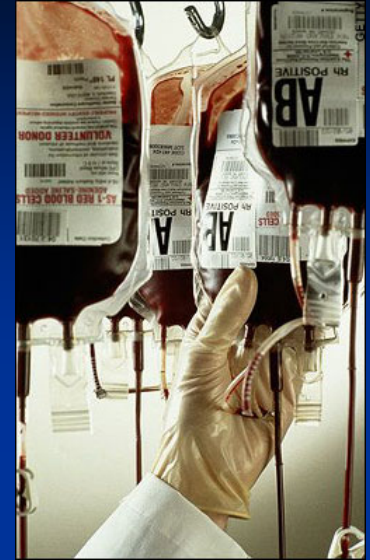
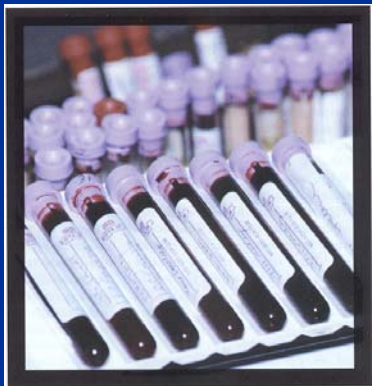




The Safety of the Blood Supply



Richard J. Davey, MD
Director, Division of Blood
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FDA



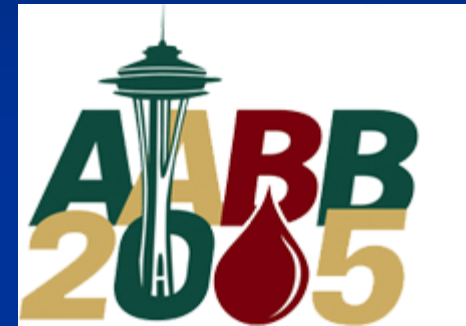
Blood Donation in the United States

- Eight million plus volunteers
- First-time donors 15-25%
- Average 1.6 donations per year
- 15 M units of whole blood collected
 - 4% autologous
 - 2% directed
- 14 M units of RBCs transfused
- % who can donate. 40 - 45%
- % who *actually* donate. 2.5 - 4.5%
- Periodic shortages and appeals.
Postponement of surgery.



Blood Organization in the USA

- **AABB.** 2400 institutions.
9000 members.
Transfusion. Standards.
Annual meeting.
- **American Red Cross.** 45%
of blood supply. 35 blood
centers. One FDA license.
- **America's Blood Centers.**
45% of blood supply. 70
blood centers. Separate
FDA licenses.
- **Hospital blood banks.** 10%
of blood supply. FDA
registered.



America's Blood
Centers

Regulation of the US Blood Supply

- FDA insures the “safety, purity and potency” of blood products. Blood is subject to both “**biologics**” and “**drug**” regulatory oversight. **cGMP**: “Current Good Manufacturing Practices”
 - Code of Federal Regulations (CFR)
 - FDA Guidances
 - FDA Registration. Local collection and testing of blood, or transfusing blood only (hospitals)
 - FDA License: Collection, testing and shipping across state lines. (blood centers)
 - FDA enforcement options: “483” observations, warning letters, suspension, revocation.
- State regulations, OSHA, CDC, AABB and CAP

Five Layers of Safety

1. Selection of suitable donors
 - Donor history questionnaire
 - Limited physical examination
2. Donor deferral registries
3. Testing for infectious agents
4. Quarantining of blood while verifying suitability
5. Taking corrective actions to address errors

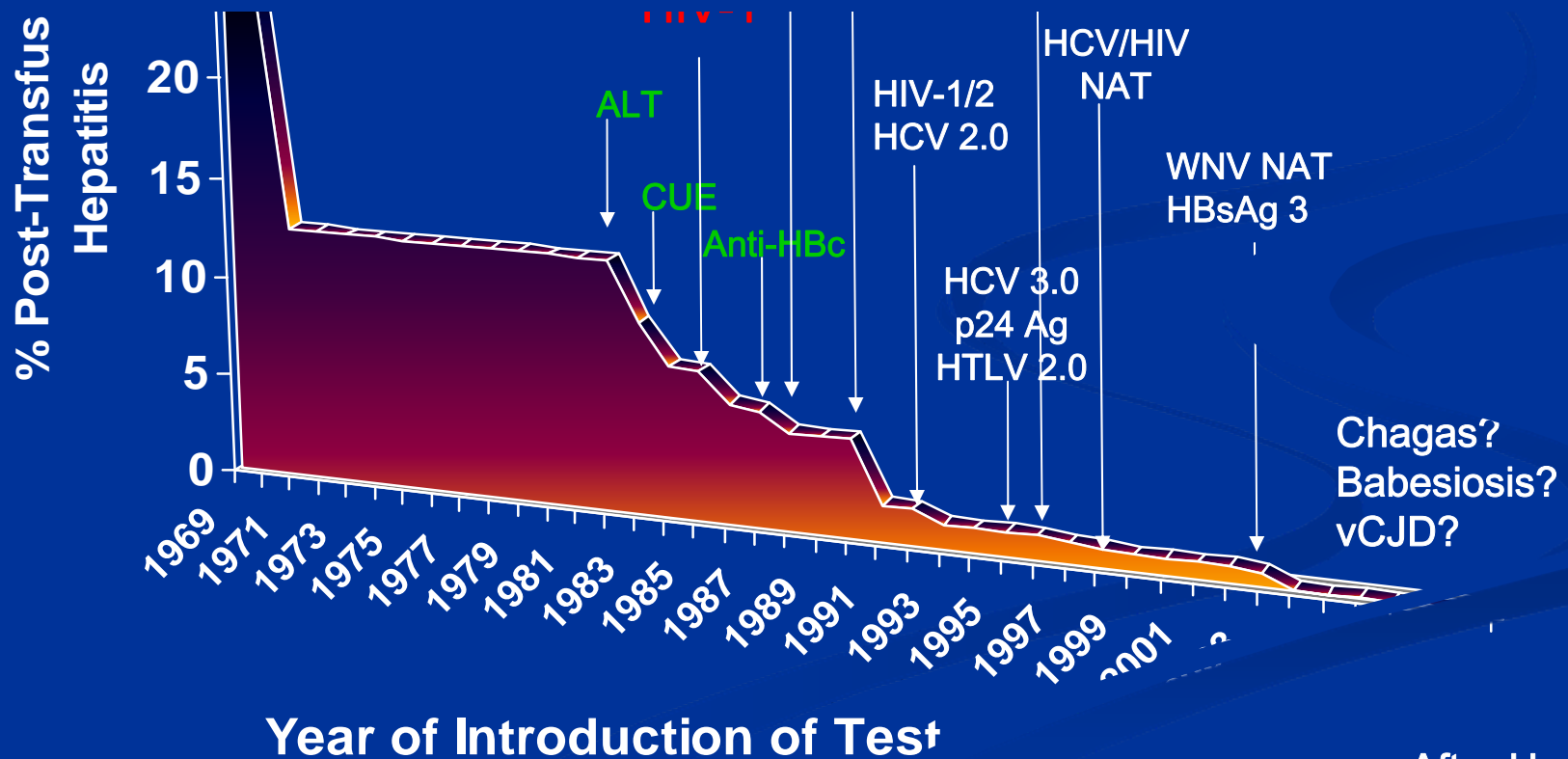
Blood Donor Qualification

- Regulations and guidances
- Hemoglobin levels
- Risk behavior questions
- Travel
 - Malaria
 - vCJD (“mad cow disease”)
- Testing
 - HIV, HCV, HBV, others
- Chagas disease
- Dengue ?
- XMRV ?



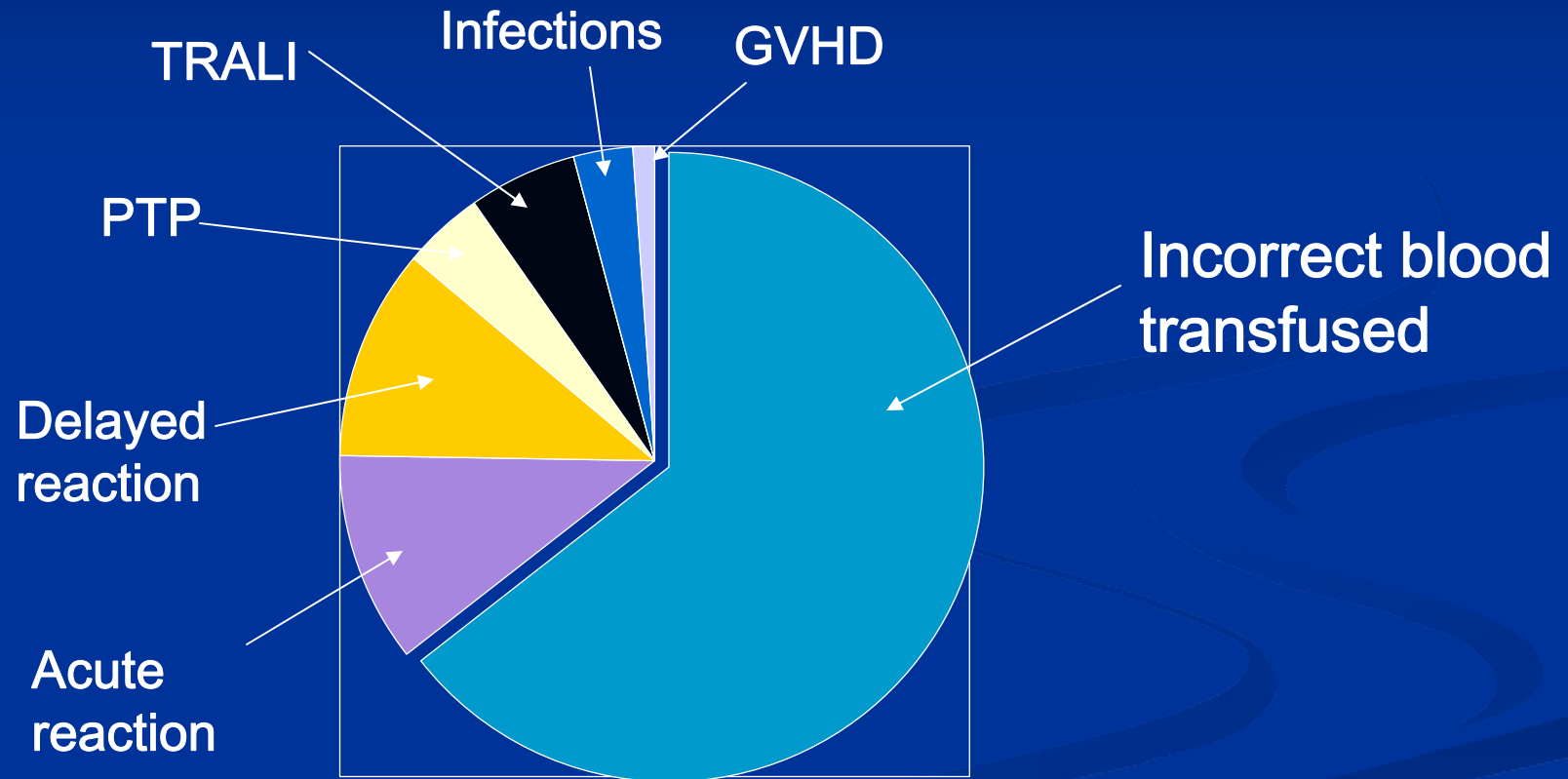
Transfusion Transmitted Disease

Post-Transfusion Hepatitis Risk: 1969-2005



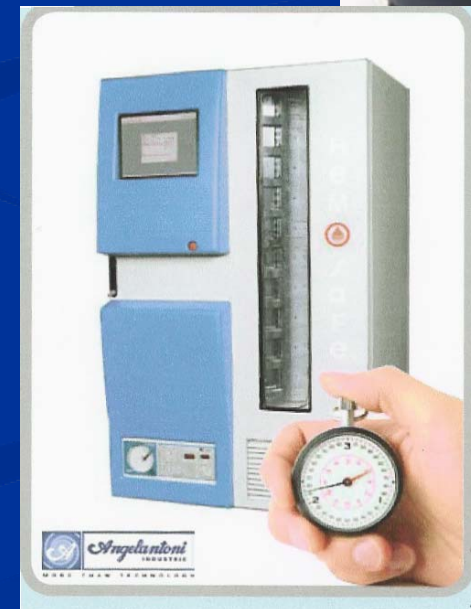
After H. Alter

Hospital Transfusion Issues: Events Reported by the SHOT Program in England, 1996-2001.



Transfusion Safety Options

- Hand-held bar code scanners
- Radio frequency “smart-tags” and readers (RFID)
- Wi-Fi technology
- Blood bag “dispenser” systems
- Dedicated phlebotomists
- Two separate blood samples on all new patients
- Transfusion Safety Officer

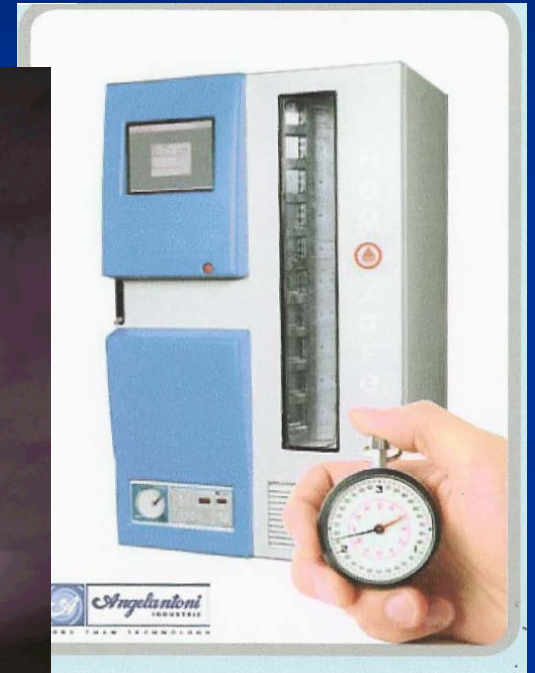


Transfusion Safety Officer

- Most serious hazards of transfusion occur *outside* of the laboratory
- The *principal role* of the TSO is to work *outside* of the laboratory to improve patient safety during transfusions
- Most TSOs are RNs or PAs with >3 yrs experience, preferably in med-surg in-patient settings



Blood Safety Innovations



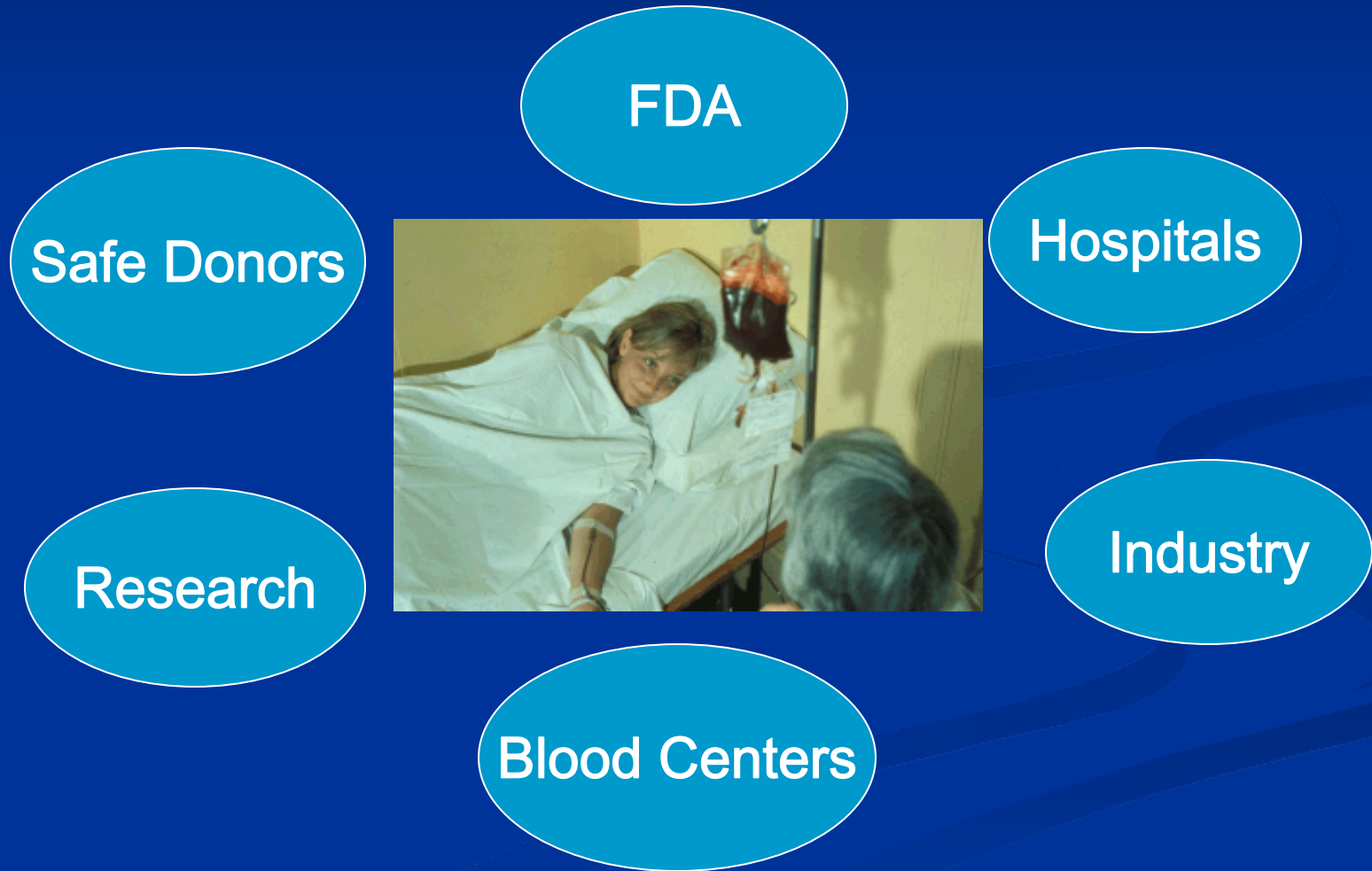
Research: Is “Old” Blood OK?



Future Directions in Transfusion Science

- Understand blood storage lesion
 - Better storage containers and conditions
- Blood management
 - Appropriate use of blood to minimize its use
- Pathogen reduction technologies
 - Minimize infectious hazards
- Artificial oxygen carriers
 - Minimize reactions, storage lesion and infectious hazards

The Primary Focus of Blood Safety: The Patient



Questions about today's webinar?

- Toll-free 1-888-INFO-FDA (888-463-6332)
- One the web www.fda.gov
- E-mail ocod@fda.hhs.gov

