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 TAGVD 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.

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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 and minimizing unnecessary costs associated with transfusion-related adverse events.

Settings
The Hemovigilance Module may be used by any U.S. healthcare facility where transfusion occurs (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 products throughout the transfusion process, from product receipt from supplier to administration to the patient. Participation in the NHSN Hemovigilance Module requires reporting of all CDC-defined adverse transfusion reactions and associated process incidents that occur **for patients transfused at or by your facility**.

Data Reporting Requirements
- At least 12 months of continuous surveillance
- An annual facility demographic and practice survey for each **calendar** year of participation
- ALL adverse reactions, classified according to CDC-defined case definition criteria
- ALL incidents (i.e., errors or accidents) associated with a reported adverse reaction
- Blood products transfused and samples collected for type and screen or crossmatch each month

Data Collection Forms and Instructions
Paper versions of all forms used to collect data in the NHSN HV 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.

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 departments. 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. Adverse reaction reports should be entered into NHSN after the 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. However, new information can be entered at any time. 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 Classification
Each CDC-defined transfusion-associated adverse reaction must be classified according to specific case definition, severity, and imputability criteria found in the criteria tables in this section.

Defined Adverse Reactions
- Transfusion-associated circulatory overload (TACO)
- Transfusion-related acute lung injury (TRALI)
- Transfusion-associated dyspnea (TAD)
- Allergic reaction (severe)
- 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)

Optional Reporting
Suspected adverse reactions where imputability is determined to be doubtful or ruled out are not required for reporting. A facility may report reactions considered doubtful or ruled out in order to use NHSN to document transfusion reaction **investigations** each month. CDC will not aggregate or analyze these adverse reaction reports. Adverse reactions that are not defined in the suveillance protocol may be reported using the 'Other' and 'Unknown' adverse reaction categories using standard severity and imputability criteria.

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 Food and Drug Administration (FDA). Hospitals and transfusion services should immediately report complications that may be related to the blood donor or to the manufacture of the blood components to the collection facility (Code of Federal Regulations. Title 21 CFR 606.170(a), 2006) and are required to report suspected transfusion-related fatalities directly to FDA (Code of Federal Regulations Title 21 CFR 606.170(b), 2006).

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 1, 2 or 3 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 volume overload are possible. **Probable:** Transfusion is a likely contributor to volume overload **AND EITHER** The patient received other fluids as well **OR** The patient has a history of cardiac insufficiency that could explain the volume overload. **Possible:** The patient has a history of pre-existing cardiac insufficiency that most likely explains volume overload. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
N/A	**N/A**	**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.

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 1, 2 or 3 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 risk factors 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 **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
N/A	**N/A**	**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.

Transfusion-associated dyspnea (TAD)

Case Definition	Severity	Imputability
Definitive: Acute respiratory distress that occurring within 24 hours of cessation of transfusion **AND** Allergic reaction, TACO, and TRALI are ruled out. **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 1, 2 or 3 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. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
N/A	**N/A**	**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.

Allergic reaction

Note: Minor allergic reactions (Severity Grade 1) presenting with only mucocutaneous signs and symptoms that respond quickly to treatment do not have to be reported in 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. For the purpose of classification, this type of allergic reaction would be graded as: **Severe** **Life-threatening** **Death** **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 1, 2 or 3 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. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING 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.

Hypotensive transfusion reaction

Case Definition	Severity	Imputability
Definitive: All other adverse reactions presenting with hypotension are excluded **AND** Hypotension • **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 1, 2 or 3 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. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
Possible: N/A	**N/A**	**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.

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. **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 1, 2 or 3 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 present that could explain symptoms, but transfusion is the most likely cause. **Possible:** Other present causes are most likely, but transfusion cannot be ruled out. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
Possible: N/A	**N/A**	**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.

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 products.

Case Definition	Severity	Imputability
Definitive: Occurs during, immediately after, or within 24 hours of cessation of transfusion with **ANY** of the following signs/symptoms: • Back/flank pain • Chills/rigors • Discolored urine (gross visual hemolysis) • Disseminated intravascular coagulation (DIC) • Epistaxis • Fever • 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 **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 clinical and laboratory criteria for acute hemolysis **AND EITHER** **(IMMUNE MEDIATED)** Physical cause is excluded but serologic testing is incomplete **OR** **(NON-IMMUNE MEDIATED)** Physical cause is suspected and serologic testing is negative. **OPTIONAL** **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 1, 2 or 3 as appropriate given the clinical circumstances related to the reaction. **Not Determined:** The severity of the adverse reaction is unknown or not stated. **OPTIONAL** N/A	**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. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated. **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.

Delayed hemolytic transfusion reaction (DHTR)

Note: Report hemolytic reactions resulting from **intentionally-**transfused incompatible blood products.

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. **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. **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.	**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 1, 2 or 3 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 explanation for symptoms or newly-identified antibody is present. **Probable:** An alternate explanation for symptoms or newly-identified antibody is present, but transfusion is the most likely cause. **Possible:** Other explanations for symptoms or newly-identified antibody are more likely, but transfusion cannot be ruled out. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
Possible: N/A	**N/A**	**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.

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:** N/A **Possible:** N/A **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
N/A	**N/A**	**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.

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 1, 2 or 3 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). **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
N/A	**N/A**	**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.

Post transfusion purpura (PTP)

Case Definition	Severity	Imputability
Definitive: Alloantibodies in the patient directed against HPA-1a or other platelet specific antigen detected at or after development of reaction **AND** Thrombocytopenia (i.e., decrease in platelets to less than 20% of pre-transfusion count). **Probable:** Alloantibodies in the patient directed against HPA-1a or other platelet specific antigen detected at or after development of reaction. **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 1, 2 or 3 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. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
REPORTING OPTIONAL		
Possible: PTP is suspected, but symptoms 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 reactions are ruled out.	**N/A**	**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.

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. **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.	**Definite:** **ONE or more of the following:** • Evidence of the pathogen in the transfused product • Evidence of the pathogen in the donor at the time of donation • Evidence of the pathogen in an additional product from the same donation • Evidence of the pathogen in an additional recipient of a product from the same donation **AND** Evidence that the recipient was not infected with the pathogen prior to transfusion **AND** No other potential exposures to the pathogen could be identified in the recipient. **Probable:** **ONE or more of the following:** • Evidence of the pathogen in the transfused product • Evidence of the pathogen in the donor at the time of donation • Evidence of the pathogen in an additional product from the same donation • Evidence of the pathogen in an additional recipient of a product 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. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.
OPTIONAL		**OPTIONAL**
NA		**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 product 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 products from the same donation were negative for this pathogen • Evidence that additional recipient(s) transfused with product(s) from the same donation were negative for this pathogen. **OR** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

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 infections potentially transfusion-transmitted:

1. Identification by testing (e.g., gram stain, other smear/staining, culture, or other method) of an unexpected 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 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 blood smear, histopathology or stool testing for ova/parasites 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/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), 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 a required by CDC. CDC does not specifically define the 'Other' or 'Unknown' adverse reaction categories, therefore the case definition criteria may only be reported as N/A. Standard criteria for severity and imputability are provided for your use.

Case Definition	Severity	Imputability
	REPORTING OPTIONAL	
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 1, 2 or 3 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-D	Anti-E	Anti-c	Anti-e	Anti-K
Anti-k	Anti-Jka	Anti-Jkb	Anti-S	Anti-Fya	Anti-Fyb	Anti-M	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: 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 red spots (with or without itching).

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 chapter 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
(Products Received from Outside Source)
- PC 00 Detail not specified
- PC 01 Data entry incomplete/not performed/incorrect
- PC 02 Shipment incomplete/incorrect
- PC 03 Product and paperwork do not match
- PC 04 Shipped under inappropriate conditions
- PC 05 Inappropriate return to inventory
- PC 06 Product confirmation
- PC 07 Administrative check (2nd check)

Product/Test Request
(Clinical Service)
- PR 00 Detail not specified
- PR 01 Order for wrong patient
- PR 02 Order incorrectly entered online
- PR 03 Special needs not indicated on order (e.g., CMV negative, auto)
- PR 04 Order not done/incomplete/incorrect
- PR 05 Inappropriate/incorrect test ordered
- PR 06 Inappropriate/incorrect blood product ordered

Sample Collection
(Clinical/Transfusion Service)
- 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

Sample Handling
(Clinical/Transfusion Service)
- SH 00 Detail not specified
- SH 01 Sample arrived without requisition
- SH 02 Requisition and sample label don't match
- SH 03 Patient ID incorrect/illegible on requisition
- SH 05 No phlebotomist/witness identification
- SH 06 Sample arrived with incorrect requisition
- SH 07 Patient information (other than ID) missing/incorrect on requisition
- SH 10 Sample transport issue

Sample Receipt
(Transfusion Service)
- SR 00 Detail not specified
- SR 01 Sample processed in error
- SR 02 Historical review incorrect/not done
- SR 03 Demographic review/data entry incorrect/not done
- SR 04 Sample incorrectly accessioned (test/product)
- SR 05 Duplicate sample sent

Sample Testing
(Transfusion Service)
- ST 00 Detail not specified
- ST 01 Data entry incorrect/not performed
- ST 02 Appropriate sample checks not done
- ST 03 Computer warning overridden
- ST 05 Sample tube w/incorrect accession label
- ST 07 Sample tubes mixed up
- ST 09 Test tubes mislabeled (wrong patient name/number)
- ST 10 Equipment problem
- ST 12 Patient testing not performed
- ST 13 Incorrect testing method chosen
- ST 14 Testing performed incorrectly
- ST 15 Test result misinterpreted
- ST 16 Inappropriate/expired reagents used
- ST 17 ABO/Rh error caught on final check
- ST 18 Current and historical ABO/Rh don't match
- ST 19 Additional testing not performed
- ST 20 Administrative check at time work performed
- ST 22 Sample storage incorrect/inappropriate

Product Storage
(Transfusion Service)
- US 00 Detail not specified
- US 01 Incorrect storage of unit in transfusion service
- US 02 Expired product in stock
- US 03 Inappropriate monitoring of storage device
- US 04 Unit stored on incorrect ABO shelf

Available for Issue
(Transfusion Service)
- AV 00 Detail not specified
- AV 01 Inventory audit
- AV 02 Product status not/incorrectly updated in computer
- AV 03 Supplier recall
- AV 04 Product ordered incorrectly/not submitted

Incident Codes

(continued)

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

Product Selection
(Transfusion Service)
- SE 00 Detail not specified
- SE 01 Incorrect product/component selected
- SE 02 Data entry incomplete/incorrect
- SE 03 Not/incorrect checking of product and/or patient information
- SE 05 Historical file misinterpreted/not checked
- SE 07 Special processing needs not checked
- SE 09 Special processing needs not understood or misinterpreted
- SE 11 Special processing not done

Product Manipulation
(Transfusion Service)
- UM 00 Detail not specified
- UM 01 Data entry incomplete/incorrect
- UM 02 Record review incomplete/incorrect
- UM 03 Wrong component selected
- UM 04 Administrative check at time of manipulation
- UM 05 Labeling incorrect
- UM 07 Special processing needs not checked
- UM 08 Special processing needs misunderstood or misinterpreted
- UM 09 Special processing not/incorrectly done

Request for Pick-up
(Clinical 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 patient not available
- RP 05 Product requested for pick-up IV not ready
- RP 06 Request for pick-up incomplete
- RP 10 Product transport issue

Product Issue
(Transfusion Service)
- UI 00 Detail not specified
- UI 01 Data entry incomplete/incorrect
- UI 02 Record review incomplete/incorrect
- UI 03 Pick-up slip did not match patient information
- UI 04 Incorrect unit selected (wrong person or right person, wrong order)
- UI 05 Product issue delayed
- UI 06 LIS warning overridden
- UI 07 Computer issue not completed
- UI 09 Not/incorrect checking of unit and/or patient information
- UI 11 Unit delivered to incorrect location
- UI 19 Wrong product issued
- UI 20 Administrative review (self, 2nd check at issue)
- UI 22 Issue approval not obtained/documented

Product Administration
(Clinical Service)
- UT 00 Detail not specified
- UT 01 Administered product to wrong patient
- UT 02 Administered wrong product to patient
- UT 03 Product not administered
- UT 04 Incorrect storage of product on floor
- UT 05 Administrative review (unit/patient at bedside)
- UT 06 Administered product w/incompatible IV fluid
- UT 07 Administration delayed
- UT 08 Wrong unit chosen from satellite refrigerator
- UT 10 Administered components in inappropriate order
- UT 11 Appropriate monitoring of patient not done
- UT 12 Floor/clinic did not check for existing products in their area
- UT 13 Labeling problem on unit
- UT 19 Transfusion protocol not followed

Other
- MS 99

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/or aliquots of specified blood products transfused each month. When reporting aliquots, the units from which they are made should **NOT** be counted as a transfused unit. The products transfused count should include autologous units. The total number of patient samples collected 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