# National Healthcare Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol

Division of Healthcare Quality Promotion
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## Version History

| Version | Release Date | Summary of Revisions |
|---|---|---|
| 1.0 | March 2009 | First version publicly released. |
| 1.1 | June 2010 | Revised background and text in main body of document. |
| | | Revised case definition criterion based on WG recommendations, pilot responses, and CDC recommendations. |
| | | Updated FNHTR definition to allow reaction without documented fever. |
| | | Defined hypotension for infants and small children |
| | | Clarified TAGVHD probable and possible criteria. |
| 1.2 | July 2010 | Corrected definition of hypoxemia in glossary of terms. |
| 1.3 | June 2011 | Added version number and version history summary. |
| | | Summarized introduction and background sections for brevity. |
| | | Reorganized surveillance methods section for ease of use. |
| | | Clarified reporting of “approved deviation” incidents. |
| | | Clarified use of “other” in adverse reaction reporting. |
| | | Clarified use of “doubtful” or “ruled out” in adverse reaction reporting. |
| | | Added denominator summary options to list of available analysis reports. |
| | | Replaced < and > signs with appropriate text for. |
| | | Added “cessation of” to time frame requirements in case definitions. |
| | | NEW probable case definition category for allergic reaction reporting. |
| | | Updated adult hypotensive reaction case definition to align with updated ISBT definition. |
| | | NEW possible imputability category for DHTR. |
| | | DELETED possible case definition category for hypotensive reaction. |
| | | NEW probable imputability category for PTP reaction. |
| | | Updated and clarified imputability categories for TAGVHD reaction. |
| | | DELETED possible case definition category for TRALI. |
| | | Simplified imputability criteria for TTI. |
| | | Clarified case definition and imputability criteria for all adverse reactions. |
| 2.0 | January 2013 | Complete revision of organization and presentation of information |
| | | Major change in incident reporting requirements. With this release, only incidents that relate to an adverse patient reaction are required for participation. |
| | | Major change in adverse reaction reporting requirements. With this release, minor allergic reactions are no longer required for participation. |
| | | Combined the signs/symptoms with laboratory/radiology columns in case definition tables for clarity. Listed criteria in alphabetical order where possible for consistency and clarity. Moved general severity requirements from the appendix to the criteria tables where they were previously missing. |
| | | Re-ordered adverse reaction tables to put respiratory reactions first. |
| | | Added Imputability criteria of Doubtful, Ruled Out, and Not Determined to the case definition tables as OPTIONAL reporting categories. The reporting is not a change, but including them in the table is new. They were added for clarity. |
| | | Added specific AHTR criteria to allow for reporting of non-immune mediated reactions. |
| | | Added a separate case definition table for Other and Unknown reactions. These categories are available for OPTONAL use. |
| | | Removed redundant and unnecessary appendices. |
| 2.1 | August 2013 | Minor revisions to verbiage throughout for clarity. |
| | | Added definitions and illustration of surveillance key terms in Section 1. |
| | | Added clarification of surveillance vs. clinical definitions in Section 1. |
| | | Added less-specific case definition categories for OPTIONAL reporting of cases that do not fully meet CDC case criteria for the following reactions: hypotension, febrile non-hemolytic, acute hemolytic and delayed hemolytic. |

| Version | Release Date | Summary of Revisions |
|---|---|---|
| | | Added a possible case definition category for TTI for OPTIONAL reporting of syndromic cases that are not laboratory confirmed. |
| 2.1.1 | September 2013 | Updated diagram in Section 1 and added version history for v2.0 and v2.1. |
| 2.1.2 | January 2014 | Updated the incident codes in Section 4 and included required reporting of discards and total crossmatch procedures on the Monthly Reporting Denominators form in Section 5. |
| 2.1.3 | August 2014 | Added a suggested citation for the surveillance protocol in Section 1. Updated the acute hemolytic case definition in Section 3 for clarity. Updated the reporting requirements in Section 5 for clarity. |
| 2.2 | January 2016 | Updated contact instructions for consistency in Section 1: User support |
| | | Updated version number in Section 1: Suggested Citation |
| | | Remove Root Cause Analysis Result from Section 4: Incident Glossary |
| | | Updated denominator report description to include Pathogen-reduced products in Section 5: Required Reporting |
| 2.3 | June 2016 | Updated denominator report description to include Table 3 description. |
| 2.4 | January 2017 | Section 1: Setting – Added additional Annual Facility form for Non-Acute Care Facilities to report. |
| | | Section 2: Annual Facility Survey – Added information about Non-Acute Care Facility Annual Facility Survey, Added links to the Annual Facility Survey – Non-Acute Care Facility form and table of instructions for clarity. |
| 2.5 | January 2018 | Section 1: Training, User Support, Data Reporting – Minor language changes for clarification |
| | | Section 3: Adverse Reaction Classification – Added information about module-generated classification designations. |
| | | Adverse Reaction Glossary: Updated the definition of fever to be consistent with FNHTR criteria. |
| 2.5.2. | April 2018 | Section 4: Incident codes - UT 06 – “incompatible” replaced with “unapproved” |
| 2.6 | March 2021 | Section 3: Adverse Reaction Classification - Updated case definition criteria for TACO reactions |
| 2.7 | October 2022 | Section 4: Updated the incident codes in Section 4 to include under-transfusion with the creation of a new process code: no blood (NB) and four incident codes |
| 2.8 | February 2023 | Section 4: Optional Reporting: Clarification regarding analysis of optional reporting |
| 2.9 | March 2025 | Section 2: Added new sex response option to acute (Question 34) and non-acute (Question 21) annual facility survey. Gender and sex at birth were removed as response options in the acute (Question 34) and non-acute (Question 21) annual facility survey.<br>Section 3: Added new sex variable in the adverse reaction data collection forms. Removed gender identity and sex at birth from adverse reaction data collection forms.<br>Updated links to NHSN blood safety website, TOIs, and annual facility surveys for clarity. |

# Table of Contents

# Section 1. Hemovigilance Module Surveillance Overview

**Purpose**
The National Healthcare Safety Network (NHSN) Hemovigilance (HV) Module was created to implement national surveillance of transfusion-associated adverse events aimed at improving patient safety, minimizing morbidity and mortality of transfusion recipients, and identifying emerging complications and pathogens associated with blood transfusion.

**Settings**
The Hemovigilance Module may be used by any U.S. healthcare facility where blood components and manufactured blood products are transfused (e.g., adult or pediatric facilities, acute or non-acute care facilities). Surveillance must be performed facility-wide, including patient care areas for emergency, general medical, and surgical patients; obstetrics and gynecology; orthopedics, oncology, and other chronic diseases; and any other facility location where transfusions are administered.

**Methods**
The NHSN Hemovigilance Module requires comprehensive surveillance of patients and blood components throughout the transfusion process, from product receipt to administration to the patient. Participation in the NHSN Hemovigilance Module requires reporting of all adverse transfusion reactions and reaction-associated incidents that occur **for patients transfused at or by your facility** as well as a monthly summary of components transfused or discarded and patient samples collected for type and screen or crossmatch.

**Data Collection**
NHSN is a web-based application used by healthcare facilities to report surveillance data. Paper versions of all forms are used to collect data prior to data entry in the NHSN Hemovigilance Module. The paper forms are available on the NHSN Blood Safety Surveillance website. A link to the appropriate form(s) and their instructions is provided in the following sections for your convenience.

**Training**
Training presentations are available on the NHSN Blood Safety Surveillance website for self-paced training and must be reviewed prior to participating in the Hemovigilance Module. CDC also provides webinar and in-person training opportunities for current NHSN participants. These opportunities are communicated through the NHSN quarterly newsletter and emails from the Hemovigilance Team.

**User Support**
CDC is available to answer your questions about the Surveillance Protocol and to help navigate the NHSN web application. Please contact us at nhsn@cdc.gov. Type **HEMOVIGILANCE** in the subject line for quickest routing to the Hemovigilance Team.

**Suggested Citation for the Hemovigilance Module Surveillance Protocol**

> U.S. Centers for Disease Control and Prevention. The National Healthcare Safety Network (NHSN) Manual: Biovigilance Component v2.9. Atlanta, GA: Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases. Available at: http://www.cdc.gov/nhsn/PDFs/Biovigilance/BV-HV-protocol-current.pdf. Accessed [enter date].

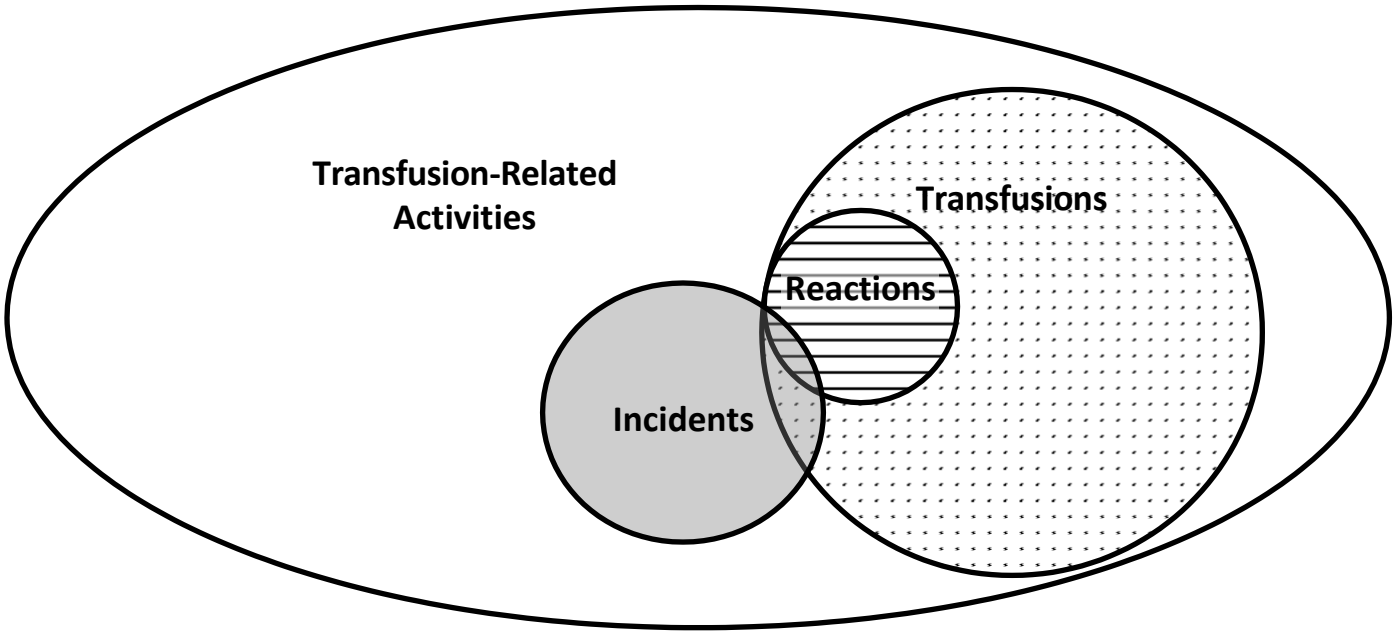
**Key Terms (see Fig. 1)**

- **Adverse event:** An unintended and undesirable occurrence before, during or after transfusion of blood or blood components. Adverse events include both incidents and adverse reactions.
- **Adverse reaction:** An undesirable response or effect in a patient temporally associated with the administration of blood or blood components. It may or may not be the result of an incident.
- **Incident:** Any error or accident that could affect the quality or efficacy of blood, blood components, or patient transfusions. It may or may not result in an adverse reaction in a transfusion recipient.
- **Near miss:** A subset of incidents that are discovered before the start of a transfusion that *could* have led to a wrongful transfusion or an adverse reaction in a transfusion recipient.

**Data Reporting (See Fig. 1)**

- An annual facility demographic and practice survey for each **calendar** year of participation
- ALL adverse reactions defined in this protocol that follow transfusion **at or by your facility**
- ALL incidents (i.e., errors or accidents) associated with an adverse reaction
- The number of blood components transfused or discarded and patient samples collected for type and screen or crossmatch each month

**Figure 1.** Venn diagram of NHSN Hemovigilance Module surveillance terms.




**Transfusion-Related Activities**

- Patient Sample Collection
- Sample Handling and Testing
- Inventory Management
- Patient Monitoring

**Transfusion**

- Number of Components
- Number of Patients

**Adverse Events**

**Reactions**

**Incidents**

Near Miss Incidents

Incidents Related to Transfusion (No Adverse Reaction)

Incidents Related to Transfusion and Adverse Reaction

## Section 2. Hemovigilance Module Annual Facility Survey

**Required Reporting**
Participating facilities must enter the Hemovigilance Module Annual Facility Survey at the time that they enroll or activate the Biovigilance Component and at the beginning of each calendar year thereafter. The survey is used by CDC to classify facilities for appropriate comparisons in aggregate data analyses and to learn more about common practices among transfusion services. The data collected in the survey covers the previous **calendar** year. For example, if the facility is enrolling in NHSN for the first time in October of 2013, report information for January 2012-December 2012 on the first Hemovigilance Module Annual Facility Survey. In January 2014, complete a new survey with data from January 2013-December 2013. CDC recommends collecting all survey information on a paper form before attempting to enter data into the web application.

As of January 2017, non-acute care facilities are able to report hemovigilance data to NHSN. Non-acute care facilities should complete Annual Facility Survey for Non-acute care facility 57.306. This form contains questions tailored to non-acute care facilities. Users may refer to the Non-Acute Care Facility Table of Instructions form 57.306 for detailed instruction about data collection.

**Form**
CDC 57.300 Hemovigilance Module Annual Facility Survey - Acute Care Facility

CDC 57.306 Hemovigilance Module Annual Facility Survey - Non-Acute Care Facility

**Form Instructions**
CDC 57.300 Hemovigilance Module Annual Facility Survey - Acute Care Facility Table of Instructions

CDC 57.306 Hemovigilance Module Annual Facility Survey - Non-Acute Care Facility Table of Instructions

# Section 3: Hemovigilance Module Adverse Reactions

### Required Reporting

All CDC-defined transfusion-associated adverse reactions that are possibly, probably, or definitely related to a **transfusion performed by the participating facility** must be reported to NHSN. If a patient experiences more than one adverse reaction during or following the same transfusion episode, complete a separate form for each reaction. Adverse reaction reports should be entered into NHSN after an investigation of the reaction has been completed and imputability has been determined to the extent possible. Reports should be entered within 30 days of the month that the reaction occurred or when the investigation is completed.

### Optional Reporting

Reporting suspected adverse reactions where imputability is determined to be doubtful or ruled out is not required. A facility may report reactions determined to be doubtful or ruled out in order to use NHSN to document transfusion reaction investigations each month. Adverse reactions that are not defined in the surveillance protocol may also be reported using the 'Other' and 'Unknown' adverse reaction categories; standard severity and imputability criteria are provided for that purpose.

### Adverse Reaction Classification

Each CDC-defined transfusion-associated adverse reaction **must** be classified according to the reaction-specific case definition, severity, and imputability criteria printed in the protocol. It is imperative that every facility classify adverse reactions according to protocol definitions. Accurate classification will usually require a detailed review of the patient record.

To assist in classification, the Module will generate and assign designations for case definition, severity, and imputability based on signs, symptoms, and lab results entered in the investigation results section of the adverse reaction form.

Surveillance definitions are distinctly different from clinical definitions. Surveillance definitions are designed to capture data consistently and reliably in order to identify trends and inform quality improvement practices. The surveillance definitions are not intended as clinical diagnostic criteria or to provide treatment guidance.

#### Defined Adverse Reactions

- Transfusion-associated circulatory overload (TACO)
- Transfusion-related acute lung injury (TRALI)
- Transfusion-associated dyspnea (TAD)
- Allergic reaction (where severity is severe, life threatening, or death)
- Hypotensive transfusion reaction
- Febrile non-hemolytic transfusion reaction (FNHTR)
- Acute hemolytic transfusion reaction (AHTR)
- Delayed hemolytic transfusion reaction (DHTR)
- Delayed serologic transfusion reaction (DSTR)
- Transfusion-associated graft vs. host disease (TAGVHD)
- Post-transfusion purpura (PTP)
- Transfusion-transmitted infection (TTI)

### Form

Adverse reaction forms are available at the NHSN Blood Safety Surveillance website.

### Form Instructions

Adverse Reaction forms' Table of Instructions are available at the NHSN Blood Safety Surveillance website.

# Adverse Reaction Case Classification Criteria Tables

## Transfusion-associated circulatory overload (TACO)

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>New onset or exacerbation of 3 or more of the following within **12 hours** of cessation of transfusion: **(At least 1 of the following:)**<br><br>•Evidence of acute or worsening respiratory distress (dyspnea, tachypnoea, cyanosis and decreased oxygen saturation values in the absence of other specific causes) **and/or**<br><br>•Radiographic or clinical evidence of acute or worsening pulmonary edema (crackles on lung auscultation, orthopnea, cough, a third heart sound and pinkish frothy sputum in severe cases); **or both AND**<br><br>•Elevated brain natriuretic peptide (BNP) or NT-pro BNP relevant biomarker<br><br>•Evidence of cardiovascular system changes not explained by underlying medical condition (Elevated central venous pressure, evidence of left heart failure including development of tachycardia, hypertension, widened pulse pressure, jugular venous distension, enlarged cardiac silhouette and/or peripheral edema)<br><br>•Evidence of fluid overload<br><br>**Probable:**<br>N/A<br>**Possible:**<br>N/A | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.<br><br>**Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>No other explanations for circulatory overload are possible.<br><br>**Probable:**<br>Transfusion is a likely contributor to circulatory overload<br>**AND EITHER**<br>The patient received other fluids as well<br>**OR**<br>The patient has a history of cardiac insufficiency that could explain the circulatory overload, but transfusion is just as likely to have caused the circulatory overload.<br><br>**Possible:**<br>The patient has a history of pre-existing cardiac insufficiency that most likely explains circulatory overload.<br><br>**OPTIONAL**<br><br>**Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Transfusion-related acute lung injury (TRALI)

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>NO evidence of acute lung injury (ALI) prior to transfusion<br>**AND**<br>ALI onset during or within 6 hours of cessation of transfusion<br>**AND**<br>Hypoxemia defined by any of these methods:<br>• PaO2/FiO2 less than or equal to 300 mm Hg<br>• Oxygen saturation less than 90% on room air<br>• Other clinical evidence<br>**AND**<br>Radiographic evidence of bilateral infiltrates<br>**AND**<br>No evidence of left atrial hypertension (i.e., circulatory overload)<br><br>**Probable:**<br>N/A<br><br>**Possible:**<br>N/A | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.<br><br>**Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>There are no alternative risk factors for ALI present.<br><br>**Probable:**<br>N/A<br><br>**Possible:**<br>There is evidence of other causes for acute lung injury such as:<br><br>Direct Lung Injury<br>• Aspiration<br>• Pneumonia<br>• Toxic inhalation<br>• Lung contusion<br>• Near drowning<br><br>Indirect Lung Injury<br>• Severe sepsis<br>• Shock<br>• Multiple trauma<br>• Burn injury<br>• Acute pancreatitis<br>• Cardiopulmonary bypass<br>• Drug overdose<br><br>**OPTIONAL**<br><br>**Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Transfusion-associated dyspnea (TAD)

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>Acute respiratory distress occurring within 24 hours of cessation of transfusion<br>**AND**<br>Allergic reaction, TACO, and TRALI definitions are not applicable.<br><br>**Probable:**<br>N/A<br><br>**Possible:**<br>N/A | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.<br><br>**Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>Patient has no other conditions that could explain symptoms.<br><br>**Probable:**<br>There are other potential causes that could explain symptoms, but transfusion is the most likely cause.<br><br>**Possible:**<br>Other present causes are most likely, but transfusion cannot be ruled out.<br><br>**OPTIONAL**<br><br>**Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Allergic reaction

**Note:** Minor allergic reactions (Non-severe) do not have to be reported to NHSN.

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>**2 or more** of the following occurring during or within 4 hours of cessation of transfusion:<br>• Conjunctival edema<br>• Edema of lips, tongue and uvula<br>• Erythema and edema of the periorbital area<br>• Generalized flushing<br>• Hypotension<br>• Localized angioedema<br>• Maculopapular rash<br>• Pruritus (itching)<br>• Respiratory distress; bronchospasm<br>• Urticaria (hives)<br><br>**Probable:**<br>**ANY 1** of the following occurring during or within 4 hours of cessation of transfusion:<br>• Conjunctival edema<br>• Edema of lips, tongue and uvula<br>• Erythema and edema of the periorbital area<br>• Localized angioedema<br>• Maculopapular rash<br>• Pruritus (itching)<br>• Urticaria (hives) | **Severe, Life-threatening, Death:**<br>Involves respiratory and/or cardiovascular systems and presents like an anaphylactic reaction. There is anaphylaxis when, in addition to mucocutaneous symptoms, there are airway symptoms, hypotension, or associated symptoms like hypotonia and syncope. The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnea, cough, wheezing, bronchospasm, hypoxemia). Such a reaction usually occurs during or shortly after cessation of transfusion.<br><br>**Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>Occurs during or within 2 hours of cessation of transfusion<br>**AND**<br>No other evidence of environmental, drug or dietary risks.<br><br>**Probable:**<br>Occurs during or within 2 hours of cessation of transfusion<br>**AND**<br>There are other potential causes present that could explain symptoms, but transfusion is the most likely cause.<br><br>**Possible:**<br>Occurs 2 - 4 hours after cessation of transfusion<br>**OR**<br>Other present causes are most likely, but transfusion cannot be ruled out. |
| **OPTIONAL** | **OPTIONAL** | **OPTIONAL** |
| **Possible:**<br>N/A | **Non-severe:**<br>There is no immediate risk to the life of the patient, and the patient responds quickly to symptomatic treatment. | **Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Hypotensive transfusion reaction

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>All other adverse reactions presenting with hypotension are excluded<br>**AND**<br>Hypotension occurs during or within 1 hour after cessation of transfusion.<br><br>• **Adults (18 years and older):**<br>Drop in systolic BP of greater than or equal to 30 mmHg and systolic BP less than or equal to 80 mmHg.<br><br>• **Infants, children and adolescents (1 year to less than 18 years old):**<br>Greater than 25% drop in systolic BP from baseline (e.g., drop in systolic BP of 120mmHg to below 90mmHg).<br><br>• **Neonates and small infants (less than 1 year old OR any age and less than 12 kg body weight):**<br>Greater than 25% drop in baseline value using whichever measurement is being recorded (e.g., mean BP).<br><br>**Probable:**<br>N/A | **Non-severe:**<br>The recipient required no more than discontinuation of transfusion and symptom management and no long-term morbidity resulted from the reaction.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to hypotension, or hypotension led directly to long-term morbidity (e.g., brain damage)<br>**AND**<br>Vasopressors were not required.<br><br>**Life-threatening:**<br>The recipient required vasopressors.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>Occurs less than 15 minutes after the start of the transfusion<br>**AND**<br>Responds rapidly (i.e., within 10 minutes) to cessation of transfusion and supportive treatment<br>**AND**<br>The patient has no other conditions that could explain hypotension.<br><br>**Probable:**<br>Onset is between 15 minutes after start and 1 hour after cessation of transfusion<br>**OR**<br>The patient does not respond rapidly to cessation of transfusion and supportive treatment<br>**OR**<br>There are other potential causes present that could explain hypotension, but transfusion is the most likely cause.<br><br>**Possible:**<br>Other conditions that could readily explain hypotension are present. |
| **OPTIONAL** | | **OPTIONAL** |
| **Possible:**<br>Hypotension occurs, does not meet the criteria above. Other, more specific reaction definitions do not apply. | | **Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Febrile non-hemolytic transfusion reaction (FNHTR)

**Note:** Reactions may be classified as FNHTRs in the absence of fever if chills or rigors occur.

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>Occurs during or within 4 hours of cessation of transfusion<br>**AND EITHER**<br>Fever (greater than or equal to 38°C/100.4°F oral and a change of at least 1°C/1.8°F) from pre-transfusion value<br>**OR**<br>Chills/rigors are present.<br><br>**Probable:**<br>N/A | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.<br><br>**Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>Patient has no other conditions that could explain signs/symptoms.<br><br>**Probable:**<br>There are other potential causes present that could explain signs/symptoms, but transfusion is the most likely cause.<br><br>**Possible:**<br>Other present causes are most likely, but transfusion cannot be ruled out. |
| **OPTIONAL** | | **OPTIONAL** |
| **Possible:**<br>FNHTR is suspected, but reported symptoms and/or available information are not sufficient to meet the criteria defined above. Other, more specific adverse reaction definitions do not apply. | | **Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Acute hemolytic transfusion reaction (AHTR)

**Note:** Report hemolytic reactions resulting from immune or non-immune causes, including when the recipient is **intentionally** transfused with incompatible blood components.

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>Occurs during, or within 24 hours of cessation of transfusion with new onset of **ANY** of the following signs/symptoms:<br>• Back/flank pain<br>• Chills/rigors<br>• Disseminated intravascular coagulation (DIC)<br>• Epistaxis<br>• Fever<br>• Hematuria (gross visual hemolysis)<br>• Hypotension<br>• Oliguria/anuria<br>• Pain and/or oozing at IV site<br>• Renal failure<br>**AND**<br>**2** or more of the following:<br>• Decreased fibrinogen<br>• Decreased haptoglobin<br>• Elevated bilirubin<br>• Elevated LDH<br>• Hemoglobinemia<br>• Hemoglobinuria<br>• Plasma discoloration c/w hemolysis<br>• Spherocytes on blood film<br>**AND EITHER**<br>**(IMMUNE-MEDIATED)**<br>Positive direct antiglobulin test (DAT) for anti-IgG or anti-C3<br>**AND**<br>Positive elution test with alloantibody present on the transfused red blood cells<br>**OR**<br>**(NON-IMMUNE MEDIATED)**<br>Serologic testing is negative, and physical cause (e.g., thermal, osmotic, mechanical, chemical) is confirmed.<br><br>**Probable:**<br>Meets signs and symptoms criteria for acute hemolysis<br>**AND EITHER**<br>**(IMMUNE MEDIATED)**<br>Physical cause is excluded but serologic evidence is not sufficient to meet definitive criteria<br>**OR**<br>**(NON-IMMUNE MEDIATED)**<br>Physical cause is suspected and serologic testing is negative.<br>**OPTIONAL**<br>**Possible:**<br>AHTR is suspected within 24 hours of cessation of transfusion, but symptoms, test results, and/or information are not sufficient to meet the criteria defined above. Other, more specific adverse definitions do not apply. | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.<br><br>**Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>ABO or other allotypic RBC antigen incompatibility is known<br>**OR**<br>Only transfusion-related (i.e., immune or non-immune) cause of acute hemolysis is present.<br><br>**Probable:**<br>There are other potential causes present that could explain acute hemolysis, but transfusion is the most likely cause.<br><br>**Possible:**<br>Other causes of acute hemolysis are more likely, but transfusion cannot be ruled out.<br>**OPTIONAL**<br>**Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Delayed hemolytic transfusion reaction (DHTR)

**Note:** Report all hemolytic reactions, including when the recipient is **intentionally** transfused with incompatible blood components.

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>Positive direct antiglobulin test (DAT) for antibodies developed between 24 hours and 28 days after cessation of transfusion<br>**AND EITHER**<br>Positive elution test with alloantibody present on the transfused red blood cells<br>**OR**<br>Newly-identified red blood cell alloantibody in recipient serum<br>**AND EITHER**<br>Inadequate rise of post-transfusion hemoglobin level or rapid fall in hemoglobin back to pre-transfusion levels<br>**OR**<br>Otherwise unexplained appearance of spherocytes. | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. | **Definite:**<br>No other explanation for symptoms or newly-identified antibody is present. |
| **Probable:**<br>Newly-identified red blood cell alloantibody demonstrated between 24 hours and 28 days after cessation of transfusion<br>**BUT**<br>Incomplete laboratory evidence to meet definitive case definition criteria. | **Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function. | **Probable:**<br>An alternate explanation for symptoms or newly-identified antibody is present, but transfusion is the most likely cause. |
| **NOTE:** Patient may be asymptomatic or have symptoms that are similar to but milder than AHTR; symptoms are not required to meet case definition criteria. | **Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. | **Possible:**<br>Other explanations for symptoms or newly-identified antibody are more likely, but transfusion cannot be ruled out. |
| **OPTIONAL** | **Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction. | **OPTIONAL** |
| **Possible:**<br>DHTR is suspected, but reported symptoms, test results, and/or available information are not sufficient to meet the criteria defined above. Other, more specific adverse reaction definitions do not apply. | **Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Delayed serologic transfusion reaction (DSTR)

**Note:** Delayed serologic reactions should only be reported for patients **transfused by your facility**.

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>Absence of clinical signs of hemolysis<br>**AND**<br>Demonstration of new, clinically-significant antibodies against red blood cells<br>**BY EITHER**<br>Positive direct antiglobulin test (DAT)<br>**OR**<br>Positive antibody screen with newly identified RBC alloantibody.<br><br>**Probable:**<br>N/A<br><br>**Possible:**<br>N/A | **Not Determined:**<br>Since this is by definition a reaction with no clinical symptoms, severity of the reaction cannot be graded. | **Definite:**<br>New alloantibody is identified between 24 hours and 28 days after cessation of transfusion<br>**AND**<br>Transfusion performed by your facility is the only possible cause for seroconversion.<br><br>**Probable:**<br>New alloantibody is identified between 24 hours and 28 days after cessation of transfusion<br>**AND**<br>The patient has other exposures (e.g. transfusion by another facility or pregnancy) that could explain seroconversion, but transfusion by your facility is the most likely cause.<br><br>**Possible:**<br>New alloantibody is identified between 24 hours and 28 days after cessation of transfusion<br>**AND**<br>The patient was transfused by your facility, but other exposures are present that most likely explain seroconversion.<br><br>**OPTIONAL**<br><br>**Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Transfusion-associated graft vs. host disease (TAGVHD)

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>A clinical syndrome occurring from 2 days to 6 weeks after cessation of transfusion characterized by:<br>• Characteristic rash: erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation.<br>• Diarrhea<br>• Fever<br>• Hepatomegaly<br>• Liver dysfunction (i.e., elevated ALT, AST, Alkaline phosphatase, and bilirubin)<br>• Marrow aplasia<br>• Pancytopenia<br>**AND**<br>Characteristic histological appearance of skin or liver biopsy.<br><br>**Probable:**<br>Meets definitive criteria<br>**EXCEPT**<br>Biopsy negative or not done.<br><br>**Possible:**<br>N/A | **Non-severe:**<br>N/A<br><br>**Severe:**<br>Patient had marked symptoms and responded to treatment.<br><br>**Life-threatening:**<br>Patient had severe symptoms and required life-saving treatment (e.g., immunosuppression).<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>WBC chimerism present in the absence of alternative diagnoses.<br><br>**Probable:**<br>WBC chimerism present<br>**BUT**<br>Other potential causes are present (e.g., stem cell transplantation).<br><br>**Possible:**<br>WBC chimerism not present or not done<br>**OR**<br>Alternative explanations are more likely (e.g., solid organ transplantation).<br><br>**OPTIONAL**<br><br>**Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Post transfusion purpura (PTP)

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia<br>**AND**<br>Thrombocytopenia (i.e., decrease in platelets to less than 20% of pre-transfusion count).<br><br>**Probable:**<br>Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia.<br>**AND**<br>Decrease in platelets to levels between 20% and 80% of pre-transfusion count. | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.<br><br>**Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>Occurs 5-12 days post-transfusion<br>**AND**<br>Patient has no other conditions to explain thrombocytopenia.<br><br>**Probable:**<br>Occurs less than 5 or more than 12 days post-transfusion<br>**OR**<br>There are other potential causes present that could explain thrombocytopenia, but transfusion is the most likely cause.<br><br>**Possible:**<br>Alternate explanations for thrombocytopenia are more likely, but transfusion cannot be ruled out. |
| **OPTIONAL** | | **OPTIONAL** |
| **Possible:**<br>PTP is suspected, but laboratory findings and/or information are not sufficient to meet defined criteria above. For example, the patient has a drop in platelet count to less than 80% of pre-transfusion count but HPA antibodies were not tested or were negative. Other, more specific adverse reaction definitions do not apply. | | **Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Transfusion-transmitted infection (TTI)

| Case Definition | Severity | Imputability |
|---|---|---|
| **Definitive:**<br>Laboratory evidence of a pathogen in the transfusion recipient.<br><br>**Probable:**<br>N/A | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function. | **Definite:**<br>**ONE or more of the following:**<br>• Evidence of the pathogen in the transfused component<br>• Evidence of the pathogen in the donor at the time of donation<br>• Evidence of the pathogen in an additional component from the same donation<br>• Evidence of the pathogen in an additional recipient of a component from the same donation<br>**AND**<br>No other potential exposures to the pathogen could be identified in the recipient.<br>**AND EITHER**<br>Evidence that the recipient was not infected with the pathogen prior to transfusion<br>**OR**<br>Evidence that the identified pathogen strains are related by molecular or extended phenotypic comparison testing with statistical confidence ($p<0.05$).<br><br>**Probable:**<br>**ONE or more of the following:**<br>• Evidence of the pathogen in the transfused component<br>• Evidence of the pathogen in the donor at the time of donation<br>• Evidence of the pathogen in an additional component from the same donation<br>• Evidence of the pathogen in an additional recipient of a component from the same donation.<br>**AND EITHER:**<br>Evidence that the recipient was not infected with this pathogen prior to transfusion<br>**OR**<br>No other potential exposures to the pathogen could be identified in the recipient.<br><br>**Possible:**<br>Case fails to meet definite, probable, doubtful, or ruled out imputability criteria. |
| **OPTIONAL** | | **OPTIONAL** |
| **Possible:**<br>Temporally associated unexplained clinical **illness** consistent with infection, but no pathogen is detected in the recipient. Other, more specific adverse reactions are ruled out.<br><br>**Note:** Possible cases cannot meet the **definite** or **probable** imputability criteria. | **Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction.**<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Doubtful:**<br>Laboratory evidence that the recipient was infected with this pathogen prior to transfusion<br>**OR**<br>Evidence is clearly in favor of a cause other than transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>**ALL** of the following (where applicable):<br>• Evidence that the transfused component was negative for this pathogen at the time of transfusion<br>• Evidence that the donor was negative for this pathogen at the time of donation<br>• Evidence that additional components from the same donation were negative for this pathogen<br>**OR**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

## Transfusion-transmitted infection (TTI)
(continued)

**Pathogens of well-documented importance in blood safety.**

These pathogens have public health significance for hemovigilance, are well-documented blood stream pathogens, and/or are routinely screened for in blood donors. A full list of potentially infectious organisms is available in the drop-down pathogen list in NHSN.

| Bacterial | Viral | Parasitic | Other |
|---|---|---|---|
| *Enterobacter cloacae*<br>*Escherichia coli*<br>*Klebsiella oxytoca*<br>*Klebsiella pneumoniae*<br>*Pseudomonas aeruginosa*<br>*Serratia marcescens*<br>*Staphylococcus aureus*<br>*Staphylococcus epidermidis*<br>*Staphylococcus lugdunensis*<br>Syphilis *(Treponema pallidum)*<br>*Yersinia enterocolitica* | Cytomegalovirus (CMV)<br>*Enterovirus spp.*<br>Epstein Barr (EBV)<br>Hepatitis A<br>Hepatitis B<br>Hepatitis C<br>Human Immunodeficiency Virus 1 (HIV-1)<br>Human Immunodeficiency Virus 2 (HIV-2)<br>Human Parvovirus B-19<br>Human T-Cell Lymphotropic Virus-1 (HTLV-1)<br>Human T-Cell Lymphotropic Virus-2 (HTLV-2)<br>West Nile Virus (WNV)<br>Zika Virus (ZIKAVI) | Babesiosis (*Babesia spp*.)<br>Chagas disease (*Trypanosoma cruzi*)<br>Malaria (*Plasmodium spp*.) | Creutzfeldt-Jakob Disease, Variant (vCJD) |

**Investigation triggers for potential transfusion-transmitted infections:**

1. Identification by testing (e.g., gram stain, other smear/staining, culture, or other method) of a bacterial, mycobacterial, or fungal pathogen in a recipient within the time period from exposure (i.e., transfusion) to onset of infection appropriate for the suspected pathogen.

2. Identification of an unexpected virus in the transfusion recipient by testing (e.g., culture, direct fluorescent antibody, or polymerase chain reaction) within the time period from exposure (i.e., transfusion) to onset of infection appropriate for the suspected virus.

3. Identification of an unexpected parasite in the recipient by testing (e.g., blood smear, histopathology, serologic testing, or polymerase chain reaction) within the time period from exposure (i.e., transfusion) to onset of infection appropriate for the suspected parasite.

4. Any of the above laboratory findings in the recipient unit upon residual testing.

5. Unexplained clinical events occurring after transfusion that are consistent with transfusion-transmitted infection, such as:
   a. Encephalitis, meningitis, or other unexplained central nervous system abnormalities.
   b. Sepsis with or without multi-organ system dysfunction.
   c. Hemolytic anemia and/or fever (e.g., in cases of transfusion-associated babesiosis or malaria).
   d. Recipient death.

6. For pathogens routinely screened in the blood donor, any infection in the recipient occurring within 6 months after transfusion if:
   a. The index donation testing was negative but
   b. The donor was subsequently found to be infected, and
   c. The recipient had no pre-transfusion history of the same infection.

## Other or Unknown

**Other:** Use this option if the recipient experienced an adverse reaction that is not defined in the Hemovigilance Module surveillance protocol (e.g., transfusion-associated acute gut injury (TRAGI), transfusion-associated immunomodulation (TRIM), iron overload, microchimerism, hyperkalemia, thrombosis).

**Unknown:** Use this category if the patient experienced transfusion-related symptoms, but the medical event that caused those symptoms could not be classified.

**Note:** Reporting 'Other' and 'Unknown' reactions is not required by CDC.

| REPORTING OPTIONAL | | |
|---|---|---|
| **Case Definition** | **Severity** | **Imputability** |
| **Not Applicable:**<br>CDC does not specifically define the 'Other' or 'Unknown' adverse reaction categories, therefore the case definition criteria may only be reported as N/A. | **Non-severe:**<br>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.<br><br>**Severe:**<br>Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.<br><br>**Life-threatening:**<br>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.<br><br>**Death:**<br>The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.<br><br>**Not Determined:**<br>The severity of the adverse reaction is unknown or not stated. | **Definite:**<br>Conclusive evidence exists that the adverse reaction can be attributed to the transfusion.<br><br>**Probable**:<br>Evidence is clearly in favor of attributing the adverse reaction to the transfusion.<br><br>**Possible:**<br>Evidence is indeterminate for attributing the adverse reaction to the transfusion or an alternate cause.<br><br>**Doubtful:**<br>Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.<br><br>**Ruled Out:**<br>There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.<br><br>**Not Determined:**<br>The relationship between the adverse reaction and the transfusion is unknown or not stated. |

# Adverse Reaction Glossary

**Antibodies often associated with AHTR, DHTR, DSTR:**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Anti-A | Anti-B | Anti-A,B | Anti-C | Anti-c | Anti-D | Anti-E | Anti-e | Anti-Fy$^{a}$ |
| Anti-Fy$^{b}$ | Anti-Jk$^{a}$ | Anti-Jk$^{b}$ | Anti-K | Anti-k | Anti-M | Anti-S | Other | |

**Bronchospasm (wheezing):** A contraction of smooth muscle in the walls of the bronchi and bronchioles, causing acute narrowing and obstruction of the respiratory airway. This constriction can result in a rasp or whistling sound while breathing.

**Chills/rigors:** A feeling of cold with shivering or shaking and pallor.

**Disseminated intravascular coagulation (DIC):** Bleeding disorder characterized by reduction in the factors involved in blood clotting due to their use in widespread clotting within the vessels. The intravascular clotting ultimately produces hemorrhage because of rapid consumption of clotting factors.

**Edema:** Swelling of soft tissues as a result of excessive fluid accumulation.

**Epistaxis:** Bleeding from the nose.

**Fever:** For the purposes of hemovigilance, greater than or equal to 38°C/100.4°F oral and a change of at least 1°C/1.8°F from pre-transfusion value.

**Hematuria:** Presence of blood or red blood cells in the urine.

**Hemoglobinemia:** The presence of free hemoglobin in the blood plasma.

**Hemoglobinuria:** Presence of free hemoglobin in the urine.

**Hypoxemia:** Abnormal deficiency in the concentration of oxygen in arterial blood. PaO2 / FiO2 less than or equal to 300 mm Hg OR oxygen saturation is less than 90% on room air.

**Jaundice:** New onset or worsening of yellow discoloration (icterus) of the skin or sclera (scleral icterus) secondary to an increased level of bilirubin.

**Oliguria:** New onset of decreased urinary output (less than 500cc output per 24 hours).

**Other rash:** Non-urticarial skin rash.

**Pruritus:** Itching.

**Shock:** A drop in blood pressure accompanied by a drop in cardiac output including rapid heart rate (increase to 100 beats per minute or more), rapid breathing, cutaneous vasoconstriction, pallor, sweating, decreased or scanty urine production, agitation and/or loss of consciousness that required fluid resuscitation, with or without inotropic support.

**Shortness of breath (dyspnea):** New onset or significant worsening of shortness of breath; or a significant increase in respiratory rate (with or without hypoxemia).

**Urticaria (hives):** Raised wheals on the skin.

# Section 4. Hemovigilance Module Incidents

**Required Reporting**
All incidents (i.e., accidents or errors) that are **associated with a reported adverse reaction** must be reported to NHSN using a detailed Incident form (CDC 57.305). If multiple incidents occur in association with an adverse reaction then report all. Incidents may occur before (e.g., wrong product released) or after (e.g., failure to report adverse reaction to blood bank) an adverse reaction. Each reaction must be reported using the detailed incident form; the incident result must be coded as 'Product transfused, reaction' to enter the associated patient identifier on the form. After the incident record is entered, the adverse reaction record must be linked to the incident record in the NHSN web application.

**Incident Classification**
Use the incident codes provided at the end of this section to classify incidents. If there is uncertainty then please contact NHSN User Support.

**Optional Reporting**
Any incident may be optionally reported to NHSN using the detailed Incident form (57.305) or the Monthly Incident Summary form (57.302). Approved deviations from standard operating procedure are not considered incidents because they did not occur by accident or in error. However, approved deviations may be optionally reported for a facility's use.

**Form**
CDC 57.305 Hemovigilance Module Incident

**Form Instructions**
CDC 57.305 Hemovigilance Module Incident Table of Instructions

**Summary Form (Optional)**
CDC 57.302 Hemovigilance Module Monthly Incident Summary

**Summary Form Instructions (Optional)**
CDC 57.302 Hemovigilance Module Monthly Incident Summary Table of Instructions

## Incident Codes

**Note:** Incident codes are based on MERS TM (US) and TESS (Canada) incident classification schemes.

**Product Check-In**
*(Transfusion Service)*
*Events that occur during the shipment and receipt of products into the transfusion service from the supplier, another hospital site, satellite storage, or clinical area.*

- PC 00 Detail not specified
- PC 01 Data entry incomplete/incorrect/not performed
- PC 02 Shipment incomplete/incorrect
- PC 03 Products and paperwork do not match
- PC 04 Shipped/transported under inappropriate conditions
- PC 05 Inappropriate return to inventory
- PC 06 Product confirmation incorrect/not performed
- PC 07 Administrative check not incorrect/not performed (record review/audit)
- PC 08 Product label incorrect/missing

**Product Storage**
*(Transfusion Service)*
*Events that occur during product storage by the transfusion service.*

- US 00 Detail not specified
- US 01 Incorrect storage conditions
- US 03 Inappropriate monitoring of storage device
- US 04 Unit stored on incorrect shelf (e.g., ABO/autologous s/directed)
- US 05 Incorrect storage location

**Inventory Management**
*(Transfusion Service)*
*Events that involve quality management of the blood product inventory.*

- IM 00 Detail not specified
- IM 01 Inventory audit incorrect/not performed
- IM 02 Product status incorrectly/not updated online (e.g., available/discarded)
- IM 03 Supplier recall/traceback not appropriately addressed/not performed
- IM 04 Product order incorrectly/not submitted to supplier
- IM 05 Outdated product in available inventory
- IM 06 Recalled/quarantined product in available inventory

**Product/Test Request**
*(Clinical Service)*
*Events that occur when the clinical service orders patient tests or blood products for transfusion.*

- PR 00 Detail not specified
- PR 01 Order for wrong patient
- PR 02 Order incompletely/incorrectly ordered (online order entry)
- PR 03 Special processing needs not indicated (e.g., CMV negative, autologous)
- PR 04 Order not done
- PR 05 Inappropriate/unnecessary (intended) test ordered
- PR 06 Inappropriate/unnecessary (intended) blood product ordered
- PR 07 Incorrect (unintended) test ordered
- PR 08 Incorrect (unintended) blood product ordered

**Product/Test Order Entry**
*(Transfusion Service)*
*Events that occur when the transfusion service receives a patient order. This process may be excluded if clinical service uses online ordering.*

- OE 00 Detail not specified
- OE 01 Order entered for wrong patient
- OE 02 Order incompletely/incorrectly entered
- online OE 03 Special processing needs not entered (e.g., CMV-, autologous)
- OE 04 Order entry not done
- OE 05 Inappropriate/unnecessary (intended) test order entered
- OE 06 Inappropriate/unnecessary (intended) blood product order entered
- OE 07 Incorrect (unintended) test ordered
- OE 08 Incorrect (unintended) blood product ordered

**Sample Collection**
*(Service collecting the samples)*
*Events that occur during patient sample collection.*

- SC 00 Detail not specified
- SC 01 Sample labeled with incorrect patient name
- SC 02 Not labeled
- SC 03 Wrong patient collected
- SC 04 Collected in wrong tube type
- SC 05 Sample QNS
- SC 06 Sample hemolyzed
- SC 07 Label incomplete/illegible/incorrect (other than patient name)
- SC 08 Sample collected in error
- SC 09 Requisition arrived without samples
- SC 10 Wristband incorrect/not available
- SC 11 Sample contaminated

## Incident Codes

(continued)

**Note:** Incident codes are based on MERS TM (US) and TESS (Canada) incident classification schemes.

**Sample Handling**
*(Service collecting the samples)*
*Events that occur when a patient sample is sent for testing.*

- SH 00 Detail not specified
- SH 01 Sample sent without requisition
- SH 02 Requisition and sample label don't match
- SH 03 Patient ID incomplete/illegible on requisition
- SH 04 No Patient ID on requisition
- SH 05 No phlebotomist/witness identification
- SH 06 Sample sent with incorrect requisition type
- SH 07 Patient information (other than ID) missing/incorrect on requisition
- SH 08 Requisition sent without sample
- SH 09 Data entry incorrect/incomplete/not performed
- SH 10 Sample transport issue (e.g., sample broken/inappropriate conditions)
- SH 11 Duplicate sample sent in error

**Sample Receipt**
*(Transfusion Service)*
*Events that occur when a sample is received by the transfusion service.*

- SR 00 Detail not specified
- SR 01 Sample accepted in error
- SR 02 Historical review incorrect/not performed
- SR 03 Demographic review/ data entry incorrect/not performed
- SR 04 Sample incorrectly accessioned

**Sample Testing**
*(Transfusion Service)*
*Events that occur during **patient sample** testing by the transfusion service.*

- ST 00 Detail not specified
- ST 01 Data entry incomplete/incorrect/not performed
- ST 02 Appropriate sample checks incomplete/incorrect/not performed
- ST 03 Computer warning overridden in error or outside SOP
- ST 05 Sample test tube incorrectly accessioned
- ST 07 Sample test tubes mixed up
- ST 09 Sample test tube mislabeled (wrong patient identifiers)
- ST 10 Equipment problem/failure/not properly QC'd
- ST 12 Sample testing not performed
- ST 13 Incorrect sample testing method chosen
- ST 14 Sample testing performed incorrectly
- ST 15 Sample test result misinterpreted

**Sample Testing (continued)**

- ST 16 Reagents used were incorrect/inappropriate/expired/not properly QC'd
- ST 17 ABO/Rh error caught on final check
- ST 18 Current/historical ABO/Rh mismatch
- ST 19 Additional testing not performed
- ST 20 Confirmatory check incorrect/not performed (at time work performed)
- ST 21 Administrative check incorrect/not performed (record review/audit)
- ST 22 Sample storage incorrect/inappropriate

**Product Manipulation/Processing/Testing**
*(Transfusion Service)*
*Events that occur while testing, manipulating (e.g., pooling, washing, aliquoting, irradiating), processing, or labeling blood products.*

- UM 00 Detail not specified
- UM 01 Data entry incomplete/incorrect/not performed
- UM 02 Record review incomplete/incorrect/not performed
- UM 03 Incorrect product (type) selected
- UM 04 Incorrect product (patient) selected
- UM 05 Product labeled incorrectly (new/updated)
- UM 06 Computer warning overridden in error or outside SOP
- UM 07 Special processing needs not checked
- UM 08 Special processing needs misunderstood or misinterpreted
- UM 09 Special processing needs performed incorrectly
- UM 10 Special processing needs not performed
- UM 11 Equipment problem/failure/not properly QC'd
- UM 12 Reagents used were incorrect/inappropriate/expired/not properly QC'd
- UM 13 Confirmatory check incorrect/not performed (at time work performed)
- UM 14 Administrative check incorrect/not performed (record review/audit)

**No Blood**

- NB 01 Inventory less than usual par level due to supplier unable to meet usual steady demand
- NB 02 Demand for blood product exceeding usual par inventory level
- NB 03 Incompatible/inappropriate units issued due to inventory constraints when demand for blood product exceeds usual par inventory levels.
- NB 04 Suboptimal dose (less than optimal quantity) transfusion or no transfusion due to inventory constraints when demand for blood product exceeds usual par inventory levels.

## Incident Codes

(continued)

**Note:** Incident codes are based on MERS TM (US) and TESS (Canada) incident classification schemes.

**Request for Pick-up**
*(Clinical Service)*
*Events that occur when the clinical service requests pick-up of a blood product from the transfusion service.*

- RP 00 Detail not specified
- RP 01 Request for pick-up on wrong patient
- RP 02 Incorrect product requested for pick-up
- RP 03 Product requested prior to obtaining consent
- RP 04 Product requested for pick-up, but patient not available
- RP 05 Product requested for pick-up, but IV not ready
- RP 06 Request for pick-up incomplete (e.g., patient ID/product type missing)
- RP 07 Pick-up slip did not match patient information on product

**Product Issue**
*(Transfusion Service)*
*Events that occur when the transfusion service issues blood product to the clinical service.*

- UI 00 Detail not specified
- UI 01 Data entry incomplete/incorrect/not performed
- UI 02 Record review incomplete/incorrect/not performed
- UI 03 Product issued for wrong patient
- UI 04 Product issued out of order
- UI 05 Product issue delayed
- UI 06 LIS warning overridden in error or outside SOP
- UI 07 Computer issue not completed
- UI 08 Issued visibly defective product (e.g., clots/aggregates/particulate matter)
- UI 09 Not/incorrect checking of unit and/or patient information
- UI 10 Product transport issues (e.g., delayed) by transfusion service
- UI 11 Unit delivered to incorrect location by transfusion service
- UI 12 Product transport issue (from transfusion service to clinical area)
- UI 18 Wrong product issued for intended patient (e.g., incompatible)
- UI 19 Inappropriate product issued for patient (e.g., not irradiated, CMV+)
- UI 20 Confirmatory check incorrect/not performed (at time work performed)
- UI 21 Administrative check incorrect/not performed (record review/audit)
- UI 22 Issue approval not obtained/documented
- UI 23 Receipt verification not performed (pneumatic tube issue)

**Satellite Storage**
*(Clinical Service)*
*Events that occur while product is stored and handled by the clinical service.*

- CS 00 Detail not specified
- CS 01 Incorrect storage conditions of product in clinical area
- CS 02 Incorrect storage location in the clinical area
- CS 03 Labeling issue (by clinical staff)
- CS 04 Floor/clinic did not check for existing products in their area
- CS 05 Product transport issues (to or between clinical areas)
- CS 06 Monitoring of satellite storage incorrect/incomplete/not performed
- CS 07 Storage tracking/documentation incorrect/incomplete/not performed

**Product Administration**
*(Clinical Service)*
*Events that occur during the administration of blood products.*

- UT 00 Detail not specified
- UT 01 Administered intended product to wrong patient
- UT 02 Administered wrong product to intended patient
- UT 03 Transfusion not performed in error
- UT 05 Bedside check (patient ID confirmation) incomplete/not performed
- UT 06 Transfused product with unapproved IV fluid
- UT 07 Transfusion delayed beyond pre-approved timeframe
- UT 09 Transfused unsuitable product (e.g., outdated/inappropriately stored)
- UT 10 Administered components in wrong order
- UT 11 Appropriate monitoring of patient not performed
- UT 14 Transfusion volume too low (per order or SOP)
- UT 15 Transfusion volume too high (per order or SOP)
- UT 16 Transfusion rate too slow (per order or SOP)
- UT 17 Transfusion rate too fast (per order or SOP)
- UT 18 Inappropriate preparation of product
- UT 19 Transfusion protocol not followed (not otherwise specified)
- UT 22 Order/consent check incorrect/not performed
- UT 23 Transfusion documentation incorrect/incomplete/not performed
- UT 24 Transfusion documentation not returned to transfusion service
- UT 26 Transfusion reaction protocol not followed

**Other**

- MS 99 Other

## Occupation Codes

| | |
|---|---|
| **Laboratory** | |
| IVT | IVT Team Staff |
| MLT | Medical Laboratory Technician |
| MTE | Medical Technologist |
| PHL | Phlebotomist/IV Team |
| **Nursing** | |
| LPN | Licensed Practical Nurse |
| CNA | Nurse Anesthetist |
| CNM | Certified Nurse Midwife |
| NUA | Nursing Assistant |
| NUP | Nurse Practitioner |
| RNU | Registered Nurse |
| **Physician** | |
| FEL | Fellow |
| MST | Medical Student |
| PHY | Attending/Staff Physician |
| RES | Intern/Resident |
| **Technicians** | |
| EMT | EMT/Paramedic |
| HEM | Hemodialysis Technician |
| ORS | OR/Surgery Technician |
| PCT | Patient Care Technician |
| **Other Personnel** | |
| CLA | Clerical/Administrative |
| TRA | Transport/Messenger/Porter |

## Occupation Codes
(continued)

| Additional Occupation Types | |
|---|---|
| ATT | Attendant/Orderly |
| CSS | Central Supply |
| CSW | Counselor/Social Worker |
| DIT | Dietician |
| DNA | Dental Assistant/Technician |
| DNH | Dental Hygienist |
| DNO | Other Dental Worker |
| DNT | Dentist |
| DST | Dental Student |
| FOS | Food Service |
| HSK | Housekeeper |
| ICP | Infection Control Professional |
| LAU | Laundry Staff |
| MNT | Maintenance/Engineering |
| MOR | Morgue Technician |
| OAS | Other Ancillary Staff |
| OFR | Other First Responder |
| OH | Occupational Health Professional |
| OMS | Other Medical Staff |
| OTH | Other |
| OTT | Other Technician/Therapist |
| PAS | Physician Assistant |
| PHA | Pharmacist |
| PHW | Public Health Worker |
| PLT | Physical Therapist |
| PSY | Psychiatric Technician |
| RCH | Researcher |
| RDT | Radiologic Technologist |
| RTT | Respiratory Therapist/Technician |
| STU | Other Student |
| VOL | Volunteer |

# Incident Glossary

**Incident Result**

**Product transfused; reaction (No recovery; harm):**
A product related to this incident was transfused; the patient experienced an adverse reaction.

**Product transfused; no reaction (No recovery; no harm):**
A product related to this incident was transfused; the patient did not experience an adverse reaction.

**No product transfused; unplanned recovery (Near miss; unplanned recovery):**
No product related to this incident was transfused; the incident was discovered ad hoc, by accident, by human lucky catch, etc.

**No product transfused; planned recovery (Near miss; planned recovery):**
No product related to this incident was transfused; the incident was discovered through a standardized process or barrier designed to prevent errors.

# Section 5. Hemovigilance Module Denominators

**Required Reporting**
Facilities must report the total number of units and aliquots of specified blood components transfused and total number of discards each month. When reporting aliquots, the units from which they are made should **NOT** be counted as a transfused unit. The components transfused count should include autologous units. The total number of patient samples collected and total crossmatch procedures must also be reported. This form must be completed each month that surveillance is conducted and data can only be entered once the calendar month is over. For instance, February data must be entered after March 1st. Additionally, data cannot be entered for upcoming months.

**Pathogen Reduced Blood Products**
The total number of transfused units of blood components which are produced with pathogen-reduction technology (PRT) should be reported each month, if applicable. These PRT units are reported in Table 2 and are a subset of total number of units and aliquots transfused that are reported in Table 1. Table 3 relates to pathogen reduced apheresis platelets, if reported in table 2. For more guidance please refer to the Denominator QuickLearn on the NHSN Blood Safety Surveillance website.

**Electronic Reporting**
In January 2017, the NHSN Hemovigilance Module can accept electronically reported denominator data via clinical documentation architecture (CDA). Compared to manual reporting, electronic reporting will decrease the time required for data collection and reporting, reduce data entry errors, and increase data granularity. In order to electronically report data, facilities' software system must have CDA functionality. For more information about electronic reporting and CDA, review CDA Frequently Asked Questions on the NHSN Blood Safety Surveillance website.

**Form**
CDC 57.303 Hemovigilance Module Monthly Reporting Denominators

**Form Instructions**
CDC 57.303 Hemovigilance Module Monthly Reporting Denominators Tables of Instructions