



Hemovigilance Module Adverse Reaction Transfusion Related Acute Lung Injury

*Required for saving

*Facility ID#: _____ NHSN Adverse Reaction #: _____

Patient Information

*Patient ID: _____ *Gender: M F Other *Date of Birth: ___/___/___
 Social Security #: _____ Secondary ID: _____ Medicare #: _____
 Last Name: _____ First Name: _____ Middle Name: _____
 Ethnicity Hispanic or Latino Not Hispanic or Not Latino
 Race American Indian/Alaska Native Asian Black or African American
 Native Hawaiian/Other Pacific Islander White
 *Blood Group: A- A+ B- B+ AB- AB+ O- O+ Blood type not done

Patient Medical History (Use worksheet on page 4 for additional codes and descriptions.)

(part 1) List the patient's admitting diagnosis. (Use ICD-10 Diagnostic codes/descriptions)

Code: _____ Description: _____
 Code: _____ Description: _____
 Code: _____ Description: _____

(part 2) List the patient's underlying indication for transfusion. (Use ICD-10 Diagnostic codes/descriptions)

Code: _____ Description: _____
 Code: _____ Description: _____
 Code: _____ Description: _____

(part 3) 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: _____

Continued >>

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Transfusion Related Acute Lung Injury

Patient Medical History (Use worksheet on page 4 for additional codes and descriptions.)

(part 4) 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: _____

(part 5) Additional Information _____

Transfusion History (Use worksheet on page 4 for additional transfusion history.)

Has the patient received a previous transfusion? YES NO UNKNOWN

***If yes, provide information about the transfusion event. If not, skip to Reaction Details section.*

Blood Product: WB RBC Platelet Plasma Cryoprecipitate Granulocyte

Date of Transfusion: ___/___/___ UNKNOWN

Did the patient experience a transfusion adverse reaction? 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 #: _____

After recognition of the transfusion reaction, was the current transfusion:
 Continued Stopped and restarted Stopped indefinitely

Continued >>

Transfusion Related Acute Lung Injury

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Donor or unit HNA specificity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recipient HLA specificity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recipient HNA specificity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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)
- None of the above

Other signs and symptoms: (check all that apply)

Generalized:	<input type="checkbox"/> Chills/rigors	<input type="checkbox"/> Fever	<input type="checkbox"/> Nausea/vomiting
Cardiovascular:	<input type="checkbox"/> Blood pressure decrease	<input type="checkbox"/> Shock	
Cutaneous:	<input type="checkbox"/> Edema	<input type="checkbox"/> Flushing	<input type="checkbox"/> Jaundice
	<input type="checkbox"/> Other rash	<input type="checkbox"/> Pruritus (itching)	<input type="checkbox"/> Urticaria (hives)
Hemolysis/Hemorrhage:	<input type="checkbox"/> Disseminated intravascular coagulation	<input type="checkbox"/> Hemoglobinemia	
	<input type="checkbox"/> Positive antibody screen		
Pain:	<input type="checkbox"/> Abdominal pain	<input type="checkbox"/> Back pain	<input type="checkbox"/> Flank pain
			<input type="checkbox"/> Infusion site pain
Renal:	<input type="checkbox"/> Hematuria	<input type="checkbox"/> Hemoglobinuria	<input type="checkbox"/> Oliguria
Respiratory:	<input type="checkbox"/> Bilateral infiltrates on chest x-ray	<input type="checkbox"/> Bronchospasm	<input type="checkbox"/> Cough
	<input type="checkbox"/> Hypoxemia	<input type="checkbox"/> Shortness of breath	

Other: (specify) _____

Continued >>

Transfusion Related Acute Lung Injury

Investigation Results (continued)

Severity

Did the patient receive or experience any of the following? *(Response definitions listed in protocol)*

- | | |
|---|---|
| <input type="checkbox"/> Symptomatic treatment only | <input type="checkbox"/> Hospitalization, including prolonged hospitalization |
| <input type="checkbox"/> Life-threatening reaction | <input type="checkbox"/> Disability and/or incapacitation |
| <input type="checkbox"/> Congenital anomaly or birth defect(s) of the fetus | <input type="checkbox"/> Death |
| <input type="checkbox"/> Other medically important conditions | <input type="checkbox"/> 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.
- Alternative explanations are more likely (e.g., solid organ transplantation).
- 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

Additional Information _____

Patient Treatment

*Did the patient receive treatment for the transfusion reaction? YES NO

If yes, select treatment(s):

Medication *(Select the type of medication)*

- | | | | | |
|---|---|---|---|------------------------------------|
| <input type="checkbox"/> Antipyretics | <input type="checkbox"/> Antihistamines | <input type="checkbox"/> Inotropes/Vasopressors | <input type="checkbox"/> Bronchodilator | <input type="checkbox"/> Diuretics |
| <input type="checkbox"/> Intravenous Immunoglobulin | <input type="checkbox"/> Intravenous steroids | <input type="checkbox"/> Corticosteroids | <input type="checkbox"/> Antibiotics | |
| <input type="checkbox"/> Antithymocyte globulin | <input type="checkbox"/> Cyclosporin | <input type="checkbox"/> H1 receptor blockers | <input type="checkbox"/> 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



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Other

Specify: _____

Continued >>

Transfusion Related Acute Lung Injury

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 (Use worksheet on page 4 for additional units.)

*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	*Unit expiration Date/Time	*Blood group of unit	Implicated Unit?
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^IMPLICATED UNIT

____/____/____ :____ ____/____/____ :____	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar	<input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit mL	____-____-____ ____-____-____ ____-____-____ ____-____-____	____/____/____ :____ ____/____/____ :____	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	Y
____/____/____ :____ ____/____/____ :____	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar	<input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit mL	____-____-____ ____-____-____ ____-____-____ ____-____-____	____/____/____ :____ ____/____/____ :____	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
____/____/____ :____ ____/____/____ :____	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar	<input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit mL	____-____-____ ____-____-____ ____-____-____ ____-____-____	____/____/____ :____ ____/____/____ :____	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N

Custom Fields

Label	Label
_____	_____
_____	_____

Comments

Hemovigilance Module Additional Worksheet

Patient Medical History

(part 1) List the patient's admitting diagnosis. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____	Description: _____
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Code: _____	Description: _____
Code: _____	Description: _____
Code: _____	Description: _____
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(part 2) List the patient's underlying indication for transfusion. *(Use ICD-10 Diagnostic codes/descriptions)*

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UNKNOWN
 NONE

Code: _____	Description: _____
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(part 4) 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: _____
Code: _____	Description: _____
Code: _____	Description: _____
Code: _____	Description: _____

(part 5) Additional Information _____

Hemovigilance Module Additional Worksheet

Transfusion History
<p>Has the patient received a previous transfusion? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><i>**If yes, provide information about the transfusion event. If not, skip to Reaction Details section.</i></p> <p>Blood Product: <input type="checkbox"/> WB <input type="checkbox"/> RBC <input type="checkbox"/> Platelet <input type="checkbox"/> Plasma <input type="checkbox"/> Cryoprecipitate <input type="checkbox"/> Granulocyte</p> <p>Date of Transfusion: ___/___/___ <input type="checkbox"/> UNKNOWN</p> <p>Did the patient experience a transfusion adverse reaction? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>If yes, provide information about the transfusion adverse reaction.</p> <p>Type of transfusion adverse reaction: <input type="checkbox"/> Allergic <input type="checkbox"/> AHTR <input type="checkbox"/> DHTR <input type="checkbox"/> DSTTR <input type="checkbox"/> FNHTR</p> <p><input type="checkbox"/> HTR <input type="checkbox"/> TTI <input type="checkbox"/> PTP <input type="checkbox"/> TACO <input type="checkbox"/> TAD <input type="checkbox"/> TA-GVHD <input type="checkbox"/> TRALI <input type="checkbox"/> UNKNOWN</p> <p><input type="checkbox"/> OTHER Specify _____</p>
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Hemovigilance Module Additional Worksheet

Component Details						
*Was a particular unit implicated in (i.e., responsible for) the adverse reaction? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A						
*Transfusion Start and End Date/Time	*Component code (check system used)	*Amount transfused at reaction onset	*Unit number	*Unit expiration Date/Time	*Blood group of unit	Implicated Unit?
____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar	<input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL	____-____-____ ____-____-____ ____-____-____ ____-____-____	____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar	<input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL	____-____-____ ____-____-____ ____-____-____ ____-____-____	____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
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____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar	<input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL	____-____-____ ____-____-____ ____-____-____ ____-____-____	____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar	<input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL	____-____-____ ____-____-____ ____-____-____ ____-____-____	____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
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____ : ____ ____ / ____ / ____ ____ :	<input type="checkbox"/> Codabar _____ _____	unit <input type="checkbox"/> Partial unit _____ mL	_____ _____	_____ _____	_____ _____	_____ _____	_____ _____	_____ _____	_____ _____
						A- <input type="checkbox"/> B + <input type="checkbox"/> O-	<input type="checkbox"/> AB- <input type="checkbox"/> O+	<input type="checkbox"/> AB+ <input type="checkbox"/> N/A	