

# U.S. Bio**vigilance** Network

Investing in patient safety and donor health



# **AABB's Patient and Donor Safety Center (a Patient Safety Organization) and Hemovigilance**



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# AABB's Patient and Donor Safety Center (a Patient Safety Organization) and Hemovigilance



- Purpose of AABB PDSC (PSO)
- What is a PSO?
- Why did AABB establish a PSO?
- How does AABB's PDSC Function?
  - Data Flow In and Out of PSO
- AABB's PDSC and Hemovigilance
- Current and Future Activity

# Purpose



- To protect and keep confidential the hemovigilance data accessed by private sector
  - Adverse event data
  - Patient data (HIPAA)

# AABB's Patient and Donor Safety Center: A Patient Safety Organization



- What is a PSO?
  - Regulated under HHS' Agency for Healthcare Research and Quality (AHRQ)
  - Entity whose primary activity is to conduct activities to improve patient safety and health care quality.
  - Entity has expertise in analyzing patient safety events.
- Why a PSO?
  - Allows the privileged and confidential reporting of patient safety information for the aggregation and analysis of patient safety events without fear of legal liability or professional sanctions.
  - AABB's Patient and Donor Safety Center is a component PSO – separate from AABB's accreditation functions.

# AABB's Patient and Donor Safety Center



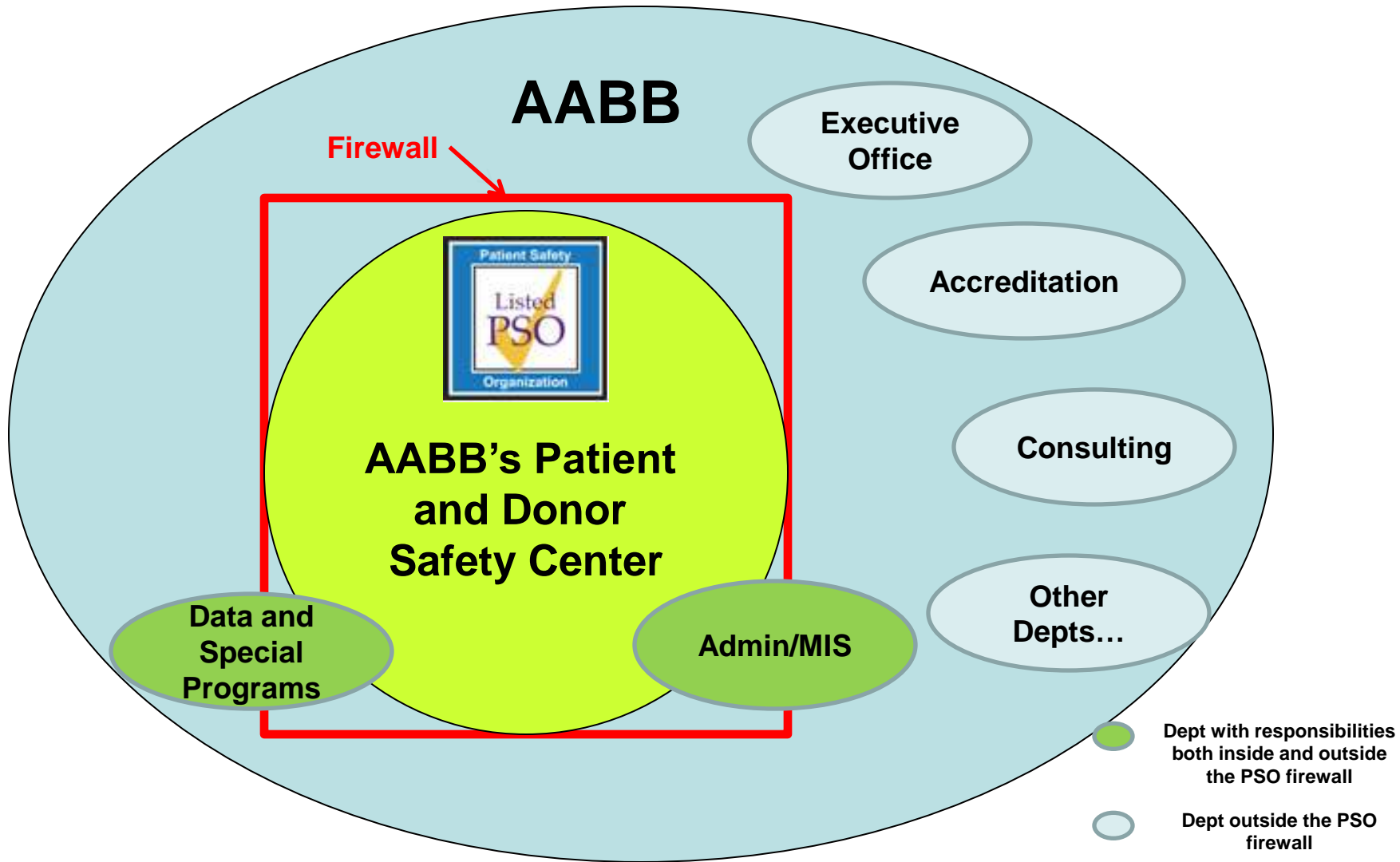
- AABB's Patient and Donor Safety Center has a separate mission to improve patient safety.
- The PDSC has policies and procedures in place to manage data and keep it confidential and protected.
- There is a firewall and **NO DATA SHARING** between the PDSC and AABB's accreditation and standards departments.

# AABB PDSC



- How does AABB's PDSC Function Internally?
  - QSEs
  - Firewall between AABB's Accreditation arm and PDSC
  - Policies and Procedures
  - Contracts with Employees and with Experts
  - HIPAA compliant: Health Insurance Portability and Accountability Act

# AABB's Patient and Donor Safety Center: A Component Patient Safety Organization





# AABB PDSC



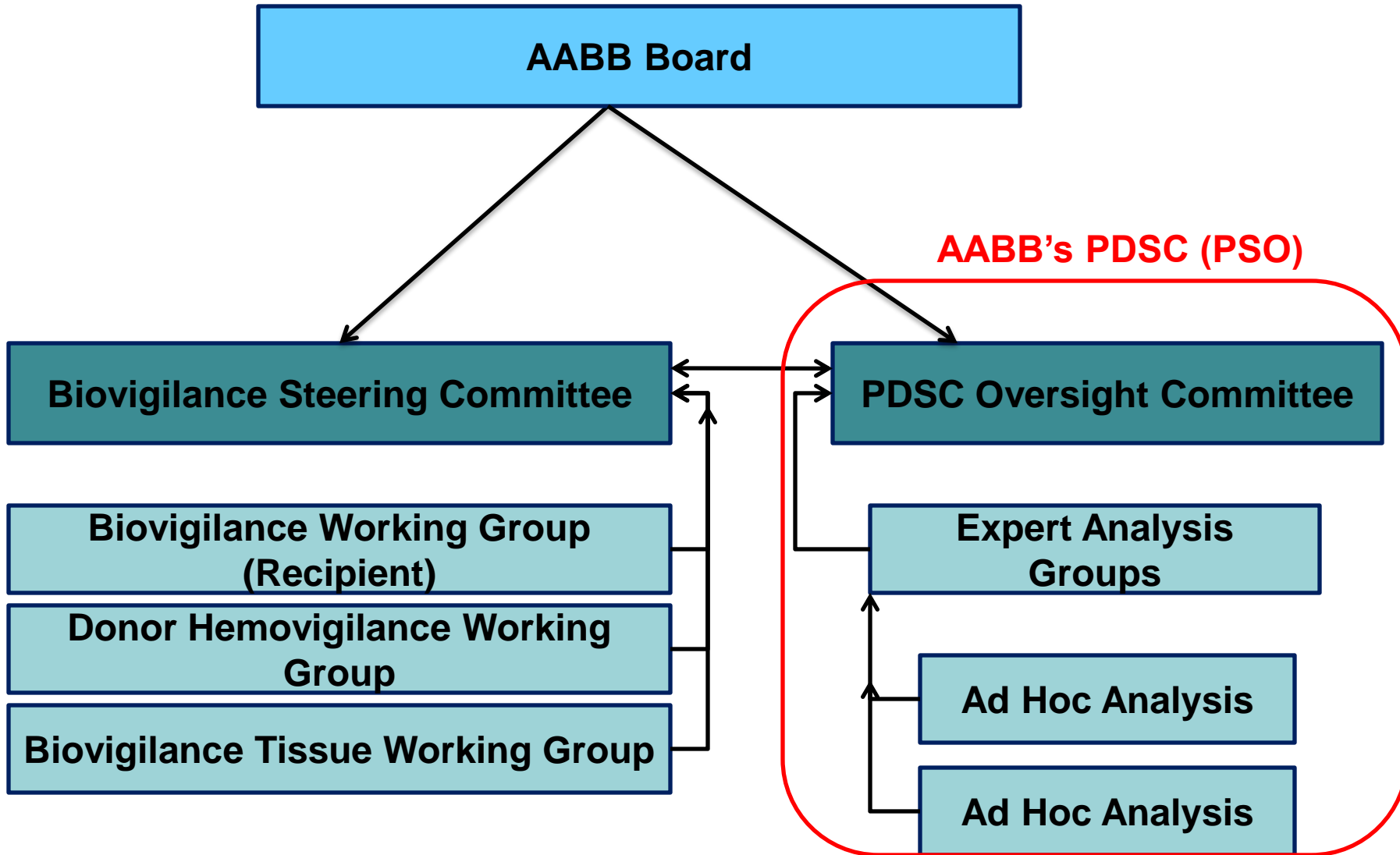
- How is AABB's PDSC Staffed?
  - AABB Employees
    - Function: Operations and Management
    - Maintain contracts to insure confidentiality of PSWP, patient information, and non-disclosure agreements
  - Outside Experts (Volunteer)
    - PDSC Function: Content Expertise and Data Analysis
    - Maintain contracts to insure confidentiality of PSWP, patient information, and non-disclosure agreements

# AABB PDSC: Data Analysis

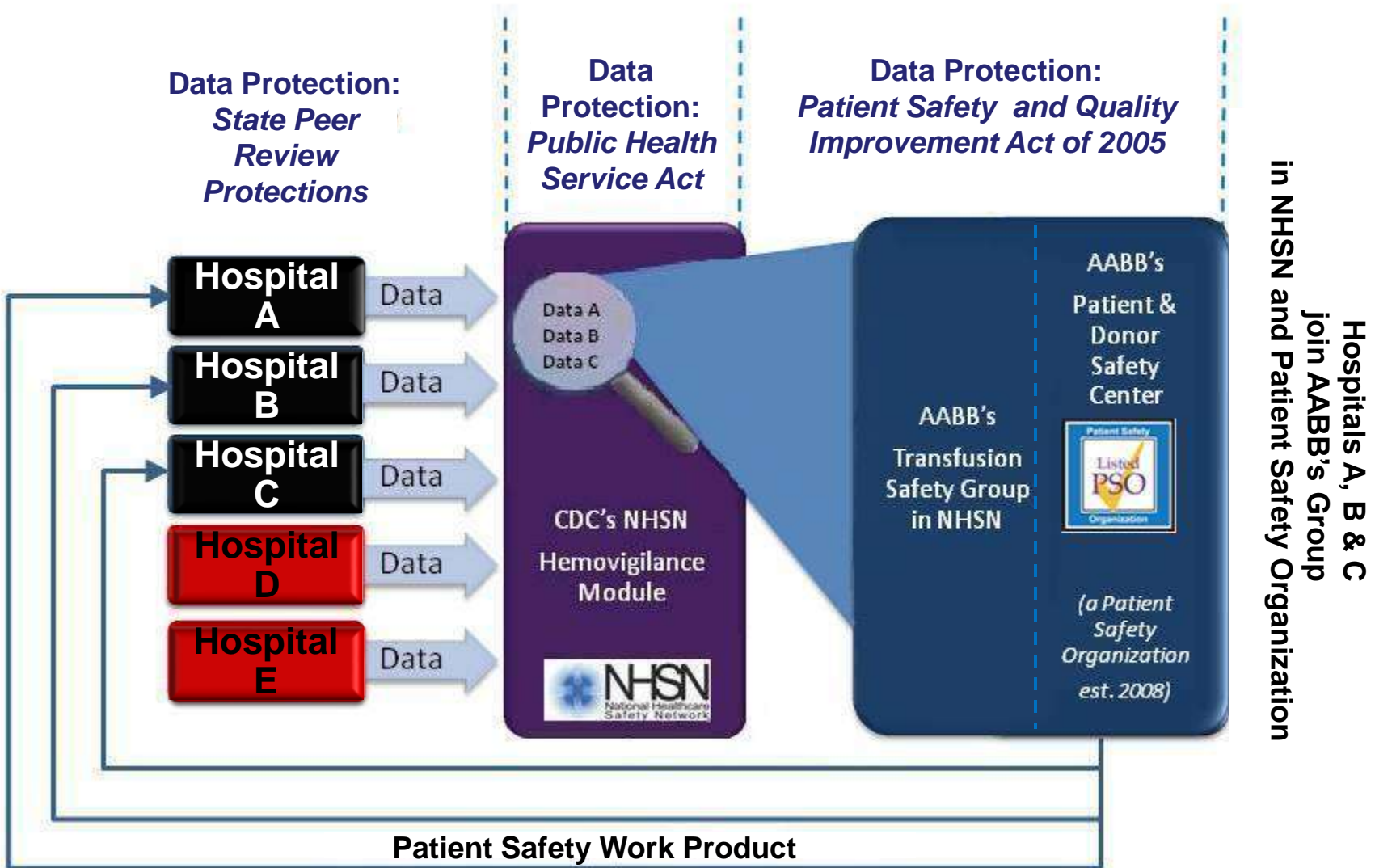


- Biovigilance Steering Committee = PDSC Oversight Committee
- PDSC Oversight Committee Responsibilities
  - Determine needs for the collection of specific quality information to address a healthcare quality goal or initiative
- Analysis: Working Group and Staff

# AABB's Biovigilance Structure



# AABB's Patient and Donor Safety Center Data Protection Diagram

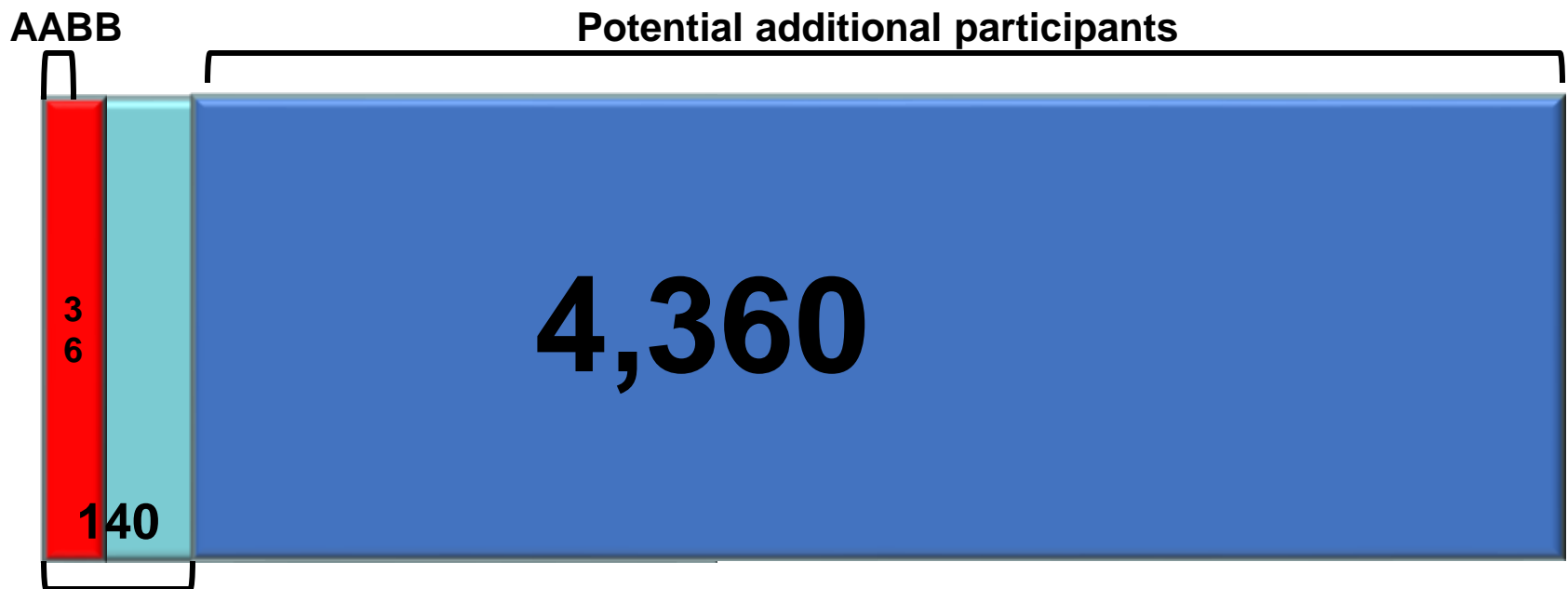


**Data Protection: HIPAA and the Patient Safety Act**

*Note: Reports, benchmarking, analysis, etc. cannot be returned to participating facility without the HIPAA Business Agreement and AABB's Participation & Confidentiality Agreement in place.*

# US Hemovigilance Participation

- USA: 4,500 transfusing hospitals
- Hemovigilance (CDC) : 140 participating hospitals
- Sharing data with AABB: 36/140 hospitals
- Committed to participate: 90 additional hospitals (growing)



Hemovigilance  
Participants

U.S. Bio**vigilance**  
Network

# Hemovigilance: Data Collection (AABB dataset)



- Adverse reactions
  - 10% subject to further validation efforts
- Incidents – process errors etc
  - Sample Collection/Handling/Product Administration
  - 30% further investigation for quality improvements
- Denominator data
  - Hospital environmental descriptors
  - Monthly and annual transfusion activity/including pediatric

# Benchmarking Reports: Quarterly (Sample)



Event Result	Total	Hospital 1	Hospital 2	Hospital 3
Patient Harm	<1%	...	...	...
Reached patient - No Harm	10%	...	...	...
Did not reach patient due to unplanned recovery	26%	...	...	...
Did not reach patient due to planned recovery step	64%	...	...	...

# Benchmarking Reports: Quarterly (Sample 2)



Event Type	Total	Hospital 1	Hospital 2	Hospital 3
Product Check-In	0.5%	...	...	...
Product/Test request	4%	...	...	...
Sample Collection	25%	...	...	...
Sample Handling	49%	...	...	...
Sample Testing	3%	...	...	...
Product administration	10%	...	...	...
Request for Pickup	3%	...	...	...



# Transfusion Reaction Rounds



- Quarterly calls with PDSC participants
- Volunteer presents complicated adverse transfusion reaction/incident
- Input from expert committee; questions and discussion from PDSC participants
- May 2012

# Current and Future Activity



- Private sector
  - Recruitment and communication
  - Continued validation of data
  - Safe table
  - Expert working group analysis
  - Close collaboration with hospitals
    - Feedback
    - Benchmarking
    - Training
  - Development of studies and interventions
  - Development and communication of best practices
- Collaboration with Federal and State governments to achieve high quality hemovigilance results

# Thank you!

[www.aabb.org/biovigilance](http://www.aabb.org/biovigilance)

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