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NHSN National Healthcare Safety Network

www.cdc.gov/nhsn

Hemovigilance Module
Adverse Reaction

*Required for saving

*Facility ID#: _____ NHSN Adverse Reaction #: _____

Patient Information

*Patient ID: _____ *Gender: ☐ M ☐ F ☐ Other *Date of Birth: __ __/__ __/__ __ __ __

Social Security #: _____ Secondary ID: _____ Medicare #: _____

Last Name: _____ First Name: _____ Middle Name: _____

Ethnicity ☐ Hispanic or Latino ☐ Not Hispanic or Not Latino

Race ☐ American Indian/Alaska Native ☐ Asian ☐ Black or African American
☐ Native Hawaiian/Other Pacific Islander ☐ White

*Blood Group: ☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ Type and crossmatch not done

*Primary underlying reason for transfusion: ☐ Coagulopathy ☐ Genetic Disorder ☐ Hematology Disorder
☐ Hemolysis ☐ Internal Bleeding ☐ Malignancy ☐ Medical ☐ Surgery ☐ Unknown
☐ Other (specify) _____

Reaction Details

*Date reaction occurred: __ __/__ __/__ __ __ __

*Time reaction occurred: __ __:__ __ (HH:MM) ☐ Time unknown

*Facility location where patient was transfused: _____

*Is this reaction associated with an incident? ☐ Yes ☐ No If Yes, Incident #: _____

*Signs and symptoms, laboratory: (check all that apply)

Cardiovascular:
- ☐ Blood pressure decrease
- ☐ Shock

Hemolysis/Hemorrhage
- ☐ Disseminated intravascular coagulation
- ☐ Hemoglobinemia
- ☐ Positive antibody screen

Generalized:
- ☐ Chills/rigors
- ☐ Fever

Cutaneous:
- ☐ Edema
- ☐ Flushing
- ☐ Jaundice
- ☐ Other rash
- ☐ Pruritus (itching)
- ☐ Urticaria (hives)

Renal:
- ☐ Hematuria
- ☐ Hemoglobinuria
- ☐ Oliguria

Pain:
- ☐ Abdominal pain
- ☐ Back pain
- ☐ Flank pain
- ☐ Infusion site pain

Respiratory:
- ☐ Bilateral infiltrates on chest x-ray
- ☐ Bronchospasm
- ☐ Cough
- ☐ Hypoxemia
- ☐ Shortness of breath

☐ Other: (specify) _____

Investigation Results (Use case definition criteria in protocol.)

*Adverse reaction: (check one)

- ☐ Allergic reaction, including anaphylaxis
- ☐ Acute hemolytic transfusion reaction (AHTR)
  - ☐ Immune Antibody: _____ ☐ Non-immune (specify) _____
- ☐ Delayed hemolytic transfusion reaction (DHTR)
  - ☐ Immune Antibody: _____ ☐ Non-immune (specify) _____
- ☐ Delayed serologic transfusion reaction (DSTR) Antibody: _____
- ☐ Febrile non-hemolytic transfusion reaction (FNHTR)
- ☐ Hypotensive transfusion reaction
- ☐ Infection

  Was a test to detect a specific pathogen performed on the recipient post-transfusion?

  ☐ Yes ☐ No If Yes, positive or reactive results? ☐ Yes ☐ No

  Org1 _____ Org2 _____ Org3 _____

  Was a test to detect a specific pathogen performed on the donor post-donation?

  ☐ Yes ☐ No If Yes, positive or reactive results? ☐ Yes ☐ No

  Org1 _____ Org2 _____ Org3 _____

  Was a test to detect a specific pathogen performed on the unit post-transfusion? (i.e., culture, serology, NAT)

  ☐ Yes ☐ No If Yes, positive or reactive results? ☐ Yes ☐ No

  Org1 _____ Org2 _____ Org3 _____
- ☐ Post transfusion purpura (PTP)
- ☐ Transfusion associated circulatory overload (TACO)
- ☐ Transfusion associated dyspnea (TAD)
- ☐ Transfusion associated graft vs. host disease (TA-GVHD)

  Did patient receive non-irradiated blood product(s) in the two months preceding the reaction? ☐ Yes ☐ No
- ☐ Transfusion related acute lung injury (TRALI)

  Antibody studies performed: (optional)

	Not Done	Negative	Test result positive		
			Cognate or cross reacting antigen present	No cognate or cross reacting antigen present	Not tested for cognate antigen
Donor or unit HLA specificity	☐	☐	☐	☐	☐
Donor or unit HNA specificity	☐	☐	☐	☐	☐
Recipient HLA specificity	☐	☐	☐	☐	☐
Recipient HNA specificity	☐	☐	☐	☐	☐

- ☐ Unknown pathophysiology
- ☐ Other (specify) _____

*Case definition criteria: ☐ Definitive ☐ Probable ☐ Possible ☐ N/A

*Severity: ☐ Non-severe ☐ Severe ☐ Life-threatening ☐ Death ☐ Not determined

*Imputability: ☐ Definite ☐ Probable ☐ Possible ☐ Doubtful ☐ Ruled Out ☐ Not determined

Outcome

*Outcome: ☐ Death+ ☐ Major or long-term sequelae ☐ Minor or no sequelae ☐ Not determined

Date of Death: __ __/__ __/__ __ __ __ **+Deaths attributable to transfusion must be reported to FDA.**

^If recipient died, relationship of transfusion to death:

☐ Definite ☐ Probable ☐ Possible ☐ Doubtful ☐ Ruled Out ☐ Not determined

Component Details (Use worksheet on page 4 for additional units.)

*Was a particular unit implicated in the adverse reaction? ☐ Yes ☐ No ☐ N/A

*Transfusion Date/Time MM/DD/YYYY HH:MM	*Component code (check system used)	*# of units	^Unit number *Required for TRALI, GVHD, Infection*	*Unit expiration Date/Time MM/DD/YYYY HH:MM	*Blood group of unit	Implicated in the adverse reaction?
^IMPLICATED UNIT						
__/__/____ __:__	☐ ISBT-128 ☐ Codabar _____	1	_____ __ _____ _____	__/__/____ __:__	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y
__/__/____ __:__	☐ ISBT-128 ☐ Codabar _____		_____ __ _____ _____	__/__/____ __:__	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
__/__/____ __:__	☐ ISBT-128 ☐ Codabar _____		_____ __ _____ _____	__/__/____ __:__	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N

Custom Fields

Label		Label	
_____	__ __/__ __/__ __ __ __	_____	__ __/__ __/__ __ __ __
_____	_____	_____	_____
_____	_____	_____	_____

Comments

_____

_____

_____

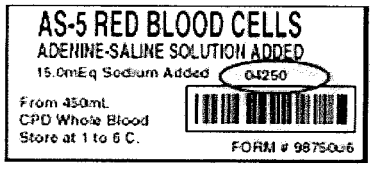
_____

Table 5. Hemovigilance Module Adverse Reaction (CDC 57.304)

Data Field	Instructions for Form Completion
Facility ID#	The Facility ID number will be auto entered by NHSN.
Adverse Reaction #	An adverse reaction number will be auto entered by NHSN.
Patient Information	
Patient ID	Required. Enter the medical record number or other facility alphanumeric identification code for the patient. *Note: Facility patient information is shared across NHSN Component. When an MRN is entered for a patient that has been previously entered for another NHSN event, the patient information will automatically populate. NHSN is HIPPA compliant; it is not recommended to devise a unique patient identifier for NHSN.*
Gender	Required. Select the gender of the transfusion recipient.
Date of birth	Required. Enter the date of birth of the transfusion recipient.
Social Security #	Optional. For local use only.
Secondary ID	Optional. For local use only.
Medicare #	Optional. For local use only.
Last Name	Optional. For local use only.
First Name	Optional. For local use only.
Middle Name	Optional. For local use only.
Ethnicity	Optional. For local use only.
Race	Optional. For local use only.
Blood group	Required. Select the blood group of the transfusion recipient. *Note: If the patient's blood type does not clearly match a single blood type, select the most relevant blood type and make a note in the comments section of the form. For example, if a patient is typing with mixed field reactions following a bone marrow transplant, select the predominant blood type and enter a note in the comments section such as, "Group A recipient of group O bone marrow transplant currently typing as mixed field."*
Primary underlying reason for transfusion	Required: Select the **primary** reason this patient received a transfusion. If none of the options are adequate, select "other" and specify the reason in detail. Avoid using "anemia" as it does not describe the underlying medical condition of the transfusion recipient.
Reaction Details	
Date reaction occurred	Required. Enter the date the reaction was first observed in the transfusion recipient.
Time reaction occurred	Required. Enter the time the reaction was first observed in the transfusion recipient using a 24-hour clock.

Data Field	Instructions for Form Completion
Facility location where patient was transfused	Required. Select the facility location where the patient was transfused. ***Note: Only report reactions for recipients transfused by your facility.***
Link/Unlink Incidents	Conditionally required. Select associated incidents from the list populated by NHSN and SAVE. *Note: The incident record must be entered into the system **first** and must include the associated Patient ID number(s). When linking the adverse reaction record, NHSN searches for matching Patient ID numbers in the incident records.*
Signs and symptoms, laboratory	Required. Check **all** signs and symptoms observed in the patient at the time the reaction occurred as well as any associated laboratory findings. These may or may not be directly related to the observed reaction as patients receiving transfusions typically have underlying medical conditions. See Appendix B in the Hemovigilance Module surveillance protocol for a glossary of signs and symptoms.
Investigation Results	
Adverse reaction	Required. Using the case definition criteria in Appendix A of the Hemovigilance Module surveillance protocol, select the adverse reaction being reported. Report only one adverse reaction per form. *Note: Report the reaction **after the investigation has been finalized**. Incomplete records cannot be saved. If new information becomes available at a later time, the record can be edited.*
• Allergic reaction, including anaphylaxis	
• Acute hemolytic transfusion reaction (AHTR)	
Type of AHTR	Conditionally required. Indicate whether the AHTR was immune-mediated (specify Ab) or non-immune mediated (specify cause).
• Delayed hemolytic transfusion reaction (DHTR)	
Type of DHTR	Conditionally required. Indicate whether the DHTR was immune-mediated (specify Ab) or non-immune mediated (specify cause).
• Delayed serologic transfusion reaction (DSTR)	
DSTR antibody	Conditionally required. Specify Antibody.
• Febrile non-hemolytic transfusion reaction (FNHTR)	
• Hypotensive transfusion reaction	
• Infection	
Was a test to detect a specific antigen performed on the **recipient** post-transfusion?	Conditionally required. Indicate whether or not a test was performed on the **recipient** to detect a specific pathogen after the blood product(s) was/were administered to the recipient.
Positive/Reactive?	Conditionally required. If a post-transfusion test was performed, indicate whether the test was positive or reactive.
Specify organism	Conditionally required. If a post-transfusion test was performed and found to be positive or reactive, report the detected organism(s).

Data Field	Instructions for Form Completion
Was a test to detect a specific antigen performed on the **donor** post-donation?	Conditionally required. Indicate whether or not a test was performed on the **donor** to detect a specific pathogen after the blood was donated.
Positive/Reactive?	Conditionally required. If a post-donation test was performed, indicate whether the test was positive or reactive.
Specify organism	Conditionally required. If a post-donation test was performed and found to be positive or reactive, report the detected organism(s).
Was a test to detect a specific antigen performed on the **unit** post-transfusion?	Conditionally required. Indicate whether or not a test was performed on the **implicated blood product** to detect a specific pathogen after the blood product(s) was/were administered to the recipient.
Positive/Reactive?	Conditionally required. If a post-transfusion test was performed, indicate whether the test was positive or reactive.
Specify organism	Conditionally required. If a post-transfusion test was performed and found to be positive or reactive, enter the detected organism(s).
• Post transfusion purpura (PTP)	
• Transfusion-associated circulatory overload (TACO)	
• Transfusion-associated dyspnea (TAD)	
• Transfusion-associated graft vs. host disease	
Did the patient receive non-irradiated blood product(s) in the two months preceding the reaction?	Conditionally required. Specify whether the patient received any non-irradiated blood products in the two months prior to the TAGVHD reaction.
• Transfusion-related acute lung injury (TRALI)	
Antibody studies performed	Optional. If antibody studies were performed on the donor and/or the recipient, enter the results.
• Unknown pathophysiology *Note: Use this category if the patient experienced transfusion-related symptoms, but the medical event that caused the symptoms could not be diagnosed.*	
• Other (specify) *Note: Use this option if the recipient was diagnosed with an adverse reaction that is not defined in the Hemovigilance Module protocol (e.g., transfusion-associated acute gut injury (TRAGI, thrombosis).*	
Case definition criteria	Required. Using the case definition criteria in Appendix A of the Hemovigilance Module surveillance protocol, select the case criteria met for the reported adverse reaction.
Severity	Required. Using the case definition criteria in Appendix A of the Hemovigilance Module surveillance protocol, select the severity criteria met for the reported adverse reaction.
Imputability	Required. Using the case definition criteria in Appendix A of the Hemovigilance Module surveillance protocol, select the imputability criteria met for the reported adverse reaction. *Note:* ***Doubtful*** *and* ***Ruled Out*** *need not be routinely reported.*

Data Field	Instructions for Form Completion
Outcome	
Outcome	Required. Enter the outcome of the transfusion recipient.
Date of death	Conditionally required. If the recipient died following the adverse reaction, enter the date of death whether or not the death was transfusion related.
Relationship of transfusion to death	Conditionally required. If the recipient died following the adverse transfusion reaction, indicate the relationship of the transfusion to death using the imputability criteria defined in Appendix C of the Hemovigilance Module surveillance protocol.
Component Details	
Was a particular unit implicated in the adverse reaction?	Required. Indicate whether or not a specific unit could be identified as the likely cause of the adverse reaction. Details for the implicated unit must be entered on the first row of the "Component Details" table. Determine "implicated" independent of case definition and imputability criteria. If only one unit was transfused, that unit must be implicated in the reaction. If TACO is being reported, no specific unit may be implicated regardless of the number of units transfused.
Transfusion Date	Required. Enter the date the transfusion began.
Transfusion Time	Required. Enter the time the transfusion began using a 24-hour clock.
Component code (check system used)	Required. Select the labeling system used for the transfused component(s). ***Note: Codabar- and ISBT 128-labeled products may be entered, but each must be entered on their own row.***
Component code	Required. Enter the component code for the product transfused using only the portion that identifies the product type. In the sample label below, the code that identifies the product type is 04250.  *Note: Enter **all** components administered within 24 hours prior to an **acute** transfusion reaction. Enter only the component(s) most likely responsible for **delayed** reactions based on temporal relationship and clinical judgment.* *Note: If the code entered does not match a product description in NHSN, "Component code not found" will appear in the product description field. **Verify your data entry before continuing;** an incorrect or unrecognized component code will not prevent you from saving the adverse reaction record.*

Data Field	Instructions for Form Completion
# of units	Required. Enter the total number of units transfused for each component type. Multiple units may be entered using up to 20 rows.
Unit number	Conditionally required. If reporting a TRALI, GVHD, or infection reaction, enter the individual unit number as it appears on the product label. Unit number is optional for all other adverse reactions. The sample ISBT-128 unit number would be entered as seen below.  W 0 0 0 0 0 7 1 2 3 4 5 6 0 0 D *Note: The check digit is optional. If the check digit is entered, the system will verify that it is correct using an internal check digit calculator. If the check digit is not entered, the space will remain blank.*
Unit expiration date	Required. Enter the expiration date of the unit(s). The expiration date for the sample label below would be 02/11/2007. 
Unit expiration time	Required. Enter the expiration time of the unit(s). NHSN will auto fill this editable field to 23:59(11:59PM). The expiration time for the sample label below would be 15:20. 
Blood group of unit	Required. Select the blood group of the unit(s) transfused; enter **N/A** for products where blood group is not applicable.
Implicated in the adverse reaction?	Conditionally required. If a particular unit was implicated, the unit details must be entered on the first row and this box will be checked. If no unit can be implicated, these boxes will be inactive.
Custom Fields	
Optional. Up to two date fields and ten alphanumeric fields may be added to this form for local use. Each custom field must be added to the form in NHSN before it can be used.	
Comments	
Optional. Enter additional information about the incident.	

The National Healthcare Safety Network (NHSN) Manual

Biovigilance Component

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

Version History

Version	Release Date	Summary of Revisions
1.0	March 2009	First version publicly released.
1.1	June 2010	Revised background and text in main body of document.
		Revised case definition criterion based on WG recommendations, pilot responses, and CDC recommendations.
		Updated FNHTR definition to allow reaction without documented fever.
		Defined hypotension for infants and small children
		Clarified TAGVD probable and possible criteria.
1.2	June 2011	Corrected definition of hypoxemia in glossary of terms.
1.3	June 2012	Added version number and version history summary.
		Added highlight feature for important changes to protocol.
		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.

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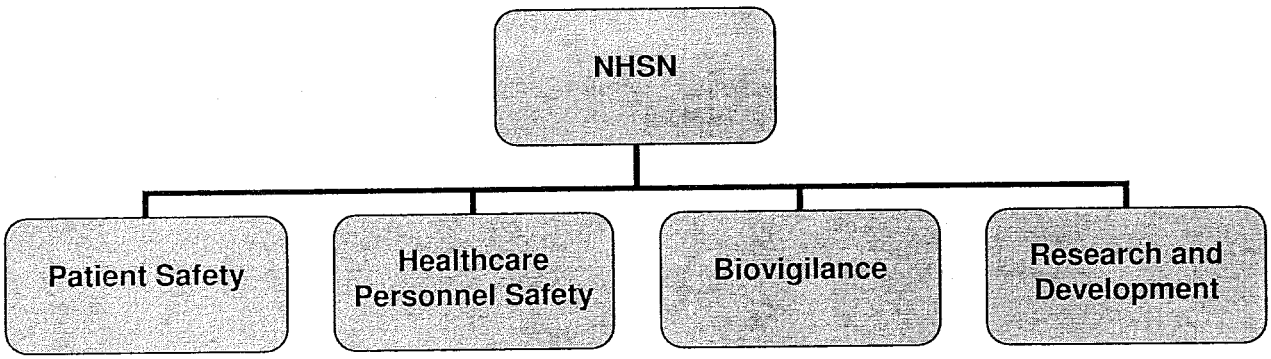
National Healthcare Safety Network (NHSN)

NHSN is a secure, internet-based surveillance system that integrates former CDC surveillance activities, 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 in their patient populations; trends in healthcare personnel safety and vaccination compliance; and adverse events related to the transfusion of blood and blood products. Some U.S. states utilize NHSN as the reporting tool for healthcare facilities that are required to submit data on healthcare-associated infections (HAIs) as mandated by specific state legislation.

The NHSN includes four components, each pertaining to various aspects of control and prevention of healthcare associated events. Those four components are Patient Safety, Healthcare Personnel Safety, Biovigilance, and Research and Development (Figure 1). NHSN users participate in the Patient Safety, Healthcare Personnel Safety, and Biovigilance Components of NHSN. NHSN users do not access the Research and Development Component of the system.

Figure 1. NHSN Structure



Patient Safety Component

Within the Patient Safety Component, similar types of surveillance are grouped into modules, each addressing healthcare procedures, devices, or medications associated with HAIs. Instructions and standardized surveillance methods and definitions for each module are provided in the Patient Safety Component manual available on the NHSN website. Patient Safety Component modules include:

- Device-associated Module
- Procedure-associated Module
- Medication-associated Module
- Multidrug-Resistant Organisms/*Clostridium difficile*-associated Disease (MDRO/CDAD) Module
- Vaccination Module

Healthcare Personnel Safety Component

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 Fluid 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 Healthcare Personnel Safety manual found on the NHSN website.

Biovigilance Component
Biovigilance is the collection and analysis 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 related to blood transfusion, including recipient adverse reactions and incidents (i.e. errors, accidents, and approved deviations).

Research and Development
The Research and Development Component is used to enable 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. Facilities do not directly access the Research and Development Component of NHSN.

A healthcare facility (acute care hospital, ambulatory surgery center, outpatient dialysis center) may use one, two, or all three available NHSN components concurrently. Although these components are likely to be managed by different individuals within the facility, there may be only one designated **NHSN Facility Administrator** that is responsible for activating and deactivating components for that facility.

If a facility is using NHSN for one purpose, it is not necessary to complete the NHSN enrollment process again to begin using additional components, such as the Biovigilance Component. Instead, the NHSN Facility Administrator must activate the Biovigilance Component in NHSN, designate a BV Component Primary Contact, and add at least one NHSN user with rights to the BV Component. Transfusion Service personnel interested in participating in NHSN should first contact the infection prevention team in their facility to determine if the facility is enrolled in NHSN. Contact NHSN user support for assistance with the enrollment or component activation process.

Biovigilance Component – Hemovigilance Module

Background

In 2006, the Department of Health and Human Services' (HHS) Advisory Committee on Blood Safety and Availability (ACBSA) convened to make recommendations for improving patient safety related to transfusion and transplantation. ACBSA recommended that a national system be developed for surveillance of adverse outcomes in recipients of blood and blood products (i.e. hemovigilance) analogous to what has been put in place in most other countries with advanced healthcare. Biovigilance encompasses hemovigilance, but also includes organ, tissue, and cellular therapy safety surveillance. Hemovigilance was the first area of focus in the development of a national surveillance system.

The Hemovigilance Module of the Biovigilance Component is intended to capture adverse transfusion reactions as well as errors and accidents related to the transfusion process for the purpose of evaluating and improving patient safety. The module was developed through a public-private collaboration between CDC and the private sector transfusion community, including AABB (formerly known as the American Association of Blood Banks).

According to the most recent National Blood Collection and Utilization Survey Report (NBCUS)[1], the total supply of whole blood and red blood cells collected in the United States in 2007 was approximately 16 million units. On average, recipients received approximately 3 units each, resulting in a national estimate of 5 million patients transfused in the U.S. each year. Additionally, 72,000 adverse reactions of sufficient severity to require diagnostic or therapeutic intervention were estimated in 2007. A total of 22,466,000 components transfused gives an adverse reaction rate of 0.32%. This rate, as estimated in the 2007 NBCUS, a voluntary survey, is low in comparison to data from Canada and the United Kingdom, countries with active hemovigilance systems.

While any transfusion-associated adverse reaction is considered rare, underreporting of transfusion-related adverse reactions in the U.S. is expected in the absence of a comprehensive, national surveillance program, and the burden of these adverse events cannot be estimated. Collection of data on all adverse events, including reactions and incidents, will provide the basis for interventions designed to improve patient safety. Although the risk of transfusion-transmitted infections has been greatly reduced, non-infectious transfusion reactions, such as transfusion-related acute lung injury (TRALI), are complications that have not been reduced due to the complex physiological mechanisms involved in transfusions. In addition, the risk of error associated with storage, handling, and use of blood products in the healthcare facility remains a persistent concern.

Surveillance Methods

The Hemovigilance Module offers facilities the ability to perform tracking, trending, and analysis of transfusion-associated adverse events, including reactions and incidents.

The Hemovigilance Module requires comprehensive, prospective, patient-based surveillance of patients throughout the transfusion process, from product receipt from supplier to administration to the patient. Participation in the NHSN Hemovigilance Module requires reporting of all adverse transfusion reactions and incidents that occur in the facility. 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.

Key Terms

Comprehensive surveillance: 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.

Prospective surveillance: Prospective surveillance involves on-going monitoring of patients for events while they are still hospitalized as opposed to retrospective surveillance, which is case-finding that is based on chart review after patient discharge.

Active and passive surveillance: When performing active surveillance, trained personnel, such as transfusion services staff, use standard definitions and a variety of data sources to identify and classify events. In passive surveillance, personnel not trained to perform surveillance are required to report transfusion adverse reactions and incidents to transfusion services staff.

Patient-based surveillance: Patient-based surveillance in hemovigilance involves monitoring individual patients for transfusion-related adverse reactions. The transfusion staff is expected to provide guidance to patient care staff in identifying and reporting transfusion-related adverse events. All reports of blood transfusion-related adverse events should be fully investigated to ensure that reporting is complete, which may include reviewing patient charts and discussing events with caregivers.

Crude rates vs. risk-adjusted rates: Crude rates assume equal distribution of risk factors for all events and have limited use for comparison between facilities. Risk-adjusted rates are controlled for variations in the distribution of risk factors associated with an event's occurrence. Risk-adjusted rates provide a more accurate basis for comparing rates between facilities. Rates in the Hemovigilance Module will be crude until enough data have been collected for risk-adjustment.

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, a biologically active product.

Incident: Any error or accident that could lead to an adverse outcome affecting the quality or efficacy 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: An incident that has high potential to result in wrongful transfusion in a recipient if the associated product is 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 NHSN high-priority incidents are designated with a "+" in the table of incident codes in Appendix F.

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).*

Settings

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

All adverse reactions and incidents will be reported by location in NHSN. NHSN location set up must be completed before events can be reported. Each physical location in the facility (e.g., unit, ward, ED) must be mapped to a standard NHSN facility location. NHSN facility locations are shared across component, therefore it is imperative that NHSN users collaborate with the NHSN Facility Administrator and other users to create and maintain NHSN locations for use in the Hemovigilance Module. More information on location definition and mapping can be found in the NHSN Resource Library, the Hemovigilance Module training slides, and by accessing **HELP** when logged into the NHSN application.

Reporting Requirements

- At least 12 months of continuous data must be reported.
- Annual Facility Survey must be entered each year.
- Monthly Reporting Plan must be entered for each month of surveillance.
- Monthly Reporting Denominators must be entered for each month of surveillance.
- ALL transfusion-associated adverse reactions that meet the NHSN case definitions must be reported each month.
- Incident surveillance must be conducted monthly; the facility 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 every high-priority incident and all incidents associated with an adverse reaction. 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 each month. This method is recommended for facilities that do not otherwise electronically track or report incidents and want to use NHSN for that purpose.

Data Collected

- **Adverse Reaction Surveillance**
  Numerators:
  - Adverse reactions that meet NHSN case definition criteria
  - Deaths related to transfusion

  Denominators:
  - Units and/or aliquots of blood products transfused

- **Incident Surveillance**
  Numerators:
  - Incidents, including near-misses and approved deviations
  - High priority incidents
  - Adverse reactions associated with incidents

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

Data Collection Forms

Six data collection forms are used in the Hemovigilance Module. The forms and instructions for completing each are available on the NHSN website. All data are reported to CDC through the NHSN web application, but the paper forms are provided to aid participating facilities in data collection.

CDC 57.300 Hemovigilance Module Annual Facility Survey

Participating facilities must enter the Hemovigilance Module Annual Facility Survey at the time that they enroll or activate the Biovigilance Component and at the beginning of each calendar year thereafter. The survey is used by CDC to classify facilities for appropriate comparisons in aggregate data analyses and to learn more about common practices among transfusion departments. The data collected in the survey covers the previous **calendar** year. For example, if the facility is enrolling in NHSN for the first time in October of 2011, report information for January 2010-December 2010 on the first Hemovigilance Module Annual Facility Survey.

CDC 57.301 Hemovigilance Module Monthly Reporting Plan

The Hemovigilance Module Monthly Reporting Plan must be entered each month before data can be entered into the application. 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 only if the facility chooses to report incidents using the summary option. When reporting using the summary option, detailed incident reports must also be completed for all high-priority incidents that occur and for incidents that are associated with a transfusion-associated adverse reaction. High-priority incidents are indicated by a "+" next to the code on the summary form as well as in the incident code list in Appendix F of the protocol. Near misses should be documented as robustly as incidents that result in harm to the patient. In addition, detailed incident reports may 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 must also be 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 Module 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 need not be routinely reported. The doubtful and ruled out categories are intended to 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. However, a facility may report reactions considered doubtful or ruled out if they are using NHSN to document transfusion reaction **investigations** each month. 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. Case definitions for the required adverse reactions are found in Appendix A of the protocol. Adverse reactions not defined by the NHSN protocol (e.g. thrombosis, TRAGI) may be reported using the "Other" category.

Note: Reporting of adverse reactions to CDC through NHSN system does **NOT** take the place of reporting requirements for blood transfusion-associated adverse events to Food and Drug Administration (FDA). Hospitals and transfusion services should immediately report complications that may be related to the blood donor or to the manufacture of the blood components to the collection facility (Code of Federal Regulations. Title 21 CFR 606.170(a), 2006) and are required to report suspected transfusion-related fatalities directly to FDA (Code of Federal Regulations Title 21 CFR 606.170(b), 2006).

CDC 57.305 Hemovigilance Module Incident

If the facility chooses "detailed reporting of all incidents" on the monthly reporting plan, a Hemovigilance Module Incident form must be completed for **every** incident that occurs. Report only one incident per form. Near misses and approved deviations should be documented as robustly as incidents associated with patient reactions. All reports should be entered within 30 days of the month of the "Date incident occurred" for the event.

If the summary reporting option is chosen on the 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 may warrant collection of detailed information on. These detailed reports should also be documented on the Monthly Incident Summary form.

Data Analysis and Reports

Facilities have the ability to generate a number of standard reports in NHSN. In addition, custom line lists and reports can be created by modifying the standard reports by selecting variables of interest within the application. Once sufficient data has been collected from participating facilities for CDC to publish a public

health report of the aggregate data, comparative values will be included in the facility-level reporting options or immediate benchmarking.

Standard facility-level reports include:

- Line lists
  - Adverse reactions, including 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
  - Denominator summaries of units/aliquots transfused by selected time period
  - Aggregate reports of monthly incident summaries

References

1. AABB Survey. *The 2007 nationwide blood collection and utilization survey report.* Available at: http://www.aabb.org/programs/biovigilance/nbcus/Documents/07nbcusrpt.pdf.

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 or more of the following occurring during or within 4 hours of cessation of transfusion: • Maculopapular rash • Urticaria (hives) • Pruritus (itching) • Generalized flushing • Localized angioedema • Edema of lips, tongue and uvula • Erythema and edema of the periorbital area • Conjunctival edema • Respiratory distress; bronchospasm • Hypotension **Probable:** **ANY 1** of the following occurring during or within 4 hours of cessation of transfusion : • Maculopapular rash • Urticaria (hives) • Pruritus (itching) • Localized angioedema • Edema of lips, tongue and uvula • Erythema and edema of the periorbital area • Conjunctival edema **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, hypotension, or associated symptoms like hypotonia and syncope. The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnea, cough, wheezing, bronchospasm, hypoxemia). Such a reaction usually occurs during or shortly after cessation of transfusion. For the purpose of classification, this type of allergic reaction would be graded as: **2: severe** **3: life-threatening** **4: death.**	**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** Other potential causes are present in an individual with known susceptibility (atopic; previous allergic reactions to transfusions). **Possible:** Occurs 2 - 4 hours after cessation of transfusion **OR** Other causes such as medication or exposures likely, but transfusion cannot be ruled out.

Acute hemolytic transfusion reaction (AHTR): Rapid destruction of red blood cells during, immediately after, or within 24 hours of cessation of 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 cessation of transfusion with **ANY** of the following: • Chills/rigors • Fever • Back/flank pain • Hypotension • Hemoglobinuria occurring during or shortly after cessation of 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.	**Definitive:** Positive direct antiglobulin test (DAT) for anti-IgG or anti-C3 **AND** Positive elution test with alloantibody present on the transfused red blood cells **AND** 2 or more of the following: • Elevated LDH • Elevated bilirubin • Low haptoglobin • Hemoglobinuria • Low fibrinogen • Elevated plasma hemoglobin	**Use severity grades as defined in Appendix C.**	**Definite:** ABO or other allotypic RBC antigen incompatibility is known **OR** Serologic work-up is consistent with AHTR and no other cause of acute hemolysis is present. **Probable:** No serologic evidence of AHTR **OR** Blood bank testing may show abnormal results but AHTR may also be due to erythrocyte auto-antibodies in the recipient. **Possible:** Evidence of non-immune contributing factors such as hemolysis-inducing mechanical factors (e.g. malfunction of a pump, use of a blood warmer, use of hypotonic solutions, etc.) is present.
Probable: Same as definitive case criteria.	**Probable:** Incomplete laboratory confirmation to meet definitive case definition criterion.		
Possible: N/A	**Possible:** N/A		

Delayed hemolytic transfusion reaction (DHTR): The recipient develops antibodies to RBC antigen(s) between 24 hours and 28 days after cessation of transfusion. Clinical signs of hemolysis are usually present. If performed, post-transfusion LDH and bilirubin levels increase and subsequently fall back to baseline in the following days. 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 symptoms that are similar to but milder than AHTR. Examples of symptoms include: • Chills/rigors • Fever • Jaundice • Back/flank pain • Hypotension • Hemoglobinuria/ hematuria • Oliguria/anuria. **NOTE:** These symptoms are **NOT** required to meet definitive case criteria. **Probable:** Same as definitive case criteria. **Possible:** N/A	**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** Not enough laboratory evidence to meet definitive criteria. **Possible:** N/A	**Use severity grades as defined in Appendix C.**	**Definite:** Meets **definitive** case definition criteria **AND** No other explanation for drop in hemoglobin. **Probable:** Meets **probable** case definition criteria **AND** No other explanation for drop in hemoglobin. **Possible:** Meets **definitive** or **probable** case definition **BUT** Other explanation(s) for drop in hemoglobin are present.

Delayed serologic transfusion reaction (DSTR): Demonstration of new, clinically significant alloantibodies against red blood cells between 24 hours and 28 days after cessation of 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: Absence of clinical 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 cessation of a transfusion that were not present in the pre-transfusion specimen **BY EITHER** Positive direct antiglobulin test (DAT) **OR** Positive antibody screen with newly identified RBC alloantibody. **Probable**: N/A **Possible**: N/A	**Use severity grades as defined in Appendix C.**	**Definite**: Meets **definitive** case definition criteria. **Probable**: N/A **Possible**: N/A

Hypotensive transfusion reaction: A drop in blood pressure occurring during or within one hour of cessation of transfusion. Other symptoms, such as facial flushing, dyspnea, or abdominal cramps may occur but usually hypotension is the sole manifestation.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	Laboratory/Radiology		
Definitive: **ALL OF THE FOLLOWING:** • Hypotension - Adults (18 years and older): Drop in **systolic** BP of greater than or equal to 30 mmHg **AND** **Systolic** BP less than or equal to 80 mmHg. - Infants, children and adolescents (1 year to less than 18 years old): Greater than 25% drop in systolic BP (e.g., drop in baseline 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). • Occurs less than 15 minutes after the start of the transfusion • Responds rapidly (within 10 minutes) to cessation of transfusion and supportive treatment. • All other adverse reactions presenting with hypotension must be excluded. **Note**: If the patient meets the criteria for another adverse transfusion reaction presenting with hypotension, the more specific adverse reaction should be reported.	**Definitive:** 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 hypotensive transfusion reaction or as a result of treatment directly related to resolving symptoms of the reaction.	**Definite:** Meets the **definitive** protocol criteria **AND** The patient has no other conditions that could explain hypotension. **Probable:** Meets the **probable** case definition criteria **OR** Other conditions that could explain hypotension are unlikely but not fully excluded. **Possible:** Meets **definitive** or **probable** case definition criteria **BUT** Other conditions that could readily explain hypotension are present.
Probable: Same as definitive criteria **EXCEPT:** 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. **Possible:** N/A	**Probable:** N/A **Possible:** N/A		

Febrile non-hemolytic transfusion reaction (FNHTR): Fever and/or chills **without** hemolysis occurring in the patient during or within 4 hours of cessation of 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. If blood culture of patient or residual component is performed, the results should be negative. Laboratory findings should show no evidence of acute hemolysis.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: Occurs during or within 4 hours of cessation of transfusion **AND EITHER** Fever (greater than or equal to 38°C oral or equivalent and a change of at least 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.	**Definitive:** N/A	**Use severity grades as defined in Appendix C.**	**Definite:** Patient has no other conditions that could explain symptoms. **Probable:** Other conditions present that could explain symptoms are unlikely but cannot be ruled out. **Possible:** Other conditions are present or were present before the transfusion that most likely explain symptoms.
Probable: N/A	**Probable:** N/A		
Possible: N/A	**Possible:** N/A		

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 less than 20% of pre-transfusion count) **Probable:** Drop in platelets to levels between 20% and 80% of pre-transfusion count. **Possible:** N/A	**Definitive:** Alloantibodies in the patient directed against HPA-1a or other platelet specific antigen detected at or after development of reaction. **Probable:** Same as definitive laboratory criteria. **Possible:** HPA antibodies not tested or negative.	**Use severity grades as defined in Appendix C.**	**Definite:** Meets **definitive** or **probable** case definition criteria **AND** Occurs 5-12 days post-transfusion **AND** Patient has no other conditions to explain thrombocytopenia. **Probable:** Meets **definitive** or **probable** case definition criteria **AND EITHER** Occurs less than 5 or more than 12 days post-transfusion **OR** Other condition(s) present that could explain thrombocytopenia are unlikely but cannot be ruled out. **Possible:** Meets **definitive or probable** case definition criteria **AND** Alternate explanations for thrombocytopenia are more likely **OR** Meets **possible** case definition criteria.

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

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: New onset or exacerbation of 3 or more of the following within 6 hours of cessation of transfusion: • Acute respiratory distress (dyspnea, orthopnea, cough) • 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)	**Definitive:** N/A	**Use severity grades as defined in Appendix C.**	**Definite:** No other explanations for volume overload are possible. **Probable:** Transfusion is a likely contributor to volume overload **AND EITHER** The patient received other fluids as well **OR** The patient has a history of cardiac insufficiency that could explain the volume overload. **Possible:** The patient has a history of pre-existing cardiac insufficiency that most likely explains volume overload.
Probable: N/A	**Probable:** N/A		
Possible: N/A	**Possible:** N/A		

Transfusion-associated dyspnea (TAD): Respiratory distress within 24 hours of cessation 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 that occurring within 24 hours of cessation of transfusion **AND** TRALI, TACO, and allergic reaction are 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.**	**Definite:** Patient has no other conditions that could explain symptoms. **Probable:** Other present conditions are unlikely but not fully excluded. **Possible:** Other present conditions are more likely to explain symptoms.

Transfusion-associated graft vs. host disease (TAGVHD): The introduction of immunocompetent lymphocytes into susceptible hosts. The allogeneic lymphocytes engraft, proliferate and destroy host cells. If performed, marrow study shows hypoplasia, aplastic anemia, or marked hypocellularity with a lymphohistiocytic infiltrate.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	**Laboratory/Radiology**		
Definitive: A clinical syndrome occurring from 2 days to 6 weeks after cessation of transfusion characterized by: • 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:** Same as definitive case criteria. **Possible:** Same as definitive case criteria.	**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. **Probable:** Meets definitive 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 required life-saving treatment (e.g., immunosuppression). **Grade 4:** Patient died from TAGVHD.	**Definite:** Meets **definitive** or **probable** case definition criteria **AND** There are matching chimeric alleles in the donor and recipient. **Probable:** Meets **definitive** or **probable** case definition criteria **BUT** Alleles could not be tested in the donor to match to the recipient. **Possible:** Meets **possible** case definition criteria **OR** Alternative explanations are more likely (e.g. solid organ transplantation).

Transfusion-related acute lung injury (TRALI): Acute hypoxemia with PaO_2/fraction of inspired oxygen [FIO_2] ratio of 300 mmHg or less combined with 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 cessation of transfusion
AND
Hypoxemia defined by any of these methods:
• PaO_2 / FiO_2 less than or equal to 300 mm Hg
• Oxygen saturation less than 90% on room air
• Other objective evidence
AND
No evidence of left atrial hypertension (i.e. circulatory overload).
 	
Probable:
N/A
 	
Possible:
N/A
	Definitive:
	Bilateral infiltrates on chest radiograph
	
	Probable:
	N/A
	
	Possible:
	N/A
		Use severity grades as defined in Appendix C.	**Definite:**
			No alternative risk factors for ALI during or within 6 hours of cessation of transfusion.
			
			Probable:
			N/A
			
			Possible:
			Evidence of other risk factors for acute lung injury during or within 6 hours of cessation of transfusion are present, 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

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	Cytomegalovirus (CMV)	Babesiosis (*Babesia* spp.)	Creutzfeldt-Jakob Disease, Variant (vCJD)
Klebsiella oxytoca	Enterovirus	Chagas disease (*Trypanosoma cruzi*)	
Klebsiella pneumoniae	Epstein Barr (EBV)	Malaria (*Plasmodium* spp.)	
Pseudomonas aeruginosa	Hepatitis A		
Serratia marcescens	Hepatitis B		
Staphylococcus aureus	Hepatitis C		
Staphylococcus epidermidis	Human Immunodeficiency Virus 1 (HIV-1)		
Staphylococcus lugdunensis	Human Immunodeficiency Virus 2 (HIV-2)		
Syphilis (*Treponema pallidum*)	Human Parvovirus B-19		
Yersinia enterocolitica	Human T-Cell Lymphotropic (or, leukemia) Virus-1 (HTLV-1)		
	Human T-Cell Lymphotropic (or, leukemia) Virus-2 (HTLV-2)		
	West Nile Virus (*Flaviviridae*)		

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.

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

<table>
<tr><th colspan="2">Case Definition Criteria</th><th>Severity</th><th>Imputability</th></tr>
<tr><th>Signs/Symptoms</th><th>Laboratory/Radiology</th><th></th><th></th></tr>
<tr><td>Definitive:
N/A

Probable:
N/A

Possible:
N/A</td><td>Definitive:
Laboratory evidence of a pathogen in the transfusion recipient.

Probable:
N/A

Possible:
N/A</td><td rowspan="2">Use severity grades as defined in Appendix C.</td><td rowspan="2">Definite:
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 by testing of the donor, the recipient unit (or retained segment), or co-component from the original donation
OR
Laboratory evidence of infection with the same organism in another recipient that received blood from the same donor.

Probable:
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 the donor by testing of the donor, the recipient unit (or retained segment), or co-component from the original donation
OR
Laboratory evidence of infection with the same organism in another recipient that received blood from the same donor.

Possible:
Recipient infection fails to meet imputability criteria for definite, probable or ruled out because essential information is missing, not available, or cannot be obtained.

Doubtful:
Laboratory evidence that the recipient had was infected with this organism prior to transfusion.

Ruled Out:
Laboratory evidence that the donor was negative for infection at the time of donation.</td></tr>
<tr><td colspan="2">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.</td></tr>
</table>

Appendix B. Adverse Reaction Clinical and Laboratory Definitions

Blood pressure decrease:

- Adults (18 years of age or older):
  Drop in systolic BP of 30 mmHg or more AND systolic BP of 80mmHg or less.
- Infants, children and adolescents (1 year to less than 18 years of age):
  Greater than 25% drop in systolic BP (e.g., drop in baseline systolic BP of 120mmHg to below 90mmHg).
- Neonates and small infants (less than 1 year of age OR any age and less than 12 kg body weight):
  Greater than 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.

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

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

Epistaxis: Bleeding from the nose.

Fever: An increase of at least 1 ℃ in temperature over the pre-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 less than or equal to 300 mm Hg OR oxygen saturation is less than 90% on room air.

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

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

Other rash: Non-urticarial skin rash.

Pruritus: Itching.

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

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

Urticaria (hives): Raised red spots (with or without itching).

Appendix C. Adverse Reaction Severity and Imputability Definitions

Severity

An assessment of the degree to which the patient developed symptoms as a result of the adverse event.

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**.

*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

An assessment of the relationship between the transfusion and the adverse event.

Definite: Conclusive evidence exists that the adverse event can be attributed to the transfusion.

Probable: Evidence is clearly in favor of attributing the adverse event to the transfusion.

Possible: Evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.

***Doubtful**: Evidence is clearly in favor of attributing the adverse event 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 event and the transfusion is unknown or not stated.

*Adverse reactions for which imputability is doubtful or ruled out need not be routinely reported. These categories are intended to be used when a reaction was initially thought to be transfusion-related but additonal information revealed a non-transfusion related cause. However, facilities may use these categories for their own purposes. For example, they can be used to keep an inventory of suspected transfusion reaction investigations.

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
Nursing	
LPN	Licensed Practical Nurse
CNA	Nurse Anesthetist
CNM	Certified Nurse Midwife
NUA	Nursing Assistant
NUP	Nurse Practitioner
RNU	Registered Nurse
Physician	
FEL	Fellow
MST	Medical Student
PHY	Attending 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 reports must be completed for each.

Appendix G. Incident Definitions (Based on MERS-TM & TESS)

Incident Result

No Recovery, harm
A product related to this incident was transfused; the patient experienced an adverse reaction.

No Recovery, no harm
A product related to this incident was transfused; the patient did not experience an adverse reaction.

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

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

Root Cause Analysis Result(s)

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

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

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

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

Other:
- Cannot be classified under any of the other categories.

References

MERS TM (2001). *Medical Event Reporting System for Transfusion Medicine reference manual version 3.0.* New York. Available at http://www.mers-tm.net.

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