

Fall 2017 Final AST OPTN/UNOS Public Comment Responses

1. [Addressing Approved Transplant Fellowship Training Program Bylaws \(Membership & Professional Standards Committee\)](#)

The American Society of Transplantation supports the proposed updates to the OPTN Bylaws as they relate to the review of the fellowship training programs as written.

These recommendations for OPTN Bylaws changes seem quite appropriate and consistent with how training fellowships are monitored currently (by other organizations, such as the AST and ASTS). We have appreciated the opportunity for joint society work group feedback in developing this proposal, and believe that it is appropriate and reasonable to continue to rely on the societies to review transplant fellowship programs rather than have the MPSC invest large amounts of resources to initiate and take on this responsibility.

2. [Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types \(Pancreas Organ Transplantation Committee\)](#)

The American Society of Transplantation is not supportive of the current proposal, and offers the following comments.

We are not convinced that this resolution will increase the number of pancreas transplants, and may further disadvantage vulnerable populations.

Kidney candidates, especially minorities, face long waits to transplantation- in many cases five years or more. The wait for pancreas transplant is much shorter and data regarding this appears to be limited. We believe that allowing this proposal to pass as currently written to include SPK will further disadvantage kidney alone candidates. The Society is, however, supportive of loosening restrictions for pancreas alone allocation.

Presently, SPKs are prioritized, in the allocation sequence, prior to pediatric candidates. This may disadvantage pediatric candidates in some areas, extending their waiting time for transplant. The AST requests modeling data on the impact of these changes on pediatric recipients at a more granular level such as regional or by DSA.

3. [Guidance on the Benefits of Pancreas After Kidney \(PAK\) Transplantation \(Pancreas Organ Transplantation Committee\)](#)

The American Society of Transplantation opposes the approval of this proposed guidance document. It is the Society's opinion that the analysis on which this guidance document is based would be more appropriately communicated to the transplant community as a peer reviewed manuscript. We offer the following comments specifically related to the analysis for consideration.

Given the paucity of good data on outcomes, and the contention generated by oppositional analysis, it seems that a cautious approach be taken that stresses individual need.

- The composition of the control group is critical in this analysis. Importantly, this study found patient and kidney survival after PAKs was better than the SPK waitlist group. However, more deaths in the SPK waitlist group that do not have a kidney transplant does not necessarily provide a strong case that PAK has a clear benefit (Figure 2). Figure 2 should provide the patient survival rate for patients who received a kidney transplant alone and never got a PAK.
- The patient survival for PAK recipients was no better than the patients waiting for a PAK. In fact, an increased risk of death was associated with PAKs within the first 90 days compared to waiting for a PAK. Although this difference was only 13 deaths within 90 days of PAK transplant, the total PAK recipient deaths were 953 of 3,358 (28%) compared to 314 of 2278 (13%). The Committee elected not to provide a figure of this data.
- The benefit of PAK demonstrating better kidney graft survival needs to be further assessed given the death rate is twice as high for PAK recipients than those waiting for PAKs (28 vs 13%). It may be helpful to compare the patient survival rates for the deceased donor renal transplant only patients (light blue line in Figure 3) with the PAKs of living and deceased donor kidneys (dark blue and green lines in Figure 3).

4. [Guidance for Transplant Program Participation in the Transplantation of non-A1/nonA1B \(A2/A2B\) Donor Kidneys into Blood Group B Candidates \(Minority Affairs Committee\)](#)

The American Society of Transplantation supports the informed consent guidance presented in this document, but presents the following comments:

- We are in agreement with guidance for programmatic establishment of titer thresholds and with the confirmation of titers every 90 days.
- Given that blood type B recipients make up 16% of the deceased donor waiting list and that 73% of minorities are B blood type, this policy has significant potential beneficial effects for these disadvantaged populations. The exact impact is unclear given that the prevalence of donor non-A1 blood type regionally is unknown. In order to facilitate safe and efficient wider implementation of this established policy, the Society suggests that donor blood be available pre procurement for verification of non-A1 blood type by the recipient center.
- Wider implementation of this existing policy would require laboratories to have the ability to efficiently and accurately perform A1 titer testing at all times. Additionally, center implementation of this existing policy will require institutional protocols for post-transplant A1 titer testing. The center costs for wider implementation of this existing policy are unclear and inclusion of cost estimates would strengthen the document. If this guidance document results in its intended effect of increased utilization of this transplant option, the impact on other vulnerable populations, specifically children, warrants careful monitoring.

5. [Improving Dual Kidney Allocation \(Kidney Transplantation Committee\)](#)

The American Society of Transplantation is supportive of this proposal as written.

6. [Improving Allocation of En Bloc Kidneys \(Kidney Transplantation Committee\)](#)

The American Society of Transplantation supports this proposal as written.

The Society values the clarifications provided to OPOs, and appreciates the modifications made based upon reviewer feedback since this proposal's initial public comment review.

7. [Improving the Efficiency of Organ Placement \(OPO Committee\)](#)

The American Society of Transplantation is supportive of the concept of improving efficiency in organ placement, but offers the following comments with regard to the individual components of the proposal for consideration:

This proposal seeks to:

Reduce the current time limits for accessing the organ offer data and for responding to organ offers from 1 hour/1 hour to 30 minutes/30 minutes respectively.

While the AST appreciates the need to place organs in a timely manner, the proposed half hour time limit for responding to organ offers may be difficult for some centers or under some circumstances. There are many reasons why the hour limit is helpful- including having sufficient time to review data, as well as enough time if multiple offers are coming in simultaneously, and enough time to review with other team members if questions upon reviewing the data arise. We offer that an exception could be made to reduce the time limit for organs that are already procured as a first step.

Update the required deceased donor information

The Society supports this modification.

Propose an organ offer acceptance limit of two

The Society supports this modification.

Require OPOs to manage the final acceptances in real time.

The Society supports this modification.

8. [Enhancing Liver Distribution](#)

The American Society of Transplantation generally supports the recent revisions to the liver distribution policy proposal, and offers the following comments for consideration..

The Society acknowledges prior efforts by the UNOS Liver and Intestinal Committee to address geographic disparities in liver transplantation with the recently approved changes to the criteria for hepatocellular carcinoma (HCC) MELD exceptions and the

creation of a National Liver Review Board. With regard to the current liver distribution proposal to further attempt to decrease geographic barriers for liver transplantation for candidates who are at high risk of mortality, the Society offers comments separately on each of the four components of the proposal.

- The Society supports the concept of prioritizing candidates with higher MELD scores within the 150-nautical mile radius circle of the donor hospital, in addition to regional sharing as a means to decrease MELD disparity at transplantation for the more urgent candidate, while limiting the distance that organs have to travel to achieve this purpose. Because of the additional cost and resource utilization of the anticipated increased travel, questions regarding responsibility for these increased financial burdens should be addressed before policy implementation. Additionally, post implementation monitoring should include cost-effectiveness in terms of per organ allocated, per life saved and per patient transplanted.

Of concern also is the effect such circles will have on coastal areas or at borders of relatively low population areas, which may be disadvantaged by low population density within the circle. A sizeable piece of the proposed circle will be lost for candidates living on coastal borders, which disadvantages areas with low population density. Additional analyses should be performed and shared with the community prior to policy implementation to understand the impact on transplant programs along the coasts.

- The Society does not support the proposed allocation of additional proximity points to the candidates within the 150 mile radius alone, but would support the allocation of additional proximity points to the candidates within the 150 mile circle AND all candidates within the donor service area (DSA)- so as to not disadvantage the high MELD candidates in the DSA who are outside the 150 nautical mile circle. This allocation model will also help to mitigate potential negative impact on OPO performance, either in the donor DSA or the recipient DSA. The issue for transfer of organs from DSAs with high-performing OPOs to DSAs with low-performing OPOs is of great concern. If this new allocation system is implemented, the Society feels strongly that there needs to be appropriate oversight of OPO performance and that there is a need for development of new metrics to allow a more systematic assessment of the quality of performance and efficacy in increasing donation rates in respective DSAs.

The Society is also not in favor of 5 proximity points but would like to see modeling of lower proximity points. In particular, there is concern that Hepatocellular Carcinoma (HCC) patients who are capped at 34 may be significantly disadvantaged by a 5 proximity point system. The Society suggests that 3 proximity points may be a better compromise to ensure that patients with elevated physiologic MELD scores are receiving the prioritization they need to be transplanted in a timely manner and that HCC candidates are not significantly disadvantaged. Another potential negative impact of the proposed allocation system is the effect on multivisceral transplantation since increased sharing has already had a deleterious effect on multivisceral transplantation. If modeling demonstrates a negative impact, the policy may need to be amended to ensure these patients have adequate access.

- The Society does support lowering the sharing threshold to MELD 29 but not below, unless data were to become available favoring a different sharing threshold below MELD 29.
- The Society supports the separate allocation system for DCD donors or donors > 70 yrs of age.

9. [Living Organ Donation by Persons with Certain Fatal Diseases who Meet the Criteria to be Living Organ Donors \(Ethics Committee\)](#)

The American Society of Transplantation is generally supportive of the proposed white paper, although the Society has some concerns and feels there are several areas where this paper could be strengthened.

While the Society sees this as ethically justified and a desirable option for individuals with certain fatal diseases, who are competent, to become a live donor, we are concerned about the unintended consequences of such a proposal going forward as policy;

- Erosion of public trust
- Potential complexity of future policy modification
- The need to include in any future policy proposal additional measures to ensure capacity for informed decision making beyond the standard psychosocial evaluation, as well as processes for assessing and communicating the expected impact of living donation in terminally ill persons on overall health status, quality of remaining life and progression to death
- Clarification of additional data elements post-surgery that should be collected

10. [Regional Review Board Guidance for Adult Congenital Heart Disease Exception Requests \(Thoracic Organ Transplantation Committee\)](#)

The American Society of Transplantation is supportive of this proposal as written given that it provides new guidance for review boards regarding congenital heart disease exception requests.

The number of patients affected is small, but this group does have high mortality on the waitlist, and the limited expertise available to the RRB is problematic. The Society has one comment that pertains to the utilization of ventilator as a criterion for Status 2 exception in single ventricles. This particular criterion had been removed as a qualifying criterion for other cardiac disease. This could be a source of contention and we request rationale behind its inclusion.

11. [Review of HLA Tables \(2016\) \(Histocompatibility Committee\)](#)

The American Society of Transplantation supports the proposal as written, but offers the following comments for consideration.

We acknowledge the value of updating of the DPB1 unacceptable antigen equivalency tables to now include G allele equivalence and the updating of other existing HLA antigen tables. Still necessary is updating of the DonorNet HLA typing section to include DPA and the ordering of the antigens in a logical path: A, B, Bw, C, DR, DR51, 52, 53, DQA1, DQB1, DPA1, DPB1. The order suggested will require a programming change but will diminish data entry errors where currently DQA1 is below DQB1 and DPA1 is sometimes entered in its place.

With regard to future phase 2 and 3, the Society does not favor allocation of resources for implementation since data is lacking that demonstrates that listing of unacceptable Epitopes rather than antigens/alleles will result in a significant decrease in unexpected positive crossmatches, prevent misallocation of organs or reduce organ discards. Presently laboratories are identifying antibodies directed against particular antigens/alleles, and only indirectly identifying particular Epitopes that may be the target of that antibody. We do not have data that an antibody directed against a particular Epitope will bind to the different HLA antigens that carry that epitope with equivalent affinity. Presently epitope specific reactivity should be evaluated by histocompatibility laboratories and the laboratory should determine if those reactions require listing all HLA antigens with that specific Epitope as unacceptable antigens based on comprehensive testing, including the use of surrogate cells.

12. [Revisions to Pediatric Emergency Membership Exception Pathway \(Pediatric Transplantation Committee\)](#)

The American Society of Transplantation is supportive of this proposal as written.

13. [Allowing Deceased Donor-Initiated Kidney Paired Donation \(KPD\) Chains \(Kidney Transplantation Committee\)](#)

The American Society of Transplantation supports the concept of a pilot program of deceased donor kidneys beginning KPD chains.

The Society supports using the list exchange model in order to increase the donor pool, facilitate increased transplants, and improve both HLA matching and avoidance of pre TX HLA antibodies that in turn will improve survival benefit. A major challenge of the policy proposed is protection of vulnerable populations including minorities and those without access to a living donor pool.

The Society supports access to this program by all transplant programs willing to participate in DD-KPD chains initiated by UNOS/OPTN following a pilot trial, and hopes that what is learned from this trial can then be more broadly applied to existing KPD programs.