National Healthcare Safety Network
Biovigilance Component
Hemovigilance Module
Surveillance Protocol

Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Atlanta, GA, USA

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.
		Added a possible case definition category for TTI for OPTIONAL reporting of syndromic cases that are not laboratory confirmed.

Version	Release Date	Summary of Revisions
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.

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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 chronic 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 from supplier 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 Forms and Instructions
Paper versions of all forms used to collect data in the NHSN Hemovigilance Module are available on the NHSN 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 Biovigilance Component 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 blast email system.

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 MODULE** in the subject line for quickest routing to the Biovigilance/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 v2.1.3. 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].

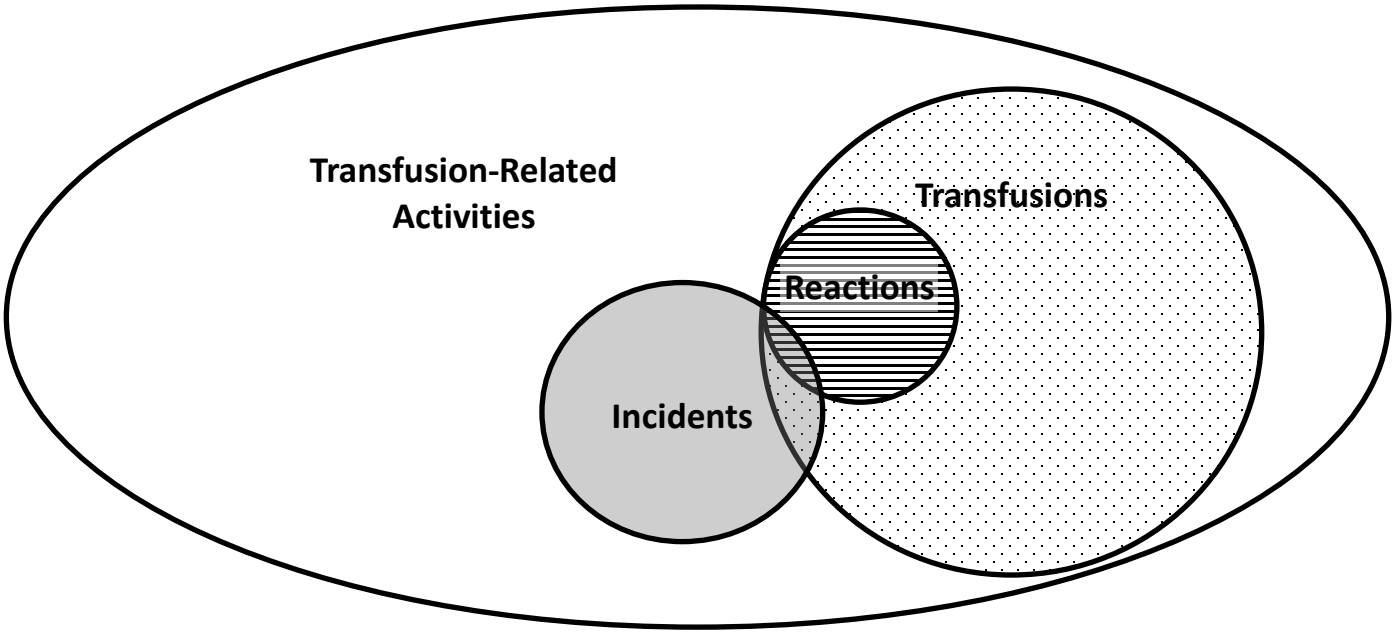
Key Terms (see Fig. 1)

- **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 Requirements (See Fig. 1)

- At least 12 months of continuous surveillance
- An annual facility demographic and practice survey for each **calendar** year of participation
- ALL adverse reactions 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.

Form
CDC 57.300 Hemovigilance Module Annual Facility Survey

Form Instructions
CDC 57.300 Hemovigilance Module Annual Facility Survey 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. Ideally, reports will be entered within 30 days of the month that the reaction occurred.

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. CDC will not aggregate or analyze these optional reports.

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 this section of 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.

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. By using standardized surveillance definitions, data can be aggregated to create national benchmarks that will permit facilities to compare their performance to a national baseline as well as within their facility over time. 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 = 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)

Note
Reporting of adverse reactions to CDC through NHSN system does **NOT** take the place of reporting requirements for blood transfusion-associated adverse events to the Food and Drug Administration (FDA).

Form
CDC 57.304 Hemovigilance Module Adverse Reaction

Form Instructions
CDC 57.304 Hemovigilance Module Adverse Reaction Table of Instructions

Adverse Reaction Case Classification Criteria Tables

Transfusion-associated circulatory overload (TACO)

Case Definition	Severity	Imputability
Definitive: New onset or exacerbation of 3 or more of the following within 6 hours of cessation of transfusion: • Acute respiratory distress (dyspnea, orthopnea, cough) • Elevated brain natriuretic peptide (BNP) • Elevated central venous pressure (CVP) • Evidence of left heart failure • Evidence of positive fluid balance • Radiographic evidence of pulmonary edema **Probable:** N/A **Possible:** N/A	**Non-severe:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** 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. **Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** No other explanations for circulatory overload are possible. **Probable:** Transfusion is a likely contributor to circulatory overload **AND EITHER** The patient received other fluids as well **OR** 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. **Possible:** The patient has a history of pre-existing cardiac insufficiency that most likely explains circulatory overload. **OPTIONAL** **Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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: NO evidence of acute lung injury (ALI) prior to transfusion **AND** ALI onset during or within 6 hours of cessation of transfusion **AND** Hypoxemia defined by any of these methods: • PaO2/FiO2 less than or equal to 300 mm Hg • Oxygen saturation less than 90% on room air • Other clinical evidence **AND** Radiographic evidence of bilateral infiltrates **AND** No evidence of left atrial hypertension (i.e., circulatory overload) **Probable:** N/A **Possible:** N/A	**Non-severe:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** 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. **Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** There are no alternative risk factors for ALI present. **Probable:** N/A **Possible:** There is evidence of other causes for acute lung injury such as: Direct Lung Injury • Aspiration • Pneumonia • Toxic inhalation • Lung contusion • Near drowning Indirect Lung Injury • Severe sepsis • Shock • Multiple trauma • Burn injury • Acute pancreatitis • Cardiopulmonary bypass • Drug overdose **OPTIONAL** **Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.

Transfusion-associated dyspnea (TAD)

Case Definition	Severity	Imputability
Definitive: Acute respiratory distress occurring within 24 hours of cessation of transfusion **AND** Allergic reaction, TACO, and TRALI definitions are not applicable. **Probable:** N/A **Possible:** N/A	**Non-severe:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** 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. **Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** Patient has no other conditions that could explain symptoms. **Probable:** There are other potential causes that could explain symptoms, but transfusion is the most likely cause. **Possible:** Other present causes are most likely, but transfusion cannot be ruled out. **OPTIONAL** **Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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: **2 or more** of the following occurring during or within 4 hours of cessation of transfusion: • Conjunctival edema • Edema of lips, tongue and uvula • Erythema and edema of the periorbital area • Generalized flushing • Hypotension • Localized angioedema • Maculopapular rash • Pruritus (itching) • Respiratory distress; bronchospasm • Urticaria (hives) **Probable:** **ANY 1** of the following occurring during or within 4 hours of cessation of transfusion: • Conjunctival edema • Edema of lips, tongue and uvula • Erythema and edema of the periorbital area • Localized angioedema • Maculopapular rash • Pruritus (itching) • Urticaria (hives)	**Severe, Life-threatening, Death:** 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. **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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** Occurs during or within 2 hours of cessation of transfusion **AND** No other evidence of environmental, drug or dietary risks. **Probable:** Occurs during or within 2 hours of cessation of transfusion **AND** There are other potential causes present that could explain symptoms, but transfusion is the most likely cause. **Possible:** Occurs 2 - 4 hours after cessation of transfusion **OR** Other present causes are most likely, but transfusion cannot be ruled out.
OPTIONAL	**OPTIONAL**	**OPTIONAL**
Possible: N/A	**Non-severe:** There is no immediate risk to the life of the patient, and the patient responds quickly to symptomatic treatment.	**Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.

Hypotensive transfusion reaction

Case Definition	Severity	Imputability
Definitive: All other adverse reactions presenting with hypotension are excluded **AND** Hypotension occurs during or within 1 hour after cessation of transfusion. • **Adults (18 years and older):** Drop in systolic BP of greater than or equal to 30 mmHg and systolic BP less than or equal to 80 mmHg. • **Infants, children and adolescents (1 year to less than 18 years old):** Greater than 25% drop in systolic BP from baseline (e.g., drop in systolic BP of 120mmHg to below 90mmHg). • **Neonates and small infants (less than 1 year old OR any age and less than 12 kg body weight):** Greater than 25% drop in baseline value using whichever measurement is being recorded (e.g., mean BP). **Probable:** N/A	**Non-severe:** The recipient required no more than discontinuation of transfusion and symptom management and no long-term morbidity resulted from the reaction. **Severe:** Inpatient hospitalization or prolongation of hospitalization is directly attributable to hypotension, or hypotension led directly to long-term morbidity (e.g., brain damage) **AND** Vasopressors were not required. **Life-threatening:** The recipient required vasopressors. **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** Occurs less than 15 minutes after the start of the transfusion **AND** Responds rapidly (i.e., within 10 minutes) to cessation of transfusion and supportive treatment **AND** The patient has no other conditions that could explain hypotension. **Probable:** Onset is between 15 minutes after start and 1 hour after cessation of transfusion **OR** The patient does not respond rapidly to cessation of transfusion and supportive treatment **OR** There are other potential causes present that could explain hypotension, but transfusion is the most likely cause. **Possible:** Other conditions that could readily explain hypotension are present.
OPTIONAL		**OPTIONAL**
Possible: Hypotension occurs, does not meet the criteria above. Other, more specific reaction definitions do not apply.		**Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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: Occurs during or within 4 hours of cessation of transfusion **AND EITHER** 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) **OR** Chills/rigors are present. **Probable:** N/A	**Non-severe:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** 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:** Patient has no other conditions that could explain signs/symptoms. **Probable:** There are other potential causes present that could explain signs/symptoms, but transfusion is the most likely cause. **Possible:** Other present causes are most likely, but transfusion cannot be ruled out.
OPTIONAL		**OPTIONAL**
Possible: 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.	**Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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: Occurs during, or within 24 hours of cessation of transfusion with new onset of **ANY** of the following signs/symptoms: • Back/flank pain • Chills/rigors • Disseminated intravascular coagulation (DIC) • Epistaxis • Fever • Hematuria (gross visual hemolysis) • Hypotension • Oliguria/anuria • Pain and/or oozing at IV site • Renal failure **AND** **2** or more of the following: • Decreased fibrinogen • Decreased haptoglobin • Elevated bilirubin • Elevated LDH • Hemoglobinemia • Hemoglobinuria • Plasma discoloration c/w hemolysis • Spherocytes on blood film **AND EITHER** **(IMMUNE-MEDIATED)** Positive direct antiglobulin test (DAT) for anti-IgG or anti-C3 **AND** Positive elution test with alloantibody present on the transfused red blood cells **OR** **(NON-IMMUNE MEDIATED)** Serologic testing is negative, and physical cause (e.g., thermal, osmotic, mechanical, chemical) is confirmed. **Probable:** Meets signs and symptoms criteria for acute hemolysis **AND EITHER** **(IMMUNE MEDIATED)** Physical cause is excluded but serologic evidence is not sufficient to meet definitive criteria **OR** **(NON-IMMUNE MEDIATED)** Physical cause is suspected and serologic testing is negative. **OPTIONAL** **Possible:** 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:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** 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. **Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** ABO or other allotypic RBC antigen incompatibility is known **OR** Only transfusion-related (i.e., immune or non-immune) cause of acute hemolysis is present. **Probable:** There are other potential causes present that could explain acute hemolysis, but transfusion is the most likely cause. **Possible:** Other causes of acute hemolysis are more likely, but transfusion cannot be ruled out. **OPTIONAL** **Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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: Positive direct antiglobulin test (DAT) for antibodies developed between 24 hours and 28 days after cessation of transfusion **AND EITHER** Positive elution test with alloantibody present on the transfused red blood cells **OR** Newly-identified red blood cell alloantibody in recipient serum **AND EITHER** Inadequate rise of post-transfusion hemoglobin level or rapid fall in hemoglobin back to pre-transfusion levels **OR** Otherwise unexplained appearance of spherocytes.	**Non-severe:** 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:** No other explanation for symptoms or newly-identified antibody is present.
Probable: Newly-identified red blood cell alloantibody demonstrated between 24 hours and 28 days after cessation of transfusion **BUT** Incomplete laboratory evidence to meet definitive case definition criteria.	**Severe:** 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:** 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:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.	**Possible:** Other explanations for symptoms or newly-identified antibody are more likely, but transfusion cannot be ruled out.
OPTIONAL	**Death:** 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: 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:** The severity of the adverse reaction is unknown or not stated.	**Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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: Absence of clinical signs of hemolysis **AND** Demonstration of new, clinically-significant antibodies against red blood cells **BY EITHER** Positive direct antiglobulin test (DAT) **OR** Positive antibody screen with newly identified RBC alloantibody. **Probable:** N/A **Possible:** N/A	**Not Determined:** Since this is by definition a reaction with no clinical symptoms, severity of the reaction cannot be graded.	**Definite:** New alloantibody is identified between 24 hours and 28 days after cessation of transfusion **AND** Transfusion performed by your facility is the only possible cause for seroconversion. **Probable:** New alloantibody is identified between 24 hours and 28 days after cessation of transfusion **AND** 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. **Possible:** New alloantibody is identified between 24 hours and 28 days after cessation of transfusion **AND** The patient was transfused by your facility, but other exposures are present that most likely explain seroconversion. **OPTIONAL** **Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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: A clinical syndrome occurring from 2 days to 6 weeks after cessation of transfusion characterized by: • Characteristic rash: erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation. • Diarrhea • Fever • Hepatomegaly • Liver dysfunction (i.e., elevated ALT, AST, Alkaline phosphatase, and bilirubin) • Marrow aplasia • Pancytopenia **AND** Characteristic histological appearance of skin or liver biopsy. **Probable:** Meets definitive criteria **EXCEPT** Biopsy negative or not done. **Possible:** N/A	**Non-severe:** N/A **Severe:** Patient had marked symptoms and responded to treatment. **Life-threatening:** Patient had severe symptoms and required life-saving treatment (e.g., immunosuppression). **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** WBC chimerism present in the absence of alternative diagnoses. **Probable:** WBC chimerism present **BUT** Other potential causes are present (e.g., stem cell transplantation). **Possible:** WBC chimerism not present or not done **OR** Alternative explanations are more likely (e.g., solid organ transplantation). **OPTIONAL** **Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.

Post transfusion purpura (PTP)

Case Definition	Severity	Imputability
Definitive: Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia **AND** Thrombocytopenia (i.e., decrease in platelets to less than 20% of pre-transfusion count). **Probable:** Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia. **AND** Decrease in platelets to levels between 20% and 80% of pre-transfusion count.	**Non-severe:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** 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. **Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** Occurs 5-12 days post-transfusion **AND** Patient has no other conditions to explain thrombocytopenia. **Probable:** Occurs less than 5 or more than 12 days post-transfusion **OR** There are other potential causes present that could explain thrombocytopenia, but transfusion is the most likely cause. **Possible:** Alternate explanations for thrombocytopenia are more likely, but transfusion cannot be ruled out.
OPTIONAL		**OPTIONAL**
Possible: 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:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.

Transfusion-transmitted infection (TTI)

Case Definition	Severity	Imputability
Definitive: Laboratory evidence of a pathogen in the transfusion recipient. **Probable:** N/A	**Non-severe:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** 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:** **ONE or more of the following:** • Evidence of the pathogen in the transfused component • Evidence of the pathogen in the donor at the time of donation • Evidence of the pathogen in an additional component from the same donation • Evidence of the pathogen in an additional recipient of a component from the same donation **AND** No other potential exposures to the pathogen could be identified in the recipient. **AND EITHER** Evidence that the recipient was not infected with the pathogen prior to transfusion **OR** Evidence that the identified pathogen strains are related by molecular or extended phenotypic comparison testing with statistical confidence ($p<0.05$). **Probable:** **ONE or more of the following:** • Evidence of the pathogen in the transfused component • Evidence of the pathogen in the donor at the time of donation • Evidence of the pathogen in an additional component from the same donation • Evidence of the pathogen in an additional recipient of a component from the same donation. **AND EITHER:** Evidence that the recipient was not infected with this pathogen prior to transfusion **OR** No other potential exposures to the pathogen could be identified in the recipient. **Possible:** Case fails to meet definite, probable, doubtful, or ruled out imputability criteria.
OPTIONAL		**OPTIONAL**
Possible: Temporally associated unexplained clinical **illness** consistent with infection, but no pathogen is detected in the recipient. Other, more specific adverse reactions are ruled out. **Note:** Possible cases cannot meet the **definite** or **probable** imputability criteria.	**Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** The recipient died **as a result of the adverse transfusion reaction.** **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Doubtful:** Laboratory evidence that the recipient was infected with this pathogen prior to transfusion **OR** Evidence is clearly in favor of a cause other than transfusion, but transfusion cannot be excluded. **Ruled Out:** **ALL** of the following (where applicable): • Evidence that the transfused component was negative for this pathogen at the time of transfusion • Evidence that the donor was negative for this pathogen at the time of donation • Evidence that additional components from the same donation were negative for this pathogen **OR** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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 *Escherichia coli* *Klebsiella oxytoca* *Klebsiella pneumoniae* *Pseudomonas aeruginosa* *Serratia marcescens* *Staphylococcus aureus* *Staphylococcus epidermidis* *Staphylococcus lugdunensis* Syphilis *(Treponema pallidum)* *Yersinia enterocolitica*	Cytomegalovirus (CMV) *Enterovirus spp.* Epstein Barr (EBV) Hepatitis A Hepatitis B Hepatitis C Human Immunodeficiency Virus 1 (HIV-1) Human Immunodeficiency Virus 2 (HIV-2) Human Parvovirus B-19 Human T-Cell Lymphotropic Virus-1 (HTLV-1) Human T-Cell Lymphotropic Virus-2 (HTLV-2) West Nile Virus (WNV)	Babesiosis (*Babesia spp*.) Chagas disease (*Trypanosoma cruzi*) 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: 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:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** 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. **Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** 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. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** Conclusive evidence exists that the adverse reaction can be attributed to the transfusion. **Probable**: Evidence is clearly in favor of attributing the adverse reaction to the transfusion. **Possible:** Evidence is indeterminate for attributing the adverse reaction to the transfusion or an alternate cause. **Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** 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, an increase of at least 1°C in temperature over the 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 57.302). If multiple incidents occur in association with an adverse reaction, report them 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' so that the associated patient identifier can be entered 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. Please contact NHSN User Support for help coding incidents if there is uncertainty.

Optional Reporting
Any incident may be optionally reported to NHSN using the detailed Incident form (57.302) or the Monthly Incident Summary form (57.305). Approved deviations from protocol are not considered incidents because they did not occur by accident or in error. However, these may be optionally reported for a facility's use. Incidents that are optionally reported will not be aggregated or analyzed by CDC.

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)

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 incompatible 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		Additional Occupation Types	
IVT	IVT Team Staff	ATT	Attendant/Orderly
MLT	Medical Laboratory Technician	CSS	Central Supply
MTE	Medical Technologist	CSW	Counselor/Social Worker
PHL	Phlebotomist/IV Team	DIT	Dietician
Nursing		DNA	Dental Assistant/Technician
LPN	Licensed Practical Nurse	DNH	Dental Hygienist
CNA	Nurse Anesthetist	DNO	Other Dental Worker
CNM	Certified Nurse Midwife	DNT	Dentist
NUA	Nursing Assistant	DST	Dental Student
NUP	Nurse Practitioner	FOS	Food Service
RNU	Registered Nurse	HSK	Housekeeper
Physician		ICP	Infection Control Professional
FEL	Fellow	LAU	Laundry Staff
MST	Medical Student	MNT	Maintenance/Engineering
PHY	Attending/Staff Physician	MOR	Morgue Technician
RES	Intern/Resident	OAS	Other Ancillary Staff
Technicians		OFR	Other First Responder
EMT	EMT/Paramedic	OH	Occupational Health Professional
HEM	Hemodialysis Technician	OMS	Other Medical Staff
ORS	OR/Surgery Technician	OTH	Other
PCT	Patient Care Technician	OTT	Other Technician/Therapist
Other Personnel		PAS	Physician Assistant
CLA	Clerical/Administrative	PHA	Pharmacist
TRA	Transport/Messenger/Porter	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.

Root Cause Analysis Result(s)
Technical:

- Technical failures beyond the control and responsibility of the facility.
- Poor design of equipment, software, labels or forms.
- Designed correctly but not constructed properly or set up in accessible areas.
- Other material defects.

Organizational:

- Failure at an organizational level beyond the control and responsibility of the facility or department where the incident occurred.
- Inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to new or inexperienced staff.
- Inadequate quality and/or availability of protocols or procedures within the department (e.g., outdated, too complicated, inaccurate, unrealistic, absent or poorly presented).
- Organizational/cultural attitudes and behaviors. For example, internal management decisions when faced with conflicting demands or objectives; an inadequate collective approach and its attendant modes of behavior to risks in the investigating organization.

Human:

- Human failures originating beyond the control and responsibility of the investigating organization. This could include individuals in other departments.
- Inability of an individual to apply their existing knowledge to a novel situation.
- An incorrect fit between an individual's training or education and a particular task.
- A lack of task coordination within a health care team.
- Incorrect or incomplete assessment of a situation including related conditions of the patient and materials to be used before starting the transfusion. Faulty task planning and execution. Example: washing red blood cells using the same protocol as that used for platelets.
- Failure in monitoring a process or patient status.
- Failure in performing highly developed skills.
- Failure in whole body movements, e.g., slips, trips, and falls.

Patient-related:

- Failures related to patient characteristics or conditions which are beyond the control of staff and influence treatment.

Other:

- Cannot be classified under any of the other categories.

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 on this form. Denominators should be entered within 30 days of the end of each month.

Form
CDC 57.303 Hemovigilance Module Monthly Reporting Denominators

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