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Hemovigilance Module
Adverse Reaction
Acute Hemolytic 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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Acute Hemolytic 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

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 #: _____

After recognition of the transfusion reaction, was the current transfusion:

☐ Continued ☐ Stopped and restarted ☐ Stopped indefinitely

Investigation Results

*☐ **Acute hemolytic transfusion reaction (AHTR)**

☐ Immune Antibody: _____ ☐ Non-immune (specify) _____

*Case Definition

Check the following that occurred **during, or within 24 hours** of cessation of transfusion with ***new*** onset:

☐ Back/flank pain ☐ Chills/rigors ☐ Epistaxis ☐ Disseminated intravascular coagulation (DIC)
☐ Oliguria/anuria ☐ Hypotension ☐ Fever ☐ Hematuria (gross visual hemolysis)
☐ Pain and/or oozing at IV site ☐ Renal failure ☐ None of the above

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Acute Hemolytic Transfusion Reaction

Investigation Results (continued)

Check all that apply:
- ☐ Decreased fibrinogen
- ☐ Decreased haptoglobin
- ☐ Elevated bilirubin
- ☐ Elevated LDH
- ☐ Hemoglobinemia
- ☐ Hemoglobinuria
- ☐ Plasma discoloration c/w hemolysis
- ☐ Spherocytes on blood film
- ☐ Positive direct antiglobulin test (DAT) for anti-IgG or anti-C3
- ☐ Positive elution test with alloantibody present on the transfused red blood cells
- ☐ Serologic testing is negative, and physical cause (e.g., thermal, osmotic, mechanical, chemical) is confirmed.
- ☐ Physical cause is excluded but serologic evidence is not sufficient to meet definitive criteria.
- ☐ Physical cause is suspected and serologic testing is negative.
- ☐ AHTR is suspected, but symptoms, test results, and/or information are not sufficient to confirm reaction.

Other signs and symptoms: (check all that apply)

Generalized:	☐ Nausea/vomiting		
Cardiovascular:	☐ Shock		
Cutaneous:	☐ Edema	☐ Flushing	☐ Jaundice
	☐ Other rash	☐ Pruritus (itching)	☐ Urticaria (hives)
Hemolysis/Hemorrhage:	☐ Hemoglobinemia	☐ Positive antibody screen	
Pain:	☐ Abdominal pain		
Respiratory:	☐ Bilateral infiltrates on chest x-ray	☐ Bronchospasm	☐ Cough
	☐ Shortness of breath	☐ Hypoxemia	

☐ 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?
- ☐ ABO or other allotypic RBC antigen incompatibility is known.
- ☐ Only transfusion-related (i.e., immune or non-immune) cause of acute hemolysis is present.
- ☐ There are other potential causes present that could explain acute hemolysis, but transfusion is the most likely cause.
- ☐ 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

Acute Hemolytic Transfusion Reaction

Investigation Results (continued)

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 _____

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

Acute Hemolytic 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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_____

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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: _____
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 _____
_____
_____
_____

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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 _____

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

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Type of transfusion adverse reaction: ☐ Allergic ☐ AHTR ☐ DHTR ☐ DSTR ☐ FNHTR

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Date of Transfusion: ____/____/_____ ☐ UNKNOWN

Did the patient experience a transfusion adverse reaction? ☐ YES ☐ NO

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☐ HTR ☐ TTI ☐ PTP ☐ TACO ☐ TAD ☐ TA-GVHD ☐ TRALI ☐ UNKNOWN

☐ OTHER Specify _____

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Hemovigilance Module
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	__ __ __ __ __	___/___/____	☐ ☐ A+ ☐ B-	N

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