The National Healthcare Safety Network (NHSN) Manual

Biovigilance Component

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National Healthcare Safety Network (NHSN)

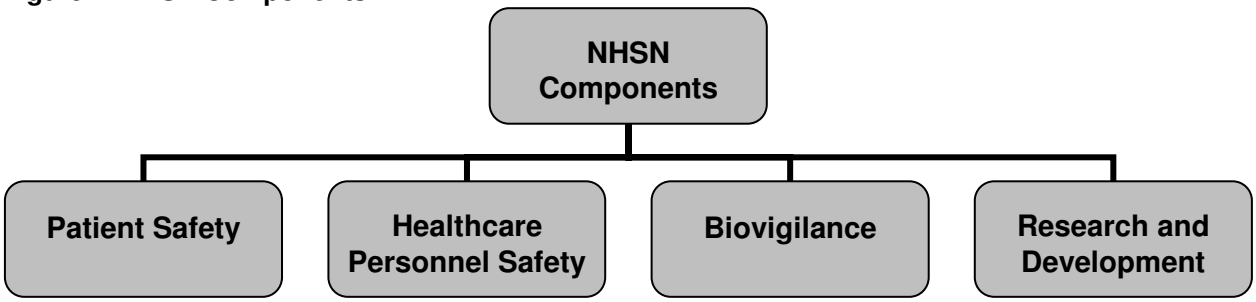
The NHSN is a secure, internet-based surveillance system that integrates former CDC surveillance systems, including the National Nosocomial Infections Surveillance System (NNIS), National Surveillance System for Healthcare Workers (NaSH), and the Dialysis Surveillance Network (DSN).

NHSN enables healthcare facilities to collect and use data about healthcare-associated infections, adherence to clinical practices known to prevent healthcare-associated infections, the incidence or prevalence of multidrug-resistant organisms within their organizations, trends and coverage of healthcare personnel safety and vaccination, and adverse events related to the transfusion of blood and blood products. Some U.S. states utilize NHSN as a means for healthcare facilities to submit data on healthcare-associated infections (HAIs) mandated through their specific state legislation.

The NHSN includes four components, each concerned with various aspects of control and prevention of HAIs. Those four components are Patient Safety, Healthcare Personnel Safety, Biovigilance, and Research and Development as illustrated below in Figure 1. NHSN users do not use the Research and Development Component of the system. NHSN users do however, access and participate in the Patient Safety, Healthcare Personnel Safety, and Biovigilance Components of NHSN.

A facility (acute care hospital, ambulatory surgery center, outpatient dialysis center) may use one, two, or all three NHSN components concurrently. Even if a facility is using more than one NHSN component, there must be only one designated NHSN Facility Administrator that is responsible for activating and deactivating components for that facility. If your facility is already using NHSN for another purpose, you will not need to complete the entire enrollment process to use the Biovigilance Component. Instead, the NHSN Facility Administrator will activate the Biovigilance Component, designate a BV Component Primary Contact, and add at least one NHSN User with rights to the BV Component. Please contact your Infection Prevention team to determine if your facility is already enrolled in NHSN. Contact nhsn@cdc.gov if you have questions about the enrollment or component activation process.

Figure 1. NHSN Components.



Research and Development

Research and Development is concerned with enabling infection control software systems, private or public, to communicate with the NHSN thereby reducing manual data entry. This component involves internal activities at CDC in partnership with software and data messaging specialists.

Patient Safety

Within the Patient Safety Component, like-types of surveillance are grouped into modules, each concerned with healthcare procedures, devices, or medications associated with HAIs. Specific types of surveillance within the Patient Safety Component are outlined below:

- Device-associated Module:
  - CLABSI - Central line-associated bloodstream infection

  - CLIP - Central line insertion practices adherence
  - VAP - Ventilator-associated pneumonia
  - CAUTI - Catheter-associated urinary tract infection
  - DE - Dialysis Event
- Procedure-associated Module:
  - SSI - Surgical site infection
  - PPP - Post-procedure pneumonia
- Medication-associated Module:
  - AUR - Antimicrobial use and resistance options
- Multidrug-Resistant Organisms/*Clostridium difficile*-associated Disease (MDRO/CDAD) Module
- Vaccination Module

Instructions and standardized surveillance methods and definitions for each module of the Patient Safety Component are provided in individual protocols available on the NHSN website. Modules may be used singly or simultaneously and each module has its own minimum time-period for required participation (see individual modules). Regardless of the combination of modules a facility chooses to participate in, a total of 6 months of data must be reported annually to NHSN for continued participation.

Healthcare Personnel Safety
There are two modules within the Healthcare Personnel Safety (HPS) Component of NHSN: the Blood/Body Fluid Exposure Module and the Influenza Vaccination Module. The Blood/Body Fluids Exposure and the Influenza Vaccination Modules may be used separately or simultaneously. Instructions and standardized surveillance methods and definitions for each module are provided in the NHSN Manual found on the NHSN website.

Biovigilance
The Biovigilance Component of NHSN was developed in collaboration with the transfusion and transplant communities. Biovigilance includes the collection of adverse event data to improve outcomes in the use of blood products, organs, tissues, and cellular therapies. The Hemovigilance Module is the first module of the Biovigilance Component to be developed in NHSN. This module is designed for staff in healthcare facility transfusion services to track adverse events, including recipient adverse reactions and quality control incidents, related to blood transfusion.

Biovigilance Component

Patient safety related to medical intervention has become an increasing public health concern in recent years. The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) intends to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients. In 2006, the Department of Health and Human Services' (HHS) Advisory Committee on Blood Safety and Availability (ACBSA) convened to make recommendations to improve patient safety related to transfusion and transplantation. ACBSA membership includes liaisons from federal public health agencies as well as representatives from industry, patient advocates, and the blood collection and transfusion communities.

A recommendation was given to the Secretary of HHS by ACSBA that a national system was needed for surveillance of recipient outcomes of blood and blood products. Such surveillance, often referred to as hemovigilance, exists in most other developed countries, but not in the United States. Subsequently, the American Association of Blood Banks (AABB) formed an Inter-organizational Task Force on Biovigilance, with representation from both governmental and non-governmental organizations in the United States. The committee defined as their main task to develop "a comprehensive and integrated national patient safety program to collect, analyze, and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues, and organs. The program should be outcome driven with the objectives of providing early warning systems of safety issues, exchanging of

safety information, and promoting education and the application of evidence for practice improvement." While biovigilance also includes organ and tissue transplant safety, blood safety, or hemovigilance, was the first topic of focus in the development of a national surveillance system.

After a review of the different systems that could be used to collect transfusion safety data, the AABB Biovigilance Task Force identified CDC's National Healthcare Safety Network (NHSN) as the surveillance system that most closely met the data requirements for a national surveillance system for blood transfusion adverse event data collection. The Hemovigilance Module of the Biovigilance Component is intended to capture both adverse transfusion reactions and errors and accidents for the purpose of evaluating patient safety.

Hemovigilance Module

Based on the last published Nationwide Blood Collection and Utilization Survey Report (NBCUS)[1], the total supply of whole blood and red blood cells collected in the United States in 2004 was approximately 15 million units. Recipients received, on average, 2.7 units each resulting in a national estimate of 5.3 million patients transfused.

While the risk of infectious disease as a result of transfusion has been estimated (for example, the risk of HIV is approximately 1 in 2 million), data on transfusion related, non-infectious adverse reactions and incidents associated with transfusion are not collected in the United States using a comprehensive reporting system with standard definitions. Therefore, estimates of the burden of adverse events related to transfusion are not possible. The 2004 NBCUS found that 1,322 medical facilities reported 32,128 transfusion-related reactions that required diagnostic or therapeutic intervention[1]. While any transfusion-associated adverse reaction is considered rare, the general consensus in the United States is that there could be considerable underreporting based on surveillance reports of similar events from national surveillance programs in the United Kingdom and Canada. Collection of data on all adverse events, including reactions, incidents, and near-misses, would provide the basis for interventions and implementation of best practices designed to improve transfusion safety.

Five layers of safeguards established by the Food and Drug Administration (FDA) have become standard operating procedure for blood establishments and others involved in the collection and distribution of blood and blood products. These safeguards include screening of blood donors, testing of blood for bloodborne pathogens (including HIV, Hepatitis B & C viruses, *Treponema pallidum* (syphilis), West Nile virus and others), maintaining lists of deferred donors (persons either temporarily or permanently excluded from blood donation), routine quarantine of all blood products until infectious disease testing and final donor eligibility determination has been completed, and investigation of any problems associated with blood products including safeguard failures, errors, accidents, or any other event that could jeopardize blood product safety.

Despite the rigorous safeguards in place, non-infectious complications of transfusion can still occur due to the complex physiological mechanisms involved in transfusions. In addition, the risk of error associated with administration of a particular blood product to a particular patient is a persistent concern. In 1999, the Institute of Medicine report, To Err is Human, estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors. In terms of blood safety, mistransfusion of blood (failure to give the right product to the right patient) is the error of greatest concern.

Adverse Reactions

Over the past three decades, emphasis on the detection and prevention of infectious disease transmission through transfused blood and blood products led to FDA requirements for routine testing of donated blood for a variety of bloodborne pathogens. With enactment of these testing requirements and the subsequent decrease in the incidence of transfusion transmitted infections, reactions with non-infectious causes became more apparent. A recent review article[2] classified these reactions as early (onset during or within hours of the transfusion) or late (onset days to months following transfusion) and

provided estimates of reaction occurrence. Although the estimates varied considerably depending on the study, severe reactions have fatal event rates of 1 per million to 1 per 8 million transfused components. Severe early reactions such as Transfusion Related Acute Lung Injury (TRALI) showed fatal events to be 1 for every 3-6.6 million blood products administered. Febrile non-hemolytic reactions, while uncomfortable for the patient, usually are not associated with severe morbidity or mortality and are reported to occur in ~1 in 100 per products transfused depending upon the type of product. The lack of consistent reporting of transfusion related adverse reactions demonstrates the need for national surveillance to provide data that are more representative of actual events.

Incidents

In transfusion medicine most incidents do not result in harm to the patient. Studies have shown the risk of erroneous or mistransfusion of red cell (RBC) units to be approximately 1 in 14,000 to 1 in 38,000 [3]. A mistransfusion is failure to give the correct blood to the intended recipient and is a preventable human error; in the worst consequence, this can result in major ABO incompatibility and patient illness or death. Transfusion incidents can involve errors in more than one step of the process of getting the right blood to the right patient. Identification of where in the process these incidents occur can provide information that will help facilities improve their procedures and potentially prevent patient harm. Data collection for incident reporting is intended to provide numbers of occurrences and types of incidents and near misses where the error is discovered before the incorrect product reaches the patient.

Using the NHSN Hemovigilance Module

The Hemovigilance Module offers facilities to perform tracking, trending, and analysis of adverse transfusion reactions as well as incidents that have led to mistransfusions, which may or may not have led to an adverse reaction. Included in incident reporting is the reporting of a near-miss, which is an incident that is discovered before an incorrect product reaches the patient. The purpose of the Hemovigilance Module is to collect, analyze, and report information on blood transfusion-related adverse events, including adverse reaction and incident reporting.

Definitions

Adverse Event†: An undesirable and unintended occurrence before, during, or after transfusion of blood or blood components that may be related to the administration of the blood or blood component. It may be the result of an incident and it may or may not result in a reaction in a recipient.

Adverse Reaction†: An undesirable response or effect in a patient temporally associated with the administration of blood or blood component. It may be the result of an incident or an interaction between a recipient and blood, which is a biologically active product.

Incident†: A case where the patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. It thus comprises transfusion errors and deviations from standard operating procedures or hospital policies that have lead to mistransfusions. It may or may not lead to an adverse reaction.

Near Miss†: An error or deviation from standard procedures or policies that is discovered before the start of a transfusion and that could have led to a wrongful transfusion or to a reaction in a recipient.

†*Defined by the International Society of Blood Transfusion (ISBT).*

For the purposes of surveillance, the NHSN Hemovigilance Module uses the following definitions:

Incident: Any error or accident that could lead to an adverse outcome affecting the safety, efficacy, or quality of blood, blood components, or plasma derivatives; or the safety of transfusion recipients. This includes errors, deviations from hospital standard operating procedures, and near misses.

High-priority Incident: Any incident that has high potential for wrongful transfusion in a recipient (for example, wrong blood in tube) if the associated product were to be transfused. These include but are not limited to sample labeling errors, patient identification errors, and special processing needs not indicated, not done, misunderstood, misinterpreted, etc. The high-priority incidents are designated with a "+" in the table in Appendix F.

Surveillance Methods

The Hemovigilance Module requires comprehensive, prospective, active and passive, patient-based surveillance of patients throughout the transfusion process (from product receipt from supplier to administration to the patient). The data collected will initially be used to produce crude event rates, but will be expanded to risk-adjusted rates as more data is available.

Comprehensive

Priority-directed surveillance objectives are defined and focused on specific events, processes, organisms, and/or patient populations. Comprehensive surveillance provides continuous monitoring of all patients receiving transfusion for transfusion-related events. Hemovigilance will use comprehensive surveillance methodology.

Prospective

Prospective surveillance involves on-going monitoring of patients for events while they are still hospitalized. Retrospective surveillance is case-finding that is based on chart review after patient discharge. Prospective surveillance is the recommended method of surveillance for hemovigilance.

Active and Passive

When performing active surveillance, trained personnel, such as staff in Hospital Blood Transfusion Services, use standard definitions and a variety of data sources to identify events. Passive surveillance in hemovigilance involves situations where personnel not trained to perform surveillance are required to report blood transfusion adverse reactions and incidents to blood transfusion services as a part of their job responsibilities. Hemovigilance will involve both active and passive surveillance methods.

Patient-based

Patient-based surveillance in hemovigilance involves monitoring individual patients for adverse reactions of transfusion. Transfusion staff will be expected to provide guidance to patient care staff in identifying and reporting blood transfusion adverse reactions. All reports of blood transfusion related events should be investigated to ensure that reporting is as complete as possible. This may include reviewing patient charts and discussing the event with caregivers.

Crude Rates vs. Risk-adjusted Rates

The last method we will discuss is the use of risk-adjusted or crude rates in analysis. Risk-adjusted rates are controlled for variations in the distribution of major risk factors associated with an event's occurrence. Comparison of risk-adjusted rates between facilities is useful. Crude rates assume equal distribution of risk factors for all events and are not useful for comparison. Rates in hemovigilance will be crude until enough data have been collected for risk-adjustment

Surveillance Data

- **Adverse Reaction Surveillance**
  Numerators:
  - Adverse reactions that meet the definitive or probable case definition criteria each month.
  - Deaths related to transfusion each month.

Denominators:
- Numbers of units and/or aliquots of blood products transfused each month.

- **Incident Surveillance**

  Numerators:
  - Incidents reported each month.
  - High priority incidents reported each month.
  - Adverse reactions associated with incidents each month.

  Denominators:
  - Number of patient blood samples collected for type and screen or crossmatch each month.

Settings

Surveillance should be performed by hospital transfusion services and can be performed in any adult or pediatric acute or chronic care facility where transfusion occurs, including patient care areas for emergency, general medical, and surgical patients; obstetrics and gynecology; orthopedics, oncology, and other chronic diseases; and any other patient care setting where transfusion services are provided.

When setting up your NHSN Facility, you will map each physical location in your facility to an NHSN Facility Location. NHSN Facility Locations are shared across component. Therefore it is imperative that you collaborate with your NHSN Facility Administrator to create and update NHSN Locations for use in the Hemovigilance Module. More information on Location designation can be found at the NHSN website, in the Hemovigilance Module training slides, and by accessing **HELP** when logged into NHSN. All incidents and adverse reactions will be reported by location in NHSN. You must complete your Location set up before reporting events.

Reporting Requirements

- Participating facilities are expected to provide at least 12 months of data when using the Hemovigilance Module.
- Participating facilities are required to enter an Annual Facility Survey once per year.
- Participating facilities must enter a Monthly Reporting Plan for each month of surveillance. Indicate on this form which method of Incident Reporting will be used each month.
- Participating facilities must report Monthly Reporting Denominators for each month of surveillance.
- Participating facilities must report all blood or blood component transfusion-associated Adverse Reactions (using NHSN Case Definitions) each month.
- Participating facilities must report all incidents that occur each month, but may choose from two methods of incident reporting:
  - Facilities may choose to enter a monthly summary report (counts only) of **ALL** incidents that occur **PLUS** detailed reports for each of those that are designated as high-priority and incidents associated with an Adverse Reaction regardless of incident code or priority designation. This method is recommended for facilities that already utilize an electronic reporting system for incident tracking.
  - Facilities may choose to enter detailed reports for every single incident that occurs. This method is recommended for facilities that do not otherwise electronically track or report incidents and want to use NHSN for that purpose.

Data Collection Forms

There are six data collection forms used in the Hemovigilance Module. Instructions for completing each form are found in the **Hemovigilance Module Tables of Instruction** posted on our website. All data are reported to CDC using the NHSN web application. Paper forms are provided to aid participating facilities in data collection.

CDC 57.300 Hemovigilance Module Annual Facility Survey
Participating facilities must enter a Hemovigilance Module Annual Facility Survey at the time that they enroll or activate the module and at the beginning of each calendar year thereafter. The Hemovigilance Module Annual Facility 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 Hemovigilance Module Annual Facility Survey covers the previous **calendar** year. For example, if you are enrolling in NHSN for the first time in October of 2010, you will collect information for January 2009-December 2009 in your first Hemovigilance Module Annual Facility Survey.

CDC 57.301 Hemovigilance Module Monthly Reporting Plan
A Monthly Reporting Plan must be entered for each month before data can be entered into the system. Plans can be copied forward for all the months of the same calendar year. The Monthly Reporting Plan is used to inform CDC of the facility's chosen method of reporting Incidents each month.

CDC 57.302 Hemovigilance Module Monthly Incident Summary
The Hemovigilance Module Monthly Incident Summary is required if the facility chooses summary incident reporting as the reporting method in the Monthly Reporting Plan. Report any incident for which an incident report has been filed in blood transfusion services. Detailed reports must also be completed for all High-priority incidents that occur and for incidents that are associated with a reported Adverse Reaction. High priority incidents are indicated by a "+" next to the code on the form. Near misses should be documented as robustly as incidents that result in harm to the patient. In addition, detailed incident reports can be filed for any incident where additional information is desired, regardless of the method of reporting used. When completing this form, ALL incidents that occur should be counted, including those for which a detailed report is also entered. Monthly Incident Summaries should be entered within 30 days of the end of each month.

CDC 57.303 Hemovigilance Module Monthly Reporting Denominators
Facilities must report the total numbers 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 total number of patient samples collected is also reported on this form. Monthly Reporting Denominators should be entered within 30 days of the end of each month.

CDC 57.304 Hemovigilance Module Adverse Reaction
All transfusion-associated Adverse Reactions are reported using the Hemovigilance Adverse Reaction form. Report only one Adverse Reaction per form. If a patient experiences more than one adverse reaction during or following the same transfusion episode, complete a separate form for each reaction. Be sure that the definition of one reaction is not included in the definition of the other. For example, a hypotensive transfusion reaction should only be reported if hypotension is not included in the symptom description of another, more specific reaction experienced by the patient during the same transfusion episode. Adverse reactions considered to be transfusion-associated are those for which imputability is determined to be definite, probable, or possible. Adverse reactions for which imputability is doubtful or ruled out should not be routinely reported. The doubtful and ruled out categories should only be used when an adverse reaction that was reported in the system was later determined **not** to be transfusion-related based on new or additional information. 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. Adverse Reaction Case Definitions are found in Appendix A.

Please Note: Reporting of adverse reactions into the NHSN hemovigilance surveillance system does **NOT** take the place of current 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).

CDC 57.305 Hemovigilance Module Incident
The Hemovigilance Module Incident form should be completed for **every** incident that occurs if "detailed reporting of all incidents" is documented on the Monthly Reporting Plan. Report any incident for which an incident report has been filed in blood transfusion services. Report only one incident per form. "Near misses" should be documented as robustly as incidents negative outcomes. All reports should be entered within 30 days of the month of the "Date of Discovery" for the event.

If the "summary incident" reporting option is chosen on your Monthly Reporting plan, the Hemovigilance Module Incident form should be completed for all high-priority incidents, all incidents that are related to an adverse reaction, and any additional incident that you would like to collect detailed information form. All incidents that occur should be documented on the Monthly Incident Summary form.

Data Analysis and Reports

Facilities will have the ability to generate a number of predetermined reports in NHSN. In addition, custom line lists and reports can be created by selecting variables of interest within the application. Once sufficient data has been collected from participating facilities and CDC has published aggregate analyses of the data, comparative values will be included in the facility-level reporting options.

Standard facility-level reports include:

- Line lists
  - Adverse Reactions, including occurrence details, product information, and patient outcomes
  - Incidents, including occurrence details, incident outcomes, and investigation outcomes
  - High-Priority Incidents, including occurrence details, incident outcomes, and investigation outcomes

- Frequency reports
  - Adverse Reactions by product(s) transfused
  - Fatalities by adverse reaction
  - Fatalities by product(s) transfused
  - Incidents as a function of total incidents reported for a selected time period
  - Incidents by number of samples collected
  - Types and numbers of units/aliquots transfused by selected time period
  - Adverse Reaction symptom report by adverse reaction reported
  - ABO incompatibility report by adverse reaction reported

REFERENCES

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2. Eder AF, Chambers L. Noninfectious complications of blood transfusion. *Arch Pathol Lab Med*. 2007; 131: 708-718.
3. Linden JV, Wagner K, Voytovich AE, Sheehan J. Transfusion errors in New York State: an analysis of 10 years' experience. *Transfusion.* 2000; 40: 1207-1213.

Appendix A. Adverse Reaction Case Definition Criteria

Allergic reaction: The result of an interaction of an allergen with preformed antibodies. In some instances, infusion of antibodies from an atopic donor may also be involved. It may present with only mucocutaneous signs and symptoms.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: ≥ 2 of the following occurring during or within 4 hours of the transfusion: • Maculopapular rash with or without pruritus • Urticaria • Pruritis • Generalized flushing • Localized angioedema • Edema of lips, tongue and uvula • Erythema and edema of the periorbital area • Conjunctival edema • Respiratory distress; bronchospasm • Hypotension **Probable:** N/A **Possible:** N/A	**Definitive:** N/A **Probable:** N/A **Possible:** N/A	**Grade 1:** No immediate risk to the life of the patient **AND** Responds quickly to symptomatic treatment. **Grade 2–4:** 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 or 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 very soon after transfusion. **For the purpose of classification this type of allergic reaction would be graded as 2) severe, 3) life-threatening, or 4) death, depending on the course and outcome of the reaction.**	**Definite:** No other evidence of environmental, drug or dietary risks **AND** Occurs during or within 2 hours after transfusion. **Probable:** Other potential causes in an individual with known susceptibility (atopic; previous allergic reactions to transfusions). **AND** Occurs during or within 2 hours after transfusion. **Possible**: Other likely causes such as medication or exposures but transfusion cannot be ruled out, usually a first reaction of this sort **AND** Occurs 2-4 hours after transfusion.

Acute hemolytic transfusion reaction (AHTR): Rapid destruction of red blood cells during, immediately after, or within 24 hours of a transfusion. Clinical and laboratory signs of hemolysis are present. No single criterion exists to definitively diagnose this rare disorder. See Appendix D for common antibodies associated with AHTR.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: Occurs during, immediately after, or within 24 hours of transfusion with **ANY** of the following: • Chills/rigors • Fever • Back/flank pain • Hypotension • Hemoglobinuria during or shortly after transfusion • Epistaxis • Oliguria/anuria • Renal failure • Disseminated intravascular coagulation (DIC) • Pain and/or oozing at IV site **AND EITHER** ABO incompatibility or other allotypic RBC antigen incompatibility **OR** Clerical check indicates that the patient's name and blood group on the blood unit are different than the recipient's name and blood group. **Probable:** Any combination of clinical features as above **Possible:** N/A	**Definitive:** Positive direct antiglobulin test for anti-IgG or anti-C3 **AND** Positive elution test with alloantibody present on the transfused red blood cells **AND** ≥2 of the following: • Elevated LDH • Elevated bilirubin • Low haptoglobin • Hemoglobinuria • Low fibrinogen • Elevated plasma hemoglobin **Probable:** Incomplete laboratory results to meet definitive case definition criterion. **Possible:** N/A	**Use severity grades as defined in Appendix C.**	**Definite:** Occurs during, immediately after or within 24 hours of transfusion. **AND EITHER** There is known ABO or other allotypic RBC antigen incompatibility **OR** Serologic work-up consistent with AHTR and no other cause of acute hemolysis. **Probable:** Occurs during, immediately after or within 24 hours of transfusion but no serologic evidence of AHTR **AND** Blood bank testing may show abnormal results but AHTR may also be due to erythrocyte auto-antibodies in the recipient. **Possible:** Occurs during, immediately after or within 24 hours of transfusion but there is evidence of non-immune contributing factors such as hemolysis-inducing mechanical factors (e.g. malfunction of a pump, blood warmer, use of hypotonic solutions, etc.).

Delayed hemolytic transfusion reaction (DHTR): The recipient develops antibodies to RBC antigen(s) between 24 hours and 28 days after a transfusion. Clinical signs of hemolysis are usually present. See Appendix D for common antibodies associated with DHTR.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: Patient may be asymptomatic or have similar to, but milder symptoms than AHTR. Examples of milder symptoms include: • Chills/rigors • Fever • Jaundice • Back/flank pain • Hypotension • Hemoglobinuria/ hematuria • Oliguria/anuria. **NOTE:** These are NOT required to meet definitive case criteria. **Probable:** Same as definitive case criteria. **Possible:** N/A	**Definitive:** Positive direct antiglobulin (Coombs) test **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. **NOTE**: If performed, post transfusion increases in LDH and bilirubin levels that subsequently fall back to baseline in the following days. **Probable:** Newly identified red blood cell alloantibody but does not meet definitive laboratory criteria. **Possible:** N/A	**Use severity grades as defined in Appendix C.**	**Definite:** Newly identified red blood cell alloantibody **AND** Occurs between 24 hours and 28 days after transfusion **AND** Positive direct antiglobulin test with identification of a new antibody either in the serum or eluate **AND** No other explanation for drop in hemoglobin. **Probable:** Occurs between 24 hours and 28 days after transfusion. **AND** No other explanation for drop in hemoglobin. **AND** No confirmation on serologic testing. **Possible:** N/A

Delayed serologic transfusion reaction (DSTR): Demonstration of new, clinically significant alloantibodies against red blood cells between 24 hours and 28 days after a transfusion despite an adequate, maintained hemoglobin response. See Appendix D for common antibodies associated with DSTR.

Case Definition Criteria		**Severity**	**Imputability**
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: No clinical or laboratory signs of hemolysis. **Probable**: N/A **Possible**: N/A	**Definitive:** Demonstration of new, clinically significant antibodies against red blood cells between 24 hours and 28 days after a transfusion that were not present in the pre-transfusion specimen **BY EITHER** Positive direct antiglobulin (Coombs) test **OR** Positive antibody screen with newly identified RBC alloantibody. **Probable**: N/A **Possible**: N/A	**Use severity grades as defined in Appendix C.**	**Definite**: Occurs 24 hours to 28 days after the transfusion **AND EITHER** Recent RBC transfusion with subsequent formation of newly identified RBC alloantibody **OR** Positive direct antiglobulin test. **Probable**: N/A **Possible**: N/A

Hypotensive transfusion reaction: A drop in systolic and/or diastolic blood pressure occurring during or within one hour of completing transfusion.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: **ALL OF THE FOLLOWING:** • Hypotension - Adults (≥18 years of age): Drop in systolic and/or diastolic blood pressure of >30 mm Hg. - Infants, children (≥1 year old) and adolescents (<18 years of age): >25% drop in systolic BP (e.g., drop in baseline systolic BP of 120mm/Hg to below 90mm/Hg). - Neonates, small infants < 1 year of age OR any age and <12 kg body weight: >25% drop in baseline value using whichever measurement being recorded (e.g., mean BP). • Occurs within 15 minutes after the start of the transfusion • Responds rapidly (within 10 minutes) to cessation of transfusion and supportive treatment • All other categories of adverse reactions presenting with hypotension are excluded. **Note 1**: Other symptoms, such as facial flushing, dyspnea, or abdominal cramps may occur but usually hypotension is the sole manifestation. **Note 2**: If the patient meets the criteria for another, more specific adverse transfusion reaction where hypotension is a symptom of that reaction, the more specific adverse reaction should be reported. **Probable:** Same as definitive criteria **EXCEPT:** Onset is greater than 15 minutes after start of transfusion **OR** The patient does not respond within 10 minutes to cessation of transfusion and supportive treatment. **Possible:** Same as definitive criteria **EXCEPT:** Other conditions are present or were present before the transfusion that could explain hypotension.	**Definitive:** N/A **Probable:** N/A **Possible:** N/A	**Grade 1:** The recipient required no more than discontinuation of transfusion and symptom management **AND** No long-term morbidity resulted from the reaction. **Grade 2:** The recipient required in-patient hospitalization or prolongation of hospitalization due to hypotension or hypotension led directly to long-term morbidity (e.g., brain damage) **AND** Vasopressors were not required. **Grade 3:** The recipient required vasopressors. **Grade 4:** The recipient died as a result of the reaction or as a result of treatment directly related to resolving symptoms of the hypotensive transfusion reaction.	**Definite:** Meets the definitive protocol criterion **AND** The patient has no other conditions that could explain hypotension. **Probable:** Other conditions that could explain hypotension are unlikely but not fully excluded. **Possible:** Other conditions that could readily explain hypotension are present.

Febrile non-hemolytic transfusion reaction (FNHTR): Fever and/or chills **without** hemolysis occurring in the patient up to 4 hours during and after transfusion. If transfusion-related, the most common cause is a reaction to passively transfused cytokines or a reaction of recipient antibodies and leukocytes in the blood product.

Case Definition Criteria		**Severity**	**Imputability**
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: Occurs during or within 4 hours of transfusion **AND EITHER** Fever (≥38°C oral or equivalent and a change of ≥1°C from pre-transfusion value) **OR** Chills/rigors are present. **NOTE:** FNHTR can be present in absence of fever if chills or rigors occur. **Probable:** N/A **Possible:** N/A	**IF PERFORMED (Not required to meet definitive criteria):** • Negative culture of residual component • Negative post-transfusion patient blood culture • Lab findings not consistent with acute hemolysis as cause of fever.	**Use severity grades as defined in Appendix C.**	**Definite:** Meets definitive protocol criterion **AND** Patient has no other conditions that could explain symptoms. **Probable:** Other conditions that could explain fever/chills are unlikely but not fully excluded. **Possible:** Other conditions are present or were present before the transfusion that could explain the symptoms.

Post transfusion purpura (PTP): Thrombocytopenia usually arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: Thrombocytopenia (decrease to <20% of pre-transfusion count) **AND** Occurs 5-12 days post-transfusion. **Probable:** Thrombocytopenia (decrease to <20% of pre-transfusion count) but 5-12 days post-transfusion timeframe not met **OR** Thrombocytopenia (decrease to <20% of pre-transfusion count) with competing explanations **OR** Drop in platelets between 20% and 80% of pre-transfusion count. **Possible:** Clinical and laboratory presentation meet definitive or probable criteria but alternate explanations more likely **OR** Clinical presentation meets definitive or probable criteria but HPA antibodies not tested or negative.	**Definitive:** Alloantibodies in the patient directed against HPA-1a or other platelet specific antigen detected at or after development of reaction. **Probable:** Alloantibodies in the patient directed against HPA-1a or other platelet specific antigen detected at or after development of reaction. **Possible:** HPA antibodies not tested or negative.	**Use severity grades as defined in Appendix C.**	**Definite:** Meets definitive **OR** probable case definition criterion. **Probable:** N/A **Possible:** Meets possible case definition criterion.

Transfusion associated circulatory overload (TACO): Infusion volume that cannot be effectively processed by the recipient either due to high infusion rate and/or volume or an underlying cardiac or pulmonary pathology.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: New onset or exacerbation of ≥ 3 of the following within 6 hours of transfusion: • Acute respiratory distress (dyspnea, orthopnea, cough) • Evidence of positive fluid balance • Elevated brain natriuretic peptide (BNP) • Radiographic evidence of pulmonary edema • Evidence of left heart failure • Elevated central venous pressure (CVP). **Probable:** N/A **Possible:** N/A	**Definitive:** N/A **Probable:** N/A **Possible:** N/A	**Use severity grades as defined in Appendix C.**	**Definite:** Meets definitive case definition criterion and no other cause of volume overload are possible. **Probable:** Meets definitive case definition **AND** Transfusion is a likely contributor to volume overload, but the patient received other fluids as well. **Possible:** Meets definitive case definition criterion but the patient has a history of pre-existing cardiac insufficiency. **NOTE:** Imputability should not be classified higher than possible if the patient has a history of pre-existing cardiac insufficiency.

Transfusion associated dyspnea (TAD): Respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not otherwise be explained by a patient's underlying or pre-existing medical condition.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: Acute respiratory distress **AND** Occurs within 24 hours of transfusion **AND** TRALI, TACO, allergic reaction and other underlying medical conditions ruled out. **Probable:** N/A **Possible:** N/A	**Definitive:** N/A **Probable:** N/A **Possible:** N/A	**Use severity grades as defined in Appendix C.**	**Use imputability criteria as defined in Appendix C.**

Transfusion associated graft vs. host disease (TAGVHD): The introduction of immunocompetent lymphocytes into susceptible hosts. The allogeneic lymphocytes engraft, proliferate and destroy host cells.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: A clinical syndrome occurring from 2 days to 6 weeks following transfusion characterized by symptoms of: • Fever • Characteristic rash: Erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation. • Hepatomegaly • Diarrhea **Probable:** Clinical presentation consistent with TAGVHD described above. **Possible:** Clinical presentation consistent with TAGVHD described above.	**Definitive:** Liver dysfunction, i.e., elevated ALT, AST, Alkaline phosphatase, and elevated bilirubin **AND** Pancytopenia **AND** WBC chimerism in the absence of alternative diagnoses **AND** Characteristic histological appearance of skin biopsy or liver biopsy. **NOTE:** If performed, marrow study shows hypoplasia, aplastic anemia, or marked hypocellularity with a lymphohistiocytic infiltrate. **Probable:** Meets definitive laboratory criteria **EXCEPT** Biopsy negative or not done. **Possible:** Meets definitive criteria **EXCEPT** Chimerism not present or not done.	**Grade 1:** N/A **Grade 2:** Patient had marked symptoms and responded to treatment. **Grade 3:** Patient had severe symptoms and alive due to treatment (e.g., immunosuppression). **Grade 4:** Patient died from TAGVHD.	**Definite:** Meets definitive case definition criterion and related to blood donor, i.e. there are matching chimeric alleles in the donor and recipient. **Probable:** Presentation consistent with TAGVHD; however, chimerism demonstrated in recipient but matching alleles could not be tested in the donor. **Possible:** Presentation consistent with TAGVHD though alternative explanations are likely and TAGVHD cannot be confirmed, as with negative chimerism studies or in the case of allogeneic solid organ transplantation.

Transfusion-related acute lung injury (TRALI): Acute hypoxemia with PaO_2/fraction of inspired oxygen [FIO_2] ratio of 300 mm Hg or less combined and chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e., circulatory overload). Onset of TRALI is abrupt in association with transfusion.

Case Definition Criteria		**Severity**	**Imputability**
Signs/Symptoms	**Laboratory/Radiology**		

Definitive:
NO evidence of acute lung injury (ALI) prior to transfusion
AND
ALI onset during or within 6 hours of transfusion
AND
Hypoxemia defined by any of these methods:
• PaO_2 / $FiO_2 \leq$ 300 mm Hg
• Oxygen saturation is < 90% on room air
• Other clinical evidence
AND
No evidence of left atrial hypertension (i.e. circulatory overload)
AND
No temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion.
 	
Probable:
N/A
 	
Possible:
Same as definitive **EXCEPT** there is a temporal relationship to one of the following alternate risk factors:
• 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
	Definitive:
	Bilateral infiltrates on chest radiograph
	
	Probable:
	N/A
	
	Possible:
	N/A
		Use severity grades as defined in Appendix C.	**Definite:**
			Meets definitive case definition criterion.
			
			Probable:
			N/A
			
			Possible:
			Meets possible case definition criterion.

Transfusion-transmitted infection: A bacteria, parasite, virus, or other potential pathogen transmitted in donated blood to transfusion recipient.

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. All infectious organisms are available from the full drop-down pathogen list in NHSN.

Bacterial	Viral	Parasitic	Other
Escherichia coli *Klebsiella oxytoca* *Klebsiella pneumoniae* *Pseudomonas aeruginosa* *Serratia marcescens* *Staphylococcus aureus* *Staphylococcus epidermidis* *Staphylococcus lugdunensis* Syphilis (*Treponema pallidum*) *Yersinia enterocolitica*	Cytomegalovirus (CMV) Enterovirus 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 (or, leukemia) Virus-1 (HTLV-1) Human T-Cell Lymphotropic (or, leukemia) Virus-2 (HTLV-2) West Nile Virus *(Flaviviridae*)	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 organism 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.

For a decision on imputability, consider various types of evidence such as the following:

1. Evidence of contamination of the recipient unit upon residual testing.
2. Pre- and post- transfusion infection status (e.g., seroconversion) in the recipient.
3. Evidence of other recipients with infection from the same organism who received blood from the same donor.
4. Evidence of the donor infection with the same organism.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: N/A **Probable:** N/A **Possible:** N/A **NOTE:** An investigation can be initiated based on clinical events occurring after transfusion that are consistent with transfusion-transmitted infection. However; there must be laboratory evidence of the suspected pathogen in the transfusion recipient to call an adverse reaction a transfusion-transmitted infection.	**Definitive:** Laboratory evidence of the suspected pathogen in the transfusion recipient. **Probable:** N/A **Possible:** N/A	**Use severity grades as defined in Appendix C.**	**Definite:** An investigation trigger with laboratory evidence of the suspected organism in the recipient **AND** Evidence that the recipient was not infected with this organism prior to transfusion **AND** Laboratory evidence of infection with the same organism in the donor **AND** Laboratory evidence of infection with the same organism in any other recipients from the same donor as the initial case recipient **OR** Laboratory evidence of the infection with the same organism in the recipient unit (or retained segment) or co-component from the original donation. **Probable:** An investigation trigger with laboratory evidence of the suspected organism in the recipient **Plus any <u>two</u> of the following:** Evidence that the recipient was not infected with this organism prior to transfusion **OR** Laboratory evidence of infection with the same organism in other recipients (if any) from the same donor as the initial case recipient **OR** Laboratory evidence of infection with the same organism the donor **OR** Laboratory evidence of infection with the same organism in the recipient unit (or retained segment) or co-component from the original donation. **Possible:** An investigation is triggered, but information essential for confirming or ruling out a case is missing, not available, or cannot be obtained **AND** Case fails to meet definition for **definite, probable** or **ruled out.** **Doubtful or Ruled Out:** (Do not file a report with NHSN) Laboratory evidence that the donor is negative for infection. **OR** Laboratory evidence that the recipient had infection with this organism prior to transfusion. **NOTE:** For bacterial cases, identification of the organism in the unit upon residual testing is equivalent to laboratory evidence of the same organism in the donor.

Appendix B. Adverse Reaction Clinical and Laboratory Definitions

Blood pressure decrease:

- Adults (≥ 18 years of age): Drop in systolic and/or diastolic blood pressure (BP) of > 30 mm Hg.
- Infants, children (≥ 1 year old), & adolescents (<18 years of age): > 25% drop in systolic BP (e.g., drop in baseline systolic BP of 120mm/Hg to below 90mm/Hg).
- Neonates & small infants (< 1 year of age OR any age and < 12 kg body weight): > 25% drop in baseline value in whatever measurement is being recorded (e.g,, mean BP).

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, occurring during or within 4 hours of transfusion.

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.

Fever: An increase of ≥ 1° C in temperature over the pre-transfusion temperature during or within 4 hours of the completion of the transfusion.

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. PaO_2 / FiO_2 ≤ 300 mm Hg OR oxygen saturation is < 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 within 72 hours of the identification of the blood transfusion reaction (< 500 cc output per 24 hours).

Other rash: Other (non-urticarial) skin rash experienced during or within 4 hours of the completion of transfusion.

Pain (abdominal, back, flank, infusion site): Pain experienced at any site during or within 4 hours of completion of transfusion.

Pruritis: Itching

Shock: A drop in blood pressure accompanied by a drop in cardiac output including rapid heart rate (increase to ≥ 100 beats per minute), 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) during or within 24 hours of the completion of transfusion.

Urticaria (hives): Raised red spots with or without itching, or generalized itching without redness during or within 4 hours of the completion of the transfusion.

Appendix C. Adverse Reaction Severity and Imputability Definitions

Severity

Grade 1: 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.

Grade 2: 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.

Grade 3: Life-threatening
Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.

Grade 4: Death
The recipient died as a result of the adverse transfusion reaction.

Note: Grade 4 should be used only 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.

Imputability

Once the investigation of the adverse transfusion reaction is completed, this is the assessment of the the relationship between the transfusion and the adverse reaction.

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 attributing the adverse reaction to a cause other than the transfusion.

***Ruled Out**: Conclusive evidence beyond reasonable doubt that the adverse event can be attributed to a cause other than the transfusion.

Not Determined: The relationship between the adverse reaction and the transfusion is unknown or not stated.

*Adverse reactions for which imputability is doubtful or ruled out should not be routinely reported. The only time these categories can be used is when a reaction was initially thought to be transfusion-related but additonal information revealed a non-transfusion related cause.

Appendix D. Antibodies Associated with Hemolytic Transfusion Reactions

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

Appendix E. NHSN Occupation Codes

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

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

Appendix F. NHSN Incident Codes (Based on MERS-TM & TESS)

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
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
(Service Collecting Samples)
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

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

+ Indicates high-priority incidents. Individual incident report must be completed for each.

Appendix G. Incident Definitions

Incident Result

No Recovery, harm
Product was transfused and the patient experienced an adverse reaction.

No Recovery, no harm
Product was transfused, but the patient did not experience an adverse reaction.

Near miss, unplanned recovery
Product was not transfused. The incident was discovered ad hoc, by accident, a human lucky catch, etc. It was not discovered through formalized facility standard operating procedures or other previously instituted system of checks and balances to prevent such incidents.

Near miss, planned recovery.
Product was not transfused. The incident was discovered through standardized processes or barriers built into the system to prevent errors.

Root Cause Analysis Result(s)

Technical:
- Technical failures beyond the control and responsibility of the facility.
- Failure due to poor design of equipment, software, labels or forms.
- Correct design but not constructed properly or set up in 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.
- Failure resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff.
- Failure relating to the quality and availability of the protocols/procedures within the department (e.g., too complicated, inaccurate, unrealistic, absent or poorly presented).
- Internal management decisions when faced with conflicting demands or objectives. Failures resulting from collective approach and its attendant modes of behavior to risks in the investigating organization. These are organizational cultural attitudes and behaviors. For example, if the organizational culture is one where compliance with safety related procedures is low or procedures are not enforced.

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. Example: a blood bank technologist who is unable to solve a complex antibody identification problem.
- The incorrect fit between an individual's training or education and a particular task. Example: expecting a technician to solve the same type of difficult problem as a technologist.
- A lack of task coordination within a health care team. Example: an essential task not being performed because everyone thought that someone else had completed the task.
- Incorrect or incomplete assessment of a situation including related conditions of the patient and materials to be used before starting the transfusion. Example: failure to correctly identify the patient by checking the wristband.

- 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. Examples: a trained technologist operating an automated instrument and not realizing that a pipette that dispenses a reagent is clogged. Failure of the patient care staff to observe an allergic reaction in a patient after a transfusion is started.
- Failure in performance of highly developed skills. Example: a technologist adding drops of reagents to a row of test tubes misses a tube or a computer entry error.
- Failure in whole body movements. "Slips, trips and falls." Examples: a blood bag slipping out of one's hands and breaking; or a person tripping over a loose tile on the floor.

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.

References

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