

Hemovigilance Module

Adverse Reaction

Transfusion Associated Graft vs. Host Disease

***Required for saving**

*Facility ID#: _____		NHSN Adverse Reaction #: _____	
Patient Information			
*Patient ID: _____		*Date of Birth: ____/____/____	
*Sex: <input type="checkbox"/> M <input type="checkbox"/> F			
Social Security #: _____		Secondary ID: _____	Medicare #: _____
Last Name: _____		First Name: _____	Middle Name: _____
Ethnicity (Specify): <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown <input type="checkbox"/> Declined to respond			
Race (Select all that apply): <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Middle Eastern or North African <input type="checkbox"/> Native Hawaiian or Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown <input type="checkbox"/> Declined to respond			
Preferred Language (Specify from the list provided): _____		Interpreter Needed: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Declined to Respond	
*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 / Rh + <input type="checkbox"/> Transitional ABO / Rh - <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			
Patient Medical History			
List the patient's admitting diagnosis. <i>(Use ICD-10 Diagnostic codes/descriptions)</i>			
Code: _____		Description: _____	
Code: _____		Description: _____	
Code: _____		Description: _____	
List the patient's underlying indication for transfusion. <i>(Use ICD-10 Diagnostic codes/descriptions)</i>			
Code: _____		Description: _____	
Code: _____		Description: _____	
Code: _____		Description: _____	
List the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. <i>(Use ICD-10 Diagnostic codes/descriptions)</i>			<input type="checkbox"/> UNKNOWN <input type="checkbox"/> 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 57.316 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).

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 associated graft vs. host disease (TA-GVHD)

*Case Definition

Did patient receive non-irradiated blood product(s) in the two months preceding the reaction? ☐ Yes ☐ No

Check all that occurred within 2 days to 6 weeks after cessation of transfusion:

☐ Clinical syndrome

Clinical syndrome characteristics:

☐ Diarrhea

☐ Fever

☐ Hepatomegaly

☐ Pancytopenia

☐ Liver dysfunction (i.e., elevated ALT, AST, Alkaline phosphatase, and bilirubin)

☐ Marrow aplasia

☐ Characteristic rash: erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation.

Check all that apply:

☐ Characteristic histological appearance of skin or liver biopsy.

☐ Biopsy negative or not done.

Other signs and symptoms: (check all that apply)

Generalized:

☐ Chills/rigors

☐ Nausea/vomiting

Cardiovascular:

☐ Blood pressure decrease

☐ Shock

Cutaneous:

☐ Edema

☐ Flushing

☐ Jaundice

☐ Other rash

☐ Pruritus (itching)

☐ 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"/> Bronchospasm	<input type="checkbox"/> Cough
	<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 alternative diagnoses.
- ☐ Other potential causes are present (e.g., stem cell transplantation).
- ☐ 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

WBC chimerism: ☐ WBC chimerism present ☐ WBC chimerism not present or not done

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)

- | | | | | |
|---|---|---|---|------------------------------------|
| <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"/> 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						
____/____/____ ____:____:____	<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

Custom Fields

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

Comments

