



Biovigilance Component Hemovigilance Incident Reporting

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Welcome to the National Healthcare Safety Network Biovigilance Component Hemovigilance Incident reporting training session.



Target Audience



- Staff in Blood Transfusion Services departments who will be collecting and/or entering incident report data into the Hemovigilance module of NHSN
- Staff who will be analyzing incident report data



This training session is intended for staff in Blood Transfusion Services departments who will be collecting and/or entering incident report data into the Hemovigilance Module of NHSN and for staff who will be analyzing Incident report data.



Prerequisites

- View Training 1: Biovigilance Component Overview
- Have copies of Hemovigilance protocol, Tables of Instructions, and the following forms available for reference:
 - Hemovigilance Module Monthly Reporting Plan
 - Incident form
 - Blood Products Incident Reporting – Summary Data
 - Monthly Denominator form

We strongly recommend that you take the Biovigilance Component Overview training before viewing this session. You may want to print out copies of the Hemovigilance protocol, Tables of Instructions, and the following forms for reference: Hemovigilance Module Monthly Reporting Plan, Incident form, Blood Products Incident Reporting – Summary Data, and Monthly Denominator form.



Objectives



- In this session we'll discuss
 - Key terms used in incident reporting
 - Why error reporting is important
 - Why employees don't always report mistakes
 - Using process codes to categorize errors
 - Using the Tables of Instructions
 - Completing a Monthly Reporting Plan
 - Completing and entering a Hemovigilance Incident form in NHSN
 - Incident result and root cause analysis definitions
 - Real case examples
 - Completing the Incident Summary data form
 - Linking Incidents with Adverse Reactions
 - Custom fields and labels

In this session we will discuss: key terms used in incident reporting, why error reporting is important, why employees don't always report mistakes, using process codes to categorize errors, using the Tables of Instructions, completing your Monthly Reporting Plan, completing and entering a Hemovigilance Incident form in NHSN, Incident result and root cause analysis definitions, real case examples, completing the Incident Summary data form, linking Incidents with Adverse Reactions, and, finally, creating custom fields and labels.



Key Terms in Hemovigilance Incident Reporting



Consistent with International Society of Blood Transfusion (ISBT) definitions

- **Incident** An accident or error that could lead to an adverse outcome affecting a) the safety, efficacy or quality of blood, blood components, or plasma derivatives; or b) the safety of recipients.
 - **Accident** An unexpected or unplanned event, not attributable to deviation from standard operating procedures.
 - **Error** An unexpected, unplanned deviation from standard operating procedure that is likely attributable to a human or system problem.
- **High priority incident** An accident or error that has high potential for wrongful transfusion in a recipient. This would include sample labeling errors, collecting a sample from the wrong patient, processing needs not indicated, not done, misunderstood, or misinterpreted.
- **Near miss** An incident that is discovered before the start of the transfusion and could have led to a wrongful transfusion or reaction in a recipient.

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Our terms are consistent with International Society of Blood Transfusion (ISBT) definitions. An incident is an accident or error that could lead to an adverse outcome affecting a) the safety, efficacy, or quality of blood, blood components, or plasma derivatives; or b) the safety of recipients. An accident is defined as an unexpected or unplanned event, not attributable to deviation from standard operating procedures while an error is an unexpected, unplanned deviation from standard operating procedure that is likely attributable to a human or system problem. In NHSN Incident reporting we also have “high priority incident” reporting. A “high priority incident” is an accident or error that has high potential for wrongful transfusion in a recipient. This would include sample labeling errors, collecting a sample from the wrong patient, special processing needs not indicated, not done, misunderstood, or misinterpreted. We define a “near miss” as an incident that is discovered before the start of the transfusion and could have led to a wrongful transfusion or reaction in a recipient.



Why Report Errors?

- Needs defined by reported events
 - Customer complaints
 - Reported incidents
 - Audit findings
- A process improvement identification tool
 - Provides a means to capture, track, and trend data
- Measure success of a process improvement initiative
 - Data can be used to promote and support change
- Compare to peers
 - Use aggregate data to compare yourself with other facilities of similar size and transfusion volume



Why report errors? Often a facility's needs can be determined by reported events such as customer complaints, incident reports, and internal and external audit findings. Error reporting is a process improvement identification tool that provides a means for capturing, tracking, and trending data. It can be used to measure the success of process improvement initiatives and promote and support change. Eventually, information can be used in aggregate to compare your facility with others of similar size and transfusion volume.



Reasons Why Employees Do Not Report Mistakes

- Too busy
- Complicated and time-consuming documentation process
- Not able to report anonymously
- Hesitancy to “tell” on someone
- Fear of disciplinary action
- Belief that it is unnecessary to report when no negative outcome
- Easier to just fix error than tell about it
- Lack of knowledge of what to report
- Lack of knowledge of how to report
- Lack of awareness of the value of reporting in order to improve safety and quality

There are a number of reasons why employees do not report mistakes. They feel they are too busy, the documentation process is complicated and time-consuming, they are not able to report anonymously, there's a hesitancy to 'tell' on someone, fear of disciplinary action, a belief that it is unnecessary to report when there is no negative outcome, sometimes it's easier to just fix the error than to tell about it, there's a lack of knowledge of what to report, a lack of knowledge of how to report, and a lack of awareness of the value of reporting in order to improve safety and quality.



Event Discovery

Ways of Reporting Errors



- Complete an incident report or other form unique to your facility
- Complete a Hemovigilance Incident form
 - Paper form entered into NHSN
 - Report directly into NHSN
- Enter information on existing supporting documentation
 - Requisition
 - Pick-up slip
 - Laboratory Information System (LIS) correction record



There are several ways of reporting errors. Complete an incident report or other form unique to your facility, complete a Hemovigilance Incident form using either the paper data collection form or reporting directly into NHSN, and entering information on existing documentation such as a requisition, pick-up slip, or Laboratory Information System (LIS) correction record.

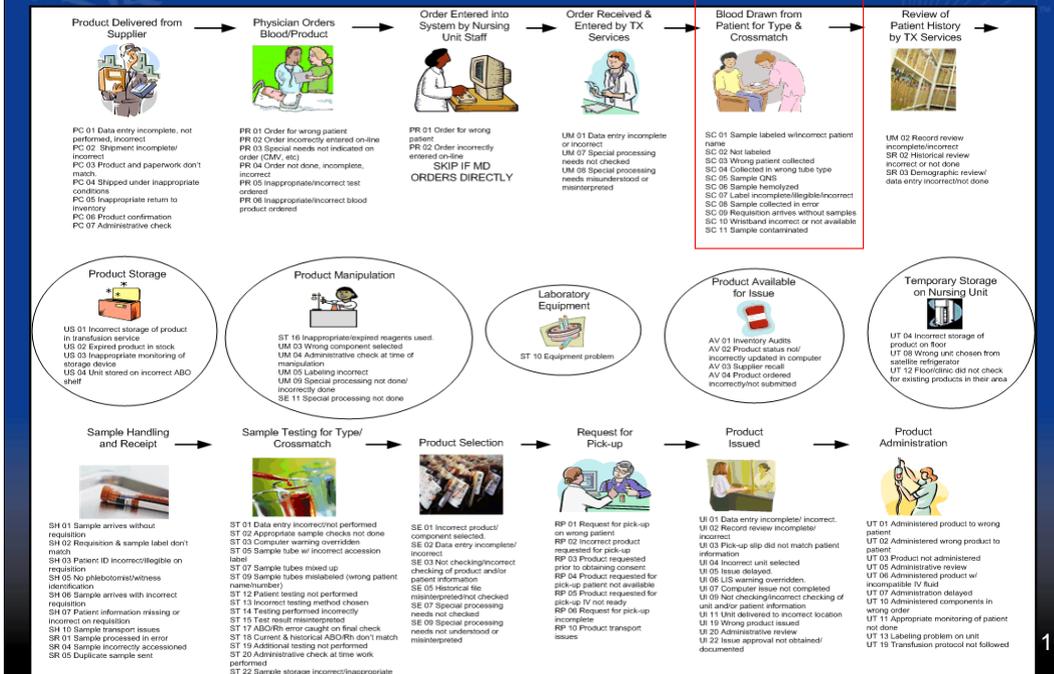


What Errors to Report

- Any error that occurs from product receipt to transfusion
- Near misses and actual events where product is administered to the patient
- Locations where errors happen:
 - Transfusion service
 - Clinical service
- Errors will be categorized using process codes

Report any error that occurs from product receipt to transfusion. Report both near misses and actual events where product is administered to the patient. Errors can occur in transfusion service departments as well as in clinical service areas. Errors will be categorized using process codes.

Getting the Right Blood to the Right Patient



This slide provides one illustration of blood processing starting from the top left corner when product is delivered to the healthcare facility, going across the top, then to the bottom left all the way to the bottom right when the blood product reaches the patient and is transfused. Errors can occur anywhere in the process. Let's take a closer look at one point in the process where blood is drawn from the patient for type and crossmatch.



**Blood Drawn
from
Patient for Type
& Crossmatch**



- SC 01 Sample labeled w/incorrect patient name**
- SC 02 Not labeled**
- SC 03 Wrong patient collected ←**
- SC 04 Collected in wrong tube type**
- SC 05 Sample QNS**
- SC 06 Sample hemolyzed**
- SC 07 Label incomplete/illegible/incorrect**
- SC 08 Sample collected in error**
- SC 09 Requisition arrives without samples**
- SC 10 Wristband incorrect or not available**
- SC 11 Sample contaminated**

You will see that a number of errors are listed that could potentially occur during the process when blood is drawn from the patient for type and crossmatch. Each error has a code next to it. For example, if the sample was drawn from the wrong patient, the process or error code would be SC03.



Transfusion Service Categories



- PC Product check-in
 - Products received from outside source
 - Return 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



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As was mentioned in an earlier slide, errors can occur in both Transfusion Services and clinical service areas. Transfusion Service process points include: PC or product check-in where products are either received from an outside source or where products are returned to inventory from a patient care area. SR or sample receipt is the point at which a patient sample is received in transfusion services. ST or sample testing includes type and crossmatch and other testing of the patient sample. US or product storage covers errors that occur during storage of blood and blood products. AV or available for issue includes quality management of product inventory. SE or product selection is the point at which products are selected for transfusion. UM or product manipulation errors occur during pooling, irradiating, dividing, thawing, and labeling products. UI or product issue is the point when products are issued to departments outside of Transfusion Services. If errors do not fall into one of the points above you can use code MS for miscellaneous or other errors.



Clinical Service Categories

- 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



Clinical service process areas include PR or product/test request when the test or product is requested by a clinical service. This can include online and paper or requisition requests. SC or sample collection errors occur at the time the sample is drawn from the patient. SH or sample handling errors involve paperwork accompanying the sample or testing. RP is request for pick-up or the time the product is requested. Finally, UT or product administration errors occur at the time the patient is transfused.



Tables of Instructions



- Provide rules for each data field.

Table 3. Instructions for Completion of the **Blood Product Incidents Reporting – Summary Data** (CDC 57.302)

Form Field	Instructions for Form Completion
Facility ID	The NHSN-assigned facility ID number will be autoentered by the computer.
Month	
Year	
Process Point	

Table 4. Instructions for Completion of **Monthly Reporting Denominators** (CDC 57.303)

Form Field	Instructions for Form Completion
Facility ID #	The NHSN-assigned facility ID number will be autoentered by the computer.

Table 5. Instructions for Completion of the **Hemovigilance Incident Form** (CDC 57.305)

Form Field	Instructions for Form Completion
Facility ID	The NHSN-assigned facility ID number will be autoentered by the computer.
Incident #	Autoentered. NHSN-assigned number.
Local Incident # or Log #	Optional. Your facility Incident report, log or other number used locally to track the incident.
Discovery	
Date of discovery	Required. Enter the date the incident was discovered. This is the earliest date at which the incident was known and should be either the same or later than the date of occurrence. It must be a date that falls within the monitoring month.
Time of discovery	Required. Enter the exact time of discovery using the 24 hour clock ("Military time"). If the exact time is not known indicate the approximate time and check the "Time Approximate" box. For example, if you know that the

which you are reporting. This after the completion of the ng which you are reporting.

sd

er of units and aliquots of radiated & leukocyte ed red blood cells not

Tables of Instructions are located on the NHSN website and include detailed rules for entering each data field. Please be sure to refer to these to make sure you correctly understand the context of each question being asked on the forms.



Steps for Reporting Incidents in NHSN



- 1) Beginning of the month – Enter Monthly Reporting Plan
- 2) Throughout the month (or at the end), enter individual Incident forms. Forms should be entered within 30 days of the close of the month whenever possible.
- 3) End of the month – Enter Blood Product Incidents Reporting - Summary Data form
- 4) End of the month – Enter Hemovigilance Monthly Denominator form



Now let's go over the steps for entering incident reports into NHSN. At the beginning of each month enter your Monthly Reporting Plan. Throughout the month (or at the end of the month), enter your individual incident forms. Forms should be entered within 30 days of the close of the month whenever possible. At the end of the month enter the Blood Product Incidents Reporting – Summary Data and Hemovigilance Monthly Denominators.



Monthly Reporting Plan Data Collection Form



 **Hemovigilance Module**
Monthly Reporting Plan

Facility ID#: _____ Month ____/ Year _____

All reporting is facility-wide.

Adverse transfusion reactions & all incidents associated with reactions

Monthly reporting denominators

Incidents reporting – summary data with detailed reporting of high priority incidents

OR

Incidents reporting – detailed reports of all incidents

Recommend

Use **detailed reports of all incidents** if your facility does not have an alternative method of collecting incident information and/or your volume of transfusions is low.

There are two methods to choose from for reporting incidents. “Incidents reporting – summary data with detailed reporting of high priority incidents” is the method we recommend. Using this method you complete a detailed incident report for all incidents that are termed “high priority” and any other errors where there was a high likelihood that the error could have resulted in harm to the patient. If you look at your summary data form, high priority codes have a plus sign next to the code. Also, any error, whether high priority or not, should have a full incident report entered if product reaches the patient, regardless of whether an adverse reaction occurs. For non-high priority or minor incidents, you will collect total numbers of errors for each category and enter those on a summary form at the end of the month. If your facility does not have an alternative method for collecting incidents or your transfusion volume is low, you may want to enter full information for every incident.



Monthly Reporting Plan

- Add Monthly Reporting Plan prior to entering any data for the month you plan to report
- If you are not sure if the plan has been entered, use Find to locate any plans previously added.

The screenshot shows the NHSN Hemovigilance Module Home Page. At the top, it displays the CDC logo and the text 'Department of Health and Human Services Centers for Disease Control and Prevention'. Below this, it identifies the user as 'NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1)' and shows the user is logged into Pleasant Valley Hospital (ID 10312) as RUBY. The main content area is titled 'NHSN Hemovigilance Module Home Page' and includes a navigation bar on the left with the following items: NHSN Home, Reporting Plan (circled in red), Patient, Incident, Reaction, Summary Data, and Analysis. The 'Reporting Plan' item is expanded to show 'Add' and 'Find' options. The main content area also includes a section for 'Assurance of Confidentiality'.

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At the beginning of each month enter a Monthly Reporting Plan to inform CDC of what you will be reporting for the month. You can enter several plans at one time. If you are not sure whether you have entered a reporting plan, click on “Find” to locate any plans that have been previously entered.



Monthly Reporting Plan

NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1) | NHSN Home | My Info | Contact us | Help | Log Out

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

Add Monthly Reporting Plan

Mandatory fields marked with *

*Facility ID: Pleasant Valley Hospital (ID 10312) ▼

*Month: January ▼

*Year: 2009 ▼

No Biovigilance Modules Followed this Month

[Print PDF Form](#)

Hemovigilance Module

All reporting is facility-wide.

Adverse transfusion reactions & all incidents associated with reactions

Monthly reporting denominators

Incidents reporting - summary data with detailed reporting of high priority incidents

OR

Incidents reporting - detailed reports of all incidents

One of these

Required

This is the NHSN screen of the Monthly Reporting Plan. Since adverse reaction reporting and monthly denominators are required for participation in the Hemovigilance Module, these fields are auto-filled by the system. All you have to do is select your reporting method for incidents. After entering your information, click on "Save."



Incident Reporting



- Complete full report for any incident
 - That results in an adverse reaction of a patient
 - That has a + sign next to the codes on the Blood Products Incident Reporting – Summary Data form
 - These are high priority codes i.e., there is potential for patient harm
 - Codes are PR 03, SC 01, SC 02, SC 03, SC 07, SC 10, SH 03, ST 03, ST 07, ST 09, UM 07, UM 08, UM 09, UI 06, UT 01, UT 02,
 - Where product reaches the patient even if there is no harm
- Provide summary data on other errors
 - Clerical or technical function errors that have little likelihood of impacting the patient



Required fields are indicated by an asterisk *

Complete a full report for any incident that results in an adverse reaction in a patient, that is a high priority incident, or where product reaches the patient even if there is no harm to the patient. Provide summary data for other errors such as clerical or technical function errors that have little likelihood of impacting the patient. Remember that required fields are indicated by an asterisk.



Incident Form



- Report any incident that is reported to and documented by your department
- Incident # - system number generated by NHSN
- Local incident # or log #
 - Your institution number for this incident (e.g., the number on the incident report that was filed)

The screenshot shows the 'Hemovigilance Incident' form. At the top left is the NHSN logo. The title 'Hemovigilance Incident' is centered. On the top right, it says 'OMB No. 0520-0066' and 'Exp. Date: 12-31-2011'. Below the title is a 'Required for saving' checkbox. The form is divided into several sections: 'Facility ID #' and 'Incident #' (with a note '[system generated]') are in the top row. Below that is a section for 'Local Incident # or Log #'. A shaded 'Discovery' section follows, containing fields for '*Date of discovery:', '*Time of discovery:' (with '(HH:MM)' and checkboxes for 'Time approximate' and 'Time unknown'), and '*Where in the facility was the incident discovered?'. The bottom section is '*How was the incident first discovered?' (Check one), with checkboxes for 'Computer system alarm or warning', 'Comparison of product label to patient information', 'Comparison of sample and paperwork', and 'Comparison of product label to physician order'.

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Report any incident that is reported to and documented by your department. Incident # is the system generated number in NHSN. The Local incident or log # is the number your facility used to track the incident such as the number on the incident report or other untoward occurrence form that was filed within your own facility.



Discovery

- Date of discovery – the earliest date at which the incident was known to have occurred
 - Should be same date or later than the date of occurrence
 - Should fall within the month you are monitoring
- Time of discovery – enter exact time using military time (24 hour clock). If you know approximate time, provide estimate, otherwise check “Time Unknown”
- Where in the facility was the incident discovered?
 - Select a facility-defined location from the drop-down list. This may or may not be the same location where the incident occurred.

Discovery	
*Date of discovery: ___/___/_____	*Where in the facility was the incident discovered?
*Time of discovery: ___:___ (HH:MM) <input type="checkbox"/> Time approximate <input type="checkbox"/> Time unknown	_____

The “date of discovery” is the earliest date at which the incident was known to have occurred. It should be the same date or later than the date of occurrence. It should also be a date that falls within the month you are monitoring. Enter the exact “time of discovery” using the 24 hour clock or “military time.” If, for example, you know the error occurred around the time of shift change at 7 a.m. but don’t know the exact time, you would enter 07:00 and check, “time approximate.” Select a location for “Where in the facility was the incident discovered?” from your facility location drop-down list. This may or may not be the same location where the incident occurred.



Discovery



- How was the incident first discovered?
 - Check the box of the description that most closely describes how the error was discovered. If “Other” is selected, include a brief description in the space provided.
- At what point in the process was the incident first discovered?
 - Check the box for the process point at the time the incident was discovered. Use the code descriptions on page 4 of the Incident form (or Appendix F in the protocol).



*How was the incident first discovered? (Check one)	
<input type="checkbox"/> Computer system alarm or warning	<input type="checkbox"/> Comparison of product label to patient information
<input type="checkbox"/> Comparison of sample and paperwork	<input type="checkbox"/> Comparison of product label to physician order
<input type="checkbox"/> Historical record/previous type check	<input type="checkbox"/> Human 'lucky catch'
<input type="checkbox"/> Observation by staff of unit/plate/reagent/sample/equipment	<input type="checkbox"/> Patient transfusion reaction
<input type="checkbox"/> Repeat or sample re-testing	<input type="checkbox"/> Routine audit or supervisory review
<input type="checkbox"/> Other (specify) _____	<input type="checkbox"/> Visual inventory review
*At what point in the process was the incident first discovered? (Check one)	
<input type="checkbox"/> Product check-in	<input type="checkbox"/> Product/test request
<input type="checkbox"/> Sample collection	<input type="checkbox"/> Sample handling
<input type="checkbox"/> Sample receipt	<input type="checkbox"/> Sample testing
<input type="checkbox"/> Product storage	<input type="checkbox"/> Available for issue
<input type="checkbox"/> Product selection	<input type="checkbox"/> Product manipulation
<input type="checkbox"/> Request for pick-up	<input type="checkbox"/> Product issue
<input type="checkbox"/> Product administration	<input type="checkbox"/> Post-transfusion review/audit
<input type="checkbox"/> Other (specify) _____	

How was the incident first discovered? Select the option that most closely describes how the incident was discovered. If you select “Other” please include a brief description. At what point in the process was the incident first discovered? Check the box for the process point at the time the incident was discovered. We are only interested in the high level process category at the time the incident was discovered. (Use the code descriptions on page 4 of the Incident form or in Appendix F of the protocol).



Occurrence



- Date and time the incident occurred
- Where in the facility did the incident occur?
- Job function of the worker involved
 - Use CDC occupation codes
 - The worker who most likely made the error

Occurrence		
*Date the incident occurred: ____/____/____	*Time the incident occurred: ____ : ____ (HH:MM) <input type="checkbox"/> Time approximate <input type="checkbox"/> Time unknown	*Where in the facility did the incident occur? _____
Job function of the worker involved in the incident (Use CDC Occupation Type codes on page 5) _____ <input type="checkbox"/> If Other (specify) _____		

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Next we will complete the section on incident occurrence. First, enter the date and time the incident occurred. If you don't know the exact time, check "time approximate" as described in slide 21. Enter the facility location where the actual incident or error happened. For example, if a sample is mislabeled at the time it is drawn from the patient, enter the location where the sample was drawn. Enter the CDC occupation code (contained at the end of the Incident form and also listed in Appendix E of the protocol) of the person most closely involved in the incident. Often this will be the worker who made the error.



Occurrence



- Where in the process did the incident first occur?
 - Incident code
 - If detail of incident is unknown but step in process is, use process code with 00 (e.g., an incident during product administration would be UT 00)
- Incident summary – brief but descriptive text of exactly what happened
- Incident result

*Where in the process did the incident first occur? (Check one)

<input type="checkbox"/> Product check-in	<input type="checkbox"/> Product/test request	<input type="checkbox"/> Sample collection	<input type="checkbox"/> Sample handling
<input type="checkbox"/> Sample receipt	<input type="checkbox"/> Sample testing	<input type="checkbox"/> Product storage	<input type="checkbox"/> Available for issue
<input type="checkbox"/> Product selection	<input type="checkbox"/> Product manipulation	<input type="checkbox"/> Request for pick-up	<input type="checkbox"/> Product issue
<input type="checkbox"/> Product administration	<input type="checkbox"/> Other (specify) _____		

*Enter Incident Code (See Incident Codes on Page 4 of Form): _ _ _ _

OR Incident detail not specified

Incident summary:

*Incident result: (Check one)

<input type="checkbox"/> 1 = No recovery, harm	<input type="checkbox"/> 2 = No recovery, no harm
<input type="checkbox"/> 3 = Near miss, unplanned recovery	<input type="checkbox"/> 4 = Near miss, planned recovery

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Enter the incident code of where in the process the incident first occurred. This is the first time point at which the error or accident occurred. Some errors occur at multiple points (for example, if a wrong unit is issued to a patient and the nurse administering the transfusion also fails to detect that the unit is for someone else, the first place the error occurred was at product issue). If you don't know the details of the incident but know the step in the process, enter the process code with a 00. For example, an incident during product administration would be UT 00. Please enter a brief, but descriptive narrative in the incident summary of exactly what happened. Then, check the final result of the incident.



Occurrence Incident Result Definitions

See Appendix G of protocol for definitions

Incident Result

1 = No Recovery, harm

Product was transfused and the patient experienced an adverse reaction.

2 = No Recovery, no harm

Product was transfused, but the patient did not experience an adverse reaction.

3 = Near miss, unplanned recovery

Product was not transfused. The incident was discovered ad hoc, by accident, a human lucky catch, etc. It was not discovered through formalized facility standard operating procedures or other previously instituted checks and balances.

4 = Near miss, planned recovery.

Product was not transfused. The incident was discovered through standardized processes or barriers built into the system to prevent errors.

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Please use the protocol definitions for Incident Result. Result 1, “No recovery, harm,” means that product reached the patient, was transfused, and the patient experienced an adverse reaction as a result of the incident. Result 2, “No recovery, no harm,” means that product was transfused but the patient did not experience an adverse reaction as a result of the incident. Result 3, “Near miss, unplanned recovery,” means that product was not transfused and the incident was discovered ad hoc, by accident, through a human “lucky-catch,” etc. In other words, the incident was not discovered through formalized facility standard operating procedures or other previously instituted checks and balances. Result 4, “Near miss, planned recovery,” means that product did not reach the patient and the incident was discovered through standardized procedures or barriers built into the system to prevent such errors.



Occurrence



- Product action
 - Use *Not applicable* when incident occurs in transfusion services and no product has been issued
- Record/other action

*Product action: (Check all that apply)

Not applicable

Product retrieved

Product destroyed

Code system used: (Check one) ISBT-128 Codabar

Indicate whether single or multiple units were destroyed:

*Single unit: a. Unit #: _____

OR b. Component Code: _____

*Multiple units: Component Code(s) _____ # of Units _____

Code _____ # of Units _____ Code _____ # of Units _____ (Add add'l)

Product issued but not transfused

Product transfused

If the unit was transfused was a patient reaction associated with this incident?

YES NO

If YES, Patient ID#: _____ Patient ID#: _____

*Record/other action: (Check all that apply)

Record corrected Floor/clinic notified Attending physician notified Additional testing

Patient sample re-collected Other (specify) _____

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Product action must coordinate with Incident Result. If your Incident Result code is 1 or 2, then product action must be that the product was transfused. "Product retrieved," "Product destroyed," and "Product issued but not transfused," can be used with code 3 or 4. If product was destroyed due to the incident (for example, a freezer breaks down), select the code system used (that is, ISBT-128 or Codabar) and enter the unit number or component code if only a single unit is involved. If multiple units are destroyed, put the component code and number of units for each component type destroyed. We'll discuss component codes in more detail in the next slide.

Use "Not applicable" when the error occurred in transfusion services and no product had yet been issued. If product was transfused indicate if a reaction was associated with the incident. Remember that your Result code must be a 1 if this is answered, "Yes." Indicate record-keeping and other actions that are taken as a result of the incident.



Blood Product Codes



Codabar (being phased out)

02461	CPDA-1 WHOLE BLOOD LEUKOCYTES REDUCED ¹ IRRADIATED LOW VOLUME	WB
02465	CPDA-1 WHOLE BLOOD LEUKOCYTES REDUCED ¹ IRRADIATED (250 ml)	WB
02480	CP2D WHOLE BLOOD LEUKOCYTES REDUCED ¹ IRRADIATED	WB
03311	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED (ACDA anticoagulant) (by pheresis)(for second bag of a double red blood cell pheresis)	LRRBC
03320	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED IRRADIATED (ACDA anticoagulant) (by pheresis)	IRLRRBC
03321	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED DIVIDED (ACDA anticoagulant)(by pheresis)(Part A or 1)	LRRBC
03322	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED DIVIDED(ACDA anticoagulant)(by pheresis)(Part B or 2)	LRRBC
03323	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED DIVIDED(ACDA anticoagulant)(by pheresis)(Part C or 3)	LRRBC
03324	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED DIVIDED(ACDA anticoagulant)(by pheresis)(Part D or 4)	LRRBC
03325	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED DIVIDED(ACDA anticoagulant)(by pheresis)(Part E or 5)	LRRBC
03326	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED DIVIDED(ACDA anticoagulant)(by pheresis)(Part F or 6)	LRRBC
03327	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED DIVIDED(ACDA anticoagulant)(by pheresis)(Part G or 7)	LRRBC
03328	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED DIVIDED(ACDA anticoagulant)(by pheresis)(Part H or 8)	LRRBC
03329	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED IRRADIATED(ACDA anticoagulant)(by pheresis)(for second bag of a double red blood cell pheresis)	LRRBC

For surveillance we are only interested in this part of the product code

ISBT-128 (new standard)

E0150	RED BLOOD CELLS CPD/450mL/refg	RBC
E0154	RED BLOOD CELLS CPD/450mL/refg Open	RBC
E0155	RED BLOOD CELLS CPD/450mL/refg Open Irradiated	IRRBC
E0156	RED BLOOD CELLS CPD/450mL/refg Open Irradiated ResLeu:<5log6	IRLRRBC
E0157	RED BLOOD CELLS CPD/450mL/refg Open Irradiated Plasma added	IRRBC
E0158	RED BLOOD CELLS CPD/450mL/refg Open ResLeu:<5log6	LRRBC
E0159	RED BLOOD CELLS CPD/450mL/refg Open Albumin added	RBC
E0160	RED BLOOD CELLS CPD/450mL/refg Open Plasma added	RBC
E0161	RED BLOOD CELLS CPD/450mL/refg Irradiated	IRRBC
E0162	RED BLOOD CELLS CPD/450mL/refg Irradiated ResLeu:<5log6	IRLRRBC

F.Y.I.

NHSN mapping codes used for analysis

As we discussed in the Hemovigilance Overview training, NHSN is set up to allow entry of ISBT-128 or Codabar codes for blood products. You must select one or the other before entering the code. When you enter a 5-digit code in NHSN, the product description should appear. If it does not, please make sure you have entered the correct code. If you have and the description still does not appear, please contact NHSN user support and provide the code and product description.



Blood Product Codes In NHSN



Product Action: Used to indicate the type of product, if product is destroyed as a result of an incident. Enter # of units destroyed for each type of product. If a single unit is destroyed you have the option of entering the unit #. Unit # can be entered for ISBT-128 or Codabar. You can add multiple component codes by clicking on the “Add Row” button.

*Select incident result: 3 - Near miss, unplanned recovery

*Product action: (Check all that apply):

- Not applicable
- Product retrieved
- Product destroyed

*Code system used: ISBT128 - ISBT-128

*Single or multiple units destroyed? M - Multiple Units

Component codes

Component code	Number of units
E0154 RBC - RED BLOOD CELLS CPD/450mL/refg Open	3

Add Row

28

This is a screen shot from NHSN to show you how the product description should look. You can add multiple component codes by clicking on the “Add row” button. You can delete rows by clicking on the trashcan that appears to the left of the code.



Investigation Results

Root Cause Analysis



Investigation Results	
*Did this incident receive root cause analysis? <input type="checkbox"/> YES <input type="checkbox"/> NO	[Future] Severity Code: (check one) <input type="checkbox"/> High <input type="checkbox"/> Medium <input type="checkbox"/> Low
If YES, indicate result of analysis: (Check all that apply)	
<input type="checkbox"/> Technical <input type="checkbox"/> Organizational <input type="checkbox"/> Human <input type="checkbox"/> Patient-related	
<input type="checkbox"/> Other (specify) _____	

- See Appendix G of protocol for definitions

Root Cause Analysis Result(s)
Technical: <ul style="list-style-type: none">• Technical failures beyond the control and responsibility of the facility• Failure due to poor design of equipment, software, labels or forms• Correct design but not constructed properly or set up in in-accessible areas• Other material defects.
Organizational: <ul style="list-style-type: none">• Failure at an organizational level beyond the control and responsibility of the facility or department where the incident occurred• Failure resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff• Failure relating to the quality and availability of the protocols/procedures within the department (e.g., too complicated, inaccurate, unrealistic, absent or poorly presented)• Internal management decisions when faced with conflicting demands or objectives. Failures resulting from collective approach and its attendant modes of behavior to risks in the investigating organization. These are organizational cultural attitudes and behaviors. For example, if the organizational culture is one where compliance with safety related procedures is low or procedures are not enforced.
Human: <ul style="list-style-type: none">• Human failures originating beyond the control and responsibility of the investigating organization. This could include individuals in other departments• Inability of an individual to apply their existing knowledge to a novel situation. Example: a blood bank technologist who is unable to solve a complex antibody identification problem

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A “root cause analysis” is a formal administrative investigation aimed at identifying the problems or causes of an incident. Please see Appendix G of the protocol for detailed definitions of root cause analysis results. Check “Yes” if a root cause analysis of this incident was performed and check all results of the analysis. If you are not sure if one was done, answer “No” to this question.



Incidents Reporting Summary Data Form

NHSN
National Healthcare
Safety Network

Hemovigilance Module
Blood Product Incidents Reporting – Summary data

Facility ID#: _____ Month ____/ Year _____

All reporting is facility-wide. Include numbers of individual reports in the totals.

*Process Point	*Total Number of Incidents	*# of Adverse Transfusion Reactions Associated w/ Incident
PC - Product Check-In (Products received from outside source)	PC 00 Detail not specified	
	PC 01 Data entry incomplete/not performed/incorrect	
	PC 02 Shipment incomplete/incorrect	
	PC 03 Product & paperwork do not match	
	PC 04 Shipped under inappropriate conditions	
	PC 05 Inappropriate return to inventory	
	PC 06 Product confirmation	
PR - Product / Test Request (Clinical Service)	PR 00 Detail not specified	
	PR 01 Order for wrong patient	
	PR 02 Order incorrectly entered on-line	
	PR 03 Special needs not indicated on order (e.g., CMV negative, auto)	
	PR 04 Order not done/incomplete/incorrect	

High
Priority
Code

At the completion of a reporting month complete an Incident Reporting Summary Data form. Count up the total number of incidents in each process code category and put the total number in each box. Indicate the number of adverse reactions associated with an incident (if any). It is expected that for each adverse reaction listed on this form, there will be an associated Adverse Reaction form entered into NHSN. High priority codes are indicated by a cross and require a full incident report.



Case #1



At 8 a.m. on 1/15/2009 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 3 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.

Now that we've gone through the Incident reporting process, let's try some real case examples. At 8 a.m. on 1/15/2009 a unit of red cells was being electronically crossmatched for a patient. When entering the unit into the laboratory information system or LIS, the technician 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 3 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 technician selected another unit rather than waiting for a correction to be made to the first unit.



Case #1 Discovery Incident Form



Required for saving	
Facility ID #: <u>_12345_</u>	Incident #: <u>_1_</u> [system generated]
Local Incident # or Log #: <u>_1262_</u>	
Discovery	
*Date of discovery: <u>_01_/_15_/2009_</u>	*Where in the facility was the incident discovered?
*Time of discovery: <u>_08:_00_</u> (HH:MM) <input type="checkbox"/> Time approximate <input type="checkbox"/> Time unknown	<u>_Blood bank_</u>
*How was the incident first discovered? (Check one)	
<input type="checkbox"/> Computer system alarm or warning <input type="checkbox"/> Comparison of product label to patient information <input type="checkbox"/> Comparison of sample and paperwork <input type="checkbox"/> Comparison of product label to physician order <input type="checkbox"/> Historical record/previous type check <input type="checkbox"/> Human 'lucky catch' <input type="checkbox"/> Observation by staff of unit/plate/reagent/sample/equipment <input type="checkbox"/> Patient transfusion reaction <input type="checkbox"/> Repeat or sample re-testing <input type="checkbox"/> Routine audit or supervisory review <input type="checkbox"/> Visual inventory review <input checked="" type="checkbox"/> Other (specify) <u>_comparison of product label to LIS_</u>	
*At what point in the process was the incident first discovered? (Check one)	
<input type="checkbox"/> Product check-in <input type="checkbox"/> Product/test request <input type="checkbox"/> Sample collection <input type="checkbox"/> Sample handling <input type="checkbox"/> Sample receipt <input checked="" type="checkbox"/> Sample testing <input type="checkbox"/> Product storage <input type="checkbox"/> Available for issue <input type="checkbox"/> Product selection <input type="checkbox"/> Product manipulation <input type="checkbox"/> Request for pick-up <input type="checkbox"/> Product issue <input type="checkbox"/> Product administration <input type="checkbox"/> Post-transfusion review/audit <input type="checkbox"/> Other (specify) _____	

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Let's look at how we would complete an Incident form for the example just given. Facility ID and Incident # will be auto-filled by NHSN on data entry. The local incident or Log # is the number the institution assigned to the error (for example, what appeared on the formal incident report or log in the facility). The date and time of discovery were the moment the technician noticed the error when entering the unit into the LIS. Since none of the descriptions of, "How the incident was first discovered" describe our scenario, we will check "Other" and write a brief description. Since the incident was discovered during an electronic crossmatch, our point-in-the process for discovery will be at "Sample testing."



Case #1 Occurrence

Occurrence		
*Date the incident occurred: _01/12/_2009_	*Time the incident occurred: _09_ : _00_ (HH:MM) <input checked="" type="checkbox"/> Time approximate <input type="checkbox"/> Time unknown	*Where in the facility did the incident occur? _Blood bank_
Job function of the worker involved in the incident (Use CDC Occupation Type codes on page 5) _M L T_ <input type="checkbox"/> If Other (specify) _____		
*Where in the process did the incident <u>first</u> occur? (Check one) <input checked="" type="checkbox"/> Product check-in <input type="checkbox"/> Product/test request <input type="checkbox"/> Sample collection <input type="checkbox"/> Sample handling <input type="checkbox"/> Sample receipt <input type="checkbox"/> Sample testing <input type="checkbox"/> Product storage <input type="checkbox"/> Available for issue <input type="checkbox"/> Product selection <input type="checkbox"/> Product manipulation <input type="checkbox"/> Request for pick-up <input type="checkbox"/> Product issue <input type="checkbox"/> Product administration <input type="checkbox"/> Other (specify) _____		
*Enter Incident Code (See Incident Codes on Page 4 of Form): <u>PC 01</u> OR <input type="checkbox"/> Incident detail not specified		
Incident summary: Comparison of product label expiry date to LIS expiry date. Dates did not match.		
*Incident result: (Check one) <input type="checkbox"/> 1 = No recovery, harm <input type="checkbox"/> 2 = No recovery, no harm <input type="checkbox"/> 3 = Near miss, unplanned recovery <input checked="" type="checkbox"/> 4 = Near miss, planned recovery		

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In the Case #1 example, the technician knew that the error had occurred 3 days earlier in the morning when the product had been checked in, so we'll enter the date and time but indicate that the time was approximate. The incident occurred in the blood bank (or Transfusion Services). The worker who checked the product in and had manually entered the wrong expiry date was a medical lab technician therefore, MLT is the occupation code. The process code is PC or "Product check-in" and the exact code is PC 01 which includes "Data entry incorrect." A brief summary of the error is provided in the text field. Our Incident result code is 4, or "Near miss, planned recovery," because the technician followed facility procedures by comparing information on the unit to what was already entered into the LIS.



Case #1 Occurrence & Investigation Result



*Product action: (Check all that apply)

Not applicable

Product retrieved

Product destroyed

Code system used: (Check one) ISBT-128 Codabar

Indicate whether single or multiple units were destroyed:

*Single unit: a. Unit #: _____

OR b. Component Code: _____

*Multiple units: Component Code(s) _____ # of Units _____

Code _____ # of Units _____ Code _____ # of Units _____ (Add add'l)

Product issued but not transfused

Product transfused

If the unit was transfused was a patient reaction associated with this incident?

YES NO

If YES, Patient ID#: _____ Patient ID#: _____

*Record/other action: (Check all that apply)

Record corrected Floor/clinic notified Attending physician notified Additional testing

Patient sample re-collected Other (specify) _____

Investigation Results

*Did this incident receive root cause analysis?

YES NO

[Future]
Severity Code: (check one)
<input type="checkbox"/> High <input type="checkbox"/> Medium <input type="checkbox"/> Low

34

Product action will be “not applicable” because no unit had been issued at the time the incident was discovered. However, “Record/other action” will be “record corrected” since the supervisor was notified and the LIS was changed. In this example, the institution did not perform a root cause analysis.



Case #2



On 1/27/2009 a specimen was received in the blood bank at 2 a.m. with a request to do a type and screen for patient J. Jones, who was in the Emergency Department. At the time of receipt the sample and request met all established acceptance criteria and the sample was processed. The patient's blood group was A positive with a negative antibody screen.

Approximately 1 hour later, the nurse that had drawn J. Jones' specimen phoned the blood bank tech and asked that the specimen be discarded as she was almost positive that the specimen was not drawn from J. Jones but from B. Smith. She was looking after both patients and believed she put J. Jones' label on B. Smith's specimen.

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Let's look at a second example. On 1/27/2009 a specimen was received in the blood bank at 2 a.m. with a request for a type and screen for patient J. Jones, who was in the Emergency Department. At the time of receipt the sample and request met all established acceptance criteria and the sample was processed. The patient's blood group was A (+) with a negative antibody screen.

Approximately one hour later, the nurse that had drawn J. Jones' specimen phoned the blood bank tech and asked that the specimen be discarded. The nurse was almost positive that the specimen was not drawn from J. Jones, but from another patient, B. Smith. She was looking after both patients and believed that she had accidentally put J. Jones' label on B. Smith's specimen.



Case #2 (cont)

At that time the technologist asked that new samples be drawn for both Jones and Smith since no sample had been received at all for Smith.

Upon receipt and completion of testing, the first type (A +) did not match the second type (O+) for patient Jones. A third confirmatory specimen was requested for Jones and tested O+. This confirmed the nurse's suspicion that the first specimen had been mislabeled.

36

At that time, the technologist asked that new samples be drawn for both Jones and Smith since no sample had been received at all for Smith. Upon receipt and completion of testing, the first type (A+) did not match the second type (O+) for patient Jones. A third confirmatory specimen was requested for Jones and was also O+. This confirmed the nurse's suspicion that the first specimen had been mislabeled.



Case #2 Discovery NHSN Screen



NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1) | NHSN Home | My Info | Contact us | Help | Log Out

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

Add Incident

Mandatory fields marked with *

[Print PDF Form](#)

*Facility ID: 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?

*At what point in the process was the incident first discovered?

Occurrence

*Date incident occurred:

*Time incident occurred: : (HH:MM) Time approximate Time unknown

*Where in the facility did the incident occur?

37

Let's enter this case using NHSN. Facility ID and Incident # are NHSN generated. Enter your local Incident or Log #. "Date of discovery" will be 1/27/2009 and "Time of discovery" will be the time the nurse called the blood bank to tell them of her possible mistake. The facility location where the incident was discovered is the Emergency Department. The incident discovery was a "Human lucky catch" based on the nurse's suspicion that she had made an error. The point in the process where the incident was first discovered was during sample testing. The incident occurred at 1:45 a.m. when the nurse drew the sample from the patient in the Emergency Department.



Case #2 Occurrence & Investigation Result



Job function of the worker involved in the incident: RNU - Registered Nurse

*Where in the process did the incident first occur? SC - Sample collection

Incident code: SC 01 - Sample labeled with incorrect patient name

Incident summary:
Nurse collecting samples from two patients placed label for one patient on the other patient's sample. She called blood bank once

*Select incident result: 3 - Near miss, unplanned 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

38

Although there are two workers involved in this incident (the nurse and the technologist in the blood bank) it is the nurse who made the error, so we will enter her job function code. The process point at which the error first occurred was during “Sample collection.” Our incident code will be “SC 01 – sample labeled with incorrect patient name.” Notice that we have entered a brief summary of the incident in the text field. Our incident result will be 3, or “Near miss – unplanned recovery” since the error was detected only because of the nurse’s feeling that she had done something wrong. “Product action” is not applicable because a unit had not yet been issued for the patient. Our “Record/other action” was that the patient sample was re-collected. In this example, no root cause analysis was performed. At the bottom of this page you would click on the “Save” button in order to save the record.



Case #3

A request for transfusion for 2 RBC units was received in the blood bank at 8:30 a.m. on 1/5/2009. The patient had a current type and screen on file and qualified for an electronic crossmatch. Two units were selected and the electronic crossmatch was performed. The units were labeled and placed in the appropriate storage unit, awaiting pick-up.

The nursing unit was subsequently notified that the blood was ready for pick-up. The porter arrived at 10:00 a.m. with appropriate documentation to pick up the first unit. When issuing the unit, the tech noticed that the unit number on the bag did not match the one on the transfusion slip. Further investigation showed that the labels had been switched when the units were labeled for transfusion.

The technologist immediately re-labeled the units and issued the first one to the porter who had been waiting.

39

Here's another example. A request for transfusion for 2 units of packed red blood cells was received in the blood bank at 8:30 a.m. on 1/5/2009. The patient had a current type and screen on file and qualified for an electronic crossmatch. Two units were selected and the electronic crossmatch was performed. The units were labeled and placed in the appropriate storage unit, awaiting pick-up.

The nursing unit was subsequently notified that the blood was ready for pick-up. The porter arrived at 10:00 a.m. with appropriate documentation to pick up the first unit. When issuing the unit, the tech noticed that the unit number on the bag did not match the one on the transfusion slip. Further investigation showed that the labels had been switched when the units were labeled for transfusion. The tech immediately re-labeled the units and issued the first one to the porter who had been waiting.



Case #3 Discovery

NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1) | NHSN Home | My Info | Contact us | Help | Log Out

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

Add Incident

Mandatory fields marked with *

[Print PDF Form](#)

*Facility ID: 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?

*Specify

*At what point in the process was the incident first discovered?

40

Our date and time of discovery are 1/5/2009 at 10:00 a.m. because that was the moment the tech noticed that the unit number on the bag did not match the one on the transfusion slip. The incident was discovered in the blood bank. Since the incident was discovered by comparison of the unit label with the transfusion slip it does not quite fit any of the pre-defined selections under "How was the incident first discovered?" so we will select "Other" and provide brief text in the specify field. The point in the process at which the incident was first discovered was UI or "Product issue."



Case #3 Occurrence



Occurrence

*Date incident occurred: 01/05/2009
*Time incident occurred: 08 : 30 (HH:MM)
 Time approximate Time unknown

Job function of the worker involved in the incident: MLT - Medical Laboratory Technician

*Where in the facility did the incident occur? NPTCBLOOD - NONPTC:NA:LAB:BLOOD

*Where in the process did the incident first occur? UM - Product manipulation

Incident code: UM 05 - Labeling incorrect

Incident summary:
Labels were switched when two units were issued at the same time.

*Select incident result: 4 - Near miss, 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 (specify)
Labels corrected and product issued

41

The date and time the incident occurred were the moment when the units were labeled. So we entered 1/5/2009 at 8:30 a.m. The incident occurred in the blood bank. The job function of the worker involved in the incident was MLT. This was the person who mislabeled the units. Our incident code is UM 05. The incident occurred during product manipulation and labeling was incorrect. A brief description of the incident is written in the “Incident summary” field. The incident result was “4 – Near miss, planned recovery.” We would call this ‘planned recovery’ because the facility had a standard operating procedure in place that unit label should always be compared with the transfusion slip before the unit is issued. “Product and Record/other action” was that product was retrieved before issue and re-labeled.



Case #3 Investigation Result

- See protocol Appendix G for description of root cause analysis results

Investigation Results

*Did this incident receive root cause analysis?

*Results of analysis: (Check all that apply)

Technical Organizational

Human Patient-related Other

- Incorrect or incomplete assessment of a situation including related conditions of the patient and materials to be used before starting the transfusion. Example: failure to correctly identify the patient by checking the wristband

A root cause analysis of this incident was performed and the result was that this was a human failure. This is defined as failure due to incorrect or incomplete assessment of a situation including related conditions of the patient and materials to be used before starting the transfusion. In our case it was incorrect labeling.



Case #4 Incident Resulting in Adverse Reaction



At 08:30 a.m. on 1/8/2009, 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 a 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 1/15/2009.

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Now let's look at one last example. This is an incident that resulted in an adverse reaction in a patient. At 8:30 a.m. on 1/8/2009, 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 4:55 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 a urine output of 40 ml/hour and a rise in creatinine, LDH, potassium, and bilirubin. Her hemoglobin dropped from 10.7 to 8.3. She 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 1/15/2009.



Case #4 Discovery



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

NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1) | NHSN Home | My Info | Contact us | Help | Log Out

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

Add Incident

Mandatory fields marked with *

[Print PDF Form](#)

*Facility ID: Incident #:

Local Incident # or Log #:

Discovery

*Date of discovery: *Where in the facility was the incident discovered?

*Time of discovery: : (HH:MM)
 Time approximate Time unknown

*How was the incident first discovered?

*At what point in the process was the incident first discovered?

44

This incident was discovered at 8:30 a.m. on 1/8/2009 when the blood bank, through routine review, discovered that a wrong unit had been issued. The point in the process at which the incident was first discovered was RA or "Post Transfusion Review/Audit."



Case #4 Occurrence



Occurrence

*Date incident occurred: 01/08/2009 (HH:MM)

*Time incident occurred: 03 : 00 (HH:MM)

Time approximate Time unknown

Job function of the worker involved in the incident:

*Where in the process did the incident first occur?

Incident code:

Incident summary:

*Select incident result:

*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?

Patients
Patient ID

45

The incident occurred on 1/8/2009 at approximately 3:00 a.m. when the wrong unit was issued by the Medical Lab Technician. Therefore, the incident occurred during product issue. The process code is UI 09 or “Not checking/incorrect checking of unit or patient information.” A brief summary of the incident is provided in the text field. The incident result is 1 – “No recovery, harm” because the error was not caught until after the patient had been transfused. The patient experienced an adverse reaction and was, therefore, harmed as a result of the incident. “Product action” is that product was transfused. We select “Yes” to the question of whether a patient reaction was associated with the incident and enter the Patient ID # for B. Thomas. This is the same Patient ID # that will be used when we complete and enter our Adverse Reaction form into NHSN.



Case #4 Investigation Result

Investigation Results

*Did this incident receive root cause analysis?

*Results of analysis: (Check all that apply)

Technical Organizational

Human Patient-related Other

Custom Fields



- A full Incident report in NHSN must be completed for any incident where product has reached the patient regardless of whether the patient is harmed.

This incident also received root cause analysis and it was deemed to be due to human failure. A full incident report in NHSN must be completed for any incident where product has reached the patient, regardless of whether the patient is harmed.



Save the Record



- Any record (“form”) in NHSN must be saved before exiting
 - You can’t partially complete a record and return later to finish
 - You can’t save a record until all required fields have been completed

Comments

Save Back

NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1) | NHSN Home | My I

Logged into Pleasant Valley Hospital (ID 10312) as RUBY, Facility Pleasant Valley Hospital (ID 10312) is following the EV component.

Add Incident

✓ Incident 130 created successfully.

Reporting Plan
Patient
Incident
Add
Find

Windows Internet Explorer

Local Incident # or Log

Are you sure you want to navigate away from this page?
Changes found. Do you want to save changes?
Press OK to continue, or Cancel to stay on the current page.

OK Cancel

If you attempt to exit a record without saving you will receive a warning.

Once you have entered your incident report into NHSN don't forget to save the record. Click on the "Save" button at the bottom of the screen. You will be told that the record has been saved successfully. If you attempt to exit the record before saving you will receive a warning message. The NHSN incident number is provided at the time the record is saved as shown in the statement, "Incident 130 created successfully."



Linking Adverse Reactions and Incidents



- Use when adverse reaction is the result of an incident
- Information from linked events is used in analysis
- Enter incident before the adverse reaction
- Fields associated with linking
 - Link/unlink on Adverse Reaction form
 - Product action on Incident form
 - If the unit was transfused was a patient reaction associated with this incident? If Yes, enter patient ID (facility assigned ID for that patient e.g., medical record number)

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Linking Adverse Reactions and Incidents. In NHSN we link adverse reactions that are the result of an incident. Information from linked events is used in analysis. In order to successfully link a record, enter the Incident form before the Adverse Reaction form. There are certain fields associated with linking on each of the two forms. We'll look at them on the next slide.

Fields Associated with Linking

Reaction Details

*Date reaction occurred: 01/10/2009
*Time reaction occurred: 10 : 0 (HH:MM)
OR Time unknown

*Facility location where reaction occurred:
INHONCSA - IN-ACUTE:SCA:HONC

Link/Unlink To Incidents Reaction is Linked

Adverse Reaction screen

Occurrence

*Date incident occurred: 01/10/2009
*Time incident occurred: 08: 00 (HH:MM)
 Time approximate Time unknown

*Where in the facility did the incident occur?
NPTCBLOOD - NONPTC:NA:LAB:BLOOD

Job function of the worker involved in the incident: CLT - Clinical Lab Technician

*Where in the process did the incident first occur? SE - Product selection
Incident code: SE 01 - Incorrect product/component selected
Incident detail not specified:

Incident summary:
Technician took incorrect component off shelf.

*Select incident result: 1 - No recovery, harm

*Product action: (Check all that apply):
 Product retrieved
 Product destroyed
 Product issued but not transfused
 Product transfused

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

Patients
Patient ID
rp57923

Incident screen

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On the Adverse Reaction event screen you have a button to select that will Link/Unlink the event to an incident. On the Incident form (and remember the Incident form is the first one you enter), Product Action will be "Product transfused." Answer "Yes" to the question of whether a patient reaction was associated with the incident and then enter the Patient ID(s) associated with the incident.



Linking

- Incident # is the NHSN-assigned number
- System will bring up incidents that have the same Patient ID as reported on the Adverse Reaction form

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

Incident Link List

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

Check all that apply	Incident #	Patient ID	Date incident occurred	Where in the process the incident first occurred	Incident code
<input checked="" type="checkbox"/>	105	rp57923	01/10/2009	SE	SE 01

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

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The actual linking process is initiated from the Adverse Reaction event screen. When you click on this button the system will bring up a list of all incidents entered that have the same Patient ID as reported on the Adverse Reaction form. The Incident # is the NHSN-assigned number as shown on slide 47.



Find an Incident



- Locate any incidents that have already been entered using:
 - NHSN incident #
 - Incident code (e.g., all incidents with code SC 01)
 - All incidents that occurred in a specific facility location
 - All incidents within a certain time period

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Facility Pleasant Valley Hospital (ID 10312) is following the DV component.

Find Incident

- Enter search criteria and click Find
- Fewer criteria will return a broader result set
- More criteria will return a narrower result set

Incident Information

Facility ID: Pleasant Valley Hospital (ID 10312) ▼

Incident #: 105

Incident code:

Location: ▼

Incident date: From: To:

Find Clear Back

–Clicking on “Find” without entering criteria will bring up a list of all incidents

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You can locate any incidents that have already been entered by using any of the following criteria: NHSN incident #, Incident process code (for example, all incidents with a code of SC 01), all incidents that occurred in a specific facility location, and all incidents reported in a particular time period. The more criteria you use, the narrower the search. If you don't enter any criteria and click on “Find” you will be given a list of all incidents that have been reported by your facility into NHSN.



Incident Reporting Summary



- In the examples provided during this training, cases 1 and 3 are not high priority and do not require a full Incident report unless your facility chooses to complete a full report on each incident. Case # 2 would require a complete report because the incident code on the form, SC01, is a high priority code
- Cases 1 and 3 could be entered under the appropriate process code on the summary form at the completion of the monitoring month
- To enter summary data:

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Facility Pleasant Valley Hospital (ID 10312) is following the BV component.

Add Hemovigilance Summary Data

Summary Data Type: Blood Product Incidents Reporting - Summary Data

Continue Back

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Completing the Incident Reporting Summary data form. In the examples provided during this training session, cases 1 and 3 do not have high priority Incident process codes and would not require a full incident report unless your facility chose to complete one. Case # 2 would require a full report because the incident code on the form, SC 01, is a high priority code. To enter summary data in NHSN, select Summary Data – Add from the left navigation bar.



Summary Data for Case Examples



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Hemovigilance Module

Blood Product Incidents Reporting - Summary Data

Mandatory fields marked with *

*Facility ID: 10312 (Pleasant Valley Hospital)

*Month: January

*Year: 2009

[Print PDF Form](#)

Process code	Incident code	Total # of incidents	# of adverse reactions
Total Monthly Reports		0	0
PC - Product check-in	PC 01 - Data entry incomplete/not performed/incorrect	1	0
SC - Sample collection	SC 01 - Sample labeled with incorrect patient name	1	0
UM - Product manipulation	UM 05 - Labeling incorrect	1	0
UI - Product issue	UI 09 - Not checking/incorrect checking of unit and/or patient information	1	1

Add Row Clear All Rows

Any adverse reaction that results from an incident requires a full incident form and adverse reaction form

Here's how we would enter our 4 case examples. Use the complete Process Code as entered in the "Occurrence" section – "Incident Code" field. First, select your point in the process, for example PC – Product Check-in. In the field to your right you will see a drop down list with all the codes under category "PC." For Case #1 the incident code was PC 01. Select it and then, put in the total number of incidents for the month that had that code. If any adverse reactions are associated with that code, put in the total number for the month. Notice that on the NSHN screen summary data form you only need to enter totals for incident process codes that were used.



Monthly Reporting Denominators

- Provide denominators for analysis of incidents and adverse reactions
- Information from facility survey provides additional denominators and information that can be used in analysis

The screenshot shows the NHSN (National Healthcare Safety Network) interface. At the top left is the CDC logo. The header text reads "Department of Health and Human Services" and "Centers for Disease Control and Prevention". Below this is a navigation bar with "NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1)" and links for "NHSN Home", "My Info", and "Contact us". The main content area is titled "Add Hemovigilance Summary Data". It shows a user logged in as RUBY from Pleasant Valley Hospital (ID 10312). A dropdown menu for "Summary Data Type" is set to "Hemovigilance Monthly Reporting Denominators". At the bottom of the form are "Continue" and "Back" buttons. On the left side, there is a navigation menu with options: "NHSN Home", "Reporting Plan", "Patient", "Incident", "Reaction", "Summary Data" (which is expanded to show "Add" and "Find" options), and "Analysis".

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Monthly Reporting Denominators. At the end of each reporting month be sure to enter your monthly denominators. Select Summary Data on the left navigation bar and Hemovigilance Monthly Reporting Denominators as your Summary Data Type.



Monthly Reporting Denominators

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

NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1)
| [NHSN Home](#) | [My Info](#) | [Contact us](#) | [Help](#) | [Log Out](#)

NHSN Home

Reporting Plan

Patient

Incident

Reaction

Summary Data

▢ Add

▢ Find

Analysis

Surveys

Users

Facility

Group

Log Out

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

Hemovigilance Module Monthly Reporting Denominators

[Print PDF Form](#)

Mandatory fields marked with *

* **Facility ID:** 10312 (Pleasant Valley Hospital)

* **Month:**

* **Year:**

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

These are total products in specific categories that have been transfused for the month. Please refer to the Tables of Instructions for details of how to complete each field. Except for the "Total" fields, other categories are mutually exclusive. We are not collecting denominators for every type of product (for example, there is no category for "Whole Blood"). These denominators will be used to calculate rates of adverse reactions or incidents so you will want to be sure they are accurate. The Hemovigilance Annual Facility Survey provides additional information that may be used in analysis.



Custom Fields and Labels



- Facilities have the option of creating custom fields
 - 2 date fields
 - 2 numeric fields
 - 10 alphanumeric
- Comments can be entered but information cannot be used in analysis

The screenshot shows a form titled "Hemovigilance Incident" with the NHSN logo on the top left and OMB No. 0920-0566 and Exp. Date: 10-01-2013 on the top right. The form is divided into two main sections: "Custom Fields" and "Comments".

Custom Fields

Label		Label	
_____	___/___/___	_____	___/___/___
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Comments

Custom Fields and Labels. Facilities have the option of creating custom fields if they are interested in collecting additional information not contained on our forms. Two date fields, 2 numeric fields, and 10 alphanumeric fields can be set up. Information in these fields is not used in aggregate analysis but is for individual facility use.



Custom Fields

Custom Field Labels

1. To label custom fields for any existing form, select the Form Type and Form from the drop down lists.
2. If one of the Summary Data forms is selected, it may be customized by location by selecting a value from the Your Location Code drop down list.
3. Enter labels for any custom fields you wish to have displayed on the screen.

Form Type*:

Form*:

Description*:

Status*: Active

Date

Label 1: Label 2:

Numeric

Label 1: Label 2:

Alphanumeric

Label 1: Label 2:

To set up custom fields in NHSN select Facility – Customize forms on the left navigation bar. Follow the instructions on the screen. You can create custom fields for the Incident form, Adverse Reaction form, and Monthly Denominator forms in Hemovigilance.



Let's Review!



- Incident reporting in NHSN provides a means to capture, track, and trend errors to:
 - Measure success of process improvement initiatives
 - Compare your facility performance with other facilities
- Enter a Monthly Reporting Plan prior to any month you intend to enter data
- High priority incidents are indicated by a (+) sign and require a complete Incident form
- Other incidents can be reported using the Blood Product Incidents Reporting - Summary Data form
- Any incident resulting in an adverse reaction of a patient requires a complete Incident form
- Any incident where product reaches the patient requires a complete Incident form regardless of whether the patient experienced an adverse reaction.

Let's briefly review what we've learned in this session. Incident reporting in NHSN provides a means to capture, track, and trend errors in order to measure the success of process improvement initiatives and compare your facility performance with other facilities. Be sure to enter a Monthly Reporting Plan prior to reporting any data for the month. High priority incidents are indicated by a plus sign on the Blood Product Incidents Reporting – Summary Data form and require a complete Incident form. Other incidents can be reported as summary information except that any incident resulting in an adverse reaction of a patient requires a complete Incident form. And, any incident where product reaches the patient requires a complete Incident form regardless of whether the patient experienced a reaction or not.



Acknowledgements



- Incident process codes are based on MERS-TM (Medical Event Reporting System for Transfusion Medicine – Columbia University) and TESS (Transfusion Error Surveillance System – Public Health Agency of Canada)
- Thank you to Helen Downie, MLT (Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada) for providing the background material on error reporting and case examples for this training.

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Our Incident process codes are based on those used in the Medical Event Reporting System for Transfusion Medicine or MERS-TM and the Transfusion Error Surveillance System or TESS. A special thank-you to Helen Downie of Sunnybrook Health Sciences Centre, Ontario, Canada for providing the background material and case examples used in this training. While the case examples are real, the names of the individuals involved have been changed.



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Questions or Need Help? Contact User Support



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That concludes our training on Incident reporting. If you have questions or need help please contact NHSN User Support at NHSN@cdc.gov.