



March 25, 2016

## **ASTS Responses to OPTN Policy Proposals**

### **1. Improving Post-transplant Communications of New Donor Information**

ASTS is very supportive of the effort to minimize data reporting that conveys no specific value regarding recipient risk to the donation/transplantation process. We agree that the numerous culture reports that enter through the center's patient safety contact contribute to data fatigue.

1. On the whole, we support the limitation of culture reporting as stated in Table 15-1.
2. Re: section 15.4 OPO responsibility, this generally sufficient yet misses the point that information may need to be "sought" if it is to become available. The specific language; "OPO must report all positive test results and other relevant information received post-procurement." If an OPO does not receive a result, do they have no responsibility to seek it out? If there is relevant information about donor risk (especially autopsy or pathology results, the final report may be days delayed past organ retrieval), the OPO should have some responsibility to pursue the results, not be a passive receiver and communicate the findings to the recipient center. We would like to be assured that OPTN "quality control" of biopsies taken during organ retrieval and read preliminarily, have the final results are communicated in a timely fashion. The policy language puts responsibility on timely communication upon the non-OPTN member donor hospital to provide the result to the OPO prior to system accountability to ensure that the information is transmitted to the recipient hospital. This is inadequate from our perspective.
3. Re: section 15.5. The issue of OPTN responsibility to risk assessment of toxoplasmosis transmission has been an unfortunate demonstration of misplaced effort. Being essentially a heart only issue, OPTN and OPOs have been reluctant to generate policy about routine toxoplasmosis testing. However, there have been a handful of instances where DTAC has found toxo discordant donor/recipient heart recipients who have become very sick/died with donor transmitted toxo. From a patient safety issue, the disease could likely have been prevented by timely prophylactic treatment in these transplants. Policy 15.5.A.1 should be rephrased to directly address donor toxoplasmosis testing specifically for the heart recipient. If the OPO is not going to be required to perform routine toxo testing and the patient safety system feels it is necessary for heart recipient quality assessment that all results are reported, then why isn't it the responsibility of the OPO to follow up with all heart programs that were allocated hearts to verify that the toxo test was performed in a timely fashion? This would appear to fall into a similar type of information "available after donation" as in section 15.4.

If donor information is important for patient safety and data completeness, the OPTN member responsible for those elements should be held accountable. In this setting it is the OPO, and the

retrieving OPO should pursue the risk assessment information whether it resides in the donor hospital or the center transplanting the heart.

## **2. Proposal to add an HLA DQA1 unacceptable antigen equivalences table**

This proposal will indeed improve the correct allocation of organs to candidates who have unacceptable DQA1 antigens. It should, at the very least, simplify the effort required for centers to list unacceptable DQA1 antigens. Therefore the American Society of Transplant Surgeons supports this proposal to simplify center activity for listing unacceptable DQA1 antigens and potentially improve the efficiency of organ allocation to sensitized candidates, allowing greater access to transplantation for these candidates.

## **3. Changes to HOPE Act Open Variance**

The American Society of Transplant Surgeons supports this proposal in general; however, the proposal assumes each center's IRB will require a Data Safety and Monitoring Board (DSMB), which is actually not necessarily the case (DSMB's are only required for randomized trials, which this is not one). Specifying a DSMB requirement is practicing medicine and interfering with IRB judgment, and will make the eventual data confusingly heterogeneous. ASTS recommends that OPTN/UNOS remove all references to a DSMB and think carefully about what data should be collected.

## **4. KAS Clarifications**

The American Society of Transplant Surgeons offers the following comments:

Removing policy on mandatory sharing: this policy requires OPOs to continue offering Kidneys with HIGH KDPI to highly sensitized recipients or to report to UNOS the reasons for bypassing them. It replaces a policy that committed the OPO to a certain number of offers after which they could go to local placement without reporting to UNOS.

ASTS supports this change and suggests that OPTN/UNOS monitor the rate of acceptance of the HIGH KDPI kidneys into 99-100 sensitized patients and the rates of kidney discard. Already the KAS system has increased the rate of discard of these kidneys, and this change may result in further increase and thus should be monitored carefully. Also, ASTS points out that allowing OPOs to take up to 8 hours from procurement to make DD kidney offers is unacceptable. This should be within a few hours (< 4 hours) of having HLA available (time stamp on the HLA report). This late allocation of kidneys, especially those less desirable kidneys with high KDPIs or anatomic anomalies/injuries, likely adds to the discard rate of procured organs. This is an easily improved event with a simple policy adjustment.

Clarifying informed consent requirements for multi-organ candidates for kidneys based on KDPI greater than 85%: ASTS notes that patients receiving multiorgan transplants are critically ill and usually accept

the kidney transplant as secondary to the heart, lung, or liver transplant. It would be inconceivable that a patient declines a heart offer because of the kidney KDPI. It is however important that patients be informed of the possibility of receiving high KDPI just like they are informed of potential infections or other high-risk designations. It would thus be appropriate to sign the consent for high KDPI at time of listing.

## **5. Proposal on Simultaneous Liver-Kidney Allocation 2016**

In general, the American Society of Transplant Surgeons supports this proposal. There should be uniform criteria for who is and is not a candidate for SLK. For the CKD category and metabolic categories, these criteria are more uniform and established. However, for the acute kidney injury, these criteria are highly variable.

There are no doubt SLK survivors who recover native renal function post transplant, thus obviating the need for SLK. This is a real problem as a transplantable kidney was placed into this subset which should have never been done. Many times, however, it is difficult to predict the recovery of the native renal function.

There is variability in allocation of kidneys by OPOs. Many times the regional OPO is unwilling to share kidneys with the life-saving liver or heart transplant. This leaves the recipient team with a difficult decision as to pass on the life-saving organ or to transplant without the kidney.

This proposal appears to address all of these issues. However, it is highly prescriptive in its medical eligibility criteria. ASTS is concerned that the guidelines may work for one patient population but endanger others. Specifically:

- Sustained acute kidney injury diagnosis time on dialysis at least once every 7 days: The acute kidney injury category would benefit from a unified approach, as some centers use dialysis dependence for 4 weeks, 6 weeks, and 8-12 weeks as criteria. However, the 6 week timeframe may pose a danger to some patients. Among the ASTS reviewers, the kidney-focused felt that 6 weeks was acceptable, while the liver-focused reviewers felt 4 weeks would be safer.
- Sustained acute kidney injury diagnosis with GFR < 25 ml per minute for 6 weeks: ASTS believes 4 weeks would be a better time frame.
- OPO will be required to offer the kidney to a medically eligible REGIONAL SLK Candidate with a MELD  $\geq$  35 (or status 1) on the match run before the K only list: ASTS believes the MELD should be lowered to 30.
- If at any point in time a renal biopsy is performed and demonstrates an irreversible process, the results should be accepted a priori as need for SLK.

ASTS applauds the prioritization safety net, which creates a mechanism to capture isolated liver recipients who do not recover renal function in the first year after transplantation and prioritize them on

the wait list. The SLK safety net group is not included in Sequence A, however, which is cause for concern.

ASTS feels an ongoing review of utilization and outcome is warranted. Though that is not addressed in this policy, there is reference to other policies forthcoming to address these areas. ASTS looks forward to the opportunity to review and comment on these.

## **6. List Covered Body Parts for VCA Proposal**

The rationale for this proposal is sound, as it is meant to resolve inconsistencies in OPTN/UNOS bylaws and policies. Though many of the listed body parts do not fit the commonly understood definition of VCA, the American Society of Transplant Surgeons supports their inclusion here with the understanding that if these body parts become widely transplanted, they would gain their own OPTN Committee and be removed from the VCA list. ASTS supports this proposal with no changes.

## **7. National Liver Review Board**

Overall, ASTS supports this proposal and believes it will lead to more similar treatment of patients with the same conditions across the Regions.

There is a typo on Page 14: Portopulmonary Hypertension: "2. Initial pulmonary vascular resistance (PVR) level." Will a value be placed at the end of the sentence, such as  $>240$  dynes.s.cm-5 or 3 Wood units as that is the accepted definition of PPH? In the current Liver policy online, it also does not have a value, just says "Initial pulmonary vascular resistance (PVR) level." ASTS would like to know what values will be included.

2. In regard to awarding exception candidates one or two MELD points below the median for the DSA, the intended result is understood, but there may be several unintended consequences when limiting this to a DSA. For example, if one DSA has an average MELD at transplant of 28, and the neighboring DSA 32, then once a liver from another DSA is being regionally allocated, two patients with the same 'exception' reason will have different allocation MELD scores. ASTS does not believe this will work in the current DSA system. Until primary allocation is over a broader area, using regional MELD at allocation will naturally advantage some patients over others based solely on where they live within a region. Also, use of an arbitrary system such as 1-2 points below the median MELD at allocation is not data based and ignores the more rational approach of attempting match mortality risk of an exception to that of non-exception patients. Mortality risk is at the center of the MELD schema and exceptions should adhere to the same as best possible. Thus better than an arbitrary point award would be to improve our predictive analyses of subgroups as best possible and continue to adjust thereafter as new data becomes available. If all patients are not provided opportunity based on a common metric, the system is corrupt and will not yield equity in access.

3. Remove the automatic 3-month MELD elevator: ASTS believes this deserves to be considered per specific diagnosis. The concept is worthy of consideration, but each diagnosis should have its data reviewed and discussed. For example, patients with portopulmonary HTN may warrant the MELD elevator effect due to their disease process, while patients with other etiologies for their MELD exception points may not.

## **8. Adult heart allocation changes**

There are 2 objectives for this proposal:

1. Divide the high urgency/status 1A group into more groups, reflective of contemporary wait-list mortality (the current system has grouped several cohorts of recipients with varying mortality risks into 1 group that is outdated).
2. Enhance geographic sharing to provide greater donor organ access to recipients with high urgency.

The American Society of Transplant Surgeons believes both these objectives are worthy of support. The current system is outdated and does not accurately reflect the wait list mortality of all patients in this group. The new proposal is a step in the right direction. However, the new system needs to be monitored closely to ensure that it does not inadvertently discriminate against another group of listed patients (specifically the dual organ recipients) and results in acceptable outcomes.

Concerns:

- 1) The use of simulation to predict post-transplant mortality has limitations. The projected survival benefit in pre-transplant mortality is about 19 patients. Considering that some of the models show increase in post-transplant mortality, the overall benefit of the system may be doubtful and may not justify the overall increase in cost. As such this modification of the system should be time limited and subject to review in a period of time (2 years) to determine modifications, etc. This requires UNOS to take on a responsibility in accurate monitoring of the system and in setting up peer review bodies to look into the impact of the system and means to improve it.
- 2) Because the advantage is given to the sickest of patients, it is reasonable to expect that more of these very ill patients would be listed, as they will have a quicker path to transplant. The increased listing and transplantation of very ill patients should be a stimulus for UNOS and the heart transplant committee to consider models in which "too sick to transplant patients" get reduced status to avoid organ shuttling for futile transplants. This would create a hybrid between share 35 and LAS score which would be ideal in preventing futile transplants.
- 3) It is important to consider the plight of the combined transplant patients. These patients will now have no prioritization based on their combined transplant status and thus will become more likely to

die. Amyloid patients with heart and liver failure, ESRD patients developing heart failure, and others will be allocated lower priority on the list and as a result will either have to use exceptions or die waiting. Many of these patients if they qualify for heart status 1 or 2 would probably be too sick for combined organ transplant.

4) ASTS is strongly in favor of monitoring and modification of system changes on a regular basis. With many of the allocation systems being changed, causing reassignment of organs (no increase in organs are being produced by the system), there has to be a means to adjust course faster than the multiple year processes now in place.

### **9. Standardize an Organ Coding System for Tracking of Organs: Requirements for OPO TransNet Use**

The American Society of Transplant Surgeons supports the use of electronic labeling and tracking of organs as a long overdue improvement to the recovery and transportation system. There are, however, several points that must be made.

1) TransNet should standardize a label for “Pancreas Vessels” or “Liver Vessels” rather than use a Misc label for this purpose

2) What is the “Documentation” label for? (The donor ID and ABO information is already available on all the other labels.)

3) Time frame for implementation is June 2017, which seems reasonable since 60% of the OPOs have already undergone voluntary training.

4) The logistics of how/what and when do not have to be as detailed as in the proposal. The degree of procedural detail will likely result in multiple inconsistencies and policy missteps as the technology evolves. ASTS suggests that policy should delineate the necessary elements of the electronic tracking methodology and chain of custody. But a Standard Operating Procedure manual should be developed to detail the processes required for compliance, not only for generation of code, but also for the detailed specifics of all organ transport. This is especially true now that an industry is growing up with the goal of “organ resuscitation.” This SOP can be modified as technology evolves, without having to return to the Board for policy changes. Such a process would allow a degree of “nimbleness” not currently available within OPTN policy. While we are enthusiastic about the concept of the proposed technological advance, the policy language is much more of an SOP than tracking system policy.

5) The policy specifically lacks language stating that the receiving center can read the bar code and match the organ with the recipient. It was our impression that the intent of bar coding process was to introduce safety and efficiency into the process of getting an organ retrieved for transplantation to a specific recipient and not just onto the plane. While ASTS recognizes the need for stepwise introduction,

the system benefit is in documenting a clear chain of custody/tracking of a specific organ with the necessary vessels, nodes and blood samples from a specific donor to a specific recipient. To the end that the policy does not meet this goal, there is weakness in this policy. ASTS requests a timeline for the development and implementation of the “complete” electronic tracking system that will facilitate tracking from donor to recipient (and not just a simple inventory system).

6) The ultimate system “benefit” is in clear electronic verification of linkage of a specific organ with a specific patient. The elimination of required labor intensive and duplicative process elements of patient safety (double verification of ABO, time verification, patient/match run and organ donor ID) should be mentioned with specific timeline goals. If this is not accomplished, the safety elements are not met. While it does not specifically need to be mentioned in the preamble associated with this policy, ASTS would like some verbiage within OPTN processes to look at making the entire system more efficient and less cumbersome.

7) A flaw in the current donation system is the absence of a unifying identification system for all products that originate from a single donor. Safety in the composite system lies in reproducibility and minimization of error. The failure of the organ donation system to speak to the weaknesses of the tissue, eye and cell donation system and the absence of uniform donor identifiers should be discussed with HRSA, FDA and CMS. We apologize for bringing this issue up in this format, but there is no other opportunity to do so.