



December 17, 2013

Howard Koh, M.D.
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
HHH Building
Washington, DC 20201

Re: Forty-fourth Meeting of the Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA),
December 4-5, 2013

Dear Dr. Koh,

I am writing on behalf of the Advisory Committee on Blood and Tissue Safety and Availability, which met on December 4-5, 2013. The Committee Members appreciated your personal remarks at the start of the meeting and welcomed your helpful guidance for framing our discussions over the two day meeting. The purpose of this meeting was to continue the discussions from previous meetings addressing optimal blood service delivery in the U.S. as well as the country's blood and tissue all-hazards preparedness and response. Additionally, the Committee discussed the progress of studies established to help inform a possible change in the blood donor deferral policy for men who have sex with men (MSM) and the creation of a national transfusion transmissible infections surveillance program.

The Committee was charged to consider:

1. Is the current U.S. infrastructure appropriately prepared to handle emergencies necessitating human tissue and/or blood and what further development is needed?
2. Is the current blood center system in the U.S. designed for optimal service delivery?
3. Should the Department consider creating a surveillance system to monitor transfusion transmitted infections in the blood supply?

Over the two day meeting, subject matter experts presented information in the following areas:

- Reports from the Blood and Tissue Safety and Availability in Emergencies Subcommittees
- Cost recovery system of blood centers
- Capacity for product and service innovation within the blood industry
- Risk-based decision making in the blood industry
- Updates on current study progress and results for the Uniform Donor History Questionnaire Study, the Quarantine Release Error Task Force, the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III), and Blood Donation Rules Opinion Study (Blood DROPS)
- Feasibility of constructing multicenter blood donation database and conducting risk factor analysis for surveillance purposes as seen with REDS-II
- The next steps in establishing a U.S. donor transfusion-transmissible infection monitoring system

Recommendation 2013-1

Whereas the Committee recognizes that the AABB Inter-organizational Task Force on Domestic Disasters and Acts of Terrorism has been established as a principal federal partner under ESF#8 in national disasters affecting the blood supply and has served the country well in disaster situations since its inception in 2001, the Committee finds that:

1. Inventory reporting from hospitals is limited, potentially affecting efficiency and effectiveness of system responses based on more complete knowledge of existing inventories.
2. Current strategies to monitor blood inventories are not tied to target benchmark levels in defined regions (e.g., by the time zones) to serve as virtual stockpiles of labile components.
3. Stockpiles of less perishable blood derivatives (e.g., PCCs, fibrinogen, and topical hemostatic agents) do not exist.
4. Stockpiles of equipment and disposables needed to make blood components do not exist and are not easily identified in settings of just-in-time delivery.
5. Disaster preparedness to assure concurrent availability of blood & tissues is not well coordinated.
6. Stable funding to address blood adequacy in disasters is not established.

Therefore, the Committee recommends that the Secretary take steps to:

1. Establish regional targets for blood inventories sufficient to address potential disaster scenarios.
2. Improve blood inventory reporting by hospitals to maintain a comprehensive knowledge of the source and availability of blood products, especially platelets.
3. Establish stockpiles of devices and consumables needed to prepare blood components.
4. Establish and maintain stockpiles of less perishable blood derivatives.
5. Improve national level coordination of the concurrent delivery of blood and tissues in disaster situations.
6. Establish stable funding mechanisms to support and coordinate the availability of blood products in disasters.
7. Enhance public communication to promote understanding of appropriate responses in disasters affecting blood availability.
8. Improve delivery systems for blood products that would be able to operate in situations of disrupted infrastructures.
9. Support research on measures that could sustain injured patients in the absence of available blood products and parallel development of regulatory science.
10. Support risk-based regulatory accommodations, as needed, to assure availability of blood products in disaster situations.

Recommendation 2013-2

Whereas the Committee finds that:

1. The current human tissue inventory, particularly for banked skin, is inadequate to support the needs of victims in large scale disasters, such as those involving more than 200 burn victims.
2. Infrastructures to support distribution and clinical use of tissues in large scale disasters are inadequate.
3. There is lack of integration of local response plans to address regional or national disasters.

Therefore, to address these deficiencies, the Committee recommends that the Secretary take steps, in cooperation with the appropriate public health agencies and relevant stakeholders to:

1. Establish a coordination body at a national level to address tissue needs in disaster situations, possibly within the responsibility of the AABB Inter-organizational Task Force on Domestic Disasters and Acts of Terrorism, in alignment with national response elements for other medical products of human origin.
2. Provide transparency of national disaster management plans that may presently exist and promote integration with local plans.
3. Promote better mechanisms of communication between tissue providers and care centers to assure mutual knowledge of inventories and available sources of tissue.
4. Improve delivery systems for tissues that would be able to operate in situations of disrupted infrastructures.
5. Explore the possibility to establish a reserve inventory of tissues, especially skin, that can be mobilized in disasters.
6. Enhance tracking and traceability of human tissues through the establishment of standards for unique identifiers for donors linked to all derived human tissues.
7. Establish sustainable mechanisms of funding to coordinate and assure availability and appropriate use of tissues in disaster situations.
8. Support research on measures that could sustain injured patients in the absence of available life-sustaining human tissues and parallel development of regulatory science.
9. Support risk-based regulatory accommodations, as needed, to assure availability of life-sustaining tissues in disaster situations.

Recommendation 2013-3

Whereas the Committee finds that:

1. Ongoing reductions in blood use have caused disruptions to the blood system that may threaten its sustainability.
2. The instability of the blood system including rapid large scale consolidations and cost based competition may inhibit safety innovations, compromise blood quality, and reduce surge capacity in the face of disasters.
3. Barriers to cost recovery by blood establishments lie at the heart of the instability.
4. Blood standards contribute significantly to cost.

Therefore, the committee recommends that the Secretary should take steps to:

1. Improve mechanisms to recover actual costs, including the costs of new safety measures required or recommended by the FDA.
2. Promote innovations in the blood system by lowering the risks and costs of new technology development.
3. Foster integration of blood establishment computer system databases with electronic health records in hospitals.
4. Encourage expanded use of risk based decision making for the blood system, including use of formal decisional tools (e.g., quantitative risk assessments), obtaining stakeholder input on acceptance of risks and consideration of economic impacts.
5. Support research to establish the global value of transfusion therapies in the larger public health context.

Recommendation 2013-4

Whereas the committee has heard expert presentations on the importance of evaluating the current blood donor deferral policy for males who have had sex with males, and the Committee has recommended that the HHS Secretary evaluate this deferral policy for a potential change at the June 2010 meeting, the Committee now recommends that the HHS Secretary establish and fund an ongoing, integrated, coordinated, and nationally representative U.S. transfusion transmissible infections monitoring system. Such a system modelled on the REDS II program “Transfusion transmitted retrovirus and hepatitis virus rates and risk factors: improving the safety of the U.S. blood supply through Hemovigilance” should be in place prior to the implementation to any change in this deferral policy. The Committee voted unanimously on all of the recommendations and feels that the adoption of Recommendations 2013-1 through 2013-4 will assist the department in achieving some of its wider goals, helping to develop strategies relating to blood and tissue products for emergency response, optimizing the current blood service delivery system, and allowing for the maintenance of a safe blood supply through the establishment of a monitoring program. We thank the Department for considering our recommendations and for the opportunity to contribute to blood and tissue safety and availability.

Sincerely,

Jay E. Menitove, M.D.
President/CEO and Medical Director

Chair, ACBTSA