haemovigilance Minimum Dataset, August 2015”, as amended for any local reporting needs.

- ABO incompatibility
- Acute haemolytic transfusion reaction (other than ABO compatibility) (AHTR)
- Allergic Reaction (Minor)
- Allergic Reaction (Severe)
- Anaphylactic or Anaphylactoid Reaction
- Delayed haemolytic transfusion reaction (DHTR)
- Delayed serologic reaction (DSTR)
- Febrile non-haemolytic reaction (FNHTR) minor
- Febrile non-haemolytic reaction (FNHTR) major
- Hypotensive transfusion reaction
- Infection-Bacterial
- Infection-Parasitic
- Infection- Viral
- Infection-Other
- Post transfusion purpura (PTP)
- Transfusion-associated circulatory overload (TACO)
- Transfusion-associated dyspnoea (TAD)
- Transfusion-associated graft versus host disease (TA-GVHD)
- Transfusion-related acute lung injury (TRALI)
- Uncertain aetiology (comment)
- Other (specify)

**ABO incompatibility**

All cases where a blood component was transfused which was (unintentionally) ABO incompatible, which lead to an adverse reaction to the patient.

*Note: Unintentional ABO incompatible transfusions which did not result in an adverse reaction are to be reported under the “Incorrect Blood Product Given” incident type on SLS.*

*These incidents are sentinel events and must be reported to the Department of Health and Ageing. Within 24 hours of confirmation that an incident is a sentinel event, the local Manager of Safety, Quality and Risk, or delegated staff, must email HealthSentinelEvents@sa.gov.au and also provide the CEO of the LHN of statewide service with a briefing.*
Acute haemolytic transfusion reaction (other than ABO incompatibility)

An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present.

Common signs of AHTR may include:

- fever
- chills/rigors
- facial flushing
- chest pain
- abdominal pain
- back/flank pain
- nausea/vomiting
- diarrhoea
- hypertension
- pallor
- jaundice
- oligoanuria
- diffuse bleeding; and
- dark urine.

Common laboratory features are:

- haemoglobinemia
- haemoglobinuria
- decreased serum haptoglobin
- unconjugated hyperbilirubinemia
- increased LDH and AST levels; and
- decreased haemoglobin levels.

Not all clinical or laboratory features will be present.

*Note: AHTRs resulting from ABO incompatibility are to be reported under the “ABO incompatibility” adverse reaction type and reported to the Department as a sentinel event.*

Allergic reaction (Minor)

An allergic reaction may present only with mucocutaneous signs and symptoms during or within 4 hours of transfusion:

- morbilliform rash with itching
- urticarial
- localised angioedema
- oedema of lips, tongue and uvula
- periorbital pruritus, erythema and oedema
- conjunctival oedema
### Allergic Reaction (severe)
One or more of the following without hypotension, and within 24hrs of transfusion;

- Rash
- Allergic dyspnoea (stridor, cyanosis, wheezing)
- Angioedema
- Generalised pruritus
- Urticaria

### Anaphylactic or anaphylactoid reaction
An allergic reaction with hypotension (drop in systolic BP ≥30mm Hg) during or within 24 hours of transfusion or intractable hypotension or shock with loss of consciousness during transfusion, and without any indication of other case.

### Delayed haemolytic transfusion reaction (DHTR)
A DHTR usually manifests between 24 hours and 28 days after a transfusion and clinical or laboratory features of haemolysis are present. Signs and symptoms are similar to AHTR but are usually less severe.

- **Common signs (not all will be present):**
  - Fever
  - Chills/rigors
  - Facial flushing
  - Pain – chest/abdomen/back/flank
  - Nausea/vomiting
  - Diarrhoea
  - Hypertension
  - Pallor
  - Jaundice
  - Oliguria / dark urine
  - Diffuse bleeding

- **Common lab features (not all will be present):**
  - Haemoglobinemia
  - Haemoglobinuria
  - Decreased serum haptoglobin
  - Unconjugated hyperbilirubinemia
  - Increased LDH and AST levels
  - Decreased haemoglobin levels.

DHTR may sometimes manifest as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion.

Blood group serology usually shows abnormal results.

### Delayed serologic reaction (DSTR)
There is a DSTR when, after a transfusion, there is demonstration of clinically significant antibodies against red blood cells which were previously absent (as far as is known) and when there are no clinical or laboratory features of haemolysis.

This term is synonymous with alloimmunization.
### Febrile Non Haemolytic Transfusion Reaction (FNHTR) - Minor

Presents with one or more of the following during or within 4hrs of transfusion, without any other cause such as haemolytic transfusion reaction or infection;

- Fever (≥38°C and change of ≥1°C from pre-transfusion level)
- Chills
- Rigors

This may be accompanied by headache and nausea.

*Note: FNHTRs involving a fever ≥39°C and change of ≥2°C from pre-transfusion level are to be recorded under the FNHTR Major reaction type.*

### Febrile Non Haemolytic Transfusion Reaction (FNHTR) - Major

Presents with a fever (≥39°C and change of ≥2°C from pre-transfusion level) and chills/rigors, without any other cause such as haemolytic transfusion reaction or infection.

*Note: FNHTRs involving a fever less than 39°C are to be recorded under the FNHTR Minor reaction type.*

### Hypotensive transfusion reaction

This transfusion reaction is characterised by hypotension defined as a drop in systolic blood pressure of ≥30 mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure ≤ 80 mm Hg.

### Infection - Bacterial

Transfusion transmitted bacterial infection should be clinically suspected if the following are present:

- Fever >39°C or a change of >2°C from pre-transfusion value and
- Rigors and
- Tachycardia >120 beats/min or a change of >40 beats/min from pre-transfusion value or a rise or drop of 30mm Hg in systolic blood pressure within 4 hours of transfusion.

Possible bacterial infection involves detection of bacteria:

- by approved techniques in the transfused blood component but not in the recipient's blood, or
- in the recipient's blood following transfusion but not in the transfused blood component and no other reasons are ascertainable for the positive blood culture.

Confirmed bacterial infection involves the detection of the same bacterial strain in the recipient's blood and also in the transfused blood product by approved techniques.

### Infection - Parasitic

Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.
### Infection - Viral

Following investigation, the recipient has evidence of infection post-transfusion and no clinical or laboratory evidence of

- infection prior to transfusion, and
- either:
  - at least one component received by the infected recipient was donated by a donor who had evidence of the same infection, or,
  - at least one component received by the infected recipient was shown to have been contaminated with the virus.

Reports should at least consider HIV, HepB, HepC and CMV.

### Infection - Other

Following investigation, the recipient has evidence of infection post-transfusion and no clinical or laboratory evidence of

- infection prior to transfusion, and
- either:
  - at least one component received by the infected recipient was donated by a donor who had evidence of the same infection, or,
  - at least one component received by the infected recipient was shown to have been contaminated with the infectious component.

*Note: Infections involving bacteria, parasites or viruses are to be recorded under the appropriate reaction type.*

### Post-transfusion purpura (PTP)

PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.

### Transfusion-associated circulatory overload (TACO)

TACO is characterised by any 4 of the following:

- acute respiratory distress
- tachycardia
- increased blood pressure
- acute or worsening pulmonary oedema on frontal chest radiograph
- evidence of positive fluid balance

occurring within 6 hours of completion of transfusion. An elevated BNP is supportive of TACO.

### Transfusion Associated Dyspnoea (TAD)

TAD is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction.

Respiratory distress should be the most prominent clinical feature and should not be explained by the patient's underlying condition or any other known cause.
Transfusion associated graft versus host disease (TA-GVHD)

TA-GVHD clinically features the following signs and symptoms 1–6 weeks post transfusion, with no other apparent cause;
> Fever
> Rash
> Liver dysfunction
> Diarrhoea and
> Cytopenia

TA-GVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes.

Transfusion related acute lung injury (TRALI)

In patients with no evidence of acute lung injury (ALI) prior to transfusion, TRALI is diagnosed if a new ALI is present during or within 6 hours of completion of transfusion. All five criteria should be met:
> Acute onset
> Hypoxemia;
  o PaO2 / FiO2 < 300 mm Hg or
  o Oxygen saturation is < 90% on room air or
  o Other clinical evidence
> Bilateral infiltrates on frontal chest radiograph
> No evidence of left atrial hypertension (i.e. circulatory overload)
> No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion.

Alternate risk factors for ALI are:
> Direct lung injury
  o Aspiration
  o Pneumonia
  o Toxic inhalation
  o Lung contusion
  o Near drowning
> Indirect lung injury
  o Severe sepsis
  o Shock
  o Multiple trauma
  o Burn injury
  o Acute pancreatitis
  o Cardiopulmonary bypass
  o Drug overdose

TRALI should be indicated with a possible imputability to transfusion if it presents a temporal relationship to an alternative risk factor for ALI as described above.

TRALI is therefore a clinical syndrome and neither presence of anti-HLA or anti-HNA antibodies in donor(s) nor confirmation of cognate antigens in recipient is required for diagnosis.
### Uncertain Aetiology

This category is to be selected when a suspected transfusion reaction has occurred, but it cannot be definitively ascribed to any of the specific categories. Please add sufficient detail to assist reviewers in the comments section.

<table>
<thead>
<tr>
<th>Other (specify)</th>
</tr>
</thead>
</table>

Other types of adverse reactions not defined above, but defined and published by the International Society for Blood Transfusion (ISBT) at: [http://www.isbtweb.org/working-parties/haemovigilance/](http://www.isbtweb.org/working-parties/haemovigilance/)

These include:

- **Haemosiderosis**: transfusion–associated haemosiderosis is defined as a blood ferritin level of $\geq 1000$ mcg/L, with or without organ dysfunction in the setting of repeated RBC transfusions.

- **Hyperkalemia**: any abnormally high potassium level ($> 5$ mmol/L, or $\geq 1.5$ mmol/L net increase) within an hour of transfusion can be classified as a transfusion-associated hyperkalemia.

- **Unclassifiable complication of transfusion**: occurrence of an adverse event or reaction temporally related to transfusion, which cannot be classified according to an already defined adverse transfusion event and with no risk factor other than transfusion and no other explaining cause.
Appendix 3 Definitions for Outcome Severity

Definitions for patient outcome severity, as contained in the “Australian Haemovigilance Minimum Dataset, August 2015”, are provided below:

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>No morbidity</td>
<td>No ill effects, no clinical effects</td>
</tr>
<tr>
<td>Minor morbidity</td>
<td>The recipient may have required medical intervention (such as symptomatic treatment) but lack of such would not have resulted in permanent damage or impairment of a body function.</td>
</tr>
<tr>
<td>Severe morbidity</td>
<td>The recipient required in-patient hospitalisation or prolongation of hospitalisation directly attributable to the event; and/or</td>
</tr>
<tr>
<td></td>
<td>- The adverse event resulted in persistent or significant disability or incapacity; or</td>
</tr>
<tr>
<td></td>
<td>- The adverse event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.</td>
</tr>
<tr>
<td>Life-threatening</td>
<td>The recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death</td>
</tr>
<tr>
<td>Death</td>
<td>The recipient died following an adverse transfusion reaction.</td>
</tr>
<tr>
<td>Outcome not available</td>
<td>Null response. The clinical outcome classification may be pending (extended time taken to assign clinical outcome).</td>
</tr>
</tbody>
</table>
Appendix 4 Human Blood Tissues Recall Notices

Required SLS actions following the receipt of a human blood tissue recall notice from the Australian Red Cross Blood Service are outlined below:

Post Donation Notification (eg due to a post donation donor illness notification)

<table>
<thead>
<tr>
<th>Product Fate</th>
<th>Recipient / Other Impact</th>
<th>SLS required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not transfused</td>
<td>N/A</td>
<td>NO</td>
</tr>
<tr>
<td>Transfused *</td>
<td>Nil</td>
<td>NO</td>
</tr>
<tr>
<td>Transfused *</td>
<td>Possible transfusion reaction / adverse effect has been or is subsequently seen.</td>
<td>YES</td>
</tr>
</tbody>
</table>

* If the blood product was transfused, the Australian Red Cross Blood Service will notify the treating clinician directly if the nature and timing of the donor illness (or other blood product leading to recall) requires this.

Bacterial Contamination Screening – Initial Machine Positive

<table>
<thead>
<tr>
<th>Product Fate</th>
<th>Recipient / Other Impact</th>
<th>SLS required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not transfused</td>
<td>N/A</td>
<td>NO</td>
</tr>
<tr>
<td>Transfused *</td>
<td>Nil</td>
<td>NO (except where positive final report – see below)</td>
</tr>
<tr>
<td>Transfused *</td>
<td>Possible transfusion reaction / adverse effect has been or is subsequently seen.</td>
<td>YES</td>
</tr>
<tr>
<td>Transfused *</td>
<td>Final report indicates growth of bacteria (even in the absence of clinical symptoms in the recipient)</td>
<td>YES</td>
</tr>
</tbody>
</table>

* The health service transfusion laboratory will follow their local procedures for urgent clinician notification of Initial Machine Positive results.

For more information

SA Health
Blood, Organ and Tissue Programs and Safety and Quality
11 Hindmarsh Square
Email: safetylearningsystem@sa.gov.au
Telephone: 08 8226 6539
www.sahealth.sa.gov.au/safetylearningsystem

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