



Blood Products and Cellular Therapies: A Symposium on Emergency Preparedness

Co-hosted by BARDA and NHLBI

November 15-16, 2012

Natcher Conference Center, NIH Building 45 – Bethesda, MD

Agenda (Version 2.0, as of October 9th, 2012)

Day 1 – Session A: Regulatory Considerations for Blood Products, Emergency Plans and Use

Discussion leader: *Joanna Prasher, PhD* (Branch Chief, Medical Countermeasures Strategy and Requirements Division, Office of the Assistant Secretary for Preparedness and Response, HHS)

1. Introduction
 - *Robin Robinson, PhD* (Director, BARDA)
 - *Keith Hoots, MD* (Director, Division of Blood Diseases and Resources, NHLBI/NIH)
2. Plenary Lecture - *Harvey Klein, MD* (Chief, Department of Transfusion Medicine, Clinical Center/NIH)
3. Blood products: Regulatory Considerations (FDA)
 - General overview - Regulation of Blood Products – *Ginette Michaud, MD* (Deputy Director, Office of Blood Research and Review, CBER/FDA)
 - Situation approvals/Emergency use - *Cynthia Kelley, MS* (Senior Advisor for Counterterrorism/Medical Countermeasures, CBER/FDA)
4. Emergency plans and use:
 - AABB Task Force: Emergency Plans - *Karen Shoos, JD* (Chief Executive Officer, AABB)
 - Red Cross: Emergency Plans - *Richard Benjamin, MD, PhD* (Chief Medical and Scientific Officer, American Red Cross)
 - American Blood Systems: Emergency Plans - *Peter Tomasulo, MD* (Chief Medical and Scientific Officer, Blood Systems)
 - NY Blood Center: Emergency Plans - *Beth Shaz, MD* (Chief Medical Officer, NY Blood Center)
 - Scenario case: Radiological/Nuclear Incident - *C. Norm Coleman, MD* (Senior Medical Advisor, OPEO/ASPR/HHS)
 - DoD Program: Challenges and Opportunities – *COL Richard McBride* (Director, Armed Services Blood Program Office)
 - Radiation Injury Treatment Network (RITN) - *David Weinstock, MD* (Medical Advisor, Radiation Injury Treatment Network, Dana Farber Cancer Institute)
5. PANEL DISCUSSION

Day 1 – Session B: Cellular Therapies with a Focus on Marrow Replacement

Discussion leader: *Harvey Klein, MD* (Chief, Department of Transfusion Medicine, Clinical Center/NIH)

1. Graft therapies
 - *Minoo Battiwalla, MD* (Principal Investigator and Staff Clinician, Hematology Branch, NHLBI/NIH)
 - *Edward Snyder, MD* (Director, Transfusion/Apheresis/Tissue/Cell Processing Services, Yale-New Haven Hospital; Professor, Yale University Medical School)
2. Bridging Therapies
 - *Joanne Kurtzberg, MD* (Director, DTRI Cell and Tissue Therapies Core; Chief, Division of Pediatric Blood and Marrow Transplantation, Duke University Medical Center)

- *Colleen Delaney, MD* (Director, Cord Blood Transplant Program, Fred Hutchinson Cancer Research Center)
3. FDA: Regulatory Considerations for Developing Cellular Therapies - *Keith Wonnacott, PhD* (Division of Cellular and Gene Therapies, CBER/FDA)
 4. PANEL DISCUSSION

Day 2 – Session C: Red Blood Cells (RBCs) and Plasma

Discussion leader: *Simone Glynn, MD, MSc, MPH* (Branch Chief, Transfusion Medicine and Cellular Therapeutics Branch, NHLBI/NIH)

1. Metabolic Changes in RBC in Storage/Possible Genetic Determinants for Variability in Storage - *Mark Gladwin, MD* (Chief, Pulmonary, Allergy and Critical Care Medicine Division, University of Pittsburgh School of Medicine)
2. Innovations to Improve Storage - *John Hess, MD, MPH* (Associate Director, University of Maryland Medical Center Blood Bank; Professor, Pathology, University of Maryland Medical Center)
3. Innovations: Blood Pharming - *Renee Wegrzyn, PhD* (Science Advisor, Defense Advanced Research Projects Agency/DSO)
4. Plasma: Best practices for Use - *John Holcomb, MD* (Chair in Surgery, Professor and Vice Chair of the Department of Surgery, Chief of the Division of Acute Care Surgery, Director, Center for Translational Injury Research, University of Texas Medical School, Houston)
5. Plasma Processing - *Toby Simon, MD* (Senior Medical Director, Plasma and Plasma Safety, CSL Behring)
6. Innovations: Plasma - *Larry Corash, MD* (Senior Vice-President, Chief Medical and Scientific Officer, Cerus Corporation)
7. PANEL DISCUSSION

Day 2 – Session D: Platelets

Discussion leader: *Keith Hoots, MD* (Director, Division of Blood Diseases and Resources, NHLBI/NIH)

1. Storage/Handling/Cold storage - *Sherrill Slichter, MD* (Director, Platelet Transfusion Research, Puget Sound Blood Center; Professor of Medicine, University of Washington School of Medicine)
2. Lyophilized products
 - *G. Michael Fitzpatrick, PhD* (President, Director of Clinical Research and Development, Cellphire Inc.)
 - *Art Bode, PhD* (Chief Scientific Officer, Entegron, Inc)
3. Thrombopoietic products
 - *James Busse, MD* (Professor & Attending Pediatrician, Weill Cornell Medical College)
 - *Ram Mandalam, PhD* (Chief Executive Officer, Cellerant Therapeutics)
4. PANEL DISCUSSION

Day 2 – Session E: Pathogen Reduction

Discussion leader: *Traci Mondoro, MD* (Deputy Branch Chief, Transfusion Medicine and Cellular Therapeutics Branch, NHLBI/NIH)

1. Pathogen reduction
 - *Stephen Wagner, PhD* (Head, Blood Components Department, Holland Laboratory, American Red Cross)
 - *Larry Corash, MD* (Senior Vice-President, Chief Medical Officer, Chief Scientific Officer, Cerus Corporation)
 - *Ray Goodrich, PhD* (Vice President, Scientific and Clinical Affairs, Terumo BCT, Inc.)
2. PANEL DISCUSSION
