

**Interim Report from the  
OPTN/UNOS Operations and Safety Committee  
April 4, 2012  
Chicago, Illinois**

**Chairman – Phillip C. Camp, Jr., MD  
Vice-Chairman – Jean Davis**

The Operations and Safety Committee (OSC) met on April 4, 2012, and considered the following items:

1. Vessel Recovery, Storage, and Transplant. The OSC reviewed the Board of Director's discussions and resolution of the committee's proposal to restrict the storage of hepatitis B surface antigen and hepatitis C antibody positive extra vessels considered at its November 2011 meeting. Many surgeons in the community did not approve of the Board's resolution, but the committee believes that their position on the proposal made an important statement about patient safety in the use of extra vessels. The committee discussed its continued efforts to re-design the extra vessel tracking system. Extra vessels disposition reporting data was reviewed. Based on the data reviewed, the committee requested additional data to identify the number of disease transmission events reported to the Organ Procurement and Transplantation Network (OPTN) that have extra vessels disposition pending at the close of the case review. This data would provide additional support for the proposal to require disposition reporting within five days and could be shared during regional meetings.
2. Review of Safety Data and Trends. Safety situations data was reviewed for events reported to the OPTN during April 2006 through January 2012. A total of 301 voluntary reports were received. The data shows voluntary reports under-represent the actual number of safety events occurring in the field day to day. However, the database of reported events continues to evolve with increases in reported safety events from year to year. Based on these data reviewed, the committee is proposing additional data elements to be programming into the safety situation electronic reporting system. These data elements will provide specific information needed to investigate safety events reported to the OPTN. The committee voted to prepare the documentation for the proposal to be approved by the OPTN/UNOS Board of Directors at its November 2012 meeting. The vote was 21 For, 0 Against, 0 Abstentions.
3. ABO Verification Standardized Documentation. The United Network for Organ Sharing's (UNOS) Department of Evaluation and Quality (DEQ) provided blood typing and verification policy compliance data for the committee's review. The data showed compliance issues with each of the policies reviewed. The committee discussed that the Centers for Medicaid and Medicare Services (CMS) also cites verification of blood type and other vital data between the organ donor and recipient as the most frequent condition-level deficiency identified during transplant program surveys. Critical steps in the process of blood type identification and verification will be documented by the committee in an attempt to identify process and policy gaps. If gaps are identified, the committee will propose solutions, and it will develop a standardized form to document the process and requirements.
4. Linking Donor Risk with Organs, Tissues, and Blood. The OSC reviewed current organ tracking and traceability mechanisms provided within UNet<sup>SM</sup>, as well as disease transmission event follow up processes required by OPTN policy. Members discussed that the current system does not provide a way to link or trace a donor to all products allocated. Many organ donors also donate tissue which has more stringent testing standards organ donation. With the differences in testing standards, test results from tissue laboratories may become available after organ transplant that would need to be communicated to all organ recipient centers quickly. The differences in center practice for analyzing

recipient and donor risk varies and the lack of standardization of this process may add to the problem of potential disease transmission recognition.

The OSC discussed the International Society of Blood Transfusion barcode symbology code 128 (*ISBT 128*) and the information that has been learned about using this standard. ISBT 128 has been used in the blood banking industry for years and is already accessible in many hospitals. It was discussed that the American Association of Blood Banks (AABB) is requiring the use of ISBT 128 for blood bank certifications in the near future. If this requirement is implemented, the standard licensing, software and equipment needed to use the standard for traceability would be available to most transplant programs, but Organ Procurement Organizations (OPO) would have to obtain the equipment and licensure required to use it. The committee believes that ISBT 128 could help organ transplantation in communicating test results that may indicate the potential for disease transmission, blood type verification and compatibility prior to organ recovery and transplant, and to decrease the number of organ transportation failures.

5. Effective Screening Update. An impact analysis was reviewed of 43 kidney programs identified to have donor screening parameters in apparent conflict with observed import (expanded criteria donor (ECD)) organ acceptance practices. Letter with these data and a survey was sent to the programs identified. For each program receiving a letter, screening criteria and acceptance data was reviewed before and after the awareness initiative. One of the 43 kidney programs modified their screening criteria as a result of the data provided. Before the letter and survey, this program received 13.5 import offers per month, of which 4.2 were import ECDs. The program decreased the maximum donor age for imports from 70 to 60 for all candidates. This one change reduced unwanted offers to 11.9 import offers of which 1.6 were ECD offers. One of the program's surgeons reviewed with the committee that this change decreased unwanted offers by approximately 20 percent. This change decreased the number of times on-call coordinators were awakened at night to review offers. Based on a review of the "Report of Organs Offered and Transplanted (ROOT)," the surgeon did not feel that his center missed an organ offer that would have been accepted.
6. Public Comment Review – The OSC considered proposed policies released for public comment on February 3, 2012 and March 16, 2012.
  - Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors – (Living Donor Committee) - The OSC voted: 20 For, 0 Against, 0 Abstentions.
    - The committee questioned whether requiring reporting of potential or proven disease transmission for up to two years post donation and transplant was an adequate time frame for reporting. The committee would have liked to have seen data that would provide evidence for this timeframe requirement but supports the intent of the proposal.
  - OPTN Bylaws Substantive Rewrite of Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs (Living Donor Committee) – The OSC voted: 0 For, 19 Against, 0 Abstentions.
    - Many safety issues reported to the OPTN do not warrant disciplinary action. They may be lesser harm or near misses that when reported help the network to address policy gaps and process concerns to prevent future occurrences. Lesser harm, no harm, and near miss events must be managed in a different way to allow members to proactively address issues in real time, provide action plans, quality improvement initiatives, and self monitoring results to the OPTN when there is noncompliance identified.

- Monitoring of patient outcomes and progress reports appears to only be applicable to members that are being considered for adverse action. Monitoring of outcomes and progress reports of members that report lesser harm events could be implemented to assess for trends that may trigger further review of the member.
  - This proposal makes it easier for a member being considered for an adverse action to get through due process but does not address member responsibility for continuous improvement. Members that identify, proactively address, and report such issues should have incentive for doing this. Such a process should be clearly defined within the Bylaws.
  - Safety data reviewed by the committee clearly shows that there is under-reporting of safety events that are occurring in the field. This proposal discourages reporting of those lesser harm and near miss events because of its punitive language. The network will not be able to address gaps in policy or process without understanding where the gaps in the system are. With this proposal members will be even more fearful to report as the language does not reflect process improvement but adjudicates penalty.
- Proposal to Document All Locally Assigned Unique Identifiers in the Donor Record – (OPO Committee) - The OSC voted: 18 For, 1 Against, 0 Abstentions.
    - The committee recommends that there be a standard for the second unique identifier rather than options. Multiple specimens may be received and sent to several labs including pathology, HLA, and core labs for processing. It is recommended that policy require the second unique identifier to be the OPO assigned unique ID rather than date of birth or donor initials that can be common among donors. Creating this standard links source documentation with donor specimens, removes ambiguity, and makes the process of searching for elements to verify more efficient.
    - It is the understanding of the committee that approximately three OPOs do not utilize electronic records limiting their capability to generate unique identifiers, but these OPOs intend to implement electronic records soon to comply with national safety standards and may have other processes in place now to generate unique IDs.
  - Proposal to Update Data Release Policies (Policy Oversight Committee) - The OSC voted: 18 For, 0 Against, 0 Abstentions.
7. Future Meeting Date – The full Committee will meet again on September 13, 2012 at O’Hare Hilton Hotel, Chicago, Illinois.

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