



Biovigilance Component Hemovigilance Module Surveillance Requirements and Data Reporting



Objectives

- ❑ **Review the Biovigilance Component Surveillance Protocol.**
- ❑ **Describe the surveillance requirements for the Hemovigilance Module.**
- ❑ **Describe data reporting forms**
 - ❑ Annual Facility Survey
 - ❑ Monthly Reporting Plan
 - ❑ Adverse Reaction
 - ❑ Incident
 - ❑ Monthly Incident Summary (optional)
 - ❑ Monthly Reporting Denominators

The NHSN Biovigilance Component Website

www.cdc.gov/nhsn/bio.html

CDC Home
Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

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National Healthcare Safety Network (NHSN)

NHSN

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Biovigilance Component

The Biovigilance Component of the National Healthcare Safety Network is available for enrollment by healthcare facilities in the United States. Biovigilance includes the 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 release of the Biovigilance Component of NHSN, and was developed through a public-private partnership between CDC and subject matter experts convened by AABB. The Hemovigilance Module is designed for transfusion services staff in healthcare facilities to monitor recipient adverse reactions and quality control incidents related to blood transfusion.

On This Page

- [Important Points Regarding NHSN Enrollment](#)
- [Protocols and Instructions](#)
- [Training](#)
- [Forms and Instructions](#)
- [Quick Reference Guides](#)

The NHSN Biovigilance Component Website

- ❑ **The website is a facilities source for:**
 - The Hemovigilance Module Surveillance Protocol
 - Self-paced Training Materials
 - Forms and Instructions
 - Quick Reference Guides

- ❑ **Facilities should save this website as a favorite in their web browser.**

Hemovigilance Module Protocol



NHSN Biovigilance Component
Hemovigilance Module Surveillance Protocol v2.0
www.cdc.gov/nhsn

National Healthcare Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol

Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Atlanta, GA, USA

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January 2013





Hemovigilance Module Surveillance Protocol

- ❑ **The protocol is a facility's guide to conducting surveillance.**
- ❑ **It provides information about the National Healthcare Safety Network (NHSN) and the Biovigilance Component.**
- ❑ **It outlines the surveillance methodology for the Module.**
 - Key terms
 - Case definitions/criteria
 - Incident codes
 - Data collection forms and instructions

Hemovigilance Module Surveillance Requirements

- ❑ **At least 12 months of continuous data must be reported.**
 - Not necessarily January through December
- ❑ **The Annual Facility Survey must be entered every calendar year.**
- ❑ **ALL transfusion-associated adverse reactions that meet the NHSN case definitions must be reported each month.**
- ❑ **ALL incidents associated with a reported adverse reaction must be reported each month.**
- ❑ **Blood products transfused and samples collected for type and screen or crossmatch must be reported each month.**

Hemovigilance Module Annual Facility Survey

- ❑ **Facilities must complete the survey at enrollment in NHSN or after activation of the Biovigilance Component.**
 - Must also be completed at the beginning of each subsequent calendar year
- ❑ **The data collected on the survey is used by CDC to classify facilities for comparisons in aggregate data analysis.**
- ❑ **The survey includes data from the previous calendar year.**
 - For example, if a facility enrolls in NHSN or activates the Biovigilance Component in Oct 2011, the survey must be completed using data from Jan 2010 – Dec 2010.
- ❑ **Detailed instructions on completing the form are provided on the website.**

Hemovigilance Module Annual Facility Survey

- ❑ Facilities should print and complete the form before entering the information into NHSN.
- ❑ From the home page, select “Survey” on the left-hand navigation bar and click “Add.”

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

NHSN - National Healthcare Safety Network (apt-v-nhsn-test:8081) | NHSN Home

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

NHSN Biovigilance Component Home Page

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

Action items

You must complete these items.

- A survey is required for [2012](#)

Alerts

- You have [3](#) missing incidents
- You have [7](#) missing adverse reactions

Hemovigilance Module Annual Facility Survey



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[NHSN Home](#)

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Add Annual Facility Survey

Mandatory fields marked with *

[HELP](#)

*Facility ID:

*Survey year:

For all questions, use information from previous full calendar year.

Facility Characteristics [HELP](#)

1. *Ownership:

2. *Is your hospital a teaching hospital for physicians and/or physicians-in-training?

If Yes, check type: MAJOR GRADUATE UNDER GRADUATE

3. Community setting of facility:

4. *How is your hospital accredited?

5. *Total beds served by Transfusion Services:



Hemovigilance Module Monthly Reporting Plan

- ❑ **Monthly Reporting Plans must be entered each month before data can be entered for that month.**
- ❑ **Facilities must select “Detailed reporting of all incidents” as the method for reporting incidents to meet the 2013 protocol requirements.**
 - This will reduce the alerts on the Biovigilance Component home page.
- ❑ **Only add Monthly Reporting Plans for months in which surveillance is being conducted.**

Hemovigilance Module Monthly Reporting Plan

- From the home page, select "Reporting Plan" on the left-hand navigation bar and click "Add."

The screenshot shows the NHSN Biovigilance Component Home page. The top header includes the CDC logo and the text "Department of Health and Human Services Centers for Disease Control and Prevention". Below this, the page is titled "NHSN - National Healthcare Safety Network (apt-v-nhsn-test:8081)". The user is logged in as KOO from Pleasant Valley Hospital (ID 10312). The left navigation bar lists various options, with "Reporting Plan" highlighted in a red box and "Add" visible below it. The main content area displays "NHSN Biovigilance Component Home" and a message: "Use the Navigation bar on the left to access the features of the application." Below this, there is a section for "Action items" with a blue header. Under "Action items", it states "You must complete these items." and lists a requirement: "A survey is required for 2012". There is also a section for "Alerts" which is partially visible at the bottom of the screenshot.

Hemovigilance Module Monthly Reporting Plan

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

NHSN - National Healthcare Safety Network (apt-v-nhsn-test:8081) | NHSN Home

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

Add Monthly Reporting Plan

Mandatory fields marked with *

[HELP](#)

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

*Month: ▼

*Year: ▼

Hemovigilance Module

All reporting is facility-wide.

Adverse transfusion reactions and all incidents associated with reactions

Monthly reporting denominators

*Select method for reporting incidents:

Summary data with detailed reporting of high priority incidents

Detailed reporting of all incidents

These options are pre-selected by the application because they are required to participate in the Hemovigilance Module.

Select "Detailed reporting of all incidents."

Hemovigilance Module Adverse Reaction

- ❑ ALL transfusion-associated adverse reactions that meet the NHSN case definitions must be reported each month.**
- ❑ Only one adverse reaction can be reported per form.**
- ❑ Reports should be entered after an investigation has been completed and imputability has been determined.**
- ❑ Find adverse reaction case definitions, in Section 3 of the protocol.**
- ❑ Detailed instructions on completing the form are provided on the website.**

Adverse Reaction Case Classification Criteria

 NHSN Biovigilance Component
Hemovigilance Module Surveillance Protocol v2.0
www.cdc.gov/nhsn

Febrile non-hemolytic transfusion reaction (FNHTR)

Note: Reactions may be classified as FNHTRs in the absence of fever if chills or rigors occur.

Case Definition	Severity	Imputability
<p>Definitive: Occurs during or within 4 hours of cessation of transfusion AND EITHER Fever (greater than or equal to 38°C/100.4°F oral and a change of at least 1°C/1.8°F from pre-transfusion value) OR Chills/rigors are present.</p>	<p>Non-severe: Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.</p> <p>Severe: Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude</p>	<p>Definite: Patient has no other conditions that could explain symptoms.</p> <p>Probable: There are other potential causes present that could explain symptoms, but transfusion is the most likely cause.</p> <p>Possible: Other present causes are most</p>

Case Definition –
Criteria used to
classify adverse
reactions

Severity – degree
to which the
patient develops
symptoms

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

Hemovigilance Module Adverse Reaction

- From the home page, select “Reaction” from the left-hand navigation bar and click “Add.”

The screenshot shows the NHSN Biovigilance Component Home Page. The left navigation bar includes the following items: NHSN Home, Alerts, Reporting Plan, Patient, Incident, **Reaction** (highlighted with a red box), Add, Find, Incomplete, Summary Data, Analysis, Surveys, Users, Facility, Group, and Log Out. The main content area displays the following information:

NHSN Biovigilance Component Home Page

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

Action items

You must complete these items.

Alerts

- You have [3](#) missing incidents
- You have [7](#) missing adverse reactions
- You have [7](#) missing denominator forms
- You have [1](#) missing high priority incident

Hemovigilance Module Adverse Reactions

These 12 adverse reactions are defined in the Hemovigilance Module.

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

Hemovigilance Module Adverse Reaction

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Centers for Disease Control and Prevention

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

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

Add Adverse Reaction

Mandatory fields marked with *
Conditionally required fields marked with ^

Patient Information [HELP](#)

*Facility ID: Pleasant Valley Hospital (ID 10312) Adverse Reaction #:

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

Secondary ID: Medicare #:

Last Name: First Name:

Middle Name:

*Gender: *Date of Birth:

Ethnicity:

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

*Blood Group:

*Primary underlying reason for transfusion:

Facilities should use a standard facility identification code for Patient ID (e.g., medical record number).

Hemovigilance Module Incident

- ❑ All incidents that are associated with a reported adverse reaction must be reported using a detailed incident form.**
- ❑ If multiple incidents occur in association with an adverse reaction, report all of them.**
- ❑ Find Incident codes in Section 4 of the protocol.**
- ❑ Detailed instruction on how to complete the form are provided on the website.**

NHSN Incident Codes

There are 100+ Incidents defined in the Hemovigilance Module.



NHSN Biovigilance Component
Hemovigilance Module Surveillance Protocol v2.0
www.cdc.gov/nhsn

Incident Codes

Note: Incident codes are based on MERS TM (US) and TESS (Canada) incident classification schemes.

<p>Product Check-In (Products Received from Outside Source)</p> <ul style="list-style-type: none">PC 00 Detail not specifiedPC 01 Data entry incomplete/not performed/incorrectPC 02 Shipment incomplete/incorrectPC 03 Product and paperwork do not matchPC 04 Shipped under inappropriate conditionsPC 05 Inappropriate return to inventoryPC 06 Product confirmationPC 07 Administrative check (2nd check)	<p>Sample Receipt (Transfusion Service)</p> <ul style="list-style-type: none">SR 00 Detail not specifiedSR 01 Sample processed in errorSR 02 Historical review incorrect/not doneSR 03 Demographic review/data entry incorrect/not doneSR 04 Sample incorrectly accessioned (test/product)SR 05 Duplicate sample sent
<p>Product/Test Request (Clinical Service)</p> <ul style="list-style-type: none">PR 00 Detail not specifiedPR 01 Order for wrong patientPR 02 Order incorrectly entered onlinePR 03 Special needs not indicated on order (e.g., negative, auto)	<p>Sample Testing (Transfusion Service)</p> <ul style="list-style-type: none">ST 00 Detail not specifiedST 01 Data entry incorrect/not performedST 02 Appropriate sample checks not doneST 03 Computer warning overriddenST 05 Sample tube w/incorrect accession labelST 07 Sample tubes mixed up

Hemovigilance Module Incident

- From the home page, select “Incident” from the left-hand navigation bar and click “Add.”

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

NHSN Biovigilance Component Home Page

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

Action items

You must complete these items.

Alerts

- You have [3](#) missing incidents
- You have [7](#) missing adverse reactions
- You have [7](#) missing denominator forms
- You have [1](#) missing high priority incident

Hemovigilance Module Incident



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Group

Log Out

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

Add Incident

Mandatory fields marked with *
Conditionally required fields marked with ^

[HELP](#)

*Facility ID:

Incident #:

Local Incident # or Log #:

Discovery [HELP](#)

*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?

Linking Incident Records to Adverse Reaction Records

The screenshot shows a portion of the NHSN Adverse Reaction form. At the top, there is a field for 'transfusion:'. Below this is the 'Reaction Details' section, which includes a 'HELP' icon. The form contains several required fields: '*Date reaction occurred:' with a date picker, '*Time reaction occurred:' with a time picker and a '(HH:MM)' label, and '*Facility location where patient was transfused:' with a text input field. A red box highlights a button labeled 'Link/Unlink To Incidents' and the text 'Reaction is not Linked' next to it. Below this, there is a section for '*Signs and symptoms, laboratory: (check all that apply)' with sub-sections for 'Generalized:', 'Cardiovascular:', and 'Cutaneous:', each containing several checkboxes for symptoms like 'Chills/rigors', 'Fever', 'Blood pressure decrease', 'Shock', 'Flus', etc.

- ❑ Incidents that are associated with adverse reactions must be linked to adverse reaction records in NHSN.
- ❑ Incident records must be entered before they can be linked to Adverse Reaction records.
- ❑ Use the “Link/Unlink To Incidents” button on the Adverse Reaction form to link the records.

Linking Incident Records to Adverse Reaction Records

Incident form

*Incident result: 1 - Product transfused; reaction

*Product action: (check all that apply)

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

*Was a patient reaction associated with this incident? Yes

Patients

*Patient ID

ABC1234

Add Row

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

- Record corrected
- Floor/clinic notified
- Attending phy

Adverse Reaction form

Mandatory fields marked with *

Conditionally required fields marked with ^

Patient Information

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

*Patient ID: ABC1234 Find Find Reactions for

Secondary ID:

Last Name:

Reaction Details

*Date reaction occurred: (Calendar icon)

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

*Facility location where patient was transfused:

Link/Unlink To Incidents Reaction is not Linked

*Signs and symptoms (check all that apply)

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

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

The Patient ID must be the same on both forms!

Linking Incident Records to Adverse Reaction Records

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

Incident Link List

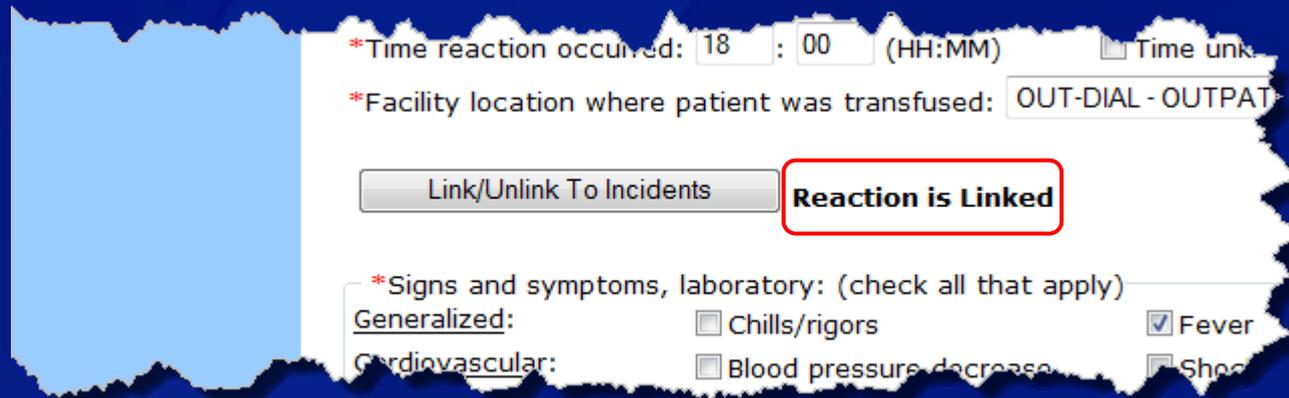
First | Previous | Next | Last Displaying 1 - 2 of 2

Check all that apply	Incident #	Patient ID	Date incident occurred	Where in the process the incident first occurred	Incident code
<input type="checkbox"/>	548	ABC1234	05/05/2012	AV	AV 00
<input checked="" type="checkbox"/>	549	ABC1234	05/06/2012	PC	PC 01

First | Previous | Next | Last Displaying 1 - 2 of 2

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

Linking Incident Records to Adverse Reaction Records



*Time reaction occurred: 18 : 00 (HH:MM) Time unk.

*Facility location where patient was transfused: OUT-DIAL - OUTPAT

Reaction is Linked

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

Generalized: Chills/rigors Fever

Cardiovascular: Blood pressure decrease Shock

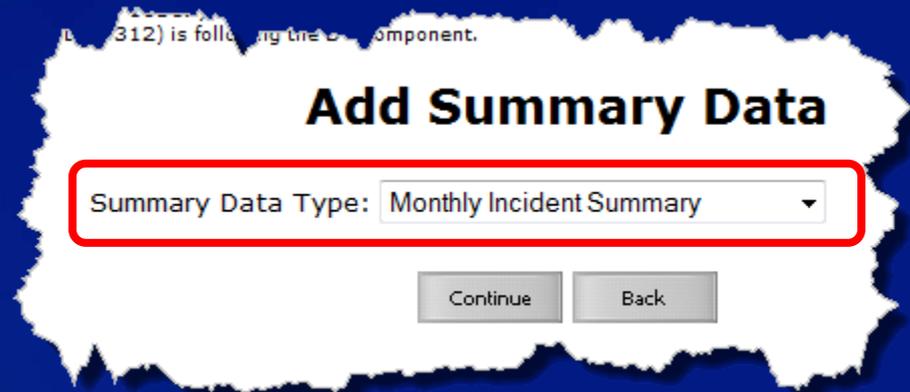
- ❑ Once the Incident record is linked to the Adverse Reaction record, "Reaction is Linked" will appear next to the "Link/Unlink To Incidents" button.
- ❑ Remember that Patient ID must match on both the Incident form and Adverse Reaction form.

Hemovigilance Module Monthly Incident Summary (Optional)

- ❑ Facilities that wish to conduct comprehensive incident surveillance can choose from the following reporting methods:**
 1. Detailed reporting using Incident forms
 2. Summary reporting using Monthly Incident Summary form
 3. Combination of detailed and summary reporting
- ❑ Optional summary reporting should also include required incident data.**
 - 4 required incidents + 6 optional incidents = 10 reported on Monthly Incident Summary form
- ❑ Detailed instructions on completing the Monthly Incident Summary form are provided on the website.**

Hemovigilance Module Monthly Incident Summary

- ❑ From the home page, select “Summary Data” from the left-hand navigation bar and click “Add.”
- ❑ Choose “Monthly Incident Summary” from the drop-down menu and click “Continue.”



Hemovigilance Module Monthly Incident Summary



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

Add Monthly Incident Summary

Mandatory fields marked with *

[Print PDF Form](#)

[HELP](#)

* Facility ID: 10312 (Pleasant Valley Hospital)

* Month:

* Year:

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

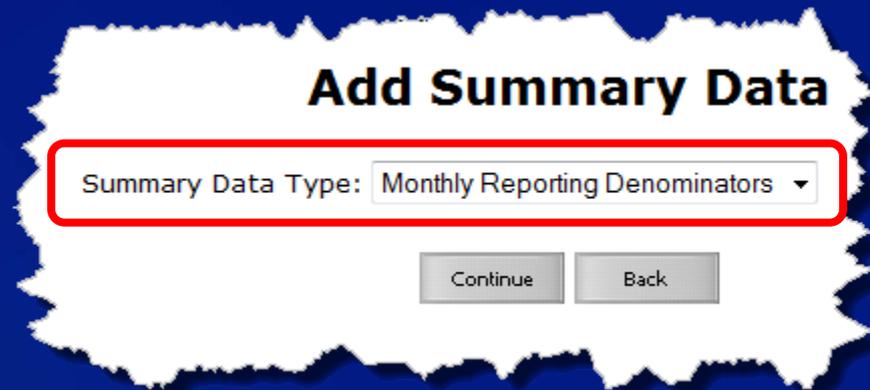
*Process code	*Incident code	*Total Incidents	*Total Adverse Reactions associated with Incidents
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Total		0	0

Hemovigilance Module Monthly Reporting Denominators

- ❑ Facilities must report the total number of units and/or aliquots of specified blood products transfused each month.**
- ❑ Total number of patient samples collected for type and screen and/or crossmatch must also be reported.**
- ❑ Data collected on this form will be used for rate calculations.**
- ❑ Detailed instruction on how to complete the form are provided on the website.**

Hemovigilance Module Monthly Reporting Denominators

- ❑ From the home page, select “Summary Data” from the left-hand navigation bar and click “Add.”
- ❑ Choose “Monthly Reporting Denominators” from the drop-down menu and click “Continue.”



Hemovigilance Module Monthly Reporting Denominators



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Summary Data

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

Add Monthly Reporting Denominators

[Print PDF Form](#)

Mandatory fields marked with *

[HELP](#)

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

* **Month:**

* **Year:**

No Adverse Reactions reported this month

No Incidents reported this month

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



**Questions or Need Help?
Contact user support**

