NHSN
NATIONAL HEALTHCARE SAFETY NETWORK

Form Approved
OMB No. 0920-0666
Exp. Date: 12/31/2027
www.cdc.gov/nhsn

Hemovigilance Module
Transfusion Transmitted Infection (TTI) 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 <u>at your facility</u>?** ☐ 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: [Multiselect Incident Code Dropdown]

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

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 60 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 H21-8, Atlanta, GA 30333, ATTN: PRA (0920-0666).

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Recipient Laboratory Testing

***Was a test to detect a specific pathogen performed on a recipient clinical sample that was collected pre-transfusion?**
☐ Yes ☐ No ☐ Pending ☐ Unknown

***If Yes, positive or reactive results?** ☐ Yes ☐ No ☐ Pending Results ***Collection Date:** ___/____/____

***Org1** _____ Org2 _____ Org3 _____

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

***If Yes, positive or reactive results?** ☐ Yes ☐ No ☐ Pending Results ***Collection Date:** ___/____/____

***Org1** _____ Org2 _____ Org3 _____

Recipient Clinical Presentation[1]

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

Generalized:	☐ Fever	☐ Headache	☐ Malaise (Fatigue)
	☐ Chills/rigor	☐ Jaundice	☐ Night sweats
	☐ Conjunctivitis	☐ Weakness	
Cardiovascular:	☐ Shock	☐ Bradycardia	☐ Tachycardia
	☐ Hypertension	☐ Hypotension	
Cutaneous:	☐ Rash	☐ Pruritus (itching)	☐ Urticaria (hives)
Pain:	☐ Body aches	☐ Retro-orbital pain	☐ Myalgia (Muscle pain)
	☐ Abdominal Pain	☐ Joint swelling	☐ Arthralgia (Joint pain)
	☐ Back pain	☐ Oozing at IV site	
Gastrointestinal:	☐ Nausea/vomiting	☐ Diarrhea	☐ Dark urine
Renal:	☐ Renal failure	☐ Hematuria	☐ Hemoglobinuria
	☐ Flank pain	☐ Oliguria/anuria	
Respiratory:	☐ Bilaterial Infiltrates on chest x-ray	☐ Pneumonia	☐ Dyspnea (Shortness of breath)
	☐ Pulmonary edema	☐ Rales	☐ Hypoxemia
	☐ Tachypnea		
Neurological:	☐ Neurologic focal signs	☐ Encephalitis	☐ Meningitis
	☐ Guillain-Barré syndrome	☐ Seizures	
Hematological:	☐ Sepsis	☐ Hemoglobinemia	☐ Anemia
	☐ Thrombocytopenia	☐ Leukopenia	

☐ Other: (specify) _____

[1]*Please refer to the NHSN Biovigilance Component Hemovigilance Module Surveillance Protocol glossary for clinical definitions.*

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

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☐ Diuretics ☐ Intravenous steroids ☐ Oral steroids ☐ Antibiotics ☐ Aspirin
☐ Other: (specify) _____
☐ Volume resuscitation
☐ 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

Recipient Epidemiologic Risk Assessment

Temporally associated unexplained clinical illness consistent with infection? ☐ Yes ☐ No ☐ Unknown
Evidence of the pathogen in an additional recipient of a component from the same donation? ☐ Yes ☐ No ☐ Unknown
Related Recipient Report IDs: _____. _____, _____, _____
Animal exposure in the 30 days prior to symptom onset? ☐ Yes ☐ No ☐ Unknown
Mosquito exposure in the 30 days prior to symptom onset? ☐ Yes ☐ No ☐ Unknown
Tick exposure in the 30 days prior to symptom onset? ☐ Yes ☐ No ☐ Unknown
Exposure to individual exhibiting similar symptoms prior to symptom onset? ☐ Yes ☐ No ☐ Unknown
International travel in the 30 days before symptom onset? ☐ Yes ☐ No ☐ Unknown
Country _____ Arrival Date: ___/___/____ Departure Date: ___/___/____
Country _____ Arrival Date: ___/___/____ Departure Date: ___/___/____
Domestic travel (outside of state of residence) in the 30 days before symptom onset? ☐ Yes ☐ No ☐ Unknown
State _____ Arrival Date: ___/___/____ Departure Date: ___/___/____
State _____ Arrival Date: ___/___/____ Departure Date: ___/___/____
Recipient has lived outside the U.S.? ☐ Yes ☐ No ☐ Unknown
Country _____ Arrival Date: ___/___/____ Departure Date: ___/___/____
Country _____ Arrival Date: ___/___/____ Departure Date: ___/___/____
Recipient traveled outside the U.S. in the last two years? ☐ Yes ☐ No ☐ Unknown
Country _____ Arrival Date: ___/___/____ Departure Date: ___/___/____
Country _____ Arrival Date: ___/___/____ Departure Date: ___/___/____

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Transfused Component Details (recipient)[2] (report all transfused components within 30 days of symptom 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?	Unit tested?	Pathogen Detected?	Pathogen
___/___/___ ___ ___:___ ___ ___/___/___ ___ ___:_____	___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit _____mL	W __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/___ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y/N/U	Y/N/U	Y/N/U	Org1: ____ Org2: ____ Org3: ____
___/___/___ ___ ___:___ ___ ___/___/___ ___ ___:_____	___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit _____mL	W __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/___ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y/N/U	Y/N/U	Y/N/U	Org1: ____ Org2: ____ Org3: ____
___/___/___ ___ ___:___ ___ ___/___/___ ___ ___:_____	___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit _____mL	W __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/___ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y/N/U	Y/N/U	Y/N/U	Org1: ____ Org2: ____ Org3: ____
___/___/___ ___ ___:___ ___ ___/___/___ ___ ___:_____	___ ___ ___ ___ ___	☐ Entire unit ☐ Partial unit _____mL	W __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/___ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y/N/U	Y/N/U	Y/N/U	Org1: ____ Org2: ____ Org3: ____

[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.

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Blood Product/Donor Investigation

***Was a test to detect a specific pathogen performed on the donor pre-donation?**

☐ Yes ☐ No ☐ Pending ☐ Unknown

***If Yes, positive or reactive results?** ☐ Yes ☐ No ☐ Pending Results ***Collection Date:** ___/____/____

***Org1** _____ Org2 _____ Org3 _____

***Was a test to detect a specific pathogen performed on the donor post-donation?**

☐ Yes ☐ No ☐ Pending ☐ Unknown

***If Yes, positive or reactive results?** ☐ Yes ☐ No ☐ Pending Results ***Collection Date:** ___/____/____

***Org1** _____ Org2 _____ Org3 _____

Investigation Findings

Adverse Reaction: Transfusion Transmitted Infection

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: Laboratory evidence of a pathogen in the transfusion recipient.

☐ Possible: Temporally associated unexplained clinical illness consistent with infection, but no pathogen is detected in the recipient. Other, more specific adverse reactions are ruled out. Note: Possible cases cannot meet the definite or probable imputability criteria.

NOTE: Possible cases cannot meet the definite or probable imputability criteria below.

***Severity**

Please select the appropriate Severity classification for the adverse reaction:

☐ Non-severe: Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.

☐ Severe: Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.

☐ Life-threatening: Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.

☐ Death: The recipient died as a result of the adverse transfusion reaction.

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☐ Not Determined: The severity of the adverse reaction is unknown or not stated.

***Imputability**

Please select the appropriate Imputability classification for the adverse reaction:

☐ Definite:

ONE or more of the following:

☐ 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

AND

☐ No other potential exposures to the pathogen could be identified in the recipient.

AND EITHER

☐ Evidence that the recipient was not infected with the pathogen prior to transfusion

OR

☐ Evidence that the identified pathogen strains are related by molecular or extended phenotypic comparison testing with statistical confidence ($p<0.05$).

☐ Probable:

ONE or more of the following:

☐ 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.

AND EITHER:

☐ Evidence that the recipient was not infected with this pathogen prior to transfusion

OR

☐ No other potential exposures to the pathogen could be identified in the recipient.

☐ Possible: Case fails to meet definite, probable, doubtful, or ruled out imputability criteria.

☐ Doubtful:

☐ Laboratory evidence that the recipient was infected with this pathogen prior to transfusion

OR

☐ Evidence is clearly in favor of a cause other than transfusion, but transfusion cannot be excluded.

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☐ Ruled Out:

ALL of the following (where applicable):

☐ 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

OR

☐ There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

☐ Not Determined: The relationship between the adverse reaction and the transfusion is unknown or not stated.

Facility/Health Department Investigation Notes

***Facility/Health Department Investigation Status:** ☐ Ongoing ☐ Complete[4]

[4]If missing required fields please include reason in Facility/Health Department Investigation Notes.

CDC Investigation (to be completed by CDC staff)

CDC Investigator ID: _____

TTI Rapid Alert Report ID: _____

Was FDA notified (required, if recipient died)? ☐ Yes (Date: ___/___/____) ☐ No

Was the blood supplier notified of this adverse reaction? ☐ Yes (Date: ___/___/____) ☐ No ☐ Not applicable

Was a traceback conducted? ☐ Yes (Date: ___/___/____) ☐ No

CDC SME Group notified? ☐ Yes (Date: _____/_____/_____) CDC SME Case ID: _____ ☐ No ☐ Not applicable

State health department notified? ☐ Yes (Date: ____/_____/____) ☐ No ☐ Not applicable

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 Investigation Notes (to be completed by CDC staff)