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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:** ___/___/____

Sex at Birth: ☐ M ☐ F ☐ Unknown Gender Identity (Specify):_____

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
☐ Transitional ABO / Rh + ☐ Transitional ABO / Rh - ☐ Transitional ABO / Transitional Rh
☐ Group A/Transitional Rh ☐ Group B/Transitional Rh ☐ Group O/Transitional Rh ☐ Group AB/Transitional Rh

Patient Medical History

List the patient's admitting diagnosis. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

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

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

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: _____

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

***☐ 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

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?

☐ No treatment required
☐ Symptomatic treatment only
☐ Hospitalization, inlcuding prolonged hospitalization
☐ Life-threatening reaction
☐ Disability and/or incapacitation
☐ Congenital anomaly or birth defect(s) of the fetus
☐ Other medically important conditions
☐ Death
☐ 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.
☐ Other causes of acute hemolysis are more 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

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)*
☐ Antipyretics ☐ Antihistamines ☐ Inotropes/Vasopressors ☐ Bronchodilator ☐ Diuretics
☐ Intravenous Immunoglobulin ☐ Intravenous steroids ☐ Corticosteroids ☐ Antibiotics
☐ Antithymocyte globulin ☐ Cyclosporin ☐ 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								
____/____/___ ___ ___:_____ ____/____/___ ___ ___:_____	☐ 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

Custom Fields

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

Comments