Public Workshop:

Use of Computer Simulation of the United States Blood Supply in Support of Planning for Emergency Preparedness and Medical Countermeasures

A Workshop Hosted by:
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Biostatistics and Epidemiology

July 24, 2012

Hyatt Regency Bethesda

Organized by

Dr. Arianna Simonetti, Dr. Richard Forshee, Dr. Steven Anderson and Dr. Mark Walderhaug
FDA/CBER/OBE

Project Advisory Group

Dr. Paul Mintz, Dr. Richard Davey, Dr. Orieji Illoh (FDA/CBER/OBRR)

Dr. Hong Yang, Dr. Lou Gallagher, Dr. Jerald Mullersman (FDA/CBER/OBE)
8:00 AM 8:30 AM  Registration and Welcome

Session 1:

*Introduction: Preparedness and Identifying Needs for the US Blood Supply*

**Chair:** Dr. Arianna Simonetti, FDA/CBER/OBE

8:30 AM 8:40 AM  *Welcome and Introduction*

Dr. Mark Walderhaug, FDA/CBER/OBE

8:40 AM 8:55: AM  *Opening Remarks: A Regulator's Perspective*

Dr. Ginette Michaud, FDA/CBER/OBRR

8:55 AM 9:15 AM  *Planning for Blood and Tissue Needs for Mass-Casualty Incidents Scenario-Based Analysis of Improvised Nuclear Device Incidents*

Dr. Timothy Lant, HHS/ASPR/BARDA and Dr. Kenneth Cliffer, HHS/ASPR/OPP

9:15 AM 9:35 AM  *HHS Blood Supply Response Perspectives*

Richard Henry, HHS/OASH

9:35 AM 9:55 AM  *Community Healthcare Framework for Managing Large Scale Incidents*

CAPT Deborah Levy, (USPHS) CDC

9:55 AM 10:15 AM  *Planning for Blood Needs as Part of Emergency Preparedness: Perspective of AABB Interorganizational Task Forces on Disasters and Pandemic Influenza*

Theresa Wiegmann, AABB

10:15 AM 10:30 AM  Coffee Break/On your own
Session 2:

**Computer Simulation Modeling: Example Applications for Blood Supply Management**

Chair: Dr. Mark Walderhaug, FDA/CBER/OBE

10:30 AM – 10:45 AM  
*How Computer Simulation Can Inform Supply Management and Inventory*

Dr. Arianna Simonetti, FDA/CBER/OBE

10:45 AM – 11:15 AM  
*Use of Simulation Modeling of the Blood Supply: A UK Example*

Prof. Sally Brailsford, University of Southampton UK

11:15 AM – 12:00 AM  
**Panel for Sessions 1 & 2:** Dr. Ginette Michaud (FDA/CBER/OBRR), Dr. Kenneth Cliffer (HHS/ASPR/OPP), Dr. Timothy Lant (HHS/ASPR/BARDA), Richard Henry (HHS/OASH), CAPT Deborah Levy (CDC), Theresa Wiegmann (AABB), Prof. Sally Brailsford (University of Southampton, UK), Dr. Richard Forshee (FDA/CBER/OBE), Dr. Celso Bianco (ABC), Dr. Richard Benjamin (ARC)

Questions/comments from the audience

Panel Moderator: Cynthia Kelley, FDA/CBER/IOD

12:00 AM – 1:00 PM  
Lunch Break/On your own

Session 3:

**An FDA Example of Computer Simulation Model of the U.S. Blood Supply: Assumptions, Results, Capabilities and Limitations**

Chair: Dr. Brian Custer, BSRI

1:00 PM – 1:45 PM  
*An FDA Example of Computer Simulation Model of the U.S. Blood Supply: Simulation of Modeling Scenarios*

Dr. Arianna Simonetti, FDA/CBER/OBE

1:45 PM – 2:30 PM  
**Panel for Session 3:** Prof. Sally Brailsford (University of Southampton, UK), Dr. Kenneth Cliffer (HHS/ASPR/OPP), Dr. Timothy Lant (HHS/ASPR/BARDA), Dr. Richard Forshee (FDA/CBER/OBE), Dr. Orieji Illoh (FDA/CBER/OBRR), Dr. Susie ElSaadany (University of Ottawa, CA), Dr. Arianna Simonetti (FDA/CBER/OBE), Dr. Brian Custer (BSRI)

Questions/comments from the audience

Panel Moderator: Dr. Samir Lababidi, FDA/CBER/OBE

2:30 PM – 2:45 PM  
Coffee Break/On your own
Session 4:
Industry and Hospital Perspectives on Possible Applications of Computer Simulation Models in Blood Supply Management

Chair/Moderator: Dr. Steven Anderson, FDA/CBER/OBE

2:45 PM 3:00 PM  
*Current Limitations and Future Enhancements of the FDA Blood Supply Model*
Dr. Richard Forshee, FDA/CBER/OBE

3:00 PM 3:20 PM  
*Simulation Modeling to Support Regulatory Decisions: A Blood Center Wish List*
Dr. Celso Bianco, ABC

3:20 PM 3:40 PM  
*Modeling the Blood Inventory: The Red Cross Perspective*
Dr. Richard Benjamin, ARC

3:40 PM 4:00 PM  
*A Hospital Perspective on Blood Use In Disasters – University of Maryland Medical Center*
Dr. John R Hess, University of Maryland School of Medicine (UMSM)

4:00 PM 4:45 PM  
**Panel for Session 4:** Dr. Richard Forshee (FDA/CBER/OBE), Dr. Celso Bianco (ABC), Dr. Richard Benjamin (ARC), Dr. John R. Hess (UMSM), Dr. Mark Walderhaug (FDA/CBER/OBE), Dr. Paul Mintz (FDA/CBER/OBRR), Dr. Jerald Mullersman (FDA/CBER/OBE)

Questions/comments from the audience

Panel Moderator: Dr. Steven Anderson, FDA/CBER/OBE

4:45 PM 5:00 PM  
**Summary and Conclusions from Afternoon Discussion Session**

Thanks to Participants and Presenters: Dr. Richard Forshee, FDA/CBER/OBE
**List of abbreviations:**

CBER: Center for Biologics Evaluation and Research

OBE: Office of Biostatistics and Epidemiology

OBRR: Office of Blood, Research and Review

ASPR: Assistant Secretary for Preparedness and Response

OPP: Office of Policy and Planning

BARDA: Biomedical Advanced Research and Development Authority

OASH: Office of the Assistant Secretary for Health

IOD: Immediate Office of the Director

CDC: Centers for Disease Control and Prevention

BSRI: Blood Systems Research Institute