Advisory Committee on Blood Safety and Availability
Department of Health and Human Services
35th Meeting Minutes
December 16 & 17, 2008

The 35th meeting of the Advisory Committee on Blood Safety and Availability was called to order at 8:30 AM by the Chairman, Dr. Arthur Bracey. The Executive Secretary, Dr. Jerry Holmberg called the roll.

I. Administrative
   a. Members present: Arthur Bracey, MD, Richard Benjamin, MBCHB, Ph.D., Anne Marie Finley, Ann Marie Benzinger, Charles Haley, MD, Julie Birkofer, Michael Ison, MD, MS, William Duffell, Jr. Ph.D., Peter Kouides, MD, Ileana Lopez-Plaza, MD, David Matyas, JD, Klaus Nether, Gregory Pomper, MD, Glenn Ramsey, MD, Linda Wade, Darrell Triulzi, MD
   Non-Voting Members: Matthew Kuehnert, MD, Jay Epstein, MD, Harvey Klein, MD, Laura St. Martin, MD, MPH, Richard Durbin

   b. Members absent: Gregg Bloche, MD, JD, Glenn Pierce, MD, Ph.D., Colonel Francisco Rentas, Ph.D., James Bowman, MD

   c. Dr Holmberg thanked those members who are rotating off for their willingness to return for an extended term until the new members come on board. Nominations to replace those members completing their appointment are on hold until the new Administration is in place to review the new nominees.

II. Committee Updates
   a. Sanjai Kumar, Ph.D., from FDA presented a summary report from the FDA's Workshop on "Approaches to Reduce the Risk of Transfusion-Transmitted Babesiosis in the United States."

   b. Barbee Whitaker, Ph.D., the Director for Data and Special Programs at AABB, provided a summary of the findings of National Blood Collection and Utilization Survey (NBCUS) Report.

   c. Michael Strong, Ph.D., Chair of the Biovigilance Task Force and Steering Committee, offered an update on donor biovigilance.

   d. Dr Holmberg presented the Executive Secretary's Status Report of Previous Recommendations and Committee Discussion.

   e. Donald Wright, MD, MPH, the Principal Deputy Assistant Secretary for Health, reiterated the Committee Charge and individually recognized the

committee service of those members rotating off. In doing so, Dr Wright presented certificates of appreciation to the following:

i. Richard Benjamin, MBCHB, PhD (5/29/08-12/01/08)
ii. Gregg Bloche, MD, JD (12/01/05-12/01/08)
iii. William Duffell, PhD (12/01/05-12/01/08)
iv. David Matyas, JD (12/01/05-12/01/08)
v. Glen Ramsey, MD (12/01/05-12/01/08)

III. Presentations and discussion on the role of blood/plasma centers in donor health and overall public health focused on the following topics:

a. Current status of regulatory and professional standards on donor health and public health
   i. Gilliam Conley, the Director of the FDA/CBER's Division of Inspections and Surveillance Office of Compliance and Biologics Quality, reported on the FDA's current regulations for donor selection and donor health management.
   ii. Darrel Triulzi, MD, the Director of the Division of Transfusion Medicine in the Department of Pathology at the University of Pittsburgh and Medical Director of the Institute for Transfusion Medicine, gave a presentation on AABB's standards and current status of blood donor health, discovery and follow-up.
   iii. Joshua Penrod, JD, presented the Plasma Protein Therapeutic Association's programs and standards to protect donor health and public health.

b. Targeted Health Wellness
   i. Richard Davey, MD, gave a presentation on Blood/Plasma Centers as potential community health resources. Dr. Davey discussed the possibility of various outreach programs that could be health screening benefits to donors.
   ii. Penelope Slade-Sawyer, P.T., RADM, USPHS, Deputy Assistant Secretary for Health, provided the Committee with an update on the Department of Health and Human Services' Health People 2010/2020.

c. Ethical Issues
   i. Ronald Domen, MD, from the Department of Pathology, College of Medicine, Milton S. Hershey Medical Center, Penn State, reported on the donor informed consent process. He also discussed ethical issues between the blood center and the donor.
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d. Medical Management

i. Barbara Bryant, MD, from the University of Texas Galveston, presented on the identification and management of iron in donors. Data were presented on the effects of donation on the donor's iron status and the limitations of the current hemoglobin criteria.

e. Current Experiences in Donor and Public Health
   i. Anne Eder, MD, the Executive Medical Officer for Biomedical Services at the American Red Cross, reported on the responsibility of blood centers to donor and public health from the Red Cross's point of view. Dr. Eder also reported data from the American Red Cross hemovigilance program.
   ii. Merlyn Sayers, MD, Ph.D, the CEO and President of Carter BloodCare, gave a presentation on a community blood center's experience with public health screening.
   iii. Robert Jones, MD, MBA, the President and CEO of New York Blood Center, reported on NYBC's community health services in various areas including experience with genetic testing and future programs.
   iv. Merlyn Sayers, on behalf of Celso Bianco, MD, the Chief Medical Officer of America's Blood Centers, presented a report on ABC member experiences

IV. Recommendations

The Committee recognized transmission of babesiosis by blood transfusion and organ and tissue transplantation as a current recipient safety concern. This concern was heightened by an apparent increase in reports of transfusion transmitted cases in the last few years. Given the potentially significant health risks of babesiosis and the current lack of accurate scientific information on the transfusion and transplantation risk, the Committee recommended the Secretary support efforts to determine the donor prevalence of babesiosis in relation to the general population, its transmissibility by transfusion and organ transplantation, and the utility of potential safety interventions, e.g. development of donor screening and/or pathogen reduction technology.

Annually, approximately 10 million people donate allogeneic blood for transfusion or source plasma for further manufacturing, many on multiple occasions. These encounters with blood and plasma collection centers can result in outcomes that are of health significance to the donors. These include a spectrum of adverse events related to donation per se, and medical findings related to vital signs, hemoglobin level and infectious disease status. Current practices vary regarding collection of safety data, notification, and medical follow-up related to adverse health information.

At the same time, donor encounters with blood and plasma collection centers provide a potential opportunity for expansion to include broader evaluations of donor health within the larger contexts of maintaining a healthy and robust donor base and of promoting public health consistent with the HHS program of Healthy People 2010. However, the actual risks, benefits and cost-effectiveness of specific practices that go beyond assuring safe donation and safe and effective blood products are not established. The following issues warrant specific consideration by the Secretary:

i. Event reporting in donors - Published data suggests disproportionate rates of adverse events in donor subgroups. The Committee supported efforts to develop a comprehensive national reporting system for blood and plasma donor adverse events.

ii. Informed consent
   1. While the current status of informed consent for blood and plasma donation is generally adequate, the Committee recognized that there are opportunities for improvement. Informed consent is performed nationally but lacks consistency in a defined set of elements which has led to individual and regional variation. As informed consent is refined, the risks of donation, especially repeat donation, warrant further evaluation.
   2. At a minimum, the known risks of donation are disclosed, but the scope of informed consent should be expanded to consider:
      a. the effects of repeat donation on the general donor population
      b. the gender specific effects of iron deficiency on donors
      c. the effects of collecting blood from anemic men using current donation thresholds
      d. the disproportionate prevalence of adverse events in the youngest donors
      e. the method and frequency of effective informed consent for repeat donations

iii. Donor notification and follow-up of medical findings
   Further standardization is needed on the manner with which (and extent to which) donors are notified of medical findings after donor suitability evaluation and product testing. By way of example:
      a. Should notification be required to be performed electronically, telephonically, or by any method chosen by the donor?

b. What categories of test results are required to be communicated to the donor (e.g., sickle cell)?
c. When a donor returns to a center, should follow-up questions related to test results be incorporated into the donor questionnaire?

iv. Wider health screening

The Committee heard statements from blood centers engaged in public health screening measures beyond those required for donor and recipient safety. The following issues/concerns arose from Committee discussions on this topic:

1. Mission dilution / Conflicts of Interest - Blood and plasma collection establishments have a primary role of manufacturing safe blood products. A risk exists that an expanded role to provide donor health screening unrelated to donor or recipient safety could result in a compromise to their primary function and could present an ethical conflict with their core relationship to the donor. In addition, absence of standard practices in this area could have negative effects on blood center competition.

2. Unexpected adverse outcomes - Although the results of public health screening may alert the donor about a possible health risk, the results of such testing could potentially affect donor access to insurance or employment, or result in an unexpected cost for further medical evaluation.

3. Undue incentives-Public health screening programs by blood or plasma centers may create undue incentives for unsafe donors who are test seekers. Given that there is no benefit in safety to the recipient or donation process, any such incentives should be evaluated.

4. Whereas the beneficial effects of health screening and interventions are well established, the effectiveness of health/wellness screening in the donor setting should be further evaluated for its effect on optimizing blood donations and blood donor health.

v. Reconsideration of the donor hemoglobin acceptance value

1. The normal distribution of hemoglobin values is higher for males than for females.
2. The current single value for accepting blood donors (12.5 g/dL) permits acceptance of a significant number of

"anemic" males while excluding many normal females. Adopting different, gender-appropriate acceptance values would reduce the number of anemic donors bled without compromising the number of red cell units collected.

vi. Healthy People 2020 - The Committee recommends the Secretary consider donor safety and health management as a topic area for Healthy People 2020.

The meeting adjourned at 4:50 PM