

American Society of Transplantation Responses to OPTN/UNOS Fall 2018 Public Comment Proposals

Proposal Title: [Addressing HLA Typing Errors](#) (*Histocompatibility Committee*)

AST RESPONSE:

The American Society of Transplantation is supportive of this proposal in concept and believes that it will reduce the number of HLA data entry errors in UNet and promote safety for both living and deceased donor transplantation, but offers the following comments:

- We support dual entry of the HLA data into UNet
- For HLA data uploaded directly into UNet, we believe that minimum criteria for data verification will strengthen this proposal if added to the policy.
- We recommend clear working to ensure that uploaded donor HLA typing data is labeled with the UNOS ID and stripped of other identifiers to comply with HIPAA regulations.
- Would suggest that HLA typing verification be performed by HLA laboratories independent of how the HLA data was entered into UNet- manually or automatic upload. This is routinely done at some laboratories as part of their QA process. We would suggest the UNOS considers incorporating this step of HLA typing verification by the HLA laboratories into the process and having a method of documentation of such review (within a short period, 30-60 days).
- We agree with attaching Raw HLA typing to the system for verification of the lab results
- There is a comment somewhere in the process of entering HLA data that states “at least one HLA antigen must be entered for each locus.” We believe this statement should be changed. If there is only one HLA antigen identified at a particular locus, the person entering the data should be required to enter something into the second field to acknowledge that only one HLA antigen was identified at that locus. For example, if patient is homozygous for A2, the person performing the data entry can enter A2, A2 or A2, ‘no second antigen’. The system should not allow the person performing data entry to enter A2 in the first box and nothing in the second box and move onto the next locus. The basis for this comment is the fact that we have seen discrepancies between UNet HLA data entry and our laboratory data based on the requirement that “only one antigen entry is mandatory.”
- We believe that an online education tutorial for “HLA data entry for Transplant Programs” will be valuable to the community. The AST would be happy to work with the OPTN/UNOS on this project if it is implemented.

Proposal Title: [Changes to Islet Bylaws](#) (*Pancreas Transplantation Committee*)

AST RESPONSE:

The American Society of Transplantation supports the proposal as written. We find these requirements to be sufficient. The change from two physician leaders to a single clinical leader should simplify the administrative procedures and help program leadership

concentrate on patient care and clarify roles amongst providers.

We also encourage establishing multidisciplinary collaboration for the management of islet cell transplantation. We suggest that the required expert medical personnel roles are expanded to include pharmacist as immunosuppression access and management expert in the delivery of islet transplant therapy - in collaboration with islet cell coordinator and physicians that specialize in abdominal surgery, portal vein access and endocrinology.

Proposal Title: [Pancreas Program Functional Inactivity](#) (*Pancreas Transplantation Committee*)

AST RESPONSE:

The American Society of Transplantation is generally supportive of his proposal, but offers the following comments:

- The CMS definition of program inactivity remains 0 transplants in 6 months (482.74 Tag X015 CMS CoP's) This will create 2 separate regulatory pathways to manage for notifications of functional inactivity.
- In concept, the MPSC reviewing fewer programs is favorable. However, the data presented in the proposal, spoke to the connection between low volume centers and poor outcomes, despite the use of higher quality organs. Adding the waitlist metric to the algorithm for program review does not seem well supported by the patient outcome data. The additional metric may decrease the number of programs flagged for review, but may not actually improve outcomes at these low outcome centers. There may be data reviewed by the Pancreas Committee linking wait times to outcomes that is not explained in the proposal. The primary aim of the proposal as stated was patient safety, but loosening the review criteria may not entirely support that aim.
- The proposal as written will require low volume, long-wait time centers to use a newly developed data report from UNOS to provide patients with center and national average wait times. While the AST is generally supportive of new secure UNOS data reports, there is already a median time to transplant metric available in the publicly available SRTR Program Specific Reports (Table B9).

Proposal Title: [Tracking Pediatric Transplant Outcomes Following Transition to Adult Care](#) (*Pediatric Transplantation Committee*)

AST RESPONSE:

The American Society of Transplantation supports this proposal. Successful transition and transfer of clinical care for the young adult transplant patient from pediatric to adult caregivers is a critical driver of long-term outcomes. The Society strongly supports the goals of this document, and feel that there is an opportunity to be innovative and strategic in identifying specific best practices and potential quality metrics that could inform future policy and standards for enduring and successful transition/transfer of care.

It is clear that the amount of psychosocial support that transplant recipients receive, dramatically impacts early recovery post-transplant, higher quality of life metrics, better medication and follow-up care adherence, and increased overall graft and patient survival. In pediatric transplant programs, the dedicated per patient resources of individual patient/family attention, education, and redundancy of patient safety systems is higher per patient than is typically seen in adult systems. This difference in the models of care delivery pose challenges which warrant a concerted strategic plan with programmatic accountability to gold standards of transition care that presently do not exist.

The AST suggests that transfer of young adult patients from pediatric to adult providers is challenging and may be best accomplished within the framework of a *formalized transition program*. Components of a transition program to be considered for inclusion and which would meet the guidance document goals include:

1. Patient and family participation in all aspects of care.
2. Use of transplant care education materials. The AST's Pediatric Transition Portal is listed in your resources. Consider adding that this site includes tools and templates that were recommended in this guidance document.
3. Use of a formal readiness assessment tool that evaluates a patient's general preparedness for independent care, identifies knowledge and practice gaps, and potential threats to graft health and patient wellness, and a mechanism for addressing deficiencies.
4. Institutional process for determining the appropriate time for each maturing pediatric transplant patient to take on greater responsibility for his/her care while still having care overseen by adult caregivers and then to eventually have their care transferred to an adult provider. Factors that must be considered here are intellectual ability, prior demonstration of willingness to engage in care, and availability of adult support to oversee behavior. A standardized institutional process does not negate the need to evaluate each patient on a case-by-case basis.
5. A process for evaluating an adult transplant program's patient –specific personnel expertise, capacity, and resources for supporting a transitioning patient, with commensurate reimbursement incentives for programmatic high performance.
6. Evidence-based tools and metrics for evaluating the short, medium, and long term effectiveness of transition to independent care beyond graft and patient survival.

The Society also offers the following comments to address “Lost to Follow-Up” concerns sited in the guidance document:

- We support efforts to reduce the incidence of “lost to follow-up” designations for all patients but particularly young adult transplant recipients transferred to adult providers. The AST recognizes that there may still be untapped opportunities for OPTN/UNOS to capture longitudinal data of pediatric transplant recipients, and have the following suggestions/comments:
 - For recipients who are transitioned to adult transplant programs, a formal transfer of the responsibility for the TRF forms to the adult program should be made in the OPTN/UNOS records, with acknowledgement of the accepting adult program. Thereafter, accepting adult programs should be required by OPTN/UNOS to file annual TRF updates on these patients.

There should be disincentives for using the “lost to follow-up” option unless there is no other choice

- For recipients who are transitioned to providers who are not affiliated with transplant programs, it must be made clear to the pediatric transplanting program that the responsibility to submit the annual TRF continues to reside with the original pediatric transplant program. To improve compliance, consideration should be given to minimization of metrics to be collected, i.e., graft function and patient status (alive or dead).
- In light of the generalized problem of too high “lost to follow up rates” within the SRTR data base and how that impacts data analyses which inform policy development, we suggest that OPTN/UNOS go beyond this guidance document which is restricted to transition of pediatric patients to adult providers and explore policy changes that would deter programs from so frequently using “lost to follow up” designation. Suggestions for policy considerations:
 - A multidisciplinary evaluation of the transferred recipient should be made by the accepting adult program (i.e., meeting with various members of the adult transplant team) to orient the recipient to the team identity and care process in the adult transplant program
 - Transitions should ideally be made through a verbal discussion between the transferring provider and the accepting provider. In addition, a structured summary of records should be made that addresses important aspects in the post-transplant course of the recipients:
 - allograft status and complications
 - surgical/technical complications
 - immunosuppression history
 - history of infections
 - medical complications
 - psychosocial development
 - immunization history
 - Transfers of TRF reporting should be formally filed with UNOS from the pediatric transplant program, with acknowledgement from the accepting adult transplant program, to avoid the gap where patients are labeled “lost to follow-up”.

There was concern regarding the recommendation that adult providers provide staff education regarding childhood and adolescent psychological development. This expertise seemed to be outside the normal realm of expertise of adult healthcare providers. In addition, there were concerns that this proposal may place increased liability on adult providers if a transferred pediatric patient did poorly due to inadequate staff education regarding psychosocial development. While there were additional resources that were provided to address some of these educational needs, further resources are needed to provide adequate staff education in this particular area.

The Society also encourages the inclusion of pharmacists as members of the multidisciplinary team that is involved in transition of care in this patient population. Clinical pharmacists play an important role in transitions of care in transplant and pediatric populations. This guidance document includes a statement [page 13, lines 113-114] that large programs utilize a multidisciplinary approach during transitions, but only specifies social workers and transition coordinators. We recommend inclusion of pharmacist in this group. Clinical pharmacist practicing alongside transplant providers in pediatric setting provide regular documentation on medication use, history of immunosuppression exposure,

patient's medication knowledge and attitudes towards taking medications, identify adherence issues, adverse events and keep track of vaccination schedule. The pharmacist helps prepare the patient for transition to adult centers. This includes reviewing medication schedules and indications, current insurance coverage and how that might change when switching to an adult center (including if primary pharmacy for obtaining medication will change), and identifying possible issues with compliance in the future. The pharmacist is responsible for preparing a portion of the transition report. Specific responsibilities include biopsy and immunosuppression history, vaccine history, current and past medication history use, identified issues with compliance, and current pharmacy information. Lastly, the multi-disciplinary teams from both hospitals (including the pharmacist) meet to verbally discuss the transition. Examples of services provided by pharmacists at the time of transitions from pediatric to adult transplant clinics are noted below as feedback to specific questions posed by the Pediatric Committee.

The OPTN Pediatric Committee specifically requested feedback on several questions, below:

1. *In what ways are recipients (transplanted before 18 years old) well prepared or ill prepared for transfer to adult medical care?*
 - a. Some patients were not ready to assume responsibility of their care; some were not prepared for the expectations that the adult transplant team had. We agree that numerical age is not a good gauge to determine time of transition, but rather developmental milestones. Transition takes time and should be started earlier than the transfer time, and a formal, objective measurement of the recipient's readiness for transition should be made.
 - b. A pediatric transplant pharmacist practicing in tandem with the pediatric transplant providers (nephrologist, cardiology, hepatologist, etc): During every visit, the pharmacist interviews and documents in patient's chart. Information that is documented includes medication reconciliation, history of immunosuppression exposure to date, medication knowledge (focus on immunosuppression) and attitudes towards taking medications, identified adherence issues, adverse events, and vaccination schedule. During transitions to adult care, verbal and written communication between pediatric and adult transplant team members (provider and pharmacist) occurs where details about adherence issues as well as access to medication issues is discussed (which medications require prior authorization, refills, etc.). During the first appointment in the adult clinic, patient is informed that verbal/written transition occurred to instill sense of continuity.
2. *Is there specific information about the recipient, or specific transfer practices that have led to an optimal hand-off from a pediatric program to your program?*
 - a. Transfer summary documents
 - <https://www.gottransition.org/> is a website dedicated to improving the pediatric to adult healthcare transition
 - Step-by-step guidelines available
 - Other transition resources at <https://www.myast.org/communities-practice/pediatric/web-resources-transition-adult-care#Hospital>

- b. Transition readiness assessment
 - <https://www.myast.org/education/specialty-resources/peds-transition>
- c. Short clinical summary (see below for suggested content)

3. *What practices help you share the recipient's health information back to the pediatric transplant program for OPTN data submission?*

Clinic notes and lab results are sent back to the pediatric transplant program 1-2x a year at each clinic visit made by the recipient, unless the adult program has taken over the TRF submissions.

4. *Recipient transfer scenarios may not fit neatly into the three types profiled in the guidance document. Do you currently use, or have you considered, any non-conventional models of transfer to adult medical care, e.g.: transfer routine medical care to a provider not affiliated with a transplant hospital (perhaps nearby to the recipient's place of residence) and arrange for periodic outpatient evaluations with a transplant program outside your institution?*

Some centers have utilized the combined clinic approach where the pediatric transplant provider accompanies the recipient to the first adult transplant clinic appointment, or the adult transplant provider attends the last pediatric transplant clinic appointment. This is only feasible if both programs are within one institution, but even then, the ability to schedule such appointments can be very difficult in today's work pace.

Proposal Title: [Frameworks for Organ Distribution](#) (Ad Hoc Geography Committee)

AST RESPONSE:

The American Society of Transplantation is supportive of the OPTN/UNOS and the Ad Hoc Geography Committee's goal to bring UNOS allocation policies in line with The Final Rule by eliminating systems of prioritization and distribution that are "based on the candidate's place of residence or place of listing, except to the extent required" while including in the allocation policies "sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, and to promote efficiency". We appreciate the opportunity to provide feedback at this stage.

Unfortunately, the American Society of Transplantation cannot, with the information provided, support any one framework over another. The lack of sufficient data and even preliminary modeling prevents informed opinion regarding impact and projection of downstream effects particularly for vulnerable populations. That said, the Society's diverse membership has carefully reviewed the proposal and does wish to take this opportunity to provide feedback regarding the frameworks suggested for consideration.

1. Fixed Distance from the Donor Hospital - This framework creates fixed geographic areas or concentric circles based on the distance between the donor hospital and the transplant candidate's listing center. While local matches may receive priority, this approach may also allow wider distribution for other characteristics such as

medical urgency. This proposal will lead to more organs being distributed along a wider geographic area compared to the current system.

- Pros –
 - Potentially shorter travel time for organ and procurement teams compared to other frameworks provided that the radius of the circle remains short
 - Potentially lower cold ischemic times, which would allow the optimal and successful transplant of higher risk, more marginal organs.
 - May allow for adjustments to widen distribution for medical urgency;
 - May incentivize OPO to increase performance and productivity;
 - May encourage local donation
 - Lower transportation cost for OPOs and Centers compared to proposals that favor a larger distribution area.
- Cons –
 - Presence of a defined line or “cliff” which would make two candidates who live on either side of the line be prioritized differently, even if they have the same medical urgency.
 - Some areas in the country may have very few or no donor hospitals nearby
 - Broader distribution circles may negatively impact efficiency of the system when organs/procurement teams will need to fly instead of drive.
 - Broader distribution circles may lead to increased organ discard rates when more marginal organs are accepted and then rejected over longer distances.
 - Broader distribution will also lead to significantly increased cost to the system.
 - Concentric circles may be less suitable for coastal areas or areas on the border with other countries

2. Mathematically Optimized Boundaries - Mathematical optimization can be used to establish distribution boundaries. The boundaries are based on a statistical formula derived from metrics and constraints and designed to achieve the best results for one or more specific goals, such as having a consistent ratio of donors to potential recipients within each distribution area. Size of distribution area can be scaled up and down.

- Pros –
 - Uses objective criteria that will provide the results.
 - Can use population density bubbles depicting differences between fixed radius circle and a fixed population circle around a transplant center.
- Cons –
 - Presence of a defined line or “cliff” which would make two candidates who live on either side of the line be prioritized differently, even if they have the same medical urgency
 - Complex to understand; statistical formula used to determine boundaries is historical and may not be sensitive to changes in organ utilization that should also impact allocation;
 - Data variables used in statistical formulas may not be known to the public; modeling data have not been shared with the public

3. Continuous distribution - Organs can be distributed to candidates using a statistical

formula that combines important clinical factors, such as medical urgency and likelihood of graft survival, along with proximity to the donor location. Using this approach, all candidates would receive a relative distribution score, but there would be no absolute geographic boundary. Candidates who best meet the combination of factors receive the highest priority.

- Pros –
 - Considers medical urgency and proximity as the most relevant factors for the best use of organs
 - May offer the most optimal framework to improve efficiency by providing a singular distribution framework while maintaining flexibility to optimize outcomes, improve efficiency and improve patient access.
- Cons –
 - Entails more travel and cost; may deter local donations; may create more disparity for smaller programs who have less capacity to travel

For liver allocation, it is not clear how MELD exceptions will be handled amongst the physiologic MELD scores in the continuous distribution framework.

For kidney allocation under any model chosen, we suggest that zero mismatch be maintained as high priority. Significant changes will need to be adopted for kidney allocation which presently represents approximately 80% of all organs allocated annually (<https://optn.transplant.hrsa.gov>).

For heart allocation, the development of a heart allocation score (HAS) will be a critical next step particularly given that the use of mechanical circulatory devices (MCS) have changed the landscape of patients with end-stage heart disease. Currently, the patient with the highest medical urgency can be stabilized with a mechanical circulatory support device and hence become a better transplant candidate. In lieu of a heart allocation score, concentric circles (#1) may be the best alternative for now until a HAS that considers the impact of MCS can be established. Once a validated HAS is developed, the continuous distribution model (#3) would likely serve as the most efficient allocation system that includes allocation of hearts. The budgetary impact of resources for heart transplantation will be substantial to establish a heart allocation score that truly represents medical urgency.

For lung allocation, the continuous distribution framework appears to be the most desirable and may work effectively as it de-emphasizes geographic allocation while considering medical urgency and proximity as relevant factors for the best use of donor organs. The current lung allocation score (LAS) represents medical urgency and has been vetted to determine true severity of illness. The proximity score would also serve to minimize long ischemic time by factoring in proximity of the donor to the recipient. The exact weighting of a medical urgency score and a proximity score would need to be assessed with simulations performed to ensure best use of donor lungs that results in acceptable post-transplant outcomes.

With regard to vulnerable populations, children and others, regardless of which framework is chosen, modeling within each organ for the effect on equity and access to organs for children and other vulnerable populations will need to be carefully analyzed for unintended consequences. The Society supports maintaining pediatric priority within the allocation policy and would like to emphasize the need to proactively assess the impact of new allocation policies on children.

The development and implementation of a new distribution framework will necessitate tremendous resources both nationally, within the OPTN/UNOS, as well as institutionally. We believe it is essential to emphasize the cost impact to programs with any changes made. If programs are going to have increase air travel (seems illogical with equally ill patients) this may result in greater cost (2 OPO fees, plane, fuel, surgeon's absence from program more) and greater risk (potential for ischemic times longer, jeopardized post-transplant outcomes). Such challenges could force programs to close or restrict who they transplant which will decrease access to transplant for patients and essentially subvert the Final Rule.

When broader distribution is considered for all organs, any policy needs to take into account the impact on utilization of marginal, life-saving donor organs. Broader sharing of higher risk organs with longer cold ischemic times may lead to higher organ discard rate. For example, with the broader sharing of kidneys with KDPI > 85% from local to regional sharing in the newly implemented kidney allocation system, organ discard rates increased. Marginal organs are less likely to be accepted and transplanted when cold ischemic times are prolonged due to longer travel distances. These factors need to be considered when deciding which deceased donor organs should be offered over a broader distribution area.

An important caveat to the development of any new organ distribution policy is the need for assurance that the new allocation algorithm will not hinder access to transplantation services for patients from less populous areas, especially where candidates lack the financial means to relocate. For instance, it is possible that some smaller centers may not be able to afford the initial investments in the most advanced technologies; however, these possibilities depend heavily on how allocation capabilities and costs change as technology changes, as well as on how the lines are drawn upon the elimination of the DSAs as a factor in allocation.

Advances in preservation technologies will likely play an important role in maximizing the potential of any chosen distribution framework.

Finally, justification for a common model across all organ allocation policies has not been made sufficiently clear. It could be argued that common allocation policies might be unnecessary, and indeed counterproductive. The Society supports the current UNOS organ specific committee work which is modeling the effects of the proposed frameworks on individual organ allocation and encourage the OPTN to remain open to potentially disparate allocation frameworks if it is felt by the organ specific committees that a single framework across all organs is not optimal.

Proposal Title: [Change to Hospital-Based OPO Voting Privileges](#) (*Membership and Professional Standards Committee*)

AST RESPONSE:

The American Society of Transplantation supports this proposal if the OPO and the transplant program are functionally separate as described.