Form Approved
OMB No. 0920-0666
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Hemovigilance Module
Adverse Reaction
Infection

*Required for saving

*Facility ID#: _____ NHSN Adverse Reaction #: _____

Patient Information

***Patient ID:** _____ ***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: _____

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Infection

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

*☐ **Infection**

***Case Definition**

Was a test to detect a specific pathogen performed on the recipient post-transfusion? ☐ Yes ☐ No

If Yes, positive or reactive results? ☐ Yes ☐ No

Org1 _____ Org2 _____ Org3 _____

Was a test to detect a specific pathogen performed on the donor post-donation? ☐ Yes ☐ No

If Yes, positive or reactive results? ☐ Yes ☐ No

Org1 _____ Org2 _____ Org3 _____

Was a test to detect a specific pathogen performed on the unit post-transfusion? (i.e., culture, serology, NAT) ☐ Yes ☐ No

If Yes, positive or reactive results? ☐ Yes ☐ No

Org1 _____ Org2 _____ Org3 _____

Check all that apply:

☐ Temporally associated unexplained clinical illness consistent with infection

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 ☐ Positive antibody screen
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 potential exposures to the pathogen could be identified in the recipient.
☐ Evidence is clearly in favor of a cause other than 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.

Check all that apply:

☐ Evidence of the pathogen in the transfused component.
☐ Evidence of the pathogen in the donor at the time of donation.
☐ Evidence of the pathogen in an additional component from the same donation.
☐ Evidence of the pathogen in an additional recipient of a component from the same donation.
☐ Evidence that the identified pathogen strains are related by molecular or extended phenotypic comparison testing with statistical confidence ($p<0.05$).
☐ Evidence that the transfused component was negative for this pathogen at the time of transfusion
☐ Evidence that the donor was negative for this pathogen at the time of donation.
☐ Evidence that additional components from the same donation were negative for this pathogen.
☐ Evidence that the recipient was not infected with the pathogen prior to transfusion.
☐ Laboratory evidence that the recipient was infected with this pathogen prior to transfusion.

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- ☐ B+ ☐ O-	☐ A+ ☐ AB- ☐ O+	☐ B- ☐ AB+ ☐ N/A	Y
____/____/___	☐ ISBT-128	☐ Entire unit	__ __ __ __ __	___/___/_____	☐ A-	☐ A+	☐ B-	N

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___ ___:___ _ ____/____/___ ___ ___:____	☐ Codabar ___ ___ ___ ___ ___ _____	☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __	_____ : _____	☐B+ ☐ O-	☐ AB- ☐ O+	☐ AB+ ☐ N/A	

Custom Fields

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

Comments