

OPTN/UNOS Liver & Intestinal Organ Transplantation Committee
Meeting Minutes
May 8, 2017
Chicago, IL

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Introduction

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (hereafter, the Committee) met in person on 05/08/2017 to discuss the following agenda items:

1. Welcome and Introductions
2. Overview of 2017 Committee Efforts
3. LSAM Results and Discussion
4. Supply and Demand
5. Access to Transplant
6. NLRB
7. Pathway to December 2017 Board Meeting
8. New Business

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

1. Welcome and Introductions

Committee and OPTN leadership introduced the meeting with an overview of the previous work by the Committee in 2017 and the necessary steps forward for the Committee's current projects. The Committee has been asked by HRSA to put in place a solution to geographic disparities in access to liver transplant by the end of this year. To do this the Committee will need to have a public comment document for July 2017 public comment cycle. The Committee was presented with the recommendations from Liver Panel Meeting that was held in Miami in January 2017. The recommendations from the panel to the Committee included additional definitions of supply and demand for liver transplant, new metrics beyond MELD at transplant, changes to the system to handle increased demands of a broader sharing, and putting in place a phased implementation plan to mitigate unforeseen consequences.

Committee leadership stated that supply and demand heat maps, prepared by UNOS staff, will be presented during the meeting and are based on metrics not dependent on DSA procurement performance and center listing practices. Additionally, during the meeting, SRTR will present three models the Committee is looking at.

Committee leadership stated that the Committee will need to figure out how to evaluate access to transplant and how it relates to the impact of broader sharing on waitlisted patients in medically underserved areas. Additionally, the Committee needs to be clear on impact of any solution at DSA level. A Committee member stated that the systems optimization workgroup, a workgroup of the Organ Procurement Organization (OPO) Committee, is working on logistics and the Committee should not anticipate talking about logistics today. A Committee member stated that the important objective is to develop a solution that the community can accept in a phased way. The first step allows us to move in the direction of solution, then develop a plan for implementation over three to five years to get to full implementation of strategy. OPTN leadership stated that a plan needs to be laid out with checks and balances and designed in a way to prevent the Committee returning to the board for decisions. It was further stated that the

Committee needs a long-range plan that is flexible enough to incorporate new ideas, and builds on the foundation of the initial policy.

2. Overview of 2017 Committee Efforts

The Committee had three major project goals to address issues with liver transplantation allocation and distribution. The projects include a broader sharing proposal, establishing a national liver review board, and modifying criteria for HCC exceptions.

The policy proposal and 3 guidance documents related to the National Liver Review Board will be considered by the Board of Directors at their June 2017 meeting. The liver redistribution project included a proposal that went out for public comment in August of 2017 that included a solution with 8 districts. A Committee member stated that the main comment and concern was the age cohort of data used to develop the concept. In response to public comment, the updated modeling results will be presented during the meeting.

Committee leadership stated that one metric of disparity is variance in the MELD score at transplant by DSA. Furthermore, since 2005 the disparity metric goes up and down but the Committee member stated that it has gotten worse over the last decade. It was stated that other metrics for the Committee to discuss are median MELD score at transplant, disparity of transplant rates and disparity of wait list mortality and potential effects of changes to the distribution system. It was stated that the Committee had asked the SRTR to do a lot of work in a short time to redo their LSAM runs to update cohort.

3. LSAM Results and Discussion

The Liver Simulated Allocation Modeling (LSAM) request consisted of two parts; updating LSAM with a more recent cohort and to use that data to simulate alternative policy scenarios; eight district models, 500-mile radius circle models, and neighborhoods.

SRTR staff presented the results of the LSAM modeling. They stated that they were asked by the Committee to update the data cohort in LSAM. The update uses a 5-year cohort collected between July 2011 and June 2016. The cohort used for data is a 3-year slice of that cohort. SRTR staff stated that they rebuilt all predictive models within the LSAM, organ acceptance model, and the post-transplant survival model and added capability to model overlapping neighborhood concepts. This data cohort includes the implementation of two policies from the Committee, cap and delay for HCC and Share35.

All of the concept scenarios produced a 3-fold decrease in the variance in median MELD at transplant. The reduction in median MELD at transplant is similar to previous modeling however, the disparity magnitude is greater in this newer cohort.

The overall transplant rate across the country has changed little between current and alternative scenarios. The 3 scenarios with a sharing threshold above MELD 28 yields higher transplant rates particularly for patients between 29 and 34, but also for MELD score of 35 or greater. Transplant rates for lower MELD groups continues to be low and SRTR staff stated it was difficult to appreciate whether there's much of a difference on any of the scenarios shown with regards to transplant rates. Variance in transplant rates is reduced in all alternative scenarios, with non-exception candidate's highest variance and largest reduction in variance of transplant rates. SRTR staff stated that higher transplant counts in the higher MELD groups are driven by a reduction in transplant counts for the lower MELD groups. Longer waiting times in these groups drive low rates shown earlier. Alternative scenarios produce some reduction in waitlist mortality and likely represents the faster transplants in the high MELD/PELD candidates. There are minor differences in waitlist mortality between the current and alternative scenarios. There's very little observed effect in post-transplant mortality.

SRTR staff stated that all scenarios would increase travel time although magnitude of median increase is small at 18 minutes. Transport distance increases with all six alternative scenarios, magnitude increase is larger, doubling in some scenarios, DSA proximity points do lead to higher increases than the circle proximity points in transport distance. All scenarios would increase the flight percentage compared to the current allocation system. Finally, SRTR staff explained that all scenarios decrease the percentage of transplants performed locally.

Discussion

It was stated that the LSAM modeling for the neighborhoods concept was based on a second set of neighborhoods was used in response to modifications which included using lower population constraints as well as a decreased distance constraint. The set of maps used for the LSAM runs is the second set of neighborhoods that was presented to the redistribution subcommittee. It was stated that for the neighborhoods concept, the parameters for local are the same across all six scenarios.

A committee member asked about how the acceptance model works with multiple offers. SRTR staff stated that the acceptance model of LSAM represents each allocation run individually, runs it to completion and then moves on to the next one. Furthermore, it doesn't attempt to simulate the scenario of centers dealing with multiple offers. Changes in acceptance behavior are not modeled. A committee member stated that these are inherent inaccuracies of the modeling and increased the importance of the Committee monitoring the effects of the changes regardless of the specific concept that is chosen. A Committee member stated that the monitoring and implementation plans will be a critical component of any proposal that goes forward out of the Committee.

SRTR staff stated that DSA level results should be ready soon on for the Committee to review. SRTR staff reiterated that the LSAM has significant limitations at the DSA level due to the overall design to predict national trends as a result of a policy change. A committee member brought up the need to implement any proposal in a stepwise manner. Examples that were provided include:

- Provide five MELD proximity points to local candidates
- Provide priority to lab MELD candidates in the initial classification.
- Expose a subset of donors to broader sharing
- Have an initial sharing threshold that can be lowered following post-implementation data

A committee member stated that there is no way to share broadly without having more travel time and certain programs will be "negatively" affected. The only way to fix geographic disparity caused by the distribution system is to change the distribution system. There was discussion that the 8-district model would not be amenable to the transplant community. There was a motion and second to no longer pursue the 8-district model at this time. The motion passed with 11 in favor, 0 against, 5 abstentions.

4. Supply and Demand

The Committee discussed the recent efforts to use different metrics to assess supply and demand for liver transplant. The recommendation from the liver panel held in Miami in January 2017 was to examine supply and demand metrics other than those already used. A committee member stated that in terms of supply metrics, the actual donors that occur are dependent on number of deaths or potential deaths that are eligible and other metrics including OPO conversion rates.

For a demand metric, a Committee member stated that the Committee has tried to look at various sources for patients suffering from liver disease as potential demand. This is a harder

metric than supply because there is no database that keeps track of all patients with liver failure. It was stated that the Committee looked at other potential sources of data that included not only the Center for Disease Control (CDC) multiple cause mortality file, but also hospitalization files.

A committee member stated that national inpatient sample data hospitalizations were looked at beginning with patients less than 70 with several diagnoses representative of liver disease. There are some limitations of this data due to the level of hospitalizations might be influenced by socioeconomic factors. A committee member stated that an inherent benefit of the Neighborhoods and Circles models is that they are not reliant on supply and demand metrics, which can be viewed as controversial.

5. Access to Transplant

The Committee discussed issues with access to transplant as it relates to broader sharing of livers. A committee member stated that they don't want to necessarily have disparate effects on one population or another. The HRSA definition of medically underserved areas (MUA) includes population to provider ratios, percent of population below poverty level, percentage over age 65, and infant mortality rates. It was explained that MUAs have subcategories and data are available by census tract but it doesn't map to zip codes or DSA. A committee member stated that this limitation makes it difficult to overlay the MUA data with the effect on access to transplant.

A committee member stated that the purpose of this discussion was to consider looking at the effects on subpopulations to understand what they're currently going through and what they might undergo should we change policy. A committee member stated that the Committee needs to make every effort with respect to the time constraints to establish how much urban and rural populations are disadvantaged by the current system and how they would be affected by any change in the allocation system.

6. NLRB

The Committee discussed the upcoming NLRB proposal to the June Board of Directors meeting and the specifics surround implementation of an approved proposal. A committee member stated that the agreed upon exception scoring in the NLRB proposal (points below median MELD for the DSA) is appropriate if the DSA is maintained in a broader sharing proposal.

UNOS staff stated that from an IT perspective, the NLRB implementation would be separate and can begin in conjunction with the public comment for a broader sharing proposal. UNOS staff explained that UNOS IT is working under a 1-year timeline from board approval to implementation. The NLRB proposal is an enterprise level project estimate, which is the highest estimate provided for committee projects. It was stated that delayed implementation could be considered as part of way to move this forward. One way to preserve the DSA-specific and region-specific constraints is to alter the number of points the regional review board gives based on geography. A committee member commented that local conditions have to be preserved in an NLRB.

A committee member stated that the Committee needs to vote on one of two choices 1) we would not make this a special situation and NLRB would be implemented pending programming and communication with community or 2) the Committee would delay parts of the implementation of NLRB until a broader sharing proposal was approved by the Board of Directors. There was a motion and second to implement now pending programming and communication with the community. The motion to move forward passed with 15 in favor, 2 opposed, 1 abstention.

A committee member stated that the Committee will need to study the effects of the NLRB proposal. One concern is the median MELD at transplant minus three for the majority of exception is not enough to balance prioritization between exception and non-exception candidates.

The Committee began discussing necessary modifications to the current proposal that would make the proposal more amenable to the Community and ease the transition to broader sharing. There was a motion to vote on the DSA as a definition of local for broader sharing. The Committee voted yes unanimously to favor the DSA as a definition of local to give proximity points.

The Committee then voted to provide 5 MELD proximity points for local candidates, with the idea that this could be modified based on the post-implementation analysis. 13 approve, 2 oppose, and 2 abstentions. A second vote was unanimous to prioritize Lab MELD candidates above the sharing threshold in the initial broader sharing classification.

A Committee member brought up the topic of transplantation of foreign nationals. The Committee discussed the topic briefly and there was a majority of agreement that at this point in time the OPTN is not in position to make that change.

7. Pathway to December 2017 Board Meeting

A Committee Member stated that the goal of the Committee is to have a proposal available to the Board of Directors for consideration at their December 2017 meeting. UNOS staff stated that the Committee would need to agree on a final proposal prior to public comment beginning on July 31st.

A Committee member stated that the Committee has demonstrated progress with this project. Furthermore, a Committee member stated that if the Committee were to identify other alternatives in the coming months, then the Committee would need to address them appropriately.

A Committee member stated that it will be important to share the proposal and the decisions made during the meeting with our constituencies, regional, professional, or otherwise to make sure the community knows what's going on with the Committee. Furthermore, it was stated that the Committee needs to be transparent with the details of the proposal. A committee member stated that the proposal may create confusion and conflict in the transplant community. A Committee member stated that it's important to explain that models are only predictions and that any change would be monitored carefully.

8. New Business

A Committee Member brought up the fact that there are ABO-incompatible transplants being done and some centers are doing ABO-incompatible transplants and turning down compatible organs. The Committee stated that this is not against policy but may go against the spirit of the policy and require further discussion. Committee members agreed that the incidence of ABO-incompatible transplants will be researched and reported back to the committee.

Upcoming Meetings

- May 18, 2017 Teleconference
- May 24, 2017 Teleconference
- June 8, 2017 Teleconference
- June 12, 2017 Teleconference