



American Society of Transplant Surgeons

Saving and improving lives with transplantation.

ASTS Responses to UNOS Proposals Open for Public Comment

October 1, 2020

1. [Guidance and Policy Addressing Adult Heart Allocation Policy](#)

The American Society of Transplant Surgeons (ASTS) supports this proposal as written. The ASTS acknowledges the need for clarifications of the Adult Heart Allocation Guidance and Policy and appreciates the work and effort of the OPTN Heart Transplantation Committee in formulating the proposal currently available for public comment. We suggest that UNOS re-emphasize the data requested supporting Adult Heart Status 4 is to be collected within 7 days of implementation of inotropes (versus a time period with respect to the date of submission). We support the effort to clarify and standardize exception requests for Adult Heart Status 2 candidates supported by Percutaneous Endovascular MCS/D or IABP. We suggest that UNOS consider a templated electronic exception request form in these settings that require the critical fields of entry to ensure standardization for both those programs submitting exception requests and for those RRB members reviewing them.

2. [COVID-19 Emergency Policies and Data Collection](#)

The American Society of Transplant Surgeons (ASTS) supports the OPTN policy proposal as written; however, we recommend the following:

- 1) ASTS believes the OPTN's Executive Committee's actions are appropriate in the current pandemic emergency.
- 2) We believe that there should be no defined expiration date for these actions. With a spike in cases at different times/parts of the country, data capturing issues will persist until the incidence rate drops to a particular level. Perhaps the expiration should be deferred until we are notified at a Federal level that the entire country has returned to a Phase III or Phase IV reopening.
- 3) COVID-19 testing should remain in DonorNet and should be mandatory. OPTN should standardize how these are reported, so that every OPO checks off the same box and there is no confusion as to where this is reported. The OPTN should also clarify which COVID-19 testing is being done.

- 4) The OPTN should not require retrospective data entry on follow-up forms that are given amnesty status under the emergency policies. That will be too onerous a process, especially when we are requesting no defined expiration date.
 - 5) We suggest that OPTN make a separate checkbox for COVID-19 antibody testing. There have been discussions amongst the transplant community about use of organs/recipients that are COVID-19 PCR negative but antibody positive. So if this could be voluntarily reported, the OPTN would strengthen itself by examining data regarding transplanting these subsets of organs and recipients.
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3. Programming VCA Allocation in UNet

The American Society of Transplant Surgeons (ASTS) supports this proposal as written. We agree with the proposal in having Transplant hospitals use UNet; noting most who donate and qualify for Vascularized Composite Allograft (VCA) are also multiorgan donors. It is also beneficial to have a unified system that includes registration of all potential recipients and donors for VCA allocation.

4. Align OPTN Policy with U.S. Public Health Service Guideline, 2020

The American Society of Transplant Surgeons (ASTS) strongly supports this policy proposal and offers the following comments and recommendations:

- 1) Living donor specimens should be stored at a maximum of two years instead of 10 which is in line with the current follow-up obligation. Since there is more reliable and detailed DRAI pre-transplant and with the ability to obtain new specimens and/or donor history on the post-transplant side, mandating 10 years for storage is not supported.
 - 2) ASTS does not agree with keeping hemodilution in the policy.
 - 3) ASTS concurs with the recommendation that liver transplant recipients should undergo HIV, HBV, and HCV NAT testing at the proposed intervals: 4-8 weeks post-transplant and HBV NAT testing at 11-13 months post-transplant.
 - 4) Any language referring to “increased risk” concerning social indicators on the donor side should be eliminated due to established and effective donor NAT testing protocols that are in place, the low chance of infection when tested NAT(-), and the direct acting antiviral therapeutic options that are available. OPOs will need training and guidance to implement this policy effectively.
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5. Update on the Continuous Distribution of Organs Project

The American Society of Transplant Surgeons (ASTS) supports the concept of continuous distribution of organs with the following concerns. We appreciate the complexity of the task,

the efforts of the OPTN Lung Transplantation Committee and the diligence of the process they are following. We do reserve judgement until the final proposal is reached as further details emerge and will solidify the final intended actions.

- 1) ASTS believes the OPTN can do better with helping the public understand how this proposal is being developed. The given algorithm is not that easy to understand. In general, the ASTS agrees with the recommended attributes to align the process with other organs and how they are considered.
- 2) We agree with the committee's recommended attributes but are concerned about the failure to account for multi-organ transplants within the proposal. Clearly, patients with the need for a multi-organ transplant are currently disadvantaged and will remain so in the proposal as it stands. We have reservations about the current proposal's approach to the pediatric patient - drawing a line at 18-years old is biologically arbitrary and binary - as such it is at odds with the overall move towards continuous variables.
- 3) The proposal fails to adequately explain the process that will be used to calculate cost (somewhat euphemistically referred to as travel efficiency) and proximity efficiency. We believe, as it currently stands, that the placement efficiency attribute is the weakest of the five and recommend it be given the least weight in the composite score. It is the most easily influenced by outside parameters (especially with the pandemic transport freeze in effect) and would prioritize largest cities over others.

We strongly support and encourage members of the ASTS, and other transplant professionals, to participate in the "exercise to prioritize the attributes." Broad participation in this will likely result in a more balanced final proposal. ASTS suggests the OPTN make the document/video more widely available understanding that weighting each of these parameters will be very important as will be voting by as many vested parties in the proposed Analytical Hierarchical Project (AHP).

We look forward to the continued development of the proposal and strongly support the stated intent for periodic re-evaluation and changes in the future.

6. Guidance Addressing the Use of Pediatric Heart Exceptions

The American Society of Transplant Surgeons (ASTS) strongly supports the concept of development of a national pediatric review board and a more standardized approach to use of exceptions for pediatric heart transplant patients by developing guidelines; however, we have the following concerns. Regarding the specific questions posed to us and the review of the current guidelines we have the following comments:

- 1) We would not support having PRA/sensitization play a role in selection of status for pediatric heart transplantation.
- 2) We support size as the main criteria for special consideration for VAD recipients listed for heart transplantation. We do not support adding any other qualifications at this time.

- 3) We are concerned the re-transplant focuses on those with coronary allograft vasculopathy (CAV), and ignores those re-transplanted for end-stage restrictive physiology without CAV. We would support clarifying that this latter group could qualify by exceptions recognized for other RCM, such as elevated pulmonary resistance and/or inotrope dependence, or for symptomatic, intractable ascites and pleural effusions. They should be considered for 1B if outpatient and 1A if inpatient.
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7. Updated Cohort for Calculation of the Lung Allocation Score (LAS)

The American Society of Transplant Surgeons (ASTS) strongly supports the concept of updating the variables used to calculate LAS based on a more contemporary cohort. We commend the OPTN Transplantation Lung Committee for its efforts to scientifically re-evaluate the most appropriate variables for the calculation. However, we suggest the OPTN should recommend timelines and updates to the cohort sooner than every 10 years. Currently guidelines exist for obtaining LAS exceptions for patients with pulmonary hypertension. We question if those guidelines will be incorporated into the revised LAS calculation as that would appear to be a reasonable adjustment based on current practice. We would support implementation of this proposal before the implementation of the Continuous Distribution changes for two reasons: 1) the move towards continuous distribution is a complex enterprise with the possibility of delays that might be difficult to predict; 2) it would allow an opportunity to assess the effect of changes to the LAS calculation independent of the impact of continuous distribution. The ASTS strongly supports the stated intent of periodically reviewing the impact of the changes and would advocate for continued re-evaluations and updates to the LAS calculation with contemporary cohorts in the future.

8. Further Enhancements to the National Liver Review Board

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to comment and supports this proposal as written. We recommend:

A. Updating Standardized Criteria for Portal Pulmonary Hypertension Exceptions:

In recent years, there has been an improved understanding of the pathophysiology and management and outcomes of patients with portal pulmonary hypertension that are receiving liver transplantation. It is very timely that the OPTN Liver and Intestinal Organ Transplantation Committee is updating the standardized criteria for portal pulmonary hypertension exceptions.

While ASTS generally agrees with the policy proposal, we offer the following specific comments and recommendations:

1. Diagnostic criteria for liver disease could include (1) Portal Hypertension and/or liver disease (clinical diagnosis-ascites/varices/splenomegaly).

2. For pretreatment criteria, the current consensus diagnostic criteria for PPHTN should include mean pulmonary artery pressure (MPAP) > 25 mmHg, PVR > 240 dynes s cm⁻⁵, and pulmonary artery occlusion pressure (PAOP) < 15 mmHg. We recommend a mandate for PVR>240 dynes s cm⁻⁵; but not MPAP> 35.
3. For post-treatment hemodynamic criteria, liver transplantation can be safely accomplished in patients with MPAP> 35 and in normal PVR with RV function that is preserved. It would be important to have a post-treatment PVR less than 240 dynes s cm⁻⁵ to obtain good outcomes. We would recommend removing 400 dynes s cm⁻⁵ and including the criteria of PVR < 240 dynes s cm⁻⁵ even in patients with MPAP <35. This could weed out patients that have fixed pulmonary hypertension who do not respond to vasodilator therapy and do not benefit from liver transplantation.
4. The committee should consider collecting data on right ventricular function in patients that are approved with MPAP >35. Previously published data shows that right ventricular dysfunction can result in sudden cardiac death upon opening the liver clamps, as there is an acute rise in pulmonary vascular resistance. Good right ventricular function is critical in patients with MPAP >35.
5. The liver committee should provide the patient and graft survival outcome data on the 75 patients that have been transplanted since 2018.

References:

Du Brock HM, Krowka MJ. The Myths and realities of Portopulmonary Hypertension, *Hepatology* <https://doi.org/10.1002/hep.31415>.

Ramsay, Michael, et al. "SEVERE PULMONARY HYPERTENSION: A CONDITIONED RIGHT VENTRICLE IS ESSENTIAL FOR SUCCESSFUL LIVER TRANSPLANTATION: A CASE SERIES.: 143." *Liver Transplantation* 12.5 (2006).

B. HCC Post-Transplant Explant Pathology For Review

ASTS generally agrees with the recommended policy changes. However, further clarification is necessary as what constitutes "evidence of HCC treatment prior to transplantation." For example, does it only include liver directed therapy, or does it also include systemic therapy or checkpoint inhibitors etc.?

C. Operational Guidelines: Pediatric Appeals Review Team and ART Leader

ASTS greatly commends the OPTN for recognizing pediatric expertise is necessary while reviewing pediatric exception cases for appeals. We support the creation of a pediatric ART. Several of our ASTS members have pediatric expertise and we could certainly volunteer members for that service. We also have several ASTS members who have the breadth and experience to serve as ART leaders and facilitators.

D. Guidance Documents:

ASTS generally agrees with the guidance document recommendations for polycystic liver kidney exception points. However, the criteria for severe protein calorie malnutrition should be objectively defined so that all patients can be evaluated similarly.

9. Modify Data Collection on Living VCA Donors

The American Society of Transplant Surgeons (ASTS) supports this proposal as written with the statement that uterus transplantation should be removed from VCA since a uterus is a solid organ.

10. Modify Living Donation Policy to Include Living VCA donors

The American Society of Transplant Surgeons (ASTS) supports the proposal's intent to streamline requirements and policies for living organ donation across all organs. We agree with:

- 1) the specific requirements in the proposed language with the exception that uterine transplantation should be separated out from Vascularized Composite Allograft (VCA) as it is a solid organ,
 - 2) the definition and description of risk in Table 1 including the definition of financial risk,
 - 3) uterine specific evaluations and tests required in Table 2, and
 - 4) that Toxoplasma should be included in living donor evaluations for uterine transplant only.
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11. Incorporating COVID-19 Related Organ Failure in Candidate Listings

The American Society of Transplant Surgeons (ASTS) supports the concept of incorporating COVID-19 related organ failure in candidate listings. We do caution bundling the COVID-19 diagnosis with other diagnoses in group D and wonder how that might affect the LAS for COVID-19 patients. We are concerned that the community does not currently understand the waitlist survival or post-transplant survival for patients carrying a diagnosis of COVID-19 and that we should not assume similar survivals as for other diagnoses in group D. We would support a neutral impact for COVID-19 diagnosis on the LAS until further data is available. In this manner, the LAS for COVID-19 patients would, for now, be governed by other measures of function that comprise the LAS equation until further information is available. We do support the OPTN establishing COVID-19 related diagnosis codes for other organs in particular heart and kidney.
