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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: ____

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)).

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CDC 57.307 Rev.0 v8.6

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

Continued >>

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.

☐ None of the above

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

Continued >>

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Acute Hemolytic Transfusion Reaction

Investigation Results (continued)

Additional Information ______________________________

____

____

Patient Treatment

*Did the patient receive treatment for the transfusion reaction? ☐ YES ☐ NO

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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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	
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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: ____
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: ____
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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

*<u>**If yes, provide information about the transfusion event. If not, skip to Reaction Details section.</u>*

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

*<u>**If yes, provide information about the transfusion event. If not, skip to Reaction Details section.</u>*

Blood Product: ☐ WB ☐ RBC ☐ Platelet ☐ Plasma ☐ Cryoprecipitate ☐ Granulocyte

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Date of Transfusion: ____/____/_____ ☐ UNKNOWN

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☐ 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	__ __ __ __ __	___/___/_____	☐ ☐ A+ ☐ B-	N

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___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ Codabar ___ ___ ___ ___ ___ ________________	unit ☐ Partial unit ______mL	— — — — — — — — — — — —	 _____ : _____	A- ☐ B+ ☐ O-	 ☐ AB- ☐ O+	 ☐ AB+ ☐ N/A	