

April 23, 2015

Wanda Jones, DrPH
Principal Deputy Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
HHH Building
Washington, DC 20201

RE: Forty-Sixth Meeting of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), April 7-8, 2015

Dear Dr. Jones,

I am writing on behalf of the Advisory Committee on Blood and Tissue Safety and Availability, which met on April 7-8, 2015. The Committee appreciated your personal remarks, acknowledging the complexity and importance of tissue tracking and traceability, the focus of the meeting. As you know, over 1.5 million tissue grafts are distributed from deceased donors to healthcare facilities each year, with up to 50 grafts from one donor. The size of this industry and potential for infectious disease transmission makes reliable tracking and traceability essential for proper biovigilance. At the start of this meeting, the committee was charged to consider:

- Based on the information that is presented, please discuss the following topics related to tissue tracking and traceability:
 1. Potential areas for improvement at tissue manufacturers (e.g., machine-readable tissue coding and labeling, clinical practice guidelines/standards).
 2. Potential areas for improvement at healthcare facilities that implant/transplant tissues (e.g., use of IT tools such as barcode readers and EHRs to capture information about graft use in recipients; clinical practice guidelines/standards).
 3. Potential areas for improvement in the interaction and communication between entities in the tissue supply chain regarding issues such as notifications related to potential donor-derived infections, feasibility of using a common donor identifier.
- What additional information is needed in order to develop approaches to improving tracking and traceability, and what are some proposed means of gathering that information (e.g., survey of healthcare facilities and surgical and dental practices)?

Over the following two days, the Committee heard presentations from a wide range of presenters, representing stakeholders from recovery to final disposition of tissue, including federal agencies (FDA, CDC, ONC, VA), professional organizations (EBAA, AATB, ADA), tissue banks, hospitals, and healthcare practitioners.

After careful consideration and thoughtful discussion, the Committee made the following recommendation:

Recommendation 2015-1

Whereas the Committee finds that,

- Medical Products of Human Origin (MPHO) contribute in major ways to improve patient care in a large spectrum of conditions

- Voluntary activities have resulted in significant advancements in the safety and availability of human tissues, including the integrity of the supply chain
- Tissue recalls since 1991 have revealed deficiencies in systems of tracking and tracing for human tissues that affect patient care
- The WHO, Veterans Administration, Eye Banks, NMDP and Blood Banks have worked with ICCBBA to adopt ISBT 128
- Regulatory and standards setting organizations have made significant advancements in tissue tracking and tracing; however, gaps in tissue tracking and tracing remain including:
 - Absence of a universally standardized unique donation identifier that would link each tissue product and other MPHOs to the donation event
 - For different tissue tracking and tracing systems
 - Lack of electronic linkage of tissue transplantation to the patient identifier (e.g., barcode)
 - Variability in linkage of the transplant to the patient medical record, including limits to searchability of EHRs for records of transplantation
 - Incomplete return of implantation records to tissue providers
 - Variable adoption of ISBT 128 as the globally recognized standard for identification of medical products of human origin (MPHO)
 - Fragmented regulatory oversight and/or standard setting across PHS agencies and transplant settings (e.g., hospitals, dental practices, and podiatry, etc.)
 - There is lack of basic knowledge on tissue practices and patient outcomes related to the absence of a comprehensive surveillance system (e.g., aggregated database on organ and tissue donation, denominator on use of tissues, accurate rates of tissue related events, product failures)
 - Patients may not be informed of their receipt of a tissue transplant and are not routinely engaged in outcome monitoring
 - Health care providers may not be fully aware of the inherent risks of tissues, which when extensively processed are highly commoditized
 - The highest risk of tissue transmitted infections is associated with fresh, fresh-frozen, freeze dried, and non-irradiated tissues
 - Common standards are lacking for adverse event investigation and reporting, including timeliness and other metrics of reporting

In consideration of its findings, the Committee recommends that the Secretary take action in a stepwise risk-based approach to

- Establish use of ISBT 128 code in electronically readable format as a universal standard for mandatory implementation of unique donation identifiers for all human tissue products
- Establish an aggregated database system for all organ and tissue donation
- Promote integration of transplantation records into searchable electronic patient records (i.e., EHRs) and the interoperability of such records across institutions
- Establish mechanisms to assure that patients are informed of and provided traceable records of receipt of a tissue product
- Establish oversight mechanisms to cover all health care settings engaged in tissue transplantation to ensure that all applicable standards are met for handling of tissues and establishment of records to support bidirectional traceability and tissue surveillance as part of global biovigilance

- Engage professional societies and organizations to help develop clinical practice standards in areas where gaps exist (e.g., end-user level, dental practices, outpatient facilities, podiatry, and orthopedics)
- Promote educational efforts to health care providers on the risks of all human tissue transplants and the consequent need to assure
 - Meaningful patient informed consent
 - Participation in activities that assure tracking and tracing of tissue products, including feedback reporting of product disposition (e.g., implant records returned to the tissue providers) and any patient adverse outcomes related to the tissue
- Provide controls and incentives for stakeholders to accomplish and comply with the above
- Establish, implement, and enhance existing mechanisms for international collaboration and data sharing on outcomes of tissue transplantation (e.g., WHA resolutions)

The Committee voted unanimously in favor of the recommendation and feels that adoption of Recommendation 2015-1 would support the Department's continued mission of biovigilance and preserving the safety of our tissue supply. We thank the Department for considering our recommendation and for the opportunity to contribute to tissue safety and availability.

Sincerely,

Jay E. Menitove, M.D.
Chair, ACBTSA

CC: Mr. James Berger, Designated Federal Official (DFO), ACBTSA