



Biovigilance Component Hemovigilance Overview

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1

Welcome to the National Healthcare Safety Network Biovigilance Component Hemovigilance Overview!



Target Audience

- This session is designed for
 - Those who will collect and analyze Biovigilance (BV) Component data or enroll a facility into NHSN to participate in the BV component
 - NHSN Facility Administrator
 - Biovigilance/Hemovigilance Primary Contact
 - Blood Transfusion Services Staff
 - A facility considering joining NHSN for Biovigilance

This session is designed for persons who will collect and analyze Biovigilance Component data or enroll a facility into NHSN to participate in the Biovigilance Component. This could include your designated NHSN Facility Administrator, Biovigilance or Hemovigilance Primary Contact, or other Blood Transfusion Services Staff who will be collecting and reporting data into NHSN. If your facility is considering joining NHSN for Biovigilance, this session provides a summary of what is required.



Objectives (1)



By the end of this session be familiar with:

- ✓ **Purposes of NHSN**
- ✓ **Components of NHSN**
- ✓ **Surveillance methodology used in NHSN**
- ✓ **Authority and confidentiality for NHSN**
- ✓ **Data entry fields in NHSN**
- ✓ **Data collection and reporting requirements**
- ✓ **Key terms used in hemovigilance**

The objectives of this session are to describe the purposes of NHSN, the components of NHSN, surveillance methodology used, authority and confidentiality for NHSN, data entry field requirements, data collection and reporting requirements, and key terms used in hemovigilance.



Objectives (2)

- ✓ **The hemovigilance protocol AND accompanying materials:**
 - ✓ **Tables of Instructions**
 - ✓ **Adverse reaction case definition criteria, severity grade, and imputability**
 - ✓ **Blood product codes use in NHSN**
 - ✓ **Facility Survey**
 - ✓ **Monthly denominators**
 - ✓ **Incident codes**
 - ✓ **Incident form**
 - ✓ **Blood Product Incidents Reporting Summary data**
 - ✓ **Adverse Reaction form**

We will also discuss the materials that are used in the Hemovigilance Module including the protocol, tables of instructions, case definitions, blood product codes, annual facility survey, monthly denominators, incident codes, and data reporting forms including the Incident form, Blood Product Incidents Reporting-Summary Data, and Adverse Reaction form.



National Healthcare Safety Network



- NHSN is an internet-based surveillance system that monitors patient and healthcare personnel safety. It integrates surveillance systems previously managed separately in the Division of Healthcare Quality Promotion (DHQP)
 - National Nosocomial Infections Surveillance system (NNIS)
 - Dialysis Surveillance Network (DSN)
 - National Surveillance System for Healthcare Workers (NaSH)

The National Healthcare Safety Network or NHSN is an internet-based surveillance system that monitors patient and healthcare personnel safety. It integrates surveillance systems that were previously managed separately in CDC's Division of Healthcare Quality Promotion: NNIS, or the National Nosocomial Infections Surveillance system, DSN or the Dialysis Surveillance Network, and NaSH, or the National Surveillance System for Healthcare Workers.



Purposes of NHSN

- Collect data from a sample of U.S. healthcare facilities to permit valid estimation of the:
 - Magnitude of adverse events among patients and healthcare personnel including:
 - Healthcare-associated infections
 - Adverse reactions associated with blood transfusion
 - Incidents associated with blood transfusion
 - Blood and body fluid exposures for healthcare personnel
- Analyze and report collected data to permit recognition of trends



The purposes of NHSN are to collect data from a sample of U.S. healthcare facilities to permit valid estimation of the magnitude of adverse events among patients and healthcare personnel including: healthcare-associated infections, adverse reactions associated with blood transfusions, incidents associated with blood transfusion, and blood and body fluid exposures in healthcare personnel. Analyzing and reporting these data permits recognition of trends.



Purposes of NHSN



- Provide facilities with data that can be used for inter-facility comparisons and local quality improvement activities
- Assist facilities in developing surveillance and analysis methods that permit timely recognition of patient and healthcare personnel safety problems and prompt intervention with appropriate measures
- Conduct collaborative research studies with members

NHSN can provide facilities with data that can be used for inter-facility comparison and local quality improvement activities. It can assist facilities in developing surveillance and analysis methods that permit timely recognition of patient and healthcare personnel safety problems and prompt intervention with appropriate measures. In addition, collaborative research can be conducted with NHSN members.

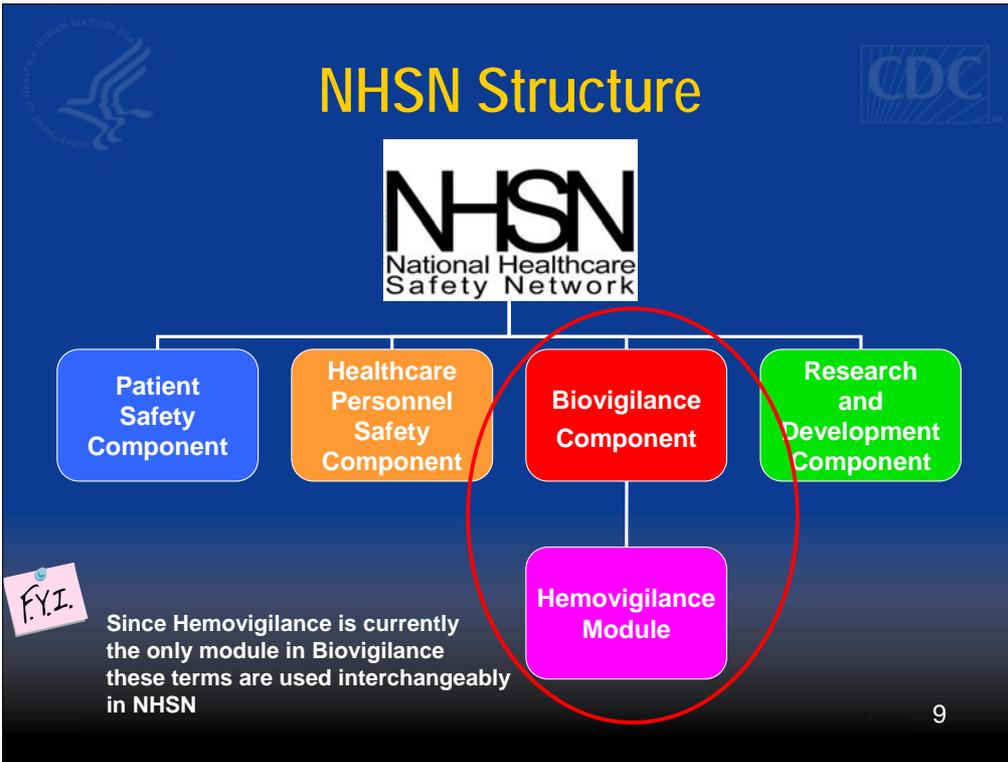


Staff Expected to Participate in the Hemovigilance Module

- Transfusion services staff responsible for quality assurance and technical oversight
- Other personnel can be trained to
 - Screen for events
 - Collect denominator data
 - Enter data
 - Analyze data



Facility staff who are expected to participate in the Hemovigilance Module include transfusion services staff responsible for quality assurance and technical oversight. Other personnel can be trained to screen for events, collect denominator data, enter data, and analyze data.



This slide depicts the current structure of NHSN. NHSN is comprised of several components: Patient Safety, Healthcare Personnel Safety, Biovigilance, and Research and Development. Each component can have one or more modules. For example, the Patient Safety Component has Device-Associated, Procedure-Associated, Medication-Associated, High Risk Inpatient Influenza, and Multidrug-Resistant and *C. difficile*-Associated Disease modules. Currently, in Biovigilance there is a single module: Hemovigilance. Therefore, the terms biovigilance and hemovigilance are used interchangeably in NHSN.



Authority and Confidentiality for NHSN



- Public Health Service Act
(42 USC 242b, 242k, and 242m(d))
- Confidentiality Protection
 - Sections 304, 306, and 308(d) of the PHS Act
“The information contained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306, and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).”



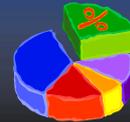
Authority and Confidentiality for NHSN is provided through the Public Health Service Act: 42 USC 242b, 242k, and 242m. Confidentiality protection states: The information contained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306, and 308d of the Public Health Service Act.



NHSN Surveillance Methodology in Hemovigilance



- Active & passive
- Patient-based
- Prospective
- Comprehensive
- Incidence rates



Next we will discuss the surveillance methodologies used in NHSN for Hemovigilance. These include: active and passive surveillance, patient-based, prospective, comprehensive, and incidence rates. Let's look at each method in more detail.



NHSN Surveillance Methodology

ACTIVE vs. PASSIVE

- **ACTIVE** Trained personnel use standard definitions and a variety of data sources to identify events
- **PASSIVE** Personnel not trained to do surveillance report events but required to report any reactions thought to be associated with a blood transfusion to transfusion services

*** Hemovigilance will include both methods**

12

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



NHSN Surveillance Methodology



PATIENT-BASED

Monitoring patients for adverse reactions of transfusion

- Educate staff to recognize and report all blood transfusion related events
- Review patient charts
- Investigate all reports of blood transfusion related events
- Discuss with caregivers

13

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



NHSN Surveillance Methodology



PROSPECTIVE vs. RETROSPECTIVE



➤ **PROSPECTIVE** Monitoring patients while still in the institution



➤ **RETROSPECTIVE** Case-finding based solely on chart review after patient discharged

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



NHSN Surveillance Methodology



PRIORITY-DIRECTED vs. COMPREHENSIVE

- **PRIORITY-DIRECTED** Objectives for surveillance are defined and focused on specific events, processes, organisms, and/or patients/populations
- **COMPREHENSIVE** Continuous monitoring of all patients for transfusion-related events

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



NHSN Surveillance Methodology



RISK-ADJUSTED vs. CRUDE RATES

- **RISK-ADJUSTED** Rates are controlled for variations in the distribution of major risk factors associated with an event's occurrence
 - Comparison of rates is useful
- **CRUDE** Rates assume equal distribution of risk factors for all events
 - Comparison of rates not recommended

Rates in hemovigilance will be crude until we have collected enough data for risk-adjustment

16

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



Hemovigilance Module Materials



■ Protocol

- Provides rules for surveillance and reference materials. **Read it before collecting and reporting data in NHSN.**
- Case definition criteria for adverse reactions of blood transfusion based on International Society of Blood Transfusion (ISBT) definitions
 - Definitive, probable, possible
 - Severity grade
 - Relationship to transfusion (imputability)
- Incident reporting definitions

17

The Hemovigilance protocol provides rules for surveillance and reference materials. It should be read before collecting and reporting any data in NHSN. Case definition criteria and definitions used for reporting incidents are also included.



Hemovigilance Module Materials



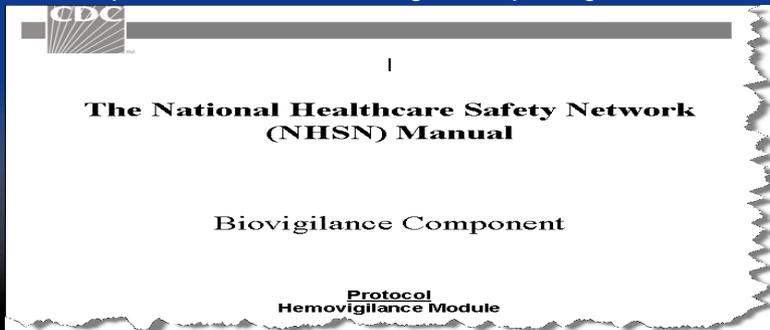
- **Incident codes**
 - Incident codes derived from MERS-TM (Columbia University) and TESS (Canadian system)
- **Blood product code lists**
 - Codabar
 - ISBT-128
- **Data collection forms**
- **Tables of Instructions**

18

Additional references or materials you will be using include Incident error process codes, blood product code lists for Codabar and ISBT-128 coding, data collection forms, and Tables of Instructions. We'll discuss the materials in more detail in the following slides.

Hemovigilance Protocol

- Provides rules for hemovigilance surveillance so that all participating facilities collect information the same way
 - Appendices include case definitions, other definitions, and code lists used in the hemovigilance module
 - Content based on input from AABB/CDC working group members
 - Approved by working group, CDC, and other agencies of HHS
 - A facility agrees to follow the protocol when they sign on to NHSN
-  READ the protocol before collecting and reporting data for NHSN



19

When a facility signs the Agreement to Participate and Consent in NHSN, they agree to follow the protocol. The Hemovigilance protocol provides the rules for surveillance and definitions that are important in ensuring that all facilities perform surveillance in the same way. Case definition criteria for adverse reactions have been developed by the Hemovigilance Working Group, a group of transfusion medicine specialists that was convened in collaboration with AABB. These case definitions were based on International Society of Blood Transfusion (ISBT) definitions and should be adhered to precisely when reporting adverse reactions. Severity grade and imputability, or relationship of the transfusion to the reaction, are also to be reported. Again, please read the protocol before collecting and reporting any data in NHSN.



Tables of Instructions



Table 1. Instructions for Completion of the **Hemovigilance Module Annual Facility Survey** (CDC 57.300)

For all questions referring to "past year" use calendar year, not fiscal year.

Form Field	Instructions for Form Completion
Facility ID	The NHSN-assigned facility ID number will be autoentered by the computer.
Survey Year	Required. This should be the most recent previous year for which annual facility statistics are available. For example, if you are completing this in February 2008, your survey year should be 2007.
Facility Characteristics	
1. Ownership	Required. Check the ownership type that most closely represents your facility.
2. Is your hospital affiliated with a medical school?	Required. If your hospital is associated with a medical school, indicate the type of affiliation: Major affiliation is defined as:

- Details and business rules for all form fields to ensure correct interpretation
- Use these each time you complete a form until you are familiar with the rules

The tables of instructions are organized by form and include details and business rules for all form fields to assist you in completing the forms. We recommend that you use these instructions each time until you become familiar with the rules.



Forms Used in Hemovigilance

- Forms
 - Annual Facility Survey
 - Monthly Reporting Plan
 - Blood Product Incidents Reporting – Summary Data
 - Monthly Reporting Denominators
 - Adverse Reaction
 - Incident

The image displays a vertical stack of six CDC hemovigilance forms. From top to bottom, they are: 1. Annual Facility Survey, 2. Monthly Reporting Plan, 3. Blood Product Incidents Reporting - Summary Data, 4. Monthly Reporting Denominators, 5. Adverse Reaction, and 6. Incident. Each form includes the CDC logo and specific instructions for data collection.

21

The data collection forms used in hemovigilance include: the Annual Facility Survey, Monthly Reporting Plan, Blood Product Incidents Reporting – Summary Data, Monthly Reporting Denominators, Adverse Reaction, and Incident.



Data Entry in NHSN

- Data entered in NHSN are available to CDC and the facility as soon as they are saved
 - There is no “transmission” lag
- Data can be edited after saving
 - Some exceptions with linked information fully explained in other training
- Most records can be deleted

22

Now let's talk about some basics of data entry in NHSN. Data entered into NHSN are immediately available to CDC and to your facility as soon as they are saved. There is no “transmission” time lag. Data can be edited after you have saved or submitted a record. There are some exceptions with linked data that are covered in detail in other trainings. Most (but not all) record types can be deleted. For example, once an annual Facility Survey is entered it can be edited but it cannot be deleted.



Types of Data Fields

- **Required fields**
 - Indicated by red asterisk(*) next to field label
 - Must be completed
- **Conditionally required**
 - Answering a field is conditional based on the answer to a previous field (e.g., Name of accrediting organization if laboratory is accredited)
- **Optional**
 - NHSN does not require the data and the information will not be used in analyses by CDC

23

Data fields in NHSN can be one of three types: required, conditionally required, or optional. Required fields are indicated by a red asterisk and must be completed in order to save the record. Patient date of birth and gender are examples of required fields in NHSN. A conditionally required field is a field that is required based on the answer to a previous question. For example, if a question about laboratory accreditation is answered in the affirmative, the system would then require that the name of the accrediting organization be completed. Optional fields provide additional information but the data are not required by CDC, are not used in CDC analysis, and the record can be saved whether the fields are completed or not. An example would be Patient First and Last Name.



NHSN Terminology for Hemovigilance Module



- Patient
 - Demographics
 - Patient ID number, gender, date of birth required
 - Includes blood group in Hemovigilance Module
- Events
 - Adverse Reaction
 - Incident
- Survey
 - Annual Facility Survey
- Summary Form
 - Blood Product Incidents Reporting – Summary Data
- Denominator
 - Monthly Reporting Denominators
- Custom Fields and Labels

24

NHSN utilizes standard terminology across and/or within a component. The patient record includes a unique facility identification number (such as medical record number), gender, and date of birth. Other fields are optional. Within the Biovigilance Component, Patient Blood Group is a required field. Events in Biovigilance include Adverse Reaction and Incident. Facilities are required to submit an Annual Facility Survey. Blood Products Incident Reporting – Summary Data form is an example of a summary form. Monthly Reporting Denominators provide breakdowns and totals of blood products transfused that can be used later on in calculating rates. Some forms allow facilities to add their own custom fields and labels.



Key Terms in Hemovigilance



- **Adverse event** – An undesirable and unintended event occurring before, during, or after transfusion of blood or blood components that may be related to the administration of the blood or component. It may be the result of an incident and may or may not result in a reaction in the recipient.
- **Adverse reaction** – An undesirable response or effect in a patient temporally associated with the administration of blood or blood components. It may be the result of an incident or an interaction between a recipient and blood, a biologically active product.



25

Key terms in hemovigilance were developed to be consistent with ISBT terminology. An adverse event is an undesirable or unintended event occurring before, during, or after transfusion of blood or blood components that may be related to the administration of the blood or component. It may be the result of an incident and may or may not result in a reaction in the recipient. An adverse reaction is an undesirable response or effect in a patient temporally associated with the administration of blood or blood components. It may be the result of an incident or an interaction between a recipient and blood, a biologically active product.



Key Terms in Hemovigilance



- **Incident** – An accident or error that could lead to an adverse outcome affecting a) the safety, efficacy or quality of blood, blood components, or plasma derivatives; or b) the safety of recipients.
- **High priority incident** – An accident or error that has high potential for wrongful transfusion in a recipient. This would include sample labeling errors, wrong patient collected, processing needs not indicated, not done, misunderstood, misinterpreted, etc.
- **Near miss** – An incident that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or reaction in a recipient.



26

An incident is an accident or error that could lead to an adverse outcome affecting the safety, efficacy or quality of blood, blood components, or plasma derivatives; or, the safety of recipients. A high priority incident in NHSN is an accident or error that has high potential for wrongful transfusion in a recipient. This would include sample labeling errors, wrong patient collected, processing needs not indicated, not done, misunderstood, misinterpreted, etc. A near miss is an incident that is discovered before the start of the transfusion and that could have led to a transfusion reaction in a recipient.



Data Collection and Reporting Requirements for Hemovigilance Module



- ✓ Submit a monthly reporting plan to inform CDC that adverse reactions will be reported for the month and select the reporting method for incidents
- ✓ Adhere to the protocol exactly as described in the *NHSN Manual: Biovigilance Component Protocol – Hemovigilance Module*
- ✓ Follow instructions for data collection as outlined in Tables of Instructions

27

Now that you have been introduced to the protocol, forms, and terminology, let's discuss the data collection and reporting requirements for participation in NHSN Biovigilance Component. First, you submit a Monthly Reporting Plan to inform CDC that adverse reactions will be reported and select the reporting method you will use for incidents. As discussed earlier, we ask that you adhere to the protocol exactly as written and follow the instructions for data collection as outlined in the tables of instructions.



Data Collection and Reporting Requirements for Hemovigilance Module



(continued)

- ✓ Use surveillance methodology as described in the protocol and in this presentation
- ✓ Report events and appropriate summary or denominator data indicated on the plan to CDC within 30 days of the end of the previous month
- ✓ Submit data for every month of the calendar year

28

Use the surveillance methodology as described in the protocol and this presentation. Be sure to report events and appropriate summary or denominator data indicated on your plan to CDC within 30 days of the end of the previous month or as directed in the protocol. In the Biovigilance Component you are expected to submit data for every month of the calendar year.



Data Collection and Reporting Requirements for Hemovigilance Module



(continued)

- ✓ Complete an annual survey for your facility
- ✓ Pass quality control acceptance checks that assess the data for completeness and accuracy
- ✓ Agree to report to state health authorities those events identified in the surveillance system for which reporting is required and any for which you are contacted by CDC



29

A facility survey will be required each year you choose to participate. You will be asked to pass quality control acceptance checks that assess data for completeness and accuracy. You agree to report to state health authorities those events identified in the surveillance system for which reporting is required and any for which you are contacted by CDC.

Data Collection and Reporting Requirements for Hemovigilance Module



AND !!

- ✓ 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)
- ✓ Report suspected transfusion related fatalities directly to the FDA (Code of Federal Regulations Title 21 CFR 606.170(b), 2006)



30

And! Please remember to follow FDA requirements for reporting which is through a system that is separate from NHSN. Report immediately any complications that may be related to the blood donor or to the manufacture of the blood components to the collection facility as required by the Code of Federal Regulations, Title 21 CFR 606.170(a). Report suspected transfusion related fatalities directly to FDA as required by Title 21 CFR 606.170(b). Remember, reporting to NHSN DOES NOT take the place of FDA reporting.



Annual Facility Survey



- Completed on enrollment for new NHSN facilities or when joining the Biovigilance Component for existing facilities
- First survey – data for the full calendar year before submission date. Completed once a year after enrollment for the previous year.
- Collects information that can be used as denominators for determining rates and facility characteristics that can be used for aggregate comparisons
- See Tables of Instructions for information on completing

 **Hemovigilance Module
Annual Facility Survey**

*Required fields

*Tracking # / Facility ID: _____ *Survey Year: _____

Facility Characteristics: (For all questions use past full calendar year annual statistics)

*1. Ownership: (Check one)

For profit Government Military Not for profit, including church
 Veteran's Affairs Physician-owned Managed Care Organization

*2. Is your hospital affiliated with a medical school? Yes No
If yes, type of affiliation: Major Graduate Limited

3. Community setting of facility: Urban Suburban Rural

*4. Total beds set up and staffed: _____

31

The Annual Facility Survey is completed on enrollment to the Biovigilance Component and must be completed before a facility can enter any data. The survey should include data for the previous full calendar year (for example, a facility enrolling in April 2009 would complete a survey using 2008 data). The survey contains information that can be used as denominators for determining rates and facility characteristics that can be used for aggregate comparisons.



Monthly Reporting Plan

- The Monthly Reporting Plan informs CDC which modules a facility is following during a given month
- Facilities choosing to participate in the Hemovigilance Module must file a plan every month and report all adverse reactions and incidents
- A facility may enter data only for months in which plans are on file.

32

As we mentioned earlier, the Monthly Reporting Plan informs CDC which modules a facility is following during a given month. A plan must be filed before your facility enters data for a given month. Facilities choosing to participate in the Hemovigilance Module must file a plan every month but their selections of what to report are limited by the protocol and must include adverse reactions and incidents.



Monthly Reporting Plan

- Hemovigilance requires monthly reporting of all adverse reactions
- Facilities can choose whether to file detailed incident reports for all incidents or provide summary-only data for minor incidents.

The screenshot shows a form titled "Hemovigilance Module Monthly Reporting Plan" with the N-HSN Safety Network logo. It includes a field for "Facility ID#: _____" and "Month ____/ Year ____". A note states "All reporting is facility-wide." Below are two sets of checkboxes: the first set includes "Adverse transfusion reactions & all incidents associated with reactions" and "Monthly reporting denominators"; the second set includes "Incidents reporting – summary data with detailed reporting of high priority incidents". An "OR" separator is present, followed by a checkbox for "Incidents reporting – detailed reports of all incidents".

33

Hemovigilance requires monthly reporting of all adverse reactions. Facilities have the option of filing a detailed (“long”) report of all incidents or can file long reports for high priority incidents and summary-only data for minor incidents.



Monthly Reporting Denominators



- Provide numbers that will be used to calculate rates of adverse events by product transfused.

 **Hemovigilance Module**
Monthly Reporting Denominators

Facility ID # _____ Month: ____ Year: _____

* Indicates required fields

*Product			*Units Transfused	*Aliquots Transfused
Red blood cells	Whole blood derived	TOTAL		
		Irradiated		
		Leukocyte reduced		
		Irradiated & leukocyte reduced		
	Apheresis	TOTAL		
		Irradiated		
		Leukocyte reduced		
		Irradiated & leukocyte reduced		
Platelets	Whole blood derived	TOTAL		
		Irradiated		
	Apheresis	Leukocyte reduced		
		Irradiated & leukocyte reduced		

34

Monthly reporting denominators will provide numbers to determine rates of adverse reactions by product transfused. Use the Tables of Instructions for guidelines on completing to make sure you are filling it out correctly.



To Start



- Contact the infection/prevention control department (and/or hospital epidemiologist) in your facility to determine if your facility is currently a member of NHSN
- If your facility already participates in NHSN for patient safety, there will be an existing facility administrator
- If your facility is joining NHSN for the first time and only for biovigilance, designate a Facility Administrator (anyone in your department who will be primarily responsible for NHSN participation)

35

Now that you have been introduced to the Biovigilance Component/Hemovigilance Module in NHSN here are steps to take to start the enrollment process. First, contact the infection/prevention control department (and/or the hospital epidemiologist) to determine if your facility is currently a member of NHSN in the Patient Safety Component. If your facility already participates in NHSN, there will be an existing Facility Administrator. If your facility is joining NHSN for the first time and only for Biovigilance, designate a Facility Administrator. The Facility Administrator is the person who will be primarily responsible for NHSN participation.



Next Steps

- Facility Administrator should view:
 - Training 2: Biovigilance Component – Enrollment for Facility New to NHSN
 - Training 3: Biovigilance Component – Enrolling an Existing NHSN Facility into Biovigilance and Facility Set-up
 - Training 5: Groups in Biovigilance
- Subject matter training for blood transfusion services personnel:
 - Training 4: Biovigilance Component – Hemovigilance Incident Reporting
 - Biovigilance Component - Adverse Reactions - Case Definition Exercises
 - Training 6: Biovigilance Component - Adverse Reaction Data Collection and Entry

36

Here are additional trainings provided depending on the type of user. If you are the Facility Administrator and your facility is new to NHSN, view Training 2: Biovigilance Component – Enrollment for Facility New to NHSN. If your facility already participates in NHSN, you and/or your Facility Administrator may want to view Training 3: Biovigilance Component – Enrolling an Existing NHSN Facility into Biovigilance and Facility Set-up. Training 5 discusses Groups in Biovigilance. The other trainings available are for transfusion services personnel who will be collecting and reporting data for NHSN:

Training 4: Biovigilance Component – Hemovigilance Incident Reporting is designed for persons collecting information on incidents. This might be the individual responsible for quality control in your department. Adverse Reactions – Case Definition Exercises discusses case definition criteria, severity, and imputability in detail and includes case examples. Training 6: Biovigilance Component – Adverse Reaction Data Collection and Entry provides details of completing the Adverse Reaction data collection form.



Questions or Need Help? Contact User Support



37

Congratulations! You have completed the Hemovigilance Overview! If you have any questions about NHSN please send an e-mail to user support: nhsn@cdc.gov