OPTN/UNOS TRANSPLANT ADMINISTRATORS COMMITTEE (TAC) INTERIM REPORT

May 25, 2011 Gene Ridolfi BA, RN

The following is a summary of the TAC OPTN deliberations that occurred via Live Meeting on May 25, 2011. The TAC reviewed and discussed the following public comment proposals:

• Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B (Pediatric and Liver and Intestinal Organ Transplantation Committees)

Committee Response: The Committee discussed and unanimously supported this proposal as written. (11-Support, 0-Oppose, 0-Abstain)

• Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B (Pediatric Transplantation Committee)

Committee Response: The Committee discussed and unanimously supported this proposal as written. (11-Support, 0-Oppose, 0-Abstain)

• Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Computed Tomography (CT) Scan if Requested by Transplant Programs, And to Modify Language in 3.7.12.3 for Currency and Readability (Thoracic Organ Transplantation Committee)

Committee Response: The Committee discussed and unanimously supported this proposal. However, the Committee would like the Thoracic Organ Transplantation Committee to take into consideration that there may be resistance from the abdominal surgeons due to the potential delay in abdominal organ procurement by the thoracic surgeons, additional costs, and transplant centers could receive resistance from OPOs for requesting CT scans for standard criteria organs. (11-Support, 0- Oppose, 0-Abstain)

• Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least Fifty, And to Modify Policy 3.7.6.3 for Currency and Readability (Thoracic Organ Transplantation Committee)

Committee Response: The Committee discussed and unanimously opposed this proposal. The Committee agreed that this policy adds a significant layer of complexity for lung programs. The number of policy changes and the new requirements in those changes are making it extremely difficult for centers to reach 100% compliance. This policy creates a significant workload for transplant centers making it difficult for centers to remain in compliance, takes away from actual patient care, impacts transplant centers' financial resources and increases UNOS audit time. The Committee questioned the data supporting the decision to change the policy to a 14 day requirement and would like to know if there is any supporting data regarding the percentage of patients that are receiving transplants with a LAS greater than 50 that would have had a LAS of less than 50 if retested at the suggested 14 days. (0-Support, 11-Oppose, 0-Abstain)

• Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time (Thoracic Organ Transplantation Committee)

Committee Response: The Committee discussed and supported this proposal. The Committee suggested that the Thoracic Organ Transplantation Committee continue to discuss the inequities of this policy. They agreed that the total artificial heart population that is discharged from the hospital with a portable driver needs to be addressed and suggested further discussion regarding the new sub-segment of patients with mechanical circulatory support. The Committee also discussed the fact that this proposal proposes changing policy to accommodate a clinical trial. The Committee commented that the reason for this policy proposal is that hospitals are now able to discharge patients with total artificial hearts and under current policy the patient would lose his/her Status 1A time. In essence, the proposed policy change is being driven by the fact that patients with total artificial hearts can be discharged with a portable driver, which is currently in clinical trial. (10-Support, 0-Oppose, 1-Abstain)

• Proposal to Improve the Reporting of Living Donor Status (Living Donor Committee)

Committee Response: The Committee did not vote on the proposal, but had the following questions and comments.

- Does this proposal specifically address which center should be responsible for the living donation process and if not it needs to be addressed in the proposal.
- The Committee was concerned that some centers will not be able to achieve compliance with this proposal.
- The Committee questioned the value of collecting this data and stated that this is an unfunded mandate and has a significant impact on transplant centers' resources.

• Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials (Living Donor Committee)

Committee Response: The Committee did not vote on the proposal, but the Living Donor Committee needs to be aware that there is concern from some transplant centers across the country that a mandate was not made making OPOs responsible for the shipping of living donor organs. The overall feeling is that the OPO is the expert in the labeling, packaging and shipping of organs. The lower volume of events for specific transplant centers will potentially create opportunity for error.

• Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation (Liver and Intestinal Transplantation Committee)

Committee Response: The Committee did not vote and had no concerns regarding this proposal.

• Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport (Organ Procurement Organization (OPO) Committee)

Committee Response: The Committee did not vote and had no concerns regarding this proposal.

• Proposal to Require Confirmatory Subtyping of Non-A1 and Non-A1B Donors (Operations and Safety Committee)

Committee Response: The Committee did not vote and had no concerns regarding this proposal.

• Proposal for Improved Imaging Criteria for HCC Exceptions (Liver and Intestinal Transplantation Committee)

Committee Response: The Committee did not vote on this proposal, but made the following comments/recommendations.

• The proposal needs to specifically state certify the imaging reports and if the transplant center needs to retain that documentation for compliance.

• Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates (Liver and Intestinal Transplantation Committee)

Committee Response: The Committee did not vote on this proposal, but made the following comments/recommendations.

- A committee member commented that there may be areas in the country where living donor livers are an alternative for smaller adults but there is an impact on access for some small adults due to living donation not being available in their local area. These candidates do not have the means to travel and/or insurance that covers travel and housing to the areas where living donation is available.
- Some centers have a significant number of deaths on their wait list and cannot receive enough organ offers; therefore, to not accept a liver because another candidate needs a liver/intestine is not logical.
- The Committee recommends broader national liver sharing policies. It is difficult to support a policy that may potentially redirect organs away from organ poor regions as deaths on the wait list continue to increase for liver alone candidates in this population. If policy changes are going to be considered for liver and intestine recipients, then changes for liver alone recipients should also be considered.
- The Committee is interested to know if an analysis was done to determine the impact on deaths on the liver alone wait list after determining the number of livers that might leave a region for a liver/intestine allocation. Specifically, what is the impact on candidates who are less than 62 inches on the liver alone wait list and already have a slightly higher death rate than those candidates who are greater than 62 inches?
- The Committee suggested also using MELD/PELD for liver/intestine candidates.