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OMB No. 0920-0666
Exp. Date: xx/xx/20xx
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Hemovigilance Module
Adverse Reaction
Delayed Serologic Transfusion Reaction

*Required for saving

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

Patient Information

*Patient ID: _____ *Gender: ☐ M ☐ F ☐ Other *Date of Birth: ___/___/____

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

Patient Medical History (Use worksheet on page 4 for additional codes and descriptions.)

(part 1) List the patient's admitting diagnosis. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 2) List the patient's underlying indication for transfusion. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 3) 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: _____

Continued >>

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Delayed Serologic Transfusion Reaction

Patient Medical History (Use worksheet on page 4 for additional codes and descriptions.)

(part 4) 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: _____

(part 5) Additional Information _____

_____

_____

Transfusion History (Use worksheet on page 4 for additional transfusion history.)

*Has the patient received a previous transfusion? ☐ YES ☐ NO ☐ UNKNOWN

***If yes, provide information about the transfusion event. If not, skip to Reaction Details section.*

Blood Product: ☐ WB ☐ RBC ☐ Platelet ☐ Plasma ☐ Cryoprecipitate ☐ Granulocyte

Date of Transfusion: ___/___/____ ☐ UNKNOWN

Did the patient experience a transfusion adverse reaction? ☐ 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 #: _____

After recognition of the transfusion reaction, was the current transfusion:

☐ Continued ☐ Stopped and restarted ☐ Stopped indefinitely

Investigation Results

*☐ **Delayed serologic transfusion reaction (DSTR)**

Antibody(ies): _____

*Case Definition

Check all that apply:

☐ Absence of clinical signs of hemolysis

☐ Positive direct antiglobulin test (DAT)

☐ Demonstration of new, clinically-significant antibodies against red blood cells

☐ Positive antibody screen with newly identified RBC alloantibody

☐ None of the above

Continued >>

Delayed Serologic Transfusion Reaction

Investigation Results (continued)

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	
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? *(Response definitions listed in protocol)*

- ☐ Symptomatic treatment only
- ☐ Hospitalization, inlcuding prolonged hospitalization
- ☐ Life-threatening reaction
- ☐ Disability and/or incapacitation
- ☐ Congenital anomaly or birth defect(s) of the fetus
- ☐ Death
- ☐ Other medically important conditions
- ☐ Unknown or not stated

*Imputability

Which best describes the relationship between the transfusion and the reaction?

- ☐ Transfusion performed by your facility is the only possible cause for seroconversion.
- ☐ The patient has other exposures (e.g. transfusion by another facility or pregnancy) that could explain seroconversion, but transfusion by your facility is the most likely cause.
- ☐ The patient was transfused by your facility, but other exposures are present that most likely explain seroconversion.
- ☐ 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

When was the new alloantibody identified?

- ☐ Occurred between 24 hours and 28 days after cessation of transfusion
- ☐ Occurred less than 24 hours after cessation of transfusion OR greater than 28 days after cessation of transfusion
- ☐ No new antibody was identified

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Delayed Serologic Transfusion Reaction

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 _____		

Additional Information _____

_____

_____

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 ☐ H1 receptor blockers ☐ 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

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Delayed Serologic Transfusion Reaction

Component Details (Use worksheet on page 4 for additional units.)

*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	*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
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ 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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Hemovigilance Module
Additional Worksheet

Patient Medical History

(part 1) List the patient's admitting diagnosis. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 2) List the patient's underlying indication for transfusion. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 3) 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: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 4) 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: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 5) Additional Information _____
_____
_____
_____

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Hemovigilance Module
Additional Worksheet

Transfusion History

Has the patient received a previous transfusion? ☐ YES ☐ NO

***If yes, provide information about the transfusion event. If not, skip to Reaction Details section.*

Blood Product: ☐ WB ☐ RBC ☐ Platelet ☐ Plasma ☐ Cryoprecipitate ☐ Granulocyte

Date of Transfusion: ____/____/_____ ☐ UNKNOWN

Did the patient experience a transfusion adverse reaction? ☐ 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 _____

Has the patient received a previous transfusion? ☐ YES ☐ NO

***If yes, provide information about the transfusion event. If not, skip to Reaction Details section.*

Blood Product: ☐ WB ☐ RBC ☐ Platelet ☐ Plasma ☐ Cryoprecipitate ☐ Granulocyte

Date of Transfusion: ____/____/_____ ☐ UNKNOWN

Did the patient experience a transfusion adverse reaction? ☐ 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 _____

Has the patient received a previous transfusion? ☐ YES ☐ NO

***If yes, provide information about the transfusion event. If not, skip to Reaction Details section.*

Blood Product: ☐ WB ☐ RBC ☐ Platelet ☐ Plasma ☐ Cryoprecipitate ☐ Granulocyte

Date of Transfusion: ____/____/_____ ☐ UNKNOWN

Did the patient experience a transfusion adverse reaction? ☐ 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 _____

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Hemovigilance Module
Additional Worksheet

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	*Unit expiration Date/Time	*Blood group of unit	Implicated Unit?
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ ___________	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ ___________	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ ___________	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ ___________	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ ___________	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ ___________	☐ Entire unit ☐ Partial unit ______mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/_____	☐ ISBT-128	☐ Entire unit	__ __ __ __ __	___/___/_____	☐ ☐ A+ ☐ B-	N

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