Ten years of US Hemovigilance: Where we are today and how your hospital can benefit

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AABB Center for Patient Safety

www.aabb.org
Overview

• Hemovigilance History
• Development of Hemovigilance in the US
• Current State of Hemovigilance
  – CDC NHSN
  – AABB Center for Patient Safety
• Thoughts for the Future
• Questions
Hemovigilance

A set of **surveillance** procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients) intended to **minimize adverse events or reactions** in donors and recipients and to **promote safe and effective use** of blood components.
Context of Hemovigilance

- **Pharmacovigilance** was established in response to the thalidomide events (unregulated clinical trial whereby many pregnant women were exposed and fetuses harmed).

  - Required that a drug be safe as well as effective before it could be approved and marketed.
Hemovigilance

• “Vigilance” – numerous facets
  – Transfusion surveillance
    • Recipient adverse reactions
    • Incidents / errors / events / occurrences
    • Outcomes
  – Donation surveillance
    • Donor adverse events
    • Deferrals
    • TTD Marker testing
  – Availability/Use Assessment
  – Infectious Disease (known and emerging) monitoring
HIV Role in Hemovigilance

- June 1981: First CDC MMR of AIDS symptoms
- July 1982: The first report of AIDS-like symptoms in three persons with hemophilia was published
- August 1982: PHS (HHS) released a plan for stepped-up blood surveillance activities, particularly to learn whether AIDS was being transmitted through blood products.
- March 1983: the PHS (HHS) recommended five "interim measures" to address transmission of AIDS:
  - Avoidance of sexual contact with those having symptoms
  - Restricting blood donation from high risk populations
  - Evaluation of donor screening procedures
  - Restraint in use of blood transfusion
  - US FDA approved heat treated clotting factors
1991-1993: France

- 1991: Magazine article providing evidence that the National Transfusion Service knowingly distributed HIV contaminated blood products to hemophiliacs in 1984 and 1985.
- 1992: Anne-Marie Casteret published a book *L'affaire du sang* leading to a public scandal leading to indictment of the former Prime Minister.
- By 1994, reporting begins.
- Hemovigilance Officers in every hospital (~1500), blood center (~150), and region (17).
1993: Japan

- 1993: Voluntary reporting of transfusion complications (including infectious transmissions)
- 1960’s Hepatitis problem
  - 50% transfusion recipients developed hepatitis (1:2)
  - Discovery of HBV (1968)
  - Paid donor population (1969)
  - Development of HBsAg test (1972)
  - Discovery of HCV (1988)
  - Development of HCV tests (1989-2000)
  - Consequent hepatitis risk reduction to 1:143,000
Canada - Hepatitis C

• 1997: Krever Report
  – Using plasma collected from high-risk prison populations in the US
  – Not using a test that may have caught as many as 90 per cent of hepatitis C cases
  – Delaying the purchase of safer, heat-treated blood products for hemophiliacs out of a desire to use up the potentially contaminated products
  – Failure to track down all those who might have been infected

• The Red Cross was stripped of its control over the blood program, and Canadian Blood Services was established.

• 2001: Canadian Supreme Court ruled that the Red Cross was negligent in the early days of the AIDS crisis, especially in comparison with how authorities in the U.S. dealt with the emerging disease.
Why Hemovigilance?

Classic TTD residual risks

Risk/unit

HCV

HBV

HIV

Why Hemovigilance?

Busch M. Transfusion. 2006
Why Hemovigilance?
Risks of transfusion no longer primarily infectious

Zilberberg, M. BMC Health Services Res. 2007.
Why Hemovigilance: Transfusion-Related Fatalities

<table>
<thead>
<tr>
<th>Complication</th>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
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<tr>
<td>TRALI</td>
<td>13</td>
<td>18</td>
<td>10</td>
<td>17</td>
<td>14</td>
</tr>
<tr>
<td>HTR (non-ABO)</td>
<td>8</td>
<td>5</td>
<td>6</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>HTR (ABO)</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Microbial Infection</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>5</td>
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<tr>
<td>TACO</td>
<td>12</td>
<td>8</td>
<td>4</td>
<td>8</td>
<td>13</td>
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<tr>
<td>Anaphylaxis</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Other</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Number of Fatalities

- TRALI: Transfusion Reactions with Lipidemia
- HTR: Hemolytic Transfusion Reactions
- Microbial Infection
- TACO: Transfusion Acute Kidney Injury
- Anaphylaxis
- Other
Hemovigilance elsewhere

• 1996 UK Serious Hazards of Transfusion (SHOT)
  • Increased participation from 23% to 100% NHS hospitals
    – Reduction in TRALI
    – Reduction in bacterial transmission
    – Reduction in ABO incompatible transfusions
• Focus on Mistakes
• 2015 Risk of death or serious harm from transfusion per components issued (imputability 1-3)
  – Death: 1 in 100,000
  – Death from error: 1 in 320,000
  – Major morbidity: 1 in 15,500
Why Hemovigilance?

Total reports and total deaths definitely due to transfusion between 1996 and 2009

[Diagram showing the number of reports and deaths over the years, with a trend line indicating a decline in reports and deaths over time.]
Mandatory Hemovigilance

- European Blood Directive,

- Directive 2002/98/EC
  - ” hemovigilance is defined as “a set of organized surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors.”
Hemovigilance Systems Around The World

Austria
Ireland
Denmark
Finland
France
Germany
Greece
Brazil
Canada
Czech Republic
Quebec
Japan

USA

Italy
Norway
Poland
Slovak Republic
Spain
Croatia
Switzerland
The Netherlands
United Kingdom
Russia
New Zealand
South Africa
2006: The State of US Hemovigilance

- HHS Blood Surveys
- FDA
  - Fatality reports (1975 onward)
  - Blood Product Deviation Reports
- CDC
  - CDC National Viral Hepatitis Surveillance System - 1979
  - CDC AIDS Surveillance – 1985
- NHLBI
  - REDS I-II
  - Other studies
- Private Sector
  - ARC

• GAP ANALYSIS
2006: Support initiated with ACBSA Recommendation

Public-private partnership between US HHS including CDC, FDA, etc. and private sector organizations involved in blood collection, transfusion, tissue and organ transplantation, and cellular therapies

Enhance patient safety and protect donor health while reducing overall health care-related costs

In 2007, the US CDC agreed to host Biovigilance in the National Healthcare Safety Network and to have a “Hemovigilance Module”

Content experts, convened by AABB, designed data specifications for a surveillance system to monitor transfusion-related adverse events nationally.
http://www.hhs.gov/ash/bloodsafety/biovigilance/

- Gap 1: Patchwork and sometimes fragmented system of various adverse event reporting
- Gap 2: Likely under-reporting of transfusion adverse events
- Gap 3: Challenges with FDA-required reporting
- Gap 4: Need for accurate recipient denominator data, precise definitions, and training
- **Gap 5:** No national surveillance of donor serious adverse events other than fatalities
- **Gap 6:** Need for accurate donor denominator data, precise definitions, and training
- **Gap 7:** Need for accurate tracking of all donor infectious disease test data
- Gap 8: Need for timely analysis of reported data
USBVN Hemovigilance Vision

• Voluntary, non-punitive, reporting system
• Web-based interface
  – System of pull-down menus and check boxes
  – Specific information:
    • The patient
    • Blood components
    • Reaction and outcomes
• Participating hospitals would be able to compare their data with other hospitals of comparable size and specialty (benchmark)
Components and Modules

**Component**

**Patient Safety**
- Events Modules
  - Device Associated
  - Procedure Assoc.
  - Medication Assoc.
  - MDRO and CDAD
  - High Risk Inpatient Influenza Vaccination

**Component**

**Healthcare Personnel Safety**
- Modules
  - Blood/Body Fluid Exposure
  - Vaccine

**Component**

**Biovigilance**
- Modules
  - Hemovigilance - patients

**Component**

**Research and Development**
- eSurveillance
  - HL7 Messages
  - HL7 CDA
  - Prevention research

>3,000 participating hospitals
Mandatory in all states
Adverse Reactions

- Allergic reaction
- Acute hemolytic transfusion reaction
- Delayed hemolytic transfusion reaction
- Delayed serologic transfusion reaction
- Hypotensive transfusion reaction
- Febrile non-hemolytic transfusion reaction
- Unknown pathophysiology
- Post transfusion purpura
- Transfusion associated circulatory overload (TACO)
- Transfusion associated dyspnea (TAD)
- TA- Graft versus host disease
- Transfusion Related Acute Lung Injury (TRALI)
- Transfusion associated infection (bacterial, viral, parasitic, other)
- Other
Categorizing Adverse Reactions

### Adverse Reaction Case Classification Criteria Tables

#### Transfusion-associated circulatory overload (TACO)

<table>
<thead>
<tr>
<th>Case Definition</th>
<th>Severity</th>
<th>Imputability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definitive:</strong></td>
<td>Non-severe:</td>
<td>Definite:</td>
</tr>
<tr>
<td>New onset or exacerbation of 3 or more of the following within 6 hours of cessation of transfusion:</td>
<td>Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.</td>
<td>No other explanations for circulatory overload are possible.</td>
</tr>
<tr>
<td>• Acute respiratory distress (dyspnea, orthopnea, cough)</td>
<td>Severe:</td>
<td>Probable:</td>
</tr>
<tr>
<td>• Elevated brain natriuretic peptide (BNP)</td>
<td>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 permanent damage or impairment of a body function.</td>
<td>Transfusion is a likely contributor to circulatory overload AND EITHER</td>
</tr>
<tr>
<td>• Elevated central venous pressure (CVP)</td>
<td>Life-threatening:</td>
<td>The patient received other fluids as well OR</td>
</tr>
<tr>
<td>• Evidence of left heart failure</td>
<td>Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.</td>
<td>The patient has a history of cardiac insufficiency that could explain the circulatory overload, but transfusion is just as likely to have caused the circulatory overload.</td>
</tr>
<tr>
<td>• Evidence of positive fluid balance</td>
<td>Possible:</td>
<td>The patient has a history of pre-existing cardiac insufficiency that most likely explains circulatory overload.</td>
</tr>
<tr>
<td>• Radiographic evidence of pulmonary edema</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Severity or Grade

1: **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.

2: **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 permanent damage or impairment of a body function.

3: **Life-Threatening**: Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.

4: **Death**: The recipient died as a result of the adverse transfusion reaction. Death should only be used if death is possibly, probably, or definitely related to transfusion. If the patient dies of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction.
Imputability

• **Definite (Certain)** – Patient has no other conditions that could explain signs/symptoms.
• **Probable (Likely)** - There are other potential causes present that could explain signs/symptoms, but transfusion is the most likely cause.
• **Possible** - Other present causes are most likely, but transfusion cannot be ruled out.

• **Doubtful** – Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.
• **Ruled Out** – There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.
• **Not Determined** – The relationship between the adverse reaction and the transfusion is unknown or not stated.
Hemovigilance: Incidents

- Incidents = occurrences, variances, process deviations, near misses
- The CDC Hemovigilance Module has an optional section for entering data about *incidents*
- Reporting incidents is *required* for events that lead to a transfusion reaction
- Most incidents never affect the patient or cause harm but understanding why they happen can prevent harmful errors
- Analysis and trending of events can advance a safety culture
- Hospitals should be able to compare with others (benchmark) and look for important differences.
- In order to prevent similar errors/events in the future....
Incident Process Steps

- Product Check-In
- Product Storage
- Inventory Management
- Product/Test Request
- Product/Test Order Entry
- Sample Collection
- Sample Handling
- Sample Receipt

- Sample Testing
- Product Manipulation/Processing/Testing
- Request for Pick-up
- Product Issue
- Satellite Storage
- Product Administration
- Other
- Custom Fields
Institute of Medicine Report: 2000

- **2000: To Err is Human**
  - Building a Safer Health System

- **Agency for Healthcare Research and Quality (AHRQ)**
  - Mission: to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable....

- **Patient Safety and Quality Improvement Act of 2005**
  - Established a voluntary reporting system designed to enhance the data available to assess and resolve patient safety and health care quality issues.
  - Provided Federal privilege and confidentiality protections for patient safety information, called patient safety work product.
  - Established Patient safety organizations (PSOs): external experts that collect and review patient safety information.
AABB Center for Patient Safety

- AABB established the Center for Patient Safety (CPS), a Patient Safety Organization, so that hospitals reporting to NHSN may share their data and maintain confidentiality and protections.

- 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 CPS is the only transfusion safety PSO
AABB Center for Patient Safety

- AABB Center for Patient Safety has a different mission (compared to CDC and DOH) to improve patient safety
  - Aggregate
  - Analyze
  - Educate
- Policies and procedures in place to manage data and keep it confidential and protected.
- There is a firewall and **NO DATA SHARING** between the CPS and AABB’s accreditation department.
AABB Center for Patient Safety

- Nearly 100 hospital members
- 10 Pediatric Hospitals
- Representing ~ 1,000,000 annual transfusions (6.5%)
- Overall Reaction rates of 25.2 per 10,000 transfusions
- 92% Reactions are Non-Severe
- 90% of Incidents never reach the patient
- 0.2% of Incidents cause patient harm
- Currently exploring pathways to participate that are not through the CDC NHSN
AABB Center for Patient Safety
Data Flow & Protection

Data Protection:
State Peer Review Protections

Hospital A
Data

Hospital B
Data

Hospital C
Data

Hospital D
Data

Hospital E
Data

CDC’s NHSN Hemovigilance Module
Data A Data B Data C

Data Protection:
Public Health Service Act

AABB Transfusion Safety Group in NHSN

Data Protection:
Patient Safety and Quality Improvement Act of 2005

A Patient Safety Organization

Data Protection:
Public Health Service Act

Data Protection:
State Peer Review Protections

Data Protection:
Patient Safety and Quality Improvement Act of 2005

Note: Reports, benchmarking, analysis, etc. cannot be returned to participating facility without the HIPAA Business Agreement and AABB’s Participation & Confidentiality Agreement in place.
AABB Center for Patient Safety (CPS): Offerings

- CPS Portal Access
- Benchmarking
  - Hemovigilance benchmark reports
  - Blood utilization benchmark reports
- Quarterly “Safe Table” conference calls with members to review data and address coding and system differences
- Education
  - Quarterly educational programs (CEUs)
- Data quality review and validation
- Development and communication of best practices
- Early access to research opportunities
Member Home

The Center’s mission is to foster a culture of safety and quality in the practice of transfusion medicine and cellular and related biological therapies that advances evidence-based medicine and enhances outcomes nationwide. The Center is dedicated to improving patient safety and the delivery of quality health care through the collection and analysis of adverse events associated with blood transfusion.

**Benchmarks**
Access quarterly benchmark reports demonstrating trends in adverse reactions and incidents.

**Data Manager**
Supplemental data entry for identified transfusion reactions and view NHSN reported data.

**Education**
Articles, newsletters, presentations and webinars designed to advance patient safety in transfusion medicine.

**Dashboard**
View dynamic charts of CPS participation and performance.

Notifications
www.aabb.org

Events
Adverse Reaction Rates by Hospital

Rate per 1,000 Units + Allquots Transfused

Aggregate Center for Patient Safety Rate
Serious Adverse Reactions
Incident Rate Comparisons

Incident Rates
Reporting Hospitals By Hospital Number*
April - June 2016

- Individual Hospital Incident Rate
- Aggregate Center for Patient Safety Rate (17.14)

*Not including 2 hospitals with zero incidents received.
RBC Components Wasted by Hospital

Wasted RBCs

Average Wasted RBC

1.20%
Outdated Platelet Components by Hospital

- Outdated Total Platelets
- Average Outdated Total Platelets

*Collects Blood

8.83%
Severity of Transfusion Reactions Reported to CPS (October 2015 – September 2016)

- Non Severe, 2652, 91.7%
- Severe, 210, 7.3%
- Life Threatening, 25, 0.9%
- Death, 5, 0.2%
Detailed Incident Reports Reported to CPS (October 2015 – September 2016)

- Reached Patient Harm, 3, 0.2%
- Reached Patient-No Harm, 116, 9.5%
- Near Miss, unplanned recovery, 60, 4.9%
- Near miss, Planned recovery 1043, 85.4%

n=1,222 incidents
Safe Table Calls: Transfusion Reaction Rounds

- Quarterly calls with PDSC participants
- A regular forum for discussion
- Volunteer presents complicated adverse transfusion reaction/incident cases for review
- Input from expert committee; questions and discussion from PDSC participants
- Facilitates consistent understanding of reporting criteria
Value of Participation

- Benchmarking with comparable hospitals nationally
- Up to four educational programs (CEUs) per year
- To provide meaningful insight into infrequent events such as transfusion reactions and mis-transfusions, a large database is required to have sufficient statistical power to identify trends and possible causal associations
- Members of the AABB CPS compare with other hospitals nationally and benefit from experience of other hospitals in shared patient safety discussions.
How to Join?

AABB Center for Patient Safety

The AABB Center for Patient Safety, a federally listed Patient Safety Organization, is dedicated to improving outcomes associated with blood transfusion. Membership provides access to blinded blood transfusion benchmark reports focused on the identification and reduction of risks and hazards associated with patient care.

- Join the Center for Patient Safety
  The AABB Center for Patient Safety is now accepting contracts from hospitals to participate in the first-ever national, public-private Biovigilance Network.
  SEE MORE

- Benchmark Reports
  Access quarterly benchmark reports to track adverse reactions and incidents associated with blood transfusions using protected and confidentially reported data.
  SEE MORE

- Education/Training
  One of our missions is to advance the practice and standards of transfusion medicine through education. The AABB Center for Patient Safety provides a portal to achieve this objective.
  SEE MORE

www.aabb.org
Join the AABB Center for Patient Safety

The AABB Center for Patient Safety is now accepting contracts from hospitals to participate in the first-ever national, public-private Biovigilance Network.

To join the AABB Center for Patient Safety (CPS), you will need to sign a Business Associate Agreement and Participation and Confidentiality Agreement. Please refer to the Forms tab and contact hemovigilance@aabb.org for more information.

In order to share data with the AABB CPS, the NHSN HV Module Facility Administrator at your hospital will need to join the AABB CPS group within CDC's National Healthcare Safety Network (NHSN).

The Facility Administrator should:
- Sign into NHSN
- Select Join under the Group section of the NHSN navigation bar (located on the left-hand side of the screen)
- Enter the AABB CPS Group ID: 14838 and Password: 1122
- You will go directly to the Confer Rights page. The AABB CPS has already pre-selected the data to be shared. Click Accept to fully join the group.
How to Join AABBB’s CPS

• Join the AABB group within CDC’s National Healthcare Safety Network (NHSN)

• The Facility Administrator should:
  – Sign into NHSN
  – Select **Join** under the **Group** section of the NHSN navigation bar (located on the left-hand side of the screen)
  – Enter the **AABB Group ID: 14838** and **Password: 1122**
  – You will go directly to the Confer Rights page. AABB has already pre-selected the data to be shared. Click **Accept** to fully join the group.

• Participating facilities will be included in AABB’s benchmarking, but will only see de-identified data from other facility’s.

• Joining AABB’s group does not prevent you from joining other NHSN groups.
AABB’S PATIENT AND DONOR SAFETY CENTER
PARTICIPATION AND CONFIDENTIALITY AGREEMENT

This Participation and Confidentiality Agreement (“Agreement”) is between the
Transfusing Facility identified below (the “Facility”) and AABB’s Center for Patient Safety Organization of the Americas (“AABB”).

WHEREAS, the Patient Safety Organization (42 U.S.C. § 299b-21 to b-26) (collectively, “Patient Safety Organizations”) voluntarily provide quality information, privileged and confidential baselines, best practice development purposes,

WHEREAS, HHS, including the Office of the Inspector General, launched the Hemovigilance Initiative

BUSINESS ASSOCIATE AGREEMENT
WITH TRANSFUSION FACILITIES

This BUSINESS ASSOCIATE AGREEMENT (this “Agreement”) is entered into as of the date first written in the signature block below (the “Effective Date”) by and between ________________________________ [insert name of Provider] (“Provider”) and the AABB Center for Patient Safety (“Center”), a Component PSO listed under the Patient Safety and Quality Improvement Act of 2005, having its principal place of business at 8101 Glenbrook Road, Bethesda, Maryland, 20814, and whose parent organization is the American Association of Blood Banks, a non-profit organization. Provider and Center may each be referred to herein as a “Party” or collectively as the “Parties.” This Agreement supplements and serves as an addendum to the Terms and Conditions for Participation with the AABB Center for Patient Safety (“Participation Agreement”) entered into between the Parties.

1. BACKGROUND AND PURPOSE. Provider has engaged Center to provide certain services to Provider through the Participation Agreement. Provider is a “covered entity” and Center is a “business associate” as such terms are defined in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the regulations promulgated thereunder at 45 C.F.R. Part 160 and Part 164, subparts A and
Blood Center Hemovigilance

- ARC and BSI have active Hemovigilance Programs that involve their customer hospitals and their donors
- Blood centers can participate in CDC NHSN as a “Group”
- AABB Common Adverse Reaction Reporting Form
  - For hospitals to report to all suppliers
  - In development by Donor HV Working Group and PSO Advisory Committee
  - To be piloted summer 2017
- Common Internationally endorsed Adverse Donor Reaction Definitions (AABB, ISBT, and IHN) and incorporated into 2015 FDA Fatality Report
- Donor Vigilance through DonorHART™
DonorHART™

- Donor Hemovigilance Analysis and Reporting Tool
- Created through collaboration among the US DHHS, Armed Services Blood Program and the private sector (AABB, ABC, ARC, BSI, hospital collectors)
- Used to track and trend adverse events associated with blood donation
- Participating facilities enter data into a web-based system with excellent intra-facility reporting and analysis tools.
- 2017 AABB Donor Hemovigilance Program – expanding ways for blood centers to participate
- 2012-2014 Donor Hemovigilance Report
- Benchmarks in 2017
2017: The State of US Hemovigilance

- HHS Blood Surveys
- FDA
  - Fatality reports
  - BPDR
  - BloodSCAN
  - Sentinel
  - TTIMS
  - Safety Rule???
- CDC
  - NHSN Hemovigilance
- NHLBI
  - REDS III-IV
- Private Sector
  - AABB Standards
  - AABB Center for Patient Safety
  - ARC and other blood collectors
  - Post-marketing Private Sector Investigations (e.g. PIPER)
State of the Gaps

• Gap 1: Still fragmented system(s)
• Gap 2: Still likely to have under-reporting of transfusion adverse events
• Gap 3: Challenges with FDA-required reporting
• Gap 4: Accurate recipient denominator data, precise definitions, and training
• Gap 5: Still no national surveillance of donor serious adverse events other than fatalities
• Gap 6: Accurate donor denominator data, precise definitions, and training
• Gap 7: Accurate tracking of all (most) donor infectious disease test data
• Gap 8: Need for timely analysis of reported data
Thoughts for the future...

- Central oversight
- Improve participation
- Electronic data submission
- Improve quality
- Educate clinicians on the value of hemovigilance
Thoughts for the future...

- **Centralized oversight**
  - States will mandate reporting (e.g. MA)
  - FDA will eventually require reporting of serious transfusion reactions

- **Participation growth**
  - Mandates will improve participation
  - AABB Standards require
    - Use of reaction common definitions
    - Plan for transfusion management for patients at risk for TACO

- **Data quality will improve as ICD-10 codes are integrated into for reporting**
  - Optional now
  - Will likely be required in future
Essential for success...

- Automated interfaces between EHR-LIS and analysis/reporting HV data
- Motivation of hospitals is the key to successful hemovigilance
  - AABB CPS benchmarking
  - Blood center support for hospital HV
  - More publications and case reports
  - Hemovigilance Rounds
  - Hemovigilance as a “Quality Initiative” to support change control and patient safety
Acknowledgements

• AABB Hemovigilance Committee
• AABB PSO Advisory Committee
• AABB CPS Member Hospitals
• Diane Killion
• Gabriela Perez
• Maxi Mbinack
• Naynesh Kamani
• Srijana Rajbhandary
Thank you!

bwhitaker@aabb.org