OMB No. 0920-0666 Exp. Date: XX-XX-XXXX



Hemovigilance Module Adverse Reaction

*Required for saving _____ *Facility ID#: NHSN Adverse Reaction #: Patient Information *Patient ID: _____ Social Security #: ____ Secondary ID: ____ First Name: Middle Name: Last Name: М F Other *Gender: Ethnicity Hispanic or Latino Not Hispanic or Not Latino American Indian/Alaska Native Asian Black or African American Race Native Hawaiian/Other Pacific Islander White A- A+ B- B+ AB- O- O+ Type and crossmatch not done *Blood Group: *Primary underlying reason for transfusion: Coagulopathy Genetic Disorder Hematology Disorder Hemolysis Internal Bleeding Malignancy Medical Surgery Unknown Other (specify) **Reaction Details** *Date reaction occurred: / / *Time reaction occurred: ___:__ (HH:MM) Time unknown *Facility location where reaction occurred: Yes No If Yes, Incident #: *Is this reaction associated with an incident? *Signs and symptoms, laboratory: (check all that apply) Cardiovascular: **Cutaneous:** Pain: Blood pressure decrease Abdominal pain Edema Flushing Back pain Shock Hemolysis/Hemorrhage Jaundice Flank pain Disseminated intravascular coagulation Infusion site pain Other rash Hemoglobinemia Pruritis Respiratory: Positive antibody screen Urticaria Bilateral infiltrates on chest x-ray Renal: Generalized: Bronchospasm Chills/rigors Hematuria Cough Fever Hemoglobinuria Hypoxemia Oliguria Shortness of breath Other: (specify)

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 10 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).

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Component	Details (Use worksh	eet on p	age 4 for addition	al units.)			
*Transfusion			^Unit number	*Expiration		Implicated	
Date/Time MM/DD/YYYY	*Component code	*# of	Required for TRALI, GVHD,	Date/Time MM/DD/YYYY		in the adverse	
HH:MM	(check system used)	units	Infection	HH:MM	*Blood group of unit	reaction?	
	☐ ISBT-128				3 - 1 p		
, ,				, ,			
/	Codabar			/	□ A- □ A+ □ B-		
					B+ AB- AB+		
<u> </u>				<u> </u>	O- O+ N/A		
					☐ A- ☐ A+ ☐ B-		
					B+		
					O- O+ N/A		
					O- O+ IN/A		
					☐ A- ☐ A+ ☐ B-		
					□B+ □ AB- □ AB+		
:				<u>:</u>	□ O- □ O+ □ N/A		
Investigation	Results (Use case	definitio	on criteria in proto	col.)			
*Was a particula	ar unit implicated in the	adverse	reaction? Ye	es No			
*Adverse reaction	on: (check one)						
Allergic rea	ction, including anaphy	laxis					
Acute hemolytic transfusion reaction (AHTR)							
☐ Immune Antibody: ☐ Non-immune (specify)							
Delayed hemolytic transfusion reaction (DHTR)							
☐ Immune Antibody: ☐ Non-immune (specify)							
Delayed serologic transfusion reaction (DSTR) Antibody:							
Febrile non-hemolytic transfusion reaction (FNHTR)							
Hypotensiv	e transfusion reaction		,				
☐ Infection							
Was a tes	t to detect a specific pa	thogen p	performed on the <u>re</u>	<u>cipient</u> post-dona	tion?		
☐ Yes	No If Yes, positive	e or rea	active results?	Yes	☐ No		
Org1		(Org2		Org3		
Was a test to detect a specific pathogen performed on the <u>donor</u> post-donation?							
Yes	No If Yes, positiv	e or rea	active results?	Yes No			
	_				Ora3		
Org1 Org2 Org3 Org3 Was a test to detect a specific pathogen performed on the <u>unit</u> post-transfusion? (i.e., culture, serology, NAT)							
Yes No If Yes, positive or reactive results? Yes No							
	-				Ora3		
	usion purpura (PTP)	(Jig2		Org3		
Transfusion associated circulatory overload (TACO)							
Transfusion associated circulatory overload (TACO) Transfusion associated dyspnea (TAD)							

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Transfusion associated graft vs. host disease (TA-GVHD)								
Did patient receive non-irradiated blood product(s) in the two months preceding the reaction?								
Transfusion related acute lung injury (TRALI)								
	Antibody studies performed: (or	otional)						
				Test result positive				
		Not		Cognate or cross reacting antigen	No cognate or cross reacting	Not tested for cognate		
		Done	Negative	present	antigen present	antigen		
	Donor or unit HLA specificity							
	Donor or unit HNA specificity							
	Recipient HLA specificity							
I	Recipient HNA specificity							
	Unknown pathophysiology							
	Other (specify)							
*Ca	se definition criteria: Def	initive [Probable	Possible	N/A			
*Sev	verity: Non-severe S	Severe [Life-threa	atening 🗌 Death	Not deter	mined		
*Imp	outability: Definite F	Probable	Possibl	e Doubtful	Ruled Out	Not determined		
Out	come							
*Ou	tcome: ☐ Death⁺ ☐ Maj	or or long	ı-term seque	elae 🔲 Minor or	no sequelae	Not determined		
Da	ate of Death://		⁺Deaths att	ributable to trans	fusion must be re	ported to FDA.		
^If	recipient died, relationship of	transfusi	on to death:					
Г	Definite Probable	Possib		ubtful Ruled (Out Not deter	mined		
Cus	Custom Fields							
Lab				Label				
Lab		1		Label	/	1		
Lab		/		Label		_/		
Lab				Label	/			
Labo				Label		_/		
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Component Details							
*Transfusion Date/Time MM/DD/YYYY	*Component code	*# of	^Unit number Required for TRALI, GVHD,	*Expiration Date/Time MM/DD/YYYY		Implicated in the adverse	
HH:MM	(check system used)	units	Infection	HH:MM	*Blood group of unit	reaction?	
	SBT-128						
	☐ Codabar				□ A- □ A+ □ B-		
					□B+ □ AB- □ AB+		
:				:	□ O- □ O+ □ N/A		
//				/	☐ A- ☐ A+ ☐ B-		
					□B+ □ AB- □ AB+		
:				:	□ O- □ O+ □ N/A		
					□ A- □ A+ □ B-		
					□B+ □ AB- □ AB+		
:				:	□ O- □ O+ □ N/A		
					☐ A- ☐ A+ ☐ B-		
					□B+ □ AB- □ AB+		
:				:	□ O- □ O+ □ N/A		
					☐ A- ☐ A+ ☐ B-		
					□B+ □ AB- □ AB+		
:				:	□ O- □ O+ □ N/A		
					☐ A- ☐ A+ ☐ B-		
					□B+ □ AB- □ AB+		
:				:	□ O- □ O+ □ N/A		
//				/	☐ A- ☐ A+ ☐ B-		
					□B+ □ AB- □ AB+		
:				:	□ O- □ O+ □ N/A		