

Hemovigilance Module Adverse Reaction Infection

***Required for saving**

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

Patient Information

*Patient ID: _____ *Gender: M F Other *Date of Birth: ____/____/____

Sex at Birth: M F Unknown

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 _____

Interpreter Needed: Yes No

Declined to Respond Unknown

Preferred Language (Specify): _____

*Blood Group: A- A+ B- B+ AB- AB+ O- O+ Blood type not done
 Transitional ABO / Rh + Transitional ABO / Rh - Transitional ABO / Transitional 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: _____

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

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		
<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	_____ _____	_____ _____	<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	_____
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Custom Fields

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

Comments