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	July 2010	Corrected definition of hypoxemia in glossary of terms.
1.3	June 2011	Added version number and version history summary.
		Summarized introduction and background sections for brevity.
		Reorganized surveillance methods section for ease of use.
		Clarified reporting of “approved deviation” incidents.
		Clarified use of “other” in adverse reaction reporting.
		Clarified use of “doubtful” or “ruled out” in adverse reaction reporting.
		Added denominator summary options to list of available analysis reports.
		Replaced < and > signs with appropriate text for.
		Added “cessation of” to time frame requirements in case definitions.
		NEW probable case definition category for allergic reaction reporting.
		Updated adult hypotensive reaction case definition to align with updated ISBT definition.
		NEW possible imputability category for DHTR.
		DELETED possible case definition category for hypotensive reaction.
		NEW probable imputability category for PTP reaction.
		Updated and clarified imputability categories for TAGVHD reaction.
		DELETED possible case definition category for TRALI.
		Simplified imputability criteria for TTI.
		Clarified case definition and imputability criteria for all adverse reactions.

Table of Contents

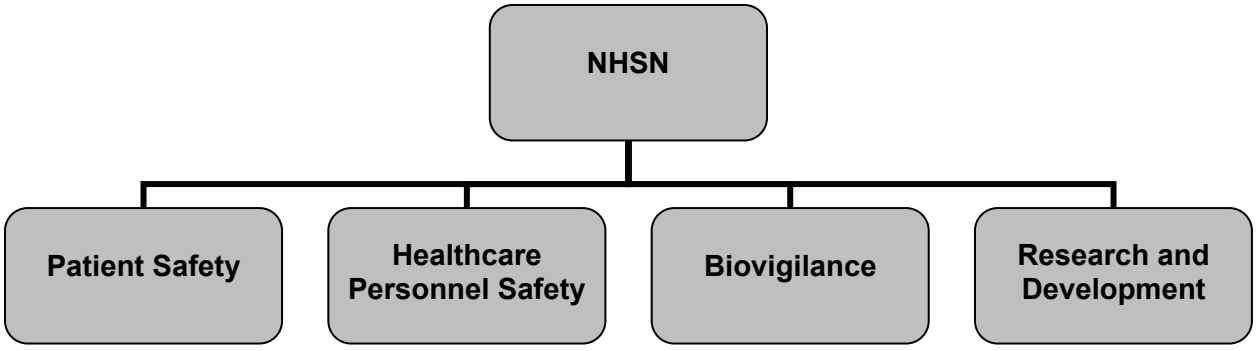
National Healthcare Safety Network (NHSN)

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.