AST Fall 2016 Public Comment – Approved by Board on October 4, 2016

The American Society of Transplantation responded to the 15 OPTN/UNOS proposals released for public comment on August 15, 2016. The responses below were entered on the OPTN website. A more detailed response to the Liver & Intestinal Organ Transplantation Committee's "Re-Designing Liver Distribution" proposal was sent directly to the Committee. Many thanks to the Communities of Practice that shared subject matter expertise utilized in these responses.

1. **Split vs. Whole Liver Allocation – Update to an Existing White Paper (Ethics Committee)**

   The American Society of Transplantation has reviewed this proposal and is supportive of the Ethics Committee's suggested updates to this white paper.

2. **Ethical Considerations of Imminent Death Donation (Ethics Committee)**

   The American Society of Transplantation has reviewed this proposal and is supportive of the document. The Society believes that it is a thoughtful and appropriate decision not to pursue donation prior to cardiac or neurologic death. The Society does wish to note that IDD type 2 raises some concern regarding the use of organ donation as an alternative to euthanasia. State laws and regulations may warrant consideration before implementation.

3. **The Ethics of Deceased Organ Recovery White Paper (Ethics Committee)**

   The American Society of Transplantation has reviewed this white paper and supports the Ethics Committee's proposed changes to the document with the following comments for consideration:

   - The "high" 75% U.S. authorization rate is provided as one justification for retaining the current "donation model." It would be useful to see the authorization rates of other countries. We are told only that they increased 25% to 30% where presumed consent and other measures were implemented.
   - (Page 6, fourth paragraph) When justifying nonuse of presumed consent, argues that the current "infrastructure of organ procurement specialists" would be overwhelmed by an increase in organ authorization if it occurred. In the context of other information in this white paper, this might be interpreted as advocacy for increased federal funding of this infrastructure and may therefore be misplaced in this guideline.
   - (Page 6, lines 313-318) This would seem to be the greater need in the US. Rather than changing the donation consent process, investment in the current infrastructure/donation process may be a more worthwhile effort - increased awareness, increased specialized training for professionals, support for families/surrogates, etc.
   - (Page 7, line 363) Another focus: improved outreach to minority populations regarding the value of transplant. Otherwise, adopting policies that will allow for

organ/tissue recovery without explicit consent will potentially feed attitudes/beliefs of high distrust of the transplantation system.

4. **Changes to HCC Criteria for Auto Approval (Liver & Intestinal Organ Transplantation Committee)**

The American Society of Transplantation has completed its review of this proposal that will ultimately create a national standard for HCC candidate eligibility for exception points, and offers the following comments for consideration:

- Single Small Cell Lesion Criteria
  - The subcommittee recognizes that despite this policy change, there may not be much change expected in the listing behavior as transplant centers may modify the locoregional interventions given to allow patients to qualify for auto MELD upgrade; thus, strict implementation of the policy to ensure that locoregional therapy was administered or fairly considered in all cases is necessary.
  - Definition of complete response should be clarified, and should include complete absence of vascular enhancement.
  - Patients with HCC MELD upgrade should not be included in regional sharing models.
- Downstaging
  - 1-month imaging after locoregional therapy is suggested, and every 3 mos. imaging subsequently
- High AFP Threshold
  - We agree with the proposal in that if the AFP declines < 500 after loco-regional therapy, the candidate should be eligible for a standardized MELD exception. As long as the level stays below 500, the AST believes that the candidate should remain eligible for the exception score provided that no other radiological findings suggest that he or she is outside of Milan criteria. The decline in AFP should be sustained for a minimum of 3 months prior to granting the exception. Rebound elevations during this period are suspicious for recurrence or lack of tumor control and should raise a red flag. Levels rising above 500 warrant another review by the review board.

5. **Re-Designing Liver Distribution (Liver & Intestinal Organ Transplantation Committee)**

A letter will be submitted directly to the Liver Committee leadership (letter was approved by Board and reviewed by Dr. Ison. The board asked that a message be posted to the PC portal to convey that a response has been submitted. The language for this message appears below and receive no additional feedback from the board.

The American Society of Transplantation has reviewed this proposal and offered its feedback directly to the Liver and Intestinal Organ Transplantation Committee via letter. Overall, the Society is supportive of the proposal's goal to ensure more equitable access for those in need of liver transplantation regardless of their place of residence or listing. However, due to the divergence in opinions within our

membership on how to best address this goal, we refrain from offering a specific vote of support or opposition at this time. The AST recognizes that this is the Committee's first call for comment on this complex topic, and looks forward to additional modifications in 2017 as the committee considers the responses from this public comment cycle.

6. **Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review (Liver & intestinal Organ Transplantation Committee)**

The American Society of Transplantation has reviewed this proposed guidance and is generally supportive. The Society does, however, offer the following comments on the MELD upgrade to be granted to cases with multiple adenomas:

- Nonresectability of adenomas must be proven and the one of the following criteria must be present:
    - Malignant transformation proven by biopsy
    - Presence of beta-catenin gene mutation which portends a higher risk for malignant degeneration
    - Presence of glycogen storage disease which increases the risk for malignant transformation
- Disease progression in size and number as stated on the proposal is vague and needs additional specifications.
- History of one or more hepatic resections (incomplete resection or recurrence) or other management (embolization) of a hepatic adenoma, despite current nonresectability, should not qualify for a MELD upgrade in the absence of evidence of malignant transformation or a high risk for malignant transformation as defined above.

Although we commend the Liver and Intestinal Organ Transplantation Committee for this work, we question it being included in policy proposals. Furthermore, as OPTN/UNOS is charged with policy making, we would respectfully suggest that the development of guidelines might be better suited to professional organizations such as AST.

7. **Modifications to Informed Consent Requirements for Potential Living Donors (Living Donor Committee)**

The American Society of Transplantation has reviewed this proposal and strongly supports efforts to improve the informed consent process for living donors.

The AST recognizes informed consent as a process between health care providers and potential living donors. Although essential elements of the informed consent process can be defined and agreed upon to inform best practice, the content of this process should be a matter of professional practice rather than regulatory policy. The AST recognizes that CMS and OPTN/UNOS has defined elements to be included in informed consent documents but questions the value of creating lengthy documents that may be confusing to donors and that may inadvertently detract from the interaction between health care providers and donors that is essential to the informed consent process. Further such changes may be adding to

the administrative burden at transplant centers without significantly improving the process for donors. The AST recognizes the importance of efforts to improve the accuracy and completeness of donor follow up data but questions the value of mandating disclosure of the completeness of reporting by individual centers. There are a number of factors that may impact a center's ability to obtain and report donor follow up data that have little to do with the quality of post-donation follow up care provided by the center. The AST is not aware of evidence that that completeness of data reporting is associated with the quality of donor care. Accordingly, the AST is concerned that mandated reporting of this information may result in erroneous inferences regarding a center's commitment to post-donation care.

Given these considerations the AST does not support the mandated inclusion of this information as part of the informed consent process as it may lead to incorrect assumptions about the quality of care provided by the center.

We also offer the following comments regarding specific modifications and additions for consideration:

- 14.2 b, former d and e – What is the value of the IDA going through the entire psychosocial and medical evaluation process but not reviewing the elements of medical and psychological risks?
- 14.2 d – This wording is awkward. 18.1 contains far more requirements than simply donor follow-up and describes no benefits to such submission, and clarification is recommended. Furthermore, the need to report adverse events should be a separate distinct element, not included with routine follow-up.
- 14.3 Table 14.1 Suggest that all these tables use roman numerals or capital letters to distinguish sections or a continuous number system. This will eliminate the need to continue to start e numbering sequence repeatedly. We also suggest uniformity in using either letters or numbers and not bullets.
- #5, #7, #8 in the third set of numbers beginning with #1 (page 6): We question whether the value in the proposed language changes justifies the additional burden to the potential donor or transplant center.
- 14.2 b (ESRD risk) and disclosure to females (pregnancy risk) (no letter, number or letter) (page 8) – These disclosures, based on good quality evidence, are worth the additional burden to both donors and transplant centers and should be supported. However, including in the consent process a) an increased risk of gestational HTN, preeclampsia and b) an increased ESRD risk over a similarly healthy cohort of individuals, qualified by the word "may", leaves interpretation and explanation to individual centers, and this ambiguity lessens the value of appropriate informed consent. Again, we believe that this is professional practice and not regulatory policy but if that concept is to be rejected, these elements are acceptable. However, if professional practice is to be dictated by policy, we suggest that the magnitude of risk also be included in mandatory language as it is very low for both risks.

- Regarding the following statement: "<u>Surgical risks may be transient or permanent and include but are not limited to potential medical or surgical risks</u>:

1. Decreased kidney function
2. Acute kidney failure and the need for dialysis or kidney transplant for the living donor"

For #2 – Does this refer to AKI developing in the peri-operative (donation) period or does this refer to future risk? It is unclear, and the AST would like to see this clarified in the final proposal.

8. Proposed Changes to the OPTN Transplant Program Outcomes Review System (MPSC)

The American Society of Transplantation is supportive of the MPSC's overall efforts to improve flagging, but oppose the current proposal. The major concerns of the Society relate to the complexity of the tiered system and the opportunity for payor misperceptions regarding random auditing. Further, the Society feels that the proposal will add additional burden to both the MPSC and the transplant centers without significantly benefiting the quality of the programs. Further, the Society is concerned that the random audits will result in center QAPI programs focusing more effort on addressing audits instead of focusing on the ongoing quality efforts of the program.

Although we applaud the intention of this change, to decrease risk avoidance behaviors caused by "fear of flagging," this proposal falls short of that goal. A two-tiered system intended to flag the centers most likely to be experiencing systemic, not random, problems impacting patient or graft survival and subjecting them to more scrutiny while delivering less scrutiny to those who are less likely to have systemic problems might be a good concept, however as proposed, the proposal results in more centers under review. Regardless of the reason (random versus statistical), MPSC review creates administrative burden for transplant programs - which means cost and attention taken away from patients and to avoid this centers will be more conservative. To be meaningful, any change in the review system, must result in less reviews. For these reasons, the AST cannot support this proposal as currently written.

We do not have confidence that this proposal will change the perception that MPSC review is a punitive process and will continue to result in conservative center behaviors. Increasing the threshold and expediting more advanced review of "Tier 1" is an acceptable positive for patient and program safety. The remainder of the proposal seems to increase the potential burden upon centers subject to "random review" in the absence of data that this is a valuable endeavor. Increasing the number of transplants is one of the top goals set by the OPTN/UNOS Board of Directors. There is a perception among the transplant community that the utilization of high-risk donors/patients and the consequences of being identified by OPTN for poor performance may lead to a more conservative behavior and would ultimately prevent further increase in transplants. Specific areas of concern are included below for MPSC consideration:

- The MPSC is proposing to eliminate the current model for identifying those underperforming programs (currently two possibilities, i.e. performing as expected vs. underperforming), and implement a 4-tier approach. The top tier (worse) would automatically undergo review. The cutoff (Observed HR>1.75) would be higher than the one currently used. The requested survey will be more involved than the currently used for flagged programs. The second tier would undergo a "Routine

Program Review". The cutoff (Observed HR>1.25-1.75) would undergo a random (50% chance) audit. The survey will be less involved than currently used and the focus will be on the implementation of quality improvement projects. If results are positive, MPSC will follow without further interventions. The third tier is similar to the second tier, but the cutoff used will be from 1.0 to 1.25 and only 10% of the programs will be randomly audit. The fourth tier (HR less than 1.0) will be considered performing as expected and will not be audit. The expectations are that only a few programs with substantial problems will fall under tier 1.

- There is concern with the "random selection" of programs in tiers 2 and 3 as being actually audit versus just simply notified may have significant consequences at the institution level, healthcare team and patient level.
- Another area of concern is how to define what is truly the difference in preventable causes of untoward program outcomes and QAPI in those with HR 1.1 and 0.9? Or 1.01 and 0.99? Or 1.15 and 0.85?
- Labeling Routine Program Review Tier 3 (HR 1.0-1.25) "at increased risk" (by subjecting these centers to the risk of random review) when there is a lack of statistical power that creates an inability to say definitively that those programs reached that level of underperformance runs counter to the goals stated of the proposal. We suggest that this tier should either be eliminated (to prevent improper labeling of centers and excessive UNOS resource utilization) or should be treated in the same manner as those programs with HR <1.0 (for the purpose of gathering data on "best practices and developing better tools that UNOS may gain in advancing transplant outcomes).
- The proposal does not provide details that clearly demonstrate that all programs will fluctuate in/out of Tier 3 and would all be subject to random review "at some point". We disagree with the conclusion that "the Task Force agreed that any program performing as expected or better should be excluded from MPSC review" when the limits of statistical power do not accurately segregate these centers from those in proposed Tier 3.

The AST does not have confidence that this proposal will change the perception that MPSC review is a punitive process and will continue to result in conservative center behaviors. Increasing the threshold and expediting more advanced review of "Tier 1" is an acceptable positive for patient and program safety. The remainder of the proposal seems to increase the potential burden upon centers subject to "random review" in the absence of data that this is a valuable endeavor.

Finally, another concern is the clustering of several programs near the cutoffs used for tier 2 and 3 might lead to an influx of programs moving from one tier to the other. However, OPTN believes that eventually most programs will be engaged in quality improvement projects leading to better overall outcomes.

9. Consider Primary Surgeon Qualification- Primary or First Assistant on Transplant Cases (MPSC) ***(Reviewed by the Joint Society Working Group)***

The American Society of Transplantation has reviewed this proposal and offers its support. The changes align the requirements by OPTN/UNOS with those of the kidney transplant fellowship and make accommodations for fellows that take an alternative fellowship that incorporates research lasting longer than 12 months. The Society agrees that specifying these qualifications will promote improved transplant outcomes and patient safety. The committee also agrees that the intestinal transplant surgeon and the pediatric transplant surgeon should have similar requirements to serve as the primary surgeon of the specific program.

10. **Subspecialty Board Certification for Primary Liver Transplant Physicians (MPSC)**
(Reviewed by the Joint Society Working Group)

The American Society of Transplantation has reviewed this proposal and is generally supportive, offering the following comments. The Society agrees that allowing this change will promote improved patient outcomes and patient safety. However, given the continuing high demand to supply situation for transplant hepatologists, consideration may be given to conditionally allow a board eligible candidate who has completed an ACGME-certified Transplant Hepatology fellowship training to serve as primary liver transplant physician in a liver transplant program, while allowing him/her to obtain certification within a reasonable time period. Such designation may be revoked if the individual has not been successful in obtaining board certification within the specified time frame.

The AST does suggest that the proposal may not fully solve the intended problem, which was to provide for primary liver physicians who have transplant hepatology certification but not gastroenterology certification- or that it solved that problem but perhaps created a new one. Now those physicians with gastroenterology certification are excluded, the Society offers a suggestion to modify the proposal to accept either board certification.

11. **Transplant Program Performance Measures Review (Outcome Measures) (MPSC)**

The American Society of Transplantation has reviewed this proposal and offers its support with comments. Increasing the number of transplants is one of the top goals set by the OPTN/UNOS Board of Directors. Utilization of high-risk kidneys (KDPI>85%) to high-risk recipients (EPTS>80%) is an opportunity as a significant number of high-risk kidneys are discarded yearly. Data shows a significant number of these kidneys lead to acceptable outcomes.

However, a limitation to the full utilization of these kidneys is the perception that despite statistical adjustment, they could potentially lead to worse outcomes. Hence this may impact program performance.

The MPSC is proposing an “operational rule” that would modify the current method of identifying programs with low performance. Under this rule, programs will only be reviewed if: 1) the program is underperforming using ALL the kidney transplants including in the analysis; AND, 2) if they also fall outside the threshold in an analysis of kidney transplants after excluding higher risk transplants. The data analyses further suggested that no programs were solely “flagged” based on poor outcomes of those recipients of high risk organs.

In summary, this proposal is aimed at increasing the utilization of high-risk organs that are currently discarded. It is relatively straight forward to implement from the programs' perspective as it will not require any additional resources. The implications of implementing this proposal is not yet clear, but the MPSC will closely monitor outcomes during the implementation, especially the potential for reducing graft survival, a concern of the AST. We agree with concerns raised in the proposal that CMS and insurance company audits are not aligned with this proposed exception and would limit the impact of the proposal. However, the proposal may provide incentive for centers who otherwise are overtly conservative to become less so, while existing centers who have broad acceptance experience under these parameters will not have behavior altered. If the transplant community is supportive, perhaps an effort can be made to discuss with CMS adoption of this exception prior to implementation, even as a "memorandum of understanding."

Given that this proposal could possibly decrease at least part of the burden of regulatory review, adds no additional administrative burden on transplant centers and would be assumed to provide centers with additional data that could perhaps be used with CMS or other payors, the AST offers its support.

12. Updating Primary Kidney Transplant Physician Requirements (MPSC)

The American Society of Transplantation has completed its review of this proposal and is supportive of updates to the bylaws to reflect that transplant nephrology fellowships lasting longer than 12 months be included as acceptable training for UNOS, but recommends some administrative changes for consideration that it suggests will improve upon these updated requirements.

- The increased requirements for the "clinical pathway" that are proposed to mirror these "training pathway" may be logistically difficult if the individual in question is indeed the program director (e.g. for donor evaluations, the individual log "should be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience"). We request more clarification as to who needs to "sign off" on this log in the case of individuals who already serve in "director" roles. Beyond this, we are pleased to see formalized the alternative fellowship pathway incorporates nephrology and transplant fellowships that are longer than 3 years with integrated research into the program.
- We recommend elimination of the need for deceased donor location, as this can be very difficult to obtain once a fellow has moved to a different center and adds no value.
- We are concerned that the new language regarding direct involvement in recipient and living donor evaluation is somewhat vague in terms of what direct involvement means and what the evaluation date means.

Additionally, there was concern related to primary transplant physicians focused in the area of living donor transplant, and the division between living donor evaluation and evaluation of potential kidney recipients. To keep these two processes independent of each other within a program, physicians often have experienced specifically focused on living donor or recipient evaluation after a transplant nephrology fellowship.

- As stated, the new requirements (involvement in evaluation of 10 potential living kidney donors) do not impact current primary kidney transplant physicians, but if a nephrologist focused specifically on potential kidney recipient evaluation was to move to a new kidney program, then that application will be reviewed relative to these new Bylaws. What is the provision for keeping the potential living donor evaluations separate while also not letting it impact the transplant physicians planning to take the role of primary transplant physician in a new program? The AST requests clarification on how this scenario would be handled.

13. Updating the OPTN Definition of Transplant Hospital (MPSC)

The American Society of Transplantation has reviewed this proposal, and believes it to be essentially sound other than the geographic limitation. The Society supports this proposal with the omission of the location standard. One-mile walking distance is arbitrary. Particularly in the case of pediatric hospitals, this may not be possible. If the hospital meets all of the other qualifications, the location seems to be not as important..

14. Infectious Disease Verification Process to Enhance Patient Safety (Operations & Safety Committee)

The American Society of Transplantation opposes the proposal as currently drafted. While the Society is supportive of reassessing infectious disease verification, the Society believes that, as written, it includes operational pitfalls that will not lead to enhanced patient safety.

Although the purpose of this proposal, to decrease the chances of unintentional disease transmission, is certainly laudable, it is unlikely that this proposal will actually add any degree of safety and will certainly add considerable administrative burden and cost which does not justify the small, if any, increase in safety. It must be emphasized that verbal verification is the least reliable form of verification and by adding more and more components to be verified and complexity to the process i.e. check in, pre-induction verification, with organ in the room verification, etc., the process has already become rote, decreasing the already limited reliability of verbal verification. If the desire is truly to add reliability and safety to the process, we suggest looking at more reliable solutions such as the barcoding systems which would allow an automated check.

Additionally, although the Society is supportive of verification of HIV and HCV, there are concerns about requirements for HBV and CMV. Results of HBV are more complex than HIV and HCV (i.e. HBsAg, HBsAb, HBcAb) with differential risk of disease transmission. Any policy that requires checks for HBV would need to address the complexity of HBV serologic testing and include NAT as well. Further, the Society questions the need for a similar high bar of secondary checks for CMV and requests additional data regarding the necessity of having a similar verification hard stop for CMV. Unless there are intestinal transplant programs that are consenting their candidates to accept or decline CMV+ donors, the AST does not currently recognize the value of this added hard stop for all donor and recipient pairs.

15. Proposal to Modify the Adult Heart Allocation System (Thoracic Organ Transplantation Committee)

The American Society of Transplantation supports this proposal. In general, the revised OPTN/UNOS donor allocation system was well received within the Society's cardiac community. The executive committee of the AST Thoracic and Critical Care Community of Practice (TCC COP) developed a survey to respond to the queries of the UNOS Thoracic Committee as well as what they believe to be contentious issues. The survey included 23 respondents from California, New York, New Jersey, Pennsylvania, Maryland, Massachusetts, Florida, Texas, South Carolina, Utah, Washington, Wisconsin, North Carolina and Louisiana.

The survey results indicated the following responses:

- A majority (69%) believed that the proposed indicators of cardiogenic shock are appropriate.
- A majority (47% + 26%) believe that regional review boards should review cases from other regions or outside of Zone A, instead of their own regions.
- A majority (65%) believe that the current policy for sensitized candidates should remain in place in light of broader sharing.
- Regarding the use of IABP:
    - A slight majority (52%) believe that IABP use is in the appropriate status (status 2).
    - A majority (65%) believe that the IABP proposal will encourage more IABP placements rather than starting inotropes with a swan.
- A majority (78%) believe that the proposed minimum doses of intravenous medications needed for status 3 listing is appropriate.
- Almost all of the data elements on the list of potential heart allocation score data are likely to be incorporated into a heart allocation score. (see below)
    - Missing data elements include type of MCS support and MCS complications
- Only the six-minute walk result was believed to be an extraneous data element.
- Data elements that should only be collected on VAD patients Include:
    - MCS support, type of MCS support (TAH, Biventricular support, LVAD)
    - MCS complications (severe, moderate, mild)

We believe that the heart allocation proposal has been thoughtfully crafted and vetted through multiple venues and feedback processes. Although there remain a handful of points which need to be vetted post implementation to validate efficacy (actual waitlist mortality, actual transplant rates relative to TSAM modeling), the AST is supportive of the proposal, and see it as an intermediate step in the process of better heart allocation. The collection of the new data points is essential to developing that better system.