OPTN/UNOS Liver & Intestinal Organ Transplantation Committee Meeting Minutes February 16, 2017 Conference Call

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

Introduction

The Liver & Intestinal Organ Transplantation Committee (hereafter, the Committee) met via Citrix GoToTraining teleconference on 02/16/2017 to discuss the following agenda items:

- 1. Liver Redistribution Update
- 2. National Liver Review Board Proposals
- 3. Neighborhoods Concept of Redistribution

The following is a summary of the Committee's discussions.

1. Liver Redistribution Update

The Committee reviewed the recommendations that resulted from a non-committee meeting that was held in Miami, Florida during the ASTS Winter Symposium. This Liver Advisory Panel was held to provide a venue for collaborative discussion on the current efforts by the Committee to develop a redistribution proposal.

Summary of discussion:

Introduction and Purpose of the Liver Advisory Panel

Current OPTN/UNOS President, Dr. Stuart Sweet, introduced the purpose and summary of the Liver Advisory Panel meeting in Miami. He stated that following the OPTN/UNOS Board of Director's meeting in December, as well as the response to the fall 2016 Redistricting Proposal, there needed to be a path to consensus moving forward for the Committee's effort to develop a solution. The Liver Advisory Panel meeting was formed to bring in stakeholders from the various OPTN/UNOS regions to meet and discuss the various options regarding the geographic disparity in liver distribution. The group met and spent a day developing recommendations that the Committee could use when developing a solution that is amendable to the broader community. The discussion and recommendations focused on 4 main topics:

- Supply/demand metrics
- Disparity, outcome and access metrics
- Logistics, finances, and post-implementation monitoring
- Solutions and implementation strategies

Committee members were asked if there were any questions on the purpose of the meeting and without further questions, the Chair began presenting the recommendations from the meeting.

Recommendations from the Liver Advisory Panel

The Chair stated that there were several recommendations from the Liver Advisory Panel including recommendations that could be handled by the Committee, recommendations that would need to be handled by other committees, and recommendations that are potentially outside of the purview of the OPTN.

The Chair stated that there has been a lot of discussion about the metrics used to represent supply and demand with any redistribution proposal. The panel wanted to discuss supply and

demand using actual donors and actual waitlisted candidates as represented supply and demand. The Chair stated that the problem with using the actual donors as the actual supply metric is that this is affected by several factors, including the rates of death, kinds of death, and somewhat affected by Organ Procurement Organization (OPO) performance. Similarly, it was stated that the actual demand metric is affected by numerous variables including access to transplant and waitlist practices. Acknowledging these factors, it was stated that the attendees at the Liver Advisory Panel wanted to discuss supply and demand metrics that were independent of both OPO performance concerns and waitlist practices. The Chair stated that in the Redistribution Subcommittee, they intend to look at the potential supply metrics. It was stated that the more difficult metric to find is to identify metrics that represent the "potential demand" for liver transplantation.

The Chair stated that in addition to the supply and demand metrics, the Committee will look at the underserved areas of the country and metrics that represent access to transplant. The Chair continued to present other metrics that the Committee will look at over the next several months. These include economic costs, logistical concerns of broader sharing, and post-implementation analyses. The logistical concerns of broader sharing will be handled primarily by the OPO Committee's system optimizations project. The Committee was reminded of the 3 allocation concepts, Concentric Circles, Optimized Districts, and Neighborhoods currently under analysis by the Scientific Registry of Transplant Recipients (SRTR). The concept proposed during the meeting in Miami, known as Unidirectional Sharing, was also introduced to the Committee. The final recommendation from the Miami meeting regarding phased-in approaches to implementing any redistribution proposal was presented. This recommendation involves several strategies the Committee will consider prior to implementation, including DonorNet enhancements and the policies around broader sharing (sharing thresholds and proximity points).

A Committee member stated that the potential analysis regarding how to allocate "marginal donors" was also a recommendation discussed in Miami. The Chair affirmed that this idea was discussed in Miami and the Committee will consider how to address marginal donors in the development of any proposal. A committee member stated that the meeting in Miami was a genuine effort by all the stakeholders involved to reach consensus on a potential proposal. Finally, a committee member asked about why the financial impacts of "Share 35" were not assessed and that future financial implications of a redistribution proposal needs to be addressed in the eventual proposal. The Chair stated that discussions regarding the financial implications of any future proposal need to involve HRSA and CMS staff due to how healthcare costs are being reimbursed. A committee member asked if all of these metrics and recommendations will be incorporated in time for an August public comment proposal. The Chair stated that he was hopeful that the Committee was still on a timeline that was conducive with the community and HRSA. The OPTN President asked the Chair his thoughts on incorporating these new metrics into the current analyses being done by the SRTR and UNOS, and their effect on a timeline moving forward. The Chair stated that the results of the different data analyses currently underway should all be complete by the end of April, thus allowing time for the Committee to review. A committee member asked about the effect of new OPO metrics on the work of the Liver Committee. HRSA staff stated that they are currently investigating the data sources surrounding OPO metrics and that this effort is on a parallel track with the work of the Liver Committee.

2. National Liver Review Board Update

The Committee reviewed the current status of the National Liver Review Board (NLRB) project, currently out for public comment.

Summary of discussion:

The Vice-chair presented the current progress of the proposal in public comment. Several regions have reviewed the proposal at this point and the feedback has been favorable. A region questioned why the exception score was based on Median MELD at Transplant by the Donor Service Area (DSA), and they recommended that it be by the Region. Additionally, the idea of a "safety net" for exception candidates that wait excessively on the waiting list was proposed at a regional meeting. Both suggestions will be discussed in more detail during a subsequent subcommittee call. The Chair commented that both of these concerns will need to be assessed post-implementation to be sure that there are not unintended consequences to changing the score for exception candidates. A committee member stated that their concern with the Median MELD at Transplant designation is that exception candidates will wait extensively for transplant. The Vice-chair stated that this concern is valid and the current plan is to evaluate the proposed changes very closely following implementation. A committee member reinforced the concern about the score being based on the DSA, versus the region, because in their region there are several single center OPOs. Therefore, there could be considerable variation at each 6-month update to the exception scores. There will be more updates provided to the Committee as the regional meetings continue over the next several weeks.

3. Neighborhoods Concept

The Committee reviewed the recent analysis provided to the Committee regarding the "Neighborhoods" concept of liver distribution.

Summary of Discussion:

The Chair reviewed the difference between the 2017 Neighborhoods analysis and the original analysis provided to the Committee in 2016. The 2017 analysis utilized different sharing thresholds than what the Committee had discussed in the past. The Chair stated that he felt less concern with the different sharing thresholds because these (and any other thresholds) could be modeled in the future. Therefore, the intent of today's presentation was to look at the new DSA maps so the Committee could request the SRTR to incorporate the new maps in their current analyses. The Committee was presented with several of the new maps and a committee member stated that the new maps appear to be more ideal than the previous maps. An attendee to the meeting that created the new Neighborhoods analysis, clarified what was different with the 2017 analysis. He stated that the sharing thresholds and proximity points were controllable variables the group used to improve the allocation system with their modeling. The Chair reinforced the fact that the concentric circles and neighborhoods concepts do not use supply and demand metrics, therefore discussion of appropriate metrics is not necessary related to these concepts. This can be viewed as an advantage of the neighborhoods and concentric circles concepts. The Redistribution Subcommittee will be meeting shortly to address the new Neighborhoods analysis in detail.

Upcoming Meetings

- March 9, 2017 (teleconference)
- April 3, 2017 (teleconference)
- April 20, 2017 (teleconference)
- May 8, 2017 (Chicago)