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

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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

- safer and more efficacious transfusion and transplantation
Risks of transfusion

- HIV
- HCV
- HBV
- Death: general anesthesia
- Death: medical error
- Death: hospital infect.
- Bacteria in platelets
- Mistransfusion
- TRALI
- GVHD
- TACO (CHF)
- TSACs/unit RBC/US ICUs


Zilberberg, M. BMC Health Services Res. 2007.

U.S. Biovigilance Network
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

U.S. Biovigilance Network
Components and Modules

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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)).

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.
Recipient Hemovigilance Module: System Components

• Initial and Annual Survey
  – Hospital descriptive demographics
  – Denominator data
• Adverse Reaction Reports
• Incident Reports
• Monthly denominator
Recipient Hemovigilance

CDC NHSN Public Health Analysis

Group

AABB’s Patient and Donor Safety Center (PSO)

Recipient Hemovigilance: Targeted Intervention Analysis

U.S. Biovigilance Network
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)
Welcome to the TTSN Web site
Please login to get started

About TTSN
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.

Important Links
AATB
CDC
EBAA
FDA
OPTN
For More Information

www.aabb.org/biovigilance

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