

AST Spring 2017 Public Comment FINAL Responses

1. OPTN/UNOS Public Comment Proposal to Establish a National Liver Review Board

The American Society of Transplantation supports the proposal, but offers the following comments.

The proposed National Liver Review Board is well-intended to “deflate the MELD score,” that is, to close the significant gap between the transplant rate and waitlist mortality of candidates awarded MELD exception points and those who are listed with their physiologic MELD scores.

To achieve this as well as standardize the MELD exception points granted across various regions, the median MELD at transplant -3 (mMaT-3) for the DSA is the proposed MELD exception score for most of the indications for a MELD exception, without any MELD elevator thereafter. This mMaT score is recalculated from the previous year’s data every 180 days.

Additional comments include:

1. The current proposal indicates that a listed candidate’s mMaT-3 assignment will remain the same even when an updated mMaT-3 of the DSA is calculated, until that candidate is up for recertification. We propose that all candidates should have an updated mMaT-3 assignment once a new mMaT-3 value is calculated, regardless of how long they have been listed. This approach will allow candidates with similar indications for the MELD exception to be at the same priority for liver transplantation all the time, other than the difference in waitlist time.
2. We assume that the decision to calculate the mMaT every 180 days is based on the current timing of standard data analysis conducted by UNOS. We would like to see data to support the absence of significant changes in the mMaT at shorter time intervals, such as every 90 days. Provided that the mMaT does not differ significantly every 90 days, the calculation every 180 days would be acceptable.

2. Liver Review Board Guidance Documents

The American Society of Transplantation supports the proposal, but offers the following comments for consideration:

The National Liver Review Board (NLRB) Guidance documents outline the criteria that would merit a MELD exception point for specific indications for liver transplantation. We agree with most of the proposed criteria. We do have additional comments:

1. Hepatic adenoma – We do agree that a patient with malignant transformation on biopsy of the adenoma can be at very high risk for progression of the malignancy and therefore be recognized as a criterion for MELD exception. It is also true that malignant transformation within the hepatic adenoma may be heterogeneous in location, and therefore, may not necessarily be captured by a liver biopsy of one area of the tumor.
2. Review criteria relative to Primary Sclerosing Cholangitis – Currently, patients with PSC may develop recurrent episodes of infectious cholangitis which is treated with antibiotics to manage the infection. Such repeated exposure places patients at risk of acquiring infections with bacteria that are challenging to treat (i.e Extended

Spectrum Beta-Lactamase (ESBL) or carbapenem-resistant gram negative organisms) and often require the use of a limited array of antibiotics that are frequently associated with adverse effects. There appears limited evidence to support a requirement of 2 ICU-level admissions over a 3-month period for hemodynamic instability as a risk factor for that requires consideration for exception. The Committee should consider either an evidence based approach (recognizing that the current evidence is very limited) or less restrictive criteria.

3. [Improving Allocation of En Bloc Kidneys](#)

The American Society of Transplantation has reviewed this proposal. The Society is supportive of efforts in increase utilization of en bloc kidneys. The acceptance of those donors is already in the construct of each program UNet profile and easy to track for future impact analysis. We offer the following comments for consideration by the Kidney Transplantation Committee:

1. En bloc kidney allocation is appropriate for <20 kg donors, as this best approximates expected graft survival of a “typical standard criteria” single kidney transplant and also approximates the inflection point at which more discards and non-recovered kidneys occur.
2. If >20 kg donor kidneys are allocated as single kidneys, a process should be developed to allow the transplant center to work with local OPO for expedited back-up placement if single kidneys are not acceptable to the centers as a way to reduce increased cold time and discard.

4. [Improving Dual Kidney Allocation](#)

The American Society of Transplantation appreciates the opportunity to review and comment on this concept paper. We support the idea of an allocation system for placement of dual kidneys, and see this as a positive step in addressing the high rate of discarded/non-recovered kidneys at higher KDPI thresholds. The benefits of concept 2 and concept 3 include simplicity and efficiency. The post-recovery criteria in concept 1 are subject to bias and inaccuracy and run the risk of slowing the allocation process. The AST therefore currently favors the use of Concept 2 (particularly 2.2).

Concept 2 offers a wider inclusion criteria than concept 3, and Concept 3 mandates use of >95% as dual. As the primary goal of this concept piece is to increase organ utilization overall, Concept 2 is likely to be more impactful and also allow more flexibility and permit greater center-level decision-making. Priority to local utilization (concept 2.2 vs 2.1) is favored due to differences in OPO practice regarding donor/organ management (e.g. pumping) that cause inefficiencies in regional placement. Prioritizing local utilization must be balanced against the potential risk of post-procurement/acceptance decision-making to split the kidneys thus increasing the time incurred in subsequently attempting to place a high KDPI kidney regionally. An expedited process for “backup” should be developed to minimize this.

Additionally, we ask that the Kidney Transplantation Committee consider:

- Examination of outcomes for dual kidney recipients. Is there a significant difference between that of single kidney recipients? If so, is additional KDPI adjustment needed?

- Enumeration- Consider the cost of completing a dual kidney transplant. Is this a barrier to their use?
- Request for exclusion from outcomes data. Removing the risk of flagging may also encourage use of these kidneys are reduce discards.

5. [Guidance Document for OPTN/UNOS Histocompatibility Laboratory Bylaws and Policies](#)

The American Society of Transplantation has reviewed this proposal. While the Society is generally supportive of the information included, we believe that this level of detail should come from ASHI and CAP rather than the OPTN. This document may be too prescriptive, and will require annual review and updates. We want to ensure these are guidelines, and not regulations that labs must adhere to. We believe both ASHI and CAP who have deemed status with CMS have created thorough accreditation requirements that labs currently follow. This document should serve as talking points or best practices for the lab and should include topics and information relevant to current histocompatibility lab practice.

Reviewers offered the following more specific comments for consideration:

1. In Table 3 we should **clarify that ELISA is a “solid phase”** as is listed for the bead based methods because of the requirement that labs **MUST** use a solid-phase detection system in HLA antibody detection. (Table 3 The Luminex beads are not run on Flow cytometers but this is minor point)
2. Section 4.8 Preservation of Excess Specimens: **Clarify that UNOS requires the OPO lab or a lab serving the OPO to retain serum on ALL deceased donors for 10 years**

6. [Rewrite of Bylaws Article II: Board of Directors](#)

The American Society of Transplantation supports the rewrite of Bylaws Article II: Board of Directors without additional comments.