ASTS Responses to OPTN Proposals Open for Public Comment

March 15, 20203

Update on Continuous Distribution of Livers and Intestines - Request for Feedback

The ASTS is in support of the challenging work being undertaken by the UNOS Liver/Intestine Committee as it works to try to develop a continuous distribution system for liver and intestines. We are also generally supportive of the attributes the committee is considering. The most complex is related to the distance from the donor hospital. We urge the committee to assess the impact of lung continuous distribution model and then incorporate any lessons learned, before continuous distribution is adopted for other organs. For liver, it will be valuable to first review the impact of the recently implemented Acuity Circle model on geographic disparity and closely examining its impact across the country before moving to another change in geographic distribution via continuous distribution. It will be important that the new policy should learn from the outcomes we have just generated from the change to acuity circles.

The ASTS supports continuing with the use of the MELD/PELD score in the first iteration of the continuous distribution system, as opposed to changing to OPOM, because this will already be an unprecedented amount of change. If we change how we measure medical urgency at the same time as all the other components of the system, it will be hard to determine which parts of the system are leading to favorable or unfavorable outcomes. Given the liver/intestine allocation system just changed to a new system 2 years ago, the opportunity for modeling may be limited, as LSAM will not have the current system data available to use. One additional concern about OPOM is that by prioritizing those with HCC who are at the highest risk of waitlist drop out/waitlist mortality, we may inadvertently prioritize patients who are at risk of post LT recurrence of HCC and thus achieve worse post LT outcomes.

The ASTS supports trying to incorporate a post-transplant survival factor, but we agree with the Liver/Intestine Committee that at present, there is not a reliable post-transplant survival prediction model and therefore the ASTS supports the committee's decision to not include this at the present time.

Whether the committee should include a factor for height or BSA will depend on the anticipated impact of choosing one versus the other. It is likely that either option may be beneficial, though it is not clear how obesity or massive ascites may impact the calculation of BSA and the predictiveness of this as a surrogate for difficult to match. Patients of short stature with massive ascites may be able to accept larger livers though this is generally not true for patients with obesity.

The ASTS is supportive of highly prioritizing prior living liver donors who subsequently require liver transplantation, and those that are closer to the time of donation should be prioritized even higher. This is anticipated to be very rare.

The ASTS is supportive of consideration of incentivizing split liver in the new system, though the ASTS recognizes the challenges of split liver including increased frequency fatty infiltration of the donor liver and potentially high acuity of the index recipient. The low frequency of split livers may not warrant adding a high amount of complexity to the allocation system. It would be valuable to determine if there are any lessons learned from the Region 8 split liver variance that can be reviewed.

Placement efficiency and population density are the most complex components of the new proposed system. It is difficult to justify placement efficiency ahead of disease acuity, yet it is also impossible to allocate across a large portion of the entire US. Importantly, transplant hospitals and donor hospitals and population densities are not evenly distributed. It is important to distribute over a broad enough area so that access and geographic disparity do not worsen in sparsely populated areas, but distributing over large areas may not be necessary in densely population areas under a new system.

The ASTS may support a donor quality scale if one was reliable and readily available. In the absence of this, DCD/age of 70 are reasonable donor quality surrogates. Donor steatosis is valuable but not reliably available.

ASTS cannot support or disagree with this public comment update on continuous distribution of liver and intestines as there are no substantial details included. ASTS does feel strongly that OPTN needs to review the actual data on the recent system outcomes on liver allocation/distribution over the last few years to understand how the most recent changes in liver allocation/distribution have affected outcomes, efficiencies, and costs of liver transplantation. OPTN also needs to show the data that becomes available on other organs, such as lung, that may utilize continuous distribution before others to understand if the outcomes achieved were as simulated.

ASTS Position: Neutral