



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

Investing in patient safety and donor health

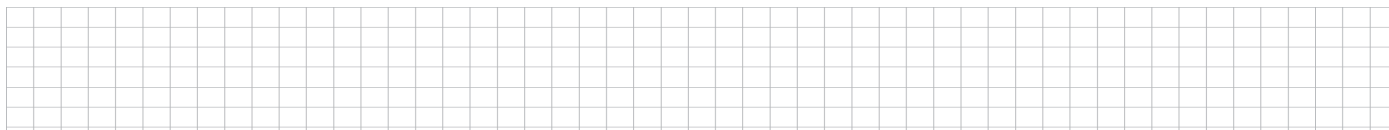
An update of the U.S. Biovigilance Network, a vital and urgent project to enhance patient safety and to protect donor health in transfusion and transplantation medicine.



# Biovigilance Systems: An Update on Hemovigilance Activities in the U.S.

Cell Therapy Liaison Meeting  
September 10, 2009

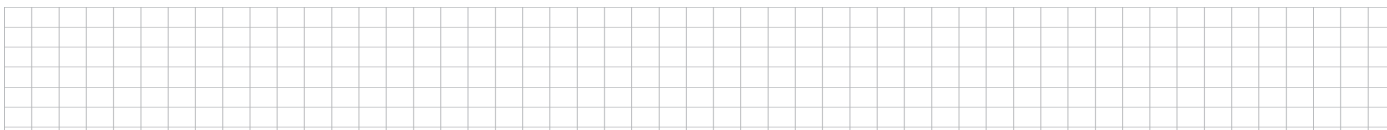
Barbee I. Whitaker, Ph.D.  
Director, Data and Special Programs  
AABB



U.S. Bio**vigilance**  
Network

# Bio/Hemovigilance

- Definitions
- Existing Systems and Sources of Data
- Developing Systems
- Future



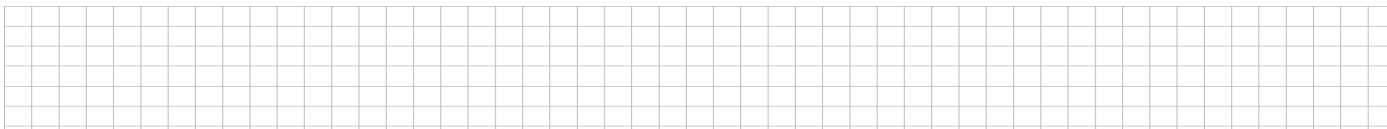
# Biovigilance

The detection, gathering and analysis of information regarding the untoward and unexpected events of blood transfusion and transplantation of cells, tissues and organs.

with the objectives of:

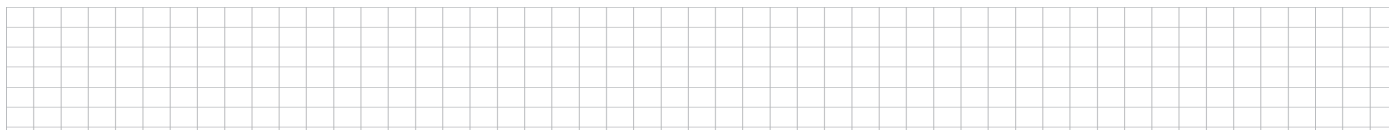
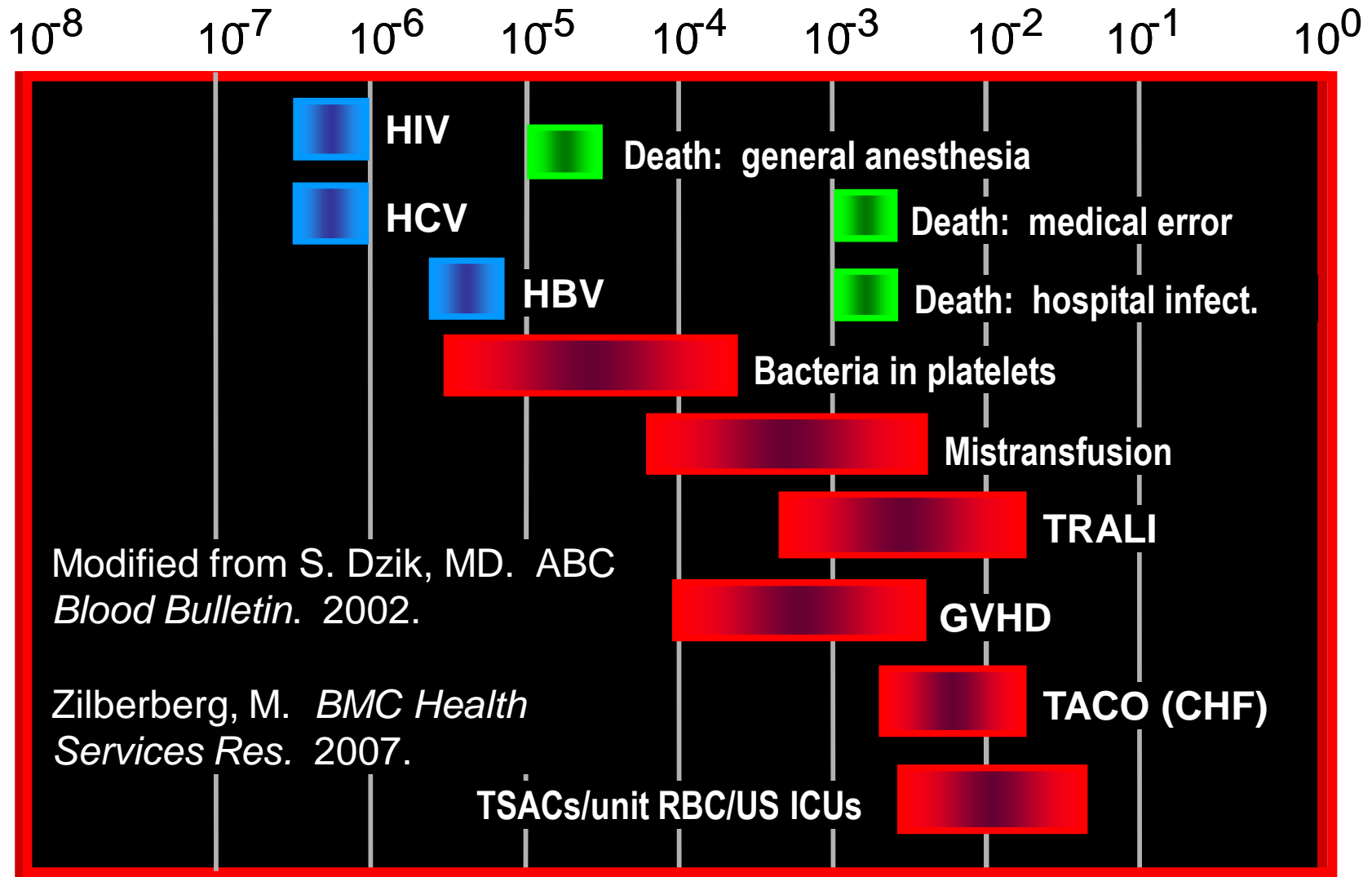
- early warning of safety issues
- exchange of valid information
- application of evidence for practice improvement
- promotion of educational activities

è safer and more efficacious transfusion  
and transplantation



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# Risks of transfusion



# Current AABB System Components

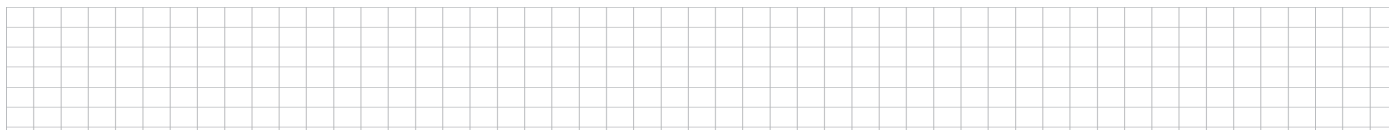
## Biovigilance in the Strategic Plan - 2006

### Initial and Annual Survey

- Hospital descriptive demographics
- Denominator data
  - RBC, Platelets, Plasma, Cryo
  - Aliquots
  - Samples collected
- Adverse Reaction/Incident Reports
- Cell Therapies
- Tissue

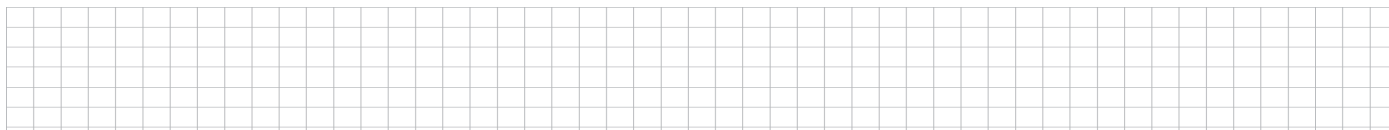
### Web data collection

- WNV
- Chagas Disease



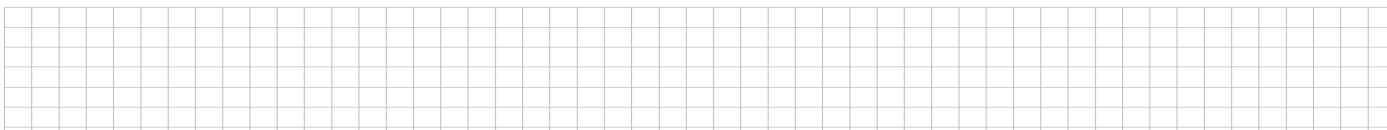
## Existing Federal Tracking Systems (FDA)

- Blood Product Deviation Reports
- Fatality Reports



# Hemovigilance System

- A national system of reporting, collecting and analyzing of transfusion safety data
  - infectious and non-infectious transfusion complications
  - near misses, errors
  - process deviations
- A voluntary system
- A confidential system
  
- And that in order to achieve the goal of preventing the occurrence or reoccurrence of adverse events, a standardized and centralized method of data collection and reporting is needed



# Unique Model: Public Private Partnerships in Biovigilance

## Recipient Hemovigilance

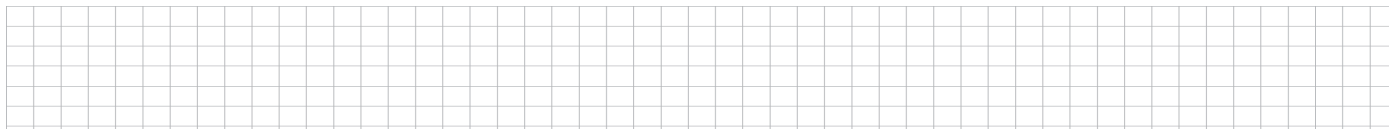
**AABB Interorganizational Task Force on Biovigilance  
(Adverse Reactions/Incidents Working Group)  
in partnership with the  
US Centers for Disease Control National Healthcare Safety Network (NHSN)**

## Donor Hemovigilance

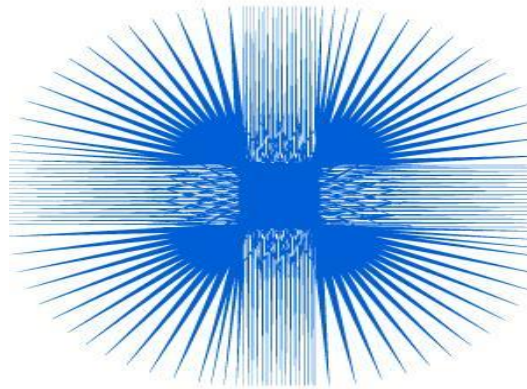
**AABB Interorganizational Task Force on Biovigilance  
Donor Biovigilance Working Group including American Red Cross,  
America's Blood Centers, and other collectors of blood in US  
In partnership with the  
US Department of Health and Human Services**

## Tissues and Organs

**CDC and the United Network for Organ Sharing in partnership with  
Multiple Tissue and Organ Associations developing TTSN**



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# NHSN

National Healthcare  
Safety Network

## 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

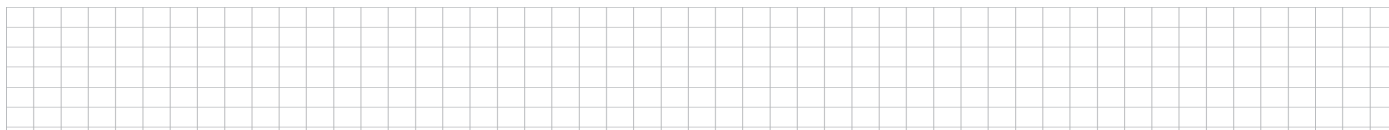
#### Modules

- Hemovigilance  
- patients

### Component Research and Development

#### eSurveillance

- HL7 Messages
- HL7 CDA
- Prevention research



NHSN 3.0.0 Home Page - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites Stop Print Mail Stop

Address http://localhost/hv/nhsnMain.do Go Links

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

NHSN - National Healthcare Safety Network | NHSN Home | My Info | Contact us | Help | Log Out


Logged into DHQP MEMORIAL HOSPITAL (ID 10018) as FAC001.  
Facility DHQP MEMORIAL HOSPITAL (ID 10018) is following the BV component.

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

## NHSN Hemovigilance Module Home Page


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

**Assurance of Confidentiality:** The 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)).

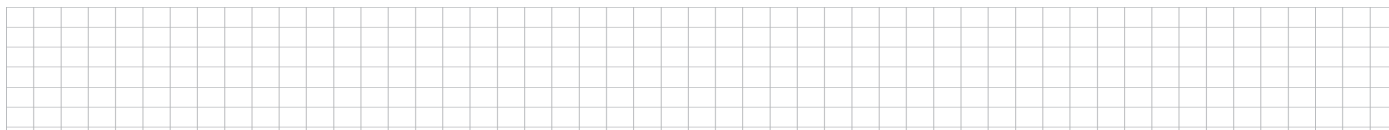
  
Advancing Transfusion and Cellular Therapies Worldwide

AABB provided technical assistance in the development of this hemovigilance module as part of a collaboration with CDC; however, AABB has no direct access to the data or other information contained in this or any other NHSN module. All data collected through this module are protected by the same information security safeguards that apply to all NHSN modules.

**NHSN maintenance may occur nightly between 12am and 6am Eastern time.**

 Get Adobe Acrobat Reader for PDF files

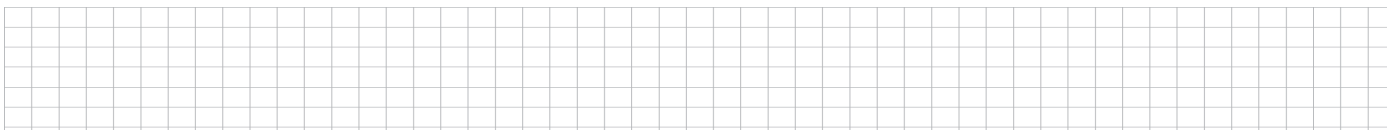
Local intranet



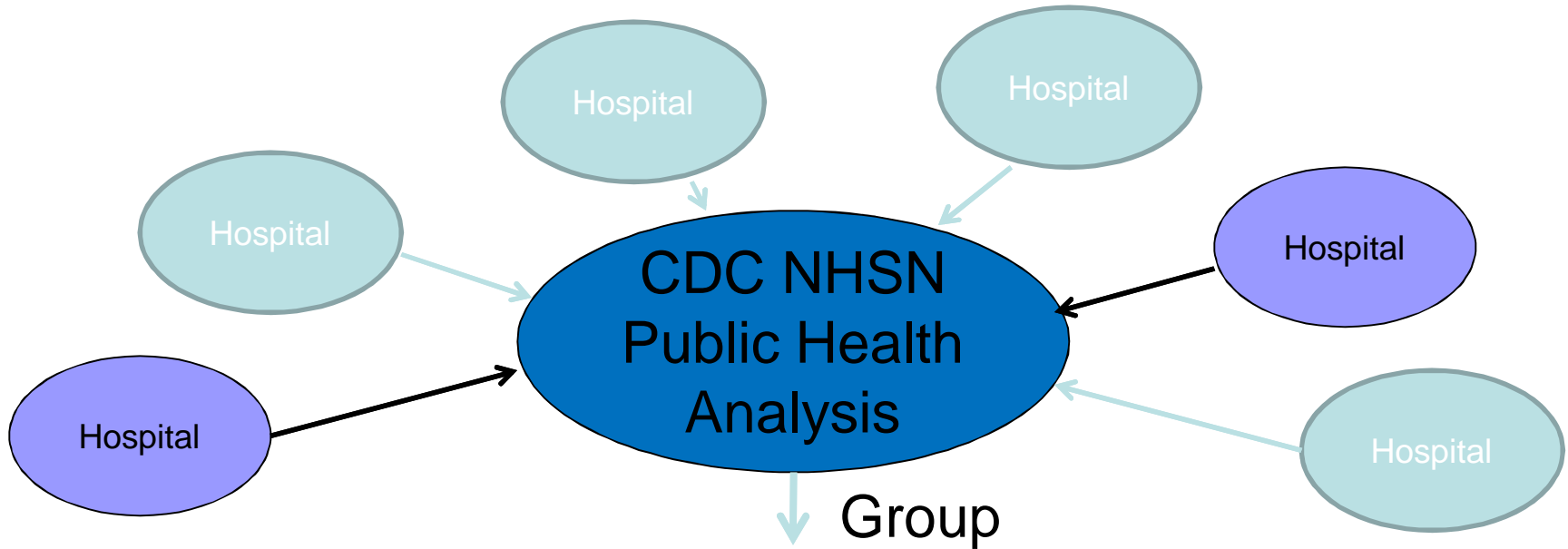
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# Recipient Hemovigilance Module: System Components

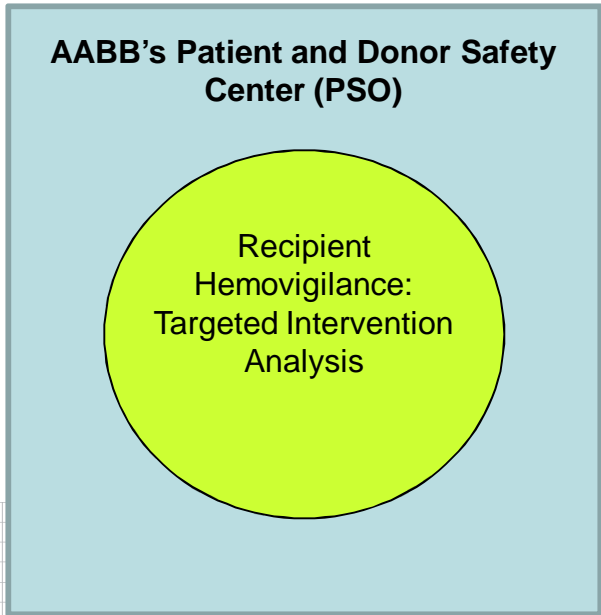
- Initial and Annual Survey
  - Hospital descriptive demographics
  - Denominator data
- Adverse Reaction Reports
- Incident Reports
- Monthly denominator



# Recipient Hemovigilance



Group



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Welcome, John Doe [Sign Out]

- Admin
- Data Entry
- Reports
- My Profile
- Help
- About

### Donor Reaction Record

To add a new reaction, please enter the following details. Fields marked with (\*) are required:

Organization\*  Region\*  Facility\*

#### DONOR INFORMATION

Donor Identifier\*  Date of Birth\*  Gender\*  Female  Male

Ethnicity

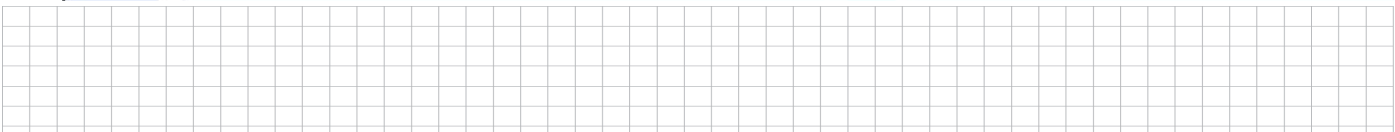
Race

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

#### DONATION INFORMATION

#### REACTION INFORMATION

Save



# Reaction Types and Categories

## Allergic

- Anaphylaxis
- Local
- Systemic

## Local Injury Related to Needle

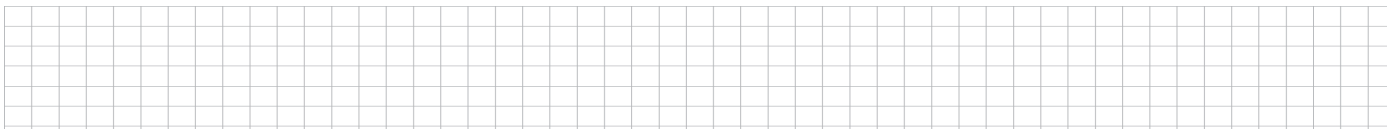
- Arterial Puncture
- Hematoma / Bruise
- Nerve Irritation

## Vasovagal

- Injury
- Loss of Consciousness (LOC) - complicated
- LOC - uncomplicated
- Pre-faint - No LOC

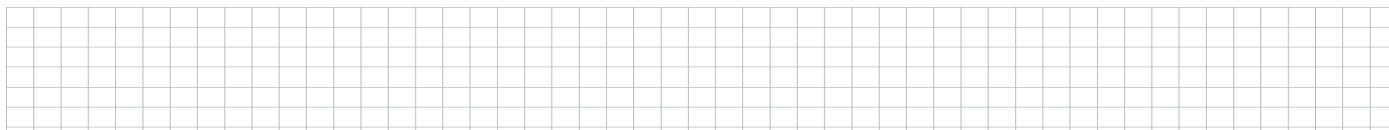
## Added For Apheresis

- Air Embolus
- Citrate
- Hemolysis



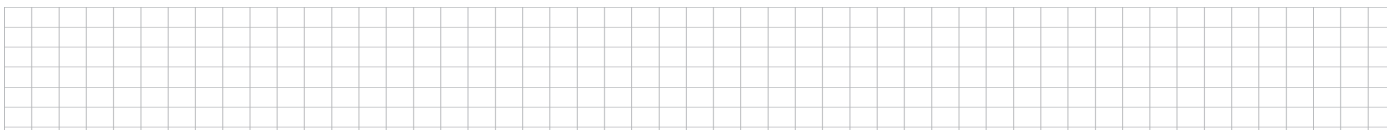
## Hemovigilance Systems Timeline

- Recipient Pilot (9 hosp) – Began May 2009
- Donor Pilot (3 blood centers) – Summer 2009
  
- Demonstrations at Annual Meeting New Orleans
- Systems open to all hospitals and blood centers –
  - Donor – Fall 2009
  - Recipient January 2010
  - 15% of transfusions committed to date




# “The US Biovigilance Collaborative”

- 4 Components
  - Blood Recipient System
    - Content – AABB Advisory Group
    - Electronic System – CDC/NHSN
  - Blood Donor System
    - Content – AABB Advisory Group
    - Electronic System – HHS
  - Tissue / Organs – TTSN
    - Content – UNOS Advisory Group
    - Electronic System – UNet-based
  - Cellular Therapies (TBD)



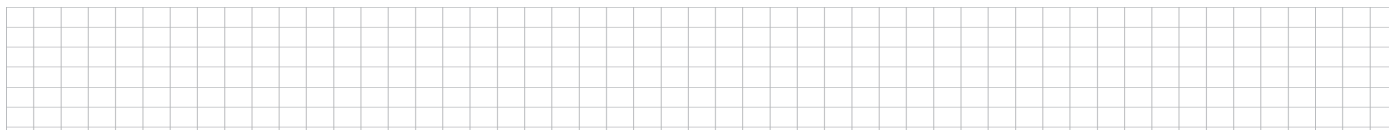


TRANSPLANTATION TRANSMISSION SENTINEL NETWORK

 <p><b>Welcome to the TTSN Web site</b></p> <p>Please login to get started</p>	<p><b>SECURE LOGIN</b></p> <p>Username  <input type="text" value="TBUser1"/></p> <p>Password  <input type="password" value="••••"/></p> <p><input type="button" value="Login"/></p> <p>This section is password-protected for secure data entry by authorized users. Contact your site administrator for information on becoming an authorized user of this system.</p>
<p><b>About TTSN</b></p> <p>The Transplantation Transmission Sentinel Network (TTSN) was established by a CDC cooperative agreement in September 2005. The United Network for Organ Sharing (UNOS), in an alliance with Association of Organ Procurement Organizations (AOPO); American Association of Tissue Banks (AATB); Eye Bank Association of America (EBAA); American Society of Transplantation (AST); and American Society of Transplant Surgeons (ASTS), was awarded the cooperative agreement. The purpose of the Sentinel Network is to establish a network for detecting, communicating, and tracking allograft donors to recipients.</p>	<p><b>Important Links</b></p> <ul style="list-style-type: none"> <li><a href="#">AATB</a></li> <li><a href="#">CDC</a></li> <li><a href="#">EBAA</a></li> <li><a href="#">FDA</a></li> <li><a href="#">OPTN</a></li> </ul>

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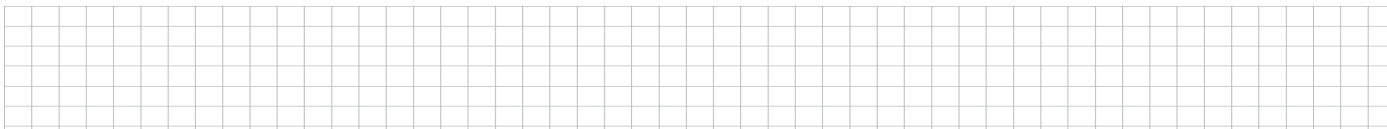
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## For More Information

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

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