Hemovigilance Module Incidents Optional Reporting

- **Incidents reported optionally are for facility use only and will not be analyzed by CDC.**
- **Facilities that wish to conduct comprehensive incident surveillance can choose from the following reporting methods:**
  - Detailed reporting using Incident forms
  - Summary reporting using Monthly Incident Summary form
  - Combination of detailed and summary reporting

Hemovigilance Module
Monthly Incident Summary (Optional)

NHSN National Healthcare Safety Network

OMB No. 0920-0666
Exp. Date: 01-31-2015

www.cdc.gov/nhsn

Hemovigilance Module
Monthly Incident Summary

*Required for saving

*Facility ID#: _____ *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
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 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 (2nd check)		
PR: 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		
SC: Sample Collection (Service collecting the samples)	SC 00 Detail not specified		
	SC 01 Sample labeled with 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 (other than patient name)		
	SC 08 Sample collected in error		
	SC 09 Requisition arrived without samples		
	SC 10 Wristband incorrect/not available		
	SC 11 Sample contaminated		
SH: Sample Handling (Service collecting the samples)	SH 00 Detail not specified		
	SH 01 Sample arrived without requisition		
	SH 02 Requisition and sample label don't match		
	SH 03 Patient ID incorrect/illegible on requisition		
	SH 05 No phlebotomist/witness identification		
	SH 06 Sample arrived with incorrect requisition		
	SH 07 Patient information (other than ID) missing/incorrect on requisition		
	SH 10 Sample transport issue		

Assurance of Confidentiality: The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

CDC

NHSN Biovigilance Component
Tables of Instruction v1.4
www.cdc.gov/nhsn

Table 3. Hemovigilance Module Monthly Incident Summary (CDC 57.302)

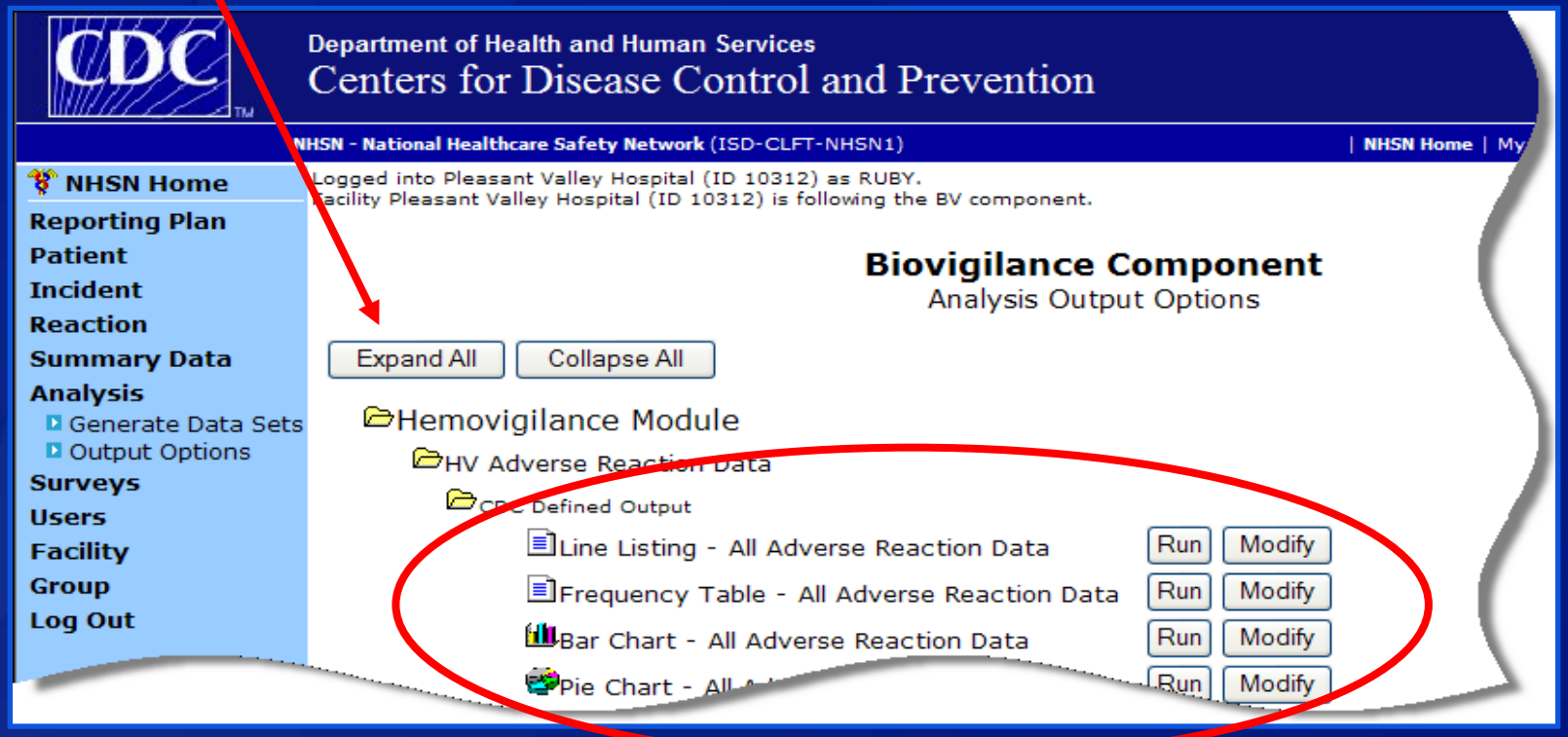
Data Field	Instructions for Form Completion
Facility ID#	The NHSN-assigned Facility ID number will be auto entered by the system.
Month	Required. Indicate the month for the summary being entered.
Year	Required. Indicate the year for the summary being entered.
Process Code	Required. Select Process Code. Only add rows for incidents that **occurred** during the month.
Incident Code	Required. Select Incident Code. Only add rows for incidents that **occurred** during the month.
Total Incidents	Required. Enter the total number of incidents that occurred for the incident code selected. Include all detailed incident records entered in your incident totals. *Note: Incidents should be reported by their discovery date. For example, if a sample collected on April 30 was mislabeled and the error was discovered on May 2, the **May** summary should include the incident as well as any associated reaction that may also have occurred.*
Total Adverse Reactions associated with Incidents	Required. Enter the total number of adverse reactions associated with each reported incident code. If no adverse reactions were associated with reported incidents, enter 0. *Note: All incidents associated with an adverse reaction must also be reported on a detailed incident form.* *Note: Enter an associated adverse reaction on the same summary report as the incident, even if it occurred in a later month. For example, if an incident discovered on August 31 is associated with a reaction that occurred on September 1, the associated reaction should be included in the **August** summary.*
Total	Required (auto sum). Totals for each column will be auto entered by the system.

Hemovigilance Module
Monthly Incident Summary (Optional)

- **Use Monthly Incident Summary forms for optional summary incident reporting.**
- **Optional summary reporting should also include required incident data.**
  - 4 required incidents + 6 optional incidents = 10 reported on Monthly Incident Summary form
- **Continue reporting incidents associated with an adverse reaction using Incident forms.**

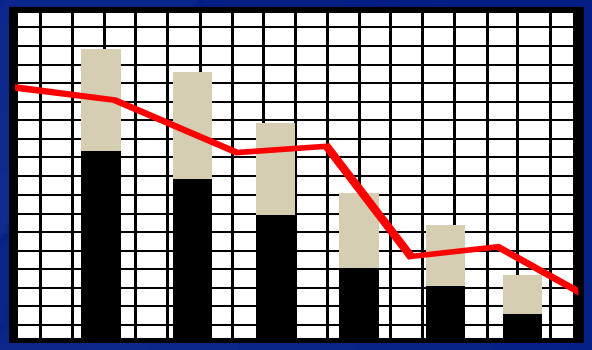
Hemovigilance Module Analysis

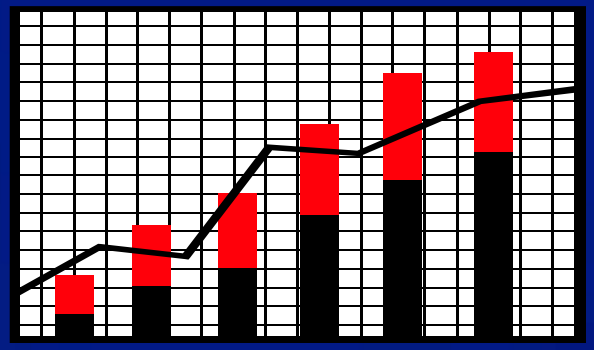
- Analysis output options available in NHSN
  - For use by facilities for internal trending and process improvement.



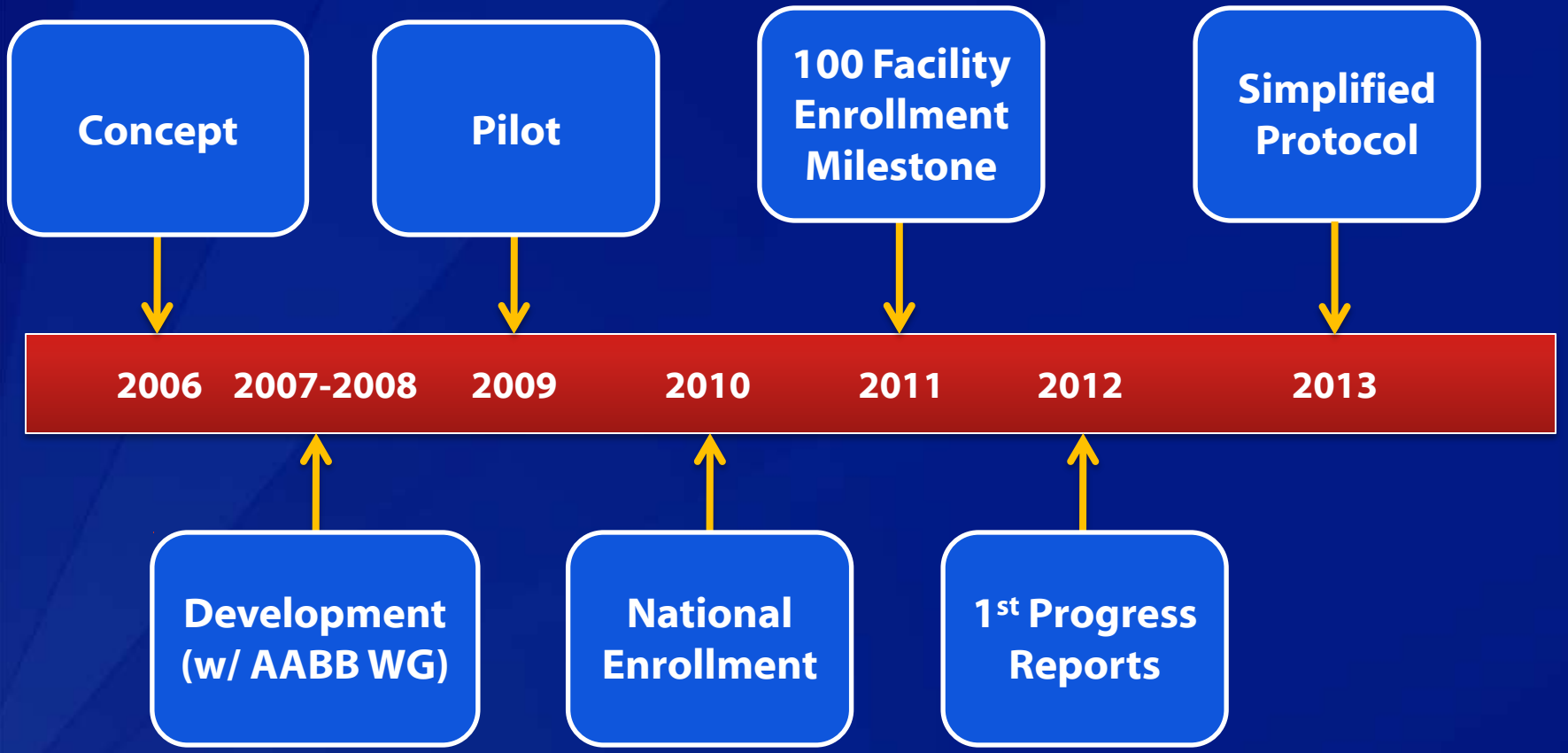
Hemovigilance Module Data Analysis

- Facilities can analyze their data as soon as it is entered
- Benchmarking capabilities are planned, but will not be available with rates until adequate data have been entered
- CDC will publish a Public Health Report with aggregate national data for 2010-2012 (mid-late 2013)

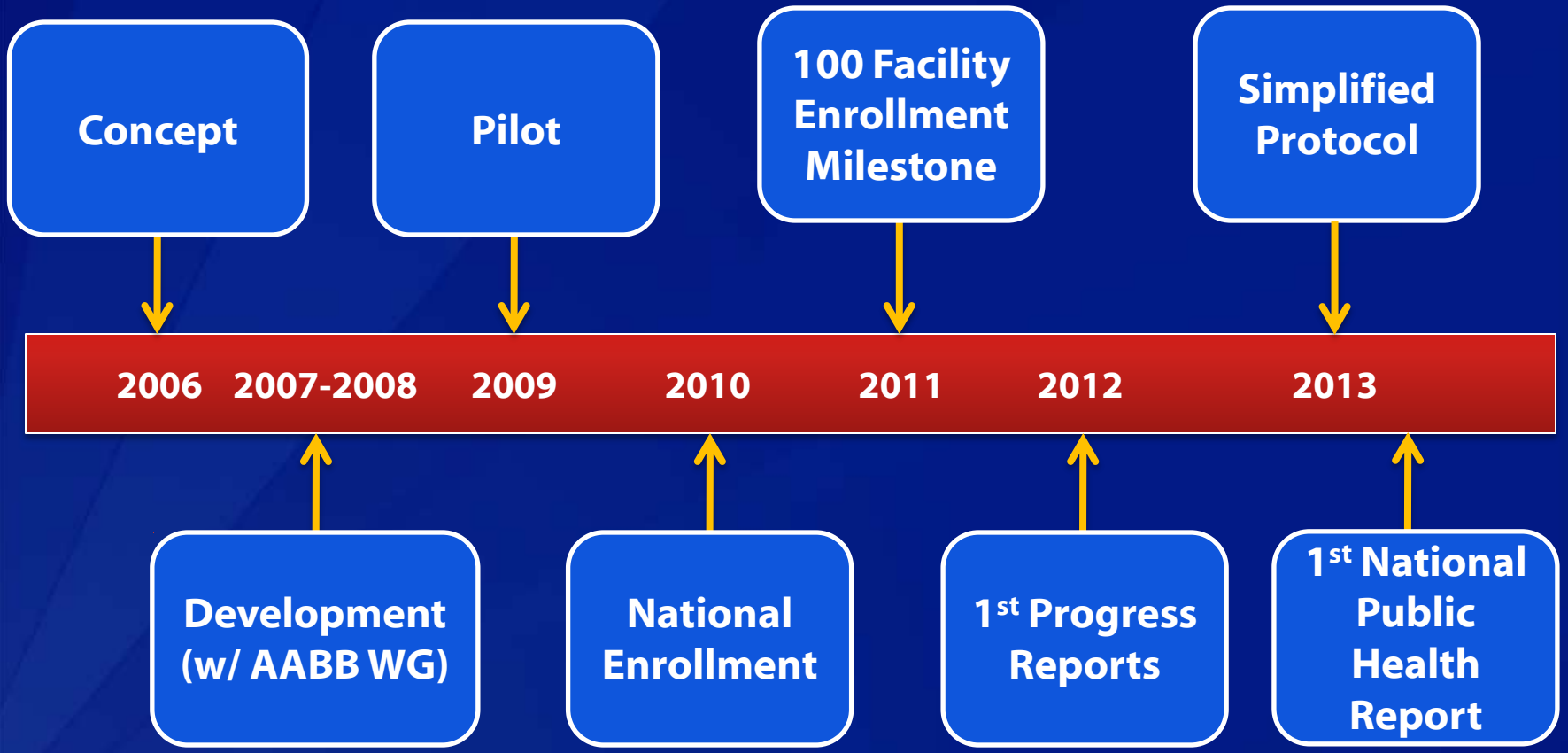




Timeline – 8 years of US Hemovigilance



Timeline – 8 years of US Hemovigilance



Blood Products Transfused, 2010-2012

	2010	2011	2012	Total
	n=27	n=49	n=58	n=69
Red Blood Cells	57%	59%	59%	---
Platelets	20%	16%	17%	---
Plasma	18%	20%	18%	---
Cryoprecipitate	5%	5%	6%	---
Total	430,000	693,000	806,000	1,929,000
Percentage of US Transfusion Volume Under Surveillance*	2.0%	3.2%	3.7%	

*Compared to 2009 NBCUS: National Estimate of US Hospital Transfusions

Unpublished data.

Adverse Reactions, 2010-2012

	2010 n=20	2011 n=49	2012 n=63	Total n=70
Allergic	54%	48%	43%	---
Febrile, non-hemolytic	32%	34%	38%	---
TACO	3%	4%	4%	---
TRALI	1%	1%	<1%	---
Dyspnea	1%	1%	2%	---
Hypotensive	1%	3%	3%	---
Delayed Serologic	4%	6%	7%	---
Delayed Hemolytic	2%	2%	1%	---
Acute Hemolytic	1%	<1%	1%	---
Infection	1%	<1%	<1%	---
Total	850	1,680	2,500	**5,030**

Cases meeting case definition, severity, and imputability criteria.

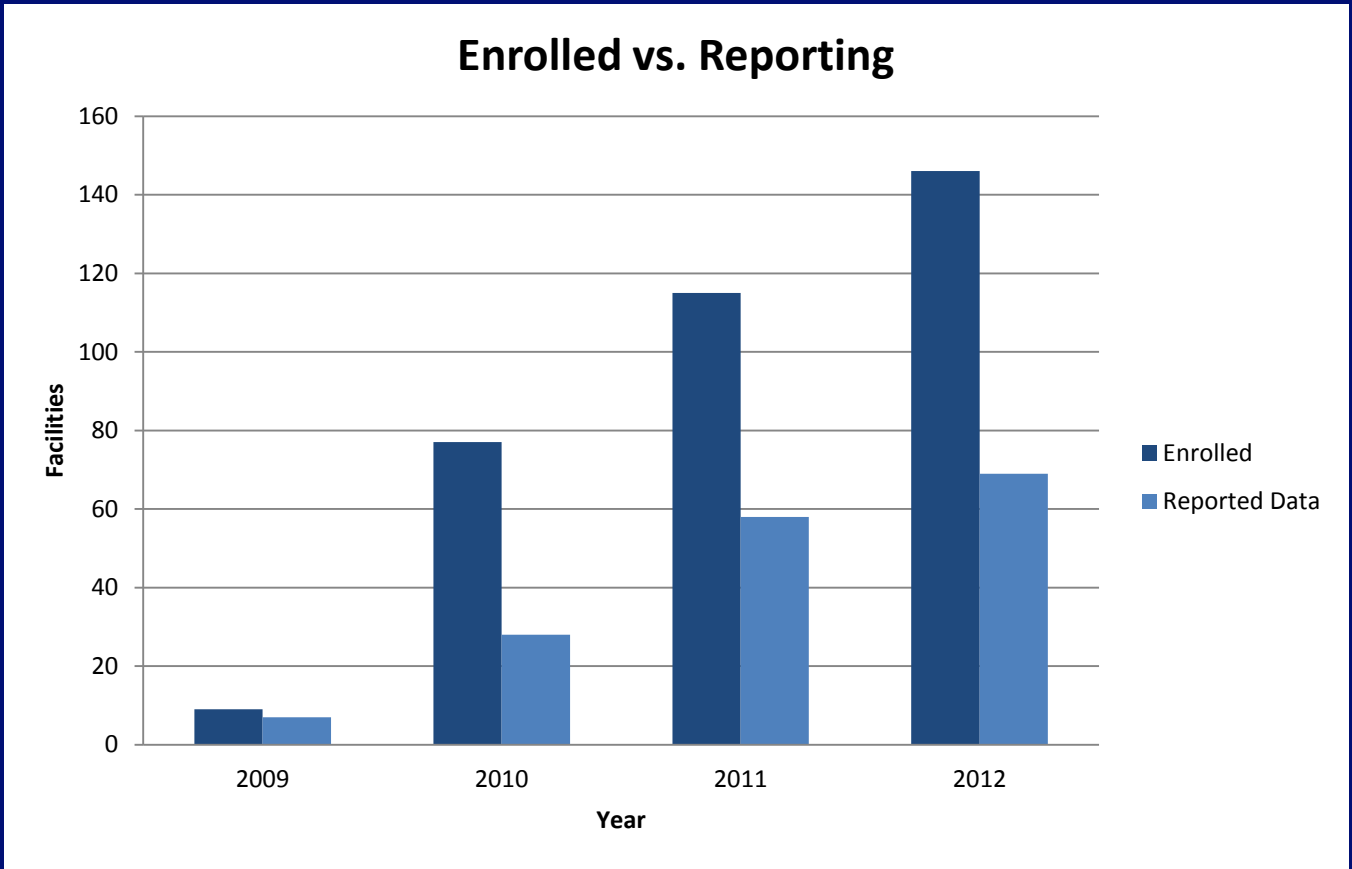
Unpublished data.

Summary Incidents Reported, 2010-2012

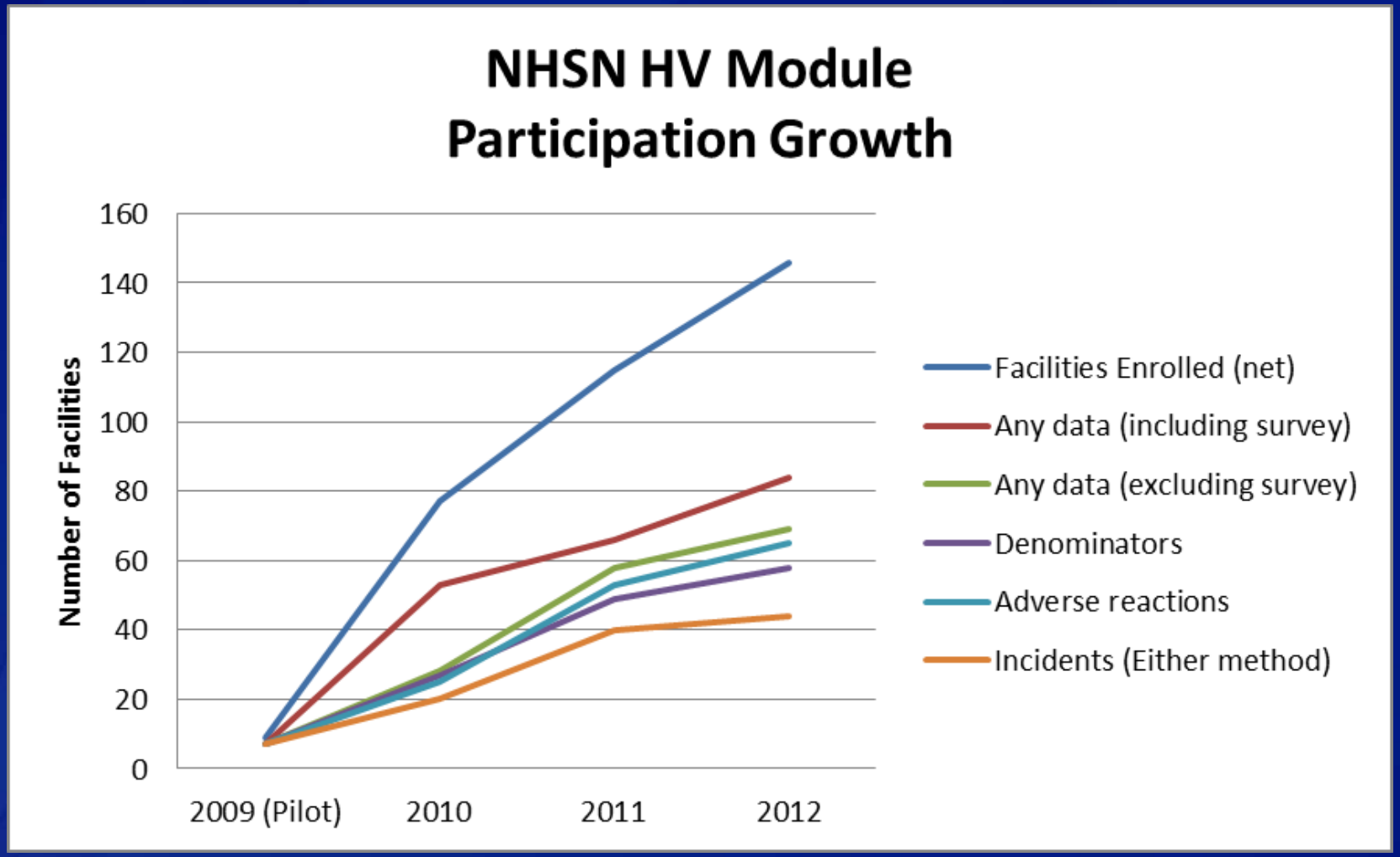
	2010	2011	2012	Total	Adverse Reactions
Product Check-In	1%	2%	1%	---	1
Product/Test Request	2%	7%	10%	---	2
Sample Collection	36%	33%	37%	---	5
Sample Handling	42%	29%	19%	---	12
Sample Receipt	<1%	1%	3%	---	1
Sample Testing	2%	5%	4%	---	4
Product Storage	<1%	2%	1%	---	0
Available for Issue	<1%	<1%	<1%	---	0
Product Selection	1%	<1%	<1%	---	1
Product Manipulation	1%	2%	1%	---	0
Pick-Up Request	3%	3%	2%	---	1
Product Issue	1%	2%	1%	---	1
Product Admin	10%	13%	16%	---	11
Miscellaneous	1%	2%	4%	---	7
Total	6,000	10,120	16,580	**32,700**	46

Unpublished data.

NHSN Hemovigilance Module Participation
Enrolled vs. Reported Data



Participation is Increasing
…but quality data incoming more slowly



What are we doing to improve?

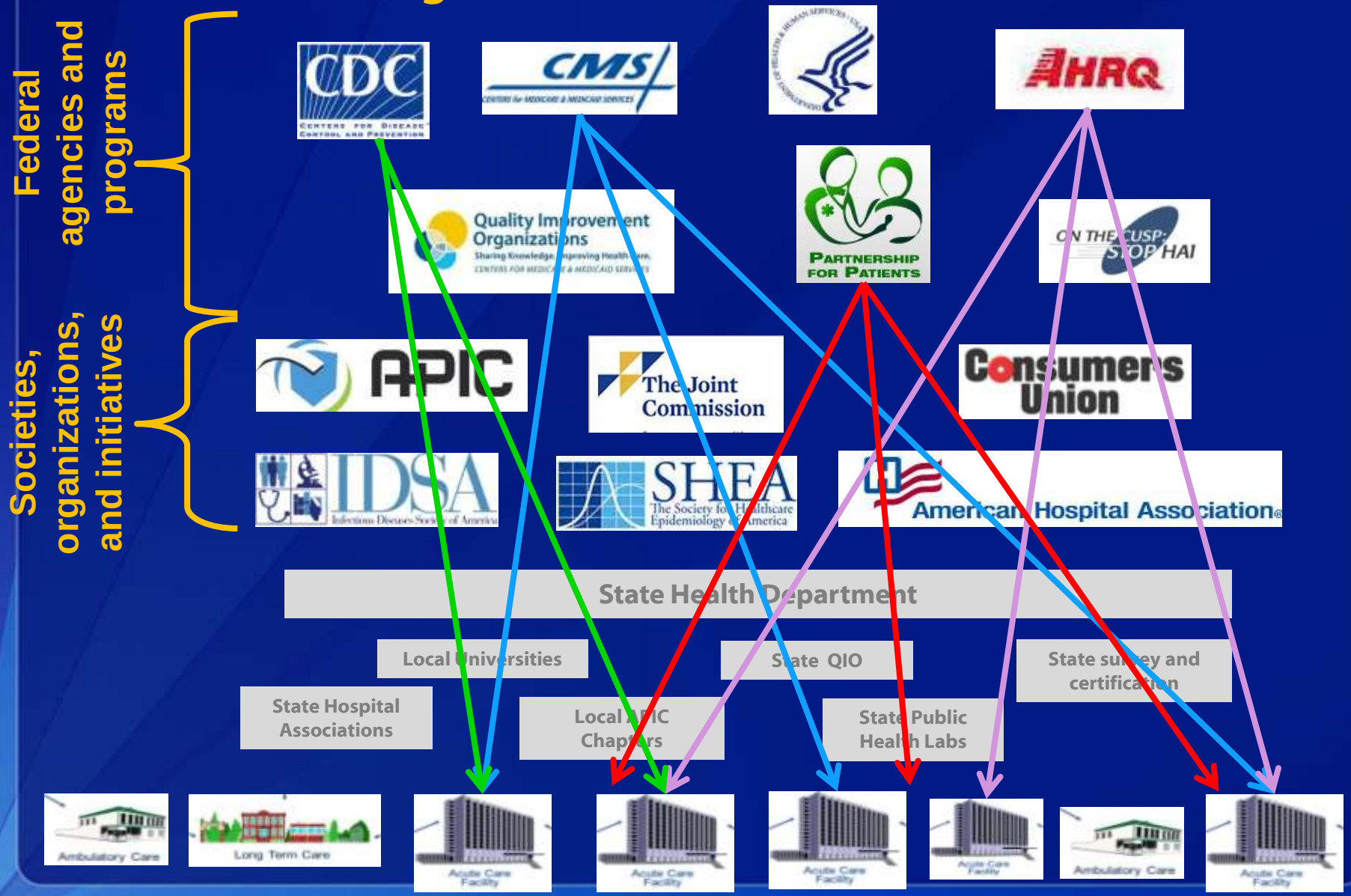
- **Reducing the reporting burden for the HV Module.**
  - No longer requiring non-severe allergic reactions, reducing adverse reaction reporting burden by ~45%.
  - No longer requiring comprehensive incident reporting, reducing incident reporting burden by ~99%.

- **Simplifying the protocol.**
  - Removed all unnecessary information (e.g., history, context, appendices).
  - Streamlined the criteria tables, while including all pertinent information (e.g., combined signs and symptoms and laboratory requirements, added severity criteria to each table.)

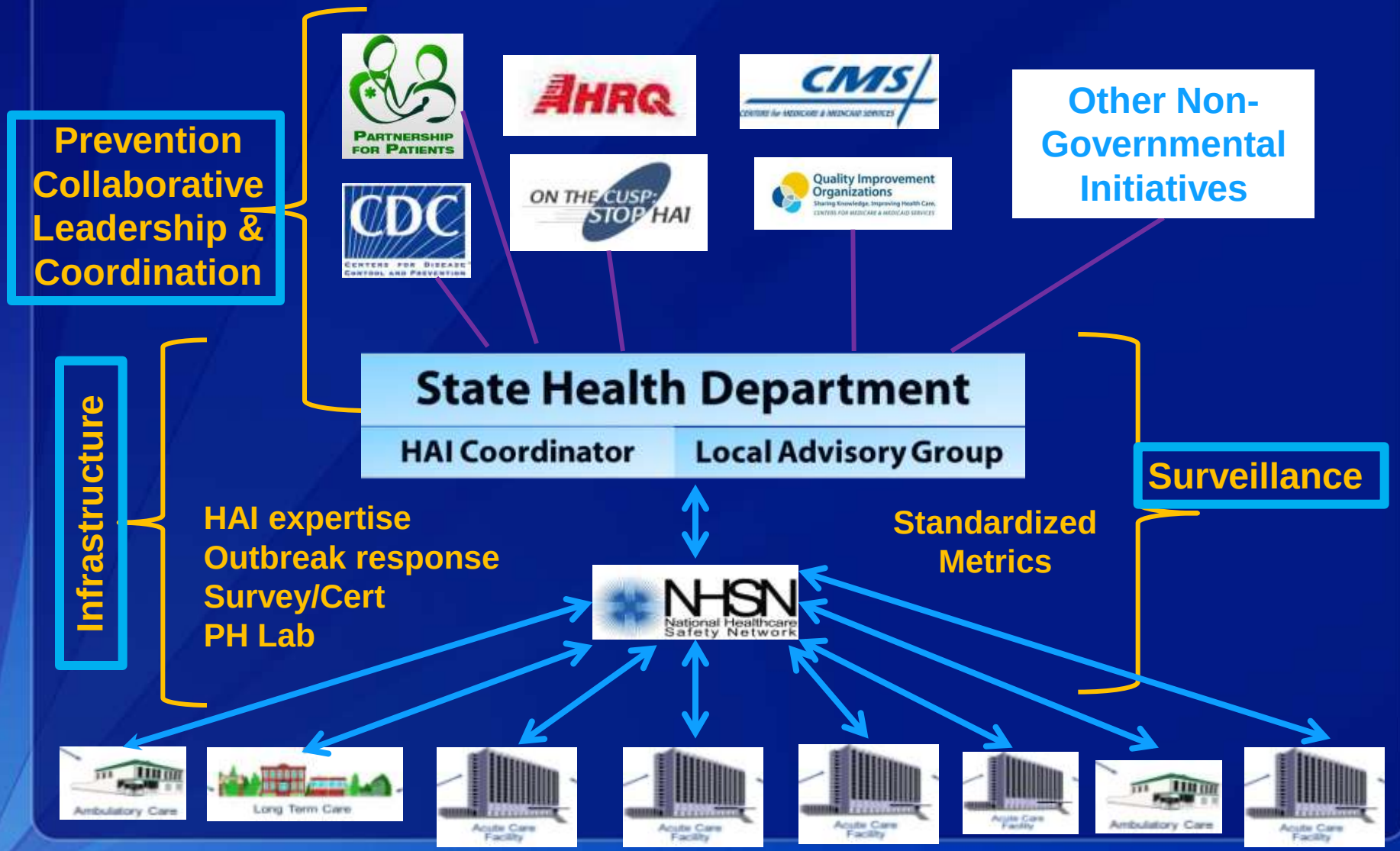
What are we doing to improve?

- **Increasing training opportunities.**
  - CDC-led webinars every other month. FREE!
  - In-person training March 6, 2013. FREE!
- **Making efforts to improve data quality so that benchmarking can be added to the HV Module.**
  - Clarifying adverse reaction and incident classification to better standardize reporting.
  - Providing direct outreach and support for our users.
- **Exploring opportunities for collaboration with partners.**

Stakeholder Landscape:
Increasing Demands, Need for Coordination



Vision: Coordinated Public Health Approach



Challenge: Healthcare facilities have multiple obligations for reporting

- **Voluntary Reporting**
  - NHSN Hemovigilance Module
  - FDA (MedWatch for clinicians)
  - Joint Commission (Sentinel Event)
- **Required Reporting**
  - FDA (for Deaths, Biologic Product Deviations)
  - Facility Quality Assurance
  - Supplying Blood Center
  - State Compliance Authorities

CDC NHSN HV Module Stakeholder Group Members, 2012-2013

Chair – CDC (Director, Office of BOOTS)
Co-chair - External partner (TBD)

- NHSN HV Module Facility User
- NHSN HV Module Group
- State Health Dept (Massachusetts)
- Transfusion Accrediting/Standards Orgs (AABB, CAP, TJC)
- FDA-Registered Blood Collection Facility (ARC)
- HHS Agency Ex-Officio (FDA, NIH, CMS)
- CDC representatives (Division of Blood Disorders, Chair of SME Group)

Convened by conference call Sept 24, 2012; in-person meeting Feb 7, 2013

NHSN HV Module Stakeholder Group

Objectives

- Provide input regarding HV Module surveillance priorities
- Suggest initiatives to increase HV Module participation and data quality
- Learn what other organizations are doing in hemovigilance and enhance collaboration, including interoperability
- Subject Matter Expert (SME) subgroup to discuss specific proposals for changes in the protocol and case definitions

NHSN HV Module Stakeholder Group Discussion Topics

- Participation
  - Create incentives for participation
  - Reduce burden of reporting
  - Make data more usable for facilities (e.g., benchmarking)
- Interoperability
  - Harmonize definitions
  - Make data more easily entered for reporting
  - Improve understanding of group function to share data

Conclusions

- Enrollment is growing at a slow, but steady pace.
- Data reporting is incomplete and inconsistent.
- Increased participation and data quality are needed before valid rates can be calculated and benchmarking can be added to the HV Module.
- Simplifications introduced in the v2.0/2.1 surveillance protocol are aimed at improving participation and data quality.
- Collaborations and partnerships are also needed to drive participation.

Acknowledgments

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

Contact Us!

- www.cdc.gov/nhsn
- nhsn@cdc.gov