Biovigilance Component
Hemovigilance Module
Adverse Reaction and Denominator Reporting

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion
Objectives

- Review adverse reaction reporting
- Provide instructions for completing an Adverse Reaction form in NHSN
  - Describe how to link adverse reactions to incidents
- Provide instructions for completing a Monthly Reporting Denominators form in NHSN
- Review an adverse reaction case study
Adverse Reactions Definition

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

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

- 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.

- Report one adverse reaction per form.
  - If a patient experiences two reactions, two separate forms must be completed.
Hemovigilance Module Adverse Reactions Reporting Requirements

- Reports should be entered after the investigation is complete and imputability has been determined.
  - After an investigation has been completed and a report entered, reports can still be edited to include new information.

- The Hemovigilance Module **DOES NOT** replace the FDA's mandatory requirements for reporting blood transfusion-related deaths or Blood Product Deviation reporting.

- Detailed instructions on completing the form are provided on the Website.
Hemovigilance Module Adverse Reactions

The 12 defined adverse reactions:

- Transfusion-associated circulatory overload (TACO)
- Transfusion-related acute lung injury (TRALI)
- Transfusion-associated dyspnea (TAD)
- Allergic reaction
- Hypotensive transfusion reaction
- Febrile non-hemolytic transfusion reaction (FNHTR)
- Acute hemolytic transfusion reaction (AHTR)
- Delayed hemolytic transfusion reaction (DHTR)
- Delayed serologic transfusion reaction (DSTR)
- Transfusion-associated graft vs. host disease (TAGVHD)
- Post transfusion purpura (PTP)
- Transfusion-transmitted infection (TTI)
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**
Before Entering Event Forms

Be sure that your facility has completed:

- Annual Facility Survey
- Monthly Reporting Plan(s)
Entering an Adverse Reaction Form

Click “Reaction,” then “Add”
Fields marked with a red asterisk (*) are mandatory.
Patient Information

- Patient information is shared across NHSN Components.
- If a Patient ID is recognized by NHSN, the system will auto-fill the patient information.
- If a Patient ID is not recognized by NHSN, a new patient can be added to NHSN directly from the Adverse Reaction form.
- Creating a unique patient identifier for Patient ID is not recommended; use medical record numbers or other standard facility identification code for Patient ID.
More information on Link/Unlink Incidents will be provided later in this training session.
Reaction Details

- **Date and time reaction occurred**
  - For acute reactions, use the date and time the symptoms were first observed.
  - For delayed reactions, use the date of test identifying new antibodies or date patient noticed symptoms.

- **Facility location where patient was transfused**
  - Only report reactions for recipients who were transfused in your facility.

- **Signs and symptoms, laboratory**
  - Check all that apply and use ‘Other’ to include signs and symptoms or laboratory results not listed.
  - See Section 3 in the protocol for a glossary of signs and symptoms.
Investigation Results

Respiratory:
- Bil. infiltrates on chest x-ray
- Bronchospasm
- Cough
- Hy
- Shortness of breath
- Other

Other:
- Other

Investigation Results (Use case definition criteria in protocol.)

*Adverse reaction:
- ALLERG - Allergic reaction, including anaphylaxis
- AHTR - Acute hemolytic transfusion reaction
- DHTR - Delayed hemolytic transfusion reaction
- DSTR - Delayed serologic transfusion reaction
- FNHTR - Febrile non-hemolytic transfusion reaction
- HTR - Hypotensive transfusion reaction
- INF - Infection
- PTP - Post transfusion purpura
- TACO - Transfusion associated circulatory overload
- TAD - Transfusion associated dyspnea
- TA-GVHD - Transfusion associated graft vs. host disease
- TRALI - Transfusion related acute lung injury
- UNK - Unknown pathophysiology
- OTHER - Other

*Severity:

*Imputability:
- PTP - Post transfusion purpura

Outcome

*Outcome:

Component Details

*Was a particular component implicated in the adverse reaction?
Investigation Results

- **Adverse Reactions**
  - Using the case classification tables in the protocol, select the appropriate reaction.
    - There are 12 defined adverse reactions.
    - If the reaction cannot be diagnosed, select ‘Unknown pathophysiology.’
    - If the reaction can be diagnosed, but does not match one of the 12 defined adverse reactions listed, select ‘Other’ and specify the reaction.

- Using the protocol, determine case definition, severity, and imputability.

- Update the record if new information becomes available after the reaction has been entered.
Outcomes

- Select the appropriate clinical outcome of the patient.
- If the recipient died following the adverse reaction, enter the date of death whether or not the death was transfusion related.
  - Enter the relationship of the transfusion to death using the imputability criteria for “Other or Unknown” in Section 3 of the protocol.
### Component Details

**Date of death: **

*If recipient died, relationship of transfusion to death:* PRO - Probable

#### Component Details

*Was a particular unit implicated in the adverse reaction? Y - Yes

<table>
<thead>
<tr>
<th>Transfusion Date / Time MM/DD/YYYY HH:MM</th>
<th>Component code (check system used)</th>
<th># of units</th>
<th>Unit number Required for TRALI, GVHD, Infection</th>
<th>Unit expiration Date / Time MM/DD/YYYY HH:MM</th>
<th>Blood group of unit</th>
<th>Implicated in the adverse reaction?</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/13/2012 08:00</td>
<td>ISBT-128 Codabar E0773 Thawed FRESH FROZEN PLASMA</td>
<td>1</td>
<td>Facility Year Sequence Vertical Digits Checksum Char</td>
<td>03/19/2012 23:59</td>
<td>A+</td>
<td></td>
</tr>
<tr>
<td>03/13/2012 14:00</td>
<td>ISBT-128 Codabar E0160 RED BLOOD CELLS</td>
<td>1</td>
<td>Facility Year Sequence Vertical Digits Checksum Char</td>
<td>03/15/2012 23:59</td>
<td>A+</td>
<td></td>
</tr>
</tbody>
</table>
Component Details

- Was a particular unit implicated in the adverse reaction?
  - If only ONE unit was transfused, that unit must be implicated in the reaction (except when reporting TACO).
  - If multiple units were transfused, and a single unit can be implicated as the cause, the implicated unit must be entered on the FIRST row.
  - If multiple units were transfused, but a single unit cannot be identified as the cause, no unit can be called implicated.
  - Enter additional rows as needed.
Component 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 application.
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.
Linking Incident Records to Adverse Reaction Records

- Incidents that are associated with adverse reactions must be linked to adverse reaction records in NHSN.
- Incident records must be entered before they can be linked to Adverse Reaction records.
- Use the “Link/Unlink To Incidents” button on the Adverse Reaction form to link the records.
- On the Incident form, select
  - Incident result: 1 – Product transfused; reaction
  - Product action: Product transfused
  - Enter Patient ID(s)

- On the Adverse Reaction form
  - Click the “Link/Unlink To Incident” button

The Patient ID must be the same on both forms!
Linking Incident Records to Adverse Reaction Records

- All incident records with matching Patient ID(s) will show on the Incident Link List.
- Select the Incident records that are associated with the adverse reaction and click “Link/Unlink.”

<table>
<thead>
<tr>
<th>Check all that apply</th>
<th>Incident #</th>
<th>Patient ID</th>
<th>Date incident occurred</th>
<th>Where in the process the incident first occurred</th>
<th>Incident code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>548</td>
<td>ABC1234</td>
<td>05/05/2012</td>
<td>AV</td>
<td>AV 00</td>
</tr>
<tr>
<td>✓</td>
<td>549</td>
<td>ABC1234</td>
<td>05/06/2012</td>
<td>PC</td>
<td>PC 01</td>
</tr>
</tbody>
</table>

Incident Link List

Displaying 1 - 2 of 2
Once the Incident record is linked to the Adverse Reaction record, “Reaction is Linked” will appear next to the “Link/Unlink To Incidents” button.

Remember that Patient ID must match on both the Incident form and Adverse Reaction form.
Topics Covered So Far...

- Navigating NHSN
- Adverse reaction case definition criteria
- Entering an Adverse Reaction form in NHSN
- Linking Adverse Reaction records to Incidents records

Coming Up Next...

- Monthly Reporting Denominators
- Adverse Reaction case study
Hemovigilance Module
Monthly Reporting Denominators

- Denominator forms are entered at the end of each reporting month.

- 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 and/or crossmatch must also be reported.

- The denominator form must be used to report when no adverse reactions or incidents occur in a month.
Entering a Monthly Reporting Denominator Form

- Select “Summary Data”
- Click “Add”
- Select “Monthly Reporting Denominators” from the drop-down menu
- Click “Continue”
Select the month and year from the drop-down menu.
Entering a Monthly Reporting Denominator Form

- Check the appropriate box when no adverse reactions or incidents occurred during the month.
- The no adverse reaction box cannot be checked if an Adverse Reaction form has been entered.
- The no incidents box cannot be checked if an Incident or Monthly Incident Summary form have been entered.
The number of modified units does not need to equal the TOTAL units/aliquots transfused

- The total units transfused is not inclusive of all modifications

Do not include the units from which aliquots were made in the units transfused count.
Case Study

At approximately 14:15 on 3/05/2012 patient J. Doe was halfway through a transfusion of plasma, which began at approximately 12:15, when she complained of bilateral itchiness on her arms. The nurse slowed the transfusion rate, but within 5 minutes, bright red macula appeared on both forearms. Diphenhydramine was administered with relief of symptoms. Transfusion reaction investigation was negative for hemolysis. The patient had not been previously transfused.
Case Study

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

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

Edit Adverse Reaction

Mandatory fields marked with *
Conditionally required fields marked with ^

Patient Information

Facility ID: NHSN Test KWC Memorial (ID 24976)
Patient ID: JD1234
Secondary ID: 
Last Name: Doe
Middle Name: 
Gender: F - Female
Ethnicity: NOHISP - Not Hispanic or Not Latino
Race: American Indian/Alaska Native
Black or African American
Native Hawaiian/Other Pacific Islander
White
Blood Group: O-
Primary underlying reason for transfusion: MEDICAL - Medical

Adverse Reaction #: 6456
Social Security #: 
Medicare #: 
First Name: Jane
Date of Birth: 11/21/1963
Case Study

- **Enter the Patient ID and select “Find”**
  - If the Patient ID is not recognized, enter the new patient information in Patient Information section.
  - Complete optional fields as desired (NHSN does not analyze optional field data).

- **Patient Information shared across all components**
  - Use MRN or other facility identification numbers for Patient ID.
  - Do not create a unique Patient ID for NHSN reporting.
## Case Study

### Reaction Details

- **Date reaction occurred:** 03/05/2012
- **Time reaction occurred:** 14:15 (HH:MM)
- **Facility location where patient was transfused:** 3MED-WEST · MEDICAL WARD 3RD FLOOR-WEST

**Link/Unlink To Incidents**

*Reaction is not Linked*

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Signs/Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generalized</td>
<td>Chills/rigors, Fever, Shock</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Blood pressure decrease, Shock, Jaundice, Other rash</td>
</tr>
<tr>
<td>Cutaneous</td>
<td>Edema, Flushing, Urticaria</td>
</tr>
<tr>
<td></td>
<td>Disseminated intravascular coagulation, Hemoglobinemia, Positive antibody screen</td>
</tr>
<tr>
<td>Hemolysis/Hemorrhage</td>
<td>Abdominal pain, Back pain, Flank pain, Infusion site pain</td>
</tr>
<tr>
<td>Pain</td>
<td>Hematuria, Hemoglobinuria, Oliguria, Hypoxemia</td>
</tr>
<tr>
<td>Renal</td>
<td>Bil. infiltrates on chest x-ray, Bronchospasm, Cough</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Shortness of breath</td>
</tr>
<tr>
<td>Other</td>
<td>Other</td>
</tr>
</tbody>
</table>

### Investigation Results (Use case definition criteria in protocol.)
### Case Study

#### Investigation Results (Use case definition criteria in protocol.)

- **Adverse reaction:** ALLERG - Allergic reaction, including anaphylaxis
- **Case definition criteria:** DEF - Definitive
- **Severity:** NS - Non-severe
- **Imputability:** DEF - Definite

#### Outcome

- **Outcome:** NOSEQ - Minor or no sequelae

#### Component Details

- **Was a particular unit implicated in the adverse reaction?** Y - Yes
Case Study

Only one unit was transfused, therefore it MUST be the implicated unit.

- If a unit is implicated, the first row auto-fills the number of units and the implicated check box.
Remember!

- Report only one adverse reaction per form.
- Enter Incident records first to link Adverse Reactions.
- Remember to SAVE!
- Enter Monthly Reporting Denominators at the end of each month.
- Continue reporting blood transfusion-associated adverse events to FDA as required.
Questions or Need Help?
Contact User Support

nhsn@cdc.gov