

**American Society of Transplantation October 2018 Fall Special Public Comment Response to
“Liver and Intestine Distribution Using Distance from Donor Hospital”**

The AST strongly supports initiatives to improve equity in access to organ transplantation. The AST understands that there are unique considerations specific to liver allocation and has endeavored to obtain a broad understanding of these issues. While we appreciate the effort and challenges in advancing a policy to address the complex issue of geographic disparity on a short time-line, we provide the following comments that reflect the feedback we have received from our members:

Any proposed allocation policy to decrease disparity that involves broader sharing of organs must consider potential negative effects, feasibility and unintended consequences. These considerations include prolonged ischemic times of marginal livers that may negatively impact outcomes, potential increases in organ discard rates, increased travel for organs and recovery teams leading to increased cost, and increased potential risk to organ recovery teams. These two competing sides of the equation require reasonable balance and compromise. While appreciating the rationale for the current proposal at hand, the Society recognizes that many important aspects of the proposal's effects have not been adequately studied- particularly with regard to the impact on the safety, health, and quality of life of transplant professionals who will by default be working harder and longer, and will be taking more risk with any broader sharing policies. These considerations are heightened given the reality of the current opioid crisis, which has already challenged the system's ability to provide safe organ donation services in some regions.

Additionally, the Society feels this current proposal misses an opportunity to increase transplantation by development of specific strategies to increase organ donation by improving OPO performance which many of our members deem to be at least as important as changing the liver distribution framework.

Finally, the Society recognizes that any proposal based on simulation methods is unable to truly predict transplant center behavior with regard to organ acceptance rates and therefore may lead to fewer liver transplants being performed.

Our responses to specific questions posed by the Liver Committee:

1. The community is asked whether they prefer the Broader 2-Circle model or the Acuity circles model.

Despite support for the Acuity 250/500 model due to its greater improvement in the variance of the median MELD at Transplant, the predicted significant increases in percentage of organs flown makes the Acuity model unacceptable. The potential for longer ischemic times to negatively impact transplant outcomes and increase organ discards and costs, as well as the increased risks due to flying for the procurement team outweigh any predicted benefit. In addition, the cost burden on small to medium sized programs as compared to larger programs will have potential negative impact on access to transplant for those served by the smaller volume programs.

2. The community is asked what MELD sharing threshold they recommend.

The AST liver community has expressed support for a sharing threshold of MELD 35 over MELD 32 given that there are minimal differences in the metrics reported in the SRTR modeling between the B2C 32 and B2C 35, including waitlist mortality. The advantage of B2C 35 over B2C 32 would be the small decrease in travel which will translate to shorter ischemic times, less cost, less risks to

transplant personnel, and more efficiency in organ allocation. It should be noted that the AST pediatric community feels that a sharing threshold of 32 would be acceptable.

3. The community is asked whether the sizes of the fixed distance circles should be larger, smaller, or remain the same.

The AST pediatric community ranks the order of simulated SRTR models as 250, 500, and then 150nm.

4. Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community

The B2C 32 allocation is predicted to result in a 10% increase in organs flown *compared to current practice*. This change will result in significant short and long-term budgetary impacts which include but are not limited to; the actual costs of flying, the longer person hours spent in procurement, the increased hospital costs that may be a consequence of negative liver transplant outcomes related to increased ischemic time. Not quantifiable but of no less importance are the increased risks to the safety and lives of the procurement teams. Again less quantifiable in terms of costs are the potential increase in organ discards due to the longer travel distances and ischemic times.

5. Should the variance to relating to the treatment of O donor livers in Hawaii be extended to Puerto Rico?

AST agrees with the proposal to extend the variance proposed for Hawaii to Puerto Rico in light of the geographic and ethnic similarities; but given the risk that such a variance would potentially disadvantage higher MELD candidates in the continental US, a clear plan for post implementation monitoring of such should be included in the policy.

The AST Pediatric community has additional feedback regarding the proposal:

- Broader liver sharing may have the unintended consequence of disincentivizing/discouraging in-situ donor liver splitting which may lead to decreasing organ access for the < 1year old candidate who presently has the highest waitlist mortality. We suggest the policy include clear commitment to monitoring the effect this policy has on age-stratified pediatric transplant rates and wait list mortality. Additionally, we suggest that consideration of additional priority be given to centers/adult recipients who are willing to split the appropriate organ with a list of suitable pediatric recipients
- We suggest that the current modeling which looks at the pediatric candidates as a group, again is inadequate to determine the effect of the B2C model on pediatric liver candidates stratified by age. We are particularly concerned that children who are 12-17 years old (considered for their MELD priority score) actually benefit from this policy change at a rate that is commensurate with adults given the combination of constraints that prioritize MELD scores >31 and cap MELD exceptions at 31. Over 30% of children are transplanted with exception points. If additional, age-stratified modeling confirms that the 12-17 yr candidates do not proportionately benefit or are disadvantaged, we suggest additional priority points be added for this age group.
- Although the proposal justifies in great detail the premise that donated livers are a national rather than local resource, we would contend that this premise overlooks the fact that many local and state organ donation initiatives are supported at the state level. Although the modeling of B2C may point to improved organ utilization, the modeling does not account for the fact that the behavior that leads to authorization for organ donation is based on local efforts of hospitals and the communities that they serve. Many OPO's leverage statistics of local and state

waitlisted patients in need of transplantation as a mechanism to assure donor families that their gift will benefit their community. The hypothesis that dissolution of DSA's will improve organ utilization will only be true if organ donation rates do not ultimately decline from decreased donation authorization.