OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Summary
April 27, 2016
Chicago, Illinois

Ryutaro Hirose, MD, Chair
Julie Heimbach, MD, Vice Chair

Discussions of the full committee on April 27, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov/.

Committee Projects

1. Liver Distribution Redesign Modeling (Redistricting of Regions)

The Committee convened with the goals of:

- Reviewing the concentric circles modeling results
- Considering the Redistricting Subcommittee's recommendation for an optimized district solution
- Evaluating optimized districts versus concentric circles
- Considering a proposal for public comment

History of Redistricting Project

The Immediate Past Chair presented a brief history of broader sharing in liver allocation policy, which included the following milestones:

March 2000 The US Department of Health and Human Services (HHS) implements the Final Rule, which states that access to transplant "shall not be based on the candidate's place of residence or place of listing."

June 2009 The OPTN/UNOS Board approves regional sharing for Status 1A and 1B and agrees to host public forum.

Dec 2009 The Liver Committee distributes a Request for Information (RFI) to solicit feedback from the transplant community and public regarding current liver allocation and distribution policy and opportunities for improvement.

April 2010 The OPTN hosts a public forum that explores ways to reduce geographic disparity.

June 2012 The OPTN/UNOS Board approves "Share 35," a policy that includes:

- National sharing for candidates with MELD/PELD scores >15
- Regional sharing for candidates with MELD/PELD scores ≥35
- National sharing for liver-intestine candidates

He then summarized two year post-implementation outcomes from Share 35 that the Committee first reviewed last October. For patients with a MELD/PELD ≥35, the analysis showed that Share 35 increased the percentage of transplants from 19% to 27% and increased regional sharing from 19% to 50%. There was no evidence of a negative impact on other patients, either in terms of waiting list deaths or survival after transplant. Even though livers did travel longer distances from donor to recipient, preservation times did not increase overall.

Despite the success of regional broader sharing, the geographic disparity in severity of disease at transplant among the regions persists. The Immediate Past Chair suggested that this is because broader sharing has been constrained by the current geographic borders. These borders were designed decades ago based on working relationships existing at the time, not with the goal of optimizing organ distribution. Today, simulation modeling suggests that fewer mathematically-optimized districts would reduce geographic variability in disease severity at transplant and reduce waitlist deaths.

In November 2012, the OPTN/UNOS Board took the official position that existing geographic disparity remains unacceptably high. It requested that organ-specific committees investigate alternatives to DSA boundaries, considering optimization as a method. Since then, the Committee has been engaged in a transparent, inclusive, and consensus-driven process, similar to that of Share 35, to develop a redistricting proposal. This has included an RFI and two public forums. The Immediate Past Chair suggested that the next opportunity for community input is to submit a redistricting proposal for public comment.

Review of Committee Work Plan

At the June 2015 public forum, we received overwhelming feedback that the current exception system also contributes to geographic differences in access to liver transplantation. In January 2016, we adopted a 2016-2017 work plan that is a series of interrelated projects that aim to improve equity in access.

Redistricting gives similar patients equal access regardless of geography. Our current system uses medical urgency, as estimated by the MELD or PELD, to distribute and allocate organs. Broader sharing requires that candidates with similar medical urgency have similar MELD or PELD scores, regardless of geography.

However, geographic differences exist in the MELD/PELD exception submission, review, and award practices. The Committee seeks to mitigate these differences by replacing Regional Review Boards (RRBs) with a National Liver Review Board (NLRB). As part of the NLRB project, the Committee is also considering revisions to the MELD scores assigned to candidates meeting criteria in policy as a means of curbing national inflation of the MELD score at transplant. The Committee will also propose revisions to the eligibility criteria for the most common MELD exception request, Hepatocellular Carcinoma (HCC or “liver cancer”).

With these revisions to the exception system, transplant professionals, patients, and the general public will be better able to trust that MELD/PELD exception scores accurately reflect the patient’s disease severity and are the same regardless of geography.

The Committee anticipates submitting the guidance documents that the specialty boards of the NLRB will use to assess exception requests, as well as the HCC proposal, for public comment in August 2017. The full NLRB proposal will be submitted for a second round of public comment in January 2017.

Liver Simulated Allocation Model (LSAM) Overview

The SRTR provided an overview of the optimization methodology and the LSAM. The presentation noted that the optimization methods used to group DSAs into districts used real-life supply and demand data and reflected Committee design priorities for the districts. Subsequent to optimization, the LSAM was used as requested by the Committee to evaluate various broader sharing concepts. The presentation included information on how the LSAM is used to evaluate proposed policies, as well as its

strengths and limitations. The presentation concluded with guidance on how to interpret LSAM projections, using Share 35 projections and observed results post-implementation as an example.

Modeling Results: Concentric Circles with Proximity Points

The SRTR presented the results of modeling of 500-mile radial distribution based on the donor hospital location, with additional proximity points given to local candidates (at radii of 150 and 250 miles). The Committee has commonly referred to this scenario as "concentric circles." Scenarios included assigning proximity points to all candidates, all lab MELD candidates, and all candidates without HCC exception points. Key findings were as follows:

- Any redistricting or 500-mile radius circle with proximity points scenario would noticeably decrease disparity in median MELD at transplant.
- Based on modeling results, none of the redistricting or concentric circles scenarios stands out as the single best.
- The variance in median MELD at transplant is expected to decrease, while the nationwide median MELD/PELD is expected to remain stable.
- All scenarios increase median transport time and distance; however, median transport distance and percentage of organs flown is lowest in the 8 district scenario.

Prior to the in-person meeting, the Immediate Past Chair asked the SRTR to provide the percentage of transplants that occur within the 500 mile radius of the donor hospital. He wanted to be sure that the disparity benefit was not due to a disproportionate increase in national sharing. He was encouraged to learn that about 95% of the transplants occur within the 500 mile radius.

After discussion of the concentric circles modeling results concluded, the Committee Chair requested that the Immediate Past Chair, who also served as the Chair of the Redistricting Subcommittee, share the Subcommittee's recommendation for an optimized district solution.

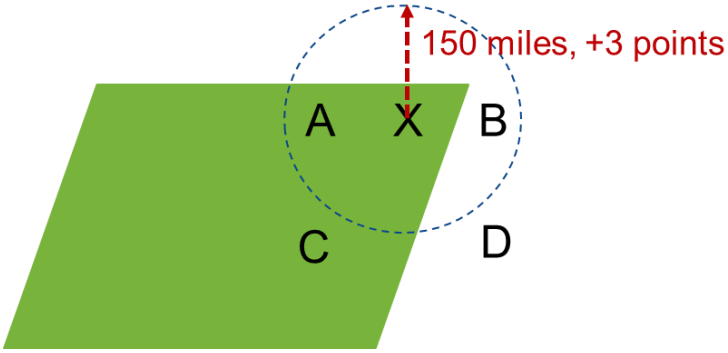
Recommendation from the Redistricting Subcommittee

The Subcommittee convened in February with the charge to recommend to the full Committee an optimized system of distribution that reduces geographic variation in access to deceased donor liver transplant. The expectation was that the full Committee would consider the optimized district solution recommended by the Subcommittee in addition to concentric circles.

The Subcommittee's recommendation was as follows:

- 8 districts
- 150-mile radius, in-district* proximity circle
- 3 MELD/PELD proximity points
- District-wide sharing of adult deceased donor livers for a subset of the waiting list before introducing local (DSA) priority; full district-wide sharing for pediatric donors
- Status 1A and 1B do not receive priority points

*The green parallelogram below represents the district. In-district priority means that an organ at donor center X (in the figure below) will first be offered to candidates at centers A and C, with center A candidates receiving 3 proximity MELD/PELD points. If the organ is not accepted during district-wide allocation, it will be offered to candidates at centers B and D, with center B candidates receiving 3 MELD/PELD proximity points.



Committee members then debated the merits of districts or concentric circles over the current distribution system. One of the Committee members expressed concern that LSAM suggests transplant rates will decrease under concentric circles or redistricting. The SRTR explained that the reason for the reduction in transplant rate can be traced back to a specific part of the LSAM, the acceptance model, which assumes that a transplant program will turn down a liver that has traveled a long distance. This acceptance behavior is based on the fact that currently organs that travel long distances are poorer quality, which would likely change under broader sharing or redistricting.

The Committee member also wanted to know how the SRTR can assume an overall reduction in waiting list mortality if some DSAs would be net exporters of deceased donor organs. The SRTR suggested that waiting list mortality may decrease overall and in most DSAs because, across the transplant system, higher acuity candidates have timely access to donor organs regardless if they are in a net-export DSA. Candidates may accrue more waiting time at lower MELD scores in net-export DSAs, but this is not predicted to result in an increased mortality rate while waiting for transplant.

Several members expressed concern for preserving access to transplant, especially in rural communities. Another member cautioned that although programs may not close as a result of the new district boundaries, some will not generate the profit they once did. In many communities, these profits are used for primary care initiatives.

The Committee Chair requested the first polls of the day to understand where members stood on the following:

1. Do you support 8 districts, 150 mile in-district proximity circles with 3 points, *giving district-wide priority to a subset of the waiting list before introducing local priority*, over the current system? (12-Yes, 5-No)
2. Do you support concentric circles, as described, over the current system? (11-Yes, 5-No)
3. Which do you recommend? (11 for 8 districts, 2 for concentric circles, 5 for neither)

Based on the overwhelming preference for 8 districts over concentric circles, the Committee Chair directed further development of the 8 district proposal.

Further Policy Development

The Immediate Past Chair reviewed three options the Subcommittee considered to achieve district-wide sharing for a subset of the waitlist before introducing local priority (for adult deceased donors only, where "X" below represents a threshold MELD or PELD score to be determined by the Committee):

- **Option 1:** District-wide sharing for all MELDs and PELDs ≥X before introducing local priority
- **Option 2:** District-wide sharing for all lab MELDs ≥X and any PELD ≥X, then exception MELDs ≥X, before introducing local priority
- **Option 3:** District-wide sharing for lab MELDs ≥X, non-HCC exception MELDs ≥X, and any PELD ≥X. Then district-wide sharing for HCC exception MELDs ≥X. Finally, introduce local priority.

The reason for prioritizing laboratory MELD candidates before exception MELD candidates is because currently scores for certain exceptions do not accurately reflect waitlist mortality. Exception submission and award practices are also influenced by geography. However, in light of the Committee efforts to implement revisions to the exception system at the same time as redistricting (see ***Review of Committee Work Plan***), the majority of members supported option 1. The Committee will clearly communicate its plan to implement the NLRB and redistricting proposals together during public comment.

The majority of members supported a MELD threshold of 29 for initial district-wide sharing of adult deceased donor livers, since currently HCC candidates receive a MELD 28 after an initial 6 months waiting at their lab MELD score. Members stated that they required evidence of the disparity benefit with a MELD threshold for initial district-wide sharing. The Committee Chair encouraged the group to proceed to public comment while collecting evidence for the final threshold. Discussion regarding the appropriate threshold can continue, but it is important and constructive to receive feedback from the community on other aspects of the proposal for which the group has strong consensus.

The Committee submitted a modeling request in the meantime to explore the impact of instituting a threshold of MELD 25, 29, and 35 on reducing geographic variance in median MELD at transplant. Members will review these results and consider whether revisions to the proposed MELD threshold are necessary post-public comment.

After reviewing proposed policy language, the Committee voted to submit the following proposal for public comment:

- 8 districts
- 150-mile radius, in-district proximity circle
- 3 MELD/PELD proximity points
- District-wide sharing of adult deceased donor livers for all MELDs and PELDs ≥29 before introducing local (DSA) priority; full district-wide sharing for pediatric donors
- Status 1A and 1B do not receive proximity points

The final vote was 13-Yes, 5-No, 0-Abstentions.

Other Significant Items

2. Simultaneous Liver Kidney (SLK) Allocation

The Chair presented the Simultaneous Liver Kidney (SLK) Allocation proposal that the Kidney Committee is submitting to the Board in June. No major modifications were made after this most recent round of public comment. If approved by the Board, the Kidney Committee will monitor the progress of the redistricting proposal to determine if changes to SLK policy prior to implementation to align the two.

Upcoming Meetings

- May 26, 2016
- June 16, 2016