Serious transfusion incident reporting guide

Revised 2020

Blood Matters

Australian Red Cross Lifeblood

VICTORIA State Government

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Contents

Version control

Version number	Date	Author
Version 1	3 May 2007	Karen Botting
Version 2	5 August 2013	Lisa Stevenson
Version 3	17 December 2014	Chris Akers
Version 4	17 July 2017	Chris Akers
Version 5	17 July 2020	Chris Akers

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Abbreviations

ABO	ABO blood groups
AHTR	acute haemolytic transfusion reaction
ALI	acute lung injury
ATR	acute transfusion reaction
BNP	B-type natriuretic peptide
BP	blood pressure
CMV	cytomegalovirus
DAT	direct antiglobulin test
DHTR	delayed haemolytic transfusion reaction
DSTR	delayed serologic transfusion reaction
FFP	fresh frozen plasma
FNHTR	febrile non-haemolytic transfusion reaction
Hb	haemoglobin
HIV	human immunodeficiency virus
HPA	human platelet antigen
IBCT	incorrect blood component transfused
LDH	lactate dehydrogenase
Lifeblood	Australian Red Cross Lifeblood (formerly Blood Service)
NBA	National Blood Authority
PTP	post transfusion purpura
RCA	root cause analysis
Rh	blood group
RhD Ig	RhD immunoglobulin
SHOT	Serious Hazards of Transfusion
STIR	serious transfusion incident reporting
TACO	transfusion associated circulatory overload
TAD	transfusion associated dyspnoea
TA-GVHD	transfusion associated graft versus host disease
The department	Department of Health and Human Services
TRALI	transfusion related acute lung injury
TTI	transfusion transmitted infection
WBIT	wrong blood in tube

Serious transfusion incident reporting: system overview

Introduction

The Blood Matters Serious Transfusion Incident Reporting (STIR) system is a voluntary state-wide system to capture serious hospital transfusion incidents, including near miss events. Since its inception in 2007 the system has expanded to include health services from Victoria, Tasmania, Australian Capital Territory and Northern Territory, with health services from both the public and private sectors participating.

Confidentiality is important to the system's success. All data is de-identified and no patient details are collected with the exception of age and gender, which are useful when analysing the reported events. Health services are identified by a code number assigned by the STIR office. Health services are not identified in any of the reports.

An Expert group oversees the actions and validates data submitted to the STIR system. This group reports to the Blood Matters Advisory Committee, including Department of Health and Human Services, Victoria, Planning, Funding and Monitoring Branch, Health and Wellbeing Division (the department) on its activities. A list of membership, as of May 2020, can be found in Appendix 1.

Validated aggregate data is extracted from STIR and provided to the National Haemovigilance report overseen by the National Blood Authority (NBA).

The National Safety and Quality Health Service standards (Australian Commission on Safety and Quality in Health Care) version 2, Blood management standard, includes actions relating to reporting of adverse blood management events:

> 7.7 The health service organisation uses processes for reporting transfusion-related adverse events, in accordance with national guidelines and criteria
>
> 7.8 The health service organisation participates in haemovigilance activities, in accordance with the national framework

These criteria highlight the importance of participation in haemovigilance programs and promoting the safe management of blood and blood products. STIR provides a means for health services to meet these actions.

Purpose

The STIR system provides a reporting mechanism for serious incidents related to transfusion. This central database is used to provide local information on the number and type of serious events that occur. The data collected by STIR is collated, aggregated and reported with recommendations to improve the quality and safety of transfusion practice.

As a component of the Blood Matters program STIR links with other program activities such as education, patient blood management and appropriate use of blood and blood products to create a comprehensive haemovigilance system.

Scope of the system

STIR receives incident reports on, clinical and procedural events, including near miss events that occur in public and private health services in Victoria, and through memorandums of understanding with health services in Tasmania, Australian Capital Territory and Northern Territory.

STIR accepts reports relating to fresh blood and components, namely red cells, platelets, fresh frozen plasma and cryoprecipitate, and includes products from volunteer donors, family donors and autologous collections. In 2015, the scope of STIR was expanded to include procedural incidents related to cell salvage and RhD immunoglobulin.

Safer Care Victoria utilise the STIR Expert group in defined sentinel event investigations providing comment on recommendations made by the implicated health service and additional recommendations if needed. STIR experts may be seconded onto health service sentinel event working groups to assist in the investigation and recommendation process.

Reporting categories for transfusion incidents

The system captures two main categories of serious transfusion incidents: clinical and procedural which are reported via data collection forms:

Clinical reporting forms –

- acute transfusion reactions – this includes febrile non-haemolytic, allergic or anaphylactic, acute haemolytic and hypotensive reactions
- transfusion-related acute lung injury (TRALI)
- transfusion-associated circulatory overload (TACO)
- transfusion-associated dyspnoea (TAD)
- delayed haemolytic transfusion reactions (DHTR)
- delayed serologic transfusion reactions (DSTR)
- RhD isoimmunisations
- transfusion-associated graft-versus-host disease (TA-GVHD)
- post-transfusion purpura (PTP)
- bacterial/other infection (transfusion transmitted infection [TTI])
- post-transfusion viral infection (TTI)
- other transfusion related reactions

Procedural reporting forms –

- incorrect blood component transfused (IBCT)
- wrong blood in tube (specific type of near-miss incident)
- cell salvage incidents
- RhD immunoglobulin (anti-D) incidents
- other near-miss incidents
- procedural -other

Definitions of each incident category are detailed in the 'Incident category definitions' section.

Components of the system

Appendix 2 includes a flowchart that describes the components of the system and the responsible authority for each stage of reporting.

Each hospital is coded in accordance with privacy principles. Codes are available through the Blood Matters program.

The system for reporting to STIR involves the following steps.

At the local level

All clinical incidents should be reported to the transfusion laboratory in a timely manner. If bacterial contamination or other TTI, TRALI or PTP is suspected, the incident should also be reported, without delay, to Australian Red Cross Lifeblood (Lifeblood).

The Blood Matters secretariat will also inform Lifeblood of any reports received of bacterial contamination or other TTI, TRALI, PTP to assist the Lifeblood to monitor incidents and any safety or quality issues.

All incidents/reactions should be reviewed by the local blood management/transfusion team, risk management or clinical governance group, or appropriate review team as decided by the health service. This local governance group should determine if the event meets STIR reporting criteria. Then the incident should be notified to the STIR system via the online reporting form, for the related category.

If there is uncertainty about the reaction and which category it may fit into, health services can contact the Blood Matters secretariat to discuss.

Notification

Health services notify STIR of an event via the notification e-form linked on the Blood Matters website <https://stir.transfusion.com.au>.

This should occur as soon as possible after the event and ideally within four weeks of the incident. If this is not possible please contact the Blood Matters secretariat to discuss.

This initial notification requires key details of the incident, including:

- hospital code
- date and time of incident
- product type implicated,
- the age and gender of the patient
- type of incident; clinical or procedural
- summary of the event; what happened
- patient outcome (if known)
- contact details of the reporter.

The reporter receives a return email that includes a unique report identification number.

Investigation

Following the initial notification to STIR a fillable MS Word form is emailed to the reporter to collect more detailed information specific to the incident. This assists the health service with further investigations if needed and provides information for the STIR expert group review.

Completed forms are expected to be returned via email to the Blood Matters secretariat within four weeks. The data is imported into an MS Access database and de-identified (neither the reporter or health service are identifiable).

Additional information to the form specific questions can be provided. This can include results of investigations, transfusion reaction reports or an explanation of a complicated incident. If additional information or reports are provided they must include the unique event identifier provide by STIR and have any patient and/or health service identifiers removed.

Sentinel events

Sentinel events are reported in accordance with the existing sentinel event procedure, through Safer Care Victoria and the department.

Blood Matters may be able to provide a team member, as an external expert, to help with the review process, in line with current Safer Care Victoria guidelines.
https://www.bettersafercare.vic.gov.au/our-work/incident-response/sentinel-events

Blood Matters STIR expert group is notified by the department after the sentinel event investigation and root cause analysis (RCA) to provide expert review and feedback on the recommendations made.

The appropriate STIR investigation form is completed once the RCA has been finalised.

Withdrawn notifications

If a report is deemed, on further investigation, not to be a transfusion-related incident or meet STIR criterion, it can be withdrawn. Contact the Blood Matters secretariat to discuss.

The Blood Matters secretariat may choose to withdraw incidents that do not meet the STIR reporting criteria, after discussion with the health service.

Feedback

STIR aggregate reports will be published by the Blood Matters program and disseminated to all participating health services and stakeholders.

Sentinel event specific reports will be provided to the reporting organisation, by the Sentinel Event program through the department.

A summary report for health services will be made available as requested or six-monthly. These summary reports include information for the reporting period on:

- number and types of events reported
- the total number of incidents reported for the health service
- total number of reports from all health services
- the number of withdrawn reports
- alterations by the expert group to reports made by the health service to event types or severity rating.

Individual health services may be contacted on occasion for clarification and feedback, or if there are major differences between the health service and expert group determination of type or severity of report.

Incident category definitions - clinical reactions

Acute transfusion reaction (ATR)

Acute transfusion reactions occur at any time during a transfusion or up to 24 hours following transfusion of a blood component. (Summary of when to report: Appendix 3)

Acute reactions may occur due to a number of causes. Some reactions are reported on a specific form designed to capture information relevant to the reaction type:

- Incorrect blood component transfused - IBCT procedural form.
- TRALI, TACO and TAD - TRALI/TACO form.
- Suspected bacterial contamination - Bacterial form.

Specific reactions reported on the acute transfusion reactions form include:

Febrile non-haemolytic transfusion reaction (FNHTR)

Fever (> 38.5°C or a change of 1.5°C above baseline), occurring during or within four hours of the transfusion with one or more of the following:

- chills/rigor
- headache
- nausea/vomiting.

Allergic reactions

Allergic reactions should be reported if the most likely cause of the allergy is the transfusion. Consider other causes for the allergic reaction, for example drug reactions.

Moderate reactions, occurring within four hours of transfusion, without **evidence of significant** hypotension, with:

- allergic dyspnoea (wheeze)
- angioedema
- urticaria
- rash, accompanied by one or more of the above.

In addition to the above signs and symptoms anaphylactoid/anaphylaxis reactions may also involve respiratory and/or cardiovascular signs or symptoms, occurring during, or within four hours of transfusion, and excluding any other identifiable cause. Signs and symptoms may include:

- hypotension (drop in systolic BP > 30 mm Hg) or requiring vasopressor treatment
- syncope or loss of consciousness
- laryngeal tightness or stridor
- cough, wheeze or bronchospasm
- hypoxemia

(National Blood Authority Australia, 2015)

Acute haemolytic transfusion reaction (AHTR)

Acute HTR is suspected if the patient has fever and other signs/symptoms of haemolysis (including dyspnoea, hypotension, tachycardia, back pain, dark urine) within 24 hours of transfusion confirmed by one or more of the following:

- failure to achieve expected rise of the Hb post-transfusion or a drop in Hb > 20g/L within 24 hours (excluding all causes for ongoing bleeding)
- rise in lactate dehydrogenase (LDH) > 50 per cent within 24 hours
- rise in bilirubin, free haemoglobin (plasma or urine)
- positive direct antiglobulin test (DAT)
- incompatible crossmatch

(SHOT, 2019)

Hypotensive

Isolated fall in systolic BP of 30 mmHg or more occurring during or within one hour of completing transfusion AND a systolic BP 80mmHg or less in the absence of allergic or anaphylactic symptoms.

More serious reactions might include hypotension, as previously defined, leading to shock (e.g. acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms.

Other

Adverse effect or reaction that is temporally related to transfusion, which cannot be classified according to already defined reactions and with no other risk factor other than transfusion and no other explaining cause.

(ISBT, 2011)

Transfusion-associated circulatory overload (TACO)

Cases of TACO reportable to STIR should demonstrate at least three of the following, occurring within six hours of transfusion. The three criteria should include at least one of the first two points:

- Acute or worsening respiratory compromise and/or
- Evidence of acute or worsening pulmonary oedema based on:
    - Clinical, physical examination and/or
    - Radiographic chest imaging and/or other non-invasive assessment of cardiac function
- Evidence of cardiovascular system changes not explained by the patients underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema.
- Evidence of fluid overload, including any of the following: a positive fluid balance, clinical improvement following diuresis
- Supportive result of a relevant biomarker, e.g. an increase of B-type natriuretic peptide levels (BNP) or N-terminal-pro brain natriuretic peptide) NT-pro BNP to greater than 1.5 times the pre-transfusion value

(SHOT, 2019)

Transfusion-related acute lung injury (TRALI)

TRALI may be immune or non-immune mediated. Serological confirmation is not required for diagnosis.

All cases of TRALI should be reported to Lifeblood at the first available opportunity to enable quarantine and testing of related components from the same donor to prevent potential reactions in other recipients.

Clinical features of TRALI include:

- acute onset respiratory distress with hypoxia
- bilateral pulmonary infiltrates, evidenced on radiology imaging
- occurs during or within six hours of transfusion
- no other apparent cause of acute lung injury (ALI)
- no evidence of TACO.

(SHOT, 2019 and National Blood Authority Australia, 2015)

Transfusion-associated dyspnoea (TAD)

TAD is characterised by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress, not explained by the patient's underlying condition or any other known cause, is the most prominent clinical feature.

(NBA: Australian Haemovigilance Minimum Data Set, 2015; SHOT, 2019)

Delayed haemolytic transfusion reaction (DHTR)

Delayed haemolytic transfusion reaction occurs, **more than 24 hours to 3 months** after a transfusion.

- there is demonstration of clinically significant antibodies against red blood cells (as described in the ANZSBT guidelines for Transfusion and Immunohaematology Laboratory Practice, 1st Edition, Revised January 2020) which were previously absent and
- where **there are** clinical and laboratory features of haemolysis.

If markers of increased red cell destruction are unavailable or not supportive of a haemolytic process, the event is classified as a delayed serologic transfusion reaction.

The reaction may be confirmed by **one or more** of the following:

- a fall in Hb or failure to increment
- rise in bilirubin and LDH
- incompatible cross match not detectable pre-transfusion.

(SHOT, 2019 and Australian Red Cross Lifeblood, 2018)

Delayed serological transfusion reaction (DSTR)

Delayed serologic transfusion reaction occurs, **within 24 hours to 3 months**, after a transfusion.

- there is demonstration of clinically significant antibodies against red blood cells (as described in the ANZSBT guidelines for Transfusion and Immunohaematology

Laboratory Practice, 1st Edition, Revised January 2020) which were previously absent and

- where **there are no** clinical or laboratory features of haemolysis. This term is synonymous with alloimmunisation.

(NBA: Australian Haemovigilance Minimum Data Set, 2015)

RhD isoimmunisation

Cases of RhD-negative women who become sensitised and are found to have developed immune anti-D, which is detected during pregnancy, either at booking or later in the pregnancy, or following and attributable to pregnancy.

(SHOT, 2019)

Transfusion-associated graft-versus-host disease (TA-GVHD)

The development of the classical symptoms of fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow aplasia occurring less than 30 days (median 8-10 days post transfusion) following transfusion, without other apparent cause.

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

Cases with a very high index of clinical suspicion should also be reported.

(SHOT, 2019)

Post-transfusion purpura (PTP)

PTP is characterised by sudden and self-limiting thrombocytopenia (typically platelet counts < 10 x 10^9/L) arising seven to ten days following transfusion of red cells or platelets. It is associated with the presence of antibodies directed against the human platelet antigen (HPA) system.

Report cases where the platelet count drops >50% following transfusion and there is a demonstrable antiplatelet antibody in the patient's plasma.

(SHOT, 2019)

Transfusion-transmitted infections (TTI)

All cases of TTI should be reported to Lifeblood at the first available opportunity to enable quarantine and testing of related components from the same donor to prevent potential reactions in other recipients.

A TTI should be reported where:

- the recipient has evidence of infection post transfusion and there was no evidence of infection with the agent of infection prior to transfusion and:
- at least one component received by the recipient was donated by a donor who had evidence of the same transmissible infection, **or**

- at least one component received by the recipient was shown to have been contaminated with the agent of infection.

The bacterial/other infections form is used for reporting all bacterial, parasitic (such as malaria) or other infections, not including serious viral infections.

The viral infection form is used for reporting viral infections, such as HIV, hepatitis or CMV.

NOTE: All suspected cases of TTI should be reported to Lifeblood as soon as possible, even before final cultures are available.

Incident category definitions - procedural events

Incorrect blood component transfused (IBCT)

This includes reports of incidents in which:

- the component did not meet the specific requirements for the patient e.g. not supplying an irradiated component when indicated
- transfusion of a component intended for another patient (ABO compatible)
- all unintentional incompatible transfusions, including ABO or RhD incompatible
- transfusion of product other than that prescribed (e.g. platelets instead of FFP)
- unnecessary or inappropriate transfusion.

Include all events even where:

- the bag was spiked, post bedside check, even if the patient did not receive any of the blood
- only a small quantity of blood was transfused
- no adverse reaction occurred

N.B. This does not include RhD Ig administered to the wrong patient or inappropriately. RhD Ig errors should be reported via the specific RhD Ig form.

(SHOT, 2019)

Near-miss incidents

Incidents where the transfusion **DID NOT** take place, and the error was detected prior to commencing the transfusion (before the bag was spiked).

A near miss is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrong transfusion or a reaction in a recipient if transfusion had taken place.

(SHOT, 2019)

Wrong blood in tube (WBIT)

WBIT errors have the potential to cause harm to patients, as labelling is consistent between the request form/electronic order and specimen and passes zero-tolerance guidelines. The blood collected is not that of the named patient and may be ABO incompatible.

WBIT includes specimens where:

- the sample is taken from the wrong patient but labelled as per the intended patient, or
- the sample is taken from the intended patient but labelled as per another patient.

Cell salvage

Incidents and near misses involving the use of intraoperative and/or postoperative cell salvage where the incident may be due to:

- operator error
- machine failure
- administration error
- adverse reactions to the reinfused product.
- prescription/ labelling error

(SHOT, 2019)

RhD immunoglobulin (RhD Ig)

Includes incidents related to RhD Ig request or administration for women of child bearing potential or following transfusion of RhD mismatched red cells or platelets. This includes incidents where:

- RhD Ig is omitted or administered late
- RhD Ig is administered to a RhD-positive woman
- RhD Ig is administered to a woman with immune anti-D
- RhD Ig is administered erroneously to the mother of a RhD-negative infant
- RhD Ig is administered to the wrong patient
- the incorrect dose of RhD Ig is administered
- errors associated with cell free fetal DNA testing
- an expired product is administered
- RhD Ig near-miss event which could have led to any of the above incidents.

Adverse reactions to RhD Ig are not reportable to STIR but should be reported to the manufacturer and Lifeblood.

(SHOT, 2019)

Procedural -other

Incidents where a patient received the correct blood product/s despite one or more prescription, identification or administration errors occurring.
This also includes problems in an aspect of the transfusion process, that don't necessarily fit well into either IBCT or near miss categories.
Examples include:

- transfusions that run over the four hour time period for administration;
- administration of blood where there is a mis-match in one or more patient identifiers e.g. DOB 5/3/64 instead of 3/5/64;
- transposed patient labels bags on blood, meaning that the donation numbers were not matching on the patient labels and the Blood Service labels.

References:

Australian Red Cross Lifeblood 2019, 'Adverse events', accessed March 2020, <www.transfusion.com.au/>.

National Blood Authority Australia 2015, The Australian haemovigilance minimum data set, version 1. https://www.blood.gov.au/system/files/aust-haemovigilance-min-data-set.pdf

SHOT Definitions of current SHOT reporting categories & what to report. Revised December 2019. <www.shotuk.org/sabre/>.

Appendix 1. STIR Expert Group Members (as of March 2020)

Dr Amanda Davis (chair), Consultant Haematologist, Alfred Hospital, Victoria

Ms Christine Akers, Transfusion Nurse, Blood Matters Program

Ms Linley Bielby, Program Manager, Blood Matters Program

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

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

Ms Bridget Glazebrook, Data Manager, Blood Matters Program

Mr Peter Beard, Data Manager, Blood Matters Program

Ms Clare Hennessy, Transfusion Nurse Consultant, Eastern Health, Victoria

Dr Chris Hogan, Director Pathology Services, Austin Health

Dr Ellen Maxwell, Director of Haematology, Melbourne Pathology, Victoria

Dr Tina Noutsos, Consultant Haematologist, Royal Darwin Hospital, Northern Territory

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

Dr Giles Kelsey, Consultant Haematologist, Royal Melbourne Hospital & Alfred Hospital, Victoria

Dr Linda Saravanan, Haematologist, Melbourne Pathology

Ms Mary Comande, Blood Bank Scientist, Royal Children's Hospital

Dr James Daly, Medical Director of Pathology Services, Australian Red Cross Lifeblood

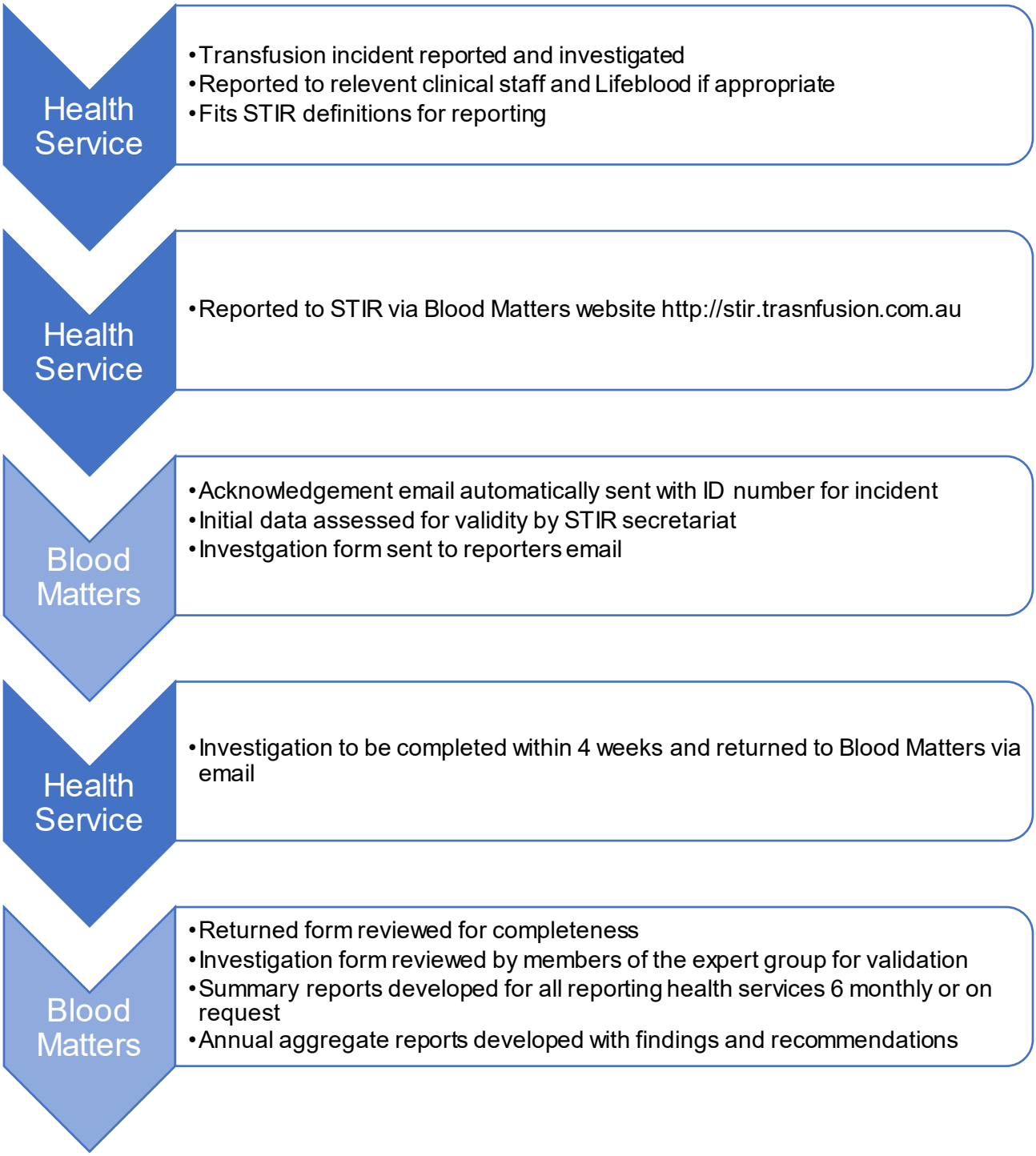
Ms Kaylene Bastin, Patient Blood Management Education Co-ordinator, Blood Matters Program, Victoria

Dr Kobie Von Wielligh, Haematologist, Australian Red Cross Lifeblood

Ms Glenda Mann, Blood Bank Scientist, Cabrini Health, Victoria

Dr Simon McCrae, Haematologist, Launceston General Hospital, Tasmania

Appendix 2. STIR reporting flowchart



Appendix 3. Signs and symptoms of acute reactions and when to report

Note: mild reactions are not reportable to STIR

	Mild	Moderate	Severe
Febrile	A temperature >38°C and a rise between 1°C and 2°C from pre-transfusion values, but no other signs or symptoms.	A rise in temperature of 1.5°C or more, or fever 38.5°C or over and or rigors/ chills, other inflammatory signs/ symptoms such as myalgia or nausea which precipitate stopping the transfusion.	A rise in temperature of 1.5°C or more, and/or rigors, chills or fever 38.5°C or over, or other inflammatory signs/ symptoms such as myalgia or nausea which precipitate stopping the transfusion, prompt medical review AND/OR directly results in, or prolongs hospital stay.
Allergic	Transient flushing urticaria or rash	Includes reactions that include the following, without evidence of significant hypotension: • allergic dyspnoea (wheeze) • angioedema • urticaria • rash, accompanied by one or more of the above.	Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention AND/OR directly result in, or prolong hospital stay, or ANAPHYLAXIS (severe life-threatening, generalised or systemic hypersensitivity reaction with rapidly developing airway AND/OR breathing AND/OR circulation problems usually associated with skin and mucosal changes)
Hypotensive		Isolated fall in systolic BP of 30 mmHg or more occurring during or within one hour of completing transfusion AND a systolic BP 80mmHg or less in the absence of allergic or anaphylactic symptoms. No/minor intervention required.	Hypotension, as previously defined, leading to shock (e.g. acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms. Urgent medical intervention required.