

**The AST Board of Directors approved the following responses to the OPTN/UNOS Spring 2019 Public Comment period during its March 13, 2019 teleconference. All responses were developed after review of feedback from the Society's communities of practice and Policy Committee.**

### **Clarifications on Reporting Maintenance Dialysis (Living Donor Committee)**

The American Society of Transplantation supports this proposal in concept, and offers the following comments for consideration:

- The need for temporary dialysis in a living donor within 2 years of donation to be considered a major adverse event, which can be made a part of the reporting requirements through the Patient Safety Portal.
- The current event phrasing "begins dialysis" is unclear in whether it means acute dialysis, chronic dialysis, and there is other inconsistent language making it difficult to determine which living donors have met the criteria for ESRD, which is the original intent.

### **Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution (Kidney and Pancreas Committees)**

The American Society of Transplantation recognizes that this is a concept paper as opposed to a policy proposal and is keenly aware of the broad spectrum of opinions on this topic across the kidney and pancreas communities, particularly given the limitations of the modeling. The Society appreciates the HRSA mandated requirement for kidney and pancreas allocation to be altered in a way that makes the allocation policy compliant with The Final Rule. The Society is supportive of the OPTN/UNOS Kidney and Pancreas Committees and applauds efforts thus far to model allocation algorithms that would broaden organ distribution and work toward a framework of continuous distribution. The Society membership found it challenging to come to consensus and provide the specific feedback requested by the Kidney and Pancreas Committees in this concept paper. Given the lack of consensus among the Society's stakeholders in this area, we offer specific comments and suggestions for consideration:

1. Acknowledging the HRSA mandate to make all organ allocation systems compliant with The Final Rule which necessitates elimination of DSA and regions as units of organ allocation, the limitations of the presented SRTR modeling makes modeled options presented appear unsatisfactory. In the current modeling variations presented for consideration, none of the options modeled outperform the transplant rates and transplant numbers that are present in the current allocation system. The rationale for acceptance of any new allocation schema that has the projected potential to decrease transplant volume and rates while increasing distance, cost and ischemia time is not clear. It is understood that the modeling does not predict future behavior and the modeling estimates for transplant rate and volume may be inaccurate and an underestimate.
2. To comment on the question if Pancreas distribution system should differ from kidney, the Committee needs to provide additional data: 'Outcomes Metrics for Five Proposed Framework Variations, Figure 4' for pancreas alone as well as for 'Allocation Distance for Pancreas, Figure 12).

3. Equity concerns: What impact will the proposed allocation system have on transplant candidates' residence preference and will that result in inequality based on the individual's financial means? In other words, with the publicly available data on 'Top Volume Donor Hospitals' and the proposed allocation system based on distance from the organ donor hospital, will more affluent transplant candidates be motivated to move to the 'desired' area to optimize their transplant opportunities?
4. Access concerns: The density of transplant candidates varies from region to region; yet the proposal uses similar distance criteria and distance point value for each of the candidates independent of the number of individuals awaiting an organ transplantation in their areas ('competition'). How does this provide equal access of similar quality (cold ischemia time) organs across the US?
5. The nautical mile allocation solution will clearly disadvantage some centers more than others. Not all centers will have access to the full nautical mile radius (i.e. coastal areas). Some areas like the NE will have more advantages as they will have access to more donor hospitals, while areas like California and Texas will likely be unchanged in overall net access.
6. What impact will this have on multi-center listing of transplant candidates, if any?
7. Minimization of cold ischemia time is an important goal. However, it is not true that Top Volume Donor Hospitals are always located near Top Volume Transplant Hospitals. With respect to transplantation, will the local run based on distance delay allocation nationally that would result in better utilization? Will transplant hospitals located near high volume donor hospitals be placed under undue pressure to accept organs that they normally would not and created increased risk for patients as well as transplant program outcomes?
8. The pediatric constituency of the Society remains concerned that there will be an increase in the mean travel distance for clinical procurement teams and organs, and consequently, increased cold ischemia times for children specifically. This will be particularly challenging in children when crossmatching logistics are coupled with mobilizing a patient who lives far from their transplant center.
9. Cost and sustainability. It is unclear who will pay for the requisite increased logistics and resources that inextricably accompany longer transport times and efforts.
10. The pediatric constituency of the Society remains concerned as to the impact of broader allocation and its effect on MOT, specifically KP transplants and the effect of increasing numbers of low KDPI kidneys being allocated to MOT. The pediatric constituency would like to see more specific data on how the proposed policy implementation would impact specific pediatric recipient cohorts, i.e. the highly sensitized pediatric patient.

11. Although challenging to model, there is no data projecting the incidence and outcomes of DGF which increase the risk of shortened graft survival which in a child is unacceptable. Children have the highest need for graft longevity and they can least afford the morbidity of prolonged dialysis.

### **Eliminate the Use of DSA in Thoracic Organ Distribution (Thoracic Committee)**

The American Society of Transplantation supports this proposal in concept and offers the following comments:

There is a strong sense among the Society's pediatric thoracic transplant community that this proposal of broader organ sharing starting at 250 NM will likely be beneficial for pediatric thoracic transplant recipients. The lung transplant field has already adopted this allocation scheme and adapted accordingly with no objective undue burden to pediatric transplant care providers or any subjective deleterious effect on the relationships that constitute the foundation of the present DSA model. Given the relative scarcity of appropriately-sized thoracic organs, adult and pediatric thoracic transplant providers have continued interest in expanding the catchment area for available organs. Therefore, while the pediatric thoracic transplant community supports this policy allocation change, it is felt that longer-term consideration for further expanding this range to 500 NM would most benefit pediatric thoracic organ recipients, and best promote safe and effective growth of the field.

Among the Society's adult thoracic transplant community there was general support from the cardiac constituency. There was suggestion that prior to adoption of the proposed Thoracic Organ distribution policy, it would be potentially informative to the heart community to more fully take advantage of the results of the lung allocation policy results by;

1. Review of the 9-month analysis of lung data that was assembled by the thoracic committee (Ref). Data reflected only an approximately 50 NM increase in median distance lungs travel from donor hospital to transplant hospital, yet anecdotally, Committee members cited a significant increase in travel and associated costs.
2. Review of a comprehensive description of the lung experience of transplant centers and OPOs relating to impact on organ acceptance, late declines, organ discard, DCDs, sensitized candidates, procurement costs.

*Reference: OPTN/UNOS Descriptive Data Report "Monitoring of the Lung Allocation Change, 9-month report removal of DSA as a Unit of location. Prepared for the OPTN/UNOS Thoracic Organ Transplantation Committee.*

### **Eliminating the Use of Regions in VCA Distribution (VCA Committee)**

The American Society of Transplantation supports the proposal as written. The selection of a fixed distance of 750 nautical miles (NM) to replace the current VCA distribution process which relies on waiting time after allocation within the Region is reasonable given that under the present system 75% of VCA transplants are performed within 200 NM of recovery and 87.5% are recovered within 500 NM of recovery. Additionally, current data does not correlate with outcome and cold ischemia time. Going forward, the AST encourages monitoring the effects of

this allocation change specifically regarding recovery costs and effect on cold ischemia time and outcomes.

### **Ethical Implications of Multi-Organ Transplants (Ethics Committee)**

The American Society of Transplantation is supportive of this white paper and offers the following comments for consideration:

The committee has done an excellent job framing the contemporary and salient features of “equity” and “utility” as these two concepts relate to the final rule interpretation of national organ distribution.

Development and refinement of policies for MOT allocation will require national consensus, oversight, and monitoring to assure balance between equity and utility and to assure fairness to potentially disadvantaged groups based on geography, socioeconomic status, and age. A focus on national standardization would assure consistency and fairness. Assessment of equity poses greater challenges in comparison to utility as outcomes such as survival are inherently more measurable. Approaches that reduce the need for MOT would likely maximize equity.

Policies should attempt to establish standardized criteria for MOT combinations based on categories of need. Given the paucity of evidence, it is anticipated that such criteria would be consensus rather than evidence-based. However, data collection and analysis resources need to be deployed to model and review outcomes related to development and implementation of these criteria. Central oversight and review will be critical from the standpoints of patient eligibility; center qualifications; and outcomes monitoring.

This white paper also acknowledges that MOT may further reduce access to already disadvantaged groups. Medically, this includes sensitized candidates and pediatric candidates. Significant ethnic disparities in MOT are illustrated. Access to health care as well as geographic and economic disparities may be further exaggerated due to potential limited geographic availability of MOT as well as potential need for greater economic resources and access to healthcare required for MOT. In addition to “minimizing additional harm to disadvantage subgroups,” efforts should be made to achieve greater balance in correcting disparities that presently exist.

Despite the successes of the paper, a significant limitation is the omission of a dedicated discussion on the needs and potential impact on pediatric transplant candidates. The Society’s pediatric constituency strongly advocates for a future effort to address the substantial effects of MOT and kidney-pancreas transplants on children.

The Society is advocating for more specific MOT data outcome collection and utilization monitoring. We suggest that the data groups be collected retrospectively to help determine inequities and possibilities based on current utilization patterns.

1. Group 1. MOT where one organ transplanted would not survive without the other (heart/lung). We do believe that futility should be considered. If the transplant is a “last ditch effort,” then survival of the recipient should be considered. This addresses the concept of utility versus futility.

2. Group 2. MOT where one organ is life saving and the other is life enhancing (liver/kidney or heart/kidney). It is our opinion that, in this instance, priority should be reconsidered and not instinctively given to the MOT for both organs- as one organ is life enhancing and one is lifesaving. We believe there is data collection and analysis needed to determine what kidney function criteria justly allocates a kidney to a patient on the heart or liver list. As an example, there is no standard way of assessing the ability of the kidney to recover function once the heart is transplanted (while undergoing hemodynamic stress on heart-lung bypass and inotropic/pressor stress perioperatively). If native renal function does return, this can lead to the possibility of the recipient of the MOT to have 3 working kidneys post-surgery and the SOT candidate still on dialysis.
3. Group 3. MOT where both are life enhancing (pancreas/kidney). Additional focus on KP and pediatric prioritization is necessary as this is an instance when low KDPI kidneys, which would normally be prioritized for children, are being given to older recipients preferentially. In the proposed policy document there is stated that a member of the OPTN/UNOS pancreas community felt that “additional focus on KP and pediatric prioritization was unnecessary”. Additional analysis of the data related to KP and pediatric DD kidney candidates is necessary. Additionally, discussion and consideration as to whether pediatric DD kidney candidates should remain behind KP candidates in the allocation sequence is needed.
4. The Society also suggests that all MOT listing criteria developed in the future be objective and not subjective. For example, ICU status should not change priority. Some more advanced centers are more comfortable keeping critical patients on the floor and less experienced centers are quicker to transfer to an ICU. These opportunities for disparities should be eliminated.

The Society is grateful for development of this white paper and supports the concept of standardization criteria for exemptions and a transparent central review committee process of these requests. We recommend that the criteria be stringent and standardized across all organs to limit the opportunity for inequity.

### **Expedited Placement of Livers (OPO Committee)**

The American Society of Transplantation is supportive of this proposal, and offers the following recommendations and comments for consideration:

- Extension of the acceptance time limit to 30 minutes to allow programs to reassess the resources currently at hand to support the expedited placement at their centers
- Incorporation into the policy consideration of distance to the transplant center (e.g., smaller circle first) to shorten ischemic time.
- Exemption of expeditiously placed livers from the mMAT calculation given that expedited placement of livers may result in placement of the organ into lower MELD patients, and as such may decrease the mMAT score of that transplant center.
- Monitoring and transparency with regard to:
  - acceptance rates for each transplant center that opts into this allocation
  - outcomes of the livers that are transplanted under these circumstances
  - OPO performance in terms of time of notification, number of expedited placements per donors, etc.

- Clarification of how the current common practice of having back-up recipients will be handled within the premise of the current proposal.

### Guidance on Effective Practices in Broader Distribution (Operations & Safety Committee)

The American Society of Transplantation is supportive of the proposal in concept, but offers the following comments for consideration:

- There is no specific language distinguishing the unique practice challenges related to pediatric organ recovery in a broader distribution scheme.
- The guidance document does not appear to be consistent with the current OPTN policies in effect;
  - Specifically, in the Histocompatibility Considerations section, the guidance document suggests that OPOS and HLA labs should rely more on virtual crossmatch data. In addition, the guidance document refers the reader to OPTN Policy 4.6. OPTN Policy 4.6 states that “Laboratories performing histocompatibility testing for kidney transplants or multi-organ transplants in which a kidney is to be transplanted must perform a final crossmatch and report the results to the Transplant Program before transplant.” Subsequently under General Crossmatching Requirements, it refers to a physical crossmatch and not a virtual crossmatch.
  - A virtual crossmatch is not a physical crossmatch. Therefore, the guidance document appears to be at odds with the current Policy 4.6 as it relates to kidney transplantation. This guidance document should be reviewed by the Histocompatibility Committee and perhaps consideration should be made to modify UNet Policy 4.6 to allow for Virtual Crossmatch in some patients.

Given the important role of organ preservation technologies in broader sharing and the increasing availability of these approaches to facilitate sharing across longer distances, the proposal could include:

1. Introduction of a framework for discussion of technologies that extend acceptable ischemic times: In the section ‘Building Relationships to Optimize Operations’ (see line 9) language could be added to promote communication about the adoption of preservation technologies.
  - a. When not already in place, OPOs and transplant centers should implement organized frameworks to evaluate and consider adoption of new technologies and products, including technologies to enhance organ recovery, assessment, and preservation. Opportunities should be given for OPOs and transplant centers to share experiences with new technology adoption and best practices to create the most effective, efficient, and satisfactory processes to evaluate new technologies.
  - b. Broader information sharing and collaboration between transplant centers, OPOs, device researchers and manufacturers and other stakeholders relating to experiences with preservation protocols being utilized.
  - c. Early communication of anticipated use of preservation technology in the organ evaluation and offer process. As fewer organ recoveries will be tied to local DSA

teams, relevant information must be shared to improve efficiency and assist in planning for multi-organ team recoveries in particular. Testing and implementation of new preservation devices has, historically, relied heavily on local partnerships. Broader sharing necessitates broader conversations.

- d. Improved data reporting on preservation devices which will be critical to analyze performance and develop predictive assessments. Key factors could include: make and model of device, preserved time, perfusate/solutions used, and key clinical metrics (e.g. expected cross clamp time, DCD, PaO<sub>2</sub>/FiO<sub>2</sub> ratio < 300 mmHg, Active Pneumonia, Organ contusion/Lacerations, Heart LV Septal Wall Thickness more than 13 mm (LVH), Down time, Fatty Liver, Drug use, others), and collection of more granular post-transplant clinical outcomes (e.g. primary graft dysfunction, graft and patient survival over time, etc.). Information about specific requirements of each device related to organ recovery should also be made available in a standardized format.
- e. Development of a database of perfused organs to offer the potential for data-driven decisions at the time of offer – not only for the individual organ, which would have information gathered during perfusion (e.g. liver ALT and AST levels), but for the eventual adoption of preservation technologies and assessing the strengths and limitations of each device.
- f. Gap analysis for process improvement with periodic review of cases where clinical and logistical challenges may have prohibited the broader distribution of organs and where organ preservation technologies may have enabled successful recovery and transplant.

Support for research: Wherever possible, organ procurement and transplant entities should support research that can facilitate effective organ sharing across broader distances. Examples include basic, translational and/or clinical research related to organ preservation, as well as assessment for transplant suitability, donor-recipient matching, OPO and transplant center decision-making under time- and distance-constraints.

### **Modify HOPE Act Variance to Include Other Organs (Ad Hoc Disease Transmission Advisory Committee)**

The American Society of Transplantation is supportive of this policy change, and offers the following comments:

- Consideration of future inclusion of testing for Donor HIV drug resistance. Although results will not likely be available at the time of allocation, it would be helpful in the management of the recipient after organ transplantation.
- Suggestion to include in the policy of the exact number of “NIH required number of HIV- to HIV+ transplants” per organ over which time frame rather than referring to another resource document.
- Given the small volume of transplants anticipated under this policy, the impact on outcomes monitoring is likely able to be managed with current resources. Budgetary impact on participating centers is more difficult to access.



## Split Liver Variance (Liver and Intestinal Transplantation Committee)

The American Society of Transplantation could not come to clear agreement within its membership to either support or oppose this proposal, but offers the following comments for consideration:

The Society's pediatric members strongly support any strategy that seeks to increase opportunities for small children to benefit from transplantation but wishes to clarify that a similar variance was created for Region 2 and an OPO in Region 5, and the unpublished data demonstrated no significant increase in split liver utilization. It is believed that the under-utilization of split liver transplants stems from a national gap in surgical expertise to safely perform the technical operation, and an overweighting of programmatic penalization for complications or poor outcomes related to these procedures.

Surgeon experience, and organ selection decision-bias continue to limit broader voluntary use of split liver practices for the smallest waitlisted patients despite improving surgical techniques and era-controlled studies demonstrating the contemporary statistically similar outcomes of technical variant grafts vs. whole organs. The highest pediatric liver waitlist mortality rate is still the neonatal (<1 year old) age group despite continuously improving patient selection and pre-transplant medical management. Utility of both technical variant grafts from the same donor is highest when the primary organ offer is to a high PELD or Status 1 small recipient requiring a liver split. (UNOS/SRTR data, 2018) In >90% of those cases, the aggregate adult transplant waitlist was not disadvantaged because the right lobe was typically transplanted into an adult recipient.

The Society's pediatric members support this present proposal as an intermediary step to encourage more split liver transplants but further advocate for development of an allocation system that mandates a liver be split from any donor that meets current criteria for potential to be split and that the left lateral segment be allocated first to the highest priority small pediatric liver recipients within the designated concentric circle. We view this strategy as a path to eliminating liver waitlist mortality. This practice in other countries has yielded a higher split graft utilization. (Hsu and Mazariegos, Liver Transplantation 23:86-95, 2017).

The Society's liver members were not in agreement on this proposal. Some members felt that the remaining segment should be offered to Status 1 and MELD >32 to avoid disparity in organ allocation, as there are programs that are currently accepting these segments for transplantation into their recipients. They proposed that if the split is decided upon prior to the recovery of the donor organ, then the remaining segment should be offered back to the allocation scheme within 250 NM distance first and then expanded out to 500 NM. If there is no acceptance for the second segment prior to the recovery, the primary center should be allowed to use the second segment for a recipient at the same center. If a split transplant is decided upon after recovery based on size of organ, the primary center should be allowed to use the other half for use on another recipient in the same center. Expedited placement for a split liver under these circumstances with prolonged cold ischemic time is not practical. Other members of the Society's liver community proposed that the remaining segment be allowed to be



transplanted into a second recipient in the same transplant center without returning to the match run to incentivize splitting livers.

AST also recommends consideration of separate monitoring of outcomes from these split liver transplants from the total deceased donor transplant outcomes so as not to disincentivize centers from splitting livers.

### MELD Exception Scores During NLRB Transition

The American Society of Transplantation opposes the timing of the implementation of the MELD Exception Score During NLRB Transition proposal – which is a month before the acuity circle allocation system, as this shorter lag between the two implementations is projected to create disparity in patient access.

The original intention was to provide a 3-month lag between the NLRB and the new acuity circle allocation system to ensure a uniform review of MELD exceptions by the NLRB, as well as to provide sufficient time between the implementation of two major policies. Furthermore, the 3-month lag would have protected against new disparities that this newest proposal would yield. Until MELD exceptions are standardized, it will be unjust to allocate over wide geographic areas, but the current proposal entails an approximately 2-month period during which livers will be allocated to patients with MELD exceptions that won't have cycled through the NLRB. In certain parts of the USA, this will likely siphon large volumes of livers from one area to another for an unfair reason. For example, the median allocation MELD in the NYRT DSA is 34, while it is 30-31 in the PADV DSA. So, patients granted exceptions based on the MMAT-3 in the NYRT DSA will receive 31 points, while those in PADV will receive 27-28. However, once acuity circles are implemented, donors in PADV will be 'local' (based on 150NM circles) to recipients in NYRT, and therefore patients in NYRT who received exceptions during the period will have higher scores for the same disease as patients in their 'local' area (PADV), thereby creating a disparity based on geography. This will be a direct result of only having 1 month between this revised NLRB exception policy and acuity circles.

We offer several potential solutions that we believe would be strong alternatives:

1. at the same time acuity circles are implemented, reset all exception points to the MMAT-3 for the 250NM circles, as proposed, rather than leave those given exception points based on their MMAT in the DSA with a potential advantage, or
2. delay the implementation of the new allocation policy by two months.

The latter option offers two major advantages: 1) it prevents the creation of new geographic disparities by having the 1-month period described above; and 2) it provides sufficient time to adjust to the new NLRB system, which will help to mitigate logistical, technical, or other issues that could occur with the initiation of two major policies in rapid succession. Keeping the 3-month delay will also be honoring the initial belief of the Liver Committee and the OPTN/UNOS Board that spacing out two major policy changes is best for the system operations and for patient care.