

Hemovigilance Module Adverse Reaction Allergic Transfusion Reaction

*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 >>

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)).

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).

Allergic Transfusion Reaction

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

Investigation Results

Allergic reaction, including anaphylaxis

*Case Definition

Check the following that occurred during or within 4 hours of cessation of transfusion:

Conjunctival edema Edema of lips, tongue and uvula Localized angioedema Hypotension
 Erythema and edema of the periorbital area Respiratory distress; bronchospasm Urticaria
 Generalized flushing Maculopapular rash Pruritus None of the above

Continued >>

Allergic Transfusion Reaction

Investigation Results (continued)	
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"/> Shock
Cutaneous:	<input type="checkbox"/> Jaundice
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"/> 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? (<i>Response definitions listed in the protocol</i>)	
<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?	
<input type="checkbox"/> No other evidence of environmental, drug or dietary risks. <input type="checkbox"/> There are other potential causes present that could explain acute hemolysis, but transfusion is the most likely cause. <input type="checkbox"/> Other present causes are most likely, but transfusion cannot be ruled out. <input type="checkbox"/> Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. <input type="checkbox"/> There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. <input type="checkbox"/> The relationship between the adverse reaction and the transfusion is unknown or not stated.	
Did the transfusion occur at your facility? <input type="checkbox"/> YES <input type="checkbox"/> NO	
When did the reaction occur in relation to the transfusion?	
<input type="checkbox"/> Occurred during or within 2 hours of cessation of transfusion. <input type="checkbox"/> Occurred 2 - 4 hours after cessation of transfusion.	
Did the same reaction occur after the transfusion was restarted (rechallenge)? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Do you agree with the case definition designation? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Please indicate your designation _____	
Do you agree with the severity designation? <input type="checkbox"/> YES <input type="checkbox"/> NO	
Please indicate your designation _____	

Continued >>

Do you agree with the imputability designation? YES NO

Please indicate your designation _____

Additional Information _____

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"/> H1 receptor blockers | <input type="checkbox"/> Other | |

Volume resuscitation (Intravenous colloids or crystalloids)

Respiratory support (Select the type of support)

- | | | |
|---|--|---------------------------------|
| <input type="checkbox"/> Mechanical ventilation | <input type="checkbox"/> Noninvasive ventilation | <input type="checkbox"/> Oxygen |
|---|--|---------------------------------|

Renal replacement therapy (Select the type of therapy)

- | | | |
|---------------------------------------|-------------------------------------|--|
| <input type="checkbox"/> Hemodialysis | <input type="checkbox"/> Peritoneal | <input type="checkbox"/> 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:

- | | | | | | |
|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|------------------------------------|---|
| <input type="checkbox"/> Definite | <input type="checkbox"/> Probable | <input type="checkbox"/> Possible | <input type="checkbox"/> Doubtful | <input type="checkbox"/> Ruled Out | <input type="checkbox"/> Not determined |
|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|------------------------------------|---|

Cause of death: _____

Was an autopsy performed? Yes No

Continued >>

Allergic Transfusion Reaction

Component Details (Use worksheet on page 4 for additional units.)						
*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?
^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 _____

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 _____

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 _____

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 _____

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"/> + <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"/> + <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"/> + <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"/> + <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"/> + <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"/> + <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"/> + <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
____/____/____ ____:____ ____/____/____ ____:	<input type="checkbox"/> ISBT-128	<input type="checkbox"/> Entire unit	_____ _____ _____	____/____/____ _____ _____ ____:	<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"/> + <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N

_____ : _____ _____ / _____ / _____ _____ : _____	<input type="checkbox"/> Codabar _____	<input type="checkbox"/> Partial unit mL _____	_____ _____	_____ : _____	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">A-</td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> B</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">+</td> <td style="text-align: center;">AB-</td> <td style="text-align: center;">AB+</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">O-</td> <td style="text-align: center;"><input type="checkbox"/> O+</td> <td style="text-align: center;">N/A</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	A-				<input type="checkbox"/> B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	+	AB-	AB+	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	O-	<input type="checkbox"/> O+	N/A	<input type="checkbox"/>
A-																									
<input type="checkbox"/> B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																						
+	AB-	AB+	<input type="checkbox"/>																						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																						
O-	<input type="checkbox"/> O+	N/A	<input type="checkbox"/>																						