The American Society of Transplantation reviewed and responded to all twelve proposals released by OPTN/UNOS Committees for the fall public comment cycle, August 14- October 14, 2015. Responses for each appear below. Many thanks to all the committees and communities of practice who provided feedback to the Board on these proposals.

1. **Establish pediatric training and experience**

   The American Society of Transplantation supports the intention of this proposal to define pediatrics as a subspecialty within the field of transplantation and to take this first step to fulfilling the need to establish pediatric program requirements. The AST appreciates the challenge of establishing minimum key personnel requirements given the need to balance access and quality of care. The AST opposes this proposal in its current form, and recommends modifications and additional analysis for consideration by the Pediatric Transplantation Committee.

   Specifically, the AST has a number of concerns regarding how the proposal impacts adolescent access to transplant, particularly thoracic transplant candidates. Society members suggest that changes in OPTN policy should benefit patients through improved outcomes and/or access to transplantation. However, this proposal would mandate that all patients under the age of 18 years undergo transplantation only in transplant programs with individuals who have specific pediatric training, disregarding the possibility that adolescent candidates may be at least as well served (and perhaps better served, depending upon the individual circumstance) by transplantation in programs with adult training background. Thus, we have concerns as to whether mandating specific pediatric training is in the best interest of the adolescent organ transplant candidate. The proposed pediatric training requirements may reduce individual patient/family choice of transplant centers without clear outcomes data that support this restriction.

   The AST believes that adolescent candidates for all organ transplants are a population that warrants more thought and assessment before implementing these changes for all pediatric organ transplant candidates. We believe that further analyses could be performed to clarify if outcomes data support the pediatric training requirement for care of the adolescent organ transplant candidates. For example, one could explore whether adolescents receiving heart transplants in an adult center (a center that would not qualify under the current proposal) have equal or superior outcomes to adolescents transplanted at pediatric centers. In the absence of clear advantages in outcomes in pediatric centers, those mature pediatric patients weighing more than 40 kg (usually ages 14 – 17 years), particularly those without complex congenital heart disease, should have a choice as to whether to be transplanted by an adult or pediatric program. These candidates are much closer in comparison to adults from a surgical perspective. Further, in heart transplantation, mechanical circulatory assist devices are routinely used as a bridge to heart transplant, and the older pediatric patient awaiting heart transplant that needs an assist device may best be served by an experienced adult program.

   To initiate this exploration, the Society requests data regarding outcomes for adolescents transplanted in adult heart programs as compared to those transplanted in pediatric programs to investigate if the adolescent patient is better served in a pediatric setting and confirm the value of the proposed training requirements. We ask that the Pediatric Transplantation Committee specifically request and review the following data:

- Compare outcomes of adult heart program doing 20 or more heart transplants per year and 30 or more VADs per year with pediatric programs currently meeting the proposed criteria for the following populations:
  - 40 kg and age 14 to 17, 15 to 17 and/or 16 to 17
  - 50 kg and age 14 to 17, 15 to 17 and/or 16 to 17
  - 60 kg and age 14 to 17, 15 to 17 and/or 16 to 17

- Compare outcomes of pediatric programs with the populations identified above to adult centers completing:
  - 30 transplants and 40 VADs
  - 40 heart transplants and 50 VADs per year.

- Repeat these analyses for patents bridged with an LVAD

- Repeat these analyses for patients bridged with bi-ventricular assist devices.

The AST suggests that if the analysis demonstrates that adolescents transplanted in adult programs have equal outcomes to those done in pediatric programs, then a mechanism be developed to allow adolescent transplant candidates and their families flexibility to choose from pediatric centers or adult programs that meet their needs. Programs not meeting the proposed bylaws requirements but demonstrating successful outcomes and adequate volume for consideration could be reviewed and approved by the Membership & Professional Standards Committee (MPSC) using an experience pathway. In the case of heart transplantation, we anticipate that there will be a threshold of adult volume with and without VADs that offsets and possibly more than offsets any advantages of care at centers meeting the proposed criteria. It is conceivable that better outcomes are occurring in adult centers with adequate volumes for heart transplants and particularly heart transplants bridged with assist devices as compared to their pediatric counterparts.

The AST recognizes the time and work put into the development of this proposal over the course of many years, but encourages the Pediatric Transplantation Committee to consider these and other comments from the constituency as it determines its path forward.

To improve the proposal, the AST suggests that the Pediatric Transplantation Committee consider the following four options as it determines its forward:

1. Split the body of the proposal into two separate motions: abdominal bylaws and thoracic bylaws for consideration and discussion

2. Define pediatric patients physiologically rather than chronologically, considering that adolescents are a much closer comparison to adults from a surgical perspective. Mature pediatric candidates weighing more than 40kg (generally aged 14-17 years old).

3. Request, review, and share requested outcomes data as outlined above prior to proceeding to the Board of Directors to seek approval for the proposal as currently written.

4. Consider creation of an experience pathway to replace the proposed conditional pathway, similar to that for living donor liver. Centers not meeting the proposed requirements will be reviewed and may seek approval through the MPSC based upon outcomes and appropriate volume requirements that may be determined through the data requested above.

2. Revise data release policies

The American Society of Transplantation is supportive of this proposal with one modification. As currently proposed, policy requires that OPTN data be released according to the Final Rule as well as both applicable federal and state laws and regulations. We propose that "and state" be struck from the statement. The OPTN data are covered by federal law. It is not practical nor particularly desirable to attempt to understand each state's differing laws well enough to endeavor to comply with each. This should be handled as an activity governed by federal law.

"The OPTN Contractor will release OPTN data according to the Final Rule and other applicable federal laws and regulations. The OPTN Contractor will release all OPTN data requested by the Secretary of the Department of Health and Human Services (HHS)."

3. Simultaneous liver kidney allocation

The American Society of Transplantation (AST) strongly supports the use of simultaneous liver kidney transplantation in patients with liver failure who have established chronic kidney disease that will not improve with liver transplantation alone. We recognize the difficulty in identifying such patients prior to transplantation and encourage the development of objective criteria to identify such patients.

The AST supports elements of the proposal, including the concept of a safety net to allow patients who underwent liver transplantation alone but failed to recover kidney function to receive priority for a kidney after liver transplant if they would benefit from kidney transplantation.

However, in the absence of sufficient data, the AST found the proposed criteria to identify SLK candidates to be arbitrary and recommends detailed prospective data collection and analysis of patients with advanced renal impairment requiring liver transplantation to better inform these criteria. Given the provision of the safety net, the proposed criteria for combined SLK were considered too inclusive and may result in unnecessary kidney transplantation. To facilitate prospective data collection and the optimal use of SLK transplantation, the AST recommends that the outcomes of SLK transplants be included in center specific liver outcomes.

The AST also suggests that a transplant nephrologist's input is critical in the evaluation of potential SLK listing, recognizing the great variability in transplant nephrology input from center to center. We recommend that SLK listings should require approval from both the transplant hospital's liver and kidney committees or the hospital's medical review board.

4. Update HLA equivalency tables

The American Society of Transplantation is supportive of the proposed updates to the HLA equivalency tables and offers no further comment.

5. Revise KPD priority points

The American Society of Transplantation is generally supportive of the proposed modifications. We believe that the revised points for candidate-donor pairs in the UNOS KPD program should lead to increased number of match offers and therefore transplant rates based on the data provided within the proposal.

The Society offers two modifications it believes will improve upon the clarity and future development of the proposed policy language:

1. Inclusion of a timeline for review of the actual data following implementation of changes to the priority points in order to understand if the goals of the UNOS KPD program are achieved as projected.

2. Modification of requirements outlined in Policy 13.8.B Logistical Requirements to be consistent with the 21-day chain requirement elsewhere in policy and allow for the reality of issues that may arise unexpectedly prior to surgery. The start of surgery should not be rushed only to meet a policy requirement.

13.8.B Logistical Requirements
In two-way or three-way exchanges in the OPTN KPD program, all KPD donor surgeries involved 58 in the exchange must BE SCHEDULED TO begin within 24 hours and only after all donor surgeons involved in the 59 exchange agree to proceed. Each matched donor recovery must begin within 24 hours of the 60 previous matched donor recovery in the exchange.

6. Requirements for therapeutic organ donation

The American Society of Transplantation is generally supportive of the clarification on reporting requirements as well as limiting the informed consent and evaluation requirements to only those which are appropriate to this small sub-group, but recommends the following modifications related to this proposal:

• Clarify definition in Policy 1.2 (Definitions) as not limited to domino heart and liver donors. Reviewers noted instances of therapeutic kidney donation that could fall into this category.

• Remove requirement to establish written protocols for these rare occurrences, as it may represent unnecessary administrative burden.

• Clarify policy to indicate whether or not these donors receive the usual priorities for transplantation, if needed, as do those given to the routine living donors.

• Consider data collection for the volume of therapeutic donors over 3 years. It will be important to easily identify these donors within the OPTN data collection for the purposes of metrics related to therapeutic organ donation.

• Require that a medical team separate from the live donor team provide the initial recommendation/treatment plan for nephrectomy/hepatectomy.

7. **Foreign equivalent in bylaws**

The American Society of Transplantation is generally supportive of this proposal that stemmed from Joint Societies Working group discussions. It offers the following comments for consideration by the Membership & Professional Standards Committee:

• The term “foreign equivalent” is not clearly defined in the current bylaws and should be removed.

• Add the following modification to section X.2.4.A, which states “Meet all requirements described in Section X.2.B below” (where X is the letter for each organ type).

- We suggest revising to “Meet all requirements described in Section X.2.A OR X.2.B below.” X.2.A is the approved fellowship pathway and X.2.B is the clinical experience pathway. This would allow a foreign-boarded surgeon to qualify via a US/Canadian fellowship.

• Ensure that wording of this proposal that conflicts with the wording contained in the other proposal also sponsored by the Membership and Professional Standards Committee’s “Changes to Transplant Program Key Personnel Procurement Requirements” is addressed if both proposals are passed by the Board. For example, the elimination of the requirement to observe multi-organ procurements remains in this proposal. Similarly, if the pediatric program proposal is passed the changes of both the proposals sponsored by the MPSC will need to be incorporated into the language of the “Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws.”

8. **Personnel procurement requirements**

The American Society of Transplantation supports the proposal. The Society is supportive of extending the time for completing the requisite number of procurements by two years (immediately following fellowship), but suggests that this proposed language be clarified. As currently drafted, it is confusing to readers. "These procurements must have been performed during the surgeons’ fellowship and/or the two years immediately following fellowship completion.”

9. **Reduced documentation shipped with organs**

The American Society of Transplantation is generally supportive of this proposal as long as it does not impact the OPO’s responsibility to enter documentation into DonorNet in a timely fashion. Reviewers noted that there are occasions where the data on a current organ donor, while donation is in progress, is not entered immediately by the OPO coordinator, making electronic access less efficient and effective than proposed.

It is also important to recognize that DonorNet is not always accessible, particularly, in the operating room. Also, OR staff may not be familiar with how to access the information. The lack of paper documentation could present challenges in instances of expected or unexpected computer downtime, which at academic medical centers and VA hospitals, frequently occurs in the middle of the night, early am- when most

transplants are done. For this reason, it is critical that donor ID, blood type and subtype, and infectious disease testing continue to travel with the organ in paper format.

Finally, the proposed modifications in Policy 16.5.A Documentation Accompanying the Organ or Vessel appear to remove the requirement for a donor authorization form to be posted to DonorNet with other donor medical records or sent with the organ. This point should be clarified or addressed.

10. Increase committee terms to three year

The American Society of Transplantation is generally supportive of increasing terms for all OPTN/UNOS committees with the exception of the Membership & Professional Standards Committee to three years, but also recognizes the potential negatives of term extension (including decreased opportunity for committee involvement for the larger transplant community due to reduced annual turnover, and potential for reduction in the breadth of representation within an individual committee- whether by ethnicity, region, or even specialty/expertise in multi-disciplinary groups such as the Pediatric Transplantation Committee due to longer terms leaving limited openings to address these concerns in any given appointment cycle).

11. Modify pediatric lung policy

The American Society of Transplantation supports this proposal as written.

12. Revise facilitated pancreas allocation policy

While supportive of the concept of allowing OPOs access to a list of transplant programs, the requirement that a pancreas program accept at least five imported pancreata in one of the last two years was seen as too high. The Society suggested that there were not adequate data to understand current practice and how these changes will improve this practice. The AST suggests that importing five pancreata over a two-year time period may be a more appropriate benchmark for inclusion on the list of centers contacted for facilitated pancreas allocation.

We believe that there should be an exception pathway or some similar mechanism available to new programs or programs with key staff changes that are expected to impact pancreas offer evaluation and acceptance practices to opt in to receive facilitated offers despite not meeting the required number of accepted organs in a given time period after review by the Membership & Professional Standards and/or Pancreas Transplantation Committee.