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American Society of Transplant Surgeons

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Robert S. Higgins, MD, MSHA
President
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Dear Dr. Higgins,

The Council and Executive Committee of the American Society of Transplant Surgeons on behalf of its constituency has reviewed and considered the following eight proposals that have been distributed by OPTN/UNOS for public comment. Below are the stated positions of the ASTS on these proposals. As a friendly suggestion, we would propose that OPTN/UNOS should re-examine the methods used to bring major change to the organization. OPTN/UNOS has been, and should be, based on consensus building when major issues have been addressed. We feel that the proposal to make a major change in liver allocation should not have come in the form of public comment on its first pass through the transplant community.

The following comments are made specifically to the proposals as outlined.

Proposal 1: Kidney Transplantation Committee and Liver and Intestinal Organ Transplantation Committee - Proposed listing requirements for simultaneous liver-kidney transplant candidates (Policy proposed: 3.5.10 - Simultaneous Liver-Kidney Transplantation)

There was moderate discussion regarding this proposal. It was felt that in its *current* form the ASTS **does not support** this.

First, the Liver and Kidney committees should recognize that the guidelines for combined liver kidney transplantation are expert opinion without substantial support in the literature. Because of this, the incorporation of these guidelines should be done with some trepidation. While there must be a balance between the use of kidneys in liver patients that don't need them versus longer waiting times/death for kidney recipients, there should be concern that having an increase in the death rate among liver only recipients is not the desired outcome.

The rationale for the policy uses a limited data analysis. Apparently the need for this policy is being driven by the finding a large number of patients who underwent liver kidney transplantation did not meet the criteria that the consensus conference found to be important. This perceived gap is what is driving the implementation of the policy. We feel that further data analysis, in particular looking at the patients who did not meet the criteria, is necessary prior to implementation of the policy.

There is a concern that the data in the analysis could be influenced by the fact that many patients in the United States are transplanted quickly at relatively low MELD scores and therefore the updating process would not allow for determination of 6 weeks of low GFR or reporting of this to the OPTN. Of the patients who received liver kidney transplants, how many were transplanted with a GFR less than 25 or on dialysis that did not have a previously updated creatinine within 6 weeks or the establishment that they met the dialysis criteria? How many of the combined liver kidney transplants were performed in patients within 30 days of initial listing? What is the sensitivity of the analysis to 21 or 30 day time periods of observation rather than 6 weeks? It is astounding that whether a patient is on chronic hemodialysis cannot be established in the analysis. Surely this population can be established by the SRTR in conjunction with CMS.

There needs to be some verifiable indication that the patient listed had portal hypertension. Perhaps this was intended in the proposal, but there were strong feelings that this needed to be identifiable and verifiable. Some exception will need to be made for those patients with renal dysfunction and HCC.

If a kidney biopsy was performed on the recipient, there should be an allowance for incorporating the results in the algorithm.

There is considerable difficulty with assessing the impact of denying L/K transplant to patients with less duration or degree of kidney failure on the liver list. The criteria looking at success of the policy change, outcome of patients who have renal dysfunction similar to the present analysis should be examined before and after the policy.

The priority system for those patients whose renal function does not return after transplantation seems to be too restrictive and not well thought out. There is little explanation in the public comment document about how these criteria were derived and the data supporting this portion of the policy. An alternative policy is to allow priority for patients who have an ongoing need for dialysis for a defined time after transplantation regardless of any pre-operative criteria. This would allow for greater latitude for the clinicians in deciding to do a combined transplant rather than taking a wait and see attitude. Particularly in areas of the country where a patient with combined liver and renal failure have a high enough MELD score to get transplanted within days, the ability to rescue the patients with kidney transplantation may be the best policy. It was also felt that we need more outcome data to show that the superior results of combined K/L outweigh the ethical concerns of having these patients getting priority allocation after transplantation, particularly if there is poor survival in these patients before and after rescue kidney transplantation. The allocation policy puts these patients below such allocations as 0MM and kidney pancreas transplantation. Is there any data to justify these relative positions?

Proposal 2: Liver and Intestinal Organ Transplantation Committee - Proposal to create regional distribution of livers for Status 1 liver candidates (Policy affected: 3.6 – Allocation of Livers)

In general, the ASTS is **supportive** of this concept.

Proposal 3: Regional Sharing by MELD of ALL LIVERS: Liver and Intestinal Organ Transplantation Committee – Proposal to create regional distribution of livers for MELD/PELD candidates (Policy affected 3.6 – Allocation of Livers)

There is much concern about this proposal from the ASTS. This proposal is **not supported** as written. The ASTS serves a broad constituency and it is clear that this is a very controversial proposal across this base. Much discussion has ensued from our members and it is clear that, in general, it is felt that this is not ready to be widely accepted. That being said, we believe opportunities for wider sharing which would provide for significant impact on waiting list deaths, without significant impact on post-transplant mortality, should be entertained and discussed.

In general, it is felt that there has been little vetting, discussion and incomplete modeling of such a policy. In addition, it has been felt by many that such a major change in allocation policy should not just "appear" in a public policy document without an attempt at consensus building within the liver transplant community.

Multiple specific comments are included:

There is concern that wide regional sharing will increase cold ischemia time significantly more than modeled. The distance is only increased by 60+ miles, but the change would *double* the median distance. Whenever median is used, obviously there are significant outliers and the western half of the country, for example, will have significantly longer distances to transport shared livers. Reporting of the average distance may provide additional information. Further data maybe available by looking at the ischemic times associated with regional sharing as compared to local sharing. It has been estimated that each hour of liver cold time increases the hospital cost of transplantation by $3000 (Schnitzler M). Given this number, what would be the yearly increase in cost for the care given post-transplant?

There are concerns of increased costs of organ procurement with this proposal. Obviously, with wider geographic areas to be accessed, the cost of travel for the OPO personnel and transplant center personnel would increase significantly. These increases are also unlikely to be reimbursed suitably.

While Region 8 outcomes are discussed, there is little data showing the outcome of this variance. It would be helpful to have a better understanding of the effect on waitlist deaths and post operative mortality in regions 8. Does the modeling appear to predict what happened in region 8? Based upon the region 8 experience, would a more rational approach be to go with a Share 29 scheme?

This plan looks at absolute MELD scores for stratifying the list. We all know that it is impossible to say that a MELD of 26 in center X and a MELD of 26 in center Y have the exact

same risk for dying on the list, or dying post-transplant, yet an organ may go to the opposite center simply based on longer time on the list while the other DSA is readying a donor organ to be sent to the other center. What is the evidence of consistencies for MELD scoring across regions or DSAs?

Will there be an effect on small to medium sized programs, especially when surrounded by very large ones? How will this affect the opportunity of a patient in these centers to have access to organs for transplant? This has the real possibility of having a significant impact on these programs and subsequently, their patients.

This proposal has the potential to actually decrease organ donors when local support for organ donation is lost from exporting many organs to areas that may not be as committed to organ donation. Did the committee consider this possibility?

Some suggestions include:

1) Consider incremental implementation of allocation change, such as Regional sharing for status 1 recipients nationwide and evaluate outcome. Continue with wider sharing proposals such as in Region 8, further evaluating its impact before making wholesale changes in liver allocation.
2) Consider local/regional tiers – such as Regional share at a MELD of 29 (or other arbitrary cut points), yet retain the organ locally if there are none in the Region. This modification might decrease the number of organs that cross the region going form one DSA to another. Potentially, to improve acceptance, a very high MELD score could be used initially and then ratcheted down over time.
3) The fundamental issue of the arbitrary definition of "local" as the DSA being the first level of allocation must be addressed. This definition of local results in organs geographically closer to patients of higher MELD being allocated to patients of lower MELD. There are inherent inequities in access to livers for sicker patients because of the tremendous variation in population base and geography of the local DSA. This problem is magnified in areas which are on the border of other UNOS regions and will not be alleviated by regional sharing. Consideration should be given to a distance concept similar to heart transplantation.

Proposal 4: Liver and Intestinal Organ Transplantation Committee - Proposal to standardize MELD/PELD exception criteria and scores (Policy affected: 3.6.4.5 - Liver Candidates with Exceptional Cases)

This proposal is **supported** by the ASTS, with the exception that many felt the point allocations were arbitrary and should be carefully followed up with data about outcomes, following implementation.

Proposal 5: Thoracic Organ Transplantation Committee - Proposal to add the factors current bilirubin and change in bilirubin to the lung allocation score (LAS) (Policy affected: 3.7.6.1 (Candidates Age 12 and Older)

The ASTS **supports** this proposal.

Proposal 6: Living Donor Committee - Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors (Policy affected: 4.1.1 - Communication of Donor History)

The ASTS **supports** this proposal.

Proposal 7: Membership and Professional Standards Committee - Proposal to change the OPTN/UNOS Bylaws to clarify the process for reporting changes in key personnel (Bylaw affected: Appendix B, Section II,E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel)

The ASTS **supports** this proposal.

Proposal 8: Organ Procurement Organization (OPO) Committee - Proposal to clarify, reorganize and update OPTN policies on OPO and transplant center packaging, labeling and shipping practices (Policy affected: 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials**)**

The ASTS **supports** this proposal.

Thank you for the opportunity to address these proposals. We would certainly be happy to participate as a Society in any further definition or revision of one or all of these potential policies if you so desire.

Sincerely,

John P. Roberts MD
President