



## 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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Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Reports Clearance Officer, 1600 Clifton Rd., MS D-74, Atlanta, GA 30333 ATTN: PRA (0920-0666).

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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						
* <input type="checkbox"/> Transfusion related acute lung injury (TRALI)						
				Test result positive		
				Cognate or cross reacting antigen present	No cognate or cross reacting antigen present	Not tested for cognate antigen
	Not Done	Negative				
Donor or unit HLA specificity	<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"/>
Recipient HLA specificity	<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"/>

**\*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 PaO<sub>2</sub>/FiO<sub>2</sub> 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

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 \_\_\_\_\_

Additional Information \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Continued >>

## Transfusion Related Acute Lung Injury

<b>Patient Treatment</b>	
*Did the patient receive treatment for the transfusion reaction?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNKNOWN
If yes, select treatment(s):	
<input type="checkbox"/> <b>Medication</b> <i>(Select the type of medication)</i>	
<input type="checkbox"/> Antipyretics	<input type="checkbox"/> Antihistamines
<input type="checkbox"/> Intravenous Immunoglobulin	<input type="checkbox"/> Inotropes/Vasopressors
<input type="checkbox"/> Antithymocyte globulin	<input type="checkbox"/> Cyclosporin
<input type="checkbox"/> Intravenous steroids	<input type="checkbox"/> H1 receptor blockers
<input type="checkbox"/> Corticosteroids	<input type="checkbox"/> Diuretics
<input type="checkbox"/> Antibiotics	<input type="checkbox"/> Other
<input type="checkbox"/> <b>Volume resuscitation</b> (Intravenous colloids or crystalloids)	
<input type="checkbox"/> <b>Respiratory support</b> <i>(Select the type of support)</i>	
<input type="checkbox"/> Mechanical ventilation	<input type="checkbox"/> Noninvasive ventilation
<input type="checkbox"/> Oxygen	
<input type="checkbox"/> <b>Renal replacement therapy</b> <i>(Select the type of therapy)</i>	
<input type="checkbox"/> Hemodialysis	<input type="checkbox"/> Peritoneal
<input type="checkbox"/> Continuous Veno-Venous Hemofiltration	
<input type="checkbox"/> <b>Phlebotomy</b>	
<input type="checkbox"/> Other	Specify: _____
<i>Continued &gt;&gt;</i>	

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

**(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 \_\_\_\_\_

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## Hemovigilance Module Additional Worksheet

### Transfusion History

Has the patient received a previous transfusion?  YES  NO

***\*\*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 \_\_\_\_\_

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 OTHER Specify \_\_\_\_\_



## 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
____/____/____ ____:____ ____/____/____ ____:____	<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
____/____/____ ____:____ ____/____/____ ____:____	<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
____/____/____ ____:____ ____/____/____ ____:____	<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



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