

## Hemovigilance Module Adverse Reaction Infection

**\*Required for saving**

*Facility ID#: _____ NHSN Adverse Reaction #: _____	
<b>Patient Information</b>	
*Patient ID: _____	*Gender: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other
Sex at Birth: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Unknown	*Date of Birth: ____ / ____ / ____
	Gender Identity (Specify): Male Female Male-to-female transgender Female-to-male transgender Identifies as non-conforming Other Asked but unknown _____
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 (Specify): (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): _____	Interpreter Needed: <input type="checkbox"/> Yes <input type="checkbox"/> No Declined to Respond Unknown
*Blood Group: <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"/> Blood type not done	<input type="checkbox"/> Transitional ABO / Transitional Rh
<input type="checkbox"/> Group A/Transitional Rh <input type="checkbox"/> Group B/Transitional Rh <input type="checkbox"/> Group O/Transitional Rh <input type="checkbox"/> Group AB/Transitional Rh	
<b>Patient Medical History</b>	
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: _____

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 57.313 Rev. 3, v9.2

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 H21-8, Atlanta, GA 30333, ATTN: PRA (0920-0666).

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: \_\_\_\_\_

## Infection

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

\* Infection

**\*Case Definition**

Was a test to detect a specific pathogen performed on the recipient post-transfusion?  Yes  No  
 If Yes, positive or reactive results?  Yes  No  
 Org1 \_\_\_\_\_ Org2 \_\_\_\_\_ Org3 \_\_\_\_\_

Was a test to detect a specific pathogen performed on the donor post-donation?  Yes  No  
 If Yes, positive or reactive results?  Yes  No  
 Org1 \_\_\_\_\_ Org2 \_\_\_\_\_ Org3 \_\_\_\_\_

Was a test to detect a specific pathogen performed on the unit post-transfusion? (i.e., culture, serology, NAT)  Yes  No  
 If Yes, positive or reactive results?  Yes  No  
 Org1 \_\_\_\_\_ Org2 \_\_\_\_\_ Org3 \_\_\_\_\_

Check all that apply:  
 Temporally associated unexplained clinical illness consistent with infection

Other signs and symptoms: (check all that apply)

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

<b>Cardiovascular:</b>	<input type="checkbox"/> Blood pressure decrease	<input type="checkbox"/> Shock		
<b>Cutaneous:</b>	<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)	
<b>Hemolysis/Hemorrhage:</b>	<input type="checkbox"/> Disseminated intravascular coagulation	<input type="checkbox"/> Hemoglobinemia		
	<input type="checkbox"/> Positive antibody screen			
<b>Pain:</b>	<input type="checkbox"/> Abdominal pain	<input type="checkbox"/> Back pain	<input type="checkbox"/> Flank pain	<input type="checkbox"/> Infusion site pain
<b>Renal:</b>	<input type="checkbox"/> Hematuria	<input type="checkbox"/> Hemoglobinuria	<input type="checkbox"/> Oliguria	
<b>Respiratory:</b>	<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		
<input type="checkbox"/> Other: (specify) _____				

**\*Severity**

Did the patient receive or experience any of the following?

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> No treatment required                                | <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"/> Other medically important conditions                 | <input type="checkbox"/> Death  | <input type="checkbox"/> Unknown or not stated |

**\*Imputability**

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

- No other potential exposures to the pathogen could be identified in the recipient.
- Evidence is clearly in favor of a cause other than 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.

Check all that apply:

- Evidence of the pathogen in the transfused component.
- Evidence of the pathogen in the donor at the time of donation.
- Evidence of the pathogen in an additional component from the same donation.
- Evidence of the pathogen in an additional recipient of a component from the same donation.
- Evidence that the identified pathogen strains are related by molecular or extended phenotypic comparison testing with statistical confidence ( $p < 0.05$ ).
- Evidence that the transfused component was negative for this pathogen at the time of transfusion
- Evidence that the donor was negative for this pathogen at the time of donation.
- Evidence that additional components from the same donation were negative for this pathogen.
- Evidence that the recipient was not infected with the pathogen prior to transfusion.
- Laboratory evidence that the recipient was infected with this pathogen prior to transfusion.

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?
____/____/____ ____:____:____	<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"/> Entire unit	____-____-____	____/____/____	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B-	N

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

**Custom Fields**

Label	Label
_____ / _____ / _____	_____ / _____ / _____
_____	_____

**Comments**