



American Society of Transplant Surgeons

*Saving and improving lives with transplantation.*

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## ASTS Responses to UNOS Proposals Open for Public Comment

March 22, 2019

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### 1. Clarifications on Reporting Maintenance Dialysis

The American Society of Transplant Surgeons (ASTS) supports this policy proposal to clarify and streamline data when reporting on living donor events. While rare, a complication in a living donor can present significant consequences for transplant centers under the current system. Namely, providers have not been able to properly distinguish between donors who have experienced an acute temporary event post-donation versus those with End-Stage Renal Disease (ESRD) when reporting to the OPTN/UNOS Patient Safety Portal. Inconsistent terminology has also been a barrier to accurately gauging center performance. ASTS welcomes the opportunity to encourage measures leading to improved clinical outcomes and reductions to additional regulatory burdens.

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### 2. Ethical Implications of Multi-Organ Transplants

The American Society of Transplant Surgeons (ASTS) strongly supports the OPTN/UNOS white paper, “Ethical Implications of Multi-Organ Transplants” and overall found this to be a thoughtful consideration of the ethical principles related to MOT. While ASTS supports this as a white paper, that support would not necessarily extend to policy derived from its contents. We strongly believe that all policy development should undergo public comment regardless of its origins as white papers or guidance documents.

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### 3. Modify HOPE Act Variance to Include Other Organs

The American Society of Transplant Surgeons (ASTS) strongly supports expansion of the HOPE Act variance to other organs. To date there have been approximately 110 transplants performed using organs from HIV+ donors into HIV+ recipients. In addition, there have been approximately 25 transplantations done using organs from

donors who initially tested positive for HIV and found later to be a false positive (an event also facilitated by the HOPE Act). These organs were transplanted into HIV+ recipients as they are the only individuals that appear on these match runs (see: AJT 2018;18:2579-2586). Early outcomes appear excellent, with one graft failure and one patient death reported to OPTN as of mid-2018.

Expansion of the HOPE Act to thoracic organ candidates is a logical extension of this policy. There are no obvious unique aspects of heart or lung transplantation that would make use of HIV+ donor organs (including their procurement, transplant, and outcomes monitoring) substantially different from liver or kidney transplantation. There are likely fewer HIV+ heart and lung candidates, although the true need for thoracic organ transplantation is not known as HIV infection has been considered by most centers as a contraindication to heart and lung transplantation. There are in fact rare but unique examples of thoracic end-organ damage (HIV cardiomyopathy, and HIV-associated COPD) that occur in HIV infected individuals for which future access to transplant would be essential.

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#### 4. Split Liver Variance

The American Society of Transplant Surgeons (ASTS) thanks the OPTN Liver and Intestinal Committee for their work on this policy proposal. ASTS supports the Region 8 variance as written but only for Region 8 until data is collected during the 3 year demonstration project.

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#### 5. Expedited Placement of Livers

The American Society of Transplant Surgeons (ASTS) appreciates the work of the OPTN/UNOS Organ Procurement Organization Committee. While the ASTS supports quick placement of organs at risk of discard, we are also concerned with the potential for unintended consequences as the community adjusts to the new liver allocation policy. With a wider radius of 250-500 miles to distribute organs, the process proposed may encourage centers to compete for organs. ASTS encourages the OPTN/UNOS to defer this proposal until the community has more data to analyze the new allocation system's performance.

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## 6. Guidance on Effective Practices in Broader Distribution

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to comment on the proposed guidance document. ASTS notes some incongruence between the document's stated goals and practices and that of the OPTN's ability to operationalize its guidance. This can leave transplant centers in an ambiguous position. For example, the document states transplant centers should identify surgeons in nearby regions they trust to recover organs. For this to work, transplant centers need: a formalized system outlining expectations from partnering centers and a communication system that functions in real time and ideally includes video monitoring. The ASTS also supports the development of regional systems to provide feedback on organ quality, procurement injury, and other concerns. When OPOs and organ transplant centers were aligned this was done in medical advisory boards. Broader distribution requires more structured communication.

When organ procurement teams are needed, it is imperative for the OPTN to define appropriate standards for travel, safety, and insurance involving air and ground transport. ASTS has been assiduously working with community stakeholders and industry to develop more definitive guidelines. Organ recovery remains the most dangerous job in medicine and this cannot be solved primarily through the use of recovery surgeons. As surgeons are going to be increasingly asked to recovery for other centers, there needs to be a standardized system to ensure medical professionals are adequately insured during this crucial work.

Better communication and coordination are essential for a broader distribution system to succeed. Transplant centers need data on proposed time and contact information to discuss offer details. Ideally, donor net would incorporate a two-way communication. The proposed indicators in Donor Net (e.g. follow donor) and not adequate. Furthermore, the community would also be better served if the guidance document were to spell out the circumstances under which OPOs can withdraw offers if a transplant hospital cannot agree on the start time for procurement. What time frames are reasonable? This should be a measure of last resort and should not be done without the involvement of the medical director of the OPO.

We also note with concern the documents HLA testing guidelines for highly sensitized patients. Virtual crossmatching may rule out donors, is often insufficient to move a patient to transplant, and can lead to increasing organ discards. It is still imperative that donor blood be sent ahead for highly sensitized patients.

Finally, organ procurement surgeon billing and fair market value is not the purview of the OPTN. The ASTS opposes national rate setting. We should allow the individual

transplant programs and their OPOs to develop appropriate arrangements. The ASTS agrees with the document in that malpractice coverage for an unrecognized injury at the time of recovery leading to a recipient's poor outcome needs to be clarified, but respectfully, not by the OPTN. This needs to be addressed at the OPO level.

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## **7. Eliminate the Use of DSAs in Thoracic Distribution**

In the OPTN/UNOS Thoracic Organ Transplantation Committee proposal to "Eliminate the Use of DSAs in Thoracic Distribution" which was put forward for public comment, OPTN/UNOS proposes to remove the donation service area (DSA) from thoracic organ distribution and propose an allocation area of 250 nautical miles (NM) from the donor hospital.

There is strong support for the concept of more broad sharing as there are arbitrary boundaries and much variability in DSAs thus giving the potential for limitations to access. Removing the DSA geographic boundaries would foster more broad regional sharing. The modeling of OPTN/UNOS has investigated variations in organ utilization and wait list mortality with several models and the 250 NM radius appears to enhance access with no overt harm.

The proposed change in geographic boundaries would have an impact on the cost of thoracic organ transplantation: increased monetary costs, increased logistic burden, and increased risk to recovery teams who would be traveling more often and farther. Concurrent to the change is geographic distribution where there have been recent changes to the heart transplantation allocation status system. In preliminary data, there are changes in practice pattern of the transplant centers in the short time since the status change has been enacted. The impact of these practice changes is likely not reflected in the organ utilization model.

While we are still early in the allocation status change, a longer temporal period that would allow reflection on and reassessment of the impact of the new model would be prudent before additional major changes are enacted. The proposed change has been developed over several years and with extensive modeling. The 250 NM radius is reasonable as the modeling does not show improvement to 500NM, in terms of organ utilization and decreasing of wait-list mortality.

The ASTS supports a proposed change in thoracic organ allocation from the DSA to a 250 NM radius from the donor hospital which may balance access issues with cost and logistical challenges associated with other models.

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## 8. Eliminate the Use of Regions in VCA Distribution

The American Society of Transplant Surgeons (ASTS) opposes the OPTN/UNOS policy proposal to eliminate the use of regions for vascularized composite allograft as written. We recommend adopting the 250 nautical mile (NM) concentric circle around a donor hospital since there are only a few active programs and they would benefit from a smaller radius. In addition, this model would minimize cold ischemia during the early developmental stages of the procedure.

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## 9. MELD Exception Scores During NLRB Transition

The American Society of Transplant Surgeons (ASTS) abstains on the OPTN/UNOS proposal to establish a MMaT exceptions score methodology aligned with DSA-based allocation for a one-month period when the NLRB is active, and the new allocation system starts on April 30, 2019 as this decision will have no long term impact.

For the future, the ASTS strongly urges UNOS to apply NLRB MELD exceptions to the largest geographic area possible to allow for equalization of MELD exceptions that would parallel the equalization of MMaT expected with the new allocation, in as close to real time as possible. The timeline for implementation and equalization of MMaT and exception scores should be as short as possible. ASTS promotes the principle that patients in the same sharing area should have equivalent exception points.

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## 10. Eliminate the Use of DSAs and Regions for Kidney and Pancreas Distribution

The American Society of Transplant Surgeons (ASTS) is responding to the request from the OPTN to indicate why one or more suggested options would be a better as replacement of the current distribution system for Kidney and Pancreas Transplantation. As the representative organization for transplant surgeons, physician assistants, and administrators at US transplant centers who are on the frontlines of transplant care, we are responding within the context that one of the options must be chosen, but remain concerned about the rapidly and foundation of this decision. The ASTS perspectives are grounded on evidence tied to the Final Rule, particularly the impact on efficiency in organ placement and on achieving the best use of donated organs. Furthermore, the ASTS will indicate its preference with

comments on the defining characteristics of the size of circles and the number of proximity points that should be awarded.

ASTS recognizes the evolving priorities of the national organ allocation system. This includes an understanding that current policy development efforts to remove donation service areas (DSAs) and OPTN regions from all organ distribution policies, including the upcoming kidney and pancreas allocation policies. This is consistent with The Final Rule requirement that policies “shall not be based on the candidate’s place of residence or place of registration, except to the extent required” by the other requirements of the Final Rule. These “other requirement” include use of sound medical judgement, achieving the best use of donated organs, avoiding wasting organs, promoting patient access to transplantation and promoting the efficient management of organ placement.

The ASTS agrees with The Workgroup’s decision to reject the option of a national allocation system that places no limitations on geographic distribution for either kidney or pancreas. This type of system is clearly likely to increase organ discard and is logistically and clinically impractical. ASTS has concerns, however, that some of the proposals in the concept document are over reaching and may have inadvertently conflated the need to eliminate DSAs with the idea that the larger the area of distribution the more it will comply with that ideal. The goal of removing geography in other organ allocation systems has been aligned with efforts to improve other metrics (equality of access, improved organ utilization, reduce waitlist mortality). It is not clear from the concept document, how these important metrics will be advanced by the proposed variations.

ASTS has concerns about the following considerations because the larger 500 NM circles (including the hybrid models) of distribution, compared to the smaller circles, result in progressively more burdensome and inefficient management of organ placement including substantially increased travel distance (longer driving distances and more flights – a safety issue) and increased costs that are not offset by a meaningful, if any, increase in organ utilization or transplant rate, number of transplants performed, wait list mortality rates, or waitlist mortality counts. In fact, all these components demonstrate setbacks compared to the current system or the smaller 150 NM option and 250 NM option. As a primary goal of the OPTN is to increase the use of organs, we would oppose any option that is likely to increase organ discard. We oppose all of the following:

1. 500 NM circle, no points:
2. 500 NM circle, shallow points:
3. 500 NM circle, steep points (the document shows the wrong option highlighted):

The modeled analysis of the larger distribution area considerations indicates that transplant rates may decrease, that wait list mortality may increase, that the proportion of kidneys requiring air travel will increase dramatically, that procurement

management will become more inefficient, costs associated with the overall organ procurement process will increase dramatically, and there are safety concerns with increasing driving times and distances and increases in air travel.

ASTS does not agree with the notion in the report that the projected decline in efficiency and organ utilization which are likely to result from an over reaching, logistically complex organ distribution system will be corrected by transplant center behavior changes. There is clear evidence the KAS system which distributed high KDPI kidneys over larger regional areas (rather than the smaller local distribution areas) resulted in poor kidney organ utilization, high discard rates, fewer patients transplanted. The experience that behavior changes did not correct an inefficient distribution system. (Please see: Stewart, D. and Klassen, D. "[Early Experience with the New Kidney Allocation System: A Perspective from UNOS](#)," *Clin J Am Soc Nephrol*; (December 2017) and Friedwald, J. and Turgeon, N. "[Early Experience with the New Kidney Allocation System: A Perspective from a Transplant Center](#)," *Clin J Am Soc Nephrol*, (December 2017)

ASTS is in favor of a DSA-free kidney distribution system that also rigorously applies sound medical judgement to achieve the best use of organs (i.e., increasing utilization and reducing discards), that avoids wasting organs, considers limiting cold ischemia time, and promotes efficiency (i.e., keeping costly and potentially less safe air travel to a minimum and limits cost increases), and considers travel safety issues. The ASTS position is that the most reasonable starting point for a new DSA-free distribution system for kidneys is to adopt a smaller fixed concentric circle model. The smaller fixed concentric circle framework variation aligns with the principles in the Final Rule and is based on sound medical judgement and promotes the best use of organs (including less cold ischemia time), as evidenced by limited impact on graft outcomes. This will also result in a starting point with less uncertainty compared to a kidney distribution system with larger circles in which undue burdens of inefficient management of organ placement, increased travel (including longer drive times, and more flights, and the attendant safety concerns) and increased costs are imposed without an increase in organ utilization or reduction in organ discards. This system also allows effective use of preservation technology (including pulsatile perfusion) and will allow the use of higher risk organs by centers with a minimal of cold ischemic time.

ASTS believes the smaller concentric circle model would provide a stable starting point on which a future continuous distribution system can be built. The ASTS supports further iterations to include additional factors such as medical urgency, likelihood of graft survival along with proximity between the donor location and the transplant hospital. Candidates who best meet the combination of factors would receive the highest priority and those at closer hospitals would receive more relative priority than those at more distant hospitals. In addition, the priority given to the distance between donor hospital and transplant hospital could be adjusted over time as data becomes available on which to base new parameters.

ASTS agrees with the Pancreas Committee recommendation that the pancreas allocation framework be determined separately as the tolerated ischemic time is lower for pancreata than kidneys. The lower tolerated ischemic time could impact acceptable travel distance, procurement process and the post-recovery organ utilization. The new Pancreas Allocation systems has been effective in stemming the reduction in the use pancreas allografts. In addition, the allocation system created a nationally consistent model which we strongly support.

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