PROCEDURE FOR THE CLINICAL MANAGEMENT AND REPORTING OF SERIOUS ADVERSE EVENTS, SUSPECTED TRANSFUSION REACTIONS AND NON CONFORMANCES,

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Document Revision History		
Edition No/Change Request No.	**Description of Change**	**Date of Issue**
Edition 01 of HP-A-BTR-ERROREVENT	**1.** Change in file name from HP-A-BTR-ERROREVENT to HP-A-BTR-REACTIONEVENT **2. Section 0.2.2:** Insert: It is the responsibility of nursing/midwifery and medical staff administering a blood transfusion to ask patients to report symptoms that develop within 24 hrs of completion of the transfusion. Unconscious patients, or those unable to report symptoms, require direct monitoring. **3. Section 0.2.3:** Insert: Nursing/midwifery and medical staff administering a blood transfusion are responsible for contacting the haemovigilance officer in the event of a suspected adverse reaction, suspected adverse event or non conformance **4. Section 0.4:** Insert related documents: 0.4.4 HF-A-BTR-ROTS Record of transfusion support 0.4.5 HF-A-BTR-ANTIDRECORD Record of transfusion support for prophylactic anti D 0.4.6 HF-A-BTR-ROTSTX Electronic record of transfusion support 0.4.7 HP-A-BTR-ADMINTRACE Procedure for blood components/products pre administration checks and traceability 0.4.8. HP-A-BTR-MONITDISP Procedure for monitoring patients during administration of blood and blood components and disposal of transfusion 0.4.9 HP-A-BTR-HAEREPOR. Investigation and reporting of serious adverse, suspected transfusion reactions, non conformances and untoward events falling within the remit of haemovigilance. **5. Section 1.1.1:** Insert: All patients should be transfused in clinical areas where they can be directly observed and where staff is trained in the administration of blood components and the management of transfused patients, including the treatment of	6th March 2013

CRL 3383 CRL1707	anaphylaxis. **6. Section 1.1.3:** Insert: Acute transfusion reactions are those occurring with 24 hours of administration of blood or blood components or blood components. **7. Section 1.1.4:** Insert: They vary in severity from minor febrile reactions to life threatening allergic, haemolytic or hypotensive events. They represent 0.5 -3% of transfusions. To minimise the risk of harm, early identification of reactions and rapid clinical assessment is essential. Acute transfusion reactions may present with an overlapping complex of signs and symptoms. **8. Section 1.1.5:** Insert: The precise nature and severity of the reaction may not be apparent at presentation. **9. Section 1.2:** Replace: 'Symptoms and sign' with 'possible features of a transfusion reaction'. Delete box and add to list 1.2.1: fever (temperature rise > 2ºC), tachycardia, collapse, flushing, urticaria, pain (bone, muscle, chest, abdominal, loin) respiratory distress, dyspnoea, stridor, wheeze, tachycardia, bradycardia, cyanosis, falling O_2 sat, rising PCO_2, myalgia, restlessness/anxiety and general malaise. **10. Section 1.2.2:** Insert**:** Refer to Appendix 1 for a summary of the frequency, causes, symptoms, signs, management and outcome of the different types of transfusion reactions. **11. Section 1.3.3:** Insert: Examine the component for unusual clumps or particulate matter or discolouration suggestive of bacterial contamination. **12. Section 1.3.9:** Insert: If a patient being transfused for haemorrhage develops hypotension, careful clinical assessment is required. If the hypotension is caused by haemorrhage, continuation of the transfusion may be life saving. If the blood component is considered the most likely cause of hypotension, then transfusion must be stopped or switched to an alternative component and appropriate management and investigation commenced. **14. Section 1.4.2.** Insert: The patient should be assessed for evidence of life threatening Airway and/or Breathing and/or Circulatory problems. Delete of ≥ 1.5°C. Add: pain (bone, muscle, chest, abdominal). **15. Section 1.4.4:** Insert: All transfusion related reactions, except minor or febrile reactions and those without a history of comparable, non serious reactions should be investigated. **16. Section 1.4.9:** Replace: 'brain naturetic peptide' with 'B-type natriuretic peptide. **17: Section 1.4.8:** Insert: 'Blood film for the presence of spherocytes'. **18. Section 1.4.9:** Replace: 'Bilirubin' with 'Liver function tests'. **19. Section 1.4.10:** Insert: Culture unit if fever is sustained (temperature ≥ 39°C or a rise of ≥ 2°C) and/or chills, rigors, myalgia, nausea, vomiting and or loin pain. **20. Section 1.5.5:** Delete: In general, if there is a temperature rise of at least 1.5°C above the baseline, the transfusion must be stopped and a suspected transfusion reaction investigation should be initiated. Replace with: If a patient develops sustained febrile symptoms or signs of moderate severity (temperature ≥ 39°C or a rise of ≥2°C and /or systemic symptoms such as chills, rigors, myalgia, nausea or vomiting), bacterial contamination or a haemolytic reaction should be considered and a suspected transfusion reaction investigation should be initiated. **21. Section 1.5.6:** Insert: (rise of 1-2°C). Delete: (≥ 1.5°C). **22. Section 1.5.7:** Insert: For patients with mild reactions, such as pyrexia (temperature of ≥ 38°C and a rise of 1-2°C), and/or pruritis or rash, but without other features, medical staff should be informed and the transfusion may be continued with	

	appropriate treatment and direct observation. **23. Section 1.5.8:** Insert: Patients with mild isolated febrile reactions may be treated with oral Paracetamol (500-1000 mg in adults). **24. Section 1.5.9:** Insert: Patients with mild allergic reactions may be managed by slowing the transfusion and treating with antihistamine. **25. Section 1.6**. Insert: Subsequent management of the patient. **26. Section 1.6.1:** Insert: Premedication with oral Paracetemol one hour before transfusion should be considered for patients who experience recurrent febrile reactions. The use of washed blood components may be an option for patients who continue to react. **27. Section 1.7:** Change numbering from 1.6 to 1.7. Serious adverse events and non conformances. **28. Section 1.8:** Change numbering from 1.7 to 1.8. Reporting of adverse reactions/events/errors **29 . Section 1.9.** Insert **1.9.1**Appendix 1: Summary of the frequency, causes, symptoms, signs and management and outcome of the different types of transfusion reactions. **1.9.2** Appendix 2: Flow diagram for recognition, initial management and subsequent management and investigations. **1.9.3** Appendix 3: Classification of Acute Transfusion reactions. **1.9.4** Appendix 4: Comparison of TRALI and TACO **30. Section 1.10.** Insert **1.10.1**: British Committee for Standards in Haematology (2012) Guideline on the investigation and management of acute reactions http://www.bcshguidelines.com/documents/ATR **1.10.2**:NBUG Guidelines for the administration of blood and blood components (2004) **1.10.3.**NHO handbook, Version 1.13 03/07/2008 , available at http://giveblood.ie/clinical **1.10.4.**NHO initial report form 2012.	

0 INTRODUCTION

0.1 Scope and purpose

0.1.1. The purpose of this document is to define the procedure for the identification and clinical management of

- serious adverse reactions (SARs)
- serious adverse events (SAEs) and
- non conformances.

0.1.2 The purpose of this document is also to define the procedure clinical staff should follow in reporting of

- serious adverse reactions (SARs)
- serious adverse events (SAEs)

- non conformances

to the blood transfusion laboratory and the haemovigilance officer.

0.2 Responsibilities

0.2.1 Nursing/midwifery and medical staff administering a blood transfusion are responsible for adhering to the procedure for clinical management and reporting of suspected adverse transfusion reactions, serious adverse events and non conformances related to the storage and transfusion of blood components/products.

0.2.2 It is the responsibility of nursing/midwifery and medical staff administering a blood transfusion to ask patients to report symptoms that develop within 24 hrs of completion of the transfusion. Unconscious patients, or those unable to report symptoms, require direct monitoring.

0.2.3 Nursing/midwifery and medical staff administering a blood transfusion are responsible for contacting the haemovigilance officer in the event of a suspected adverse reaction, suspected adverse event or non conformance.

0.2.4 It is the responsibility of the haemovigilance officer to review and investigate suspected adverse events, reactions and other ward based non conformances.

0.2.5 The haemovigilance officer is responsible for reporting adverse transfusion reactions and serious adverse events to the National Haemovigilance Office (NHO), following consultation with the consultant haematologist and/or the patient's primary physician.

0.2.6 Reporting of serious adverse reactions and serious adverse events is mandatory following implementation of European and national legislation on blood and blood components.

0.3 Definitions

0.3.1 Non Conformance: non fulfilment of a requirement or non adherence to a procedure.

0.3.2 Serious adverse event: Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might:

- Lead to death,
- Be life-threatening,
- Cause disabling or incapacitating conditions for patients,
- Results in, or prolongs, hospitalisation or morbidity.

0.3.3 Serious adverse reaction: An unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood components that is:

- Fatal,
- Life-threatening,
- Disabling,
- Incapacitating, or, results in, prolongs, hospitalisation or morbidity.

0.4 Related Documents

0.4.1	HI-A-BTR-SIGNSYM	Summary of the frequency, causes, symptoms, signs and management and outcome of the different types of transfusion reactions
0.4.2	HI-A-BTR-ACUTR	Management of an Acute Transfusion Reaction
0.4.3	Blood Bank 3 Request Form	Transfusion Reaction Investigation Request Form
0.4.4	HF-A-BTR-ROTS	Record of transfusion support
0.4.5	HF-A-BTR-ANTIDRECORD	Record of transfusion support for prophylactic anti D
0.4.6	HF-A-BTR-ROTSTX	Electronic record of transfusion support
0.4.7	HP-A-BTR-ADMINTRACE	Procedure for blood components/products pre-administration checks and traceability.
0.4.8.	HP-A-BTR-MONITDISP	Procedure for monitoring patients during administration of blood

0.4.9. HP-A-BTR-HAEREPORT	and blood components and disposal of transfusion Investigation and reporting of serious adverse, suspected transfusion reactions, non conformances and untoward events falling within the remit of haemovigilance.

0.5 Abbreviations

0.5.1 SAE	Serious adverse event
0.5.2 SAR	Serious adverse reaction
0.5.3 NHO	National Haemovigilance Office
0.5.4 TACO	Transfusion associated circulatory overload
0.5.4 TRALI	Transfusion associated acute lung injury

1 PROCEDURE

1.1 Acute transfusion reactions

1.1.1 All patients should be transfused in clinical areas where they can be directly observed and where staff are trained in the administration of blood components and the management of transfused patients, including the treatment of anaphylaxis.

1.1.2 Acute transfusion reactions can be associated with significant morbidity and can result in mortality.

1.1.3 Acute transfusion reactions are those occurring with 24 hours of administration of blood or blood components or blood components.

1.1.4 They vary in severity from minor febrile reactions to life threatening allergic, haemolytic or hypotensive events. They represent 0.5 -3% of transfusions. To minimise the risk of harm, early identification of reactions and rapid clinical assessment is essential. Acute transfusion reactions may present with an overlapping complex of signs and symptoms.

1.1.5. The precise nature and severity of the reaction may not be apparent at presentation.

1.1.6. Prompt recognition and management is critical.

1.2 Features of an acute transfusion reaction may include:

1.2.1 Fever (temperature rise > 2ºC), chills, rigors, tachycardia, hyper or hypotension, collapse, flushing, urticaria, pain (infusion site, bone, muscle, chest, abdominal, loin) respiratory distress, dyspnoea, stridor, wheeze, tachycardia, bradycardia, cyanosis, falling O_2 sat, rising PCO_2, nausea/vomiting, myalgia, restlessness/anxiety general malaise.

1.2.2 Refer to Appendix 1 for a summary of the frequency, causes, symptoms, signs and management and outcome of the different types of transfusion reactions.

1.3 Action to be taken by nursing/midwifery staff when a transfusion reaction is suspected:

1.3.1 When a transfusion reaction is suspected, temporarily stop the transfusion and notify medical staff and the blood transfusion laboratory immediately.

1.3.2 The unit labels, compatibility forms and patient identification details must be checked by the nurse/midwife/doctor to confirm that the unit was intended for that patient. (Compatibility labels may have been transposed and another patient could be at risk.)

1.3.3 Examine the component for unusual clumps or particulate matter or discolouration suggestive of bacterial contamination.

1.3.4 Record the patient's temperature, pulse, blood pressure, respiratory rate and oxygen saturation (either) in the designated section of the ROTS or in the medical notes.

1.3.5 On the advice of the doctor, the unit of blood with the giving set attached should be removed and venous access maintained.

1.3.6 Seal off the giving set with a red bung to maintain sterility.
1.3.7 Do not transfuse any further units from this crossmatch request.
1.3.8 Contact the haemovigilance officer by phone. (Leave a voicemail if the haemovigilance officer is unavailable.)
1.3.9 If a patient being transfused for haemorrhage develops hypotension, careful clinical assessment is required. If the hypotension is caused by haemorrhage, continuation of the transfusion may be life saving. If the blood component is considered the most likely cause of hypotension, then transfusion must be stopped or switched to an alternative component and appropriate management and investigation commenced.

1.4 Action to be taken by medical staff when a transfusion reaction is suspected:

1.4.1 Refer to Appendix 1 for information on symptoms and signs of transfusion reactions.
1.4.2 The patient should be assessed for evidence of life threatening Airway and/or Breathing and/or Circulatory problems. See Appendix 2 for recognition, initial management and subsequent management and investigations.
1.4.3 Seek advice from the haematology registrar/consultant in all cases of suspected acute transfusion reaction.
1.4.4 All transfusion related reactions, except minor or febrile reactions and those without a history of comparable, non serious reactions, should be investigated.
1.4.5 Record the details of the reaction in the medical notes.
1.4.6 Complete a suspected transfusion reaction investigation form for the blood transfusion laboratory.
1.4.7 The following samples accompanied by the appropriate request forms must be sent to the relevant department(s) if indicated:
1.4.8 Blood Transfusion:
Post transfusion sample (7.5 ml EDTA)
Post transfusion urine sample. If haemolysis is suspected, request a second urine sample 6 hours after the reaction.
Blood pack with giving set attached.
1.4.9 Haematology:
Full blood count
Coagulation screen
Blood film for the presence of spherocytes
1.4.9 Biochemistry:
Urea & electrolytes, creatinine, liver function tests
Urinary Hb
Pre and post transfusion samples for B-type natriuretic peptide in cases of suspected TACO or TRALI. Samples should be taken within 2 hours of suspected TACO or TRALI reaction.
IgA levels in cases of suspected moderate/severe allergic reaction

1.4.10 Microbiology:
Culture unit if fever is sustained (temperature ≥39°C or a rise of ≥ 2°C) and/or chills, rigors, myalgia, nausea, vomiting and/or loin pain.

1.5 Increase in temperature

1.5.1 Temperature increase is a common problem associated with blood transfusion.
1.5.2 Temperature increases may be as a result of the transfusion or the underlying illness and can occur at any time during the transfusion.
1.5.3 Each patient must be assessed individually.
1.5.4 If the doctor attributes the temperature increase to the transfusion, then the suspected transfusion reaction investigation process described in sections 1.3 and 1.4 must be initiated.
1.5.5 If a patient develops sustained febrile symptoms or signs of moderate severity (temperature

≥ 39°C or a rise of ≥ 2°C and/or systemic symptoms such as chills, rigors, myalgia, nausea or vomiting), bacterial contamination or a haemolytic reaction should be considered and a suspected transfusion reaction investigation should be initiated.

1.5.6 In cases of frequently transfused haematology patients with a non-haemolytic febrile reaction (rise of 1-2 °C), the decision to recommence a transfusion must be made by a senior member of the haematology/oncology team (registrar or above).

1.5.7 For patients with mild reactions, such as pyrexia (temperature of ≥ 38°C and a rise of 1-2°C) and /or pruritis or rash but without other features, medical staff should be informed and the transfusion may be continued with appropriate treatment and direct observation.

1.5.8 Patients with mild isolated febrile reactions may be treated with oral Paracetamol (500-1000 mg in adults).

1.5.9 Patients with mild allergic reactions may be managed by slowing the transfusion and treating with antihistamine.

1.6 Subsequent management of the patient

1.6.1 Pre-medication with oral paracetemol one hour before transfusion should be considered for patients who experience recurrent febrile reactions. The use of washed blood components may be an option for patients who continue to react.

1.7 Serious adverse events and non conformances

1.7.1 When non conformances (i.e. non adherence to a blood transfusion procedure, including serious adverse events) are discovered on the ward, the discoverer must inform the blood transfusion laboratory.

1.7.2 If an incorrect/inappropriate transfusion is in progress, it must be discontinued immediately.

1.7.3 If the pre-transfusion specimen is potentially implicated in the adverse event/non-conformance, a repeat specimen must be taken immediately.

1.7.4 Details of any adverse effects must be fully documented in the medical notes by the doctor, including management of any suspected reaction (see sections 1.3-1.4).

1.8 Reporting of adverse reactions/events/errors

1.8.1 Suspected SAEs, suspected SARs and non conformances are reported to the haemovigilance department and investigated by the haemovigilance officer.

1.8.2 Reports of confirmed transfusion reactions are reviewed by a consultant haematologist and by the hospital transfusion committee.

1.8.3 A copy of the transfusion reaction investigation is filed in the patient's medical notes.

1.8.4 Non conformances (including serious adverse events) are tracked and trended for discussion at hospital transfusion committee and annual management review.

1.8.5 Any non conformances (including SAEs) that result in potential/actual harm to a patient are also reported to the clinical risk department.

1.8.6 The results of investigations of non conformances (including SAEs) are not routinely documented in the patient's notes, unless they result in adverse effects.

1.8.7. The Mid-Western Area haemovigilance department participates in the mandatory adverse reaction and event reporting system mandated by legislation.

1.9 Appendices

1.9.1 Appendix 1: Summary of the frequency, causes, symptoms, signs and management and outcome of the different types of transfusion reactions. Guidelines for the administration of blood and blood components (2004)

1.9.2 Appendix 2: Flow diagram for recognition, initial management and subsequent management and investigations.
1.9.3 Appendix 3: Classification of Acute Transfusion reactions.
1.9.4 Appendix 4: Comparison of TRALI and TACO

1.10 References

1.10.1 British Committee for Standards in Haematology (2012) Guideline on the investigation and management of acute reactions http://www.bcshguidelines.com/documents/ATR
1.10.2 NBUG Guidelines for the administration of blood and blood components (2004)
1.10.3 NHO handbook Version 1.13 03/07/2008, available at http://giveblood.ie/clinical
1.10.4 NHO initial report form 2012