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July 20, 2015

Dr. Ryutaro Hirose
c/o Ashley Archer-Hayes
UNOS Liver & Intestinal Organ Transplantation Committee
700 North 4th street
Richmond, VA 23219

RE: *Urgency to Adopt Policies to Reduce Geographic Disparities in Access to Liver Transplantation*

Dear Dr. Hirose:

On behalf of the liver transplant professionals in Region 9, the New York Center for Liver Transplantation (NYCLT) submits the following comment regarding the recent Educational Public Forum on Redesigning Liver Distribution held by the UNOS Liver and Intestinal Organ Transplantation Committee.

The NYCLT understands the Committee is committed to fully exploring the various metrics of disparity; and the impact of a new liver distribution scheme on OPO logistics, transplant center financial viability, and transportation concerns. We applaud the Committee's action to adopt a metric of disparity at its meeting on June 23, 2015 and continue to ask for urgency in the development and adoption of a proposal. However, while we appreciate the Committee's effort to foster a productive and collaborative environment that provides input that is measured and balanced, particularly as the community considers a change to national policy; we have noted several discrepancies between data presented at the Forum and that which we know to be true. It is unacceptable in a public forum with so much at stake to have flawed assumptions and biased conclusions based upon skewed data presented.

Demand and Liver Disease Burden: Demand for liver transplantation is best measured by looking at the number of newly listed liver transplant candidates in each UNOS region. There is no data to support the assumption that competition among transplant programs in population dense areas is artificially inflating waitlists. We disagree with the flawed assumption that death rates accurately measure demand. Death rates as a measure of demand can be manipulated. As an example - viral hepatitis infection is a significant risk factor for severe liver disease that is known to vary across populations. Region 9 has rates similar to the entire nation (3.2 deaths per 100,000 in NY compared to 3.1 for US). ***Unfortunately, unfairly and inexcusably, data presented at the Forum excluded several codes for viral hepatitis, which is the most common underlying indication for transplantation in the US.*** The idea that Region 9 has low rates is further exacerbated in part because NY has low alcoholic liver disease (4.9 deaths per 100,000 people, compared to 6.9 for US). Leaving out viral hepatitis codes and adding in alcoholic liver deaths make NY's rates appear lower than the US.

The charge for the transplant community is to minimize geographic disparity in liver availability. Changes to liver distribution are not likely to have an impact on overall death rates due to liver disease. It is beyond the scope of the Committee to correct for limited access to medical care in general.

MELD as the Metric of Disparity: Region 9 patients have a higher *allocation* MELD score at transplant than in most parts of the country – the median MELD score of a Region 9 patient at transplant is 29+. However, *lab* MELD scores at transplant vary within Region 9 by center (range: 17-31). At a glance, allocation MELD scores appear inflated in parts of Region 9. On closer inspection, we make the following observations:

- The MELD score at transplant at any given center in Region 9 can be compared to the number of “national share” organs used to transplant its patients. “National share” organs are those livers that are offered outside the local OPO because all local centers have turned down the liver for use in transplant. 20-25% of transplants done at our largest centers are done using “national share” organs. Frequently these livers are used to transplant patients with relatively lower MELD scores, thus reducing the average MELD at transplant for the region. While we believe exception points should be included in our models, if we are to seriously consider excluding them, we should also exclude transplants done with “national share” organs from the analysis.
- Region 9 experience indicates exception point cases survive longer at higher MELDS and thus have a larger window of opportunity to capture an allocated liver. Many of our high MELD liver failure patients die of infection because a suitable organ does not become available. Some centers elect to selectively list those candidates that are likely to survive the long wait times in the region. There are a number of reasons the HCC patients have a biased statistical representation in NY.
- HCC exception cases should not be eliminated from the final metric of disparity. We acknowledge the challenges involved in assigning exception points for HCC, and support the Committee’s efforts to fine-tune that process. Capping exception points for HCC at 34 and delaying the score assignment by 6 months may correct for the disparity in waitlist dropout rates for this patient population; one must note this UNOS approved change assumes HCC patients still require exception points to maintain fair access to transplantation.

UNOS has a long history of assigning additional MELD points to correct for a number of inefficiencies in the liver allocation and distribution system. The most recent example is the idea of proximity circles in one of the redistribution models which would assign additional MELD points for prioritization to ensure livers aren’t needlessly being transported long distances for a relatively modest difference in MELD. We expect continued refinements to the allocation system regardless of changes in liver distribution. Two constants have remained – Region 9 patients continue to wait longer, and are sicker at transplant than in most regions of the US; and through all the policy changes, *allocation* MELD has been the standard for practice and should be used in developing liver redistribution models.

OPO Performance: Last year the Committee presented a concept document related to changing liver distribution which clearly indicated there is no relationship between OPO performance and the current geographical differences in access to transplantation for listed candidates. In fact, under a new redistricting plan, transplant programs in higher-yielding OPOs (higher O:E, higher conversion) would be expected to transplant at lower MELDs than those in poorer-performing OPOs. Despite this comprehensive look at OPO performance last year,

some of the data presented at the June 2015 forum continued to link OPO performance to disparities in access; suggesting areas with lower-performing OPOs would stand to “benefit” the most from redistricting. While we believe in the importance of increasing donation rates and have worked with the four OPOs in NYS to identify opportunities for improvement; our charge as a transplant community is to focus on patients that are suffering under the current system; patients that have little control over whether they reside in a high-performing or low-performing DSA.

It is imperative that we review and vet all data that is to be presented at public forums where the intent is to develop and change national policy. Transplant centers that have enjoyed a distinct advantage in arbitrary geographic boundaries for liver distribution have been consistent opponents of broader sharing proposals, despite impassioned pleas for change to the liver distribution system. Arguments against redistricting liver distribution have been thoroughly considered and countered; as a community we must acknowledge the urgency for change and move forward with purpose and focus. Any further delays will result in patient deaths, as the modeling has clearly shown the proposed system will save more lives than the current system.

Thank you for the opportunity to comment.

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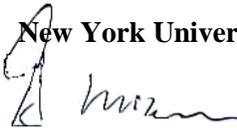


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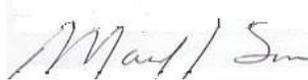
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