



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

July 11, 2008

Joxel Garcia, M.D. M.B.A.
Assistant Secretary for Health
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Dr. Garcia,

The Advisory Committee on Blood Safety and Availability met on May 29 and 30, 2008. The Committee heard updates from the staff of the Food and Drug Administration (FDA) and the Health Resources and Services Administration (HRSA) on safety initiatives in transfusion, tissue and transplantation. The primary discussion of the meeting was focused on two key evolving areas of transfusion safety, detection of bacterial contamination of platelets for extended shelf life and adverse clinical outcomes associated with blood storage.

The latter topics were discussed in-depth by the Committee as it was charged by Dr. Wright to address risk associated with bacterial contamination of platelets and its detection as well as recent scientific discussions on clinical significance associated with the age of the red cell. All felt that many issues raised in these sessions are in need of action by the Department to advance the safe practice of blood transfusion.

Regarding the risk of bacterial contamination of platelet concentrates, "the Committee appreciates that interventions including culture and diversion have reduced the risk of bacterial transmission; however, more effective methods are needed to further limit or eliminate the risk of bacterial contamination of platelets. Additionally the current status of disparate levels of safety for platelet products is highly problematic.

The Committee recommends that additional measures (e.g. prevention, detection, pathogen inactivation) be adopted to reduce the difference in safety profile between whole blood and apheresis platelets and reduce the overall risk of bacterial contamination of platelets. The Department should monitor the current status of platelet availability and potential for meeting future needs. Support should be established for initiatives to extend platelet storage life as a strategy to improve platelet availability."

Based on the available scientific data of red cell storage “the committee is concerned about the potential toxicity associated with progressive storage of red blood cells particularly in certain clinical settings (e.g. cardiac surgery, ICU, trauma). However, absent the availability of definitive safety data from adequately controlled clinical trials, and in the absence of any analysis of the impact of shortened red cell dating on blood availability, the committee believes that a change in practice is premature. The committee recommends efforts to optimize blood transfusion practices in these settings through research and promulgation of clinical practice guidelines based on scientific evidence of safety and efficacy. As needed, the Committee recommends the Department be supportive of operations research on management of blood inventory.

The Committee finds that the available scientific data from observational and limited prospective clinical studies are insufficient to resolve concerns regarding safety of progressive stored red cells. Therefore, adequately controlled clinical research is needed to correlate basic science findings on the adverse effects of progressive red cell storage with clinical outcomes. In parallel, studies are needed to establish the efficacy of transfusion therapies in various clinical settings. The Committee recommends new and sustained investment in basic and clinical research in this area.”

“While the committee was not specifically charged with developing a response to questions on the organ transplant safety, the committee felt that the flowing recommendation would help the Department in its efforts to monitor and improve transplantation safety offering the following resolution on public health matters associated with tissue and organ transplantation.

Whereas the HHS Advisory Committee on Blood Safety and Availability is charged with advising the Assistant Secretary on public health issues related to the safety of tissue and organ transplantation, and after review of the current status of safety and utilization reporting for organs and tissues, the Committee recommends:

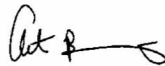
1. Enhanced acquisition of data on tissue distribution and utilization to allow current surveillance activity to better determine the frequency of adverse events,
2. Capture of appropriate data regarding etiologic agents of infections reported following organ transplantation to allow for better assessment of infectious risk related to transplantation,
3. Support the acceleration of the development of rapid infectious disease assays for use in the organ transplant setting as a strategy to improve both safety and availability of organs, and

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4. Enhance utilization of the Center for Medicare and Medicaid Services' (CMS) and other available databases to improve monitoring of organ transplantation practices and related outcomes through cooperative arrangements with other agencies.”

The committee sincerely appreciates the efforts of the Department in following its recommendations on matters of blood, tissue and transplantation safety. We are ready to help in any way in developing and advancing the strategic initiatives of HHS relevant to our Charter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Art W. Bracey', with a stylized flourish at the end.

Arthur W. Bracey, M.D.