

Hemovigilance Module

Transfusion Transmitted Infection (TTI) Investigation Form

Data Field	Instructions for Form Completion
Facility ID#	Required. The NHSN- assigned Facility ID number will be auto generated by the NHSN application.
Reporter Name	Required. Select the name of the facility's personnel that will be completing and submitting the form.
NHSN Adverse Reaction #	An adverse reaction number will be auto generated by the NHSN application.
Recipient Information	
Last Name	Optional. List the recipient's last name.
First Name	Optional. List the recipient's first name.
Middle Name	Optional. List the recipient's middle name.
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>
Date of Birth	Required. Enter the date of birth of the transfusion recipient.
State of Residence	Required. Select the state of residence for the transfusion recipient.
Sex	Required. Select the sex of the transfusion recipient.
Medical Record #	Required. List the facility's record number for the recipient.
Ethnicity	Optional. Select the transfusion recipient's ethnicity.
Race	Optional. Indicate the transfusion recipient's race. Select all that apply.
Blood group	Optional. Select the blood group of the transfusion recipient. <i>Note: If the recipient'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 recipient is typing with mixed field reactions following a bone marrow transplant, select the predominant blood type and enter a note in the Facility Investigation Notes section such as, "Group A recipient of group O bone marrow transplant currently typing as mixed field."</i>
Recipient Medical History	
Did the recipient have any of the following comorbid conditions present at the time of transfusion?	Required. Indicate if the recipient had sickle cell disease or thalassemia at the time of the transfusion.

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Sickle cell disease	Select 'Yes', 'No', or 'Unknown'.
Thalassemia	Select 'Yes', 'No', or 'Unknown'.
Recipient Adverse Reaction Details	
Date reaction occurred (Onset Date)	Required. Enter the date the reaction was first observed in the transfusion recipient or mark 'Unknown'.
Time reaction occurred	Optional. Enter the time the reaction was first observed in the transfusion recipient using a 24-hour clock or mark 'Unknown'.
Did the transfusion occur at your facility?	Required. Indicate whether the recipient's transfusion occurred at your facility by selecting either 'Yes' or 'No'.
If no, facility name:	Required. Enter the facility's name where the transfusion occurred.
If no, facility address:	Required. Enter the facility's address where the transfusion occurred.
Facility location where patient was transfused	Optional. Based on CDC location list, select the location where the patient was transfused at your facility. If your facility is not the transfusing facility, leave blank.
Is this reaction associated with an incident?	Optional. Select 'Yes' or 'No' if this reaction is associated with an incident.
If Yes, Incident Type:	Optional. Select all incident codes that apply to the patient's reaction incident.
Was this reaction reported following a massive transfusion protocol?	Required. Select 'Yes', 'No', or 'Unknown' if the reaction was reported after a massive transfusion protocol.
Recipient Laboratory Testing	
Was a test to detect a specific pathogen performed on a recipient clinical sample that was collected pre-transfusion?	Required. Select 'Yes', 'No' or 'Pending' to indicate whether a test was performed on a recipient's clinical sample, collected pre-transfusion, to detect a specific pathogen.
If Yes, positive or reactive results?	Required. Indicated whether the test results were positive or reactive by selecting 'Yes', 'No', or 'Pending Results'.
Collection Date	Required. Indicate the date that the clinical sample was collected pre-transfusion.
Org1:	Required. Identify the organism that was detected.
Org2:	Optional. Identify the organism that was detected.
Org3:	Optional. Identify the organism that was detected.
Was a test to detect a specific pathogen performed on a recipient post-transfusion?	Required. Select 'Yes', 'No' or 'Pending' to indicate whether a test was performed on a recipient's clinical sample, collected post-transfusion, to detect a specific pathogen.
If Yes, positive or reactive results?	Required. Indicated whether the test results were positive or reactive by selecting 'Yes', 'No', or 'Pending Results'.

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Collection Date	Required. Indicate the date that the clinical sample was collected post-transfusion.
Org 1:	Required. Identify the organism that was detected.
Org2:	Optional. Identify the organism that was detected.
Org3:	Optional. Identify the organism that was detected.
Recipient Clinical Presentation	
Signs and symptoms	Optional. Select all signs and symptoms that the recipient has experienced. Refer to the NHSN Biovigilance Component Hemovigilance Module Protocol for glossary for definitions.
Other	Optional. Complete if the recipient displayed any signs and symptoms not listed above.
Recipient Treatment	
Did the patient receive treatment for the transfusion reaction?	Optional. Indicate whether the recipient received treatment for the transfusion transmitted infection.
If yes, select treatment(s):	Optional. Indicate the type of treatment provided in response to the transfusion transmitted infection. Select all that apply.
Select type of medication(s), volume resuscitation, respiratory support, or renal replacement therapy	Optional. Complete if recipient received medication(s), volume resuscitation, respiratory support, renal replacement therapy, phlebotomy (to decrease blood volume) or other. Select the type of medication(s), volume resuscitation, respiratory support, or renal replacement therapy.
Other, Specify	Optional. If other, specify the type of treatment.
Recipient Outcome	
Outcome	Required. Enter the outcome of the transfusion recipient.
If Death, Date of Death	Required. If the recipient died following the adverse reaction, enter the date of death whether the death was transfusion related.
If death, cause of death:	Required. Indicate the International Classification of Diseases (ICD) -10-CM code for the recipient's cause of death.
If recipient died, relationship of transfusion to death:	Required. Indicate the relationship between the transfusion and recipient's death by selecting 'Definite', 'Probable', 'Possible', 'Doubtful', 'Ruled Out', or 'Not Determined' using FDA criteria.
Recipient Epidemiologic Risk Assessment	
Temporally associated unexplained clinical illness consistent with infection	Optional. Check box.
Evidence of the pathogen in an additional recipient of a component from the same donation	Optional. Check box.

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	Related Recipient Report IDs:	Optional. List the Adverse Reaction IDs from the related recipient.
	Animal exposure in the 30 days prior to symptom onset	Optional. Check box.
	Mosquito exposure in the 30 days prior to symptom onset	Optional. Check box.
	Tick exposure in the 30 days prior to symptom onset	Optional. Check box.
	Exposure to individual exhibiting similar symptoms prior to symptom onset	Optional. Check box.
	International travel in the 30 days before symptom onset	Optional. Check box.
	International travel Country	Optional. Enter the country name that the recipient traveled to.
	International travel Arrival Date	Optional. Enter the date that the recipient arrived at this country.
	International travel Departure Date	Optional. Enter the date that the recipient departed from this country.
	Domestic travel (outside of state of residence in the 30 days before symptom onset)	Optional. Check box.
	Domestic travel State	Optional. Enter the state name that the recipient traveled to.
	Domestic travel Arrival Date	Optional. Enter the date that the recipient arrived in the state.
	Domestic travel Departure Date	Optional. Enter the date that the recipient departed from the state.
	Recipient has lived outside the U.S.?	Optional. Check box.
	Country	Optional. Enter the country name that the recipient has resided in.
	Arrival Date	Optional. Enter the date the recipient arrived at this country.
	Departure Date	Optional. Enter the date that the recipient departed from this country.
	Recipient traveled outside the U.S. in the last two years?	Optional. Check box.
	Country	Optional. Enter the country name that the recipient traveled to.

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	Arrival Date	Optional. Enter the date the recipient arrived at this country.
	Departure Date	Optional. Enter the date that the recipient departed from this country.
Transfused Component Details (recipient)		
<i>Include all transfused components the patient received in the 30 days prior to symptom onset.</i>		
	Transfusion Start Date	Required. Enter the date the transfusion started.
	Transfusion Start Time	Required. 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.
	ISBT-128 Component code	Required. Indicate the ISBT-128 component code for the product transfused using only the portion that identifies the product type.
	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, in whole numbers (no decimals).
Donor Identification Number (DIN)	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. The sample ISBT-128 unit number would be entered as seen below.  <u>W</u> <u>0</u> <u>0</u> <u>0</u> <u>0</u> <u>0</u> <u>7</u> <u>1</u> <u>2</u> <u>3</u> <u>4</u> <u>5</u> <u>6</u> <u>0</u> <u>0</u> <u>D</u>	
Unit expiration date	Required. Enter the expiration date of the unit(s). The expiration date for the sample label below would be 02/11/2007.  Expiration Date/Time 11 FEB 2007 15:20	
Unit expiration time	Required. Enter the expiration time of the unit(s). The expiration time for the sample label below would be 15:20.	

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Unit Blood group	Required. Select the blood group of the unit(s) transfused; enter N/A for products where blood group is not applicable.
Implicated unit?	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.
Unit tested?	Optional.
Pathogen Detected?	Optional.
Pathogen	Optional. Report pathogens detected in component. If more than three, notify HV team.
Blood Product/ Donor Investigation	
Was a test to detect a specific pathogen performed on the donor pre-donation?	Required. Select 'Yes', 'No', 'Pending', or 'Unknown' to indicate whether a test was performed on the donor's pre-donation to detect a specific pathogen.
If Yes, positive or reactive results?	Required. Indicated whether the test results were positive or reactive by selecting 'Yes', 'No', or 'Pending'.
Collection Date	Required. Indicate the date that the donor's sample was collected pre-donation.
Org 1	Required. Identify the organism that was detected.
Org2:	Optional. Identify the organism that was detected.
Org3:	Optional. Identify the organism that was detected.
Was a test to detect a specific pathogen performed on the donor post-donation?	Required. Select 'Yes', 'No', 'Pending', or 'Unknown' to indicate whether a test was performed on the donor's post-donation to detect a specific pathogen.
If Yes, positive or reactive results?	Required. Indicated whether the test results were positive or reactive by selecting 'Yes', 'No', or 'Pending Results'.
Collection Date	Required. Indicate the date that the donor's sample was collected post-donation.
Org 1	Required. Identify the organism that was detected.
Org2:	Optional. Identify the organism that was detected.
Org3:	Optional. Identify the organism that was detected.
Investigation Findings	
Adverse Reaction	Auto populated as Transfusion Transmitted Infection.
Case definition	Required. Refer to case definition in the NHSN Biovigilance Component Hemovigilance Module Protocol.
Severity	Required. Refer to severity classification in the NHSN Biovigilance Component Hemovigilance Module Protocol.

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Imputability	Required. Refer to imputability classification in the NHSN Biovigilance Component Hemovigilance Module Protocol.
Facility/ Health Department Investigation Notes	
Facility Investigation Notes	Optional. Enter additional information about the incident.
Facility/ Health Department Investigation Status	Required. Select the status of this investigation. If report is marked as 'Complete', but some required fields are missing, include reasoning in 'Facility Investigation Notes' section.
CDC Investigation (to be completed by CDC staff)	
CDC Investigator ID	This section will be completed by CDC staff only.
TTI Rapid Alert Report ID	This section will be completed by CDC staff only.
Was FDA notified?	This section will be completed by CDC staff only.
Was the blood supplier notified of this adverse reaction?	This section will be completed by CDC staff only.
Was a traceback conducted?	This section will be completed by CDC staff only.
CDC SME Group notified?	This section will be completed by CDC staff only.
CDC SME Case ID	This section will be completed by CDC staff only.
State health department notified?	This section will be completed by CDC staff only.
Report status	This section will be completed by CDC staff only.
CDC Investigation Notes	This section will be completed by CDC staff only.