



Hemovigilance Module Adverse Reaction

*Required for saving

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

Share report with FDA

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+ Type and crossmatch not done Hematology

*Primary underlying reason for transfusion: Coagulopathy Genetic 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 patient was transfused: _____

*Is this reaction associated with an incident? Yes No If Yes, Incident #: _____

*Signs and symptoms, laboratory: (check all that apply)

Cardiovascular: <input type="checkbox"/> Blood pressure decrease <input type="checkbox"/> Shock	Cutaneous: <input type="checkbox"/> Edema <input type="checkbox"/> Flushing <input type="checkbox"/> Jaundice <input type="checkbox"/> Other rash <input type="checkbox"/> Pruritus (itching) <input type="checkbox"/> Urticaria (hives)	Pain: <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Back pain <input type="checkbox"/> Flank pain <input type="checkbox"/> Infusion site pain
Hemolysis/Hemorrhage <input type="checkbox"/> Disseminated intravascular coagulation <input type="checkbox"/> Hemoglobinemia <input type="checkbox"/> Positive antibody screen	Renal: <input type="checkbox"/> Hematuria <input type="checkbox"/> Hemoglobinuria <input type="checkbox"/> Oliguria	Respiratory: <input type="checkbox"/> Bilateral infiltrates on chest x-ray <input type="checkbox"/> Bronchospasm <input type="checkbox"/> Cough <input type="checkbox"/> Hypoxemia <input type="checkbox"/> Shortness of breath
Generalized: <input type="checkbox"/> Chills/rigors <input type="checkbox"/> Fever <input type="checkbox"/> Nausea/vomiting <input type="checkbox"/> 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)).

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).

Investigation Results (Use case definition criteria in protocol.)

*Adverse reaction: (check one)

- Allergic reaction, including anaphylaxis
- 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(ies): _____
- Febrile non-hemolytic transfusion reaction (FNHTR)
- Hypotensive transfusion reaction
- Infection

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 _____

- Post transfusion purpura (PTP)
- Transfusion associated circulatory overload (TACO)
- Transfusion associated dyspnea (TAD)
- Transfusion associated graft vs. host disease (TA-GVHD)

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

- Transfusion related acute lung injury (TRALI)

Antibody studies performed: (optional)

	Not Done	Negative	Test result positive		
			Cognate or cross reacting antigen present	No cognate or cross reacting antigen present	Not tested for cognate antigen
Donor or unit HLA specificity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Donor or unit HNA specificity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recipient HLA specificity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recipient HNA specificity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Unknown
- Other (specify) _____

*Case definition criteria: Definitive Probable Possible N/A
 *Severity: Non-severe Severe Life-threatening Death Not determined
 *Imputability: Definite Probable Possible Doubtful Ruled Out Not determined

Outcome

*Outcome: Death+ Major or long-term sequelae Minor or no sequelae Not determined
 Date of Death: ___/___/_____*Deaths attributable to transfusion must be reported to FDA.
 ^If recipient died, relationship of transfusion to death:
 Definite Probable Possible Doubtful Ruled Out Not determined

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 End Date/Time	*Component code (check system used)	*# of units	^Unit number Required for TRALI, GVHD, Infection	*Unit expiration Date/Time	*Blood group of unit	Implicated in the adverse reaction?
^IMPLICATED UNIT						
___/___/_____ :	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar	1	_____ _____ _____	___/___/_____ :	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	Y
___/___/_____ :	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		_____ _____ _____	___/___/_____ :	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
___/___/_____ :	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		_____ _____ _____	___/___/_____ :	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N

Custom Fields

Label	Label
_____ / ___ / _____	_____ / ___ / _____
_____	_____
_____	_____

Comments

Component Details (continued)

*Transfusion End Date/Time	*Component code (check system used)	*# of units	^Unit number Required for TRALI, GVHD, Infection	*Unit expiration Date/Time	*Blood group of unit	Implicated in the adverse reaction?
/ /	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		----- ---	/ /	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
:			----- ---	:		
/ /	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		----- ---	/ /	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
:			----- ---	:		
/ /	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		----- ---	/ /	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
:			----- ---	:		
/ /	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		----- ---	/ /	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
:			----- ---	:		
/ /	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		----- ---	/ /	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
:			----- ---	:		
/ /	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		----- ---	/ /	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
:			----- ---	:		
/ /	<input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar		----- ---	/ /	<input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A	N
:			----- ---	:		