NATIONAL HEALTHCARE SAFETY NETWORK

Biovigilance Component Hemovigilance Module Protocol Version 3.0

Division of Healthcare Quality Promotion

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Atlanta, GA, USA

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Section 1. Hemovigilance Module Overview

Purpose

The Hemovigilance Module within the National Healthcare Safety Network's (NHSN) Biovigilance Component serves as the national surveillance platform for reporting blood safety events among blood product recipients in U.S. healthcare facilities. The primary objective of the Hemovigilance Module is to improve transfusion safety, including enabling facilities and public health authorities to detect emerging pathogens in the blood supply and guide timely implementation of safety interventions. Activating the Biovigilance Component enrolls your facility into the Hemovigilance Module.

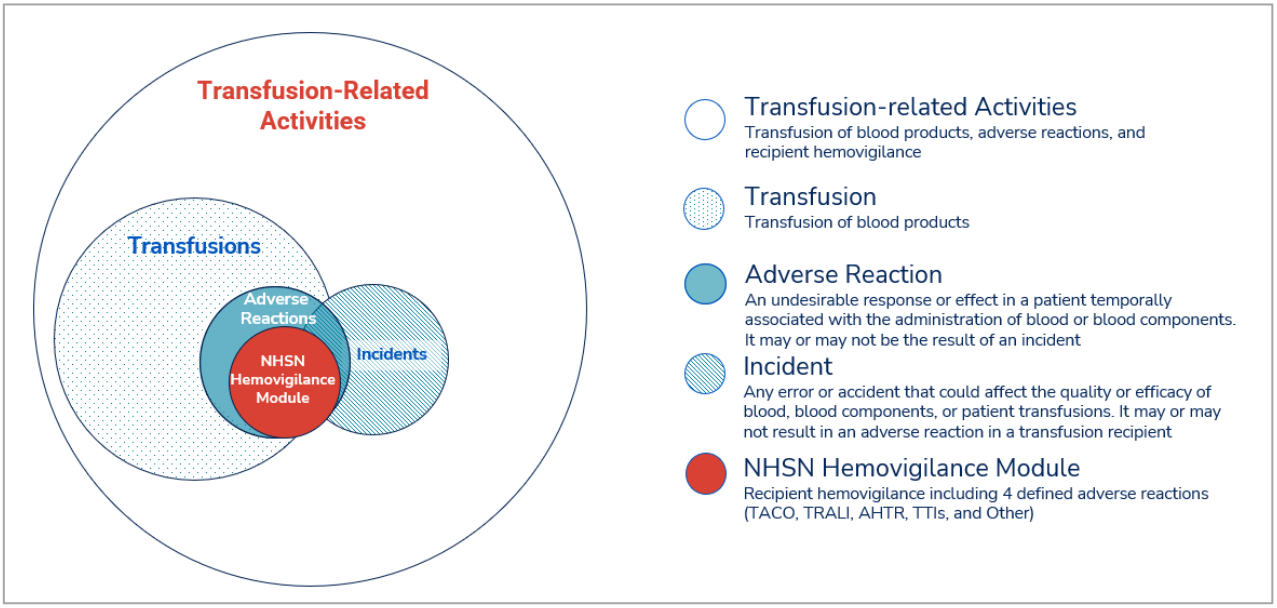
Settings

Any U.S. healthcare facility that transfuses blood components and manufactured blood products (e.g., adult or pediatric facilities, acute or non-acute care facilities) may report into the Hemovigilance Module. The Centers for Disease Control and Prevention (CDC) recommends hemovigilance surveillance 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.

Overview of Transfusion-Related Activities

The Hemovigilance Module is designed to capture a set of serious adverse reactions including acute hemolytic transfusion reaction (AHTR), transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), and transfusion-transmitted infections (TTIs). These reactions are a subset of possible transfusion-related adverse reactions - and incidents resulting in adverse reactions - that can occur **(Figure 1)**.

Figure 1. NHSN Biovigilance Component Hemovigilance Module Surveillance



Abbreviations: AHTR, acute hemolytic transfusion reaction; NHSN, National Healthcare Safety Network; TACO, transfusion-associated circulatory overload; TRALI, transfusion-related acute lung injury; TTI, transfusion-transmitted infection

Methods

CDC recommends that facilities complete an Annual Facility Survey and per-occurrence Transfusion-Transmitted Infection (TTI) Rapid Alerts, TTI Investigation Forms, and Adverse Reaction Forms within the web-based NHSN application **(Table 1).** This is a reduction in requested data collection forms - from twenty to just four - from prior years (See **Section 6** and **Section 7** for classification tables and details related to prior versions).

Table 1. Hemovigilance Module Reports

Reports	Description	Frequency	Reporting Time Estimate	Forms
Annual Facility Survey	Survey of facility characteristics, electronic health record management systems, and transfused or discarded units by product type.	Annual	30 minutes	Survey Survey TOI
Transfusion-Transmitted Infection Rapid Alert	Alert to CDC that an infection with a pathogen of interest was detected in a patient with a history of blood transfusion in the 30 days prior to pathogen detection or symptom onset. Alert will enable CDC to inform local/state health department for potential assistance with TTI investigation.	Per TTI occurrence within 72 hours of potential TTI identification	5 minutes per occurrence	TTI Alert TTI Alert TOI
Transfusion-Transmitted Infection Investigation Form	Form provides details of the TTI investigation.	Per TTI occurrence within 7 days of potential TTI identification	60 minutes per occurrence	TTI Form TTI Form TOI
Adverse Reaction Form	Form includes details of transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), acute hemolytic transfusion reaction (AHTR), or other reaction for which the facility would like to report.	Per adverse reaction occurrence within 30 days of reaction onset	20 minutes per occurrence	Adverse Reaction Form Adverse Reaction Form TOI

Data Collection

All data should be entered into the web-based NHSN application. To facilitate gathering necessary data, Word and PDF versions of the forms are available on the NHSN Blood Safety Surveillance website.

Surveillance Definitions

Each transfusion-associated adverse reaction **must** be classified according to the CDC-defined reaction-specific case definition, severity, and imputability criteria printed in this protocol. Standardized reporting enables CDC to aggregate statewide and nationwide data for meaningful comparisons.

Surveillance definitions are distinct from clinical definitions. The case definitions in the NHSN Hemovigilance Module are surveillance definitions only and are not intended to be used for clinical care decisions. Surveillance definitions are designed to capture data consistently and reliably in order to identify trends.

Analysis & Reporting

- **Facility Report:** CDC provides reporting facilities with a report summarizing the data submitted by the facility to the module for the previous calendar year. This report is currently only shared with the reporting facility.
- **Statewide and Nationwide Reports:** CDC aggregates statewide and nationwide data reported to the module for monthly/annual reports, internal/external dashboards, presentations, and publication in scientific journals.

Training

CDC provides web-based and other training for NHSN facilities to ensure users understand how to use the NHSN application to submit the annual facility survey and report adverse reactions to CDC through the module. Trainings can be found on the Biovigilance Component (BV) Training webpage.

Office Hours

CDC hosts regular office hours to provide reporting facilities with additional support and guidance. Office hours offer facilities the opportunity to ask questions and provide feedback on the module. Please email hemovigilance@cdc.gov to obtain the calendar invitation.

User Support

CDC is available to answer questions about the Hemovigilance Module Protocol and to help navigate the NHSN web application. For hemovigilance-specific questions, please contact hemovigilance@cdc.gov. For questions or issues related to the NHSN web application, please contact nhsn@cdc.gov or submit a helpdesk ticket through the NHSN application.

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 Hemovigilance Module Protocol Version 3.0. 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].

Section 2. Annual Facility Survey

The Hemovigilance Module's Annual Facility Survey collects data on the previous **calendar** year. For example, if a facility enrolls in NHSN in October 2026, the facility will report information for January 2025-December 2025 on the Hemovigilance Module Annual Facility Survey.

The Annual Facility Survey collects information on:

- **Facility Characteristics:** high-level characteristics about the facility and transfusion service including facility type, setting, patient admissions, trauma level, number of surgeries, laboratory testing, staffing, and accreditation.

- **Transfusion Computerization:** information about electronic reporting systems for blood banks, transfusions, and transfusion-related adverse events. CDC requests information about computer systems and technology to facilitate the future development of clinical documentation architecture (CDA) and FHIR reporting to the hemovigilance module.

- **Annual Transfused and Discarded Units:** total number of units transfused and discarded for the survey year. Only totals for red blood cells, platelets, plasma, cryoprecipitated antihemophilic factor, and whole blood are required fields. Facilities may also report the total number of transfused and discarded units collected by apheresis, derived from whole blood, irradiated, leukoreduced, or produced with pathogen-reduction technology (PRT). CDC will use annual denominator data to calculate rates of adverse reactions at a facility-level and national level at the end of the calendar year. Facilities that provide detailed data will have more robust data for analysis and monitoring trends by specific product type.

The Annual Facility Survey is used by CDC to classify facilities for appropriate comparisons in aggregate data analyses. The survey will be used to stratify adverse reaction data to ensure appropriate comparisons and enable accurate statistical rate estimates of transfusion reactions.

Section 3. Transfusion-Transmitted Infection (TTI)

Reporting a transfusion-transmitted infection (TTI) involves submitting two reports to the Hemovigilance Module – a two-question TTI Rapid Alert and a longer TTI Investigation Form. Facilities are encouraged to work with their local or state health department to complete the TTI Investigation Form. Any facility can report a TTI to the module, but reporting requirements may vary by state.

TTI Rapid Alert Form

The TTI Rapid Alert notifies CDC that an infection with a pathogen of interest was detected in a patient with a history of blood transfusion in the 30 days prior to pathogen detection or symptom onset. **Table 2** provides a list of pathogens of interest. Pathogens of interest are those known or presumed to be transfusion-transmissible, but which (except *Babesia; Acinetobacter* in platelets) are not routinely screened for following blood donation.

Timeline

CDC recommends the TTI Rapid Alert form be submitted within 72 hours of identification of a potential TTI.

The TTI Rapid Alert Form collects the following information:

- Recipient information (patient ID, sex, date of birth, medical record number, state of residence)
- Pathogen of Interest
- Transfusion in the 30 days prior to symptom onset or pathogen detection

After submitting the TTI Rapid Alert form:

- CDC will inform the state and/or local health department, if not already notified by the facility. The health department may offer the facility assistance in completing the TTI investigation form.
- CDC recommends the reporting healthcare facility completes and submits the TTI investigation form
    - If the facility reporting the TTI is not the transfusing facility, CDC recommends the reporting facility notify the transfusing facility. The transfusing facility is the preferred facility to submit the TTI investigation form to the module.

Table 2. Transfusion-Transmitted Infections (TTI) Pathogens of Interest.

Viral	Bacterial	Parasitic
Cache Valley virus	*Acinetobacter baumannii*	*Babesia* spp*
Colorado tick fever virus	*Anaplasma phagocytophilum*	*Leishmania* spp.
Dengue virus	*Brucella* spp.	*Plasmodium* spp.
Eastern Equine Encephalitis virus	*Coxiella burnetii*	
Hepatitis A virus	*Ehrlichia* spp.	
Hepatitis E virus	*Leclercia adecarboxylata*	
Japanese Encephalitis virus	*Rickettsia rickettsii*	
Oropouche virus		
Powassan virus		
St. Louis encephalitis virus		
Tick-borne encephalitis virus		
Chikungunya virus		
Yellow Fever virus		
Zika Virus		

*In May 2019, the FDA released guidance to test all donations collected in the 14 states considered Babesia endemic or contiguous to an endemic state: Maine, Vermont, New Hampshire, Connecticut, Massachusetts, New York, New Jersey, Delaware, Rhode Island, Maryland, Pennsylvania, Virginia, Minnesota, and Wisconsin and in the District of Columbia. Link to FDA Guidance: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry

TTI Investigation Form

The TTI Investigation Form provides CDC with details of an ongoing TTI investigation, including patient demographics, clinical symptoms, transfusion history, laboratory results, epidemiologic risk assessment, and overall investigation findings. CDC assists state and local health departments and hospitals in investigating reports of potential infectious disease transmission. The investigation form streamlines communication between the facility, health department, and CDC to detect emerging pathogens in the blood supply and guide timely implementation of safety interventions.

Timeline

CDC recommends the TTI Investigation Form be started within 7 days of identification of a potential TTI. Facilities are encouraged to work with their local or state health department to complete the TTI Investigation Form **(Figure 2).**

Begin data entry as soon as information becomes available; do not wait until all information is complete. Early completion of the transfused component details table during a TTI investigation enables timely donor traceback, allowing public health authorities and blood collection agencies to trace and quarantine additional donor co-components before transfusion into other recipients.

Reporting

Requirements for TTI reporting may vary by state, but all TTI investigations can be reported to the module. When known, please select the appropriate case definition, severity, and imputability classifications (**Table 3**). Upon completion of the investigation, set the Facility/Health Department Investigation Status as "Complete."

The TTI Investigation form collects the following information:

- Demographic information (name, sex, date of birth, state of residence, race, ethnicity, and blood group)
- Medical history
- Adverse reaction details (date reaction occurred, where patient was transfused, etc.)
- Laboratory results
- Clinical presentation
- Treatment
- Outcome (death, intensive care unit, hospitalization, etc.)
- Epidemiologic risk assessment
- Transfused component details
- Blood product/donor investigation
- Investigation findings (case definition, severity, and imputability classifications)
- Facility/Health Department investigation notes
- CDC investigation notes

TTI Investigation Triggers

CDC recommends the following serve as triggers for initiating an investigation:

1. Identification by testing (e.g., gram stain, other smear/staining, culture, serology, molecular test 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, 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 transfusion 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.

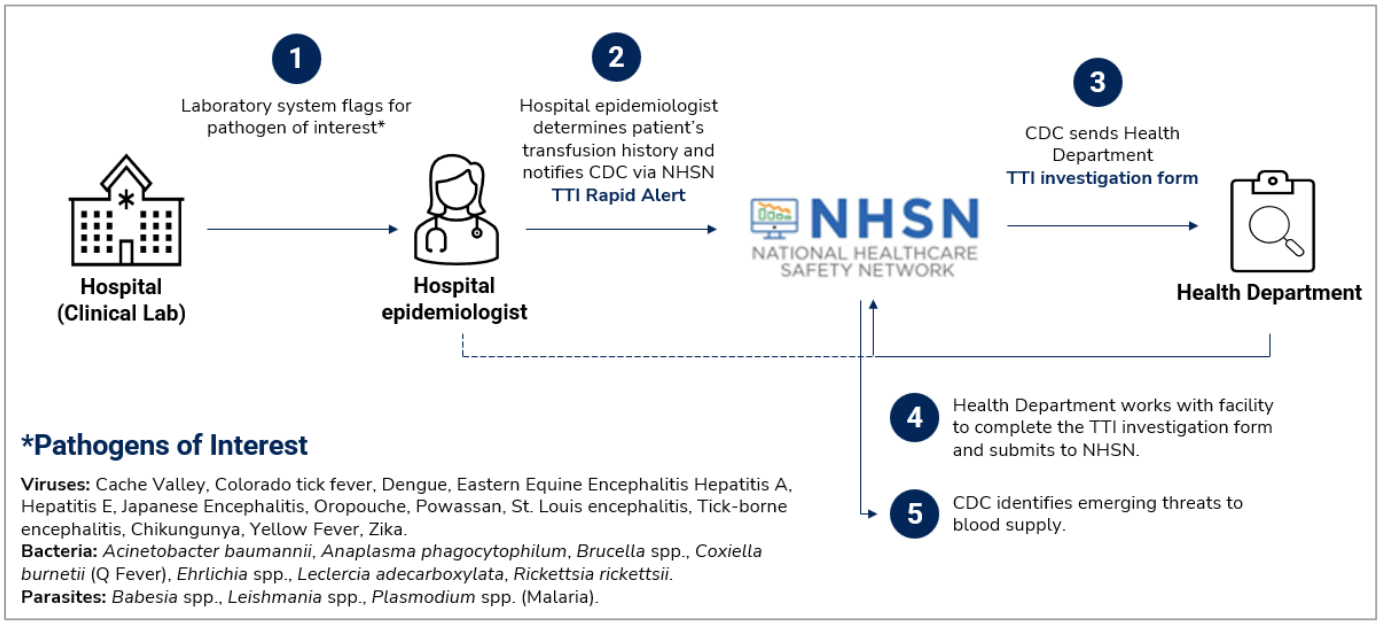
4. Any of the above laboratory findings in the residual blood product upon further testing.

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 (human immunodeficiency viruses [HIV 1,2], T. *cruzi* [Chagas], Hepatitis B, Hepatitis C, Human T-Lymphotropic virus (HTLV-1/2), T. *pallidum* [syphilis], West Nile Virus, Babesia), 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.

Relationship of transfusion to death:
Please report all transfusion-related deaths to the Food and Drug Administration (FDA). Indicate the relationship between the transfusion and recipient's death by selecting 'Definite', 'Probable', 'Possible', 'Doubtful', 'Ruled Out', or 'Not Determined' using FDA criteria.[1]

Figure 2. Framework for transfusion-transmitted infection (TTI) reporting



[1]Food and Drug Administration. *Notifying FDA of Fatalities Related to Blood Collection or Transfusion Guidance for Industry*. Silver Spring, MD: Office of Communication, Outreach and Development; 2021. Available at: https://www.fda.gov/media/70676/download. Accessed February 12, 2026.

Table 3. Transfusion-transmitted infection (TTI)

<table>
<tr><th>Case Definition</th><th>Severity</th><th>Imputability</th></tr>
<tr><td rowspan="2">Definitive:
Laboratory evidence of a pathogen in the transfusion recipient.

Probable:
N/A

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.</td><td rowspan="2">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.</td><td>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.</td></tr>
<tr><td>OPTIONAL
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.</td></tr>
</table>

Section 4. Adverse Reactions (AHTR, TACO, TRALI, Other)

Timeline
CDC recommends the Adverse Reaction Form be submitted after the reaction has been completed and imputability has been determined to the extent possible, within 30 days from reaction onset.

Case Definitions
Each transfusion-associated adverse reaction **must** be classified according to the CDC-defined reaction-specific case definition, severity, and imputability criteria printed in the protocol **(Tables 4-7).**

Adverse reactions aside from AHTR, TACO, TRALI, and TTI (e.g., defined reactions previously reportable to the module such as transfusion-associated acute gut injury [TRAGI], transfusion-associated immunomodulation [TRIM], iron overload, microchimerism, hyperkalemia, thrombosis) may be reported using the 'Other' adverse reaction categories and standard severity and imputability criteria are provided; however, CDC will not use "Other" category data to calculate rates. Case definitions for reactions previously included in the module can be found in **Section 6** of the protocol.

Incident codes related to an adverse reaction can be found in **Table 8.**

The Adverse Reaction Form collects the following information:

- Demographic information (name, sex, date of birth, state of residence, race, ethnicity, and blood group)
- Medical history
- Adverse reaction details (date reaction occurred, where patient was transfused, etc.)
- Clinical presentation
- Treatment
- Outcome (death, intensive care unit, hospitalization, etc.)
- Transfused component details
- Laboratory results
- Investigation findings (case definition, severity, and imputability classifications)
- Facility investigation notes
- CDC case management/notes

Relationship of transfusion to death:
Please report all transfusion-related deaths to FDA. Indicate the relationship between the transfusion and recipient's death by selecting 'Definite', 'Probable', 'Possible', 'Doubtful', 'Ruled Out', or 'Not Determined' using FDA criteria.[2]

[2]Food and Drug Administration. *Notifying FDA of Fatalities Related to Blood Collection or Transfusion Guidance for Industry*. Silver Spring, MD: Office of Communication, Outreach and Development; 2021. Available at: https://www.fda.gov/media/70676/download. Accessed February 12, 2026.

Table 4. Acute hemolytic transfusion reaction (AHTR)

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.	**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		**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.		**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.

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

Table 5. Transfusion-associated circulatory overload (TACO)

Case Definition	Severity	Imputability
Definitive: New onset or exacerbation of 3 or more of the following within **12 hours** of cessation of transfusion: **(At least 1 of the following:)** •Evidence of acute or worsening respiratory distress (dyspnea, tachypnoea, cyanosis and decreased oxygen saturation values in the absence of other specific causes) **and/or** •Radiographic or clinical evidence of acute or worsening pulmonary edema (crackles on lung auscultation, orthopnea, cough, a third heart sound and pinkish frothy sputum in severe cases); **or both** **AND** •Elevated brain natriuretic peptide (BNP) or NT-pro BNP relevant biomarker •Evidence of cardiovascular system changes not explained by underlying medical condition (Elevated central venous pressure, evidence of left heart failure including development of tachycardia, hypertension, widened pulse pressure, jugular venous distension, enlarged cardiac silhouette and/or peripheral edema) •Evidence of fluid 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:** 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.

Table 6. 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.

Table 7. Other transfusion reaction

Note: Adverse reactions aside from AHTR, TACO, TRALI, and TTI may be reported using the 'Other' adverse reaction categories and standard severity and imputability criteria are provided; however, CDC will not use "Other" category data to calculate rates. Case definitions for reactions previously included in the module can be found in Section 6 of the protocol.

Case Definition	Severity	Imputability
Not Applicable: CDC does not specifically define the 'Other' 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.

Section 5. Hemovigilance Glossary and Incident Codes

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.

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 resulting from excessive fluid accumulation.

Epistaxis: Bleeding from the nose.

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

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

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

Hemoglobinuria: Presence of free hemoglobin in the urine.

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

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**(Table 8)**.

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

Oliguria/ anuria: 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.

Table 8. Incident Codes

Note: Incident codes are based on the Medical Event Reporting System – Transfusion Medicine (MERS-TM) (US) and Transfusion Error Surveillance System (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 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 /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 negative, 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

Sample Collection (cont'd)
- 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
(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)

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

Product Manipulation/Processing/Testing
(Transfusion Service)
Events that occur while testing, manipulating (e.g., pooling, washing, aliquoting, irradiating), processing, or labeling blood products.
- UM 00 Detail not specified
- UM 01 Data entry incomplete/incorrect/not performed
- UM 02 Record review incomplete/incorrect/not performed
- UM 03 Incorrect product (type) selected
- UM 04 Incorrect product (patient) selected
- UM 05 Product labeled incorrectly (new/updated)
- UM 06 Computer warning overridden in error or outside SOP
- UM 07 Special processing needs not checked
- UM 08 Special processing needs misunderstood or misinterpreted
- UM 09 Special processing needs performed incorrectly
- UM 10 Special processing needs not performed
- UM 11 Equipment problem/failure/not properly QC'd
- UM 12 Reagents used were incorrect/ inappropriate/expired/not properly QC'd
- UM 13 Confirmatory check incorrect/not performed (at time work performed)
- UM 14 Administrative check incorrect/not performed (record review/audit)

No Blood
- NB 01 Inventory less than usual par level due to supplier unable to meet usual steady demand
- NB 02 Demand for blood product exceeding usual par inventory level
- NB 03 Incompatible/inappropriate units issued due to inventory constraints when demand for blood product exceeds usual par inventory levels.

No Blood (cont'd)

NB 04 Suboptimal dose (less than optimal quantity) transfusion or no transfusion due to inventory constraints when demand for blood product exceeds usual par inventory levels.

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 positive)

Product Issue (cont'd)

UI 20 Confirmatory check incorrect/not performed (at time work performed)
UI 21 Administrative check incorrect/not performed (record review/audit)
UI 22 Issue approval not obtained/documented
UI 23 Receipt verification not performed (pneumatic tube issue)

Satellite Storage

(Clinical Service)

Events that occur while product is stored and handled by the clinical service.

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

Product Administration

(Clinical Service)

Events that occur during the administration of blood products.

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

Product Administration (cont'd)	**Other**
UT 23 Transfusion documentation incorrect/incomplete/not performed UT 24 Transfusion documentation not returned to transfusion service UT 26 Transfusion reaction protocol not followed	MS 99 Other

Section 6. Previously Used NHSN Classifications for Other Adverse Reactions

Purpose

The purpose of this section is to ensure that previously used NHSN classifications for other adverse reactions remain available for facilities wishing to continue reporting adverse reactions beyond AHTR, TACO, TRALI, and TTIs.

The information described below is no longer requested for the NHSN Hemovigilance module; classifications have been retained so they may be accessed by public health and hemovigilance partners.

Archived Documents:

- Allergic reaction
- Delayed hemolytic transfusion reaction (DHTR)
- Delayed serologic transfusion reaction (DSTR)
- Febrile non-hemolytic transfusion reaction (FNHTR)
- Hypotensive transfusion reaction (HTR)
- Post transfusion purpura (PTP)
- Transfusion-associated dyspnea (TAD)
- Transfusion-associated graft vs. host disease (TAGVHD)
- Hemovigilance Module Denominators
- Occupation Codes
- Incident Glossary

Adverse Reactions

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 **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.

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. **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 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.
OPTIONAL		**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.		**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.

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 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 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.		**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 (HTR)

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.

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-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.

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.

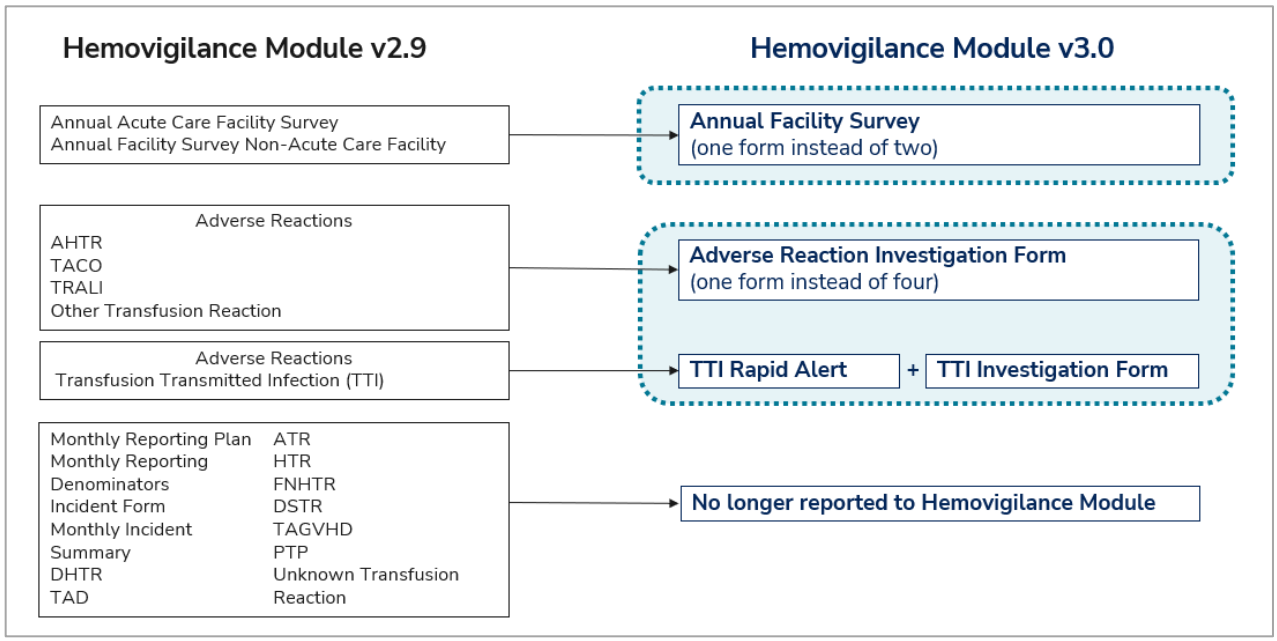
Section 7. Version History

Protocol Version	Protocol 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 working group 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 OPTIONAL use.
		Removed redundant and unnecessary appendices.

Protocol Version	Protocol Release Date	Summary of Revisions
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.
2.1.1	September 2013	Updated diagram in Section 1 and added version history for v2.0 and v2.1.
2.1.2	January 2014	Updated the incident codes in Section 4 and included required reporting of discards and total crossmatch procedures on the Monthly Reporting Denominators form in Section 5.
2.1.3	August 2014	Added a suggested citation for the surveillance protocol in Section 1. Updated the acute hemolytic case definition in Section 3 for clarity. Updated the reporting requirements in Section 5 for clarity.
2.2	January 2016	Updated contact instructions for consistency in Section 1: User support
		Updated version number in Section 1: Suggested Citation
		Remove Root Cause Analysis Result from Section 4: Incident Glossary
		Updated denominator report description to include Pathogen-reduced products in Section 5: Required Reporting
2.3	June 2016	Updated denominator report description to include Table 3 description.
2.4	January 2017	Section 1: Setting – Added additional Annual Facility form for Non-Acute Care Facilities to report.
		Section 2: Annual Facility Survey – Added information about Non-Acute Care Facility Annual Facility Survey, Added links to the Annual Facility Survey – Non-Acute Care Facility form and table of instructions for clarity.
2.5	January 2018	Section 1: Training, User Support, Data Reporting – Minor language changes for clarification
		Section 3: Adverse Reaction Classification – Added information about module-generated classification designations.
		Adverse Reaction Glossary: Updated the definition of fever to be consistent with FNHTR criteria.
2.5.2	April 2018	Section 4: Incident codes - UT 06 – “incompatible” replaced with “unapproved”
2.6	March 2021	Section 3: Adverse Reaction Classification - Updated case definition criteria for TACO reactions
2.7	October 2022	Section 4: Updated the incident codes in Section 4 to include under-transfusion with the creation of a new process code: no blood (NB) and four incident codes
2.8	February 2023	Section 4: Optional Reporting: Clarification regarding analysis of optional reporting
2.9	March 2025	Section 2: Added new sex response option to acute (Question 34) and non-acute (Question 21) annual facility survey. Gender and sex at birth were removed as response options in the acute (Question 34) and non-acute (Question 21) annual facility survey.
		Section 3: Added new sex variable in the adverse reaction data collection forms.
		Removed gender identity and sex at birth from adverse reaction data collection forms.
		Updated links to NHSN blood safety website, tables of instruction (TOIs), and

Protocol Version	Protocol Release Date	Summary of Revisions
		annual facility surveys for clarity.
3.0	January 2026	Major changes to reporting requirements **(Figure 3):** • Facilities can submit the annual facility survey. • Facilities can report transfusion-transmitted infections (TTIs) to the module via the new TTI rapid alert form and complete the TTI investigation form. • Facilities can report TACO, TRALI, AHTR, and Other reports to the module.
		Major changes to incident reporting. With this release, individual incident reports and monthly incident data are no longer reportable to the module. Incident codes related to an adverse reaction can now be captured within the updated adverse reaction form.
		Major changes to adverse reaction reporting requirements. With this release, DHTR, TAD, ATR, HTR, FNHTR, DSTR, TAGVHD, and PTP are no longer requested reporting to the module. Only TTI, TACO, TRALI, AHTR, and Other are requested to be reported to the module.
		Protocol sections have been renamed, repurposed, and reorganized. A new Section 6 has been added to ensure that previously used NHSN classifications for other adverse reactions and other related documents remain available for facilities.

Figure 3. Overview of changes to NHSN Hemovigilance Module.



Abbreviations: AHTR, acute hemolytic transfusion reaction; DHTR, delayed hemolytic transfusion reaction; TACO, transfusion-associated circulatory overload; TRALI, transfusion-related acute lung injury; TTI, transfusion transmitted infection; TAD, transfusion-associated dyspnea; ATR, allergic transfusion reaction; HTR, hypotensive transfusion reaction; FNHTR, febrile non-hemolytic transfusion reaction; DSTR, delayed serologic transfusion reaction; TAGVHD, transfusion-associated graft versus host disease; PTP, post-transfusion purpura.