



October 14, 2016

## ASTS Responses to OPTN Policy Proposals

### 1. Redesigning Liver Allocation

ASTS appreciates the opportunity to comment on the Redesigning Liver Allocation proposal. Because ASTS members have a variety of opinions on this proposal, the Society will not take a position for or against it. However, ASTS will make several points along the spectrum of member perspectives.

ASTS strongly supports the well-established policy process of the OPTN and opposes efforts to circumvent it or to involve legislators, the media, or public opinion. Though some of our members have advocated for their patients and centers to these audiences, the Society as a whole believes that the issue is best addressed by those with a firm grasp of the nuances and complexity of organ allocation. The optimum solution will come through civil and constructive discourse among those in the transplant community. Everyone in the transplant community shares the same goal: the best care for patients with the most access to lifesaving treatments.

ASTS believes the transplant community must remain mindful of our aspiration to inspire hope in those with end stage organ failure and to maintain the public trust that we will make the best use of donated organs. Public discord may cause lasting damage to our image as an inspiration for hope and, in the worst case, have a negative impact on donation and injury to those we wish to help. We must not lose sight of the larger picture in this debate.

With that in mind, ASTS submits two different perspectives on this proposal. They can be found at <http://asts.org/docs/default-source/optn-unos/asts-comments-on-optn-changes-to-liver-allocation-proposal-october-14-2016.pdf?sfvrsn=2>.

### 2. HCC Auto Approval Criteria Changes

**ASTS does not support this proposal as currently written.** We are concerned that this proposal dictates how to practice medicine and further study is needed in order to streamline the process. ASTS would like to provide the following comments for consideration by the Liver and Intestine Committee as they deliberate changes to the proposal.

- a. Small single lesions - Proposal sets out to identify some T2 tumors that should not get MELD exception. It bases this on success of mandated ablation therapies. If a 2-3 cm tumor ablative therapy is successful, the candidate would not get automatic priority. This, by inherent nature, may prompt centers to “intentionally” undertreat during ablation, so as not to lose priority. This does not promote patient safety. As transplant centers are mandated to treat all single small lesions, transplant centers may choose to “hide” these patients until the tumor grows beyond 3 cm so that they don’t fall into this mandate.
- b. Downstaging – proposal seeks to expand and standardize the downstaging protocols. If the large tumors (up to total size of 8 cm) are successfully downstaged, they will be allowed the same priority as regular T2 lesions. The protocol does not describe how to standardize successful downstaging. ASTS suggests repeat imaging 4-6 weeks after ablation therapy to determine successful downstaging.

- c. The proposal also looks for help for defining residual vs recurrent tumor. ASTS suggests that if the first post ablation scan (4-6 weeks after) shows tumor, then this should be defined as residual. If not, but then is seen on subsequent scans to this (as part of the MELD extension), then this can be defined as recurrent.
- d. AFP level – Proposal states that patients with AFP > 1000 should not be eligible for exception. If it falls to < 500 after ablation, then they would qualify. If goes again above 500, then would proceed to RRB.
- e. ASTS suggests the Liver and Intestine Committee develop a demonstration project with 10 transplant centers to evaluate the concepts in this proposal and help streamline the system.

### 3. Adult MELD Exception Review Guidance

**ASTS supports this proposal**, which is designed to standardize based on huge discrepancies in exceptions currently being granted for various conditions. This document serves as guidance for what conditions may be worth considering for exceptions, such as post-transplant complications, multiple hepatic adenomas, etc., and provides supporting literature. This guidance document would be very helpful to individuals who serve on regional review boards (RRB).

### 4. Modify Adult Heart Allocation 2016 2nd Round

The proposal by the Thoracic Committee to stratify the most urgent category of patients awaiting heart transplantation, and enhance wider geographic sharing, is a worthy cause supported by ASTS. Specifically, the proposal ensures that allocation of organs to multi-organ recipients will likely remain unchanged and will be driven by the “most urgent” organ. Additionally, the proposed change suggests use of concentric circles of 500 miles up to 1000 miles over the local DSA in order to promote increased sharing. Greater geographic sharing has been shown to decrease waitlist mortality without adverse effects on the allograft function and is consistent with the OPTN “Final Rule.” However, ASTS is concerned that assigning the highest category to ECMO patients may offer heart transplantation to the sickest patients, but will likely increase post-transplant deaths. With markedly increased use of ECMO in the past 5 years, this category may rapidly become one of the most commonly used classes. Incorporation of post-transplant survival into the allocation algorithm may balance this phenomenon as it did with the Lung Allocation Score(LAS). The members of the OPTN Thoracic Committee state that the reason for not incorporating the 1-year post transplant survival is the “lack of robust data.” As a reminder, there were similar concerns expressed related to LAS yet it was ultimately included. Incorporation of post-transplant survival data in organ allocation minimizes “futile care” and is required/consistent with OPTN guidelines.

### 5. Changes to Informed Consent Requirements for Potential Living Donors

**ASTS does not support this proposal as written.** ASTS is generally supportive of the concepts contained in the “Modifications to Informed Consent Requirements for Potential Living Donors” proposal but not how it is accomplished. Education and transparency is certainly a shared goal. However, we feel that the proposed process is too prescriptive. Informed consent is a process that begins with the first contact with a potential donor and is an ongoing acquisition of information during the entire process. A lengthy written consent document can be confusing and actually obfuscate appropriate transmission of important details. We have concerns that this prescriptive mandate may have a negative impact on living donation.

Specifically, follow-up rates are based on whether the follow-up is actually completed and do not account for the transplant center's attempts or efforts. There are many reasons donors do not follow-up as designed, and a significant proportion of these are the donor's choice not to return. These rates are not indicative of the transplant center's dedication to its living donors. Concepts about “permanent loss of renal function” and increased chances of gestational hypertension or preeclampsia should be put into appropriate perspective with attempts to quantify the

risks to the individual. This requires center flexibility in order to deliver the correct message. Again, these are important issues and should be accomplished in an educational setting, rather than a single written consent form.

#### **6. Transplant Program Outcomes Review System Changes**

**ASTS does not oppose this proposal as currently written but feels it is not ideal.** The proposal represents a step in the right direction and is better than the current process. However, the proposal represents a compromised stance that includes a random audit component that is likely unnecessary. We hope there can be continuing improvements in this process.

#### **7. Transplant Program Performance Outcome Measures**

**ASTS supports this proposal** but believes it is too restrictive and would prefer a broader group than EPTS >80. We hope the MPSC will continue to make improvements in these measures.

#### **8. Update Transplant Hospital Definition**

**ASTS does not support this proposal as currently written.** The proposal sets out to create definitions of what a transplant center's attributes should be. The proposal is needlessly onerous and likely unnecessary for the smooth functioning of a transplant center. There is required documentation of physical addresses with maps to show which operating rooms are used for transplant. This seems unnecessary and it takes out of consideration that hospitals may have new construction, there may be temporary relocation during disasters, etc. If the intent is to better gauge patient safety as related to infrastructure, this could easily be asked of a specific transplant center during an MPSC review, as opposed to making every transplant center do this. The proposal also sets out to describe geographic limits of a transplant center. It states that all operating facilities of a transplant center either be in the same contiguous campus, or within a mile's distance of each other. This proposal also seems unnecessary as many transplant centers may have satellite centers or pediatric hospitals which are physically more than a mile away, and are based on the size and demographics of the city they serve. As long as the medical and administrative teams are the same, this physical distance should not have a bearing on the program's ability to perform safe and effective transplants.

#### **9. Primary Transplant Surgeon Requirement Changes**

ASTS supports this proposal.

#### **10. Primary kidney transplant physician update**

ASTS supports this proposal.

#### **11. Primary Liver Transplant Physician Subspecialty Requirement Changes**

ASTS supports this proposal.

#### **12. Infectious disease verification**

ASTS strongly opposes this proposal. This proposal was a response to 3 potential or actual accidental transmissions of infectious diseases in living and deceased donor transplantation. The proposing committee also feels that added verification of infectious disease results is indicated to ensure safety given the increasing use of hepatitis B and hepatitis C positive donor organs. In addition, the passage of the HOPE Act permits the use of HIV positive organs in the setting of a clinical trial and may be expanded in the future outside of a trial if the initial experience is successful, which, in the opinion of the proposing committee, requires increased vigilance to prevent accidental transmission.

- i. The proposal specifies additional responsibilities for transplant programs and OPOs to document review of infectious disease results at multiple time points prior to performance of the transplant. The proposal requires that transplant programs document review of donor infectious disease screening in the operating room at the time of ABO verification prior to beginning the transplant if the organ is present or during the procedure if the organ arrives subsequently. It requires that 2 licensed health care professionals (presumably the surgeon and circulating RN) review source documents which confirm the Hepatitis B,C, and HIV status of the donor prior to the transplant. Acceptable source documents will include the electronic medical record in the hospital for living donors and the DonorNet system for deceased donor organs.
- ii. ASTS strongly supports the need to ensure recipient safety in the transplant system. Our members safely perform thousands of transplants annually and have designed systems that review and document the infectious results of candidates at the time of listing. These data already inform organ acceptance decisions through the DonorNet portal. We also have systems in place to document patient acceptance of PHS higher risk donor organs as well as donor organs with known infection. These risks are documented in the medical record and on the operative consent. This is done prior to beginning the procedure.
- iii. ASTS believes that the requirement that these results be reviewed within the operating room creates additional complexity with minimal benefit for the nation's transplant centers. The operating room staff are not trained nor credentialed within the DonorNet system. They are also not trained in the interpretation of these results. Therefore, to comply with this new mandate, surgeons will need to break scrub, sign into the DonorNet system, navigate to the attachment section (which cannot be done with a mobile device), and review the source document with the circulating nurse. It will be impossible to include this source document with the hospital EMR as it has HIPPA protected information on the donor. Thus, documenting which results were reviewed will be difficult. It will also be necessary to provide interpretive guidelines for RN staff to clearly explain how to interpret these results.
- iv. This new requirement poses an undo requirement for transplant centers which will be difficult to implement. This differs from the ABO requirement as the recipient source document is in the hospital EMR and the donor ABO is on the paperwork that accompanies the organ. This paperwork cannot be used for infectious disease verification according to the policy as there may be pending results were not available at the time organ was packed. Thus, only the DonorNet system or the donor organ tracking system (which is not universally available) can be used as source documentation.
- v. According to the supporting documentation, there have been 3 donor cases of unintentional transmission that may be the fault of human error over the period between 1/08 and 10/13. This represents a potential error in approximately 3 in 90,000 donors. Furthermore, these cases were of HCV transmission which is now nearly universally curable. Currently protocols are in place to transplant HCV positive donor livers and kidneys into HCV negative recipients, as the benefit of organ transplant far outweighs the risk. Thus, it is not clear that this proposal fundamentally increases donor safety.
- vi. In regard to organs transplanted under the HOPE Act, this is a very specific population in which both donor and recipient HIV status will be known prior to the OR. We are already required to document that the UNOS Donor ID matches the Donor ID for the organ intended for that recipient. Thus, we confirm that a HIV+ donor organ is transplanted into the intended recipient through current processes.
- vii. In summary, the organ transplant community already engages in an extensive process of reviewing and documenting key clinical information. We remain committed to providing safest care possible for all patients but do not support this proposal as it is unlikely to improve patient safety given current processes, is difficult

to safely implement, and has the potential to negatively impact patient care by requiring surgeons to log into the DonorNet system in the middle of procedures.

### **13. Split vs. whole liver transplantation white paper**

ASTS supports this paper, with the understanding that it is a white paper and not a policy change.

### **14. Ethical considerations of imminent death donation**

ASTS suggests that the white paper should not be released at this time. We are aware of a study supported by the Greenwall Foundation designed to understand current societal views toward imminent death donation and encourage OPTN to wait until the results of this study are complete before releasing a public statement.

### **15. Ethics of deceased organ recovery white paper**

The **ASTS Ethics Committee supports and agrees with the UNOS/OPTN Ethics Committee's revised white paper** on "The Ethics of Deceased Organ Recovery without Requirements for Explicit Consent or Authorization." It is a well thought out summary of the current ethical issues behind the major models of consent for deceased donor organ donation and it clearly states the current position of the UNOS/OPTN Ethics Committee.

The current allocation system model in the United States, where the donor (or their surrogate) must explicitly consent for donation, values the rights of the individual and considers the choice to donate organs to be a manifestation of a person's unfettered right to give (or to not give). This "Donation Model" comports with the culture, the values, and the laws of the American people while delivering excellent rates of consent. It rests on solid ethical principles and enjoys a strong legal foundation. To change it would require monumental efforts and resources that would likely be better used pursuing other approaches to increase organ donation in the United States. We agree with the OPTN/UNOS Ethics Committee that, while supporting innovation, we should not change the current donation approach from the current "Donation Model" to an allocation model of "Deceased Organ Recovery without Requirements for Explicit Consent or Authorization."