National Healthcare Safety Network
Hemovigilance Module

Progress Report and Protocol Updates

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Office of Blood, Organ, and Other Tissue Safety

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Objectives

- Describe the National Healthcare Safety Network (NHSN) Hemovigilance Module, including simplified reporting requirements.

- Describe how hospitals can use their data for internal process improvements.

- Describe how NHSN’s Group function can be used to reduce the burden of blood safety data reporting.

- Provide an update on growth and participation.
The National Healthcare Safety Network (NHSN) is a secure, internet-based system that integrates patient and healthcare personnel safety surveillance managed by the Division of Healthcare Quality Promotion (DHQP) at CDC.
NHSN Structure

Patient Safety Component

Healthcare Personnel Safety Component

Biovigilance Component

Long Term Care Component

NEW!
Why use the NHSN Hemovigilance Module?

- Provides standard definitions, protocols and methodology
  - Adverse reactions
  - Process incidents
- CDC provides training and user support
- Confidentiality
- Useful analysis tools are included
- Not just a reporting tool - comparative rates can be used for performance improvement
- Ability to share data with other entities
Hemovigilance Module Surveillance Protocol (v2.0) is available on our Website.
Hemovigilance Module Surveillance Protocol

The protocol outlines the surveillance methodology and includes the following:

- Surveillance overview
- Reporting requirements
- Adverse reaction case classification tables
- Incident codes
- Links to data collection forms and instructions
Hemovigilance Module
Surveillance Methods

- Any U.S. facility where transfusions occur may use the Hemovigilance Module.
- Comprehensive surveillance of patients and blood products must be conducted facility-wide.
- Only report adverse reactions and associated incidents that occur for patients transfused at or by your facility.
Hemovigilance Module
Data Collection

- Participation minimum: 12 months consecutive data

- Required Data Collection
  - Annual Facility Survey
  - Monthly Reporting Plan
  - Adverse Events
    - Adverse Reactions
    - Incidents (errors, accidents)
  - Monthly Denominators

Hemovigilance Module Annual Facility Survey

For all questions, use information from previous full calendar year.

**Facility Characteristics**

1. Ownership
   - Government
   - Military
   - Not for profit, including church
   - For profit
   - Veteran’s Affairs
   - Physician-owned

2. Is your hospital a teaching hospital for physicians and/or physicians-in-training?
   - Yes
   - No

3. Community setting of facility
   - Urban
   - Suburban
   - Rural

4. How is your hospital accredited? (check one)
   - National Integrated Accreditation for Healthcare Organizations (NIA)
   - The Joint Commission
   - American Osteopathic Association (AOA)
   - Other Accrediting Organization

5. Total beds served by Transfusion Services.

6. Number of surgeries performed per year: Inpatient: Outpatient: ___

7. At what trauma level is your facility certified?
   - I
   - II
   - III
   - IV
   - V
   - N/A

**Transfusion Services Characteristics**

8. Primary classification of facility area served by Transfusion Services (check all that apply)
   - General medical and surgical
   - Obstetrics and gynecology
   - Orthopedic
   - Cancer center
   - Chronic disease
   - Children’s general medical and surgical
   - Children’s orthopedic
   - Children’s cancer center
   - Children’s chronic disease
   - Other (specify)

9. Does your healthcare facility provide all of its own transfusion services, including all laboratory functions?
   - Yes
   - No
   - No, we contract with a blood center for some transfusion service functions.

10. Is your Transfusion Services part of the facility’s core laboratory?
    - Yes
    - No

11. How many dedicated Transfusion Services staff members are there?
    - Number of technical FTEs (including supervisors) __________
    - Number of dedicated physician FTEs: __________
    - Number of MLTs: __________

**Data Field**

- Facility ID:
- Survey Year:

**Instructions for Form Completion**

- The NHSN-assigned Facility ID number will be auto entered by the system.
- Enter the most recent full calendar year. For example, if you completed this survey in February 2008, the survey year will be 2007.

**Facility Characteristics**

1. Ownership
   - Required. Check the ownership type that most closely describes your facility.

2. Is your hospital affiliated with a medical school?
   - Required. Check Yes if your hospital is affiliated with a medical school.

3. Type of affiliation
   - Major affiliation: Facility is a program for medical students and postgraduate medical training.
   - Graduate affiliation: Facility is a program for postgraduate medical training (i.e., residency or fellowships).
   - Undergraduate affiliation: Facility has a program for medical students only.

4. Community setting of facility
   - Optional. Check the setting that most closely describes the location of your facility.
   - Urban: Areas classified as a Metropolitan Statistical Area by the U.S. Census Bureau; each area must have at least one urbanized area of 50,000 or more inhabitants.
   - Suburban: Areas classified as a Metropolitan Statistical Area by the U.S. Census Bureau; each Metropolitan statistical area must have at least one urban cluster of at least 10,000 but less than 50,000 inhabitants.
   - Rural: Areas classified as Non-MSA or Counties by the Census Bureau; there are no urban areas of at least 10,000 inhabitants.

5. Total beds served by Transfusion Services
   - Required. Total beds in the facility served by Transfusion Services.

6. Number of surgeries performed per year
   - Required. Total number of inpatient and outpatient surgeries performed at your facility in the past full calendar year.

7. At what trauma level is your facility certified?
   - Required. Indicate the trauma level (I, II, III, IV, NA) of your facility.

**Assurance of Confidentiality**

The voluntarily provided information obtained 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 purpose stated, and will not otherwise be disclosed or released, for the consent of the individual, or to the institution in accordance with Sections 301, 302, 304, 306, and 320 of the Public Health Service Act (42 USC 242b, 242g, and 242h).

Public reporting burden of this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate to CDC, Reports Clearance Officer, 1600 Clifton Rd., MS-D7, Atlanta, GA 30333 ATTN: OMB (0002-0651).
Hemovigilance Module Annual Facility Survey

- Facilities are required to complete the survey at enrollment in NHSN or after activation of the Biovigilance Component and every year thereafter.

- The survey includes data from the previous calendar year.
  - If a facility enrolls in NHSN or activates the Biovigilance Component in Oct 2013, the survey must be completed using data from Jan 2012– Dec 2012.

- The data collected on the survey is used by CDC to classify facilities for comparisons in aggregate data analysis.
Hemovigilance Module Adverse Reactions
Hemovigilance Module
Adverse Reactions

- A transfusion-related adverse reaction is a response or effect in a patient temporally associated with the administration of blood or blood components\(^1\).

- All CDC-defined transfusion-associated adverse reactions that are possibly, probably, or definitely related to a transfusion performed by the participating facility must be reported to NHSN on an Adverse Reaction form.

\(^1\)Defined by the International Society of Blood Transfusions (ISBT)
Hemovigilance Module
Patient Adverse Reactions

- Allergic reaction
- Acute hemolytic transfusion reaction (AHTR)
- Delayed hemolytic transfusion reaction (DHTR)
- Delayed serologic transfusion reaction (DSTR)
- Hypotensive transfusion reaction
- Febrile non hemolytic transfusion reaction (FNHTR)
- Post transfusion purpura (PTP)
- Transfusion associated circulatory overload (TACO)
- Transfusion associated dyspnea (TAD)
- Transfusion associated graft vs. host disease (TA-GVHD)
- Transfusion-related acute lung injury (TRALI)
- Infection
Hemovigilance Module Adverse Reaction Case Classification Tables

- **Case Definition**
  - Criteria used to classify adverse reactions

- **Severity**
  - Degree to which the patient developed symptoms

- **Imputability**
  - Assessment of the relationship between the transfusion and the adverse reaction

- **Reporting Optional section added**
Hemovigilance Module
Incident Codes

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

- There are 100+ Incidents defined in the Hemovigilance Module.
Hemovigilance Module
Process Incidents

- **Transfusion Service**
  - Product Check-In
  - Sample Receipt
  - Sample Testing
  - Product Storage
  - Available for Issue
  - Product Selection
  - Product Manipulation
  - Product Issue

- **Clinical Service**
  - Product/Test Request
  - Sample Collection
  - Sample Handling
  - Request for Pick-up
  - Product Administration
Hemovigilance Module

Incidents

Sample Collection –
Blood drawn from patient for type and crossmatch

SC 01 Sample labeled w/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
SC 08 Sample collected in error
SC 09 Requisition arrives without samples
SC 10 Wristband incorrect or not available
SC 11 Sample contaminated
Hemovigilance Module Incident Reporting Requirements

- All incidents that are associated with a reported adverse reaction must be reported to NHSN using a detailed Incident form.

- Incidents can occur before or after an adverse reaction.
  - Before an adverse reaction: Administered wrong product to patient (UT 02) leading to an acute hemolytic transfusion reaction
  - After an adverse reaction: Transfusion protocol not followed (UT 19) after an adverse reaction, not reported to the blood bank
Hemovigilance Module Incident Reporting

Incident Result

- Product transfused, reaction
- Product transfused, no reaction
- No product transfused, unplanned recovery
- No product transfused, planned recovery
### Hemovigilance Module

**Monthly Reporting Denominators**

<table>
<thead>
<tr>
<th>Facility ID#</th>
<th>Required: Indicate the facility ID number entered by the system.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month</td>
<td>Required: Indicate the month the form is being entered.</td>
</tr>
<tr>
<td>Year</td>
<td>Required: Indicate the year the form is being entered.</td>
</tr>
</tbody>
</table>

#### Table 4. Hemovigilance Module Monthly Reporting Denominators (CDC 57.303)

<table>
<thead>
<tr>
<th>Product</th>
<th>Units Transfused</th>
<th>Aliquots Transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood derived</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red blood cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irradiated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukocyte reduced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irradiated and leukocyte reduced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apheresis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irradiated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukocyte reduced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irradiated and leukocyte reduced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apheresis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irradiated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukocyte reduced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irradiated and leukocyte reduced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma (all types)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total whole blood derived</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total apheresis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td></td>
<td></td>
</tr>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

#### Data Field | Instructions for Form Completion

- **Facility ID#**: The NHSN-assigned Facility ID number will be auto entered by the system.
- **Month**: Required. Indicate the month the form is being entered.
- **Year**: Required. Indicate the year the form is being entered.

#### Units and Aliquots Transfused

- **Total**: Required. Enter the total number of units and aliquots of whole blood derived WBD red blood cells (RBCs) transfused during the month that were irradiated only, leukocyte reduced only, irradiated and leukocyte reduced, and not modified by any of these methods. If none, enter 0. Do not include the units from which aliquots were made in unit count.
- **Whole blood derived**: Required. Enter the number of units and aliquots of WBD RBCs transfused during the month that were leukocyte reduced only. If none, enter 0. Do not include the units from which aliquots were made in unit count.
- **Leukocyte reduced**: Required. Enter the number of units and aliquots of WBD RBCs transfused during the month that were leukocyte reduced only. If none, enter 0. Do not include the units from which aliquots were made in unit count.
- **Irradiated and leukocyte reduced**: Required. Enter the number of units and aliquots of WBD RBCs transfused during the month that were both irradiated and leukocyte reduced. If none, enter 0. Do not include the units from which aliquots were made in unit count.
- **Total** (apheresis): Required. Enter the total number of units and aliquots of apheresis RBCs transfused during the month that were irradiated only, leukocyte reduced only, irradiated and leukocyte reduced, and not modified by any of these methods. If none, enter 0. Total may be more than the three modification columns combined. Do not include the units from which aliquots were made in unit count.
- **Irradiated** (apheresis): Required. Enter the number of units and aliquots of apheresis RBCs transfused during the month that were irradiated only. If none, enter 0. Do not include the units from which aliquots were made in unit count.
- **Leukocyte reduced** (apheresis): Required. Enter the number of units and aliquots of apheresis RBCs transfused during the month that were leukocyte reduced only. If none, enter 0. Do not include the units from which aliquots were made in unit count.
- **Irradiated and leukocyte reduced** (apheresis): Required. Enter the number of units and aliquots of apheresis RBCs transfused during the month that were both irradiated and leukocyte reduced. If none, enter 0. Do not include the units from which aliquots were made in unit count.
Hemovigilance Module
Monthly Reporting Denominators

- Facilities must report the total number of units and/or aliquots of specified blood products transfused each month.

- The total number of samples collected for type and screen or crossmatch must also be reported.