



American Society of Transplant Surgeons

Saving and improving lives with transplantation.

ASTS Responses to UNOS Proposals Open for Public Comment

October 2, 2019

1. [Modify Appointment Process for the Histocompatibility Vice Chair](#)

The American Society of Transplant Surgeons (ASTS) supports this proposal as written. We agree that standardizing and aligning election bylaw requirements for the Vice-Chair to the Histocompatibility Committee with that of other OPTN committees would be well advised.

2. [Clarification of Pre-Existing Liver Disease](#)

The American Society of Transplant Surgeons (ASTS) thanks the OPTN Liver and Intestinal Organ Transplantation Committee for their work on this policy proposal. ASTS supports the committee's recommendations as written for patients with a diagnosis of fulminant liver failure and their qualifications for Status 1A on the waiting list.

3. [Data Collection to Evaluate the Logistical Impact of Broader Distribution](#)

The American Society of Transplant Surgeons (ASTS) recognizes the need to decisively address the increasing challenges in the logistics of organ transportation. The OPTN Operations and Safety Committee has developed guidance documents to provide suggestions for best practices in organ transportation. The development of these documented highlighted the lack of national data on organ transportation. The submitted proposal is designed to prospectively collect data on the mode of transportation (air/ground), the provider of this transportation, and the time from pick up to arrival at the transplant program. These data will be collected through the DDR form by the recovering OPO.

The ASTS supports the effort to increase knowledge of transportation issues and the use of the DDR to rigorously collect the data. The preliminary proposal includes

basic data that should be readily available at the time of the organ placement. However, there are other elements that will not be captured using this data that are important in assessing the impact of changing allocation on organ placement.

1. The Committee should consider adding a field for organ discard due to transportation issues. This would capture organs that were discarded due to prolonged cold ischemic time resulting from the lack of commercial aircraft or issues with charter services.
2. Was an organ discarded due to damage from a transportation related issue?
3. Was the organ reallocated after initial acceptance due to a transportation issue (prolonged delay resulting in primary center refusing the organ)?
4. For renal allografts in particular, it would be useful to know if the organ was placed on the pump: A) never, B) transported to accepting center on pump, C) initially on pump and then changed to cold storage, or D) placed on cold storage and then perfused at accepting OPO?
5. Can OPOs document delays due to pilot in-service time issues (e.g. timing out at the recovery center)? Specifically, was crossclamp delayed?
6. Can OPOs document which organs are recovered at organ recovery centers and which are recovered at the donor hospital?

The ASTS appreciates the opportunity to comment. We also caution the committee that issues including cost and safety of organ recovery teams must also be addressed in addition to efficiency and accessibility in considering the logistical issues in organ transportation. While capturing cost data directly may be difficult, it should be possible to work with subject matter experts to develop a mean cost per mile transported for air and ground which can be applied to the collected data to determine an estimated cost.

4. [Expedited Liver Placement](#)

The American Society of Transplant Surgeons (ASTS) supports this proposal overall and thanks the OPTN Organ Procurement Organization Committee for continuing to examine the issue of timely organ placement. However, we are concerned that the policy does not address the relatively common practice of transplant programs procuring a liver for their respective hospitals, then refusing it a few hours later for size or anatomy incompatibility. This results in the expedited process starting after the liver has several hours of cold time. At that point, the liver will most likely be refused by everyone except the procuring program, who often will have their own backup recipient in the hospital. This practice is known as creating an “open offer.” Policy should dictate that the procuring program decide to accept or decline the liver in the donor operating room.

In another scenario, when a case involves a high-risk recipient where problems with the transplant can occur prohibiting liver implantation and the liver is still in the donor hospital. It should be the responsibility of the accepting program to alert the OPO so as to create a back-up list based on expedited offer policy to incorporate programs willing to accept a liver within 3-hours of cross clamp. In these cases, the liver can't leave the procuring operating room/hospital without that decision. OPO's should implement a policy of not allowing cross clamping to occur until the accepting team has accepted for a specific recipient on the match run.

We also recommend that later refusals resulting in open offers should be tracked and reviewed. If a pattern or repeat practice is noted with a particular program, this should be referred to the OPTN's Membership and Professional Standards Committee (MPSC).

Lastly, we support expedited placement of designated high-risk livers, such as those with significant steatosis or recovered from older or DCD donors. This will likely decrease the discard rate as well.

5. Modify Data Submission Policies

The American Society of Transplant Surgeons (ASTS) opposes this proposal as written. We have critically reviewed this proposal from several perspectives including: transplant hospitals (TXC), HLA laboratories (HLA), and Organ Procurement Organizations (OPOs). We have sought feedback from a number of experienced personnel within these spheres and herein summarize responses to the following questions asked in the proposal.

- 1) What are the most common reasons your organization changes data values after they have been officially submitted?
 - New information comes available after submission deadline (affects OPO>>HLA>TXC).
 - Missing results or tardiness of outside entity reports (i.e. autopsy, cultures) limit completion in the current time frame (OPO).
 - Mistakes made due to quantity of variables per form (TXC).
 - New risk adjustment model coefficient (i.e. PVD) is not necessarily known until the validation period prior to public reporting (this is really up to center but has not traditionally been communicated well) (TXC).
 - Differing degrees in the use of technology over time. The shift from people to early technology may be cause of missingness (TXC).
 - Quality review post-transplant that identifies human errors in documentation (all).

- 2) What circumstances or conditions prevent your organization from submitting accurate data within the current deadlines?
- Delays in receiving updated information when relying upon other organizations for source data (OPO).
 - Labor cost may increase, increased working out of scope of practice. Human error will always be a risk (TXC).
 - Sheer number of data elements is a great burden for the transplant center. While future deadlines may be extended, clinical care always takes precedence. The alignment of resources to need may be difficult (TXC).
 - Internal EMR limitations and staffing of transplant centers result in a wide variation in data reporting and audit practices (TXC).
- 3) In addition to what is currently available, what data quality resources or electronic tools would help your organization ensure data are submitted accurately and within the established timeframes?
- Decrease the number of variables, especially those that have limited if any value or are subjective (i.e.: functional status) (TXC).
 - Leverage technology for submission-based flagging when a variable is an outlier or missing (don't wait for SRTR validation period) (OPO, TXC).
 - Consider allowing changes on SRTR risk adjustment coefficient changes (when new or weight changes).
 - OPTN support for all entities to electronically transfer data. Currently EPIC allows this but is not a robust process (all).

In summary, ASTS provides the following feedback.

Increasing the time for data submission may result in a greater proportion of accurate forms, with less need for updating later, particularly for the OPO and HLA related forms. There was strong support for this proposal from those stakeholders. This policy proposal, while well intentioned, is problematic for transplant centers who are already strained to the maximum to complete a large number of forms with a large number of data elements. It is unclear due to variations in practice and staffing across transplant centers whether the proposed policy change would accomplish the goal of increasing TXC form completion or decreasing post-completion needs for revision for accuracy, due to the significant increased burden for administrative review to add data after the submission deadline. The proposal, as current drafted, actually has the potential to *decrease* data accuracy if the TXC does not have enough resources to accommodate the new administrative burden of post-submission edits, which may exacerbate the problem of missing data elements.

The problem at the TXC is that non-clinical work is always a lower priority. Several leading centers really struggle to handle the large volume of forms because of experienced staff turnover and other more pressing transplant center problems. Even an EPIC interface aimed to decrease the human effort has not yet performed as robustly as hoped, and the technology needs to be optimized. There exists significant variation across programs of different sizes as to how the form completion burden is distributed and by what scope of practice. Transplant center sentiment is rather than adopting policy that can increase cost and potentially increase penalties for centers trying their best to meet deadlines, it would be more impactful for the OPTN to focus on making policy that helps optimize systems. We encourage the OPTN to avoid making policy that can likely have unintended consequences of further constraining already limited resources.

A suggestion for modification of the proposal to ease the TXC community's opposition would be to 1) increase the submission deadline to 120 days, 2) consider allowing entry of *previously missing* data after the submission date without administrative signoff, and 3) require administrative signoff (including reason for the change) only for post-submission deadline editing of existing data. This may contribute towards increased transparency and provide additional granularity around the frequency and reasons for data edits and how they may impact outcomes research and model construction.

We noted an over-arching theme of support for increasing the OPTN's efforts to leverage advanced technology with the aim of easing the burden of reporting and to explore meaningful and standardized new ways that data can be acquired, allowing our community to move away from the unsustainable era of human form completion.

6. [Eliminate the Use of DSAs and Regions in Kidney Allocation Policy](#)

The American Society of Transplant Surgeons (ASTS) opposes this policy proposal as written. We recommend the OPTN take an iterative approach to all new organ allocation policies by taking small steps with regular reassessments (e.g., one year) to identify successes and unintended consequences, particularly concerning logistical issues.

1. **What factors should be used to select a circle size that distributes kidneys broadly and efficiently?**

We do not agree with the working committee that utilizing a circle of 500 NM would be optimal for maximizing deceased donor kidney utilization and minimizing organ discards. We support a 250.250.2.4 model. This would also be consistent with our

recommendation of the pancreas allocation system. These two would have among the lowest negative impact on the total number of kidneys estimated to be transplanted. The 250.250.4.2 model for kidney allocation would also substantially smooth out the kidney transplant rate by DSA. It would also have one of the highest transplant rates per patient-year. It also would have the lowest waitlist mortality rate per patient-year. It also has the best predicted the shape of travel distribution and distribution of travel distance giving it an advantage in travel logistics. Kidneys from older donors especially those with higher KDPI do not tolerate longer cold ischemia times. Also, it takes longer to transport kidneys to smaller rural centers whose cities are distant from a major airline hub where the organs are initially flown in when coming in from long distances greater than 250 NM. Being away from a major airline hub considerably extends transportation times because the organs are often transported by road from a city with a major airline hub. Overextending the circle size to 500 nm will worsen the transportation times and result in increased risk of discard rates.

2. Should proximity points be used inside the 500 NM circle? Should they be used outside the distribution circle? How should the assigned values be weighted in relation to other kidney allocation policies?

The use of proximity points within the 250 NM range could certainly help with operational efficiency and minimize cold preservation times. Once the distance to travel increases between 250 and 500 NM the proximity points still help, however, greater than 500 NM, there is little value in allocating proximity points, since the kidneys probably traveled by plane, and it is unlikely that any gains in preservation times could be achieved. The assigned values of proximity points should take into consideration the donor quality and age. This could certainly reduce the discard rates for the higher KDPI and order kidneys.

3. What priority do you think is appropriate for pediatric candidates? Should prioritization be applied inside the distribution circle? Should prioritization be applied outside the distribution circle?

There are several concerns regarding pediatric candidates in this proposal.

- I. Although the modeling suggests that the pediatric candidates could receive higher priority, the eventual outcome could be otherwise. For example, after implementation of KAS there was a decrease in the number of pediatric transplants.
- II. More importantly, this proposal does not address the organs from the pediatric donors. The organs from pediatric donors should be first allocated to pediatric recipients. Perhaps, this could be national allocation as these younger donors could tolerate longer, cold ischemia times.

III. The pediatric allocation priority: pediatric candidates should be listed above the candidates that receive multi-organ transplants.

4. What priority do you think is appropriate for prior living donor candidates? Should prioritization be applied inside the distribution circle?

The number of candidates receiving transplants that had prior living donation are small in number. They should receive higher priority inside the distribution circle.

5. What operational concerns should the committee consider as this policy is being prepared for OPTN board action and implementation?

This proposal does not significantly show any advantage of increasing organ transplants, decreasing waitlist mortality or increasing utilization of organs. The committee should consider these elements when performing the modeling prior to OPTN board action. ASTS suggests an interim review of this policy after 1 year to consider unique geographic challenges and to look at the data to ensure the policy is achieving its objectives.

6. Should medical urgency criteria be defined? If so, what specific conditions would qualify? Where the new medically urgent classification should be placed within allocation tables? Should placement within allocation tables vary depending on the KDPI of the donor kidney? How should two medically urgent candidates be prioritized - should two appear on the same match run?

We do not believe that there are many cases of kidney allocation predicated on medical urgency. The committee should provide data on the number of medically urgent transplants that have been performed in each region by year for, say, the past 5 years, and the specific conditions for which medical urgency was utilized. Perhaps utilizing this data, criteria should be defined. We believe most of these cases are according to loss of vascular access as the medical urgency. We do not believe that specific medical conditions as the etiology of kidney disease should be used as a classification of a medical urgency. If there are medically urgent patients (i.e., loss of vascular access), those candidates should be offered transplantation with the next available kidney as is the current practice. Waiting time should be used to prioritize two medically urgent candidates.

7. When import back up is granted, do you support the use of an import match run for the import OPO to reallocate the kidney? Should the match run use the same size circle as the original allocation but with increased points for proximity? Should the circle size be smaller? If so, what distance will promote the efficient reallocation of kidneys?

Once a kidney is imported and declined by the primary center, it is very likely that the kidney would have had significant cold ischemia time. The kidney is likely to be

at the OPO office. To minimize discards, it would be advantageous to place the kidney as quickly as possible. Perhaps a smaller circle of 150 NM from the receiving OPO should be used to match run to promote efficient reallocation of the kidney. Also, there should be some discretion given to the OPO to emergently place the organ according to their judgement in as timely a manner as possible to avoid an unnecessary discard.

7. Eliminate the Use of DSAs and Regions in Pancreas Allocation Policy

The American Society of Transplant Surgeons (ASTS) opposes this policy proposal as written. We recommend the OPTN take an iterative approach to all new organ allocation policies by taking small steps with regular reassessments (e.g., one year) to identify successes and unintended consequences, particularly concerning logistical issues.

The American Society of Transplant Surgeons appreciates the opportunity to comment on the OPTN Pancreas Committee Proposal to modify the current Pancreas allocation system to eliminate DSA and Region in allocation. The new proposal would replace the existing allocation system with a proposed 500nm allocation circle (which would define primary allocation) and national allocation beyond this geographic area. The proposal attempts to balance competing priorities including efficiency, access to care, and medical necessity by including graded proximity points which are designed to allocate pancreata (and kidneys where appropriate) to patients who are closer to the donor hospital if allocation priority is relatively similar. While there are significant positive aspects of the proposal, including the inclusion of proximity points, the choice 500nm as the initial unit of allocation may significantly harm access to transplant, organ utilization, and, consequently, patient outcomes as outlined below.

While the proposal includes provisions to balance equity and efficiency, the choice of 500nm as the initial allocation region may adversely impact access to pancreas transplant by further concentrating pancreas transplant in larger urban centers. Access to transplant is not simply a function of organ availability. Patients must first have the resources to travel to a center, complete the evaluation, undergo transplant, and return for follow-up in the post-transplant period. As is clear from the policy proposal's revisions, the volume of transplants performed will significantly increase at a small number of large centers, leaving remaining centers at risk of functional inactivity. If the highest quality donated organs are accepted and transplanted predominantly in larger centers, this may lead to loss of access for vulnerable populations who lack private insurance coverage with travel benefits.

Second, organ utilization has already been decreasing nationally. While the proposal suggests that this is due to risk aversion in some centers, in fact, there are multiple factors that contribute to organ discard that may be compounded by the current proposal. As noted, pancreata are more likely to be lost to graft thrombosis than other organs. Among the major risk factors for graft loss is excessive cold ischemic times. Given that most programs are reluctant to add \$20,000 for a charter to the cost of an already unprofitable procedure, travel distances which preclude driving will likely lead to organ decline. Furthermore, the majority of programs attempt to keep cold ischemic time less than 10 hours to improve outcomes. Based on figure 13, limiting CIT to 12 hours is best accomplished within a 250nm circle rather than a 500nm circle. Finally, given the lack of pancreas transplant volume nationally, many centers are reluctant to allow inexperienced surgeons to recover organs remotely. As travel exceeds 250 miles, teams will have to fly their teams for the organ or will decline, especially in the case of an organ of marginal quality. Conversely, if the organ can be easily recovered and transplanted locally, centers may be more likely to consider a marginal donor organ as this can be accomplished with existing staff. The proposal's suggestion that centers will have to increase surgical staff to accommodate this change reflects a lack of understanding that Simultaneous Pancreas-Kidney (SPK) and especially isolated pancreas transplants are generally money losing procedures and centers will not invest more resources to support these programs.

Third, the proposal is predicted to lead to further reduction in Pancreas after Kidney (PAK) transplants. Broader use of SPK transplant will reduce kidney transplant alone. Furthermore, lack of access to high quality grafts for PAK will discourage the use of living donor kidney transplant with PAK to follow. This may exacerbate the decrease in access to high quality kidneys, particularly for minority populations who less often receive SPKs. The proposal should ensure access to high quality pancreata for isolated pancreas transplants, as prior studies have confirmed a higher rate of graft loss in this population when marginal donor organs are used. The currently model results clearly demonstrated that the committee's choice will negatively impact access to isolate organs.

For these reasons, the ASTS strongly suggests that the committee reconsider the 250/2/4 option evaluated by the committee. The 250 mile radius would still be consistent with the final rule. As noted, it would allow most organs to be driven rather than flown, reducing cold ischemic time and cost. It would also allow centers to more easily evaluate marginal organs, potentially reducing organ discard. Centers in the 250-500 mile radius would still have improved access with the 4 proximity point system. Thus, if the local center chooses not to use the organs, there is a good chance that the organ may still be used. This will increase competition as desired by

the committee. The 250/2/4 allocation system is a balanced approach to expanded sharing and elimination of DSA/Region, while still allowing centers to efficiently transplant organs. After a period of implementation, the proposal could be revisited to assess the benefits of even broader sharing.

The ASTS fully supports the decision to reduce the threshold for inclusion in expedited placement to 2 imported pancreata over 2 years. Limiting the program to only 16 centers nationally under the old proposal is not equitable for patients nor practical. In addition, if the threshold for expedited acceptance was 250 NM rather than 500 NM it is likely that more centers would be able to participate.

The proposal also needs to be clear that the pancreas offers for SPK candidates both within and outside of either circle are offered with a kidney if needed. Currently, many regions will not share kidneys outside of “local” allocation regions. This limits enthusiasm for imported organs. While implied in the proposal, the language must specify the sharing of the kidney is not at the discretion of the offering OPO regardless of distance.

In summary, the ASTS commends the committee for a thoughtful review of the issue. The Society feels that the 500nm circle relies on untested models and may have a detrimental impact on both access and utilization. Implementation of the 250nm allocation system would allow the committee to validate the key policy assumptions, ensure efficacy, and limit potential harm should the logistical barriers to organ transport result in greater organ discard and/or program closure.

8. [Continuous Distribution of Lungs Concept Paper](#)

The American Society of Transplant Surgeons (ASTS) opposes the suggested proposals from the concept paper as written. We recommend the OPTN take an iterative approach to all new organ allocation policies by taking small steps with regular reassessments (e.g. defined trial time before broad adoption, regional vs national wide scale change etc.) to identify successes and unintended consequences, particularly concerning logistical issues and outcomes.

The American Society of Transplant Surgeons (ASTS) thanks the OPTN Thoracic Committee for its work on the “Continuous Distribution of Lungs Concept Paper.” At this time, we oppose the proposal as written due to ongoing issues that impact a successful implementation of the continuous distribution of lungs. While changing the model does re-distribute the current volume of lungs to what would appear to be the ideal candidate, this model does not account for variations in practice, recipient-donor matching based on actual clinical management perspectives, and the potential

for a marked increase in travel time and distance with implications on acceptance/recovery practices. The latter may have been alluded to with “efficient management of organ placement” though distance of travel and associated logistics are not outlined or well understood. Furthermore, it is not clear what is meant with “low,” “medium,” and “high efficiency.”

Changing the model of allocation does not address variabilities involving centers’ acceptance or utilization and recovery of lungs and donor management. This may undermine the efforts of many progressive centers that work closely with their OPO to develop protocols that increase lung donation through effective donor management and optimal organ recovery practices.

A continuous allocation system may seemingly even out access to organs. An unintended consequence is when patients can afford to dual list, getting better access to transplant, resulting in a socioeconomic inequity to those unable to dual list.

Incorporating the “time on wait list” may change the dynamic of listing patients who may be a bit early, changing allocation priorities and adding burden/cost to listing practices.

With the proposed model, highly sensitized patients may indeed get better access to transplants; however, the contribution of various components of the composite score and designated weights allow for great and unpredictable variability. This fact, compounded by wider distribution, is cause for concern on patient impact if there are different regions and program positioning across states and regions.

We encourage UNOS to include, in any future policy, metrics for successful procurement and transplantation of lungs and considerations to optimize and standardize management of such donors. In our view, centers that are aggressive by going on more recoveries, using EVLP and employing ECMO strategically, will continue to do so. Changing the model will incur additional travel costs and impose more air travel for transplant surgeons and recovery teams often during unconventional hours. We urge UNOS to take these issues into consideration when policies result in a significant increase in personnel travel without the ability for organ recovery by local teams.
