



**Table 5. Hemovigilance Module Adverse Reaction (CDC 57.304)**

| 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.   |
| <b>Patient Information</b>                |  |
| 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>   |
| Gender                                    | Required. Select the gender 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.  |
| 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> |
| Primary underlying reason for transfusion | Required: Select the <b>primary</b> reason this patient received a transfusion. If none of the options are adequate, select "other" and specify the reason in detail. Avoid using "anemia" as it does not describe the underlying medical condition of the transfusion recipient.  |
| <b>Reaction Details</b>                   |  |
| 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.   |



| Data Field   | Instructions for Form Completion  |
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| Facility location where patient was transfused   | Required. Select the facility location where the patient was transfused. <b>Note: Only report reactions for recipients transfused by your facility.</b>   |
| 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 <b>first</b> 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>  |
| Signs and symptoms, laboratory   | Required. Check <b>all</b> signs and symptoms observed in the patient at the time the reaction occurred as well as any associated laboratory findings. These may or may not be directly related to the observed reaction as patients receiving transfusions typically have underlying medical conditions. See Section 3 in the Hemovigilance Module surveillance protocol for a glossary of signs and symptoms. |
| <b>Investigation Results</b>   |   |
| Adverse reaction   | Required. Using the case definition criteria in Section 3 of the Hemovigilance Module surveillance protocol, select the adverse reaction being reported. Report only one adverse reaction per form. <b>Note: 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.</b>            |
| <ul style="list-style-type: none"> <li>• Allergic reaction, including anaphylaxis</li> </ul>           |   |
| <ul style="list-style-type: none"> <li>• Acute hemolytic transfusion reaction (AHTR)</li> </ul>        |   |
| Type of AHTR   | Conditionally required. Indicate whether the AHTR was immune-mediated (specify Ab) or non-immune mediated (specify cause).  |
| <ul style="list-style-type: none"> <li>• Delayed hemolytic transfusion reaction (DHTR)</li> </ul>      |   |
| Type of DHTR   | Conditionally required. Indicate whether the DHTR was immune-mediated (specify Ab) or non-immune mediated (specify cause).  |
| <ul style="list-style-type: none"> <li>• Delayed serologic transfusion reaction (DSTR)</li> </ul>      |   |
| DSTR antibody  | Conditionally required. Specify Antibody(s).  |
| <ul style="list-style-type: none"> <li>• Febrile non-hemolytic transfusion reaction (FNHTR)</li> </ul> |   |
| <ul style="list-style-type: none"> <li>• Hypotensive transfusion reaction</li> </ul>                   |   |
| <ul style="list-style-type: none"> <li>• Infection</li> </ul>  |   |
| Was a test to detect a specific antigen performed on the <b>recipient</b> post-transfusion?            | Conditionally required. Indicate whether or not a test was performed on the <b>recipient</b> to detect a specific pathogen after the blood product(s) was/were administered to the recipient.   |
| Positive/Reactive?   | Conditionally required. If a post-transfusion test was performed, indicate whether the test was positive or reactive.   |
| Specify organism   | Conditionally required. If a post-transfusion test was performed and found to be positive or reactive, report the detected organism(s).   |



| Data Field   | Instructions for Form Completion   |
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| Was a test to detect a specific antigen performed on the <b>donor</b> post-donation?   | Conditionally required. Indicate whether or not a test was performed on the <b>donor</b> to detect a specific pathogen after the blood was donated.  |
| Positive/Reactive?   | Conditionally required. If a post-donation test was performed, indicate whether the test was positive or reactive.   |
| Specify organism   | Conditionally required. If a post-donation test was performed and found to be positive or reactive, report the detected organism(s).   |
| Was a test to detect a specific antigen performed on the <b>unit</b> post-transfusion?   | Conditionally required. Indicate whether or not a test was performed on the <b>implicated blood product</b> to detect a specific pathogen after the blood product(s) was/were administered to the recipient.   |
| Positive/Reactive?   | Conditionally required. If a post-transfusion test was performed, indicate whether the test was positive or reactive.  |
| Specify organism   | Conditionally required. If a post-transfusion test was performed and found to be positive or reactive, enter the detected organism(s).   |
| <ul style="list-style-type: none"> <li>• Post transfusion purpura (PTP)</li> <li>• Transfusion-associated circulatory overload (TACO)</li> <li>• Transfusion-associated dyspnea (TAD)</li> <li>• Transfusion-associated graft vs. host disease</li> </ul>  |  |
| Did the patient receive non-irradiated blood product(s) in the two months preceding the reaction?  | Conditionally required. Specify whether the patient received any non-irradiated blood products in the two months prior to the TAGVHD reaction.   |
| <ul style="list-style-type: none"> <li>• Transfusion-related acute lung injury (TRALI)</li> </ul>  |  |
| Antibody studies performed   | Optional. If antibody studies were performed on the donor and/or the recipient, enter the results.   |
| <ul style="list-style-type: none"> <li>• <i>Unknown Note: Use this category if the patient experienced transfusion-related symptoms, but the medical event that caused the symptoms could not be diagnosed.</i></li> <li>• <i>Other (specify) 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></li> </ul> |  |
| 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.   |
| Severity   | Required. Using the case definition criteria in Section 3 of the Hemovigilance Module surveillance protocol, select the severity criteria met for the reported adverse reaction.   |
| Imputability   | Required. Using the case definition criteria in Section 3 of the Hemovigilance Module surveillance protocol, select the imputability criteria met for the reported adverse reaction. <i>Note: <b>Doubtful</b> and <b>Ruled Out</b> need not be routinely reported.</i> |



| Data Field  | Instructions for Form Completion   |
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| <b>Outcome</b>  |  |
| 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 reactions defined in Section 3 of the Hemovigilance Module surveillance protocol.  |
| <b>Component Details</b>  |  |
| 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 <b>End</b> Date   | Required. Enter the date the transfusion ended.  |
| Transfusion <b>End</b> 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). <b>Note: Codabar- and ISBT 128-labeled products may be entered, but each must be entered on their own row.</b>  |
| 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> <div data-bbox="537 1373 919 1539" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p><b>AS-5 RED BLOOD CELLS</b><br/>           ADENINE-SALINE SOLUTION ADDED<br/>           15.0mEq Sodium Added 04250<br/>           From 450mL<br/>           CPD Whole Blood<br/>           Store at 1 to 6 C.</p>  <p>FORM # 98750u5</p> </div> <p><i>Note: Enter <b>all</b> components administered within 24 hours prior to an <b>acute</b> transfusion reaction. Enter only the component(s) most likely responsible for <b>delayed</b> 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. <b>Verify your data entry before continuing</b>; an incorrect or unrecognized component code will not prevent you from saving the adverse reaction record.</i></p> |
| # of units  | Required. Enter the total number of units transfused for each  |



| Data Field   | Instructions for Form Completion  |
|--|---|
| Unit number  | <p>component type. Multiple units may be entered using up to 20 rows.</p> <p>Conditionally required. If reporting a TRALI, GVHD, or infection reaction, 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.</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> <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  | <p>Required. Select the blood group of the unit(s) transfused; enter <b>N/A</b> for products where blood group is not applicable.</p>   |
| Implicated in the adverse reaction?  | <p>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.</p>   |
| <b>Custom Fields</b>   |   |
| <p>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.</p> |   |
| <b>Comments</b>  |   |
| <p>Optional. Enter additional information about the incident.</p>  |   |