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## Proposal: [Continuous Distribution of Kidneys, Update Summer 2024](#)

### **Summary**

Regarding the latest iteration of OPTN request for feedback on the *Continuous Distribution of Kidneys Update*, **we continue to be generally supportive of the concept of a continuous allocation system**. We are gratified to see this latest expression of the OPTN's commitment to dealing with the innumerable pragmatic operational issues in kidney and pancreas allocation under a CAS, and overall are supportive of the focus on operational items that provide evidence that a transition to a CAS will be actionable and safe. We point out that the allocation system has seen major changes, and consequently disruptions, over the last few years, and we advocate strongly for an operational philosophy in the design of CAS for all organs that specifically aims to avoid massive changes in allocation patterns at the outset. We appreciate the malleability of CAS and expect that post-implementation monitoring will be vigorous and course corrections frequent, and hope that the fundamental strategic pillar of increasing the number of transplants performed with adequate safety guides future adjustments of the CAS.

### **Questions for the Community**

#### *Modeling and Optimization*

**In the most recent round of modeling, OASim modeling suggested that median travel distance for pediatric candidates could be over 650 nautical miles for each simulated continuous distribution policy. Do you feel that it is appropriate to slightly reduce the weight of pediatric priority to reduce median travel distances within a more feasible range?**

Pediatric patients should maintain priority for high quality and low travel distance organs. ASTS is not convinced the proposed solution completely addresses this need.

ASTS would support priority at current or even higher levels to ensure access to high quality and local organs. We agree filters would need to be in place to adequately screen organs not accepted without increasing time to transplant.

**Do you support the updated optimized CPRA rating scale that ensures access for the most highly sensitized candidates?**

ASTS supports maintaining access for the 99.9% group. ASTS is not convinced continuous distribution is better than what we have now for this portion of the highly sensitized.

#### *Defining Hard to Place*

**Do you support a multi-pronged approach to defining hard-to-place kidneys, such that a kidney may be considered "hard to place" by meeting clinical criteria, allocation thresholds, and/or a cold ischemic time threshold?**



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ASTS agrees with most of these identified barriers. We support a process that takes these into consideration and could be the most impactful. Organ offer filters should be "updated" in real time when new information is available for a kidney. We propose things like: WIT avail; CIT reaches >X hours + offer is not primary or backup; biopsy results avail; a system for post cross-clamp kidneys with all data available to offer to accept for a specific patient, and the OPO able to place quickly to that patient without significant delay.

## Clinical Criteria:

**Do you support stratifying clinical criteria by KDPI, such that a donor with a lower KDPI may need to meet multiple clinical criteria to be considered "hard to place?"**

Yes

**Do you have any feedback or recommendations on whether anatomy characteristics should be incorporated in a definition of "hard to place?" If so, which anatomy characteristics?**

- Kidneys that reach 6-hours CIT not on pump or 8-hours on pump without acceptance for standard adult candidates.
- KDPI  $\geq 90\%$ .
- Any kidney with **DCD** donor status and donor **age greater than 60 years**.
- Biopsy: Severe arterial disease, interstitial fibrosis, or GS > 10% on biopsy.
- Procurement gross anatomic criteria: Ulcerative renal arterial plaque.

## Allocation thresholds:

**Do you support a "hard to place" allocation threshold based on number of programs having responded with a total center decline, defined as declining for all candidates at the program?**

This is a good surrogate for hard to place. But does program equal one patient from that program.

## Cold ischemic time thresholds:

**Do you support the use of a cold ischemic time threshold of 5 hours, based on SRTR data analyzing increasing risk of non-use past 5 post-cross-clamp?**

Some OPOs are quicker than others to have data available after cross-clamp. Five hours is an extremely tight timeframe and may be problematic if universally applied. OPOs should be committed to having data available in a timely manner.

## Expedited Placement

**Specifically, do you have any recommendations, or support recommendations discussed here, on how to achieve effective offering, appropriate timing, reducing cold ischemic time, maintaining flexibility, and ensuring transparency and equity in expedited placement?**

OPOs still function very differently and OPO input will be key to this discussion.



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## Proposal: [Continuous Distribution of Livers and Intestines Update, Summer 2024](#)

This current update provides details on new proposed attributes which may be used in continuous distribution, as well as a proposed schedule and a proposed use of a new method of mathematical modeling. We are generally supportive of the update and have provided multiple detailed feedback items below.

### **Questions for the Community:**

- **Please provide any feedback on the identified attributes as well as their drafted purposes and initial rating scales.** The new attributes include: Body Surface Area (BSA), Medical Urgency Score, Utilization Efficiency, Hepatocellular Carcinoma (HCC) Stratification, Travel Efficiency, and Pediatric Priority.

*For **Body Surface Area**, the committee is considering adding points for candidates within the bottom 15%, 10% or 5% for BSA. However, the public comment document does not provide enough detail regarding the proposed number of points which will be added, or the impact of those points for the various proposed percentages for the ASTS to comment on this specific attribute or the proposed rating scales. The ASTS does recommend that before any change for BSA is made, it will be important to analyze the impact and any interaction of adding BSA adjustment to MELD 3.0, which is already adjusting for female, which are most of small individuals. It may also be important to consider whether the candidate has ascites, given this allows larger livers to be utilized.*

*The **Medical Urgency score** which has been selected is MELD/PELD, which as noted below, the ASTS supports. The ASTS is also supportive of the proposed metrics of success and proposed rating scale.*

***Utilization Efficiency** is intended to make difficult to place organs less difficult to place. The committee has decided to define difficult to place organs to be the same as the current system which is DCD donor or donor age over 70. The ASTS supports this definition and supports the committee's plan for this to evolve over time, given the benefits of machine perfusion for DCD livers. The ASTS expects that DCD livers will become less difficult to place over time, but there is still considerable uncertainty related to whether cardiac death may occur during the expected time frame and the challenges related to travel given that uncertainty. Importantly, the ASTS is **not supportive** of using historical acceptance practices for the allocation of medically complex donors given the current rapid evolution of system level issues such as perfusion technology, MPSC performance standards, and allocation systems as well as center level changes such as staffing levels and waitlisted patient medical urgency which directly impacts whether it is or is not suitable to accept a medically complex donor for a patient. Using historical data is not a patient-centered approach and has a risk of worsening disparity in access to transplant.*

***Hepatocellular Carcinoma (HCC) Stratification** has been selected by the committee to be a patient access issue, which the ASTS agrees with. The ASTS also agrees that some patients with HCC have a higher risk of wait list drop out than others, though also recognizes that offering*



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*increased priority for high-risk tumors has a risk for impacting post-transplant survival, and if this is added, then an adjustment to the MPSC post-transplant outcome metric should also be considered.*

*The Liver Committees stated purpose of **Travel Efficiency** is to reduce distance between donor hospital and transplant program, specifically related to increasing the opportunities for driving the organ to the transplant center versus flying the organ to the transplant center. However, the ASTS does not support this concept, given that in less densely populated areas of the United States, nearly all organs are flown due to the larger distances between donor and recipient hospitals, whereas in more densely populated areas, organs may be flown due to ground traffic restrictions. If the United States had an even distribution of donors and recipients and transplant hospital and donor hospitals, this would be feasible. In the absence of a clear impact on transplant outcomes, prioritizing travel efficiency risks worsening disparity in access to transplant and is not a patient friendly approach. A central problem with continuous distribution is that while it is a rational theory which is easily supported, how to determine how much priority to give for proximity remains very complex.*

***Pediatric Priority** is discussed in the current public comment document including how to convert 1A/1B candidates into a points-based allocation system, but there are not specific proposals or ideas to comment on except that the committee intends to eliminate the pediatric waitlist, which the ASTS agrees is a laudable goal.*

**Please provide any feedback on the Committee’s decision to utilize MELD and PELD as the medical urgency score model within the first version of continuous distribution.**

*The ASTS appreciates the Committee’s consideration of alternative models to a medical urgency score and found the comparative table in the public comment document to be very helpful. The ASTS is very supportive of the Committee’s decision to select MELD/PELD for use in the proposed continuous distribution plan.*

**Please provide any feedback specific to the pediatric population within liver continuous distribution.**

*See above.*

**Please provide feedback on when your organization begins to fly rather than drive for organ procurement as well as any feedback on travel practices.**

*See above.*

**Please provide feedback on the BSA attribute including the decision to use BSA, the options for rating scales, and donor modifiers.**

*See above.*



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**Please provide feedback on the Utilization Efficiency attribute including input on the options for how to award candidates points and the definition of a medically complex liver offer.**

*See above.*

**Please provide feedback on how to incorporate exceptions into the continuous distribution framework, including HCC stratification, and whether any specific donor modifiers are necessary.**

*The ASTS agrees with the committee's deliberations that exceptions will continue to remain an important patient access issue and recognize that the system of continuous distribution may provide a different method for considering their need for transplantation relative to patients whose access to transplant and risk of waitlist mortality is predicted by MELD/PELD.*

**Please provide feedback on other aspects of this project including any additional considerations that are not addressed in this paper which warrant Committee discussion.**

*No additional comments, though the ASTS would like to recognize the committee's diligent work and appreciates the opportunity to provide comment.*

**What areas can be improved to address the needs of patients including areas that need better communication and education?**

*The ASTS suggests that further information about the anticipated benefits that patients and the transplant community will experience under a system of Continuous Distribution may be valuable given the significant complexities presented in the current document and given that the Liver-Intestine allocation policy has already changed significantly within the past 5 years (circle-based distribution, adoption of median MELD for exceptions versus elevator, adoption of a revised PELD score, and adoption of MELD-3.0.)*



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**Proposal:** [Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN](#)

## **Executive Summary**

Reporting within the proposed 24-hour timeframe is feasible. This does not represent an unusual burden on HLA labs. Required reporting of split-group-different error reporting is a good idea. The new definition of HLA typing critical error is clarifying and helpful for the community. The anticipated administrative burden is reasonable.

- Does the proposal address the purpose of the project?
  - Yes.
- Does the proposal sufficiently explain the reasoning and provide sufficient evidence for the solution?
  - Needs work. The Executive Summary should include mention of immunologic events leading to graft injury or graft loss, not just those leading to “severe, potentially fatal, immunologic reaction.” In other words, this is an issue for graft and for patient survival.
- Were appropriate stakeholders engaged?
  - N/A. ASTS does not know which stakeholders were engaged in this process.
- Are there any questions for community feedback that should be included, but aren't already identified in the proposal?
  - No. The questions are appropriate in number and scope.

**ASTS Position: Support**

**Proposal: [Update on the Continuous Distribution of Hearts Update, Summer 2024](#)**

**Background:**

This OPTN document updates the transplant community on the ongoing development of a continuous distribution framework for donor hearts. It details the results of the recently conducted values prioritization exercise. Notably there was agreement amongst responders from all backgrounds on the degree of priority afforded to the six factors that were examined- with medical urgency receiving highest priority, and proximity the lowest priority. The document details several concerns that have been raised by responders and the thought that the committee has given to those concerns. While the committee acknowledges the importance of these concerns, in particular determination of medical urgency, they have not made commensurate changes to the proposed allocation system.

**Executive Summary:**

We remain concerned that the proposed model for continuous distribution of hearts does not include a reassessment of criteria for medical urgency or a component accounting for post-transplant survival. Objective criteria do exist to guide medical urgency; their presence has been conceded by the Committee in this OPTN document, thus making their omission from the proposed allocation system even more surprising.

**Questions for the community:**

1. Overall, do you agree with the general priority of attributes as identified by the VPE results? Why or why not?
  - Agree. The VPE has gauged the importance given to these factors from responders of different backgrounds and there was broad agreement.
2. Do you agree with the relatively low prioritization of the proximity efficiency attribute suggested by the VPE results?
  - Neutral. The VPE had agreement from responders of different backgrounds lending credence to the results. We do have concerns, similar to the committees, about the implications of this low priority for organ efficiency. We wonder if a slight increase in weighting for this attribute above the VPE results is warranted and prudent.
3. How should the Committee consider the use of new perfusion technologies and their impact on travel distance?



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- We agree that the application of these technologies is an important factor. However, the decision of a center to utilize these technologies is individualized and dependent on numerous donor, recipient, center-driven, and logistic factors. As things currently stand, these factors cannot be known by OPTN at the time of assigning an allocation score. Therefore, it would be difficult to account for the use of these perfusion technologies at the time of allocation.
4. Is there any additional information the OPTN could provide to help you better understand the concepts associated with the continuous distribution framework for organ allocation? (Note: The Committee is very interested in hearing from those with a personal connection to organ donation and transplantation.)
- Donor proximity has a substantial impact on ischemic time, logistics and efficiency. It might be helpful to the community for OPTN to share some information on this- such as how distance affects ischemic time (an important consideration for hearts), cost, travel, and its human impact (more time away from work, family, burnout).



**Proposal: [Continuous Distribution of Pancreata Update, Summer 2024](#)**

**Summary**

Regarding the latest iteration of OPTN request for feedback on the *Continuous Distribution of Pancreata Update*, **we continue to be generally supportive of the concept of a continuous allocation system**. We are gratified to see this latest expression of the OPTN's commitment to dealing with the innumerable pragmatic operational issues in kidney and pancreas allocation under a CAS, and overall are supportive of the focus on operational items that provide evidence that a transition to a CAS will be actionable and safe. We point out that the allocation system has seen major changes, and consequently disruptions, over the last few years, and we advocate strongly for an operational philosophy in the design of CAS for all organs that specifically aims to avoid massive changes in allocation patterns at the outset. We appreciate the malleability of CAS and expect that post-implementation monitoring will be vigorous and course corrections frequent. We are hopeful that the fundamental strategic pillar of increasing the number of transplants performed while maintaining quality outcomes guides future adjustments of the CAS.

**Questions for the Community:**

**How might encouraging OPOs to have procurement teams for all abdominal organs, including pancreas, impact procurement?**

ASTS supports local procurement expertise that will decrease the need for teams to travel long distances for procurement. We are generally supportive of OPO efforts to create local procurement teams but are concerned about the potential impact of those OPO efforts on surgical training programs. ASTS feels that it is critical that OPO-based procurement in general, and ORCs in particular, remain open to the participation of vetted and qualified transplant center staff, including fellows, residents, and medical students, so that promotion and promulgation of procurement skills and best practices can be learned and disseminated.

We strongly encourage a focus on transparency regarding individuals performing organ procurement. At a minimum, the professional affiliations and qualifications of all individuals performing the complex and critical task of deceased donor organ procurement should be available to all THs receiving those organs for transplant. We support efforts to enhance transparency and to standardize qualifications based on competency. We support the establishment of coherent and universally applied certification and/or credentialing criteria for individuals performing organ procurement.

**In what ways might the establishment of dedicated directors for pancreas programs influence effectiveness, outcomes, and growth of the program?**

We would not support new layers of requirements being mandated by regulators in this regard, as THs already have guidance and requirements in this regard in the form of OPTN Key Personnel requirements. We agree that dedicated leadership should be in place for pancreas programs at



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every TH engaging in this complex clinical activity. That support aligns well with current OPTN policy, as each program must already have a primary physician and a primary surgeon. ASTS believes that effective and dedicated surgical leadership is a prerequisite for the growth and maintenance of effective, high-volume pancreas transplant programs.

**What innovative strategies could be implemented to enhance fellowship training and cultivate greater interest in pancreas transplantation among medical professionals?**

Transplant fellows are eager to learn these skills. The best way to cultivate interest and grow skills is for THs to grow their pancreas transplant program volumes. Support for fellows to attend and participate in workshops like the ASTS pancreas transplantation surgical skills workshops will also cultivate skills and interest in pancreas transplantation.

**Proposal: [Promote Efficiency of Lung Donor Testing](#)**

**ASTS Comment on Proposal:**

A combination of changes in lung allocation, OPO incentives, and the efforts of transplant centers continue to increase the volume and quality of lung transplantation in the United States. Since introduction of continuous distribution for lung allocation, there has been a marked increase in lung transplantation, with a 16.6% increase in the post-policy era, accompanied by a 28.9% decrease in weight list mortality, and decreased waitlist times for our sickest patients. While the increase in lung transplantation and effective utilization has improved, the marked increase has come to place new burdens on the systems of lung allocation.

The OPTN proposal *Promote Efficiency of Lung Donor Testing*, which addresses both the required information for deceased lung donors as well as the guidance on requested deceased donor information, aims at improving the effectiveness of the required information for lung donors through the offer, acceptance, and recovery process. This is done through a focus on standardizing donor diagnostics, reducing redundant testing, and modernizing language surrounding donor workup.

The changes appropriately have centered on providing up to date information at the time of donor organ offer and have standardized diagnostic work up significantly. There may be a slight increase in the effort required given the increased frequency and standardization of some of the diagnostic values, but these tests are routinely available at hospitals throughout country, regardless of the donor hospital location. The demand associated with increase in standardization and frequency of required testing is balanced by reduction in redundant cardiac workup and reduction in delays associated with image processing and review. This not only aids to support prompt placement of donor organs but reduces unnecessary workup by the donor hospital and OPO.

While the OPTN proposal *Promote Efficiency of Lung Donor Testing* will provide improved and prompt data to transplant centers it fails to recognize the importance of bronchoscopy in lung donor testing and optimization. In the current state, bronchoscopy is frequently not performed even though it provides important information about organ quality and is also therapeutic. This is to the detriment of organ yield and is particularly problematic in DCD donors in whom non-utilization of lungs is extremely high; a concern that has been repeatedly highlighted in the transplant community. Efficient work up and placement of donor organs is vital not only to continue to improve lung transplantation but also to honor the gift of donation made by the patient and their family. While we broadly agree with the OPTNs effort to standardize diagnostic work up we **oppose** the current iteration of the proposal as it misses the opportunity to strengthen the emphasis on bronchoscopy.

We also have significant concerns about the proposal's timeframe for allowing alveolar recruitment and concerns about the ability of this policy to be operationalized in the community hospital setting. We are concerned that the rigidity of some of the elements of the clinical details of the proposal will impose significant burdens for OPOs and may lead to loss of transplantable organs



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from potential donors. We are concerned that the proposal as written essentially provided zero flexibility for OPO variance in donor testing and no distinction between the workflows of DCD and DBD donors or the clinical differences in these donor candidates. We fear that, particularly in the community hospital setting, the combination of more intensive requirements, unrealistic timeframes, and lack of flexibility in performance of these may lead to non-utilization of otherwise suitable donors and loss of potentially transplantable organs.

### **Questions for the community:**

1. Do community members think the proposed lung donor testing requirements strike the proper balance between requiring information transplant programs need to decide on an offer and what OPOs are reasonably able to provide?
  - The proposal appropriately prioritizes high value data points on donors, with an improved focus on standardization and workflow throughput. However, the proposal does not afford reasonable flexibility to OPO operations in accomplishing the shared goals of maximizing the gift of life.
2. Do community members believe any of the proposed requirements for OPTN Policy 2.11.D should be moved to Guidance on Requested Deceased Lung Donor Information?
  - No, the committee has placed appropriate emphasis on standardizing laboratory studies, underscoring the importance of early access to imaging, and preventing delays associated with allocation of other organs, radiologist interpretation, and image processing.
3. Are OPOs able to provide the proposed lung donor testing results for arterial blood gasses (ABGs), chest computed tomography (CT) scans, chest x-rays, and echocardiograms/right heart catheterizations (RHCs) in the OPTN Donor Data and Matching System?

Changes include: standardizing the ‘challenge’ ABG results in offer notification to be within 2 hours of the first electronic notification with ventilator settings at FiO<sub>2</sub> 100%, Vt 6-8ml/Kg, and PEEP 5-8cmH<sub>2</sub>O and providing ABGs every 4 hours from offer to acceptance and every 8 hours from acceptance to recovery; no challenge gases should be drawn within 30 min of a recruitment maneuver. CXRs are now timed within 3 hours and require either the image or the interpretation, preventing delays associated with awaiting radiologist interpretation. CT chest has been moved from recommended guidance to required donor information policy as ‘if performed’ given concerns about access to imaging for donors in rural areas.

Echocardiogram or right heart catheterization have been made required components of



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donor information to help streamline the workflow without heart allocation as means of identifying pulmonary hypertension and to prevent redundant testing in donors who have undergone RHC prior to echo.

- The OPOs may not be able accommodate these changes in testing for lung donation. The great majority of these changes reduce redundant testing and prevent delays associated with image review or processing. Further, standardization of this testing and timeline provides more uniform data for transplant center review to facilitate more efficient organ placement. The frequency of serial arterial blood gas testing may be burdensome, although it is vital for transplant centers and of relatively low cost. Despite the acknowledged utility of serial ABG testing, the resources available in community hospitals may not allow OPO staff to comply with the policy as written. We suggest ABGs every 6 hours from offer to acceptance and every 8 hours after acceptance might be a reasonable compromise.
4. Is the proposed guidance for fungal and bacterial cultures, chest CT scans, chest x-rays, and RHCs appropriate?

Changes include nomenclature change to refer to the “mycology sputum smear” to “fungal culture results” to better reflect common practice and also distinguish “bacteria culture results” separately; both remain as guidance but not mandatory donor information. CT chests now mandatory to include if performed as per above, including guidance on lung windowing and ideally performed within 72 hours of initial offer. CXR changes to include images within 3 hours of initial offer and interpretation every 24 hours to reduce delays associated with radiologist review as per above. Right heart catheterization may be utilized in place of echocardiography as part of mandatory donor information. In patients with echocardiography who are high risk or with abnormal echo, transplant centers can request an RHC.

- The proposed guidance is better reflective of current practice when resources allow. Additionally, this provides important emphasis on having the appropriate imaging and diagnostic data available quickly without delays associated with image processing and review.
5. Do community members support the use of the National Heart, Lung, and Blood Institute (NHLBI) Acute Respiratory Distress Syndrome (ARDS) Network formula for Ideal Body Weight (IBW), or prefer to use a different formula when calculating IBW? The NHLBI ARDS



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Network formula is as follows: 8, 9 o Male: Ideal Body Weight (IBW) (kg) =  $50 + 2.3 (\text{height (in)} - 60)$  o Female: IBW (kg) =  $45.5 + 2.3 (\text{height (in)} - 60)$

Utilized in the standardization of the challenge blood gases for FiO<sub>2</sub> 100%, Vt 6-8ml/Kg, and PEEP 5-8cmH<sub>2</sub>O.

- Yes, this is an appropriate and broadly accepted formula from which to derive a standardized tidal volume.
6. Do patients and donor family members support modified donor testing requirements to make it easier for lung transplant programs to assess whether lungs can be accepted for their candidates?
- Effective and efficient utilization of the gift a patient and their family has chosen to give is of the utmost importance, and the proposed changes honor maximizing utilization of donor lungs while minimizing burden to donor hospitals and OPOs.

**ASTS Position: Oppose**