



# **Biovigilance Component Hemovigilance Module Adverse Reaction and Denominator Reporting**

# 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**

## Hemovigilance Module Adverse Reactions

- ❑ **All transfusion-associated adverse reactions that meet NHSN criteria are reported on the Adverse Reaction form.**
- ❑ **Report one adverse reaction per form.**
  - If a patient experiences multiple reactions, complete a separate form for each.
- ❑ **Reports should be entered after the investigation is complete and imputability has been determined.**
- ❑ **The Hemovigilance Module DOES NOT replace the FDA's mandatory requirements for reporting blood transfusion-related deaths or Blood Product Deviation reporting.**

# Adverse Reaction Case Definition Criteria

NHSN Biovigilance Component  
Protocol v1.3.1  
[www.cdc.gov/nhsn](http://www.cdc.gov/nhsn)

**Appendix A. Adverse Reaction Case Definition Criteria**

**Allergic reaction:** The result of an interaction of an allergen with preformed antibodies. In some instances, infusion of antibodies from an atopic donor may also be involved. It may present with only mucocutaneous signs and symptoms.

Case Definition Criteria		Severity	Imputability
<b>Signs/Symptoms</b>	<b>Laboratory/Radiology</b>		
<b>Definitive:</b> 2 or more of the following occurring during or within 4 hours of cessation of transfusion: <ul style="list-style-type: none"><li>• Maculopapular rash</li><li>• Urticaria (hives)</li><li>• Pruritus (itching)</li></ul>	<b>Definitive:</b> N/A	<b>Grade 1:</b> No immediate risk to the life of the patient <b>AND</b> Responds quickly to symptomatic treatment.  <b>Grade 2 – 4:</b> Involves respiratory and/or cardiovascular systems and presents like an anaphylactic	<b>Definitive:</b> Occurs during or within 2 hours of cessation of transfusion <b>AND</b> No other evidence of environmental, drug or dietary risks.  <b>Probable:</b>

Case Definition – criteria used to categorize adverse reactions

Severity – degree to which the patient is affected by a reaction

Imputability – assessment of the relationship between the transfusion and the adverse reaction

<http://www.cdc.gov/nhsn/PDFs/Biovigilance/BV-Protocol-1-3-1-June-2011.pdf>

# Adverse Reaction Form and Table of Instructions



OMB No. 0920-0666  
Exp. Date: 05-31-2014  
www.cdc.gov/nhsn

## Hemovigilance Module Adverse Reaction

*\*Required for saving*

*Facility ID#:		NHSN Adverse Reaction #:	
<b>Patient Information</b>			
*Patient ID:	*Gender: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other	*Date of Birth: ___/___/___	
Social Security #:	Secondary ID:	Medicare #:	
Last Name:		First Name:	
Ethnicity <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Not Latino			
Race <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American			
<input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> White			
*Blood Group: <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> Type and crossmatch not done			
*Primary underlying reason for transfusion: <input type="checkbox"/> Coagulopathy <input type="checkbox"/> Genetic Disorder <input type="checkbox"/> Hematology Disorder			
<input type="checkbox"/> Hemolysis <input type="checkbox"/> Internal Bleeding <input type="checkbox"/> Malignancy <input type="checkbox"/> Medical <input type="checkbox"/> Surgery <input type="checkbox"/> Unknown			
<input type="checkbox"/> Other (specify): _____			
<b>Reaction Details</b>			
*Date reaction occurred: ___/___/___			
*Time reaction occurred: ___:___ (HH:MM) <input type="checkbox"/> Time unknown			
*Facility location where patient was transfused: _____			
*Is this reaction associated with an incident? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> If Yes, incident #: _____			
*Signs and symptoms, laboratory: (check all that apply)			
<b>Cardiovascular:</b>	<b>Cutaneous:</b>	<b>Pain:</b>	
<input type="checkbox"/> Blood pressure decrease	<input type="checkbox"/> Edema	<input type="checkbox"/> Abdominal pain	
<input type="checkbox"/> Shock	<input type="checkbox"/> Flushing	<input type="checkbox"/> Back pain	
<b>Hemolysis/Hemorrhage</b>	<input type="checkbox"/> Jaundice	<input type="checkbox"/> Flank pain	
<input type="checkbox"/> Disseminated intravascular coagulation	<input type="checkbox"/> Other rash	<input type="checkbox"/> Infusion site pain	
<input type="checkbox"/> Hemoglobinemia	<input type="checkbox"/> Pruritus (itching)	<b>Respiratory:</b>	
<input type="checkbox"/> Positive antibody screen	<input type="checkbox"/> Urticaria (hives)	<input type="checkbox"/> Bilateral infiltrates on chest x-ray	
<b>Generalized:</b>	<b>Renal:</b>	<input type="checkbox"/> Bronchospasm	
<input type="checkbox"/> Chills/rigors	<input type="checkbox"/> Hematuria	<input type="checkbox"/> Cough	
<input type="checkbox"/> Fever	<input type="checkbox"/> Hemoglobinuria	<input type="checkbox"/> Hypoxemia	
	<input type="checkbox"/> Oliguria	<input type="checkbox"/> Shortness of breath	
<input type="checkbox"/> Other: (specify) _____			
<p><small>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 purposes stated, and will not otherwise 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, 242c, and 242m(5)).</small></p> <p><small>Public reporting burden of this collection of information is estimated to average 10 minutes 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 or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Reports Clearance Officer, 1600 Clifton Rd., MS D-74, Atlanta, GA 30333 ATTN: PRA (0920-0666).</small></p>			

CDC 57.304 Rev. 3, v6.8.1

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NHSN Hemovigilance Component  
Table of Instruction v1.3  
www.cdc.gov/nhsn

Table 5. Hemovigilance Module Adverse Reaction (CDC 57.304)

Data Field	Instructions for Form Completion
Facility ID#	The Facility ID number will be auto entered by NHSN.
Adverse Reaction #	An adverse reaction number will be auto entered by NHSN.
<b>Patient Information</b>	
Patient ID	Required. Enter the medical record number or other facility alphanumeric identification code for the patient. Note: Facility patient information is shared across NHSN Component. When an MRN is entered for a patient that has been previously entered for another NHSN event, the patient information will automatically populate. NHSN is HIPPA compliant; it is not recommended to devise a unique patient identifier for NHSN.
Gender	Required. Select the gender of the transfusion recipient.
Date of birth	Required. Enter the date of birth of the transfusion recipient.
Social Security #	Optional. For local use only.
Secondary ID	Optional. For local use only.
Medicare #	Optional. For local use only.
Last Name	Optional. For local use only.
First Name	Optional. For local use only.
Middle Name	Optional. For local use only.
Ethnicity	Optional. For local use only.
Race	Optional. For local use only.
Blood group	Required. Select the blood group of the transfusion recipient. Note: If the patient's blood type does not clearly match a single blood type, select the most relevant blood type and make a note in the comments section of the form. For example, if a patient is typing with mixed field reactions following a bone marrow transplant, select the predominant blood type and enter a note in the comments section such as, "Group A recipient of group O bone marrow transplant currently typing as mixed field."
Primary underlying reason for transfusion	Required. Select the primary reason this patient received a transfusion. If none of the options are adequate, select "other" and specify the reason in detail. Avoid using "anemia" as it does not describe the underlying medical condition of the transfusion recipient.
<b>Reaction Details</b>	
Date reaction occurred	Required. Enter the date the reaction was first observed in the transfusion recipient.
Time reaction occurred	Required. Enter the time the reaction was first observed in the transfusion recipient using a 24-hour clock.

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April 2012

# Before Entering Event Forms

**Be sure that your facility has completed:**

- **Annual Facility Survey**
- **Monthly Reporting Plan(s)**

# Navigating NHSN

The screenshot shows the NHSN Hemovigilance Module Home Page. At the top left is the CDC logo. To its right is the text: "Department of Health and Human Services" and "Centers for Disease Control and Prevention". Below this is a blue navigation bar with the following links: "NHSN - National Healthcare Safety Network (apt-v-nhsn-test:8081)", "NHSN Home", "My Info", "Contact us", "Help", and "Log Out". The "Help" link is circled in red. Below the navigation bar, the page content includes: "Logged into KWC Test Hospital (ID 10976) as KOO.", "Facility KWC Test Hospital (ID 10976) is following the BV component.", and the heading "NHSN Hemovigilance Module Home Page". Below the heading is the text: "Use the Navigation bar on the left to access the features of the application." and a paragraph of text under the heading "Assurance of Confidentiality". On the left side of the page, there is a vertical navigation bar with the following items: "NHSN Home", "Reporting Plan", "Patient Incident Reaction Summary Data Analysis Surveys Users Facility Group Log Out". This navigation bar is circled in red. Two red arrows point from the labels "Navigation Bar" and "NHSN Help Feature" at the bottom of the slide to the respective elements in the screenshot.

Navigation Bar

NHSN Help Feature

# Navigating NHSN

## ❑ **User rights determine navigation bar options**

- Users with Administrator Rights have access to all navigation bar options including User, Facility, and Group options.
- Users with Add/Edit/Delete and Analyze Data Rights only have access to forms and analysis features.

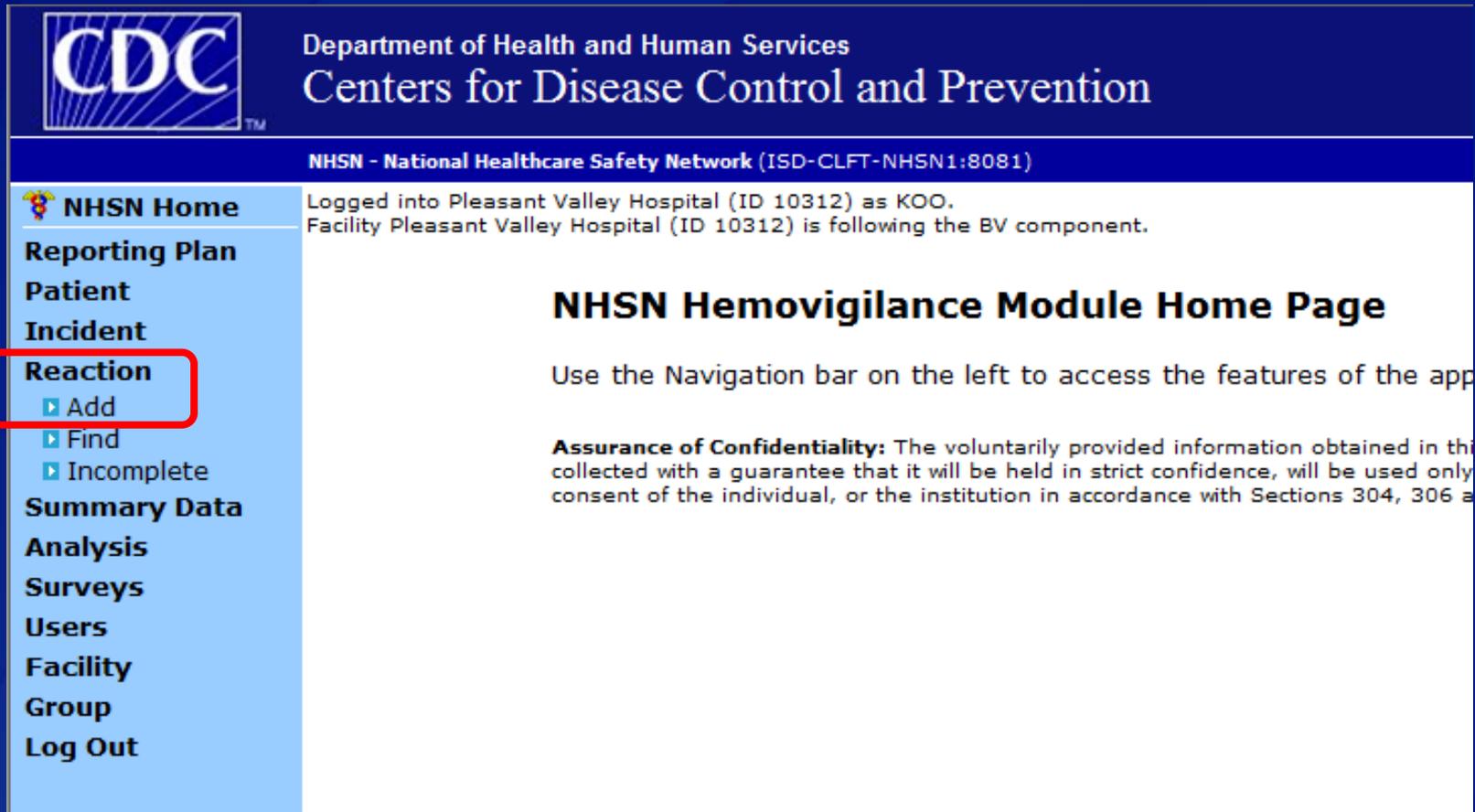
## ❑ **Add**

- Allows users to create new records.

## ❑ **Find**

- Allows users to search for records using filters.
- Leaving search fields blank and selecting “Find” will generate a list of all records.

# Entering an Adverse Reaction Form



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

NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1:8081)

Logged into Pleasant Valley Hospital (ID 10312) as KOO.  
Facility Pleasant Valley Hospital (ID 10312) is following the BV component.

## NHSN Hemovigilance Module Home Page

Use the Navigation bar on the left to access the features of the app.

**Assurance of Confidentiality:** The voluntarily provided information obtained in this system, which is collected with a guarantee that it will be held in strict confidence, will be used only with the informed consent of the individual, or the institution in accordance with Sections 304, 306 and 308 of the HIPAA Privacy Rule.

Click "Reaction," then "Add"

# Patient Information



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

NHSN - National Healthcare Safety Network

[NHSN Home](#) | [My Info](#) | [Contact us](#) | [Help](#) | [Log Out](#)

[NHSN Home](#)

[Reporting Plan](#)

[Patient](#)

[Incident](#)

[Reaction](#)

[Add](#)

[Find](#)

[Incomplete](#)

[Summary Data](#)

[Analysis](#)

[Surveys](#)

[Users](#)

[Facility](#)

[Group](#)

[Log Out](#)

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

## Add Adverse Reaction

Mandatory fields marked with \*  
Conditionally required fields marked with ^

### Patient Information

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

Adverse Reaction #:

\*Patient ID: ABC123

Social Security #:

Secondary ID:

Medicare #:

Last Name: Smith

First Name: Joe

Middle Name:

\*Gender: M - Male ▼

\*Date of Birth: 05/05/1955

Ethnicity:

Race:  American Indian/Alaska Native  Asian  
 Black or African American  Native Hawaiian/Other Pacific Islander  
 White

\*Blood Group: A- ▼

\*Primary underlying reason for transfusion: MEDICAL - Medical ▼

Fields marked with a red asterisk (\*) are mandatory

# Patient Information

**Patient Information**

Incomplete

**Summary Data**  
**Analysis**  
**Surveys**  
**Users**  
**Facility Group**  
**Log Out**

\*Facility ID: KWC Test Hospital (ID 10976) Adverse Reaction #:

\*Patient ID:  Find Find Reactions for Patient Social Security #:

Secondary ID:  Medicare #:

Last Name:  First Name:

Middle Name:

\*Gender:  \*Date of Birth:

Ethnicity:

Race:  American Indian/Alaska Native  Asian  
 Black or African American  Native Hawaiian/Other Pacific Islander  
 White

\*Blood Group:

\*Primary underlying reason for transfusion:

Reaction Details

## 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.

# Reaction Details

## Reaction Details

\*Date reaction occurred: 03/14/2012   
\*Time reaction occurred: 15 : 00 (HH:MM)  Time unknown  
\*Facility location where patient was transfused: IN-DIAL - INPATIENT DIALYSIS

[Link/Unlink To Incidents](#)

Reaction is not Linked

More on Link/Unlink Incidents later

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

- |                              |   |   |   |   |
|------------------------------|---|---|---|---|
| <u>Generalized:</u>          | <input type="checkbox"/> Chills/rigors                          | <input type="checkbox"/> Fever                |   |   |
| <u>Cardiovascular:</u>       | <input type="checkbox"/> Blood pressure decrease                | <input type="checkbox"/> Shock                |   |   |
| <u>Cutaneous:</u>            | <input type="checkbox"/> Edema                                  | <input checked="" type="checkbox"/> Flushing  | <input type="checkbox"/> Jaundice                 | <input type="checkbox"/> Other rash         |
|                              | <input type="checkbox"/> Pruritus                               | <input checked="" type="checkbox"/> Urticaria |   |   |
| <u>Hemolysis/Hemorrhage:</u> | <input type="checkbox"/> Disseminated intravascular coagulation | <input type="checkbox"/> Hemoglobinemia       | <input type="checkbox"/> Positive antibody screen |   |
| <u>Pain:</u>                 | <input type="checkbox"/> Abdominal pain                         | <input type="checkbox"/> Back pain            | <input type="checkbox"/> Flank pain               | <input type="checkbox"/> Infusion site pain |
| <u>Renal:</u>                | <input type="checkbox"/> Hematuria                              | <input type="checkbox"/> Hemoglobinuria       | <input type="checkbox"/> Oliguria                 |   |
| <u>Respiratory:</u>          | <input type="checkbox"/> Bil. infiltrates on chest x-ray        | <input type="checkbox"/> Bronchospasm         | <input type="checkbox"/> Cough                    | <input type="checkbox"/> Hypoxemia          |
|                              | <input type="checkbox"/> Shortness of breath                    |   |   |   |
| <u>Other:</u>                | <input type="checkbox"/> Other                                  |   |   |   |

Investigative results (e.g., hemoglobinuria, hemoglobinemia, col.)

## 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 Appendix B 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

## 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

\* Case definition crit

\* Severity:

\* Imputability:

### Outcome

\* Outcome:

### Component Details

\* Was a particular component implicated in the adverse reaction?

# Investigation Results

## ❑ Adverse Reactions

- Using the case definitions 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 is not one of the 12 defined adverse reactions listed, select 'Other' and specify the reaction.

## ❑ Using the protocol, determine case classification, severity, and imputability.

## ❑ Update the record if new information becomes available after the reaction has been entered.

# Outcome

\*Imputability: DEF - Definite

---

**Outcome**

\*Outcome: DEATH - Death

**Note: deaths attributable to transfusion must be reported to FDA**

Date of death:

\*If recipient died, relationship of transfusion to death:

---

**Component Details**

\*Was a particular unit implicated in the adverse reaction?

## □ Outcomes

- Select the appropriate clinical outcome of the patient after an investigation has been completed and imputability has been determined.
- Report death whether or not it is attributable to transfusion.
  - Enter the relationship of the transfusion to death using the imputability criteria in Appendix C of the protocol.

# Component Details

Date of birth:

\*If recipient died, relationship of transfusion to death:

## Component Details

\*Was a particular unit implicated in the adverse reaction?

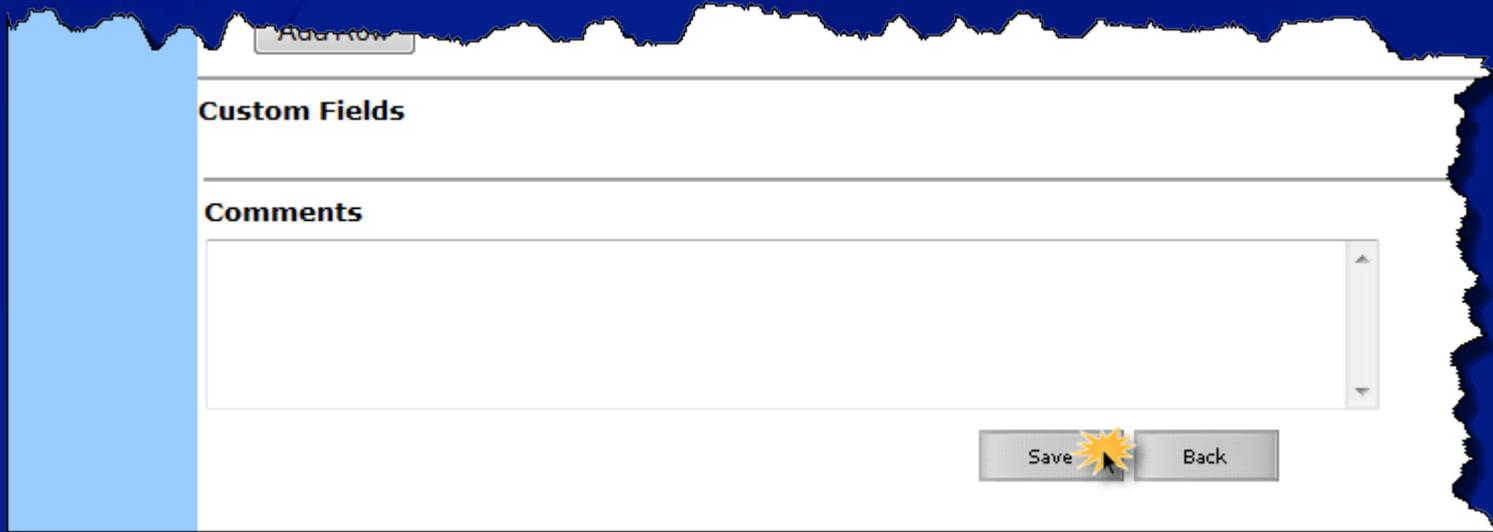
	*Transfusion Date / Time MM/DD/YYYY HH:MM	*Component code (check system used)	*# of units	^Unit number <i>Required for TRALI, GVHD, Infection</i>	*Unit expiration Date / Time MM/DD/YYYY HH:MM	*Blood group of unit	Implicated in the adverse reaction?
	03/13/2012 08 : 00	<input checked="" type="radio"/> ISBT-128 <input type="radio"/> Codabar <input type="text" value="E0773"/> Thawed FRESH FROZEN PLASMA   CPD/XX/refg	<input type="text" value="1"/>	Facility <input type="text"/> Year <input type="text"/> Sequence <input type="text"/> Vertical Digits <input type="text"/> Checksum Char <input type="text"/> <input type="text"/>	03/19/2012 23 : 59	A- <input type="text"/>	<input checked="" type="checkbox"/>
	03/13/2012 14 : 00	<input checked="" type="radio"/> ISBT-128 <input type="radio"/> Codabar <input type="text" value="E0160"/> RED BLOOD CELLS   CPD/450mL/refg   Open   Plasma added	<input type="text" value="1"/>	Facility <input type="text"/> Year <input type="text"/> Sequence <input type="text"/> Vertical Digits <input type="text"/> Checksum Char <input type="text"/> <input type="text"/>	03/15/2012 23 : 59	A- <input type="text"/>	<input type="checkbox"/>

## Custom Fields

## 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.

# Don't forget to **SAVE!**



A screenshot of a web form interface, presented as if it were a piece of paper with torn edges. The form has a light blue sidebar on the left. The main content area is white and contains two sections: "Custom Fields" and "Comments". Below the "Comments" section, there are two buttons: "Save" and "Back". A yellow mouse cursor is clicking on the "Save" button. At the top of the form, there is a "Return" button. The background of the slide is dark blue.

- ❑ **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 Adverse Reactions to Incidents

\*Time reaction occurred: [ ] : [ ] (HH:MM)  Time unknown

\*Facility location where patient was transfused: [ ]

**Reaction is not Linked**

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

Generalized:  Chills/rigors  Fever

Cardiovascular:  Blood pressure decrease  Shock

- ❑ **When an adverse reaction is associated with one or more incidents, the incident(s) MUST be entered in NHSN.**
  - Enter the Incident record(s) first to link Adverse Reactions.
- ❑ **Records are linked by Patient ID.**
  - Patient ID is the unique facility identifier for a patient (e.g., a medical record number or other facility identification code).
  - Patient ID must be the same on the Adverse Reaction and Incident forms.

# Linking Adverse Reactions to Incidents

## Incident form

\*Incident result: 1 - Product transfused; reaction

\*Product action: (check all that apply)

- Not applicable
- Product retrieved
- Product destroyed
- Product issued but not transfused
- Product transfused

\*Was a patient reaction associated with this incident? Y-Yes

Patients

\*Patient ID

ABC1234

Add Row

\*Record/other action: (check all that apply)

- Record corrected
- Floor/clinic notified
- Attending phy

- On the Incident form, select
  - Incident result: 1 – Product transfused; reaction
  - Product action: Product transfused
  - Enter Patient ID(s)

## Adverse Reaction form

Mandatory fields marked with \*

Conditionally required fields marked with ^

Patient Information

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

\*Patient ID: ABC1234 Find Find Reactions for

Secondary ID:

Last Name:

Reaction Details

\*Date reaction occurred: (Calendar icon)

\*Time reaction occurred: (HH:MM)  Time unk

\*Facility location where patient was transfused:

Link/Unlink To Incidents Reaction is not Linked

\*Signs and symptoms (check all that apply)

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

**The Patient ID must be the same on both forms!**

# Linking Adverse Reactions to Incidents

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

NHSN - National Healthcare Safety Network | NHSN Home | My Info | Contact us | Help | Log Out

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

## Incident Link List

First | Previous | Next | Last Displaying 1 - 1 of 1

Check all that apply	<a href="#">Incident #</a>	<a href="#">Patient ID</a>	<a href="#">Date incident occurred</a>	<a href="#">Where in the process the incident first occurred</a>	<a href="#">Incident code</a>
<input type="checkbox"/>	6277	ABC1234	03/12/2012	PC	PC 01

First | Previous | Next | Last Displaying 1 - 1 of 1

- ❑ All incident records with matching Patient ID(s) will populate on the Incident Link List.
- ❑ Check all that apply, and select “Link/Unlink.”

## 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

The screenshot displays the NHSN web application interface. At the top left is the CDC logo. The header includes the text "Department of Health and Human Services" and "Centers for Disease Control and Prevention". Below the header, there is a navigation bar with "NHSN - National Healthcare Safety Network (apt-v-nhsn-test:8081)" and links for "NHSN Home", "My Info", and "Contact us". A user login message states: "Logged into KWC Test Hospital (ID 10976) as KOO. Facility KWC Test Hospital (ID 10976) is following the BV component." The main content area is titled "Add Summary Data". On the left, a navigation menu lists "NHSN Home", "Reporting Plan", "Patient", "Incident", "Reaction", "Summary Data" (highlighted with a red box), "Add", "Find", "Incomplete", "Analysis", "Surveys", "Users", and "Facility". The "Summary Data" section contains a dropdown menu labeled "Summary Data Type:" with the following options: "Monthly Reporting Denominators" (selected), "Monthly Reporting Denominators", and "Monthly Incident Summary". Below the dropdown are "Continue" and "Back" buttons. Red arrows point to the selected option and the "Continue" button.

- ❑ Select "Summary Data"
- ❑ Click "Add"
- ❑ Select "Monthly Reporting Denominators" from the drop-down menu
- ❑ Click "Continue"

# Entering a Monthly Reporting Denominator Form

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

NHSN - National Healthcare Safety Network (apt-v-nhsn-test:8081) | NHSN Home | My Info | Contact us | Help | Log Out

Logged into KWC Test Hospital (ID 10976) as KOO.  
Facility KWC Test Hospital (ID 10976) is following the BV component.

## Add Monthly Reporting Denominators

Mandatory fields marked with \*

\*Facility ID: 10976 (KWC Test Hospital)

\*Month:   
\*Year:

No Adverse Reactions reported this month  No Incidents reported this month

Product	*Units Transfused	*Aliquots Transfused
Red blood cells		
Whole blood derived		
TOTAL		

[Print PDF Form](#)

Select the month and year from the drop-down menu.

# Entering a Monthly Reporting Denominator Form

\*Facility ID: 10976 (KWC Test Hospital)

\*Month:

\*Year:

No Adverse Reactions reported this month  No Incidents reported this month

Product	*Units Transfused	*Aliquots Transfused
Red blood cells	<input type="text"/>	<input type="text"/>
Whole blood derived	<input type="text"/>	<input type="text"/>
TOTAL	<input type="text"/>	<input type="text"/>
Irradiated	<input type="text"/>	<input type="text"/>

- ❑ Check the appropriate box when no adverse reactions or incidents occurred during the month.
- ❑ These boxes cannot be selected if an Incident, Adverse Reaction, or Monthly Incident Summary form has been submitted for the month.
- ❑ If an event form is later entered, the appropriate box is automatically unchecked.

# Entering a Monthly Reporting Denominator Form

Month: March  
\*Year: 2012

No Adverse Reactions reported this month  No Incidents reported this month

Product			*Units Transfused	*Aliquots Transfused
Red blood cells	Whole blood derived	TOTAL	500	30
		Irradiated	100	10
		Leukocyte reduced	200	10
		Irradiated and leukocyte reduced	100	10
	Apheresis	TOTAL	200	10
		Irradiated	75	0
		Leukocyte reduced	100	0
		Irradiated and leukocyte reduced	25	10
Platelets	Whole blood derived	TOTAL		

- ❑ **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
  - CANNOT be more than the total units and/or aliquots transfused
- ❑ **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

NHSN - National Healthcare Safety Network

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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 ^

[Print PDF Form](#)

### Patient Information

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

Adverse Reaction #: 6456

\*Patient ID: JD1234

[Reassign](#)

[Find Reactions for Patient](#)

Social Security #:

Secondary ID:

Medicare #:

Last Name: Doe

First Name: Jane

Middle Name:

\*Gender: F - Female ▼

\*Date of Birth: 11/21/1963

Ethnicity: NOHISP - Not Hispanic or Not Latino ▼

Race:  American Indian/Alaska Native

Asian

Black or African American

Native Hawaiian/Other Pacific Islander

White

\*Blood Group:

O-

\*Primary underlying reason for transfusion:

MEDICAL - Medical ▼

## 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

transfusion:

## Reaction Details

\*Date reaction occurred: 03/05/2012



\*Time reaction occurred: 14 : 15 (HH:MM)

Time unknown

\*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)

Generalized:

Chills/rigors

Fever

Cardiovascular:

Blood pressure decrease

Shock

Cutaneous:

Edema

Flushing

Jaundice

Other rash

Pruritus

Urticaria

Hemolysis/Hemorrhage:

Disseminated intravascular coagulation

Hemoglobinemia

Positive antibody screen

Pain:

Abdominal pain

Back pain

Flank pain

Infusion site pain

Renal:

Hematuria

Hemoglobinuria

Oliguria

Respiratory:

Bil. infiltrates on chest x-ray

Bronchospasm

Cough

Hypoxemia

Shortness of breath

Other:

Other

Investigation Results (Use case definition criteria in protocol.)

\*Investigation results (Use case definition criteria in protocol.)

# Case Study

Other:  Other

## 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



## 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**

