



Thoughts on Hemovigilance From America's Blood Centers

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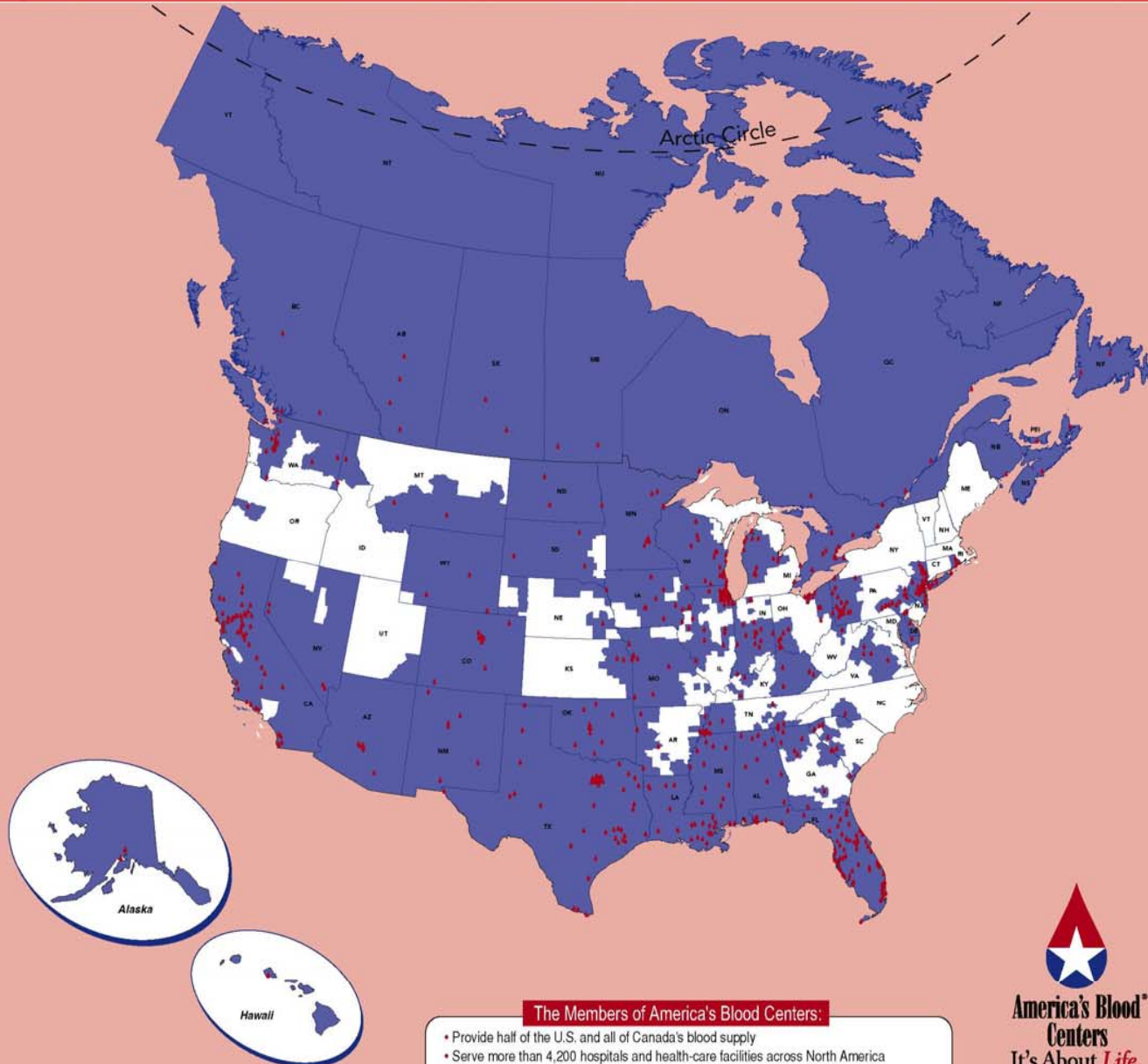


**America's Blood[®]
Centers**
It's About *Life.*

ACBSA, August 30, 2006

America's Blood Centers

- 🇺🇸 **Founded in 1962, America's Blood Centers is North America's largest network of community-based, not-for-profit blood programs**
- 🇺🇸 **78 blood programs serving 180 million people in 45 States and all of Canada**
 - 🇺🇸 **> 9 million donations**
 - 🇺🇸 **>600 collection sites**
 - 🇺🇸 **Over 2.5 million blood recipients at 3,500 hospitals**
 - 🇺🇸 **Half the U.S., and all of Canada's volunteer donor blood supply**
- 🇺🇸 **ABC members also provide therapeutic and transfusion services, recruit marrow, cord and stem cell and tissue donors**



The Members of America's Blood Centers:

- Provide half of the U.S. and all of Canada's blood supply
- Serve more than 4,200 hospitals and health-care facilities across North America
- Serve local communities totaling more than 180 million people at more than 600-plus sites



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Hemovigilance/Biovigilance in the U.S.

- 🇺🇸 The approach is not new!
- 🇺🇸 21 CFR codified traceability and reporting of adverse reactions similar to drugs (Part 200) in the 1995 Quality Guideline
- 🇺🇸 Blood centers have been carrying out aspects of hemovigilance for many years, including
 - 🇺🇸 Cradle to grave traceability
 - 🇺🇸 Fatality Reports
 - 🇺🇸 Blood Product Deviation Reports
 - 🇺🇸 Product retrievals
 - 🇺🇸 Donor and recipient notification - lookback

New focus is on process instead of product

- 🇺🇸 **“Hemovigilance” was created in France (1994) as follow up to the tragedy of AIDS**
- 🇺🇸 **European Hemovigilance Network created in the 90’s; VIIIth meeting, Portugal, Feb 2006**
- 🇺🇸 **SHOT, a voluntary hemovigilance program in the UK started in 1996**
- 🇺🇸 **Voluntary or mandatory programs were gradually instituted in Canada, several European countries, Japan and Brazil**
 - 🇺🇸 **Engelfriet CP and Reesink HW. Hemovigilance. Vox Sang 2006;90-207-241**

Hemovigilance has been codified by the EU

- 🔥 Hemovigilance was codified by the new EU Regulatory system and is a mandated requirement**
- 🔥 Commission Directive 2005/61/EC implementing Directive 2002/98/EC of the European parliament and of the Council (traceability requirements and notification of serious adverse reactions and events.)**

U.S. issues

🇺🇸 FDA law centered on

- 🇺🇸 Safety and efficacy of products
- 🇺🇸 The focus of our current activities

🇺🇸 Hemovigilance

- 🇺🇸 Addresses the process of transfusion of blood and blood products
- 🇺🇸 Requires more hospital and clinical involvement

U.S. needs

- 🇺🇸 **A future U.S. hemovigilance/biovigilance program will need to address**
 - 🇺🇸 **Donors – adverse reactions**
 - 🇺🇸 **Not included in all initiatives**
 - 🇺🇸 **Blood Center activities – reports of adverse reactions from consignees, investigation and, when appropriate, corrective action**
 - 🇺🇸 **Hospitals – patient outcomes data**

The success of a U.S. program depends on

- 🇺🇸 The standardization and acceptance of event definitions by the participants, for example
 - 🇺🇸 Donors
 - 🇺🇸 donor reactions
 - 🇺🇸 Patients –
 - 🇺🇸 Hemolytic reactions
 - 🇺🇸 TRALI
 - 🇺🇸 Transfusion-related bacterial sepsis
 - 🇺🇸 Transfusion-transmitted infection

The success of a U.S. program depends on

- ▲ Active participation of the various organizations involved, among them:
 - ▲ AABB
 - ▲ accredits hospitals, coordinates nationally
 - ▲ ABC, ARC
 - ▲ supply blood, monitor donors, trace products
 - ▲ CAP (College of American Pathologists)
 - ▲ accredits laboratory and transfusion service
 - ▲ ASH (American Society of Hematology)
 - ▲ physicians for transfusion patients, transfusion medicine professionals
 - ▲ JCAHO, AHA – accredit, represent hospitals

What ABC would like to see

- 🇺🇸 A voluntary system like SHOT UK
- 🇺🇸 Focused on donors and patients
- 🇺🇸 Addressing both utilization and adverse events
- 🇺🇸 Data analysis and development of policies based on data

What are ABC's concerns?

- 🔥 Creation of another reporting system that accumulates data but does not contribute to improvements in patient safety
 - 🔥 Action based on the data is key
- 🔥 Addition of regulatory layers
- 🔥 Unfunded mandates – who will pay for the system? Unfortunately, the current economic environment restricts funding for these types of activities

What ABC plans to do in the near future

- 🇺🇸 Organize a volunteer system for collection and analysis of data from ABC blood center members
 - 🇺🇸 Adverse events associated with blood donors
 - 🇺🇸 Hospital complaints about blood products that they received
 - 🇺🇸 Adverse events associated with transfusion recipients

What ABC plans to do in the near future

- 🇺🇸 Support the AABB interorganizational efforts to establish a hemovigilance/biovigilance system at the hospital level
- 🇺🇸 Participate in the analysis of data and in the development of policies as appropriate



Thank you!

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