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 <u>DOES NOT</u> 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.**

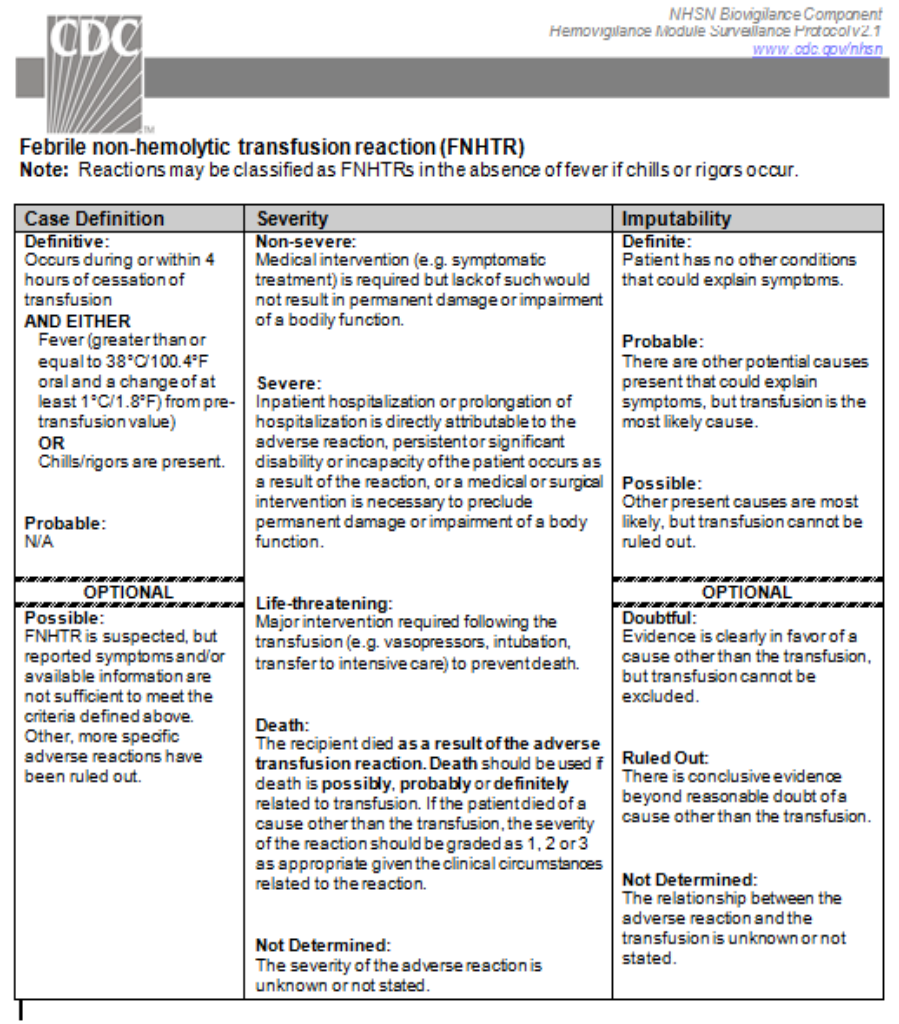
Hemovigilance Module Adverse Reactions

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**



Febrile non-hemolytic transfusion reaction (FNHTR)
Note: Reactions may be classified as FNHTRs in the absence of fever if chills or rigors occur.

Case Definition	Severity	Imputability
Definitive: Occurs during or within 4 hours of cessation of transfusion **AND EITHER** Fever (greater than or equal to 38°C/100.4°F oral and a change of at least 1°C/1.8°F) from pre-transfusion value) **OR** Chills/rigors are present.	**Non-severe:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.	**Definite:** Patient has no other conditions that could explain symptoms.
Probable: N/A	**Severe:** Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.	**Probable:** There are other potential causes present that could explain symptoms, but transfusion is the most likely cause.
		Possible: Other present causes are most likely, but transfusion cannot be ruled out.
OPTIONAL		OPTIONAL
Possible: FNHTR is suspected, but reported symptoms and/or available information are not sufficient to meet the criteria defined above. Other, more specific adverse reactions have been ruled out.	**Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.	**Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.
	Death: The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly, probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as 1, 2 or 3 as appropriate given the clinical circumstances related to the reaction.	**Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.
	Not Determined: The severity of the adverse reaction is unknown or not stated.	**Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.

Before Entering Event Forms

Be sure that your facility has completed:

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

Adverse Reaction Form and Table of Instructions

NHSN National Healthcare Safety Network

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 #: _____

Patient Information

*Patient ID: _____ *Gender: ☐ M ☐ F ☐ Other *Date of Birth: __ __/__ __/__ __ __ __

Social Security #: _____ Secondary ID: _____ Medicare #: _____

Last Name: _____ First Name: _____ Middle Name: _____

Ethnicity ☐ Hispanic or Latino ☐ Not Hispanic or Not Latino

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

*Blood Group: ☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ Type and crossmatch not done

*Primary underlying reason for transfusion: ☐ Coagulopathy ☐ Genetic Disorder ☐ Hematology Disorder
☐ Hemolysis ☐ Internal Bleeding ☐ Malignancy ☐ Medical ☐ Surgery ☐ Unknown
☐ Other (specify) _____

Reaction Details

*Date reaction occurred: __ __/__ __/__ __ __ __

*Time reaction occurred: __ __:__ __ (HH:MM) ☐ Time unknown

*Facility location where patient was transfused: _____

*Is this reaction associated with an incident? ☐ Yes ☐ No If Yes, Incident #: _____

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

Cardiovascular:	Cutaneous:	Pain:
☐ Blood pressure decrease	☐ Edema	☐ Abdominal pain
☐ Shock	☐ Flushing	☐ Back pain
Hemolysis/Hemorrhage	☐ Jaundice	☐ Flank pain
☐ Disseminated intravascular coagulation	☐ Other rash	☐ Infusion site pain
☐ Hemoglobinemia	☐ Pruritus (itching)	**Respiratory:**
☐ Positive antibody screen	☐ Urticaria (hives)	☐ Bilateral infiltrates on chest x-ray
Generalized:	**Renal:**	☐ Bronchospasm
☐ Chills/rigors	☐ Hematuria	☐ Cough
☐ Fever	☐ Hemoglobinuria	☐ Hypoxemia
	☐ Oliguria	☐ Shortness of breath

☐ Other: (specify) _____

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, 242k, and 242m(d)).

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).

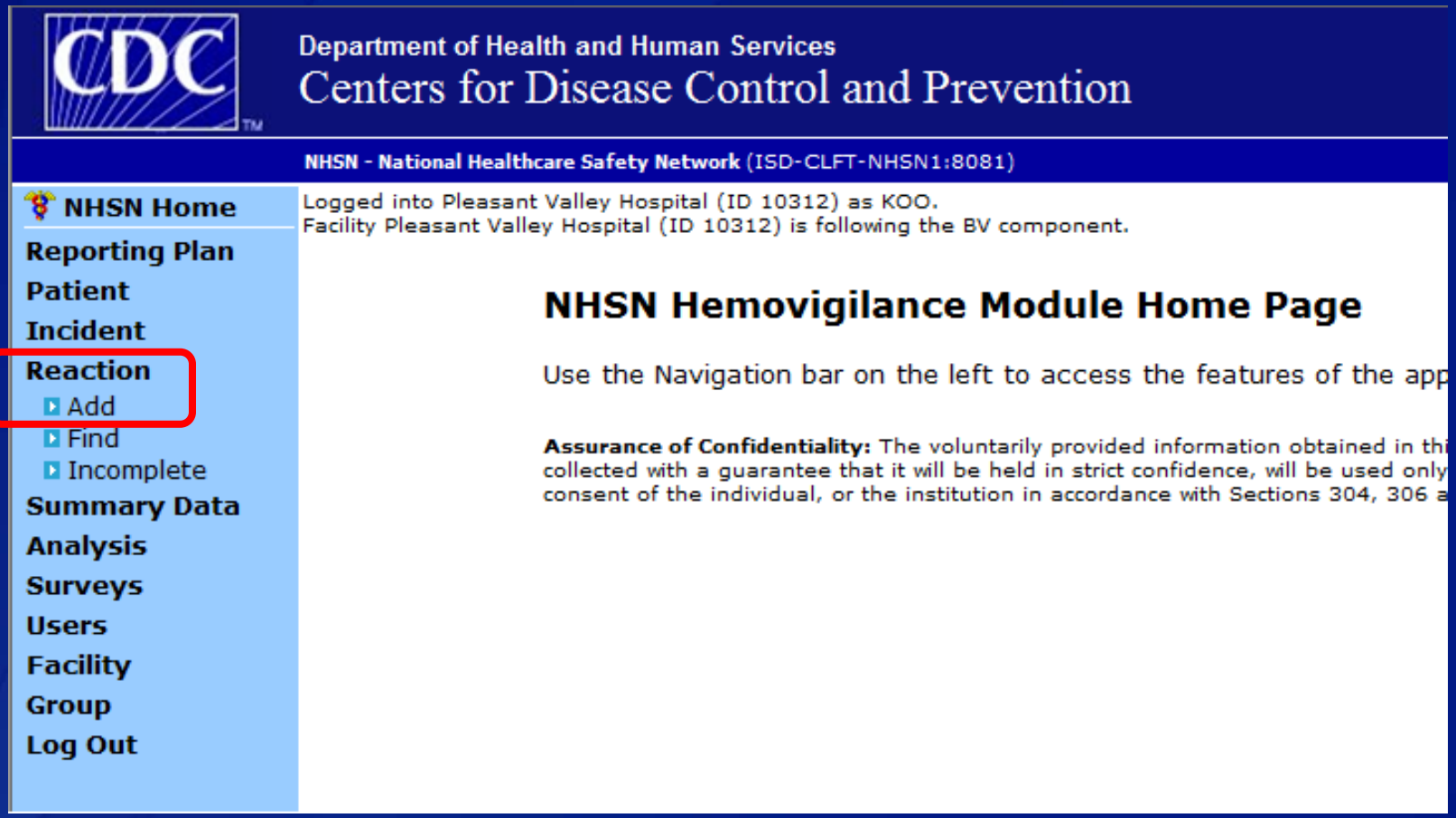
CDC 57.304 Rev. 3, v6.6.1

CDC

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.
Patient Information	
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.
Reaction Details	
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.

Entering an Adverse Reaction Form



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 Find Find Reactions for Patient
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

Incomplete
Summary Data
Analysis
Surveys
Users
Facility
Group
Log Out

Patient Information

*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

transfusion:

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)

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			

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

Investigation Results (Use case definition criteria in protocol.)

*Adverse reaction:

*Case definition crit

*Severity:

*Imputability:

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

Outcome

*Outcome:

Component Details

*Was a partic 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.**

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.
  - 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: __/__/20__

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

Component Details

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

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

Add Row

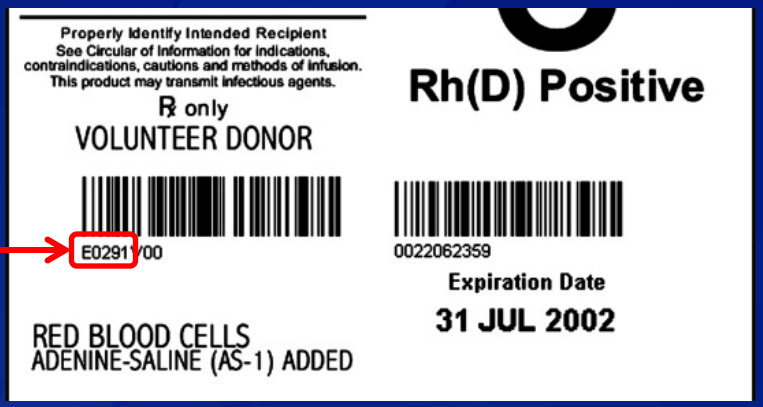
Custom Fields

Component Details

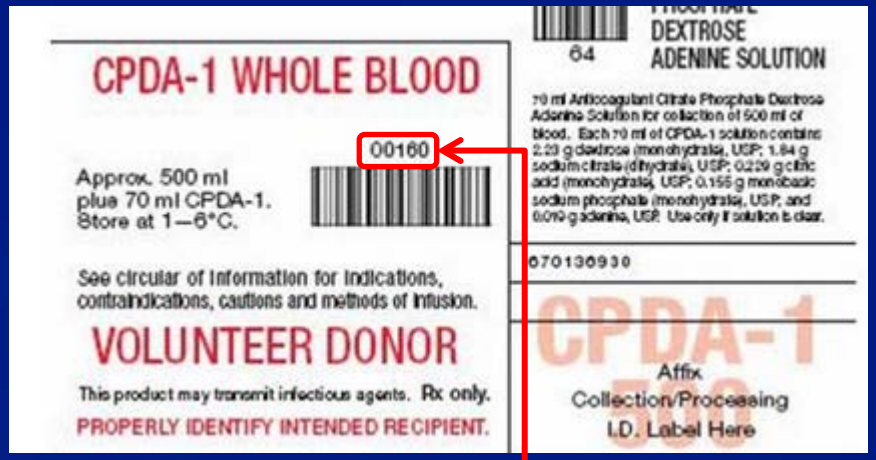
- **Was a particular unit implicated in the adverse reaction?**
  - If only ONE unit was transfused, that unit must be **implicated** in the reaction (except when reporting TACO).
  - If multiple units were transfused, and a single unit can be **implicated** as the cause, the implicated unit must be 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.

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.**

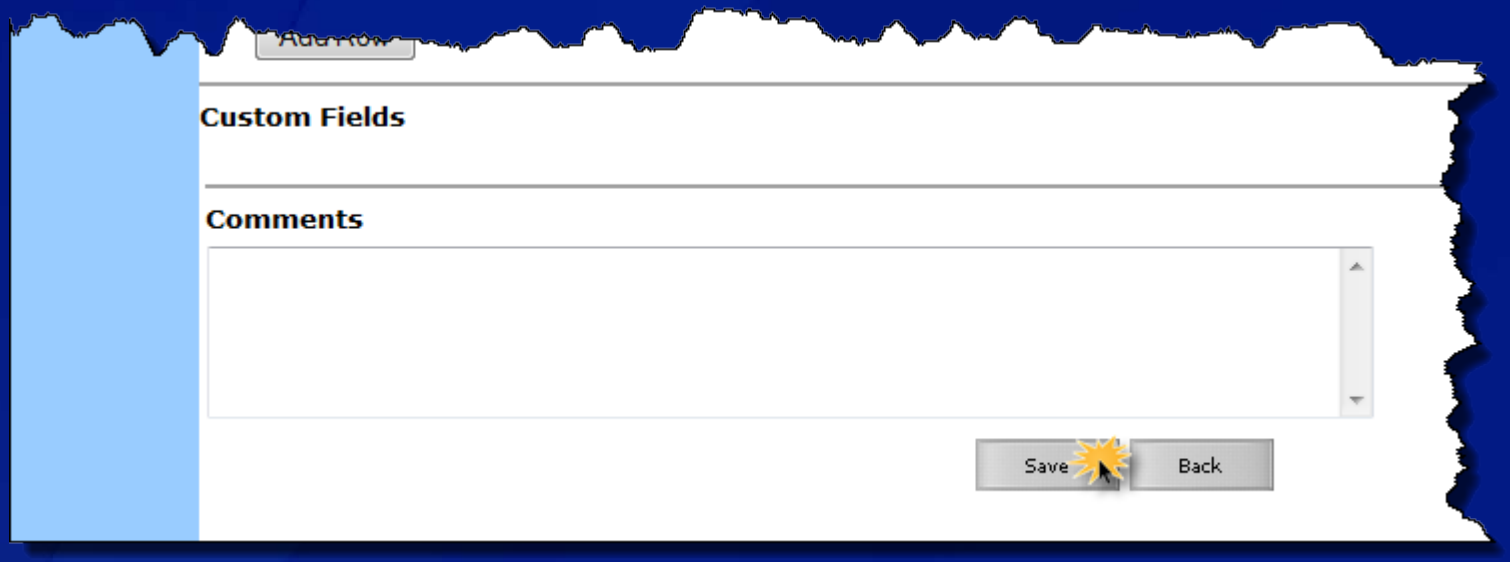


ISBT-128 product code



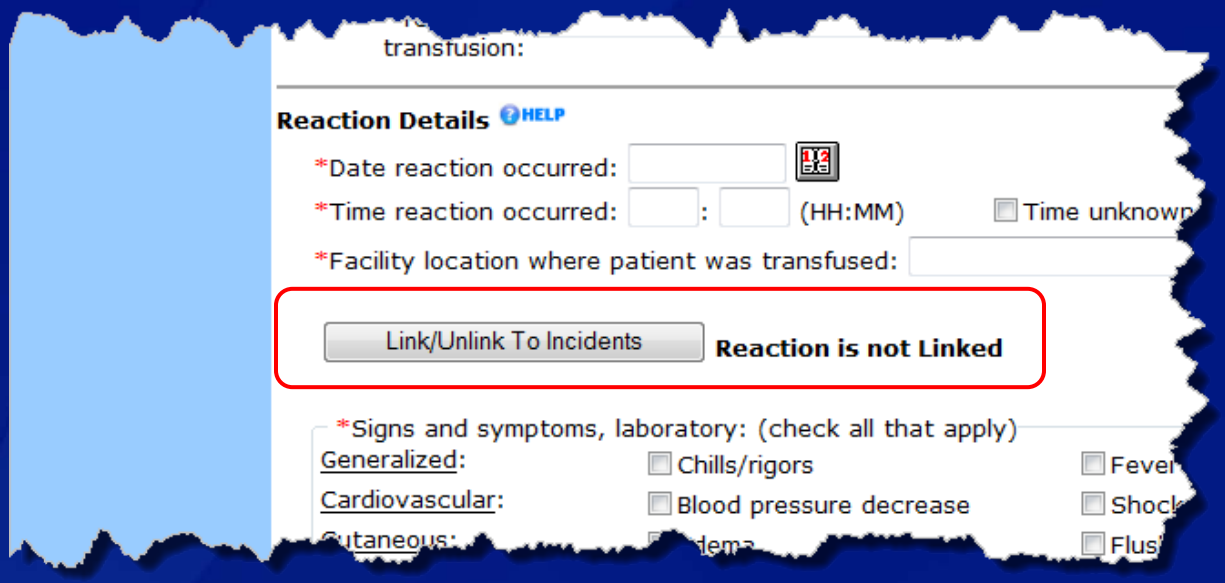
Codabar product code

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.

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.

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
- [x] 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

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 fo

Secondary ID:

Last Name:

Reaction Details

*Date reaction occurred:

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

*Facility location where patient was transfused:

Link/Unlink To Incidents **Reaction is not Linked**

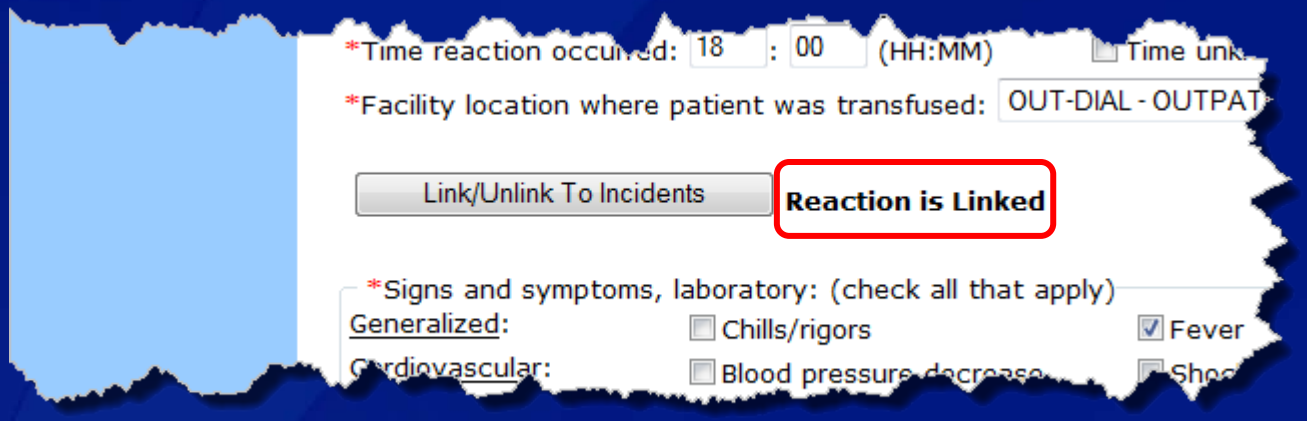
- On the Incident form, select
  - Incident result: 1 – Product transfused; reaction
  - Product action: Product transfused
  - Enter Patient ID(s)
- On the Adverse Reaction form
  - Click the "Link/Unlink To Incident" button

<u>The Patient ID must be the same on both forms!</u>

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."

Linking Adverse Reaction to Incidents



- 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

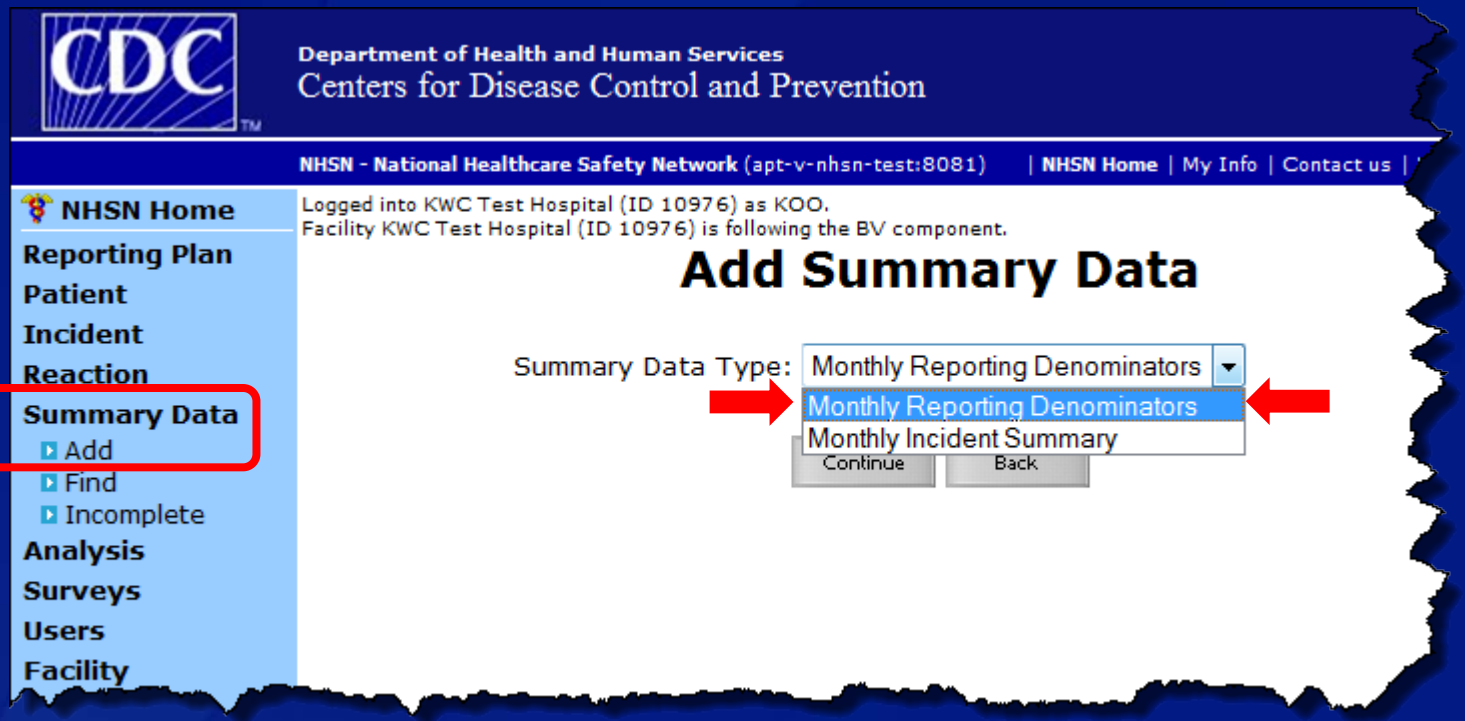
Coming Up Next…

- 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

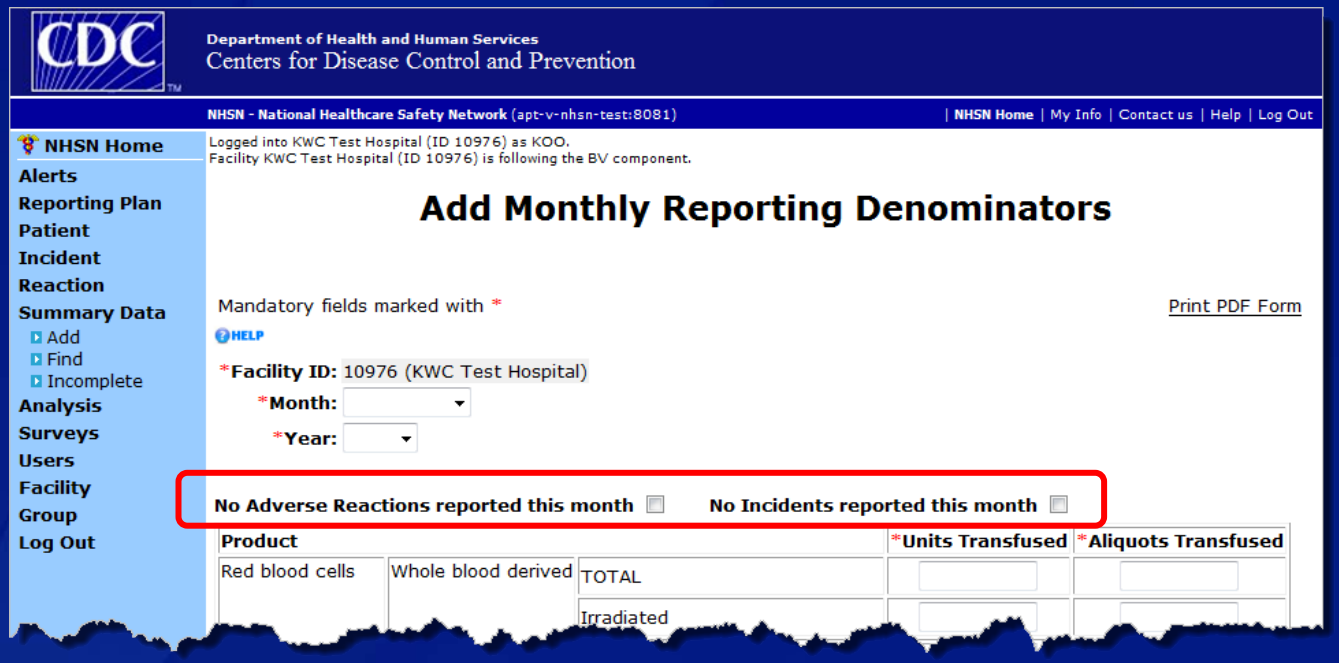


- Select "Summary Data"
- Click "Add"
- Select "Monthly Reporting Denominators" from the drop-down menu
- Click "Continue"

Entering a Monthly Reporting Denominator Form

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.

Hemovigilance Module
Monthly Reporting Denominators Form

Incomplete
Analysis
Surveys
Users
Facility
Group
Log Out

*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
- **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 | 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.

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
- [x] 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.)

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

Case Study

Component Details

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

	*Transfusion Date / Time MM/DD/YYYY HH:MM	*Component code (check system used)	*# of units	^Unit number *Required for TRALI, GVHD, Infection*	*Unit expiration Date / Time MM/DD/YYYY HH:MM	*Blood group of unit	Implicated in the adverse reaction?
	03/05/2012 12 : 15	ISBT-128 Codabar E1325 Thawed Apheresis FRESH FROZEN PLASMA|NaCitrate/XX/refg	1	Facility Year Sequence Vertical Digits Checksum Char	03/13/2012 23 : 59	O-	☑

Add Row

- **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