

The AST Board of Directors approved the following responses to the OPTN/UNOS Fall 2019 Public Comment period during its September 25, 2019 teleconference. All responses were developed after review of feedback from the Society's Communities of Practice and Policy Committee.

Modify Appointment Process for Histocompatibility Vice Chair (Histocompatibility Committee)

The American Society of Transplantation is supportive of this proposed change to the appointment process for the Histocompatibility Vice Chair with no further comment.

Clarification for Pre-Existing Liver Disease (Liver and Intestinal Organ Transplantation Committee)

The American Society of Transplantation is supportive of the proposed clarification for pre-existing liver disease as written and offers no further comment.

Data Collection to Evaluate Logistical Impact of Broader Distribution (Operations & Safety Committee)

The American Society of Transplantation is supportive of this proposal in concept, recognizing that the change to broader organ distribution will have significant impacts on organ procurement and transportation.

The Society offers the following comments from our constituents for the Operation and Safety Committee's consideration:

General comments

- The impact of broader distribution of organs may result in cost increases due to increasing time spent for procurement, greater frequency of "dry runs", and increased use of advanced technology for organ preservation. While we agree that it will be challenging to capture all costs, collection of this data is important, and we encourage the OPTN Operations and Safety Committee's ongoing efforts to develop methodology for cost assessment.
- Potential impacts provide strong justification for capture of cost information. These impacts include:
 - Viability of transplant programs. This impact may be greater for smaller centers and centers in areas of lower population density.
 - The loss of programs may impose additional travel burdens on patients requiring transplant evaluation and care.
 - Potential disproportionately higher burdens may be borne by programs with unfavorable payor mixes.

Transportation related items

- If organ was flown, ease and time to hiring aircrafts (aircraft and pilot availability), type of chartered aircraft, number of pilots, and other measures of air travel safety
- On the “drive” dropdown within transportation modes, OPO Staff Vehicle and Hospital Staff Vehicle are confusing. If these are intended to include vehicles owned by the OPO or hospital, staff should be removed. If they are intended to describe staff using their own private vehicles, separate options should be added for OPO- or hospital-owned vehicles.
- All modes of transportation that were considered (air, land, both) and rationale for selection and if it a second choice was made.
- Were multiple organs transported by the same transport service (same flight or vehicle)?

Preservation

- Collection of mode of preservation i.e. cold static vs pump vs other

Recovery personnel

- Number of transplant surgeons involved in procurement and transplantation of organ, particularly those organs that are procured by the center itself. Did a procuring physician procure multiple organs for one program, or for multiple centers?
- Procurement by local surgeon?

Time of organ transport

- To fully assess the time impact of broader organ sharing, the “round trip” time needs to be assessed. The total time spent by the procuring team is an important component of the logistical impact of broader sharing. The time for coordination of multiple teams from multiple centers is likely to be affected. The total time should include the time for travel to and from the donor hospital as well as the time spent at the donor hospital prior to and including procurement.
- Factors affecting delays such as: weather, traffic, team and OR coordination should be noted.
- For time of transportation, using receipt in OR does not account well for organs preserved on pump or normothermic device outside the recipient hospital OR. Additionally, such time should probably be accounted (as it might be intentional delay, not a consequence of travel/allocation/logistics). We would suggest recording departure time from donor hospital, time placed on preserving perfusion device (if any), time of removal from perfusion device (if any), and time of entry into recipient hospital OR. This also doesn’t deal with organs that are delivered to one hospital and then redirected, though that may be infrequent enough to ignore.

Data collection

- Placing the responsibility of reporting on the OPO will alleviate the burden from the recipient transplant center but will mandate clear communication regarding the timing of recipient operations, travel times, costs associated with transplantation, etc.
- Consideration should be given to having the OPO collect the data elements leading up to arrival in recipient OR – that would better be added to the TRR form to be recorded by the recipient hospital: Time of arrival at the transplant center, and the actual OR time; Both to be reported by the receiving Transplant Center. (This would enable identifying

the time the organ is stored at the center, which clinical data indicates is an option utilized for machine perfused organs.)

- Better granularity in the decline codes should be offered to help understand why organs are discarded (did logistics and/or travel play a factor?).

Pediatric considerations

- Broader sharing is predicted to result in increased transplant rates for pediatric DD candidates, but the pediatric community is concerned that broader sharing may also lead to higher CIT and hence higher DGF rates which in turn may lead to higher rejection rates and lower GFR and shorter graft survival. Prior allocation policies under which children have been advantaged, have also resulted in poorer matching with negative downstream effects which are not captured in 1-year graft survival rates. These effects will be an unaccounted for “cost” that is neither measured by this proposal nor measured well by current OPTN policy.
- For adult and pediatric recipients (of at least kidney transplants), the cost of dialysis required post-transplant due to DGF should be considered in the calculation of effects and costs of broader sharing.
- Successful transplantation of children is accomplished by expedited transplant with well-matched, suitable kidneys which result in low DGF rates, low rejection rates and longer graft survival. The projected need for a functioning kidney in a child is longer than that required in many older adults. The Society’s pediatric constituencies support any policies that adequately address these aggregate concerns that jeopardize the safety and quality life-years of the most vulnerable transplant candidates.

Expedited Placement of Livers (Liver and Intestinal Organ Transplantation Committee)

The American Society of Transplantation is supportive of the proposal for expedited placement of livers. We agree that this proposal has the potential to decrease the disparity that currently exists with expedited placement of organs by increasing transparency and allowing more transplant centers to participate in the process. The patient opt-in process would help OPOs place livers that are turned down in the donor operating room more quickly and identifying these patients on the original liver match run would help the OPO prepare for the expedited placement.

Specific comments relating to this proposal offered by our constituencies include;

- To limit ischemic times and avoid organ discards, it is imperative that each transplant center that opts-in patients for expedited placement must be logistically and operationally prepared to accept such organs
- Review of participating center acceptance practice within this policy as planned would be crucial in avoiding unnecessary organ discards.
- This proposal requires close monitoring and audits of how quickly and often OPOs initiate the expedited placement, as well as the specific triggers for expedited placement so as to not disadvantage or inadvertently bypass viable back-up recipients on the existing match run who may not have been designated for expedited placement by their transplant centers.
- Was consideration given to machine perfused livers which could affect both the time availability to reallocate, and the decision of the transplant centers to accept?

- Prioritization for pediatric donor livers to be offered using expedited algorithm to pediatric recipients first. Expedited placement attempts should not bypass pediatric patients that meet the criteria for inclusion on the expedited match list.
- Livers meeting criteria for ex-situ split should still be offered to pediatric patients that met the expedited placement criteria, with allocation of the remnant segment in expedited fashion to a center close to the pediatric center.
- Consideration be given to exclusion of donor weight in the expedited center information as this variable is redundant with donor height and BMI which are more predictive of potential risk factors for recipient complications.
- Consideration of additional provision and language inclusion for alternative expedited placement algorithms for livers to centers performing hepatocyte transplantation.

Modify Data Submission Policies (Data Advisory Committee)

The American Society of Transplantation is supportive of the proposal to modify data submission policies with its aim at improving data accuracy, completeness, and integrity of the OPTN data set and requiring clearly documented justification for data changes. This aligns with the Final Rule requirement that timely and institution-specific performance data be made publicly available in order to appraise the quality of transplant programs.

Extending the time to submit data should help ensure that data is accurate at the time of submission and there should be fewer reasons one should be allowed to change data after that process is complete. A 30-day extension and the provision of additional resources to improve data quality on a real-time basis before the deadline arrives (i.e., weekly reporting of “Data Validation Reports” and a new data quality dashboard) can help avoid the need to go through the cumbersome correction process by prompting the center to make the corrections before the deadline arrives.

While this proposal helps to establish a formalized process, some within our constituencies have expressed concerns that it may result in an increased burden on members to be in compliance with these proposed changes and that even with the revised timelines, data (particularly those coming from multiple disciplines) may not always be available.

Eliminate the Use of DSAs and Regions in Kidney Allocation (Kidney Transplantation Committee)

The American Society of Transplantation appreciates the opportunity to comment on the proposed models for kidney allocation that remove Donor Service Areas (DSA) and regional boundaries from kidney allocation policy. The Society leadership and constituencies acknowledge that to be compliant with the Final Rule, it is necessary to modify the allocation policy with the intent to decrease variance in access and transplant rates related to geography. We recognize that the OPTN Kidney Transplantation Committee has been tasked with the challenging mandate to analyze the problem and put forth to the community, what they have determined is the best option moving forward to improve equity in access and to move kidney allocation closer to a continuous distribution model.

While it is recognized that the current DSA and Regions are arbitrary and do not allow for equity in access nationally, some of our members have expressed concern that the proposal does not address other substantial factors that contribute to variation in access. Specifically, they are concerned that the proposed broader distribution will shift available organs from areas that have high performing OPOs to areas with lower performing OPOs without mandating improved/minimum OPO performance standards and expectations.

The shortcoming of the proposal to “Eliminate the Use of DSAs and Regions in Kidney Allocation” is the attempt to take a complex, multifaceted problem of access to transplant and put forth a narrowly focused solution. While this policy proposal does fulfil the HRSA mandate to be compliant with the Final Rule, it falls short of addressing other significant components of the allocation system (beyond DSA) that contribute to inequity in access.

The Society, which includes representatives from DSAs all over the country, including those in regions with both shorter and longer candidate wait times, ultimately supports any efforts to improve equity and organ availability on a national level. Regrettably, given the diversity of our Society, the concerns related to this narrowly focused proposal, and the need for a multi-pronged approach to address system performance and inequities, The American Society of Transplantation is unable to endorse the proposal “Eliminate the Use of DSAs and Regions in Kidney Allocation” put for by the OPTN Kidney Transplantation Committee in its current form.

The Society offers the following comments regarding this proposal for consideration:

- Costs and Resources
 - This proposed change in allocation will increase distances for organ and procurement team travel. The added costs and resources, the potential for further reduction in efficiencies in allocation, the adverse consequences for transplant programs and the potential for increased cold ischemia time/delayed graft function and organ discards are of concern to many of our members. We recognize the OPTN Operations and Safety Committee for proactively addressing these concerns with the proposed policy currently out for public comment “*Data Collection to Evaluate the Logistical Impact of Broader Distribution*”.
- Cold Ischemia Time and Organ Quality
 - Although challenging to model, there is no data projecting the incidence and outcomes of DGF although projected increased mean and median organ travel distances will likely increase DGF rates. This is of particular concern to our pediatric community, since any proposal that increases DGF rates will likely increase adverse long-term outcomes which are not captured in 1-year graft survival rates. The projected increased volume for pediatric transplants does not take into account the potential for increased offer decline rates for pediatric candidates on the basis of distance and concern for prolonged cold ischemia times and increased DGF risk.
- Wait List Mortality
 - Although the projected number is small, the proposed allocation model, as well as all the broader distribution models, project an increase in waitlist mortality which is not projected in the smaller distribution models i.e.; 250 and 150 NM radius models. If the 500 NM proposal is adopted into policy, particular attention will need to be paid to the monitoring of waitlist mortality in general and

specifically as it occurs in relationship to a candidate's place of listing (rural, metropolitan, etc.).

- Medical Urgency
 - Medically urgent criteria may be more appropriately addressed as a separate policy proposal particularly since criteria for the designation of “medically urgent” have yet to be determined and are likely to require public comment and discussion if there is a desire to achieve uniformity across the nation.
- Vulnerable Populations
 - The proposal under consideration does include encouraging predictions of pediatric kidney transplant total volume although the predictions do not take into account potential changes in physician acceptance patterns related to longer cold ischemia times and higher risk of delayed graft function. The Society's pediatric membership would like to see more specific data on how the proposed policy implementation would impact pediatric recipients at a more granular level. The monitoring plan proposed includes monitoring transplant rates by age but does not specifically address the concerns of the pediatric transplant community relating to the projected increase in the volume of kidney-pancreas transplants. The proposed allocation policy, done in isolation without consideration of the effect of prioritization of kidney-pancreas recipients within allocation sequence, will potentially further adversely impact, with an uneven distribution, pediatric patients that are within proximity of high-volume kidney-pancreas transplant centers. The pediatric constituency has asked that the OPTN Kidney Transplantation Committee address these concerns and include a comprehensive plan for assessment and monitoring of current and future kidney-pancreas transplant volume effects on pediatric kidney transplant volume and transplant rates at a more granular level than national.
 - The modeling projects decreased transplant rates in small town and rural areas. Some of our members have concern that the proposed allocation system may divert organs away from rural and low-income communities in the South, Midwest and Northwest and to larger metropolitan areas. The analyses performed looked at these issues on a national level but not more regionally.
- Multiorgan Transplants
 - The current prioritization of multiorgan candidates at the top of the allocation sequence is of concern to The Society. The proposal under consideration projects an increase in volume of kidney pancreas transplants which has raised concerns from our pediatric constituency. Given the requirement to make major changes in allocation to be compliant with the Final Rule, this would seem to be an opportune time to address broader community concerns with how multiorgan transplants are prioritized and allocated. The proposed allocation policy, done in isolation, without consideration of the effect of prioritization of kidney-pancreas recipients within allocation sequence will potentially adversely impact not only pediatric candidates but also the highly sensitized, prior living donors and adult kidney-alone candidates that are within proximity of high-volume kidney-pancreas transplant centers.
- Considerations other than DSA that Contribute to Inequities in Access

- Some of The Society constituents believe that the 11 Regions and 58 DSAs that were created years ago as part of the national allocation system can ultimately meet the Final Rule's "equity in access for all that is not limited by geography" mandate. This would require all OPOs to be held to the goals that HRSA and the OPTN have set forth. There is concern that the current broader distribution will shift available organs away from areas that have high performing OPOs without mandating improved/minimum OPO performance standards and expectations. Additionally, if system performance improvements are made to both OPOs and transplant programs, this would likely increase the supply and utilization of donated organs available for transplant. While the Society leadership recognizes that it is not feasible to think the variance in access and transplantation related to geography is likely to be improved without the elimination of DSA and Regions from allocation policy, they are also respectful of The Society's members who have expressed dismay that there is nothing included in this proposal to address uneven OPO performance or transplant program organ acceptance practices. The Society leadership recognizes and encourages ongoing OPTN and OPO efforts to identify standardized metrics by which OPOs and transplant centers can be held accountable and by which access may be improved.
- The Society membership has also expressed concern that multiple demographic factors such as; lack of access to healthcare, higher concentrations of poverty, residential segregation, higher proportions of uninsured patients, low health literacy rates, fewer transplant centers, long distances to a transplant center, for-profit dialysis facilities and lower organ availability (especially in southeastern states) which affect DSAs in an uneven distribution, will continue to adversely impact potential transplant candidates in the allocation model proposed. While we recognize that such considerations were beyond the scope of the OPTN Kidney Transplantation Committee charge, such factors may negate the projected improvements in access that are strived for with the proposal under consideration.
- We feel the need to reiterate a point that has been made previously in prior public comment periods. The nautical mile allocation solution will 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 Northeast 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. If this proposal is adopted into policy, we suggest closely monitoring of the downstream effects specifically on coastal regions.

Eliminate the Use of DSAs and Regions in Pancreas Allocation (Pancreas Transplantation Committee)

The American Society of Transplantation appreciates the opportunity to comment on the proposed models for pancreas allocation that remove Donor Service Areas and Regional boundaries from allocation policy. The Society leadership and constituencies acknowledge that to be compliant with the Final Rule, it is necessary to modify allocation policy with the intention

to decrease variance in access and transplant rates related to geography. We understand that the OPTN Pancreas Transplantation Committee has put forth this proposal to the community with the intention to improve equity in access after carefully and scientifically analyzing the problem and potential solutions.

The American Society of Transplantation is an expansive and inclusive organization. The Society leadership is committed to accurately represent the interests and expert opinions of its varying constituencies. As such, efforts to construct a unified statement regarding significant changes in allocation policy from The Society may not allow for satisfactory representation of all of our invested members and in reality, may do disservice to the complexities of the proposals which we are being asked to consider. This proposal attempts to address the multidimensional problem of access to transplant by putting forth a narrowly focused solution. Given the diversity of our Society, which reflects the diversity of the nation, The American Society of Transplantation is unable to render a definitive vote in support or opposition to this proposal.

The American Society of Transplantation offers the following comments regarding this proposal to the Pancreas Transplantation Committee of the OPTN:

- The Society in general agrees with the 500NM circle for pancreas allocation although some constituents expressed that a primary determinate of circle size should be reasonable driving distance beyond which the costs of air transport may be cost prohibitive. This was felt to be less significant of an issue for pancreas allocation compared to kidney allocation since the importance of getting pancreata to those centers who are actually willing to transplant pancreata is of critical importance to improve utilization.
- Import back up initial distance of 150 NM was favored by the kidney and pancreas constituency.
- Use of proximity points only inside the circle was favored by the kidney and pancreas constituency but others who expressed an opinion felt that they should be used inside and outside the circle. There was concern that the proximity points should not be weighted as high as other allocation variables. There was also concern that a large trauma center/large donor center that also had a transplant program would be unfairly advantaged by proximity points compared to another transplant center in the same city that did not have a large volume of donor procurements. It was for this reason that some of our members expressed a preference for a proximity points "plateau" which we understand was eliminated as an option for consideration by the OPTN Pancreas Transplantation Committee.
- All felt that close monitoring of logistics and cost going forward will be key for determining effectiveness and efficiency of any new allocation proposal.
- Facilitated pancreas placement should be considered for programs that qualify with 5 transplants in the past 2 years.
- Efforts from local procuring surgeons will be needed to carefully consider all pancreas donors to minimize pancreas discards.

- Complete data capture for SPKs that are allocated as dual organs will be necessary in the situation where the pancreas is NOT transplantable, and the kidney alone is allocated. Transparency and accurate monitoring by the OPO is key, particularly if out of sequence allocation occurs.
- While it is recognized that the current DSAs and regions are arbitrary and do not allow for equity in access nationally, the proposed models do not address the root cause of the variations. Instead, these proposed models have the potential to shift available organs from areas that have high performing OPOs to compensate for areas with lower performing OPOs. Regardless of using currently defined regional boundaries or a fixed number of nautical miles from donor hospitals, variations in size, shapes, and populations will still exist and impact equity unless the disparities associated with lower performing OPOs and wide variations in organ acceptance patterns of transplant programs are addressed.
- While this allocation proposal is an attempt to decrease disparity related to geography, it does not address disparity in access that is related to geographic concentration of poverty, lack of insurance, lack of health education, etc.
- What will be the effect of this allocation policy on pediatric kidney alone recipients? The monitoring plan proposed includes monitoring transplant rates by age but does not specifically address the concerns of the pediatric transplant community relating to the projected increase in volume of kidney-pancreas transplants. There is clear acknowledgement among the pediatric transplant community that modifying the allocation policy to be in compliance with the Final Rule is necessary with the intention to decrease variance in transplant rates related to geography. Nevertheless, this proposed allocation policy, done in isolation, without consideration of the effect of prioritization of kidney-pancreas recipients within allocation sequence will potentially further adversely impact, with an uneven distribution, pediatric patients that are within proximity of high-volume kidney-pancreas transplant centers. The pediatric constituency of The Society reiterates its concern for the current prioritization of kidney-pancreas patients above children, the highly sensitized and prior living donors. The pediatric constituency asks that the Pancreas Transplantation Committee address these concerns and include a comprehensive plan for assessment and monitoring of current and future kidney-pancreas transplant volume effects on pediatric kidney transplant volume and rates at a more granular level than national.

Many of the comments submitted by The Society relating to the proposal to “Eliminate the Use of DSA and Regions from Kidney Allocation” are appropriate to be voiced in this context also, particularly those relating to *multiorgan transplant priority* within the allocation system. The proposed allocation policy, done in isolation, without consideration of the effect of prioritization of kidney-pancreas recipients within allocation sequence will potentially adversely impact not only pediatric candidates but also the highly sensitized, prior living donors and adult kidney-alone candidates that are within proximity of high-volume kidney-pancreas transplant centers. Given the requirement to make major changes in allocation to be compliant with the Final Rule, this would seem to be an opportune time to address broader community concerns with how multiorgan transplants are prioritized and allocated.

Continuous Distribution of Lungs Concept Paper (Thoracic Organ Transplantation Committee)

The American Society of Transplantation acknowledges that this is a concept paper, not a policy proposal. This concept paper appropriately outlines the challenges evident with the current process of recipient matching to donor lungs via geographical mileage circles, ABO compatibility, age and categories of illness, among others. This concept paper outlines the changes necessary to move from a classification-based system to a points-based system of lung allocation. This would entail determining points and weighting for pertinent variables such as medical priority, blood type compatibility, ischemic time, efficiency factor, waiting time, sensitization and others deemed relevant. Recipients would ultimately be given a “score” on a donor run match list. This approach has been approved by the UNOS Board and is the direction that all allocation policies are (or will be) working towards.

The relevant constituencies of AST are in agreement that a continuous distribution system has advantages including; ability to be modified when new variables are deemed important, variables evolve to have new points or weighting and ease of programming. Addition factors offered for consideration include; population density, OPO efficiency, cost estimates, quality of life, single vs double lung, age, short stature and blood group O as a disadvantaged group.

To assure consistency and fairness to all potential recipients at all centers, all variables on which the composite score is based should be rigorously defined in the development process with clearly detailed procedures for measurement and determination. This would include components of the current Lung Allocation Score (LAS) as well as HLA sensitization.

Part of designing a process should also be consideration for evaluation — how will we decide that the process that we’ve designed is working to serve the communities that it needs to serve? The current document has relatively little to say about how we will evaluate our success, both during this process and after it is complete.

We specifically would like to bring attention to a few key considerations for the UNOS Thoracic Organ Transplantation Committee to consider in this process going forward.

- Single vs double lung allocation. Current allocation does not consider whether one or both lungs are being allocated to a recipient. In a new system, this should be incorporated into assessment of urgency, outcomes and efficiency. The urgency and benefit of a second lung (i.e. double lung transplant vs. single) may be significantly different depending on the patient’s diagnosis and physiology. This issue is of relevance to determination of “best use of donated organs”, “allocation efficiency” and “patient access to transplantation.”
- Placement efficiency and ischemic time appear to be overlapping variables largely derived from distance and travel time. Center-specific factors could also affect placement efficiency and could lead to bias favoring better-resourced centers. There is also inherent conflict with the Final Rule requirement that allocation policies “not be based on the candidate’s place of residence or place of listing.”
- Ex vivo perfusion devices; How would this play into the scoring? Their evolution allows the potential for previously unusable organs to now be used but their cost is significant for programs and the outcomes still somewhat unpredictable. Usage of these devices are

often in the higher ischemic time and longer distances matches and could be used against the transplant program if only those variables were included without the device support taken into account.

- Pediatric candidates. We appreciate the acknowledgement of there being different allocation systems that apply to pediatric candidates. Again, there is relative obscurity about how age will factor into a composite score. The pediatric community is fully committed to the prioritization of pediatric organs for pediatric candidates, and we would urge the parties responsible for this process to maintain our collective commitment to protecting the needs of children.
- Preservation mode. We recommend consideration of preservation mode in the composite score. Advances in transportation practices are quickly evolving. Technologies such as perfusion may challenge the current assumptions related to WIT and CIT, among others, and the formulas developed would ideally be flexible enough to incorporate such changes as clinical data comes in.
- Outcomes score. This is likely to be based largely on survival. The survival time point post-transplant used in the allocation score is critical. While the use of short-term outcomes (as in the present LAS) may not identify differences, long-term outcomes diverge significantly for different patient populations. In lung transplantation, examples include older patients and re-transplants. This score could also incorporate donor and recipient risk factors for PGD to avoid unfavorable donor/recipient combinations.