Biovigilance Component
Hemovigilance Module
Incident Reporting
Objectives

- Review key terms used in incident reporting
- Provide instructions for incident reporting:
  - Detailed method
  - Summary method
- Review incident case studies
Key Terms in Incident Reporting

- **Incident** – An error or accident that could lead to an adverse outcome affecting the quality or efficacy of blood, blood components, plasma derivatives, or the safety of transfusion recipients.
  - Error – An unexpected, unplanned deviation from Standard Operating Procedures (SOP) that is likely attributable to a human or system problem.
  - Accident – An unexpected or unplanned event that is not attributable to deviations from SOP.

- **High Priority Incident** – An incident that has high potential for wrongful transfusion in a recipient.

- **Near Miss** – An error or deviation from SOP that was discovered before the start of transfusion.
Incident Codes

- Incident codes can be found in Appendix F of the protocol.
- A plus (+) sign indicates high priority incidents.
Incident Categories

**Transfusion Services**
- **PC** Product Check-in
  - Products received from outside source
  - Returned to inventory from patient care area
- **SR** Sample Receipt
  - Receipt of sample in transfusion services
- **ST** Sample Testing
  - Testing of sample, type & crossmatch
- **US** Product Storage
  - Storage of blood and blood products in Transfusion Services
- **AV** Available for Issue
  - Quality management of product inventory
- **SE** Product Selection
  - When products are selected for transfusion
- **UM** Product Manipulation
  - When pooling, irradiating, dividing, thawing, and labeling products
- **UI** Product Issue
  - Issue of blood products from Transfusion Services
- **MS** Other

**Clinical Services**
- **PR** Product/Test Request
  - Request of a test or product by clinical service (online or requisition)
- **SC** Sample Collection
  - Service collecting the samples
- **SH** Sample Handling
  - Paperwork accompanying the sample for testing
- **RP** Request for Pick-up
  - Product request
- **UT** Product Administration
  - Product transfused
- **MS** Other
Hemovigilance Module Incident Form and Table of Instructions

Hemovigilance Module Incident

*Required for saving

| Facility ID# | NHSN Incident # | Local Incident # or Log # |

**Discovery**

*Date of discovery: ___ / ___ / ___
Time of discovery: ___ : ___ (HH:MM) [Time approximate] [Time unknown]
*Where in the facility was the incident discovered?

**How was the incident first discovered?** (check one)
- Communication from lab to floor
- Comparison of product label to patient information
- Comparison of product label to physician order
- Comparison of sample to paperwork
- Observation by staff of 
- Patient transfusion reaction
- Repeat or sample re-testing
- Routine audit or supervisory review
- Computer system alarm or warning
- Historical record/previous type check
- Human ‘lucky catch’
- Notification or complaint from floor (nurse, MD, etc.)
- Other (specify)

**At what point in the process was the incident first discovered?** (check one)
- Product check-in
- Product receipt
- Product storage
- Request for pick-up
- Other (specify)

**Occurrence**

*Date incident occurred: ___ / ___ / ___
Time incident occurred: ___ : ___ (HH:MM) [Time approximate] [Time unknown]
*Where in the facility did the incident occur?

Job function of the worker involved in the incident: (Use NHSN Occupation Codes on page 5.)

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Table 6. Hemovigilance Module Incident (CDC 57.365)

<table>
<thead>
<tr>
<th>Data Field</th>
<th>Instructions for Form Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility ID#</td>
<td>The Facility ID number will be auto-entered by NHSN.</td>
</tr>
<tr>
<td>NHSN Incident #</td>
<td>An incident number will be auto-entered by NHSN.</td>
</tr>
<tr>
<td>Local Incident # or Log #</td>
<td>Optional. Enter your facility’s incident report, log, or other locally assigned incident number.</td>
</tr>
</tbody>
</table>

**Discovery**

*Date of discovery: Required. Enter the date the incident was discovered. It must be on or after the date the incident occurred.*
Time of discovery: Required. Enter the time the incident was discovered using a 24-hour clock. If only an approximate time is known, check the “Time approximate” box. If the time cannot be determined, select “Time unknown.”

Where in the facility was the incident discovered?: Required. Select the location where the incident occurred. This may or may not be the same as the location where the incident occurred.

How was the incident first discovered?: Required. Select the description that most closely represents how the incident was first discovered. If “other” is selected, briefly describe how the incident was discovered.

At what point in the process was the incident first discovered?: Required. Select the process point at which the incident was first discovered. This may or may not be the same process point at which the incident occurred.

**Occurrence**

Date incident occurred: Required. Enter the date the incident occurred. It must be on or before the date the incident was discovered.
Time incident occurred: Required. Enter the time the incident occurred using a 24-hour clock.
Where in the facility did the incident occur?: Required. Select the location where the incident occurred. This may or may not be the same as the location where the incident was discovered.

Job function of the worker involved in the incident: Optional. Enter the job function of the worker involved in the incident using the codes on page 5 of the form. This is the worker who was involved in and may have been responsible for the incident, but not necessarily. In cases such as equipment malfunction, this may be the person who discovered the incident.

At what point in the process did the incident first occur?: Required. Select the process point at which the incident first occurred. Note: A single incident may result in a cascade of future incidents related to the same sample or blood product. Report only the earliest incident known to have occurred.

**Incident code**

Required. Enter the NHSN-defined incident code. Incident codes are found on page 4 of the form. For each process code (PC: Product Check-in, etc.) there is an option for unspecified incidents, if no process code is defined or the process is
Before Entering Event Forms

- Be sure that your facility has completed:
  - Annual Facility Survey
  - Monthly Reporting Plan(s)
Hemovigilance Module Incidents

- Incident surveillance must be conducted monthly.

- Facilities choose one of the following reporting methods:
  1. Detailed reporting of all incidents
     - Incident forms must be completed for every incident that occurs.
  2. Summary reporting of incidents
     - Monthly Incident Summary form that includes ALL incidents that occurred during the reporting month must be completed.
     - Detailed Incident forms are required for ALL high priority incidents and incidents associated with an adverse reaction.

- An incident might result in a cascade of future incidents. Report only the earliest incident known to have occurred.
Hemovigilance Module Incidents
Detailed Reporting

Enter Monthly Reporting Plan

Enter detailed Incident forms for all incidents

Enter Monthly Reporting Denominators form
On the Monthly Reporting Plan:
- Check “Detailed reporting of all incidents”
- Click “Save”
Complete an Incident form for each incident that occurred during the reporting month.
Hemovigilance Module Incidents Detailed Reporting

- Select “Incident”
- Click “Add”
Hemovigilance Module Incidents Detailed Reporting

- **Date and time of discovery**
  - Enter the date and time the incident was first noticed by staff.

- **Where in the facility was the incident discovered?**
  - Select a facility-defined NHSN location.
  - This may or may not be the same location where the incident occurred.
Hemovigilance Module Incidents
Detailed Reporting

- **How was the incident first discovered?**
  - Select the description that most closely describes how the error was *initially* discovered by staff.
  - If “Other” is selected, include a brief description in the space provided.

- **At what point in the process was the incident first discovered?**
  - Use the Incident Categories or Appendix F in the protocol to help select the appropriate process point.
Hemovigilance Module Incidents Detailed Reporting

- Date and time the incident occurred
  - Enter the date and time the incident first happened.
- Where in the facility did the incident occur?
  - Select the facility-defined NHSN location.
- Job function of the worker involved in the incident (optional)
  - Use the CDC occupation codes in Appendix E of the protocol.
Hemovigilance Module Incidents Detailed Reporting

- **At what point in the process did the incident first occur?**
  - Select the process point at which the incident began.

- **Incident code**
  - See Appendix F of the protocol for a list of incident codes.

- **Incident summary (optional)**
  - Enter a brief, descriptive text of exactly what happened.
Hemovigilance Module Incidents
Detailed Reporting

Incident Results

1 – **Product transfused, reaction**
A product related to this incident was transfused; the patient experienced an adverse reaction

2 – **Product transfused, no reaction**
A product related to this incident was transfused; the patient did not experience an adverse reaction

3 – **No product transfused, unplanned recovery**
No product was transfused; the incident was discovered ad hoc, by accident, by a human lucky catch, etc.

4 – **No product transfused, planned recovery**
No product was transfused; the incident was discovered through a standardized process or barrier designed to prevent errors
Product action

- Not applicable – incident was not related to a product, or the incident was discovered before a product was selected for transfusion
- Product retrieved – product was intercepted or withdrawn and was not transfused
Hemovigilance Module Incidents
Detailed Reporting

- **Product action (cont.)**
  - Product destroyed – product was destroyed as a result of the incident
    - Single or multiple units destroyed?
    - Code system used (e.g., Codabar, ISBT-128)
  - Product issued but not transfused – product was issued to the patient care area but was not transfused
  - Product transfused – product was transfused
    - Was a patient reaction associated with this incident?
    - Enter the patient ID #(s) of the patient that experienced an adverse reaction

- **Record/other action – follow-up actions that were performed**
Blood Product Codes

- Two code systems used for blood products:
  - ISBT-128
  - Codabar

- The 5-digit code for the blood product entered in NHSN should match the product description generated by the system.
Hemovigilance Module Incidents
Detailed Reporting

- Root Cause Analysis
  - A facility may choose to conduct a formal administrative investigation aimed at identifying the problems or causes of an incident.
  - If a root cause analysis is performed, check all results that apply. Detailed definitions of root cause analysis results can be found in Appendix G of the protocol.
Don’t forget to SAVE!

- Remember to SAVE before leaving the page.
  - Forms cannot be left unfinished and completed later.
  - Forms cannot be saved unless all required fields are entered.
Topics Covered So Far…

- Key terms in incident reporting in NHSN
- Detailed reporting of incidents

Coming Up Next…

- Summary reporting of incidents
- Incident case studies
Hemovigilance Module Monthly Incident Summary Form and Tables of Instructions

<table>
<thead>
<tr>
<th>Process Code</th>
<th>Incident Code</th>
<th>Total Incidents</th>
<th>Total Adverse Reactions associated with Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC: Product Check-In (Products received from outside source)</td>
<td>PC 00: Detail not specified</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PC 01: Data entry incomplete/incorrect</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PC 02: Shaun hornet's horn</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PC 03: Product and paperwork do not match</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PC 04: Storage under inappropriate conditions</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PC 05: Inappropriate return to inventory</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PC 06: Product confirmation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PC 07: Administrative check (3rd check)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PC 09: Detail not specified</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PR: Product/Test Request (Clinical Service)</td>
<td>PR 00: Order incorrectly entered online</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PR 01: Special order not indicated on order (e.g., CMF, negative, auto)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PR 02: Order not close/opened/corrected</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PR 03: Inappropriate/incorrect log type</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PR 04: Inappropriate/incorrect blood product entered</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SC: Sample Collection (Service collecting the samples)</td>
<td>SC 01: Sample labeled with incorrect patient name</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 02: Not labeled</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 03: Wrong patient collected</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 04: Collected in wrong tube type</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 05: Sample hemolyzed</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 06: Sample hemolyzed</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 07: Label incompletely legible (other than patient name)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 08: Sample collected in error</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 09: Reaction without sample</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 10: Wrong patient demographics</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SC 11: Sample contaminated</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SH: Sample Handling (Service collecting the samples)</td>
<td>SH 01: Sample arrived without documentation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SH 02: Reaction and sample label don't match</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SH 03: Parent D ID incomparable on reaction</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SH 04: No hemocompatibility identification</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SH 05: Sample arrived with incorrect requisition</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SH 06: Patient identification (other than ID: missing/incorrect on requisition)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>SH 10: Sample transport issue</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Indicates high-priority incidents; individual incident report must be completed for each.

Assurance of Confidentiality: The voluntarily provided 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 otherwise be disclosed or released without the consent of the individual or the institution to which it pertains. (Public Health Service Act, 42 USC 264a, 242k, and 324m).

Public reporting burden of 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. Comments should be addressed to the Centers for Disease Control and Prevention, 1600 Clifton Rd., MS-D24, Atlanta, GA 30333, attn: PM 0502 (0502-0656).

**Table 3. Hemovigilance Module Monthly Incident Summary (CDC 57.302)**

<table>
<thead>
<tr>
<th>Data Field</th>
<th>Instructions for Form Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility ID#</td>
<td>The NHSN-assigned Facility ID number will be auto entered by the system.</td>
</tr>
<tr>
<td>Month</td>
<td>Required. Indicate the month for the summary being entered.</td>
</tr>
<tr>
<td>Year</td>
<td>Required. Indicate the year for the summary being entered.</td>
</tr>
<tr>
<td>Incident Code</td>
<td>Required. Select Incident Code. Only add rows for incidents that occurred during the month.</td>
</tr>
<tr>
<td>Total Incidents</td>
<td>Required. Enter the total number of incidents that occurred for the incident code selected. Include all detailed incident records entered in your incident total.</td>
</tr>
</tbody>
</table>

Note: All high-priority incidents must also be reported on a detailed incident form. High-priority incidents are indicated by a plus sign (+) on the paper form and in the incident code list in the protocol.

**Total Adverse Reactions associated with Incidents**

Required. Enter the total number of adverse reactions associated with each reported incident code. If no adverse reactions were associated with reported incidents, enter 0.

Note: All incidents associated with an adverse reaction must also be reported on a detailed incident form.

**Total**

Required (auto sum). Totals for each column will be auto entered by the system.
Hemovigilance Module Incidents Summary Reporting

Enter Monthly Reporting Plan

Track incident data throughout the month

Enter Monthly Incident Summary

Enter Monthly Denominators
Hemovigilance Module Incidents
Summary Reporting

On the Monthly Reporting Plan:

- Check “Summary data with detailed reporting of high priority incidents”
- Click “Save”
Complete a Monthly Incident Summary form that includes ALL incidents that occurred during the reporting month.
Hemovigilance Module Incidents Summary Reporting

- Select “Summary Data”
- Click “Add”
- Select “Monthly Incident Summary” from the drop-down menu
- Click “Continue”
Select the Month and Year from the drop-down menus.
Hemovigilance Module Incidents
Summary Reporting

- Process and Incident code
  - Use Appendix F in the protocol to help select the appropriate code(s). Add additional row(s) as needed.

- Total Incidents and Adverse Reactions associated with Incidents
  - Enter ‘0’ (zero) if no adverse reactions were associated with the incident.
Important Summary Reporting Reminders

- Complete a Monthly Incident Summary form that includes ALL incidents that occurred during the reporting month.
- Detailed Incident Forms are required for ALL high priority incidents and incidents associated with an adverse reaction.
INCIDENT REPORTING
CASE STUDIES
Case Study #1

At 8 a.m. on 3/15/2012, a unit of red cells was being electronically crossmatched for a patient. When entering the unit into the laboratory information system (LIS), the tech noticed that the expiry date in the LIS did not match the date on the unit.

Upon further investigation, it was discovered that the bar code reader had not been used when the product had been checked into inventory three days before (sometime in the morning), resulting in the manual entry of an incorrect expiry date.

The supervisor was notified, and the expiry date of the unit was corrected in the LIS. There was no delay in providing blood for the patient as the tech selected another unit rather than waiting for a correction to be made for the first unit.
Case Study #1

The facility has chosen detailed reporting of all incidents on the Monthly Reporting Plan.

- An Incident form must be completed for all events.
Case Study #1
Incident Form

Department of Health and Human Services
Centers for Disease Control and Prevention

Log into NHSN Test KWC Memorial (ID 24976) as KWC. Facility NHSN Test KWC Memorial (ID 24976) is following the BV component.

Add Incident

Mandatory fields marked with *
Conditionally required fields marked with ^

*Facility ID: NHSN Test KWC Memorial (ID 24976)

Incident #: [Enter Incident Number]
Local Incident # or Log #: XYZ9876

Discovery

*Date of discovery: 03/15/2012
*Time of discovery: 08:00 (HH:MM)
[ ] Time approximate [ ] Time unknown

*Where in the facility was the incident discovered?
BB - BLOOD BANK

*How was the incident first discovered?
OTHER - Other
[ ] Specify
Comparison of product label to LIS

*At what point in the process was the incident first discovered?
ST: Sample testing
Case Study #1
Occurrence

<table>
<thead>
<tr>
<th>Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date incident occurred:</strong> 03/12/2012</td>
</tr>
<tr>
<td><strong>Time incident occurred:</strong> 09:00 (HH:MM)</td>
</tr>
<tr>
<td><strong>Time approximate</strong></td>
</tr>
<tr>
<td><strong>Job function of the worker involved in the incident:</strong> MLT - Medical Laboratory Technician</td>
</tr>
<tr>
<td><strong>Where in the facility did the incident occur?</strong> BB - BLOOD BANK</td>
</tr>
<tr>
<td><strong>At what point in the process did the incident first occur?</strong> PC: Product check-in</td>
</tr>
<tr>
<td><strong>Incident code:</strong> PC.01 - Data entry incomplete/not performed/incorrect</td>
</tr>
<tr>
<td><strong>Incident summary:</strong> (500 characters max)</td>
</tr>
<tr>
<td><strong>Incident result:</strong> 4 - No product transfused; planned recovery</td>
</tr>
<tr>
<td><strong>Product action:</strong> (check all that apply)</td>
</tr>
<tr>
<td>✓ Not applicable</td>
</tr>
<tr>
<td>✗ Product correction</td>
</tr>
</tbody>
</table>
Case Study #1
Investigation Result

*Incident result: 4 - No product transfused, planned recovery

*Product action: (check all that apply)
- Not applicable
- Product retrieved
- Product destroyed
- Product issued but not transfused
- Product transfused

*Record/other action: (check all that apply)
- Record corrected
- Floor/clinic notified
- Attending physician notified
- Additional testing
- Patient sample re-collected
- Other

Investigation Results

*Did this incident receive root cause analysis? N - No

Custom Fields

Comments

Save  Back
Case Study #2

At 08:30 a.m. on 3/20/2012, the blood bank discovered that a wrong unit may have been issued to patient B. Thomas. The technologist called the ICU and asked the nurse to check the identification of two units that had been issued for patient B. Thomas. One of the bags issued had the name and hospital number of another patient with the same last name. The patient had already received the incorrect unit starting at 04:55 a.m. that day.

The attending physician and hematologist were notified immediately. At 8:45 a.m. the patient began to experience dyspnea, chest pain, nausea, and developed acute kidney failure with an urine output of 40 mL/hr and a rise in creatinine, LDH, potassium, and bilirubin. The hemoglobin dropped from 10.7 to 8.3.

The patient did not require dialysis, and urine output was normal by the next day. In the days that followed, hydration was maintained at 80 mL/hr and the patient’s renal function continued to improve. She was discharged on 3/25/2012.
This facility has chosen summary incident reporting on the Monthly Reporting Plan.
Case Study #2

- At the end of the month, the facility must complete the Monthly Incident Summary form.
- Remember, that detailed Incident forms are required for all high priority incidents and incidents associated with an adverse reaction.
Case Study #2

Logged into NHSN Test KWC Memorial (ID 24976) as KWC. Facility NHSN Test KWC Memorial (ID 24976) is following the BV component.

**Edit Incident**

Mandatory fields marked with *
Conditionally required fields marked with ^

*Facility ID: NHSN Test KWC Memorial (ID 24976) |
Incident #: 6396
Local Incident # or Log #: XYZ6543

**Discovery**

*Date of discovery: 03/20/2012 |
*Where in the facility was the incident discovered? 
EB - BLOOD BANK

*Time of discovery: 08:30 (HH:MM) 

Time approximate | Time unknown

*How was the incident first discovered? 
AUDIT - Routine audit or supervisory review

*At what point in the process was the incident first discovered? 
RA: Post Transfusion Review/Audit

**Occurrence**
Case Study #2

This is the same Patient ID # that will be used when we complete and enter an Adverse Reaction form into NHSN.
Remember to SAVE the record before navigating away from any form in NHSN.
Questions or Need Help?
Contact User Support

nhsn@cdc.gov

S.O.S.