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Howard K. Koh, M.D., M.P.H.
Assistant Secretary for Health
Office of the Secretary
U.S. Department of Health & Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Dr. Koh,

The Advisory Committee on Blood Safety and Availability (ACBSA) greatly appreciated your opening remarks, during the June 7 and 8, 2011 meeting at the National Institute of Health (NIH) Campus, Bethesda, Maryland. It was an opportunity to hear the updates from previous ACBSA recommendations, and the Department's perspective on the charge of our meeting – to review the World Health Assembly (WHA) Resolutions concerning transplant safety and patient blood management and identify areas that will improve our patient care practices.

The purpose of the meeting was to review and comment on, a) how can best practices be identified and promoted for improving the safety and efficacy of donations and transplantations, b) how can the U.S. collaborate in collecting data on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation, c) address the system for the safe and rational use of blood products, d) determine if data supports guidelines or performance measures for the rational use of blood in patient blood management, e) determine if there are areas of safety and sustainable ability of blood and blood products that should be addressed by the Committee in the future.

During the two day meeting, a number of experts in the field presented information that fostered a vigorous debate among Committee and public members of the audience. After careful consideration of collective input, the Committee developed the following two sets of recommendations:

Transplantation Safety:

After hearing Committee discussion, the following transplant safety issues were addressed:

- endorsed WHA Resolution 63.22;
- recognized that the U.S. is the largest user of organ for transplantation;
- identified that global leadership is needed to both promote best practices in organ transplantation and eliminate human rights abuses related to organ trafficking and transplant tourism; and
- acknowledged that U.S. participation in transplant tourism may undermine global objectives for safety, availability and ethical conduct of organ transplantation.

In light of these acknowledgements, the Committee recommends the Secretary establish a task force to:

1. Identify mechanisms to obtain data on U.S. participation in transplant tourism and utilization of U.S. organs by foreign nationals to inform efforts to resolve practical and ethical dilemmas.
2. Recommend steps to increase the availability of organs in the U.S. and to lower patient transplantation costs.
3. Identify research opportunities for organ failure prevention, organ regeneration, and xenotransplantation.
4. Identify ways to promote adoption of standardized systems (e.g., ISBT-128) for identification and codification of all organ transplants (including country of origin for those acquired abroad) to facilitate tracking and traceability.
5. Coordinate with established biovigilance efforts to ensure reporting, tracking and monitoring of transplantation related adverse events to improve outcomes.

The Committee believes that adoption of the recommendations identified for transplant safety will place the Department on firm footing for promoting best practices in organ transplantation and eliminate human rights abuses related to organ trafficking and transplant tourism. While the Committee recognizes that the availability of organs are beyond its Charter, it is hoped that this will be address by the Advisory Committee on Organ Transplantation.

Patient Blood Management:

Recognizing the significant role of transfusion practices in the quality of health care and its costs, the committee found that:

- blood transfusion carries significant risk that may outweigh its benefits in some settings and add unnecessary costs;
- wide variability, in the use of transfusions, indicates that there is both excessive and inappropriate use of blood transfusions in the U.S.;
- medical advances and ageing of the population are expected to drive demands for transfusions that could exceed supplies in one to two decades;
- improvements in rational use of blood have lagged behind improvements in the quality and safety of the products;
- additional data on blood utilization and clinical outcomes are needed to identify gaps in knowledge in order to effectively manage transfusions and support evidence based practices; and
- programs of patient oriented blood management at some hospitals have demonstrated significant reduction in blood use, without increase in patient harm, based on expert decision making (Methods have included correction of anemia and coagulopathy, blood conservation including minimizing blood loss, and conservative use of blood products).

In light of these patient blood management acknowledgements, the Committee recommends that the Secretary:

1. Identify mechanisms to obtain data on patient blood management, utilization of transfusion and clinical outcomes.
2. Support development and promulgation of national standards for blood use recognizing the value of patient management, blood conservation and conservative blood use
 - a. Consider a consensus development conference;
 - b. Ask the Agency for Healthcare Research and Quality (AHRQ) to evaluate available clinical guidelines and to sponsor comparative effectiveness research in patient blood management and transfusion;
 - c. Acknowledge the role and leverage the efforts of professional organizations;
 - d. Improve the quality of health for Medicare beneficiaries by monitoring transfusion practices and outcomes.
2. Take steps to establish transfusion expertise as integral to transfusion practices in hospitals and other patient care settings.
3. Establish metrics for good practices of blood use and patient blood management.
4. Advise the Office of National Coordination of Healthcare Information Technology (ONC HIT) on the need to integrate patient blood management and blood utilization into electronic health records.
5. Promote education of medical students and practitioners on optimizing patient blood management and use of transfusion and elevate awareness of the essential role of blood management in the quality and cost efficiency of clinical care.
6. Promote patient education about the risks, benefits and alternatives of transfusion to promote their empowerment in transfusion decision making.
7. Support demonstration projects on patient blood management.
8. Support research on non-invasive clinical measures to define indications for transfusion e.g., ischemia, hemostasis, platelet function and patients functional status.

The Committee believes the recommendations identified for patient blood management may promulgate national professional standards on blood use and conservation. Please accept my sincerest gratitude for the opportunity to present to you the Committee's recommendations that address both transplant safety and patient blood management issues. It is the Committee's genuine desire to continue working with the Department in guiding and recommending the best path forward in the development of its plans and initiatives for transplant safety and patient blood management. The Committee looks forward to meeting with you again in person at future meetings and to continue to provide advice on critical safety issues with regard to both blood transfusion, and cell, organ, and tissue transplantation.

Sincerely,



Michael G. Ison, M.D., M.S.
Chair, ACBSA