Form Approved
OMB No. 0920-0666
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Hemovigilance Module
Adverse Reaction
Delayed 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
☐ 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: ____

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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).

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 *(Only answer questions listed under the selected reaction type.)*

*☐ **Delayed hemolytic transfusion reaction (DHTR)**

☐ Immune Antibody: ______________ ☐ Non-immune (specify) ______________________

***Case Definition**

Check the following that occurred **between 24 hours and 28 days** after cessation of transfusion:

- ☐ Positive direct antiglobulin test (DAT)
- ☐ Newly-identified red blood cell alloantibody in recipient serum
- ☐ Positive elution test with alloantibody present on the transfused red blood cells
- ☐ Inadequate rise of post-transfusion hemoglobin level or rapid fall in hemoglobin back to pre-transfusion levels
- ☐ Otherwise unexplained appearance of spherocytes

Check all that apply:

- ☐ Incomplete laboratory evidence
- ☐ DHTR is suspected, but reported symptoms, test results, and/or available information are not sufficient

Other signs and symptoms: (check all that apply)

Generalized:	☐ Chills/rigors	☐ Fever	☐ Nausea/vomiting
Cardiovascular:	☐ Blood pressure decrease	☐ Shock	
Cutaneous:	☐ Edema	☐ Flushing	☐ Jaundice
	☐ Other rash	☐ Pruritus (itching)	☐ Urticaria (hives)
Hemolysis/Hemorrhage:	☐ Disseminated intravascular coagulation		☐ Hemoglobinemia

Pain:	☐ Abdominal pain ☐ Back pain ☐ Flank pain ☐ Infusion site pain
Renal:	☐ Hematuria ☐ Hemoglobinuria ☐ Oliguria
Respiratory:	☐ Bilateral infiltrates on chest x-ray ☐ Bronchospasm ☐ Cough ☐ Hypoxemia ☐ Shortness of breath

☐ 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?

☐ No other explanation for symptoms or newly-identified antibody is present.
☐ An alternate explanation for symptoms or newly-identified antibody is present, but transfusion is the most likely cause.
☐ Other explanations for symptoms or newly-identified antibody 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 ☐ Intravenous steroids ☐ Corticosteroids ☐ Antibiotics

Immunoglobulin
☐ 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	
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Comments