OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Summary
April 29, 2015
Conference Call

David Mulligan, MD, Chair
Ryutaro Hirose, MD, Vice Chair

Discussions of the full committee on April 7th and April 29th, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at http://optn.transplant.hrsa.gov/ .

Committee Projects

1. **Redesigning Liver Distribution**

   Following the September forum, the committee established three ad hoc subcommittees to further refine the metrics of access and disparity as well as ways to optimize distribution, to identify financial implications of alternative sharing methods, and to address transportation and logistical issues associated with broader sharing.

   The Committee was updated on the planning already underway for the second Public Forum on Redesigning Liver Distribution, to be held in June 2015 at the Loew's Chicago O'Hare. The subcommittees are continuing their deliberations and review of data. Although the format of the forum and specific agenda items have not yet been finalized the Committee plans to have representatives from the subcommittees present the findings and recommendations to the community and to solicit further feedback.

2. **Guidance Document on MELD/PELD Exceptions, PSC Updates**

   The first of two installations on the Guidance Document on MELD/PELD Exceptions was presented and approved during the June 2014 Board of Directors Meeting. The Committee has continued to develop guidelines for Regional Review Board (RRB) representatives in order to aid in the case review and approval of exception applications for common diagnoses, specifically for Primary Sclerosing Cholangitis (PSC) on this installment.

   Additionally, the Committee has requested to incorporate some guidelines and request some additional voluntary data collection for candidates applying for an Portopulmonary Hypertension exception. A revised template for exception application submission will accompany this guidance for the purposes of policy development.

   The Committee briefly met on April 7th for the sole purpose of casting an official vote on what projects to forward to the Board of Directors for consideration during the June 2015 meeting. After careful consideration, the Committee unanimously voted in support of forwarding the guidance document to the Board for consideration by a vote of 12 in favor, 0 opposed, 0 abstentions.

3. **Criteria for Intestine Surgeons**

   There are currently no OPTN/UNOS requirements for qualifying intestinal programs, physicians, and surgeons. Currently, any transplant program that is approved to perform liver transplants can perform intestinal transplants. The Committee submitted a proposal for Membership and Personnel Requirements for Intestine Transplant Programs for

public comment in August 2006, but it was not well supported, and the proposal was withdrawn.

The Committee was aware that the American Society of Transplant Surgeons (ASTS) was developing its own criteria for intestinal program accreditation that would set levels for volume and experience, so it agreed to postpone this effort until after the ASTS made its recommendations. The ASTS finalized its criteria for fellowship training programs in September 2008.

The Proposal for Membership and Personnel Requirements for Intestine Transplant Programs was circulated for public comment from March 14, 2014 - June 13, 2014. While public comment was largely favorable, the Committee recognized an opportunity to further improve the proposal before presenting it to the Board for consideration. The proposal was redrafted to address the concerns of the community and it was recirculated for public comment from January 27, 2015 - March 27, 2015.

The Committee briefly met on April 7th for the sole purpose of casting an official vote on what projects to forward to the Board of Directors for consideration during the June 2015 meeting. The Committee considered and addressed public comment feedback on its proposed language. After careful consideration, the Committee unanimously voted in support of forwarding the proposal to the Board for consideration by a vote of 12 in favor, 0 opposed, 0 abstentions.

Committee Projects Pending Implementation

4. Regional Review Board Educational Materials

At the request of the Committee and in conjunction with the liver transplant programs in Region 5, staff have developed educational materials currently being piloted with the newest incoming RRB members in Region 5. This online tutorial includes a slide set with speaker notes and an assessment tool. Additionally, rotation schedules were updated to eliminate many of the complications attributed to constant member turnover. The first group to pilot this effort completed the tutorial provided. In December 2014, the first half of this group rotated off the Board and new members were provided the same online tutorial.

While it is too early to determine if these materials significantly impacted the process of the RRB, members have provided positive reviews. The Committee has developed similar materials for each region and will begin training the RRB Chairs in July, 2015. Each Chair will then train RRB members during the Fall 2015 regional meeting cycle.

The Committee will continue to monitor the effort and plan to implement the training as a requirement if shown to improve the system and anticipates an update report to the Board of Directors during the December 2015 meeting.

Implemented Committee Projects

5. Regional Distribution of Livers for Critically Ill Candidates, (Share 35)

The “Share 35” liver allocation policy was implemented on June 18, 2013. The policy gives greater priority to candidates with MELD/PELD scores of 35 and higher. The Committee has been monitoring the impact of the policy to ensure that the results are as intended.

The 18-month analyses were very consistent with the 6-month and 1-year data. As seen previously, the percentage of regional sharing increased, from 20.5% to 31.53% of

deceased donor transplants. The percentage of transplants in recipients with MELD/PELD scores of 35 and higher increased from 18.9% to 26.4%. Six regions showed a slight increase in cold ischemia times (CIT). Overall, the median CIT increased from 6.0 to 6.1 hours.

Organ travel distance increased in 9 regions; the overall median distance increased from 56 to 83 miles. The percent of livers recovered for transplant and not transplanted decreased slightly, from 10.4% to 9.4%. The percentage of donors from whom livers were not recovered decreased from 13.8% to 13.0%.

Post-transplant survival was unchanged in the post-era (90.57% vs 90.58%); the adjusted rates were also not statistically different. Overall, the crude waiting list mortality rate was slightly lower. While most regions experienced lower mortality rates following Share 35, several Regions (4 and 6) showed increases. Candidates reaching a MELD/PELD score of 35 or higher had a greater transplant rate and a lower death rate in the post-policy era. The Committee will continue to review the effects of Share 35 at six-moth intervals.

Other Significant Items

6. Membership and Professional Standards Committee (MPSC) Memorandum Regarding the Use of the Karnofsky/Lansky Scores in Liver Risk Adjusted Models

The Committee received a memorandum from the MPSC regarding the use of the Karnofsky/Lansky Scores in the Liver Risk Adjusted Models. The MPSC has noted the highly subjective nature of the Karnofsky scale, the lack of information available to members regarding the appropriate application of Karnofsky scores, and, consequently, the inconsistent application of Karnofsky scores among programs.

The inclusion of data elements in risk adjusted models that may be loosely interpreted undermines the reliability of the outcomes data the MPSC uses to determine those programs that require review for post-transplant performance. The scores have already been removed from the kidney risk adjusted model because of the subjectivity.

Functional Status scores are currently incorporated into the liver graft and patient survival risk adjustment models (including 1-year graft and patient survival models for adults and pediatrics and 3- year graft and patient survival for adults). Although there are limitations of data collection and uniformity of reporting for these scores, the functional status scores appear to be an important predictor of patient risk.

The Scientific Registry of Transplant Recipients (SRTR) is due to begin rebuilding the liver model in the fall of 2015 with a preview during the Spring 2016 PSR. The Committee discussed developing a guidance document for centers on reporting the functional status scores to support broader uniformity of reporting or the possibility of developing liver-specific functional status definitions and indicators that could be collected as part of the OPTN/UNOS dataset.

The Committee agreed that at this juncture developing guidance to the centers to support broader uniformity of reporting for these scores would be preferable and will work in conjunction with the SRTR and the MPSC to do so.

7. Review Liver Wait Time Modification Reports, September 2014-February 2015

The Organ Center sends monthly waiting time modification reports to the Committee for review. The Committee reviewed these reports dated September 2014-February 2015 and does not recommended any further action with regards to these waiting time modifications.

Upcoming Meetings

- June, 2015