Form Approved
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Hemovigilance Module
Adverse Reaction
Transfusion Related Acute Lung Injury

*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 / Transitional Rh
☐ Transitional ABO / Rh + ☐ Transitional ABO / 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: _____

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)).

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

*☐ **Transfusion related acute lung injury (TRALI)**

	Not Done	Negative	Test result positive: Cognate or cross reacting antigen present	Test result positive: No cognate or cross reacting antigen present	Test result positive: Not tested for cognate antigen
Donor or unit HLA specificity	☐	☐	☐	☐	☐
Donor or unit HNA specificity	☐	☐	☐	☐	☐
Recipient HLA specificity	☐	☐	☐	☐	☐
Recipient HNA specificity	☐	☐	☐	☐	☐

***Case Definition** (*Check all that apply*)

- ☐ NO evidence of acute lung injury (ALI) prior to transfusion.
- ☐ ALI onset during or within 6 hours of cessation of transfusion
- ☐ Hypoxemia – defined as PaO2/FiO2 less than or equal to 300 mm Hg
- ☐ Hypoxemia – defined as Oxygen saturation less than 90% on room air
- ☐ Hypoxemia – defined as Other clinical evidence
- ☐ Radiographic evidence of bilateral infiltrates
- ☐ No evidence of left atrial hypertension (i.e., circulatory overload)

Other signs and symptoms: (check all that apply)

Generalized:	☐ Chills/rigors ☐ Fever ☐ Nausea/vomiting
Cardiovascular:	☐ Blood pressure decrease ☐ Shock
Cutaneous:	☐ Edema ☐ Flushing ☐ Jaundice ☐ Itching ☐ ☐ Other rash

	Hives
Hemolysis/Hemorrhage:	☐ DIC ☐ Hemoglobinemia ☐ Positive antibody screen
Pain:	☐ Abdominal pain ☐ Back pain ☐ Flank pain ☐ Infusion site pain
Renal:	☐ Hematuria ☐ Hemoglobinuria ☐ Oliguria
Respiratory:	☐ Bronchospasm ☐ Cough ☐ 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?

☐ There are no alternative risk factors for ALI present.
☐ There is evidence of other causes for acute lung injury.
☐ 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

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