Form Approved
OMB No. 0920-0666
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Hemovigilance Module
Adverse Reaction
Transfusion Associated Graft vs. Host Disease

***Required for saving**

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

Patient Information

***Patient ID:** _____ ***Date of Birth:** ___/___/_____

***Sex:** ☐M ☐F

Social Security #: _____ Secondary ID: _____ Medicare #: _____

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

Ethnicity (Specify): ☐Hispanic or Latino ☐Not Hispanic or Latino ☐Unknown ☐Declined to respond

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

Preferred Language (Specify from the list provided):_____ Interpreter Needed: ☐Yes ☐No ☐Declined to Respond ☐Unknown

***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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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 associated graft vs. host disease (TA-GVHD)**

***Case Definition**

Did patient receive non-irradiated blood product(s) in the two months preceding the reaction? ☐ Yes ☐ No

Check all that occurred **within 2 days to 6 weeks** after cessation of transfusion:

☐ Clinical syndrome

Clinical syndrome characteristics: ☐ Diarrhea ☐ Fever ☐ Hepatomegaly ☐ Pancytopenia ☐ Liver dysfunction (i.e., elevated ALT, AST, Alkaline phosphatase, and bilirubin) ☐ Marrow aplasia ☐ Characteristic rash: erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation.

Check all that apply:

☐ Characteristic histological appearance of skin or liver biopsy.

☐ Biopsy negative or not done.

Other signs and symptoms: (check all that apply)

Generalized:	☐ Chills/rigors	☐ 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:	☐ 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?

☐ No other alternative diagnoses.
☐ Other potential causes are present (e.g., stem cell transplantation).
☐ Alternative explanations are more likely (e.g., solid organ transplantation).
☐ 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

WBC chimerism: ☐ WBC chimerism present ☐ WBC chimerism not present or not done

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

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

Custom Fields

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

Comments