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OMB No. 0920-0666
Exp. Date: 12/31/2027
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Hemovigilance Module
Adverse Reaction
Investigation Form

***Required fields**

***Facility ID#:** _____ ***Reporter Name:**_____ NHSN Adverse Reaction #: _____ ***Medical Record #:** _____

Recipient Information

Last Name: _____ First Name: _____ Middle Name: _____

***Patient ID:** _____ ***Date of Birth:** ____/____/_____ ***State of Residence:** _____

***Sex:** ☐ M ☐ F ☐ Missing

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Not Latino ☐ Unknown ☐ Declined to Respond

Race (check all that apply): ☐ American Indian/Alaska Native ☐ Asian ☐ Black or African American
☐ Middle Eastern/North African ☐ Native Hawaiian/Other Pacific Islander
☐ White ☐ Unknown ☐ Declined to Respond

***Blood Group:** ☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+
☐ Indeterminate ABO / Rh + ☐ Indeterminate ABO / Rh - ☐ Indeterminate ABO/Indeterminate Rh
☐ Group A/ Indeterminate Rh ☐ Group B/ Indeterminate Rh ☐ Group O/ Indeterminate Rh
☐ Group AB/ Indeterminate Rh ☐ Blood Group Not Tested

Recipient Medical History

***Did the recipient have any of the following comorbid conditions present at the time of transfusion?**

Sickle cell disease ☐ Yes ☐ No ☐ Unknown

Thalassemia ☐ Yes ☐ No ☐ Unknown

Recipient Adverse Reaction Details

***Date reaction occurred (Onset Date):**___/____/____ ☐ Unknown Time reaction occurred: __ __:__ __ ☐ Unknown

***Did the transfusion occur at your facility?** ☐ Yes ☐ No

***If no, facility name:** _____ ***If no, facility address:** _____

Facility location where patient was transfused: [CDC Location Dropdown]

Is this reaction associated with an incident? ☐ Yes ☐ No

If Yes, Incident Type (select all that apply): _____ [Multiselect Incident Code Dropdown]

*** Was this reaction reported following a massive transfusion protocol?** ☐ Yes ☐ No ☐ Unknown

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Recipient Clinical Presentation[1]

Signs and symptoms: (check all that apply): ☐ Asymptomatic

Generalized: ☐ Fever ☐ Headache ☐ Chills/rigors

Cardiovascular: ☐ Hypotension ☐ Tachycardia ☐ Jugular venous distension (JVD)
☐ Hypertension ☐ Evidence of left heart failure ☐ Peripheral edema
☐ No evidence of left arterial hypertension ☐ Widened pulse pressure ☐ Enlarged cardiac silhouette

Cutaneous: ☐ Flushing ☐ Bleeding at IV site
☐ Jaundice ☐ Rash ☐ Pruritus (itching)
☐ Oozing at IV site ☐ Urticaria (hives)
☐ Cyanosis

Pain: ☐ Back pain ☐ Abdominal pain ☐ Flank pain

Gastrointestinal: ☐ Nausea/vomiting ☐ Diarrhea

Renal: ☐ Oliguria/anuria ☐ Renal failure ☐ Hematuria (gross visual hemolysis)
☐ Hemoglobinuria

Respiratory: ☐ Bilateral infiltrates on chest x-ray ☐ Bronchospasm ☐ Cough ☐ Dyspnea
☐ Hypoxemia ☐ Orthopnea ☐ Pulmonary edema on chest x-ray
☐ No evidence of acute lung injury prior to transfusion ☐ Acute lung injury during or within 6 hours of cessation or transfusion
☐ Tachypnea ☐ Acute or worsening pulmonary edema

Hematological: ☐ Epistaxis ☐ Disseminated intravascular coagulation (DIC) ☐ Hemoglobinemia
☐ Plasma discoloration c/w hemolysis

Laboratory: ☐ Decreased fibrinogen ☐ Decreased haptoglobin ☐ Elevated bilirubin
☐ Positive direct antiglobulin test (DAT) for anti-IgG or anti-C3 ☐ Elevated LDH
☐ 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.
☐ Elevated NT-pro BNP relevant biomarker ☐ Elevated brain natriuretic peptide (BNP)
☐ Spherocytes on blood film ☐ Elevated central venous pressure (CVP)
☐ Positive antibody screen ☐ Decreased oxygen saturation values in absence of other specific causes

☐ Other: (specify) _____

[1]*Please refer to the NHSN Biovigilance Component Hemovigilance Module Surveillance Protocol glossary for clinical definitions and case definition criteria (i.e. signs/symptom onset within 12 hours for TACO or 24 hours for AHTR). For example, only report back/flank pain if onset within 24 hours of cessation of transfusion for AHTR reactions.*

Recipient 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 ☐ Epinephrine ☐ Other Inotropes ☐ Vasopressors ☐ Bronchodilator
☐ Diuretics ☐ Intravenous steroids ☐ Oral steroids ☐ Antibiotics ☐ Aspirin
☐ Ascorbic acid ☐ Other: (specify) _____

☐ Volume resuscitation (select type of therapy)
☐ Intravenous colloids ☐ Intravenous crystalloids

☐ Respiratory support *(Select the type of support)*

☐ Intubation and mechanical ventilation ☐ ECMO ☐ Oxygen ☐ Noninvasive positive pressure ventilation
☐ Non-Rebreather Mask ☐ Nasal Cannula ☐ Increased oxygen concentration

☐ Renal replacement therapy *(Select the type of therapy)*
☐ Hemodialysis ☐ Peritoneal dialysis ☐ Continuous Veno-Venous Hemofiltration

☐ Phlebotomy (to decrease blood volume)

☐ Other: (specify) _____

Recipient Outcome

***Outcome:** ☐ Death ☐ Intensive care unit (ICU)
☐ Hospitalization directly attributable to adverse reaction, including prolonged hospitalization
☐ Life-threatening reaction ☐ Disability and/or incapacitation ☐ Symptomatic treatment

***If Death, Date of Death**: ____/____/_____ ***If Death, Cause of death**: [ICD-10 code dropdown]

***If recipient died, relationship of transfusion to death:**
☐ Definite ☐ Probable ☐ Possible ☐ Doubtful ☐ Ruled Out ☐ Not Determined

Transfused Component Details (recipient)[2] (report all transfused components within 24 hours of reaction onset)

*Transfusion Start and End Date/Time	*ISBT-128 Component code	Amount transfused at reaction onset	*Donation Identification Number (DIN)	*Unit expiration Date/Time[3]	*Unit Blood group	*Implicated Unit?
____/____/___ ___ ___:_____ ____/____/___ ___ ___:_____	___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit _____mL	W ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y/N/U
____/____/___ ___ ___:___ _ ____/____/___ ___ ___:_____	___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit _____mL	W ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y/N/U

[2]NHSN Hemovigilance module will generate Blood Collection Organization from the DIN. Module will generate pathogen reduction technology status based on ISBT-128 code. [3]Enter the expiration date/time of the unit(s) based on unit label.

Laboratory Results (donor and recipient)

Test results relevant to this investigation (Coombs, Direct Antiglobulin Test [DAT], Elution, HLA/HNA antibody testing, Alloantibody):

Donor or Recipient Test name: _____ Collection date: ___/___/_____ Test result: _____
Donor or Recipient Test name: _____ Collection date: ___/___/_____ Test result: _____

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Investigation Findings

***Adverse Reaction:**

☐ Transfusion-associated circulatory overload (TACO) ☐ Transfusion-related acute lung injury (TRALI)

☐ Acute hemolytic transfusion reaction (AHTR) ☐ Other: _____

If AHTR: ☐ *Immune: Antibodies (select all that apply):*

☐ *anti-A* ☐ *anti-A,B* ☐ *anti-B* ☐ *anti-c* ☐ *anti-C* ☐ *anti-D* ☐ *anti-e*
☐ *anti-E* ☐ *anti-Fy^a* ☐ *anti-Fy^b* ☐ *anti-JK^a* ☐ *anti-JK^b* ☐ *anti-k*
☐ *anti-K* ☐ *anti-M* ☐ *anti-S* ☐ *Other:* _____

☐ Physical cause is excluded but serologic evidence is not sufficient to meet definitive criteria

☐ *Non-Immune:*

☐ Serologic testing is negative, and physical cause (e.g. thermal, osmotic, mechanical, chemical) is confirmed.
☐ Physical cause is suspected and serologic testing is negative.

Please refer to the NHSN Hemovigilance Module Protocol for CDC-defined transfusion-associated adverse reactions case definition, severity, and imputability classifications.

***Case Definition**

Please select the appropriate Case Definition classification for the adverse reaction:

☐ Definitive
☐ Probable [DO NOT SELECT FOR TACO OR TRALI]
☐ Possible [DO NOT SELECT FOR TACO OR TRALI]

***Severity**

Please select the appropriate Severity classification for the adverse reaction:

☐ Non-severe
☐ Severe
☐ Life-threatening
☐ Death
☐ Not Determined

***Imputability**

Please select the appropriate Imputability classification for the adverse reaction:

☐ Definite
☐ Probable [DO NOT SELECT FOR TRALI]
☐ Possible
☐ Doubtful
☐ Ruled Out
☐ Not Determined

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Facility Investigation Notes

_____

_____

_____

***Facility Investigation Status:** ☐ Ongoing ☐ Complete[4]

[4]If report is missing required fields please include reason in Facility Investigation Notes.

CDC Case Management (to be completed by CDC Staff)

CDC Case Manager ID: _____

Report status: ☐ Open ☐ Closed[5]

[5]Report will be locked. Requests for reports to be unlocked should be sent to nhsn@cdc.gov with "Hemovigilance" in subject line.

CDC Case Management Notes (to be completed by CDC staff)