DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington DC 20201

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Steven K. Galson, M.D., M.P.H.
Acting Assistant Secretary for Health
Office of Public Health and Science
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Rear Admiral Galson:

The 35th meeting of the Advisory Committee on Blood Safety and Availability (ACBSA) was held in Rockville, MD on December 15 and16, 2008. The ACBSA heard updates on blood safety issues, including babesia transmission through the blood supply. Presentations were also made from a number of blood center experts on issues related to donor health in response to blood/plasma donation and of the potential role of blood/plasma centers in promoting public health.

Based on the data presented and recommendations from the babesiosis workshop in September 2008, 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 recommends that 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."

After hearing presentations on donor health and safety, the Committee expressed concern regarding the extent of monitoring for donor adverse events and the potential impact of health promotion on the balance of the public benefit to overall safety of blood donated through altruism versus health screens or health promotions.

The Committee provides the following statement and embedded recommendations to the Secretary.

"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 suggest disproportionate rates of adverse events in donor subgroups. The committee supports efforts to develop a comprehensive national reporting system for blood and plasma donor adverse events.

II. Informed consent

While the current status of informed consent for blood and plasma donation is generally adequate, the Committee recognizes 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.

At a minimum, the known risks of donation are disclosed, but the scope of informed consent should be expanded to consider:

-the effects of repeat donation on the general donor population
-the gender specific effects of iron deficiency on donors
-the effects of collecting blood from anemic men using current donation thresholds
-the disproportionate prevalence of adverse events in the youngest donors
-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:

- Should notification be required to be performed electronically, telephonically, or by any method chosen by the donor?
- What categories of test results are required to be communicated to the donor (e.g., sickle cell)?
- 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:

A. 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.

B. 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.

C. 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.

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.

D. Reconsideration of the donor hemoglobin acceptance value

The normal distribution of hemoglobin values is higher for males than for females. 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.

E. Healthy People 2020

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

The Committee is appreciative of your concern for public health in both your position of Acting Assistant Secretary for Health and Acting Surgeon General. We hope that these most recent recommendations will provide the new Secretary with a useful approach to important questions related to public health. Furthermore, we hope that the outcome of this meeting will ensure that we are optimally engaged in promoting the welfare of a national treasure, our volunteer blood donors.

Sincerely,

Arthur W. Bracey, M.D.
Chairman, ACBSA