

Date Received		Level		Imputability		Signature	
Incident No HV				Age:		Gender	

National Haemovigilance Office Initial Report Form

1. Patient Details

Hospital:	Unique Patient Identifying Number	Gender <i>Please ✓</i>	Male <input type="checkbox"/>	Age <i>Please ✓ appropriate denominator</i>	Years	
			Female <input type="checkbox"/>		Months	
					Days	

2. List unit numbers of components/products used

	Unit Numbers
Red Cells	
Platelets Apheresis	
Platelets Pooled	
Solvent detergent (SD) Plasma	
FFP	
Cryoprecipitate	
Blood Products (<i>please specify</i>)	

3. Other Details

Date of transfusion	___/___/___	Time Transfusion Started	___:___ am/pm	Date reaction noticed	___/___/___	Time reaction noticed	___:___ am/pm
Date error discovered	___/___/___	Time error discovered	___:___ am/pm	Date error occurred	___/___/___	Time error occurred	___:___ am/pm
Fluid balance recorded? <i>Please ✓</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>			Volume transfused	_____mls		

4. Baseline observations prior to reaction

Temp:		Pulse:		BP:	
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5. What is the patient's primary diagnosis? <i>Please ✓</i>	Surgical <input type="checkbox"/>	Oncology/Haematology <input type="checkbox"/>
	Medical <input type="checkbox"/>	Other <input type="checkbox"/>
	Obstetric <input type="checkbox"/>	
Details:		

6. What was the reason for the transfusion? <i>Please ✓</i>	Low Platelet Count / Platelet Function Deficit <input type="checkbox"/>	Ante Natal <input type="checkbox"/>
	Haemorrhage <input type="checkbox"/>	Post Natal <input type="checkbox"/>
	Anaemia <input type="checkbox"/>	Other <input type="checkbox"/>
	Plasma Coagulation Disorder <input type="checkbox"/>	
Details:		

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7. Previous medical or surgical history?

History <i>Please ✓</i>	Details
Surgical <input type="checkbox"/>	
Medical <input type="checkbox"/>	
Obstetric <input type="checkbox"/>	
Oncology/Haematology <input type="checkbox"/>	
Other <input type="checkbox"/>	

8. Transfusion History

Year	Month	Outcome	Details

9. Pre-transfusion haematology values

If red cells transfused state pre-transfusion Hb		Pre-transfusion PT	
If platelets transfused state pre-transfusion platelet count		Pre-transfusion APTT	
If plasma transfused state pre-transfusion INR		Was Vitamin K administered? <i>Please ✓</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>

10. Summary of Error/Omission

11. Was the transfusion an emergency? <i>Please ✓</i> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/>	12. Interval between commencing transfusion and onset of symptoms	Minutes		
		Hours		
		Days		
		Weeks		
		Months		
Further interval information if necessary:				

13. Symptoms present in the case of a reaction (tick and or record details in relevant boxes)

Symptom	✓	Details	Symptom	✓	Details
Temperature Rise			Fever		
Urticaria			Chills/Rigors		
Hypotension			Back pain		
Hypertension			Substernal discomfort		
Tachycardia			GI symptoms, including cramps		
Bradycardia			Falling haemoglobin		
Dyspnoea			Falling urinary output		
Stridor / Wheeze			Haemoglobinuria		
Cyanosis			Pain along infusion site		
Falling O2 saturation			Restlessness/anxiety		
Rising pCO2			Other		
Chest X ray changes					

14. Has your supplying IBTS Quality Assurance Dept been informed?	Yes <input type="checkbox"/>	If Yes, person informed			
	No <input type="checkbox"/>	If Yes, date Informed	____/____/____		
15. OFFICE USE ONLY	Was a QC File Initiated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	QC File No:	
	Was a product recall initiated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Recall No:	

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Nature of Incident

Serious Adverse Event	✓	Details
Blood to wrong patient (if no reaction)		
Incorrect ABO and Rh D group transfused (if no reaction)		
Incorrect ABO group transfused (if no reaction)		
Incorrect Rh D group transfused (if no reaction)		
Transfusion of other antigen incompatible RCC (if no reaction)		
Incorrect component/product transfused		
Inappropriate transfusion		
Failure to irradiate		
Failure to give CMV negative component		
Transfusion of an incorrectly labelled component		
Transfusion of expired component		
Transfusion of incorrectly stored component		
Transfusion of incorrectly distributed component		
Failure to administer product (Anti D)		
Delay in giving product (Anti D)		
Other		
Serious Adverse Reaction	✓	Details
Immunological haemolysis due to ABO incompatibility		
Immunological haemolysis due to other allo-antibody (Acute > 24 hrs)		
Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs)		
Non-immunological haemolysis		
Anaphylaxis/hypersensitivity		
Febrile Non Haemolytic Transfusion Reaction		
Transfusion Associated Circulatory Overload		
Transfusion Associated Dyspnoea		
Hypotensive Transfusion Reaction		
Previously un-reported complication of transfusion (PUCT)		
Other -Unclassified SAR		
Pre-deposit autologous donation		
Post transfusion purpura		
Graft versus host disease		
Transfusion-transmitted bacterial infection*		
Transfusion related acute lung injury (TRALI)*		
Transfusion transmitted viral infection (HBV)*		
Transfusion transmitted viral infection (HCV)*		
Transfusion transmitted viral infection (HIV-1/2)*		
Transfusion transmitted viral infection - Other (please specify)*		
Transfusion transmitted parasitical - Malaria*		
Transfusion transmitted parasitical - Other (please specify)*		
Transfusion-transmitted prion infection*		
Imputability of serious adverse reaction	Excluded - 0 <input type="checkbox"/> Unlikely - 0 <input type="checkbox"/> Possible - 1 <input type="checkbox"/> Likely/Probable - 2 <input type="checkbox"/> Certain - 3 <input type="checkbox"/> Not Assessable - NA <input type="checkbox"/>	

*** NB**
 If suspected please contact **Quality Control Laboratory** or Medical Scientist on duty at your blood supply centre:

Cork : 021 480 7400
Dublin : 01 432 2800

Report made by:

Name: _____	Title: _____
Working Address: _____	
Telephone: _____	Date: ____/____/____

Consultant Haematologist/Pathologist or patient's Primary Consultant must review each Initial Report prior to it being sent to:

The National Haemovigilance Office
At The National Blood Centre, James's Street, Dublin 8

Tel : 01 432 2890/432 2891
 Fax: 01 432 2933

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Glossary: Initial report form

For specific information on completing the form please consult The Haemovigilance Handbook: Requirements for Reporting Serious Adverse Reactions and Events to the National Haemovigilance Office.

1.0 Serious Adverse Reactions

1.1 Classification of Serious Adverse Reactions

- **Immunological Haemolysis**
 - **Due to ABO incompatibility-** Haemolysis following transfusion of an ABO incompatible unit - (Acute Haemolytic Transfusion Reaction)
 - **Due to other allo-antibody-** Haemolysis due to other incompatible antigen e.g. anti Rh Kell or Jk^a antibodies (Acute /Delayed Haemolytic Transfusion Reaction)
- **Non- Immunological Haemolysis** - Haemolysis as a result of other causes e.g. drugs mixed with the blood component.
- **Anaphylaxis/hypersensitivity** - Symptoms encompass mild allergic-type reactions such as urticaria/ pruritis associated with or without gastrointestinal discomfort, to major reactions with a stridor, wheeze, angioedema, bronchospasm and hypotension (Acute Allergic and Anaphylactic Transfusion Reaction)
- **Febrile non haemolytic transfusion reactions** - These are defined as fever of >1.5°C, than normal baseline value *together* with rigors or chills, occurring during or within four hours following transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition. These reactions may be accompanied by other symptoms such as headache, nausea, hypertension (defined as a systolic BP rise of >30mmHg), hypotension (defined as a systolic BP fall of >30 mmHg).
- **Transfusion Associated Circulatory Overload-** Circulatory overload following transfusion
- **Transfusion Associated Dysopnea-** is characterized by respiratory distress within 24 hours of transfusion that do not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition or any other known cause
- **Hypotensive Transfusion Reaction-** is characterized by a drop in systolic and /or diastolic blood pressure of > 30mmHg occurring during or within one hour of completing transfusion, with no other symptoms.
- **Previously Unreported Complication of Transfusion (PUCT)** Occurrence of an adverse effect or reaction temporally related to transfusion which cannot be classified according to an already defined categories of SAR, which have never previously been reported and with no risk factor other than transfusion.
- **Other-Unclassified SAR** - Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined categories of SAR, and with no risk factor other than transfusion. This category differs from PUCT and captures SAR, which have been previously reported, but cannot be classified within current categories.
- **Pre- Deposit Autologous Donor Incidents** - This is defined as an adverse or unforeseen event, which is experienced by the donor during or following a pre-deposit autologous donation procedure.
- **Post Transfusion Purpura** -This is characterised by thrombocytopenia arising 5-12 days following transfusion of blood components.
- **Transfusion Associated Graft-versus-Host Disease** - This occurs where viable donor lymphocytes transfused in a blood component attack recipient tissues in immunosuppressed or immunodeficient patients. It has rarely occurred in transfusion recipients who have no evidence of immunodeficiency and where HLA haplotypes are shared between donor and recipient.
- **Transfusion Related Acute Lung Injury-** This is characterised by acute respiratory distress, with bilateral pulmonary oedema but no evidence of cardiac failure or fluid overload. Symptoms typically begin within 1-2 hours of transfusion and always within 6 hours (Kleinman et al, 2004).
- **Transfusion Transmitted bacterial infection-** Infection following the transfusion of a bacterially contaminated blood component.
- **Transfusion Transmitted Viral Infection** - Viral infection post transfusion.
- **Transfusion Transmitted Parasitical Infection-** Infection following the transfusion of a contaminated blood component.

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- **Transfusion Transmitted Prion Infection-** Infection following the transfusion of a contaminated blood component.

1.2 Serious Adverse Reactions - imputability levels

Imputability		
NA	Not assessable	When there is insufficient data for imputability assessment
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely - probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component

2.0 Serious Adverse Events

Report only Serious Adverse Events, where the patient has actually been transfused.

REFERENCES

Commission Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Blood and Blood Components and amending Directive 2001/83/EC.

Commission Directive 2005/61/EC of the European Parliament and of the Council of 30 September 2005 implementing directive 2002/98/EC of the European Parliament and the Council as regards traceability and notification of serious adverse reactions and events.

National Haemovigilance Office (2007) Haemovigilance Handbook; Requirements for reporting serious adverse reactions and events to the National Haemovigilance Office. Available at; www.ibts.ie (Haemovigilance pages). Accessed: 11.06.2007

Poposky, M, Robillard, P, Schipperus, M, Stainsby, D., Tissot, JD., Wiersum, J. Proposed standard definitions for surveillance of Adverse Transfusion Events. Proceedings of International Society of Blood Transfusion Conference, 2006, September. Capetown, South Africa.

Kleinman, S., Caulfield, T., Chan, P., Davenport, R., McFarland J, Mc Phedran S, Meade, M, Morrison, D, Pinsent, T, Robillard, P and Slinger, P. (2004) Toward an understanding of transfusion-related acute lung injury; statement of consensus protocol, *Transfusion*, 44, pp.1774-1789

International Society of Blood Transfusion Working Party (2006) Proposed Standard Definition for surveillance of non-infectious adverse transfusion reactions. International Society of Blood Transfusion Meeting, Capetown, South Africa, 2006).