



American Society of Transplant Surgeons

Saving and improving lives with transplantation.

ASTS Responses to UNOS Proposals Open for Public Comment

March 24, 2020

1. HLA Equivalency Tables Update 2020

The American Society of Transplant Surgeons (ASTS) supports the OPTN policy proposal to expedite updates to HLA Equivalency Tables and to adopt the new DPB epitope strategy to optimize matching. This strategy will make assigning DPB alleles more efficient and more accurate. We believe these changes will promote patient safety and improve the overall system.

2. Modify Blood Type Determination and Reporting Policies

The American Society of Transplant Surgeons (ASTS) strongly supports this proposal to enhance the safety of recipients. Accurate ABO typing is important and patients with discordant results need to be addressed. We would suggest that the OPTN Operations and Safety Committee provide best practice guidance documents (e.g. repeat testing, genetic testing, etc.) to guide OPOs and transplant programs in developing policies necessary to meet this requirement.

3. Guidance on Blood Type Determination

The American Society of Transplant Surgeons (ASTS) strongly supports this proposal and recognizes the hard work and contribution of this guidance document. It provides important information for all clinicians caring for transplant patients. Accurate ABO typing is crucial for the safety of our patients. Transplant centers and OPOs should review and incorporate new and more reliable assays as they become commercially available. In addition, this information needs to be reviewed when considering deceased donation from a prior stem cell recipient. While currently rare, it is possible that this situation could more commonly arise in the future.

4. Update to VCA Transplant Outcomes Data Collection

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to comment and strongly supports this proposal as written. We agree OPTN data submission requirements for Vascular Composite Allograft (VCA) transplants need to be improved to better assess patient outcomes, address limitations and inconsistencies in VCA data collection, and achieve consistency in data reporting. ASTS concurs with the addition of new data elements to the Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) forms. However, the ASTS feels strongly that uterine transplant is an abdominal organ that should be considered under its own egis and not as a vascular allograft. Recipients of uterine transplants require unique considerations to address their specific needs including coordination with other medical specialties such as infertility medicine. When uterine transplants are performed, we recommend offspring are observed at the following intervals: birth to record APGAR score, 1 month to record early survivability and growth, 1 year, and 6 years to record physical and intellectual development.

5. Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients

The American Society of Transplant Surgeons (ASTS) generally supports this policy, however we feel strongly that uterine transplant is an abdominal organ that should be considered separately under its own egis and not as a vascular allograft. Recipients of uterine transplants require unique considerations to address their specific needs including coordination with other medical specialties such as infertility medicine. When uterine transplants are performed, we recommend offspring are observed at the following intervals: birth to record APCAR score, 1 month to record early survivability and growth, 1 year, and 6 years to record physical and intellectual development. We also suggest the OPTN VCA Transplantation Committee seek legal and ethical guidance on concerns related to: HIPPA, collecting data on offspring as a non-transplant patient, and potential regulatory challenges. Guidance might be sought from legal entities and from the gynecological, obstetrics, and pediatric communities.

6. National Heart Review Board for Pediatrics

The American Society of Transplant Surgeons (ASTS) approves and supports the formation of the National Heart Review Board for Pediatrics. ASTS understands that these national boards are being introduced as part of the broader sharing agreements. However, we encourage the OPTN/UNOS and its various committees to engage in a conversation regarding the unintended consequences of these broad national committees as they can become themselves impediments to new innovations and the exploration of new indications in transplantation. ASTS would be pleased to collaborate on such an effort with UNOS.

7. Data Collection to Assess Socioeconomic Status and Access to Transplant

The American Society of Transplant Surgeons (ASTS) supports this proposal. There are national disparities in access to transplantation and post-transplantation care for low socio-economic status (SES) groups (2-8). Overcoming barriers to transplantation requires identification and resource allocation. We agree that socioeconomic status (SES) of the individual heavily influences access to transplantation and may be a modifiable predictor of transplantation outcomes. Identifying high-risk patient populations, i.e. low SES, for listing and graft failure could help transplant teams better understand and allocate resources to candidates at risk. However, in order to accomplish improved access and allocation, a greater understanding of the breath of disparity is required with objective, granular, individual, and reliable information. Policies to require timely referral for transplantation have been considered by the Centers of Medicare and Medicaid Services (CMS), but are difficult to implement without national data on referrals (9-13).

Presently, the only SES variables that UNOS and OPTN collect are: primary source of payment, highest level of education, and whether the candidate is working for income. We support data collection by larger regulatory bodies such as UNOS/OPTN and/or CMS in the form of household size and household income to avoid the inaccuracy of data collection based on ZIP code. Such a proposal is presently going through public comment through UNOS/OPTN (14). With household income and size data, it would be possible to calculate the official poverty index, a variable that is well validated and used by the U.S. government to decide on the eligibility of assistance programs (15). This data collection is confidential and will not be shared. This will not lead to a significant data collection burden since this data is already collected by most transplant centers during the psych-social and financial evaluation and during the transplant evaluation phase. The income would be sent to UNOS as ranges and not absolute numbers. Reporting this information to UNOS will not affect patients' allocation in any way.

Access to transplantation is essential to upholding the OPTN Final Rule of Transplantation (16). Without understanding and attempting to modify barriers to transplantation with regulatory and governmental support, the disparity gap will persist and patients with low SES will be disadvantaged. In addition, obtaining validated and individual SES data will support initiatives to provide targeted interventions (e.g., psycho-social support, medication compliance, public policies for immunosuppression coverage) to our underserved transplant population.

Regarding use of Zip code as SES:

Zip code data is not granular and is likely misclassifying individuals. Furthermore, our zip code data collection on patients has known issues. We do not assess the quality of those zip codes as they are reported due to the following inaccuracies:

state of zip code differs from state reported for patient, missing/truncated zip code digits, digits that are obviously transposed, zip codes reported that do not exist or which are not considered residential zip codes for which the Census won't have poverty or income measures.

References:

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The organ procurement and transplantation network final rule of 2000, 42 U.S.C. §§ 121. <https://www.ecfr.gov/cgi-bin/text->

8. Addressing Medically Urgent Candidates in New Kidney Allocation Policy

The American Society of Transplant Surgeons (ASTS) supports this policy proposal. It defines the criteria for medical urgency in kidney transplantation in a more comprehensive and coherent fashion to address the needs of these unique patients. ASTS believes the priority for the new classification for medical urgency should be confined to the 250 Nautical Mile (NM) circle. We also contend that priority should be given only to medically urgent candidates inside the circle to: 1) avoid delayed graft function in patients with poor dialysis access and 2) minimize cold ischemic time. As this is relatively unusual, the majority of these patients would be transplanted promptly using only the 250NM circle. ASTS supports a policy where living donors receive priority over others when determining medical urgency within each KDPI category. Documentation to ensure patients are properly assessed for this classification should include: 1) recent notes from interventional radiology or surgery with imaging confirming thrombosis or severe, untreatable stenosis of the vascular structures and 2) evidence the patient has received a translumbar or transhepatic catheter.

9. Distribution of Kidneys and Pancreata from Alaska

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

Modifications are needed to the new allocation policy for donated kidneys and pancreata from Alaska: to address the absence of a transplant hospital within 250 nautical miles (NM), to promote efficient organ placement, and to prevent organ loss. ASTS agrees with the proposal to designate the Seattle-Tacoma Airport (SeaTac) as the “administrative” center for Alaska’s allocation circle with two proximity points inside and four points outside the circle. We recommend however that the OPTN extend the circle to 500NM to increase the chance for placement.

10. Modifications to Released Kidney & Pancreas Allocation

The American Society of Transplant Surgeons (ASTS) opposes the proposal as written. We recommend the OPTN take an iterative approach to all new organ allocation policies by taking small steps with regular reassessments (e.g., one year)

to identify successes and unintended consequences, particularly concerning logistical issues.

ASTS appreciates the opportunity to comment on the proposed policy for reallocation of kidney and pancreata when the accepting recipient is unable to utilize the organ. In our opinion, the most important outcome of any reallocation proposal is minimization of unnecessary organ discard. Given the urgent need for transplantation and the ongoing and excessive kidney discard rate, all efforts need to be made to reduce discards and ensure successful use of donated organs. Our response considers kidney and pancreas reallocation separately as the period of organ viability differs.

With regard to the kidney proposal, in concept we agree with many aspects of the current proposal. The ASTS supports a clinically sensible system that differs based on the location of the kidney in regard to the original donor hospital.

1. If the kidney is still at the OPO, donor hospital, or if the accepting center is within 250 miles of the donor hospital, the initial OPO should retain responsibility for allocation. If the primary center declines, the kidney should be reallocated using the original match run by initial OPO. This allows all centers with patients on the initial match run to have an opportunity for transplant. This also reduces the likelihood that centers who have already declined the kidney will be reoffered the organ. Finally, as the originating OPO is familiar with local allocation issues (transportation, coordination), this offers the best opportunity to use the organ. If no center accepts the organ, the allocation should be referred to the UNOS call center with a new match run as outlined in the process below.
2. If the organ has already been transported to a hospital > 250 miles from the donor hospital, the kidney should be reallocated using an algorithm that allows the organ to be driven to a new center (avoiding more airline delays) using pulsatile perfusion if requested. To accomplish this, the ASTS favors reallocation using a 150 mile circle around the transplant center which declined the organ. This small circle was initially proposed and appears to be a reasonable compromise between equity and utility. The responsibility for allocation should be offered first to the originating OPO which can decline. Next, the accepting center's OPO should administer the reallocation based on the 150 mile circle. If no center within 150 miles accepts, UNOS should step in and attempt to allocate based on the expedited placement algorithm. The ASTS believes that the proposed circle of 250 miles is too large, will result in unacceptable delays due to air transport, and will lead to greater organ discard.

Pancreas allografts (either isolated or as part of simultaneous kidney-pancreas transplant) should have a separate system.

1. If the pancreas is within 250 miles of the donor hospital (either at the OPO or local transplant program) it should be offered to other centers based on the initial match run. If no center accepts, then it should be given to UNOS for reallocation using the expedited placement system. This system would offer the pancreas to the original accepting center for any recipient prior to reallocation, though other centers with recipients higher on the list would also have an opportunity.
2. If the pancreas has already travelled more than 250 miles, the accepting center should be given the opportunity to use it for any patient they deem appropriate. Pancreata not accepted by that center should be offered by UNOS call center based on the expedited placement algorithm.
3. If the accepting center declines the pancreas, the accompanying kidney should be reallocated as part of an SPK transplant in centers as above. If no center accepts the pancreas and the kidney is within 250 miles of the original donor center, the kidney should be then reallocated based on the kidney allocation process using the original list. If the declining center is outside of 250 miles, the kidney will be allocated based on the 150 mile circle.

The ASTS would strongly encourage UNOS to develop and implement a tracking system for all organs, specifically those that are reallocated to reduce unnecessary CIT.

11. Enhancements to the National Liver Review Board

The American Society of Transplant Surgeons (ASTS) generally supports this proposal, with some specific comments as noted. The purpose of the NLRB has been to empower a group of experts to uniformly and consistently review requests for MELD and PELD exception scores. While this is true in the majority of the cases, the NLRB might be faced with unique exception requests. NLRB members should have the latitude to use their medical judgment and holistically consider each patient's case while operating within OPTN policy. To that end, ASTS also believes reviewers should refrain from suggesting alternative medical care on a given case and focus on the merits of the requests and supporting evidence.

ASTS strongly supports removing reviewers if they do not participate in examining 5% of the caseload during a six-month interval. We believe an inactive reviewer who is permitted to remain on the board for 12 months could be detrimental to patient care.

ASTS agrees with the policy for automatic approval of extensions for HCC exceptions, provided they meet standard criteria. We suggest a review of random

samples every quarter to make sure that programs are meeting extension request criteria. Randomly reviewing HCC documentation (imaging and alpha fetal protein levels) may be helpful to periodically evaluate and validate the process.

ASTS recommends the following with regard to the Guidance Documents: 1) Adult patients with secondary sclerosing cholangitis should be afforded similar consideration as patients with primary sclerosing cholangitis. 2) Adults with metabolic symptoms belong to a patient subgroup whose clinical presentation can vary depending on the specific metabolic defect. For example, some patients may present with very minimal symptoms and others with severe symptoms affecting quality of life. Awarded exception points should depend on each individual case. In fact, there are varying opinions regarding the use of liver transplantation in certain subgroups versus medical management. It would be deleterious to other patient subgroups if all adult patients with metabolic symptoms were awarded similar priority (MMaT-3. 3). For adult patients with hepatocellular carcinoma (HCC), we agree with proposed language to reduce ambiguity.

As for recommended improvements of NLRB, ASTS recommends the OPTN Liver and Intestinal Organ Transplantation Committee use data on pediatric exceptions as a means to improve the PELD scoring system.
