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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: _____

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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:	☐ Chills/rigors ☐ Fever ☐ Nausea/vomiting
Cardiovascular:	☐ Shock
Cutaneous:	☐ Jaundice
Hemolysis/Hemorrhage:	☐ Disseminated intravascular coagulation ☐ Hemoglobinemia ☐ Positive antibody screen
Pain:	☐ Abdominal pain ☐ Back pain ☐ Flank pain ☐ Infusion site pain
Renal:	☐ Hematuria ☐ Hemoglobinuria ☐ Oliguria
Respiratory:	☐ Bilateral infiltrates on chest x-ray ☐ Cough ☐ Hypoxemia ☐ Shortness of breath

☐ Other: (specify) _____

*Severity

Did the patient receive or experience any of the following? *(Response definitions listed in the protocol)*

- ☐ Symptomatic treatment only
- ☐ Hospitalization, inlcuding prolonged hospitalization
- ☐ Life-threatening reaction
- ☐ Disability and/or incapacitation
- ☐ Congenital anomaly or birth defect(s) of the fetus
- ☐ Death
- ☐ Other medically important conditions
- ☐ Unknown or not stated

*Imputability

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

- ☐ No other evidence of environmental, drug or dietary risks.
- ☐ There are other potential causes present that could explain acute hemolysis, but transfusion is the most likely cause.
- ☐ Other present causes are most likely, but transfusion cannot be ruled out.
- ☐ 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

When did the reaction occur in relation to the transfusion?

- ☐ Occurred during or within 2 hours of cessation of transfusion.
- ☐ Occurred 2 - 4 hours after cessation of transfusion.

Did the same reaction occur after the transfusion was restarted (rechallenge)? ☐ YES ☐ NO

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 _____

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)*

☐ Antipyretics ☐ Antihistamines ☐ Inotropes/Vasopressors ☐ Bronchodilator ☐ Diuretics

☐ Intravenous Immunoglobulin ☐ Intravenous steroids ☐ Corticosteroids ☐ Antibiotics

☐ Antithymocyte globulin ☐ Cyclosporin ☐ H1 receptor blockers ☐ 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

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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? ☐ 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?
^IMPLICATED UNIT						
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N

Custom Fields

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

Comments

_____

_____

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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: _____
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(part 2) List the patient's underlying indication for transfusion. *(Use ICD-10 Diagnostic codes/descriptions)*

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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)*

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☐ NONE

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Code: _____ Description: _____
Code: _____ Description: _____
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(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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Additional Worksheet

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	*Unit expiration Date/Time	*Blood group of unit	Implicated Unit?
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____	☐ ISBT-128	☐ Entire unit	__ __ __ __ __	___/___/_____	☐ ☐ A+ ☐ B-	N

___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ Codabar ___ ___ ___ ___ ___ _____	☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __	_____ : _____	A- ☐ B+ ☐ O-	☐ AB- ☐ O+	☐ AB+ ☐ N/A	