

National Healthcare Safety Network Hemovigilance Module Progress Report, 2010-2011

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Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

International Hemovigilance Network
XIV International Hemovigilance Seminar
Montreal, Canada
April 26, 2012



Objectives

- ❑ **Describe the National Healthcare Safety Network (NHSN)**
- ❑ **Describe the NHSN Hemovigilance (HV) Module**
- ❑ **Describe NHSN HV Module enrollment and data reported in 2010-2011**
- ❑ **Outline needs for continued growth and improvement**



The National Healthcare Safety Network (NHSN) is a secure, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion (DHQP) at CDC.

NHSN Structure

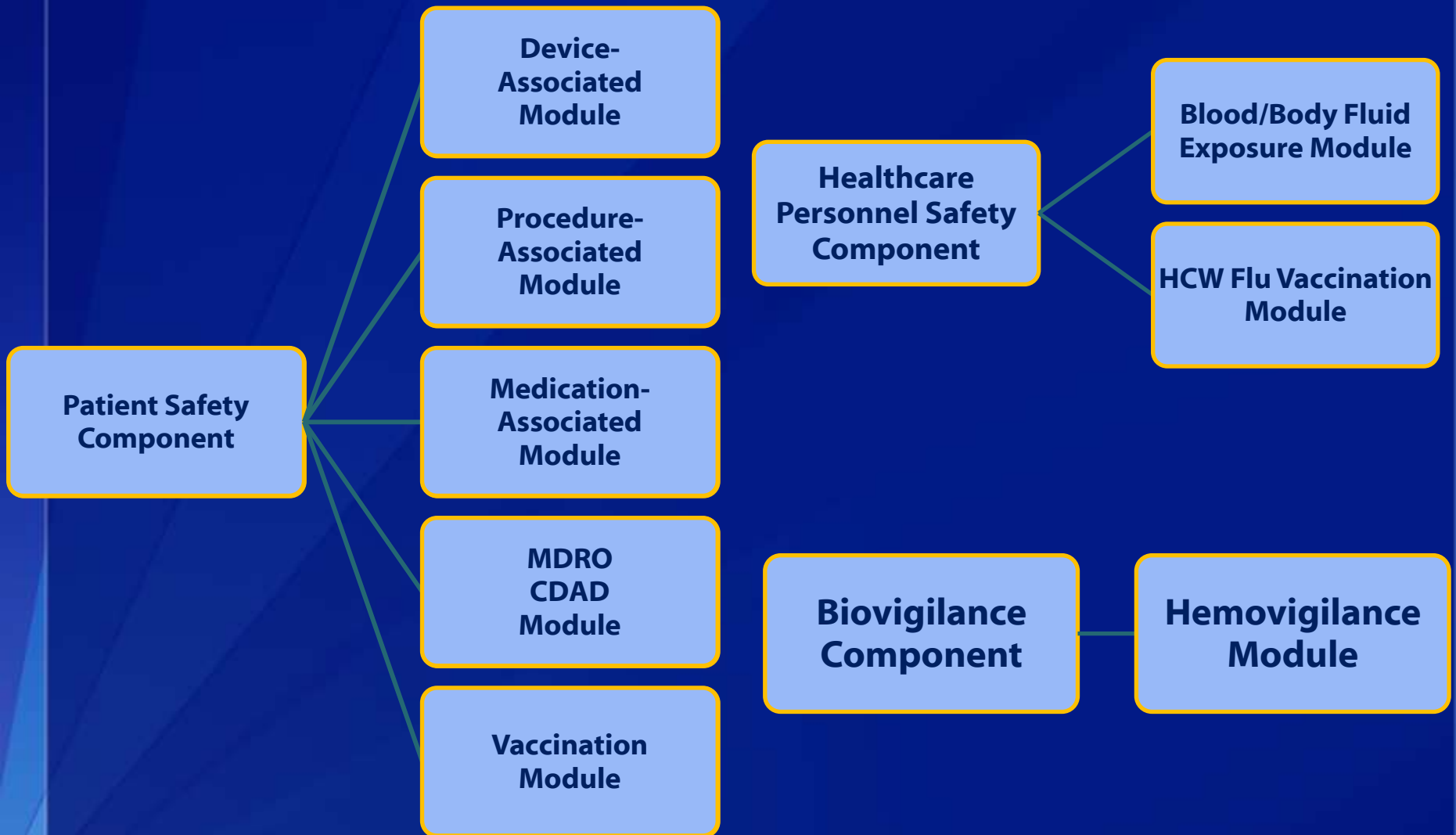


**Patient Safety
Component**

**Healthcare
Personnel
Safety
Component**

**Biovigilance
Component**

NHSN Structure



Hemovigilance Module Data Collection

❑ Participation minimum: 12 months consecutive data

❑ Required Data Collection

- Annual Facility Survey
- Monthly Reporting Plan
- Adverse Events
 - Adverse Reactions
 - Incidents (errors, accidents)
- Monthly Denominators

❑ Protocol, forms, instructions:
www.cdc.gov/nhsn/bio.html



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A-Z Index [A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#) <#>

National Healthcare Safety Network (NHSN)

NHSN

- About NHSN
- Communication Updates
- Enrollment Requirements
- Patient Safety Component
- Healthcare Personnel Safety Component
- Biovigilance Component**
- Data Collection Forms
- NHSN Training
- Data & Statistics
- Resource Library
- Contact NHSN

[NHSN](#)

Biovigilance Component

The Biovigilance Component of the National Healthcare Safety Network is a public/private collaboration between CDC and the transfusion and transplant communities. Biovigilance includes collection of adverse event data to improve outcomes in the use of blood products, organs, tissues, and cellular therapies.

The **Hemovigilance Module** is the first part of the new Biovigilance Component to be developed in NHSN. The result of a unique public-private partnership between CDC and subject matter experts convened by AABB, this module is designed for staff in healthcare facility transfusion services to track adverse events, including recipient adverse reactions and quality control incidents, related to blood transfusion. Adverse reactions and incidents related to blood transfusion that occur in healthcare can be reported by participating facilities now that standard definitions and criteria for categorizing and reporting adverse reactions and incidents have been developed. Participating facilities will be able to analyze their own data, and, where appropriate, independently compare their data with national aggregate rates in a confidential manner through NHSN.

The NHSN Hemovigilance Module Protocol and Tables of Instructions are provided for your information. This module is being piloted in nine facilities across the United States. Open enrollment for all facilities is planned soon. See topics: [About NHSN](#) and [NHSN Enrollment](#) for details and requirements of enrollment.

Corresponding Materials

Protocol and Instructions



[NHSN Manual: Biovigilance Component Protocol Hemovigilance Module](#)

Guidelines and procedures for monitoring hemovigilance. March 2009. PDF (523 KB / 32 pages)



[Hemovigilance Module Tables of Instructions](#) Feb. 2009 PDF (279 KB / 19 pages)

Training

[Hemovigilance Module Overview](#)

Audience: All NHSN users including Facility Administrators and Group Administrators.

[Enrollment for Facility New to NHSN](#)

Audience: Facility Administrators and Group Administrators.

[Enrolling an Existing NHSN Facility into Biovigilance and Facility Set up](#)

Audience: Facility Administrators and Group Administrators.

On This Page

- [Protocol and Instructions](#)
- [Training](#)

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Centers for Disease Control and Prevention
National Healthcare Safety Network
MS-A24
1600 Clifton Rd
Atlanta, GA 30333



nhsn@cdc.gov

[More contact info »](#)

FAQs About...

- Enrollment
- Security
- Digital Certificates
- Training
- Protocols
- Mandatory Reporting
- HIPAA Privacy Rule

Hemovigilance Module Surveillance Protocol

- ❑ Surveillance methodology, reporting instructions, and case definitions are found in the Hemovigilance Module Protocol.
- ❑ www.cdc.gov/nhsn/bio.html



**The National Healthcare Safety Network
(NHSN) Manual**


Biovigilance Component

**Protocol
Hemovigilance Module**

Hemovigilance Module Annual Facility Survey

- ❑ Used to categorize facilities for appropriate comparisons in aggregate analyses.
- ❑ The **Annual Facility Survey** must be entered before any other data can be entered.
- ❑ An **Annual Facility Survey** is required each year.

OMB No. 0920-0666
Exp. Date: 09-30-2012

 **NHSN**
National Healthcare
Safety Network

**Hemovigilance Module
Annual Facility Survey**

*Required fields

*Tracking # / Facility ID: _____ *Survey Year: _____

Facility Characteristics: (For all questions use past full calendar year annual statistics)

*1. Ownership: (Check one)


☐ For profit ☐ Government ☐ Military ☐ Not for profit, including church
☐ Veteran's Affairs ☐ Physician-owned ☐ Managed Care Organization

*2. Is your hospital affiliated with a medical school? ☐ Yes ☐ No

If yes, type of affiliation: ☐ Major ☐ Graduate ☐ Limited

Hemovigilance Module Monthly Reporting Plan

- ❑ Used to communicate to CDC/NHSN monthly participation and method of Incident reporting.
- ❑ Must be entered before monthly data may be entered.

 **Hemovigilance Module
Monthly Reporting Plan**

CDC No. 1002-0001
GHT, June 09-30 2009

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

Hemovigilance Module

Adverse Reactions



- ☐ Allergic reaction
- ☐ Acute hemolytic transfusion reaction (AHTR)
- ☐ Delayed hemolytic transfusion reaction (DHTR)
- ☐ Delayed serologic transfusion reaction (DSTR)
- ☐ Hypotensive transfusion reaction
- ☐ Febrile non hemolytic transfusion reaction (FNHTR)
- ☐ Post transfusion purpura (PTP)
- ☐ Transfusion associated circulatory overload (TACO)
- ☐ Transfusion associated dyspnea (TAD)
- ☐ Transfusion associated graft vs. host disease (TA-GVHD)
- ☐ Transfusion-related acute lung injury (TRALI)
- ☐ Infection

Adverse Reaction Case Definition Criteria

Transfusion-related acute lung injury (TRALI): Acute hypoxemia with PaO₂/fraction of inspired oxygen [FIO₂] ratio of 300 mm Hg or less combined and chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e., circulatory overload). Onset of TRALI is abrupt in association with transfusion.


Case Definition Criteria		Severity	Imputability
Signs/Symptoms	Laboratory/Radiology		
<p>Definitive: NO evidence of acute lung injury (ALI) prior to transfusion AND ALI onset during or within 6 hours of transfusion AND Hypoxemia defined by any of these methods:</p> <ul style="list-style-type: none"> • PaO₂ / FiO₂ ≤ 300 mm Hg • Oxygen saturation is < 90% on room air • Other clinical evidence <p>AND No evidence of left atrial hypertension (i.e. circulatory overload) AND No temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion.</p>	<p>Definitive: Bilateral infiltrates on chest radiograph</p> <p>Probable: N/A</p> <p>Possible: N/A</p>	<p>Use severity grades as defined in Appendix C.</p>	<p>Definite: Meets definitive case definition criterion.</p> <p>Probable: N/A</p> <p>Possible: Meets possible case definition criterion.</p>

http://www.cdc.gov/nhsn/PDFs/hemovigModuleProtocol_current.pdf

Hemovigilance Module Adverse Reaction Form

- Used to report all **definite, probable, or possible** transfusion-related adverse reactions according to NHSN case definitions.

OMB No. 0920-0666
Exp. Date: 09-30-2012


 **Hemovigilance Adverse Reaction**

* Required Field

Facility ID #: _____	Adverse Reaction #: _____
Patient Information	
*Patient ID: _____ *Gender: <input type="checkbox"/> M <input type="checkbox"/> F *Date of birth: ____/____/____	
*Patient's blood group: <input type="checkbox"/> A+ <input type="checkbox"/> A- <input type="checkbox"/> B+ <input type="checkbox"/> B- <input type="checkbox"/> O+ <input type="checkbox"/> O- <input type="checkbox"/> AB+ <input type="checkbox"/> AB- <input type="checkbox"/> Type and crossmatch not done	
*Primary underlying cause for transfusion: _____ <input type="checkbox"/> Unknown	
Reaction Details	
*Date reaction occurred: ____/____/____	*Facility location where reaction occurred: _____
*Time reaction occurred: ____:____ (HH:MM) OR Time unknown <input type="checkbox"/> _____	

Hemovigilance Module

Adverse Reaction Reporting

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

NHSN - National Healthcare Safety Network

| NHSN Home |

NHSN Home
Reporting Plan
Patient
Incident
Reaction
Add
Find
Summary Data
Analysis
Surveys
Log Out

Logged into NHSN Harvey Test Memorial (ID 15709) as BARBEE.
Facility NHSN Harvey Test Memorial (ID 15709) is following the BV component.

Add Adverse Reaction

Mandatory fields marked with *

Conditionally required fields marked with ^

Patient Information

*Facility ID: NHSN Harvey Test Memorial (ID 15709) Adverse Reaction #:

*Patient ID: Find Find Reactions for Patient

Social Security #: Secondary ID:

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 cause for transfusion: Unknown

Hemovigilance Module

Adverse Reaction Reporting



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[NHSN Home](#)

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

Reaction Details

*Date reaction occurred: 
*Time reaction occurred: : (HH:MM) ☐ Time unknown
*Facility location where reaction occurred:

[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

☐ Pruritis

☐ 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

Hemovigilance Module Adverse Reaction Reporting



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NHSN Home

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

Component Details

*Transfusion Date / Time MM/DD/YYYY HH:MM	*Component code (check system used) <input type="radio"/> ISBT-128 <input type="radio"/> Codabar	*# of units	*Unit number <i>Required for TRALI, GVHD, Infection</i>	*Unit expiration Date / Time MM/DD/YYYY HH:MM	*Blood group of unit	Implicated in the adverse reaction?
<div>  </div>			Facility <input type="text"/> Year <input type="text"/> Sequence <input type="text"/> Vertical Digits <input type="text"/> Checksum Char <input type="text"/> <input type="text"/>	<div>  </div>	<input type="text"/>	<input type="checkbox"/>

Investigation Results (Use case definition criteria in protocol.)

*Was a particular unit implicated in the adverse reaction?

*Adverse reaction:

*Case definition criteria:

*Severity:

*Imputability:

Outcome

*Outcome:

Hemovigilance Module

Incidents

❑ Transfusion Service

- Product Check-In
- Sample Receipt
- Sample Testing
- Product Storage
- Available for Issue
- Product Selection
- Product Manipulation
- Product Issue
- Other



❑ Clinical Service

- Product/Test Request
- Sample Collection
- Sample Handling
- Request for Pick-up
- Product Administration
- Other



Hemovigilance Module

Incidents

**Sample Collection –
Blood drawn from patient for type
and 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

Incident Codes



NHSN Biovigilance Component
Protocol v1.3.1
www.cdc.gov/nhsn

Appendix F. NHSN Incident Codes (Based on MERS-TM & TESS)


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 and paperwork do not match PC 04 Shipped under inappropriate conditions PC 05 Inappropriate return to inventory PC 06 Product confirmation PC 07 Administrative check (2 nd check) Product/Test Request (Clinical Service) PR 00 Detail not specified PR 01 Order for wrong patient PR 02 Order incorrectly entered online +PR 03 Special needs not indicated on order (e.g., CMV negative, auto) PR 04 Order not done/incomplete/incorrect PR 05 Inappropriate/incorrect test ordered PR 06 Inappropriate/incorrect blood product ordered Sample Collection SC 00 Detail not specified +SC 01 Sample labeled with incorrect patient name +SC 02 Not labeled	Sample Testing (Transfusion Service) ST 00 Detail not specified ST 01 Data entry incorrect/not performed ST 02 Appropriate sample checks not done +ST 03 Computer warning overridden ST 05 Sample tube w/incorrect accession label +ST 07 Sample tubes mixed up +ST 09 Test tubes mislabeled (wrong patient name/number) ST 10 Equipment problem ST 12 Patient testing not performed ST 13 Incorrect testing method chosen ST 14 Testing performed incorrectly ST 15 Test result misinterpreted ST 16 Inappropriate/expired reagents used ST 17 ABO/Rh error caught on final check ST 18 Current and historical ABO/Rh don't match ST 19 Additional testing not performed ST 20 Administrative check at time work performed ST 22 Sample storage incorrect/inappropriate Product Storage (Transfusion Service) US 00 Detail not specified US 01 Incorrect storage of unit in transfusion service US 02 Expired product in stock US 03 Inappropriate monitoring/storage device	Request for Pick-up (Clinical Service) RP 00 Detail not specified RP 01 Request for pick-up on wrong patient RP 02 Incorrect product requested for pick-up RP 03 Product requested prior to obtaining consent RP 04 Product requested for pick-up patient not available RP 05 Product requested for pick-up IV not ready RP 06 Request for pick-up incomplete RP 10 Product transport issue Product Issue (Transfusion Service) UI 00 Detail not specified UI 01 Data entry incomplete/incorrect UI 02 Record review incomplete/incorrect UI 03 Pick-up slip did not match patient information UI 04 Incorrect unit selected (wrong person or right person, wrong order) UI 05 Product issue delayed +UI 06 LIS warning overridden UI 07 Computer issue not completed UI 09 Not/incorrect checking of unit and/or patient information
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Hemovigilance Module

Detailed Incident Form

❑ Detailed reporting of **ALL** Incidents

- Recommended for facilities that do not electronically track or report incidents by some other method.
- This method provides the most usable data for targeted process improvements.

 Hemovigilance Incident		CMB No. 0920-0668 Exp. Date: 09-30-2012
<small>* Required for saving</small>		
Facility ID #: _____	Incident #: _____ [system generated] Local Incident # or Log #: _____	
Discovery		
*Date of discovery: ____/____/____ *Time of discovery: ____:____ (HH:MM) <input type="checkbox"/> Time approximate <input type="checkbox"/> Time unknown		*Where in the facility was the incident discovered? _____
*How was the incident first discovered? (Check one) <input type="checkbox"/> Communication from lab to floor <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"/> Computer system alarm or warning <input type="checkbox"/> Historical record/previous type check <input type="checkbox"/> Human 'lucky catch' <input type="checkbox"/> Notification or complaint from floor (nurse, MD, etc.)		

Hemovigilance Module

Detailed Incident Data Reporting

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Centers for Disease Control and Prevention

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NHSN Home
Reporting Plan
Patient
Incident
Add
Find
Reaction
Summary Data
Analysis
Surveys
Users
Facility
Group
Log Out

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

Add Incident

Mandatory fields marked with *
Conditionally required fields marked with ^

*Facility ID: Pleasant Valley Hospital (ID 10312) 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?
Job function of the worker involved in the incident: ☐ Worker unknown
*At what point in the process did the incident first occur?
*Incident code:

Hemovigilance Module Summary Incident Form

- ❑ **Monthly Incident Summary PLUS** detailed reporting of:
 - High priority incidents
 - Any incident associated with an adverse reaction

 **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		
	PC 07 Administrative check (2 nd check)		
PR - Product/Test Request (Clinical Service)	PR 00 Detail not specified	4	2
	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)	4	0
	PR 04 Order not done/incomplete/incorrect		

Hemovigilance Module

Summary Incident Data Reporting



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[Patient](#)

[Incident](#)

[Reaction](#)

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[Users](#)

[Facility](#)

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[Log Out](#)

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

View Monthly Incident Summary

☒ Save of Summary Data successful.

Mandatory fields marked with *

[Print PDF Form](#)

*Facility ID: 10312 (Pleasant Valley Hospital)

*Month: February

*Year: 2009

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

*Process code	*Incident code	*Total Incidents	*Total Adverse Reactions associated with Incidents
PC: Product check-in	PC 01 - Data entry incomplete/not performed/incorrect	20	10
SE: Product selection	SE 11 - Special processing not done	1	1
UT: Product administration	UT 19 - Transfusion protocol not followed	3	1
Total		24	12

Edit


Delete

Back

Hemovigilance Module

Monthly Denominators

- ❑ Total units and/or aliquots of blood products transfused
- ❑ Total patient samples collected for type and cross match



Hemovigilance Module Monthly Reporting Denominators

Facility ID # _____ Month: ____ Year: ____

* Indicates required fields

			*Units Transfused	*Aliquots Transfused
Red blood cells	Whole blood derived	TOTAL		
		Irradiated		
		Leukocyte reduced		
		Irradiated & leukocyte reduced		
	Apheresis	TOTAL		
		Irradiated		
		Leukocyte reduced		
		Irradiated & leukocyte		

Hemovigilance Module Analysis

□ Analysis output options available in NHSN

- Reports are “canned” with pre-defined variables but can be modified by the user

The screenshot displays the NHSN (National Healthcare Safety Network) interface. The top header includes the CDC logo and the text "Department of Health and Human Services Centers for Disease Control and Prevention". Below this, a navigation bar shows "NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1)" and links for "NHSN Home" and "My". The left sidebar contains a menu with items: "NHSN Home", "Reporting Plan", "Patient", "Incident", "Reaction", "Summary Data", "Analysis", "Surveys", "Users", "Facility", "Group", and "Log Out". The "Analysis" menu item is highlighted, and a red arrow points from it to the "Expand All" button on the main page. The main content area is titled "Biovigilance Component Analysis Output Options". It features two buttons, "Expand All" and "Collapse All", and a tree view structure. The tree view shows a folder named "Hemovigilance Module" which contains a sub-folder "HV Adverse Reaction Data". Under "HV Adverse Reaction Data" is a folder "CDC Defined Output". Below this folder is a list of analysis options, each with a "Run" and "Modify" button. The analysis options are: "Line Listing - All Adverse Reaction Data", "Frequency Table - All Adverse Reaction Data", "Bar Chart - All Adverse Reaction Data", and "Pie Chart - All Adverse Reaction Data". A red oval highlights the "Hemovigilance Module" section, including the "HV Adverse Reaction Data" folder and the list of analysis options.

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

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

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

Biovigilance Component
Analysis Output Options

Expand All Collapse All

Hemovigilance Module

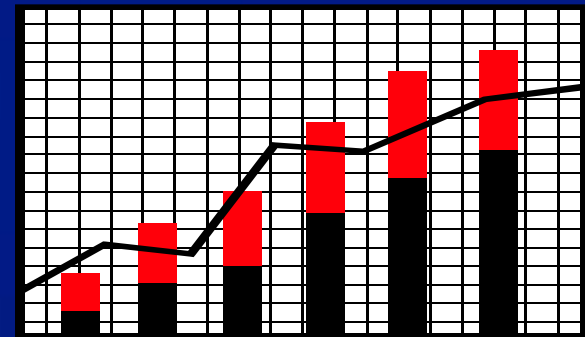
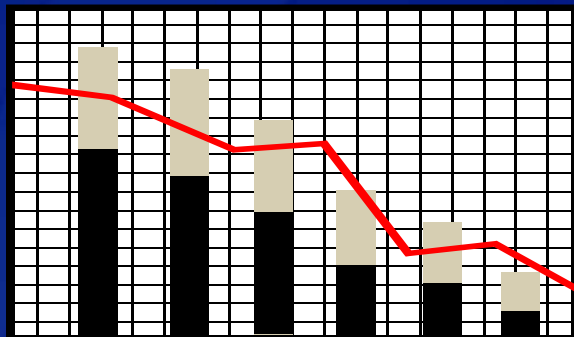
HV Adverse Reaction Data

CDC Defined Output

Line Listing - All Adverse Reaction Data	Run	Modify
Frequency Table - All Adverse Reaction Data	Run	Modify
Bar Chart - All Adverse Reaction Data	Run	Modify
Pie Chart - All Adverse Reaction Data	Run	Modify

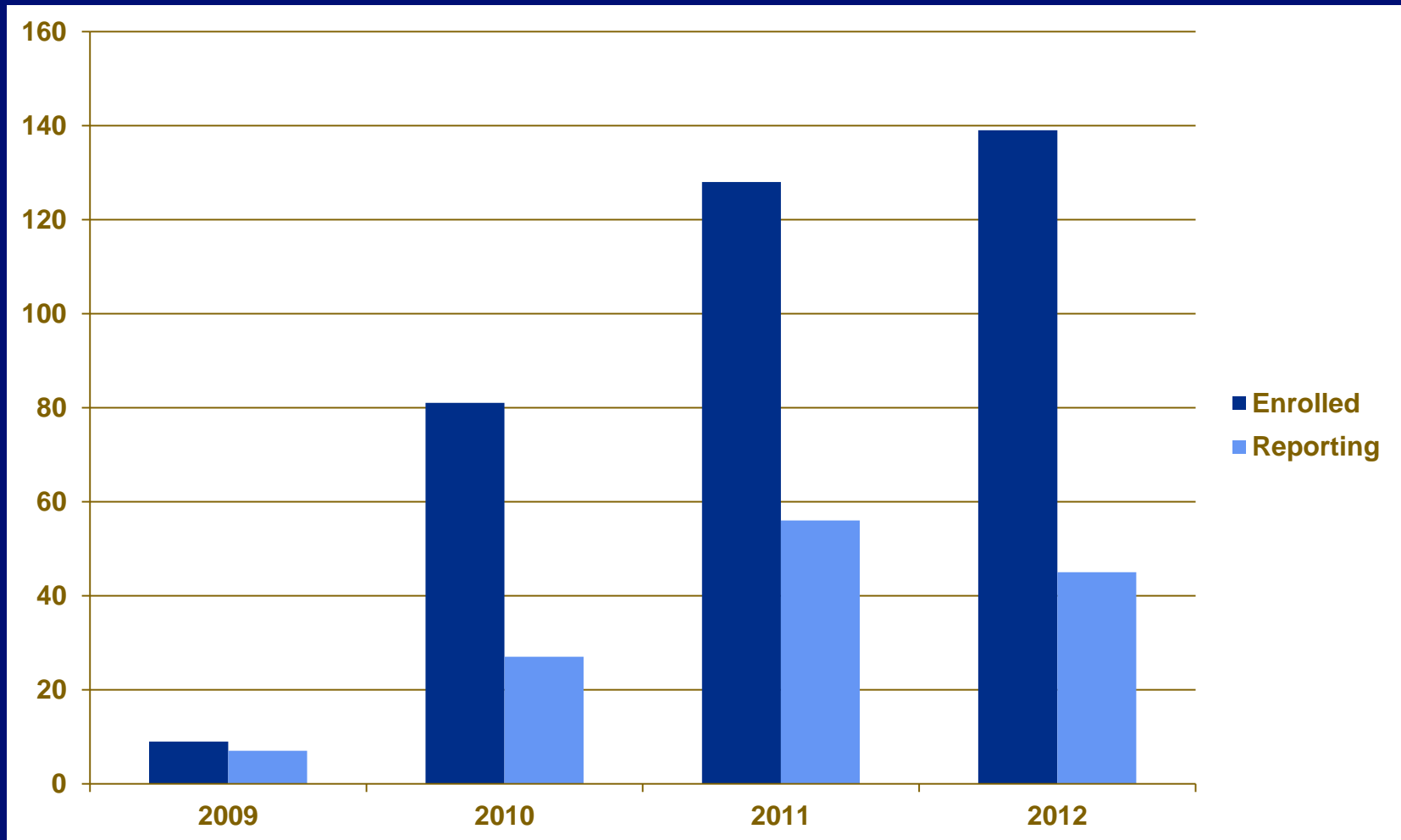
Hemovigilance Module Data Analysis

- ❑ Facilities can analyze their data as soon as it is entered
- ❑ Benchmarking capabilities are planned but will not be available until adequate data has been entered for CDC to publish a Public Health Report of aggregate data



NHSN Hemovigilance Module

Facility Enrollment vs. Reporting



Facility Characteristics, n=56

NHSN HV Module Progress Report, 2010-2011

Characteristic	Minimum	Maximum	Median
Beds Served by Txn Svcs	10	1,051	365
Surgeries	991	52,000	12,854
Samples Collected	287	90,378	14,033
Transfusion Service FTEs	0	42	8
Blood Products Transfused			
• Red Blood Cells	169	45,579	7,315
• Platelets	4	19,867	1,040
• Plasma	2	16,593	2,169
• Cryoprecipitate	0	6,166	276

Adverse Reactions, n=58

NHSN HV Module Progress Report, 2010-2011

Reaction	Reported	Percent
Allergic	1256	50.7%
Febrile Non-Hemolytic	829	33.5%
Acute Hemolytic	10	0.4%
Delayed Hemolytic	55	2.2%
Delayed Serologic	132	5.3%
Circulatory Overload	89	3.6%
Hypotensive	62	2.5%
Acute Lung Injury	18	0.7%
Dyspnea	17	0.7%
Infection	7	0.3%
Total	2475	100%

Adverse Reactions, n=58

NHSN HV Module Progress Report, 2010-2011

Reaction	Reported	% of Total	Severe	% Severe
Allergic	1256	50.7%	92	7.3%
Febrile Non-Hemolytic	829	33.5%	7	0.8%
Acute Hemolytic	10	0.4%	3	30.0%
Delayed Hemolytic	55	2.2%	11	20.0%
Delayed Serologic	132	5.3%	2	1.5%
Circulatory Overload	89	3.6%	32	36.0%
Hypotensive	62	2.5%	13	21.0%
Acute Lung Injury	18	0.7%	16	88.9%
Dyspnea	17	0.7%	7	41.2%
Infection	7	0.3%	6	85.7%
Total	2475	100%	189	7.6%

Adverse Reactions, n=58

NHSN HV Module Progress Report, 2010-2011

Reaction	Reported	% of Total	Severe	% Severe
Allergic	1256	50.7%	92	7.3%
Febrile Non-Hemolytic	829	33.5%	7	0.8%
Acute Hemolytic	10	0.4%	3	30.0%
Delayed Hemolytic	55	2.2%	11	20.0%
Delayed Serologic	132	5.3%	2	1.5%
Circulatory Overload	89	3.6%	32	36.0%
Hypotensive	62	2.5%	13	21.0%
Acute Lung Injury	18	0.7%	16	88.9%
Dyspnea	17	0.7%	7	41.2%
Infection	7	0.3%	6	85.7%
Total	2475	100%	189	7.6%

Incidents, n=33

NHSN HV Module Progress Report, 2010-2011

Process Code	Reported	Percent
Product Check-In	251	1.6%
Product/Test Request	439	2.9%
Sample Collection	4,766	31.3%
Sample Handling	4,928	32.3%
Sample Receipt	179	1.2%
Sample Testing	711	4.7%
Product Storage	266	1.7%
Available for Issue	67	0.4%
Product Selection	156	1.0%
Product Manipulation	198	1.3%
Pick-Up Request	475	3.1%
Product Issue	354	2.3%
Product Administration	2,051	13.5%
Miscellaneous	405	2.7%
Total	15,246	100.0%

Incidents, n=33

NHSN HV Module Progress Report, 2010-2011

Process Code	Reported	Percent
Product Check-In	251	1.6%
Product/Test Request	439	2.9%
Sample Collection	4,766	31.3%
Sample Handling	4,928	32.3%
Sample Receipt	179	1.2%
Sample Testing	711	4.7%
Product Storage	266	1.7%
Available for Issue	67	0.4%
Product Selection	156	1.0%
Product Manipulation	198	1.3%
Pick-Up Request	475	3.1%
Product Issue	354	2.3%
Product Administration	2,051	13.5%
Miscellaneous	405	2.7%
Total	15,246	100.0%

Denominators, n=53

NHSN HV Module Progress Report, 2010-2011

Product Type	Units Transfused	Percent
Red Blood Cells, whole blood derived	513,687	54.5%
Red Blood Cells, apheresis	45,240	4.8%
Platelets, whole blood derived	21,683	2.3%
Platelets, apheresis	130,310	13.8%
Plasma, whole blood derived	169,976	18.0%
Plasma, apheresis	11,255	1.2%
Cryoprecipitate	50,491	5.4%
Total	942,642	100.0%
Samples collected for type and screen/crossmatch	1,025,375	

Conclusions

- ❑ **Most commonly reported reactions are allergic and FNHTRs, which tend to be non-severe.**
- ❑ **Less commonly reported reactions are AHTR, TAD, TRALI and TTI, which tend to be severe when reported, especially TRALI and TTI.**
- ❑ **Most commonly reported incidents are in the sample collection/handling and product administration processes.**

Conclusions

- ❑ Enrollment is growing at a steady pace.
- ❑ Data reporting is incomplete and inconsistent.
- ❑ Increased education and outreach is necessary to improve data quality.
- ❑ Increased participation and data quality are needed before valid rates can be calculated and benchmarking can be added to the HV Module.



Future NHSN Developments

❑ **Clinical Document Architecture (CDA) for Biovigilance**

- Electronic data capture from vendor software in development.
- Pilot scheduled for second half of 2011.

❑ **Analysis Options for the Biovigilance Component**

- Incorporating transfusion denominators to calculate rates.
- Blood component usage reports.
- Incident summaries by month to permit trend analyses.

❑ **Comparing data to facilities of similar characteristics**

- After CDC publishes aggregate data analysis.
- Incorporating published data into NHSN to permit benchmarking.



Potential Needs for NHSN HV Module Growth and Success

□ Simplify reporting requirements?

- No longer require minor allergic reactions?
- Make incident reporting optional?
- Fewer adverse reaction classification categories?
- Require a subset of incidents to be reported (e.g. WBIT, IBCT)?

□ Reporting interoperability?

- BPDR and fatality reporting to FDA?
- Sentinel reporting to The Joint Commission?
- Adverse event reporting to blood suppliers?
- State-mandated blood safety reporting?



Potential Needs for NHSN HV Module Growth and Success

□ Stay the Course?

- Focus more on recruitment?
- Increase education and training?
- Incentivize reporting?

We built it...will they come?

Acknowledgments

- ❑ **AABB Staff**
- ❑ **AABB Recipient Hemovigilance Working Group**
- ❑ **USBVN Interorganizational Task Force on Biovigilance**
- ❑ **CDC Division of Healthcare Quality Promotion**
- ❑ **NHSN Participants!**

Contact Us!

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