



Hemovigilance Module Adverse Reaction Transfusion related acute lung injury (TRALI)

Data Field	Instructions for Form Completion
Facility ID#	The Facility ID number will be auto entered by NHSN.
Adverse Reaction #	An adverse reaction number will be auto entered by NHSN.
Patient Information	
Patient ID	Required. Enter the medical record number or other facility alphanumeric identification code for the patient. <i>Note: Facility patient information is shared across NHSN Component. When an MRN is entered for a patient that has been previously entered for another NHSN event, the patient information will automatically populate. NHSN is HIPPA compliant; it is not recommended to devise a unique patient identifier for NHSN.</i>
Sex	Required. Select the sex of the transfusion recipient.
Date of birth	Required. Enter the date of birth of the transfusion recipient.
Social Security #	Optional. For local use only.
Secondary ID	Optional. For local use only.
Medicare #	Optional. For local use only.
Last Name	Optional. For local use only.
First Name	Optional. For local use only.
Middle Name	Optional. For local use only.
Ethnicity	Optional. For local use only.
Race	Optional. For local use only.
Preferred Language	Optional. For local use only.
Interpreter Needed	Optional. For local use only.
Blood group	Required. Select the blood group of the transfusion recipient. <i>Note: If the patient's blood type does not clearly match a single blood type, select the most relevant blood type and make a note in the comments section of the form. For example, if a patient is typing with mixed field reactions following a bone marrow transplant, select the predominant blood type and enter a note in the comments section such as, "Group A recipient of group O bone marrow transplant currently typing as mixed field."</i>
Patient Medical History	
List the patient's admitting diagnosis.	Optional. Indicate the patient's admitting diagnosis. <i>NOTE: For more information about the Patient Medical History question, please refer</i>



Data Field	Instructions for Form Completion
	to the Patient Medical History QuickLearn on the NHSN Blood Safety Surveillance website .
Code:	Indicate the International Classification of Diseases (ICD) -10-CM code for the patient's admitting diagnosis.
Description:	Indicate the International Classification of Diseases (ICD) -10-CM description for the patient's admitting diagnosis.
List the patient's underlying indication for transfusion. (Use ICD-10 Diagnostic codes/descriptions)	Optional. Indicate the patient's underlying indication for transfusion.. <i>NOTE: For more information about the Patient Medical History question, please refer to the Patient Medical History QuickLearn on the NHSN Blood Safety Surveillance website.</i>
Code:	Indicate the International Classification of Diseases (ICD) -10-CM code for the patient's underlying indication for transfusion.
Description:	Indicate the International Classification of Diseases (ICD) -10-CM description for the patient's underlying indication for transfusion.
List the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. (Use ICD-10 Diagnostic codes/descriptions)	Optional. Indicate the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. <i>NOTE: For more information about the Patient Medical History question, please refer to the Patient Medical History QuickLearn on the NHSN Blood Safety Surveillance website.</i>
Code:	Indicate the International Classification of Diseases (ICD) -10-CM code for the patient's comorbid conditions at the time of the transfusion related to the adverse reaction.
Description:	Indicate the International Classification of Diseases (ICD) -10-CM description for the patient's comorbid conditions at the time of the transfusion related to the adverse reaction.
UNKNOWN	Check box if the patient's comorbid conditions at the time of the transfusion related to the adverse reaction are unknown.
NONE	Check box if the patient has <u>NO</u> comorbid conditions at the time of the transfusion related to the adverse reaction.
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)	Optional. Indicate the patient's relevant medical procedure including past procedures and procedures to be performed during the current hospital or outpatient stay. <i>NOTE: For more information about the Patient Medical History question, please refer to the Patient Medical History QuickLearn on the NHSN Blood Safety Surveillance website.</i>
Code:	Indicate the International Classification of Diseases (ICD) -10-CM code for the patient's relevant medical procedure including past procedures and procedures to be performed during the current hospital or outpatient stay.
Description:	Indicate the International Classification of Diseases (ICD) -10-CM description for the patient's relevant medical procedure including past



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	procedures and procedures to be performed during the current hospital or outpatient stay.
UNKNOWN	Check box if the patient's relevant medical procedure including past procedures and procedures to be performed during the current hospital or outpatient stay are unknown.
NONE	Check box if the patient has <u>NO</u> relevant medical procedure including past procedures and procedures to be performed during the current hospital or outpatient stay.
Additional Information	Optional. Include additional information related to the patient's medical history not included in the previous questions.
Transfusion History	
Has the patient received a previous transfusion?	Required. Indicate if the patient experienced an adverse reaction during a previous transfusion that is related to the current adverse reaction event being reported.
If yes, provide information about the transfusion event.	Optional. If the patient received a previous transfusion, complete the next section. If not, skip to Reaction Details section.
Blood Product:	Optional. Indicate the previously transfused blood product.
Date of Transfusion:	Optional. Indicate the date of the previous transfusion.
Did the patient experience a transfusion adverse reaction?	Optional. Indicate whether the patient experienced a transfusion adverse reaction related to the previous transfusion.
Type of transfusion adverse reaction:	Optional. Complete if the patient experienced a transfusion adverse reaction. Indicate the type of transfusion adverse reaction.
Specify	Optional. Complete if the patient experienced an "Other" transfusion adverse reaction. Specify the transfusion adverse reaction. <i>Note: Use this option if the recipient was diagnosed with an adverse reaction that is not defined in the Hemovigilance Module protocol (e.g., transfusion-associated acute gut injury (TRAGI), thrombosis).</i>
Reaction Details	
Date reaction occurred	Required. Enter the date the reaction was first observed in the transfusion recipient.
Time reaction occurred	Required. Enter the time the reaction was first observed in the transfusion recipient using a 24-hour clock.
Facility location where patient was transfused	Required. Select the facility location where the patient was transfused. <i>Note: Only report reactions for recipients transfused by your facility.</i>
Link/Unlink Incidents	Conditionally required. Select associated incidents from the list populated by NHSN and SAVE. <i>Note: The incident record must be entered into the system first and must include the associated Patient ID number(s). When linking the adverse reaction record, NHSN searches for matching Patient ID numbers in the incident records.</i>



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After recognition of the transfusion reaction, was the current transfusion:	Conditionally required. Indicate what action was taken with the blood product after the transfusion adverse reaction was recognized.
Investigation Results	
Transfusion related acute lung injury (TRALI)	<p>Required. Using the case definition criteria in Section 3 of the Hemovigilance Module surveillance protocol, select the adverse reaction being reported. Check the box if you are reporting Transfusion related acute lung injury (TRALI). Proceed with the next question. If you are reporting a different type of transfusion reaction, STOP. Select the form for the correct type of transfusion reaction.</p> <p>Note: Report only one adverse reaction per form. Report the reaction after the investigation has been finalized. Incomplete records cannot be saved. If new information becomes available at a later time, the record can be edited.</p>
Antibody studies performed	Optional. If antibody studies were performed on the donor and/or the recipient, enter the results.
Case definition criteria	Required. Using the case definition criteria in Section 3 of the Hemovigilance Module surveillance protocol, select the case criteria met for the reported adverse reaction.
	Check all that apply:
Other signs and symptoms	Required. Check all signs and symptoms observed in the patient at the time the reaction occurred as well as any associated laboratory findings. See Section 3 in the Hemovigilance Module surveillance protocol for a glossary of signs and symptoms.
Severity	Optional. Check all additional signs and symptoms observed in the patient at the time the reaction occurred as well as any other associated findings.
	Required. Using the severity criteria in Section 3 of the Hemovigilance Module surveillance protocol, select the severity criteria met for the reported adverse reaction.
	Did the patient receive or experience any of the following? Required. Check all options that apply. See Section 3 in the Hemovigilance Module surveillance protocol for severity definitions.
Imputability	Required. Using the imputability criteria in Section 3 of the Hemovigilance Module surveillance protocol, select the imputability criteria met for the reported adverse reaction. Note: <i>Doubtful and Ruled Out</i> need not be routinely reported.
	Which best describes the relationship between the transfusion and the reaction? Required. Check ONE option that best describes the relationship between the transfusion and the reaction. See Section 3 in the Hemovigilance Module surveillance protocol for imputability definitions.
	Did the transfusion occur at your facility? Required. Indicate whether the transfusion that likely caused the transfusion reaction occurred at your facility.



Data Field		Instructions for Form Completion
Case Definition		Automatically assigned based on responses in case definition section.
	Do you agree with the case definition designation?	Required. Indicate whether you agree with the automatically assigned case definition.
	Please indicate your designation.	Conditionally required. Select your facility's case definition.
Severity		Automatically assigned based on responses in severity section.
	Do you agree with the severity designation?	Required. Indicate whether you agree with the automatically assigned severity designation.
	Please indicate your designation.	Conditionally required. Select your facility's severity designation.
Imputability		Automatically assigned based on response selections in imputability section.
	Do you agree with the imputability designation?	Required. Indicate whether you agree with the automatically assigned imputability designation.
	Please indicate your designation.	Conditionally required. Select your facility's imputability designation.
Additional Information		Optional. Provide any additional relevant information.
Patient Treatment		
Did the patient receive treatment for the transfusion reaction?		Required. Indicate whether the patient received treatment for the transfusion adverse reaction. If the patient received treatment, complete the following section. If not, skip to the component details section.
	Select treatment(s):	Optional. Indicate the type of treatment provided in response to the transfusion adverse reaction. Select all that apply.
	Select type of medication(s), respiratory support, or renal replacement therapy	Optional. Complete if patient received medication(s), respiratory support, or renal replacement therapy. Select the type of medication(s), respiratory support, or renal replacement therapy.
	Other, Specify	Optional. Complete if patient received another type of treatment not listed above. Specify the type of treatment.
Outcome		
Outcome		Required. Enter the outcome of the transfusion recipient.
Date of death		Conditionally required. If the recipient died following the adverse reaction, enter the date of death whether or not the death was transfusion related.
Relationship of transfusion to death		Conditionally required. If the recipient died following the adverse transfusion reaction, indicate the relationship of the transfusion to death using the imputability criteria for "Other/Unknown" adverse



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	reactions defined in Section 3 of the Hemovigilance Module surveillance protocol.
Cause of death:	Optional. Indicate the cause of death.
Was an autopsy performed?	Optional. Indicate whether an autopsy was performed.
Component Details	
Was a particular unit implicated in (i.e., responsible for) the adverse reaction?	Required. Indicate whether or not a specific unit could be identified as the likely cause of the adverse reaction. Details for the implicated unit must be entered on the first row of the “Component Details” table. Determine “implicated” independent of case definition and imputability criteria. If only one unit was transfused, that unit must be implicated in the reaction. If TACO is being reported, no specific unit may be implicated regardless of the number of units transfused.
Transfusion Start Date	Optional. Enter the date the transfusion started.
Transfusion Start Time	Optional. Enter the time the transfusion started using a 24-hour clock.
Transfusion End Date	Required. Enter the date the transfusion ended.
Transfusion End Time	Required. Enter the time the transfusion ended using a 24-hour clock.
Component code (check system used)	Required. Select the labeling system used for the transfused component(s). Select Other to list a local blood product code. Note: Codabar- and ISBT 128-labeled products may be entered, but each must be entered on their own row.
Component code (_____)	<p>Required. Enter the component code for the product transfused using only the portion that identifies the product type. In the sample label below, the code that identifies the product type is 04250.</p>  <p><i>Note: Enter all components administered within 24 hours prior to an acute transfusion reaction. Enter only the component(s) most likely responsible for delayed reactions based on temporal relationship and clinical judgment.</i></p> <p><i>Note: If the code entered does not match a product description in NHSN, “Component code not found” will appear in the product description field. Verify your data entry before continuing; an incorrect or unrecognized component code will not prevent you from saving the adverse reaction record.</i></p>
Blood collection establishment	Optional. Complete if Codabar component code was entered above. Indicate the blood collection establishment that collected the blood product.



Data Field	Instructions for Form Completion
Amount transfused at reaction onset	Optional. Indicate the amount transfusion at reaction onset.
Entire unit	Select if the entire unit was transfused at reaction onset.
Partial unit	Select if only part of the unit was transfused at reaction onset.
Volume transfused _____ mL	Complete if a partial unit was transfused. Indicate the volume transfused at reaction onset, use whole numbers (no decimals).
Unit number	<p>Required. For all reaction types, enter the individual unit number as it appears on the product label. Unit number is optional for all other adverse reactions.</p> <p>The sample ISBT-128 unit number would be entered as seen below.</p> <div style="display: flex; align-items: center; justify-content: center;">  <div style="text-align: center;"> <p><u>W</u> <u>0</u> <u>0</u> <u>0</u> <u>0</u></p> <p><u>0</u> <u>7</u></p> <p><u>1</u> <u>2</u> <u>3</u> <u>4</u> <u>5</u> <u>6</u></p> <p><u>0</u> <u>0</u></p> <p><u> </u> <u>D</u></p> </div> </div> <p><i>Note: The check digit is optional. If the check digit is entered, the system will verify that it is correct using an internal check digit calculator. If the check digit is not entered, the space will remain blank.</i></p>
Unit expiration date	<p>Required. Enter the expiration date of the unit(s). The expiration date for the sample label below would be 02/11/2007.</p> <div style="text-align: center;">  </div>
Unit expiration time	<p>Required. Enter the expiration time of the unit(s). NHSN will auto fill this editable field to 23:59(11:59PM). The expiration time for the sample label below would be 15:20.</p> <div style="text-align: center;">  </div>
Blood group of unit	Required. Select the blood group of the unit(s) transfused; enter N/A for products where blood group is not applicable.
Implicated in the adverse reaction?	Conditionally required. If a particular unit was implicated, the unit details must be entered on the first row and this box will be checked. If no unit can be implicated, these boxes will be inactive.
Custom Fields	
Optional. Up to 50 custom fields may be added to this form for local use. Custom data may be collected in an alphanumeric, numeric, or date format.	



Data Field	Instructions for Form Completion
Comments	
Optional. Enter additional information about the incident.	