

Hemovigilance Module Adverse Reaction Transfusion Related Acute Lung Injury

***Required for saving**

*Facility ID#: _____		NHSN Adverse Reaction #: _____	
Patient Information			
*Patient ID: _____		*Date of Birth: ____/____/____	
*Sex: ☐ M ☐ F			
Social Security #: _____		Secondary ID: _____ Medicare #: _____	
Last Name: _____		First Name: _____ Middle Name: _____	
Ethnicity (Specify): ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Declined to respond			
Race (Select all that apply): ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Middle Eastern or North African ☐ Native Hawaiian or Pacific Islander ☐ White ☐ Unknown ☐ Declined to respond			
Preferred Language (Specify from the list provided): _____		Interpreter Needed: ☐ Yes ☐ No ☐ Unknown ☐ Declined to Respond	
*Blood Group: ☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ Blood type not done ☐ Transitional ABO / Transitional Rh ☐ Transitional ABO / Rh + ☐ Transitional ABO / Rh - ☐ Group A/Transitional Rh ☐ Group B/Transitional Rh ☐ Group O/Transitional Rh ☐ Group AB/Transitional Rh			
Patient Medical History			
List the patient's admitting diagnosis. (Use ICD-10 Diagnostic codes/descriptions)			
Code: _____		Description: _____	
Code: _____		Description: _____	
Code: _____		Description: _____	
List the patient's underlying indication for transfusion. (Use ICD-10 Diagnostic codes/descriptions)			
Code: _____		Description: _____	
Code: _____		Description: _____	
Code: _____		Description: _____	
List the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. (Use ICD-10 Diagnostic codes/descriptions)			☐ UNKNOWN ☐ NONE
Code: _____		Description: _____	
Code: _____		Description: _____	
Code: _____		Description: _____	

Assurance of Confidentiality: The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)). CDC 57.317 Rev. 3, v9.2

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List the patient's relevant medical procedure including past procedures and procedures to be performed during the current hospital or outpatient stay. (Use ICD-10 Procedure codes/descriptions)

☐ UNKNOWN
☐ NONE

Code: _____ Description: _____

Code: _____ Description: _____

Code: _____ Description: _____

Additional Information _____

Transfusion History

Has the patient received a previous transfusion? ☐ YES ☐ NO ☐ UNKNOWN

Blood Product: ☐ WB ☐ RBC ☐ Platelet ☐ Plasma ☐ Cryoprecipitate ☐ Granulocyte

Date of Transfusion: ____/____/____ ☐ UNKNOWN

Was the patient's adverse reaction transfusion-related? ☐ YES ☐ NO

If yes, provide information about the transfusion adverse reaction.

Type of transfusion adverse reaction: ☐ Allergic ☐ AHTR ☐ DHTR ☐ DSTR ☐ FNHTR

☐ HTR ☐ TTI ☐ PTP ☐ TACO ☐ TAD ☐ TA-GVHD ☐ TRALI ☐ UNKNOWN

☐ OTHER Specify _____

Reaction Details

*Date reaction occurred: ____/____/____ *Time reaction occurred: ____:____ ☐ Time unknown

*Facility location where patient was transfused: _____

Is this reaction associated with an incident? ☐ Yes ☐ No If Yes, Incident #: _____

Investigation Results

*☐ Transfusion related acute lung injury (TRALI)

		Not Done	Negative	Test result positive		
				Cognate or cross reacting antigen present	No cognate or cross reacting antigen present	Not tested for cognate antigen
Donor or unit HLA specificity		☐	☐	☐	☐	☐
Donor or unit HNA specificity		☐	☐	☐	☐	☐
Recipient HLA specificity		☐	☐	☐	☐	☐
Recipient HNA specificity		☐	☐	☐	☐	☐

*Case Definition (Check all that apply)

- ☐ NO evidence of acute lung injury (ALI) prior to transfusion.
☐ ALI onset during or within 6 hours of cessation of transfusion
☐ Hypoxemia – defined as PaO₂/FiO₂ less than or equal to 300 mm Hg
☐ Hypoxemia – defined as Oxygen saturation less than 90% on room air
☐ Hypoxemia – defined as Other clinical evidence
☐ Radiographic evidence of bilateral infiltrates
☐ No evidence of left atrial hypertension (i.e., circulatory overload)

Other signs and symptoms: (check all that apply)

Generalized: ☐ Chills/rigors ☐ Fever ☐ Nausea/vomiting

Cardiovascular: ☐ Blood pressure decrease ☐ Shock

Cutaneous: ☐ Edema ☐ Flushing ☐ Jaundice ☐ Itching ☐ Other rash

	Hives	
Hemolysis/Hemorrhage:	☐ DIC ☐ Hemoglobinemia ☐ Positive antibody screen	
Pain:	☐ Abdominal pain ☐ Back pain ☐ Flank pain ☐ Infusion site pain	
Renal:	☐ Hematuria ☐ Hemoglobinuria ☐ Oliguria	
Respiratory:	☐ Bronchospasm ☐ Cough ☐ Shortness of breath ☐ Other: (specify)	

*Severity

Did the patient receive or experience any of the following?

- | | |
|---|---|
| ☐ No treatment required | ☐ Symptomatic treatment only |
| ☐ Hospitalization, including prolonged hospitalization | ☐ Life-threatening reaction |
| ☐ Disability and/or incapacitation | ☐ Congenital anomaly or birth defect(s) of the fetus |
| ☐ Other medically important conditions | ☐ Death ☐ Unknown or not stated |

*Imputability

Which best describes the relationship between the transfusion and the reaction?

- ☐ There are no alternative risk factors for ALI present.
- ☐ There is evidence of other causes for acute lung injury.
- ☐ Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.
- ☐ There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion
- ☐ The relationship between the adverse reaction and the transfusion is unknown or not stated.

Did the transfusion occur at your facility? ☐ YES ☐ NO

Module-generated Designations

NOTE: Designations for case definition, severity, and imputability will be automatically assigned in the NHSN application based on responses in the corresponding investigation results section above.

***Do you agree with the case definition designation?** ☐ YES ☐ NO

^Please indicate your designation _____

***Do you agree with the severity designation?** ☐ YES ☐ NO

^Please indicate your designation _____

***Do you agree with the imputability designation?** ☐ YES ☐ NO

^Please indicate your designation _____

Patient Treatment

Did the patient receive treatment for the transfusion reaction? ☐ YES ☐ NO ☐ UNKNOWN

If yes, select treatment(s):

- ☐ Medication (*Select the type of medication*)
- | | | | | |
|---|---|---|---|------------------------------------|
| ☐ Antipyretics | ☐ Antihistamines | ☐ Inotropes/Vasopressors | ☐ Bronchodilator | ☐ Diuretics |
| ☐ Intravenous Immunoglobulin | ☐ Intravenous steroids | ☐ Corticosteroids | ☐ Antibiotics | |
| ☐ Antithymocyte globulin | ☐ Cyclosporin | ☐ Other | | |
- ☐ Volume resuscitation (Intravenous colloids or crystalloids)
- ☐ Respiratory support (*Select the type of support*)
- | | | |
|---|--|---------------------------------|
| ☐ Mechanical ventilation | ☐ Noninvasive ventilation | ☐ Oxygen |
|---|--|---------------------------------|

- ☐ Renal replacement therapy (*Select the type of therapy*)
 ☐ Hemodialysis ☐ Peritoneal ☐ Continuous Veno-Venous Hemofiltration
☐ Phlebotomy
☐ Other Specify: _____

Outcome

*Outcome: ☐ Death ☐ Major or long-term sequelae ☐ Minor or no sequelae ☐ Not determined

Date of Death: ____/____/____

^If recipient died, relationship of transfusion to death:

☐ Definite ☐ Probable ☐ Possible ☐ Doubtful ☐ Ruled Out ☐ Not determined

Cause of death: _____

Was an autopsy performed? ☐ Yes ☐ No

Component Details

*Was a particular unit implicated in (i.e., responsible for) the adverse reaction?

☐ Yes ☐ No ☐ N/A

Transfusion Start and End Date/Time	*Component code (check system used)	Amount transfused at reaction onset	^Unit number (Required for Infection and TRALI)	*Unit expiration Date/Time	*Blood group of unit	Implicated Unit?
^IMPLICATED UNIT						
____/____/____ ____:____ ____/____/____ ____:	☐ ISBT-128 ☐ Codabar	☐ Entire unit ☐ Partial unit mL	____-____-____ ____-____-____	____/____/____ ____:____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y
____/____/____ ____:____ ____/____/____ ____:	☐ ISBT-128 ☐ Codabar	☐ Entire unit ☐ Partial unit mL	____-____-____ ____-____-____	____/____/____ ____:____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N

Custom Fields

Label	Label
____/____/____	____/____/____
____	____

Comments

